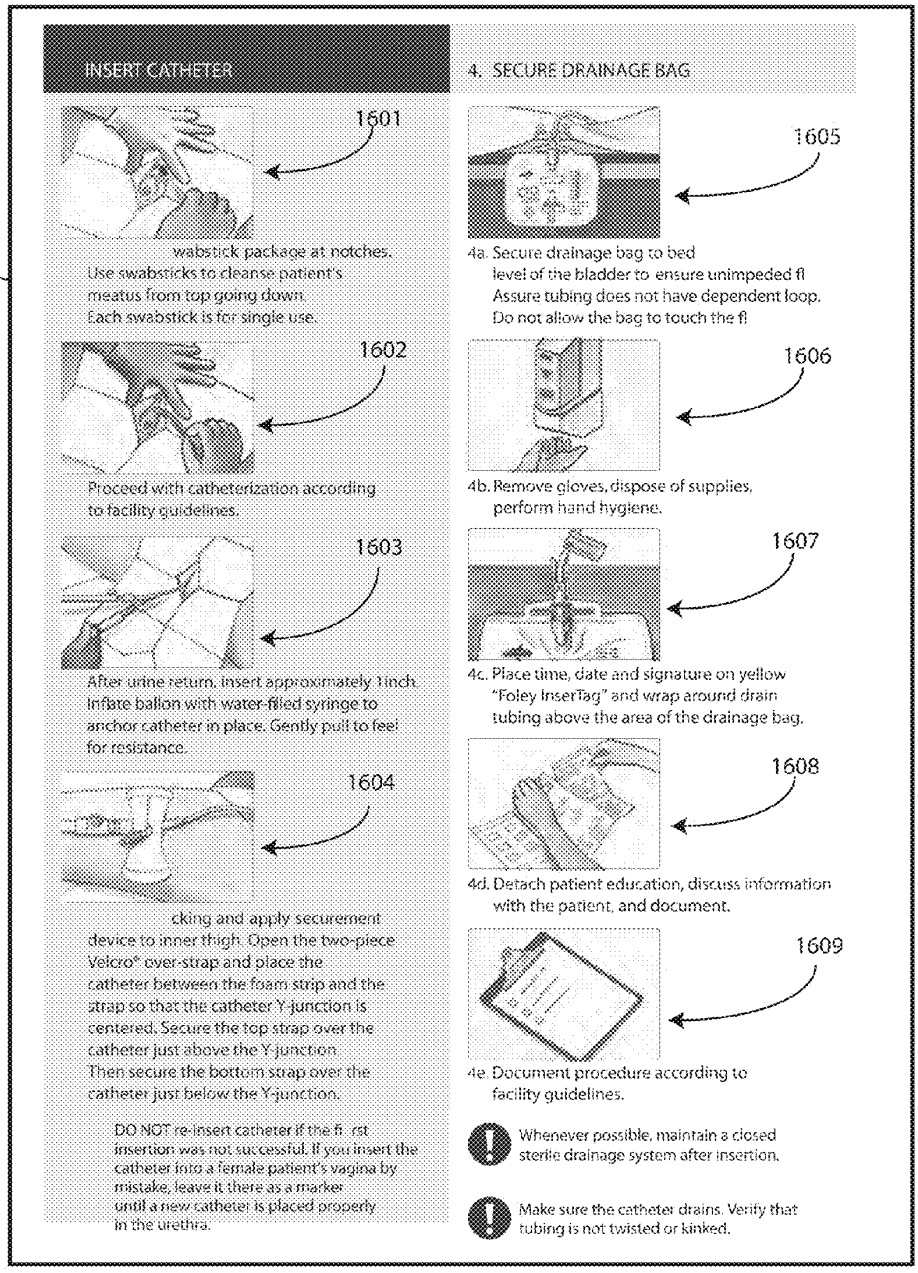

1302
INSERT CATHETER
1601
wabstick package at notches.
Use swabsticks to cleanse patient's meatus from top going down.
Each swabstick is for single use.
1602
Proceed with catheterization according to facility guidelines.
1603
After urine return, insert approximately 1inch.
Inflate ballon with water-filled 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

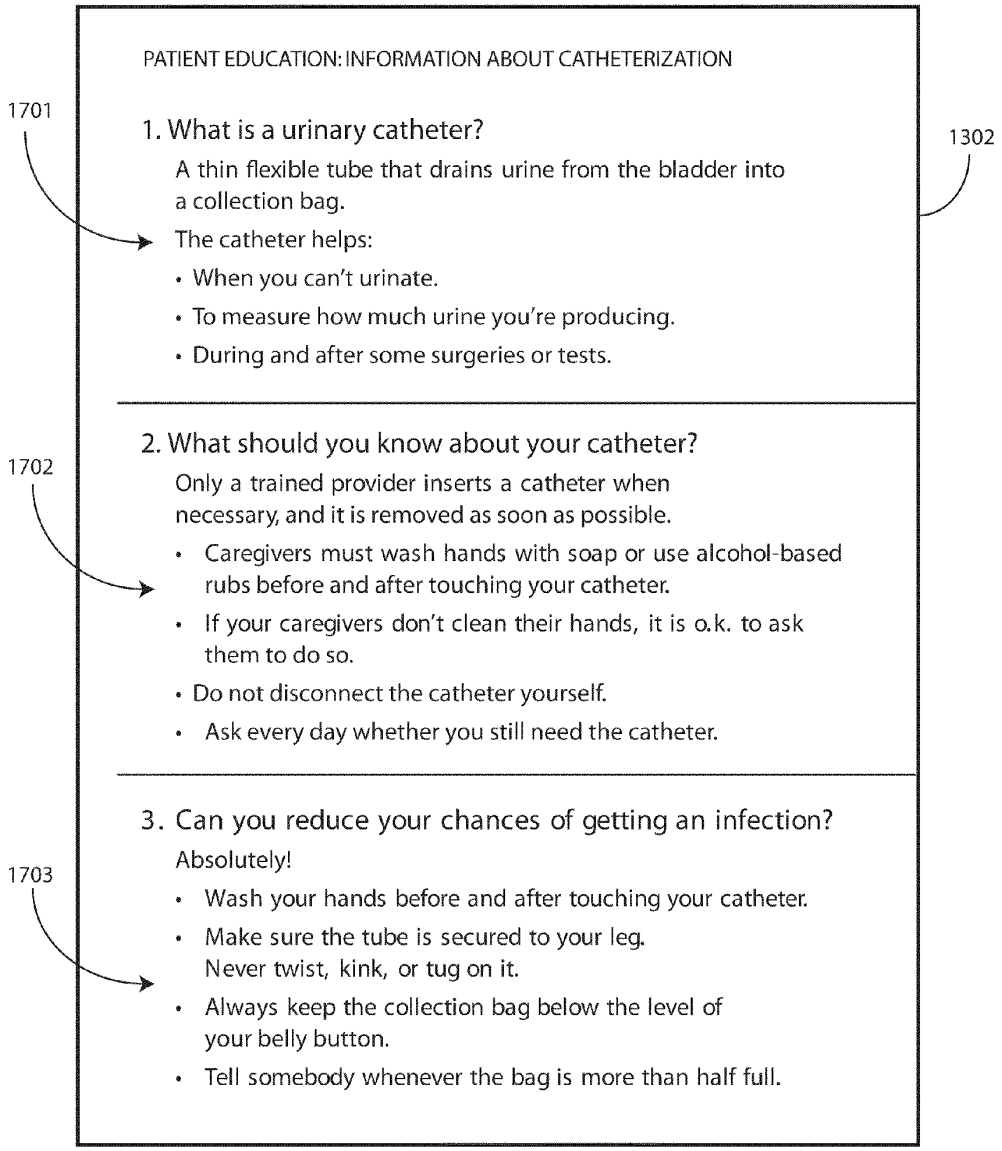

PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1701
1. What is a urinary catheter?
A thin flexible tube that drains urine from the bladder into a collection bag.
The catheter helps:
• When you can't urinate.
• To measure how much urine you're producing.
• During and after some surgeries or tests.
1302
1702
2. What should you know about your catheter?
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.
1703
3. Can you reduce your chances of getting an infection?
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

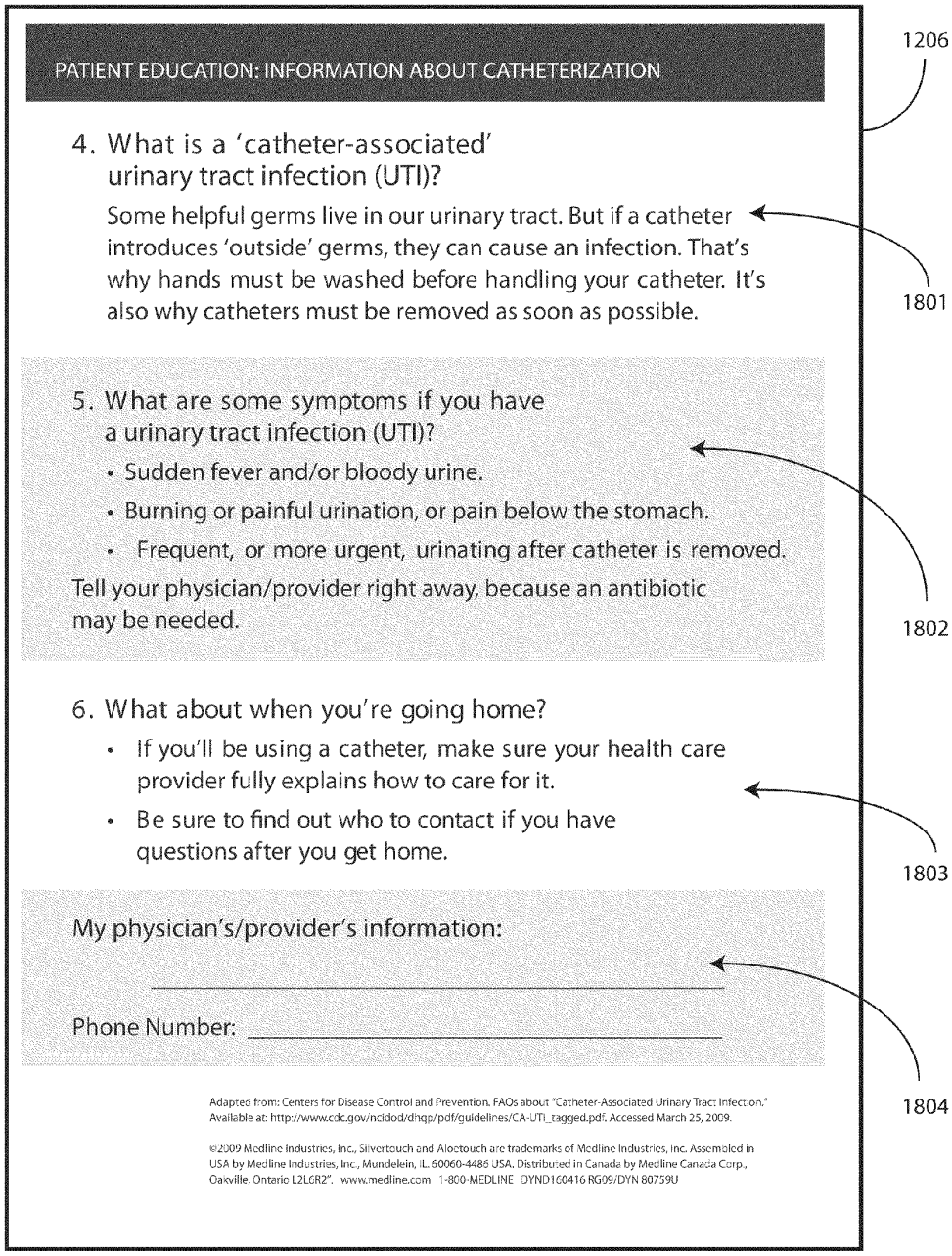

PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
4. What is a 'catheter-associated' urinary tract infection (UTI)?
Some helpful germs live in our urinary tract. But if a catheter introduces 'outside' germs, they can cause an infection. That's why hands must be washed before handling your catheter. It's also why catheters must be removed as soon as possible.
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.
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.
My physician's/provider's information:
Phone Number:
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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1206
1801
1802
1803
1804

FIG. 18

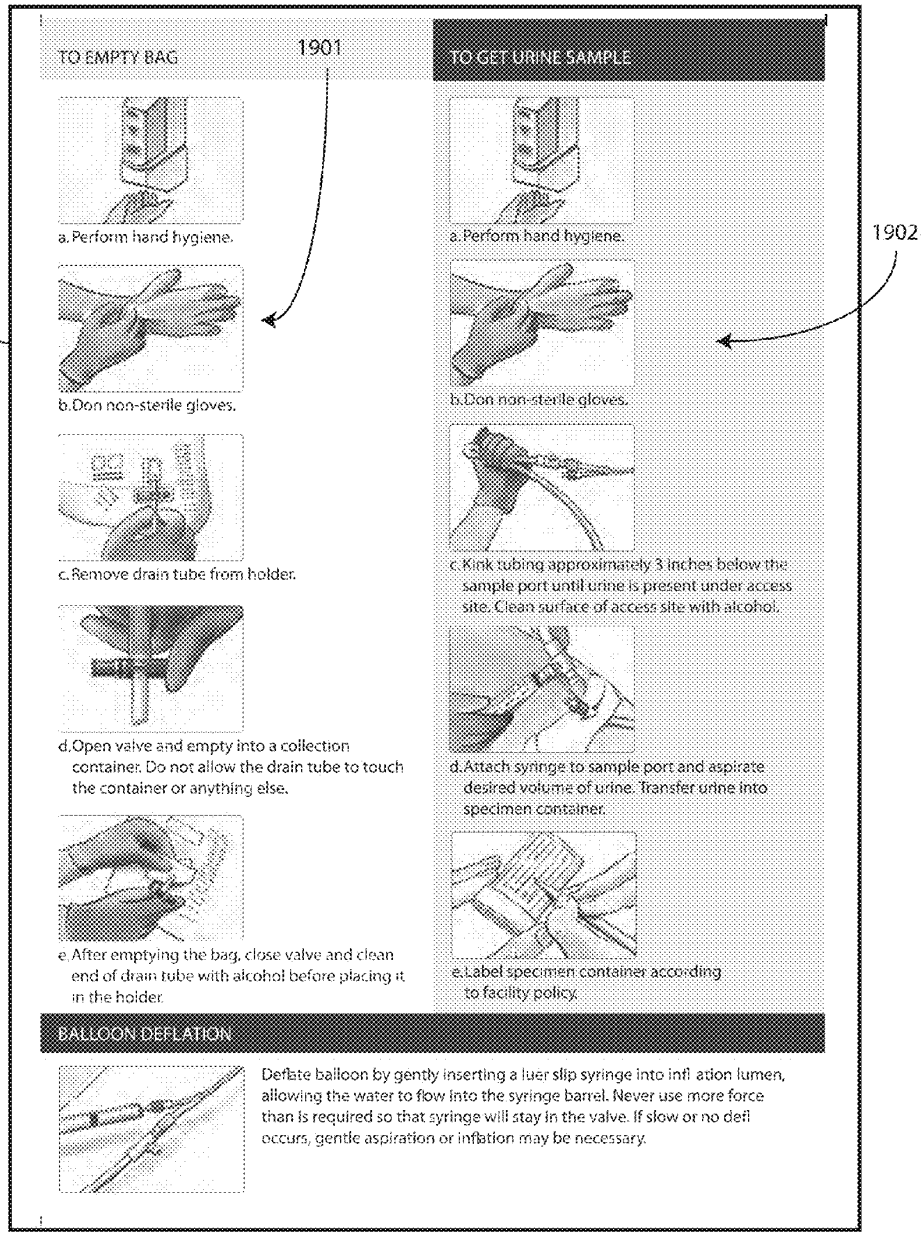

1205
1901
1902
TO EMPTY BAG
TO GET URINE SAMPLE
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Remove drain tube from holder.
d. Open valve and empty into a collection container. Do not allow the drain tube to touch the container or anything else.
e. After emptying the bag, close valve and clean end of drain tube with alcohol before placing it in the holder.
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

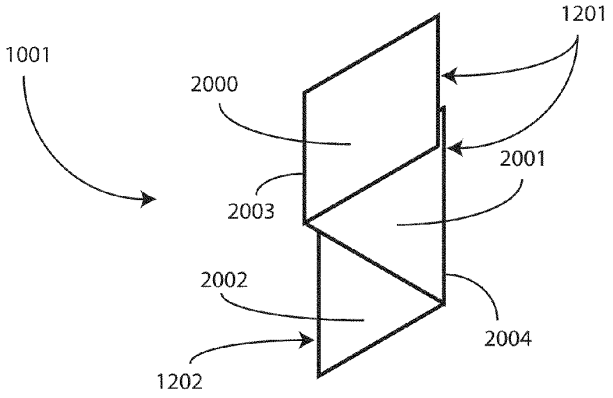

1001
1201
2000
2001
2003
2002
2004
1202

FIG. 20

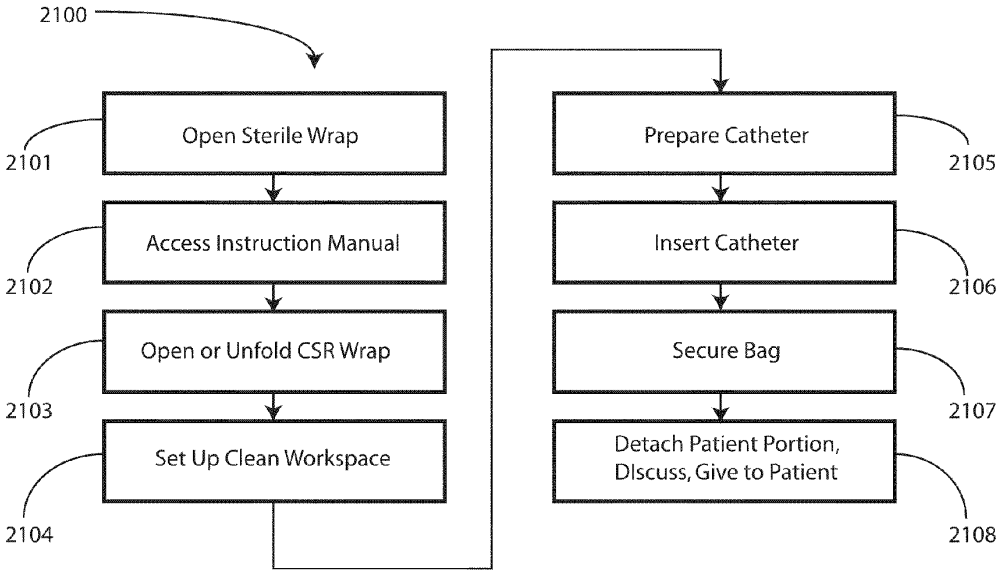

2100
Open Sterile Wrap
2101
Access Instruction Manual
2102
Open or Unfold CSR Wrap
2103
Set Up Clean Workspace
2104
Prepare Catheter
2105
Insert Catheter
2106
Secure Bag
2107
Detach Patient Portion, Discuss, Give to Patient
2108

FIG. 21

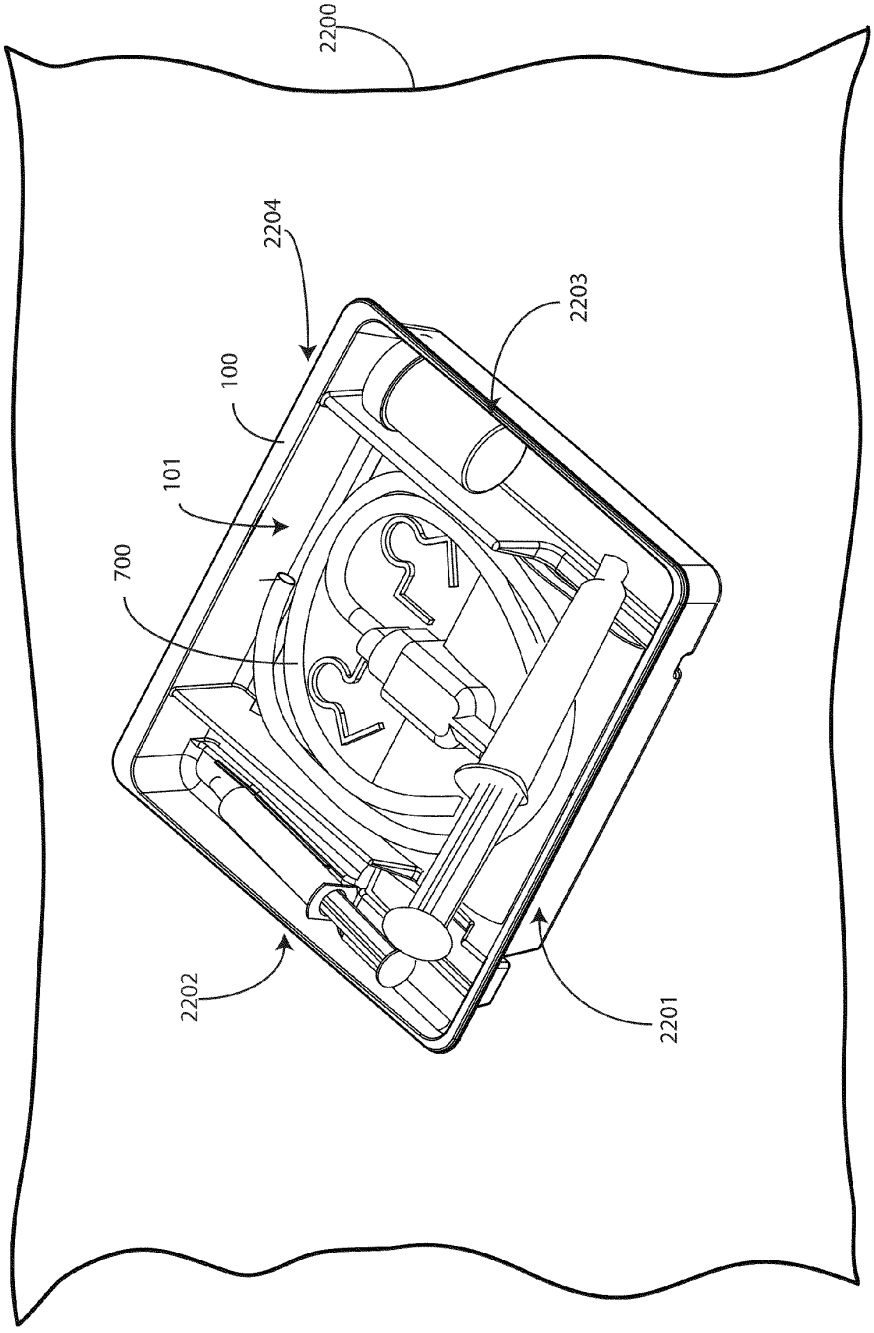


FIG. 22

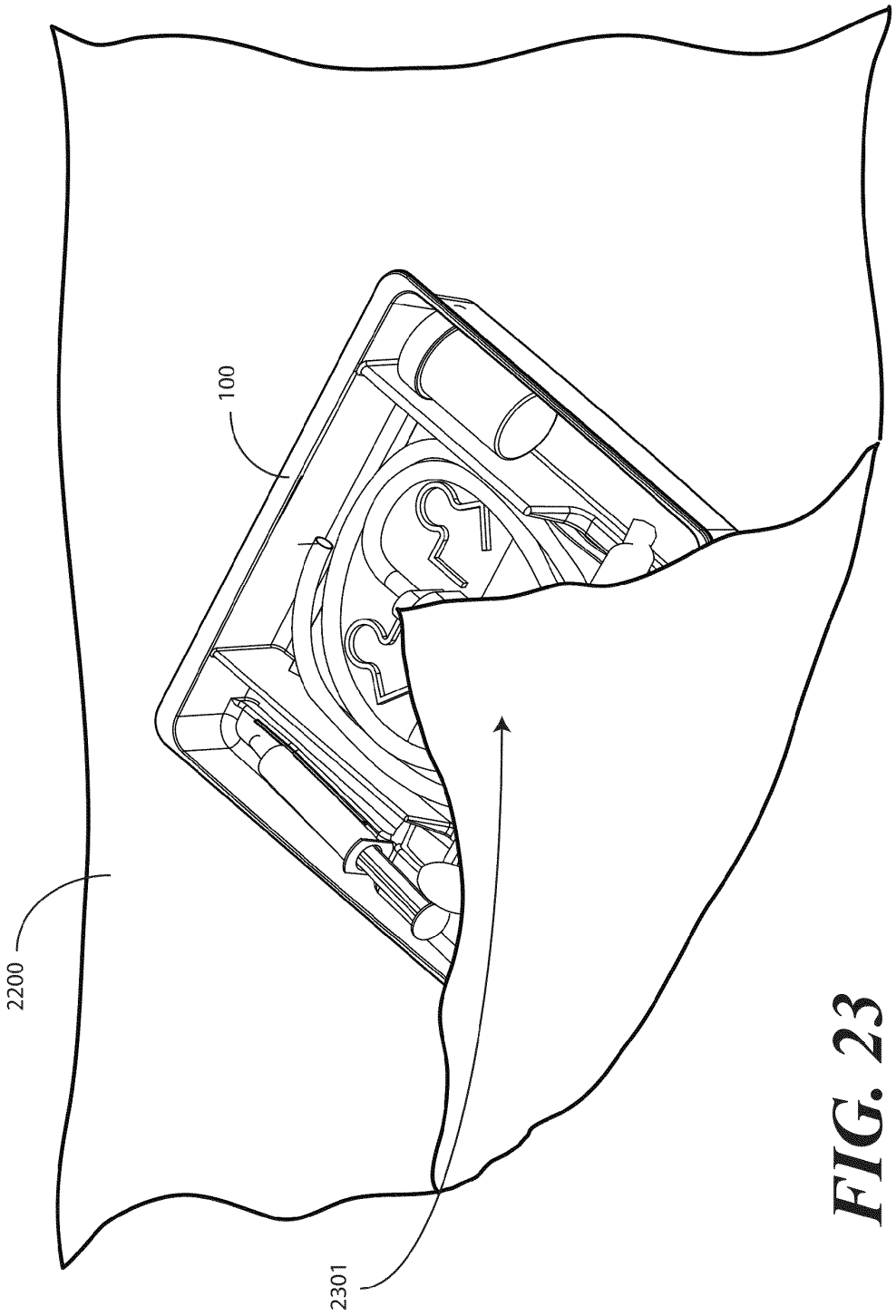


FIG. 23

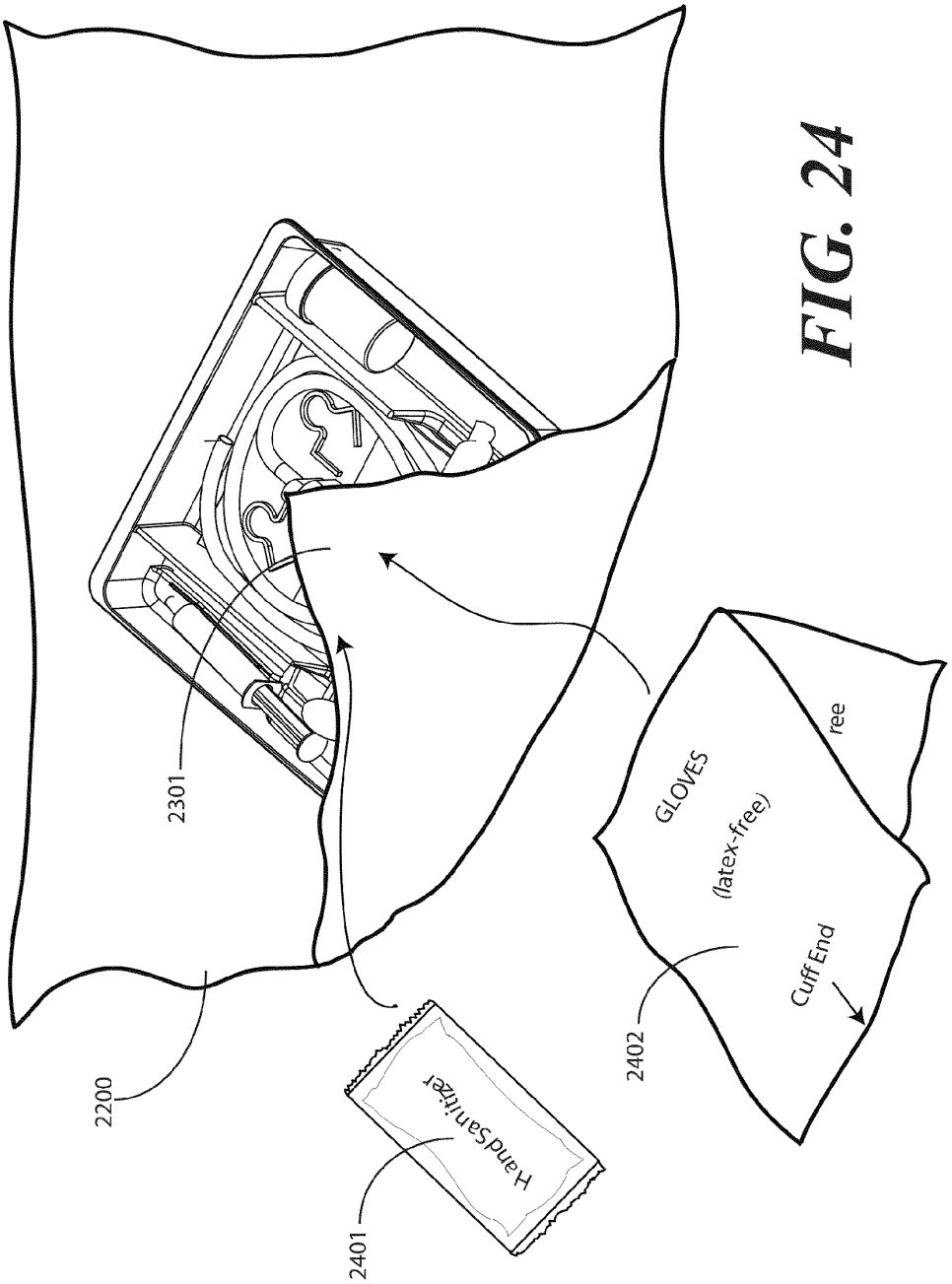

2301
2200
2401
HandSanitizer
2402
GLOVES
(latex-free)
Cuff End
ree

FIG. 24

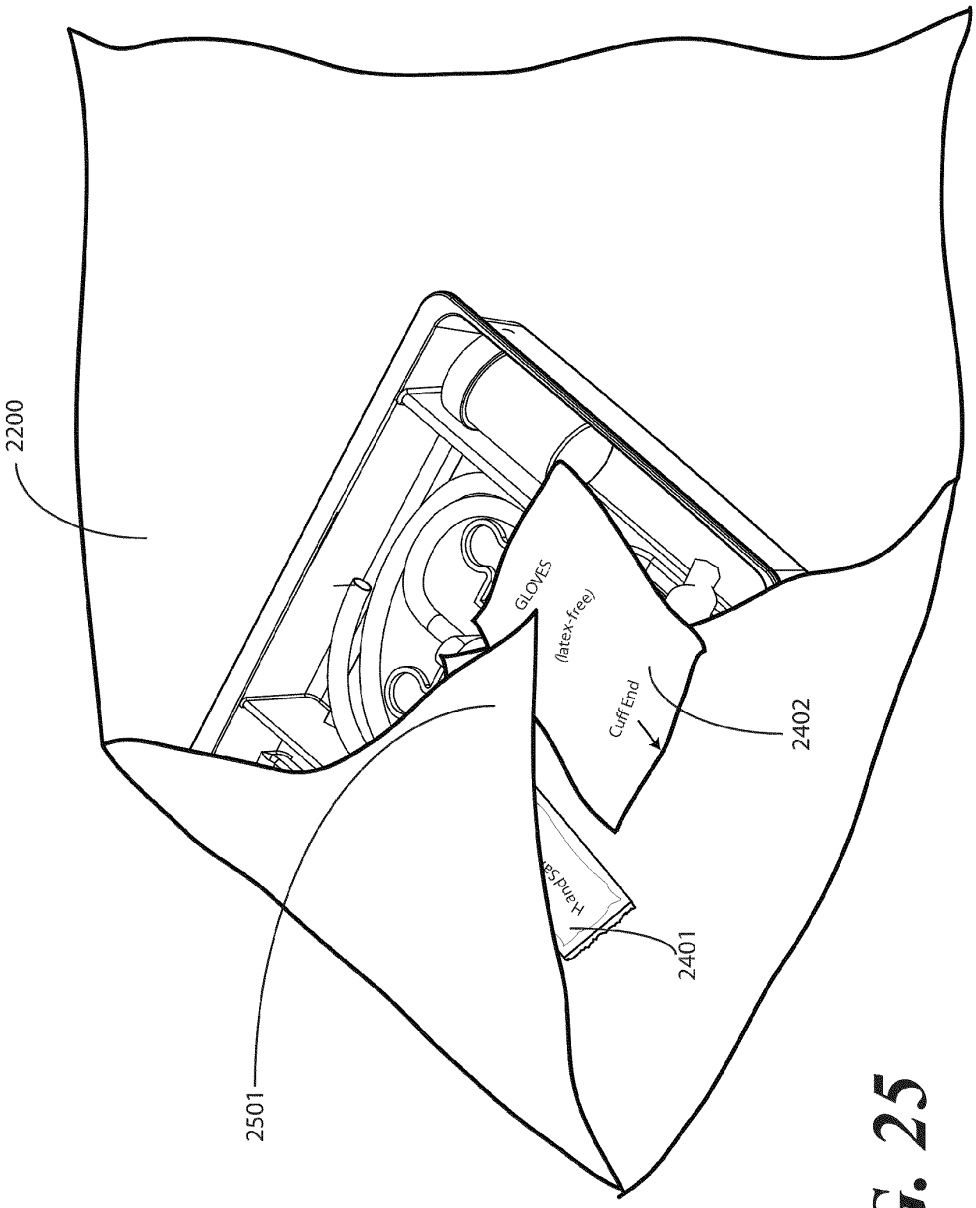


FIG. 25

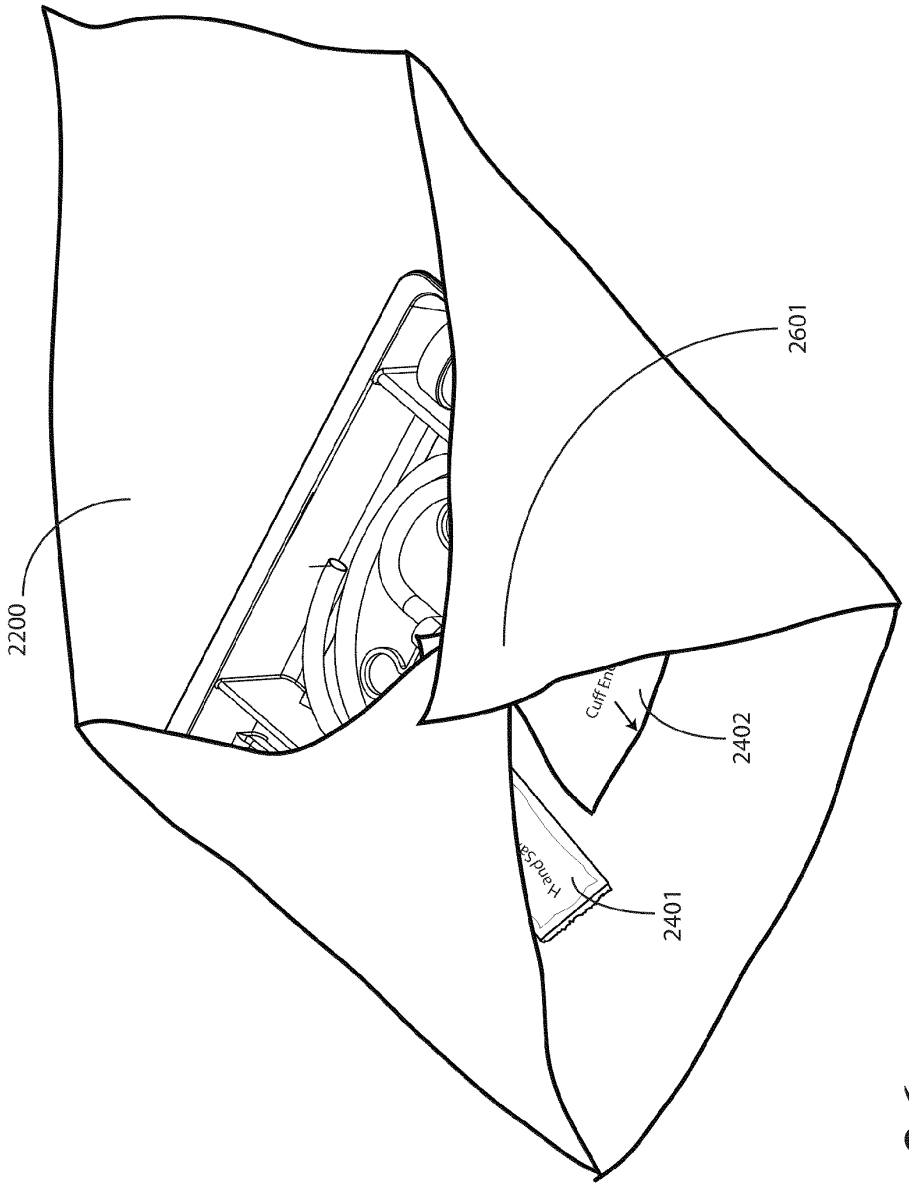


FIG. 26

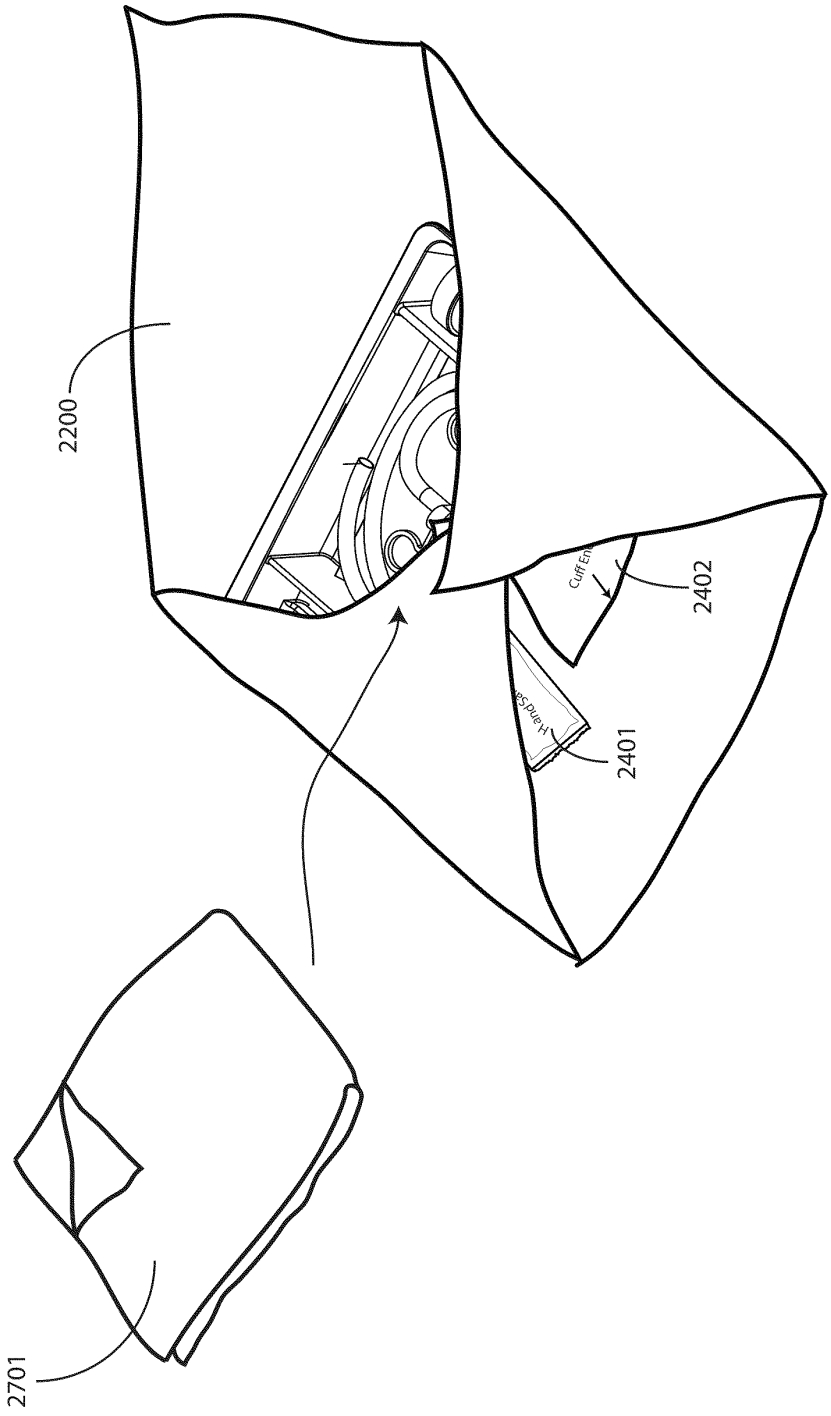


FIG. 27

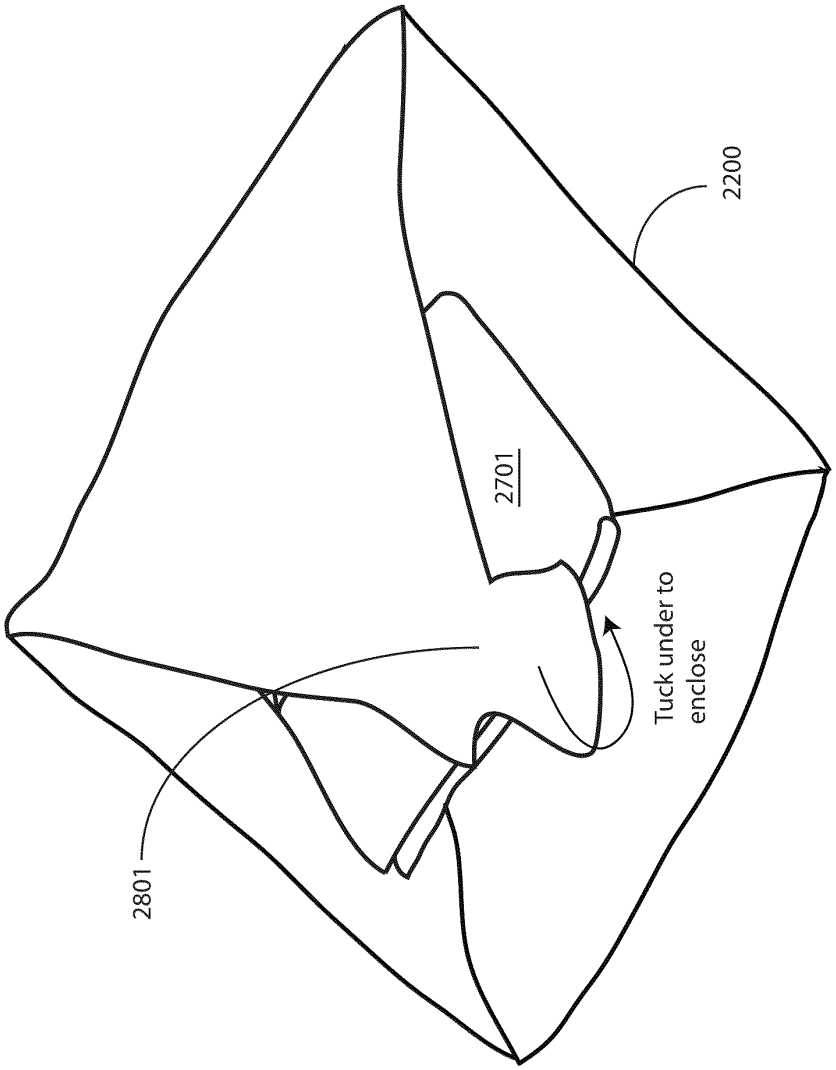


FIG. 28

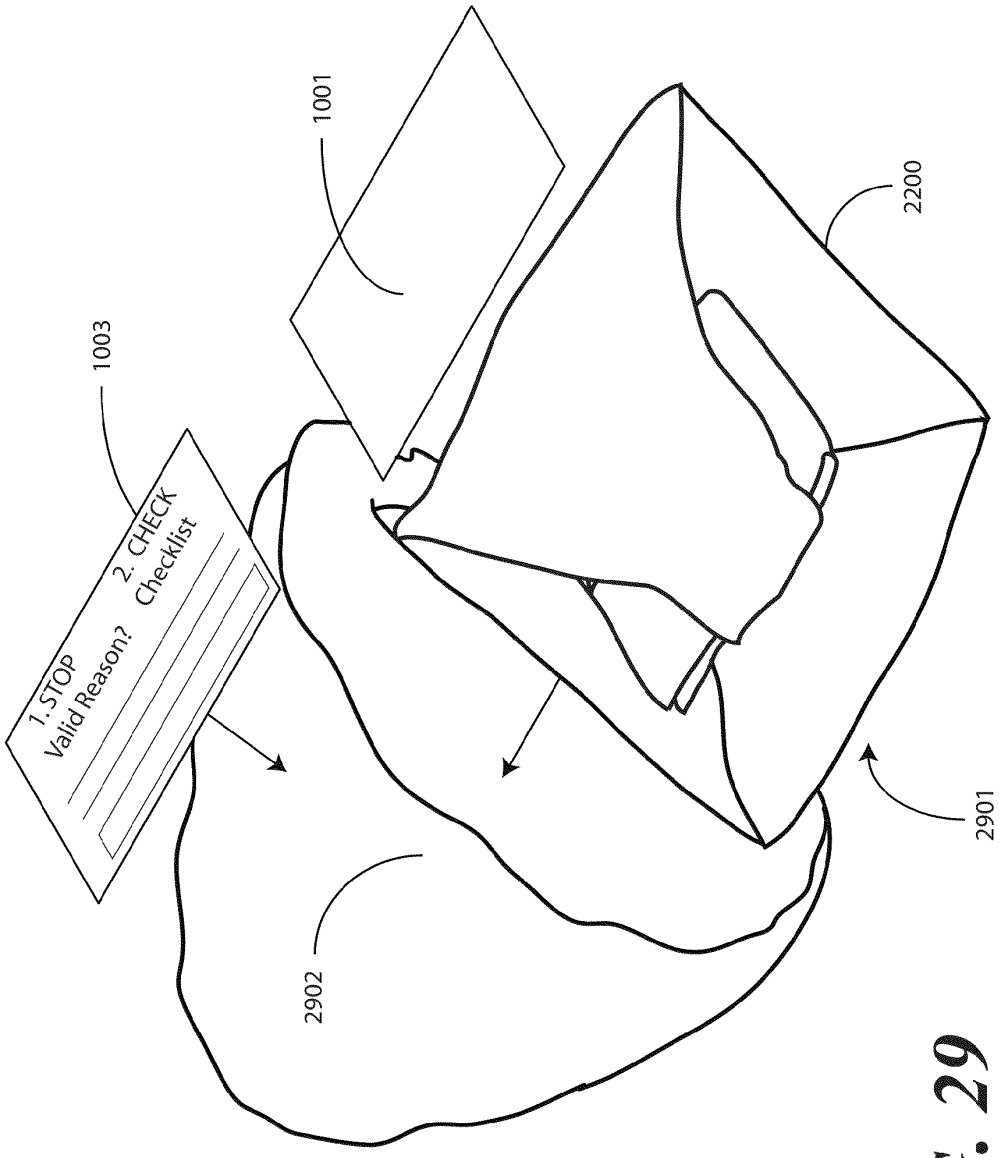

1001
2200
1003
1. STOP
Valid Reason?
2. CHECK
Checklist
2902
2901

FIG. 29

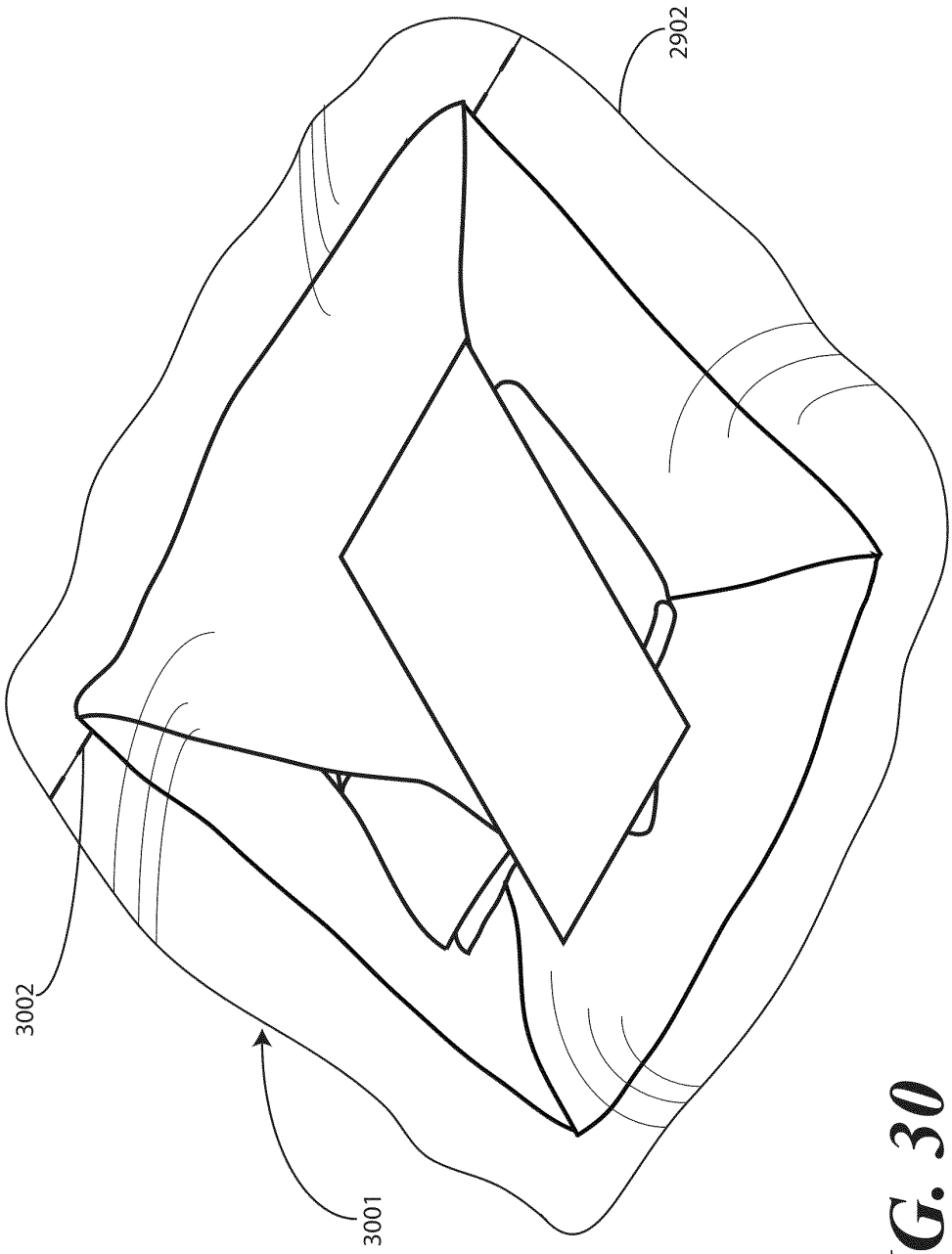


FIG. 30

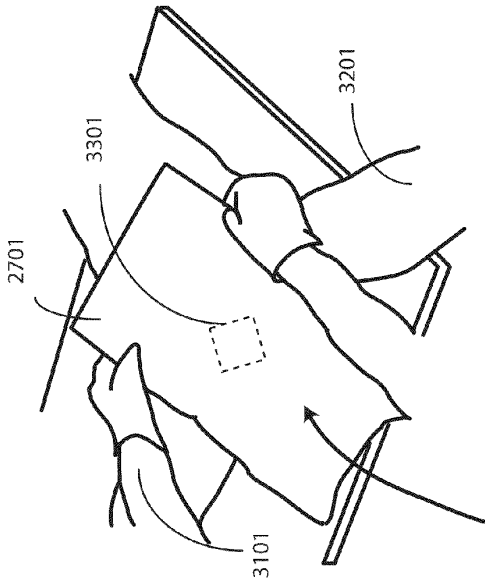


FIG. 33

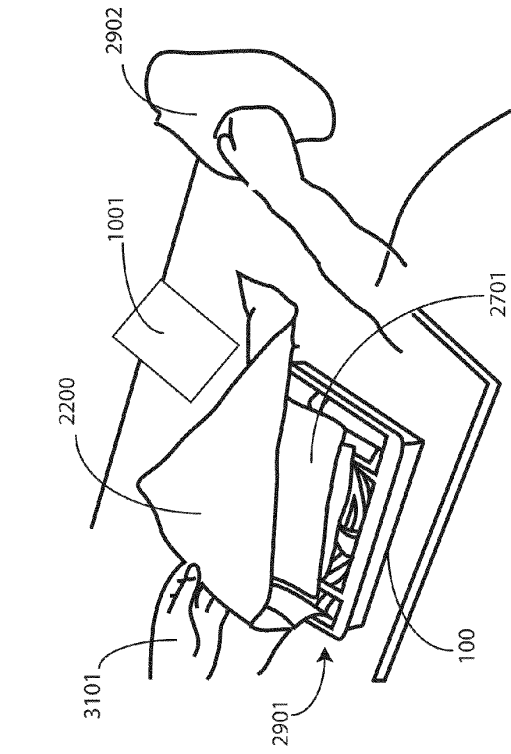


FIG. 31

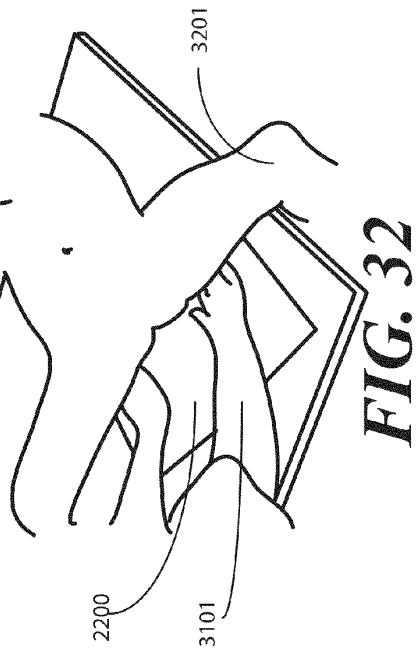


FIG. 32

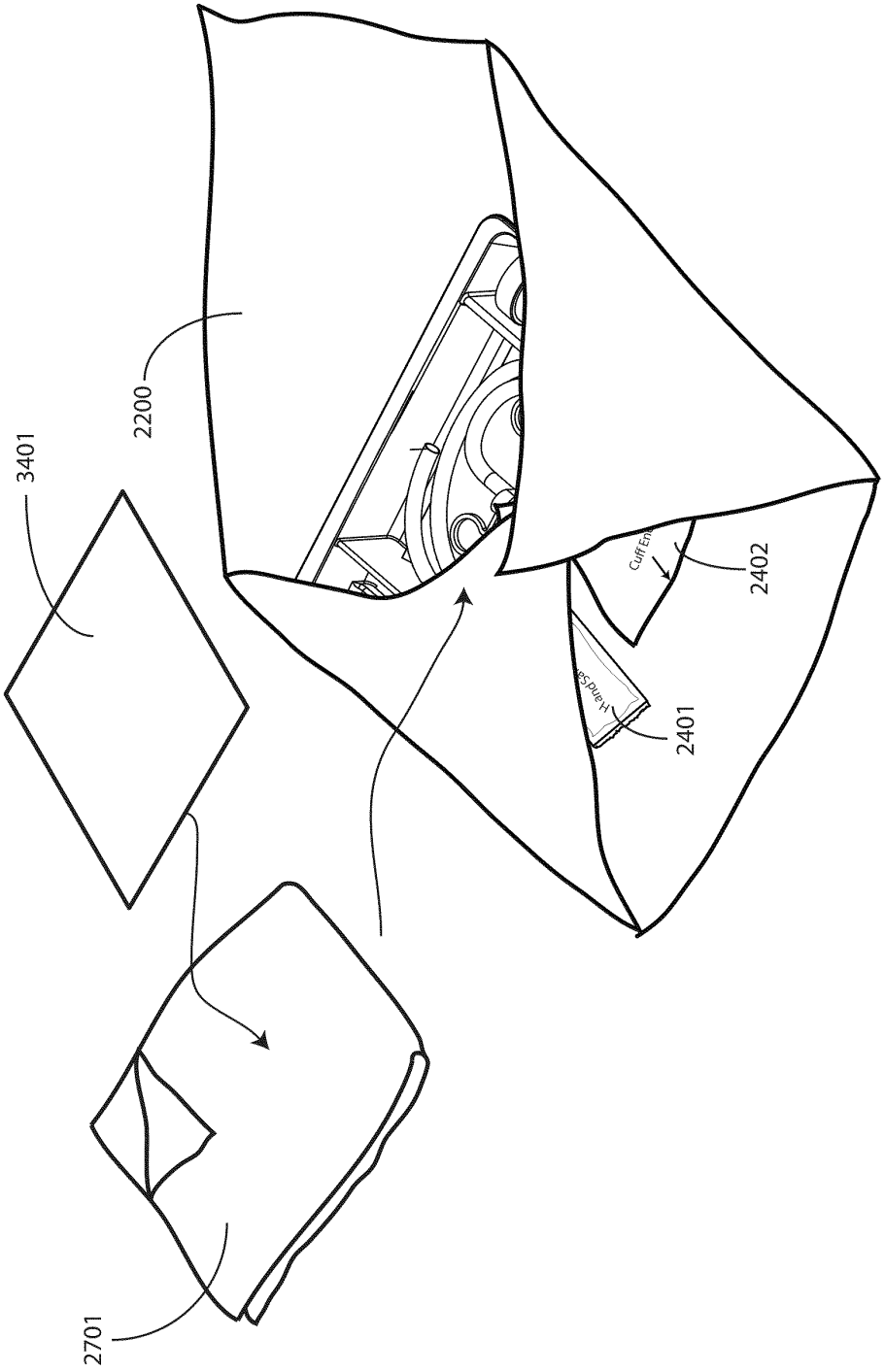


FIG. 34

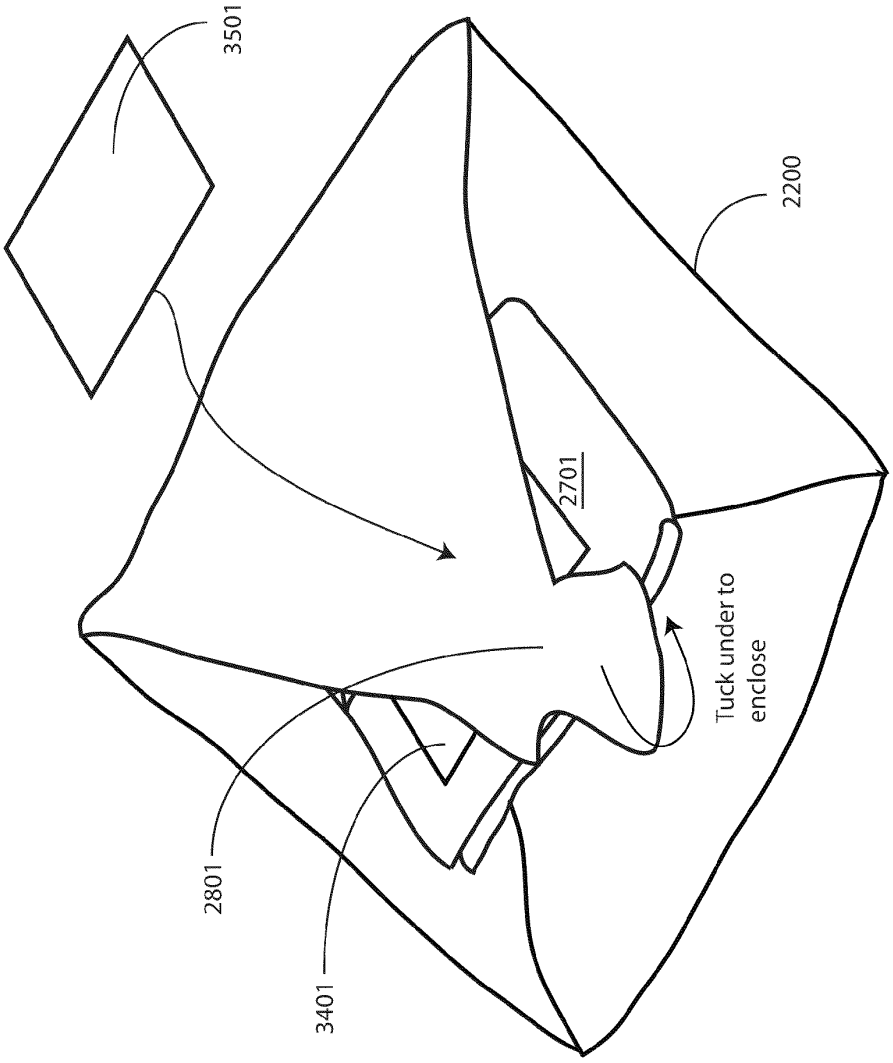


FIG. 35

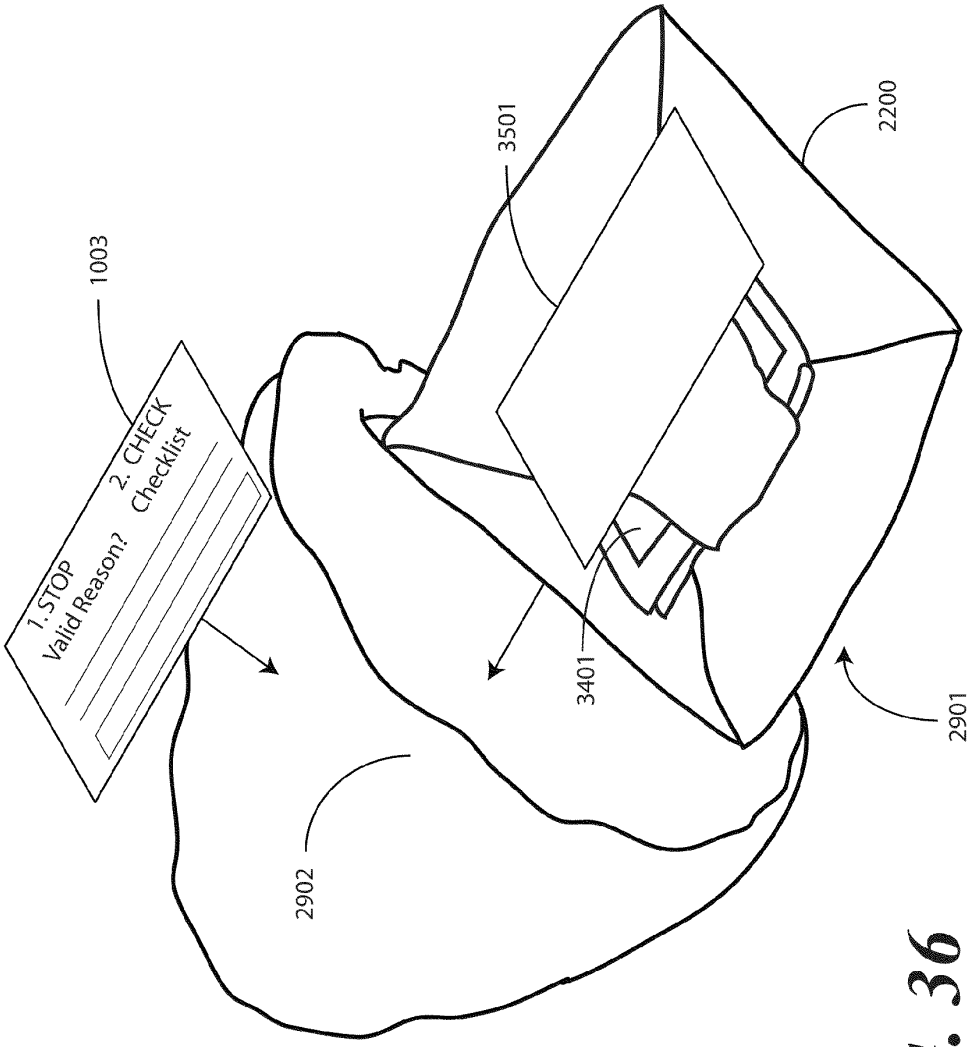

1003
1. STOP
Valid Reason?
2. CHECK
Checklist
3501
2200
3401
2901
2902

FIG. 36

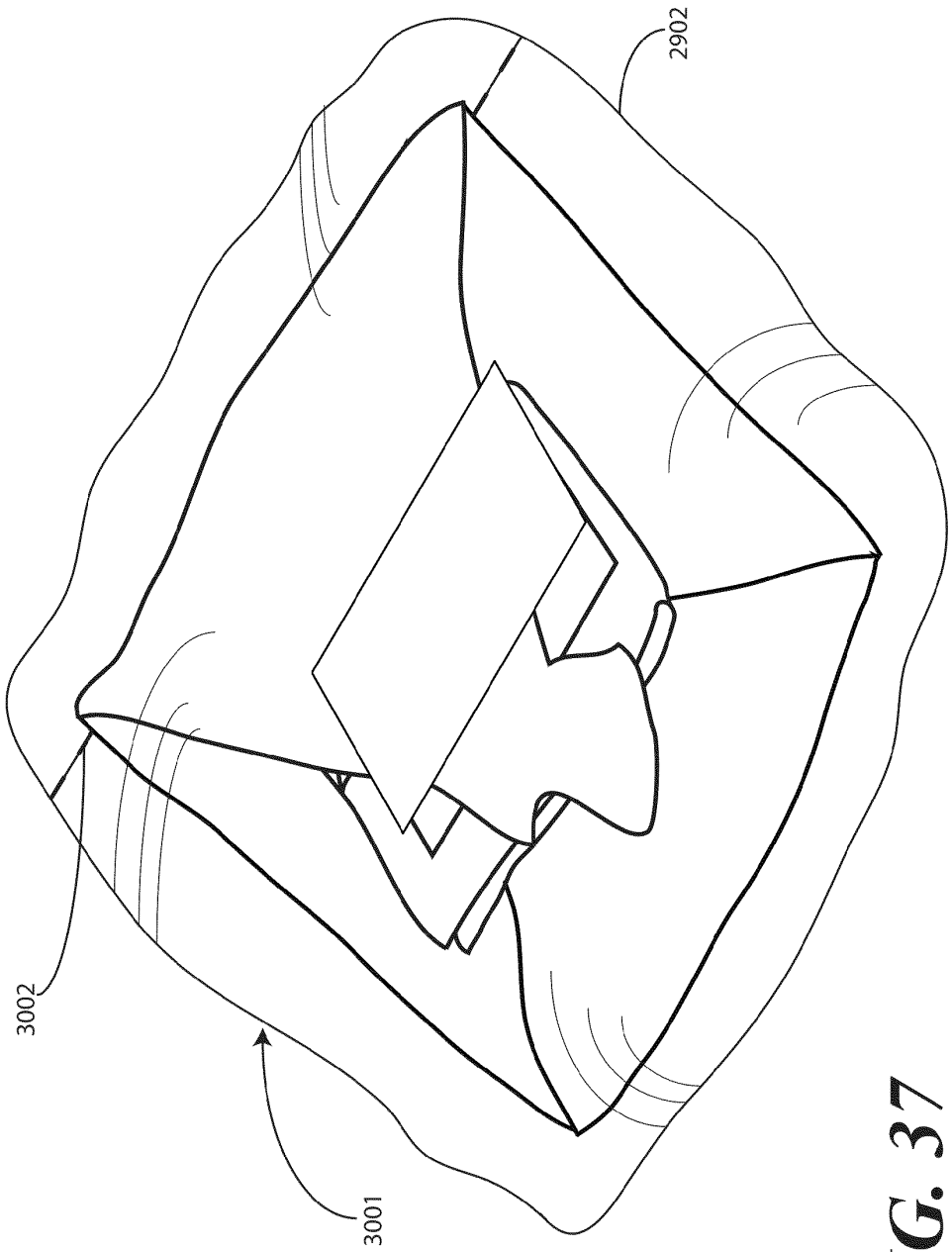


FIG. 37

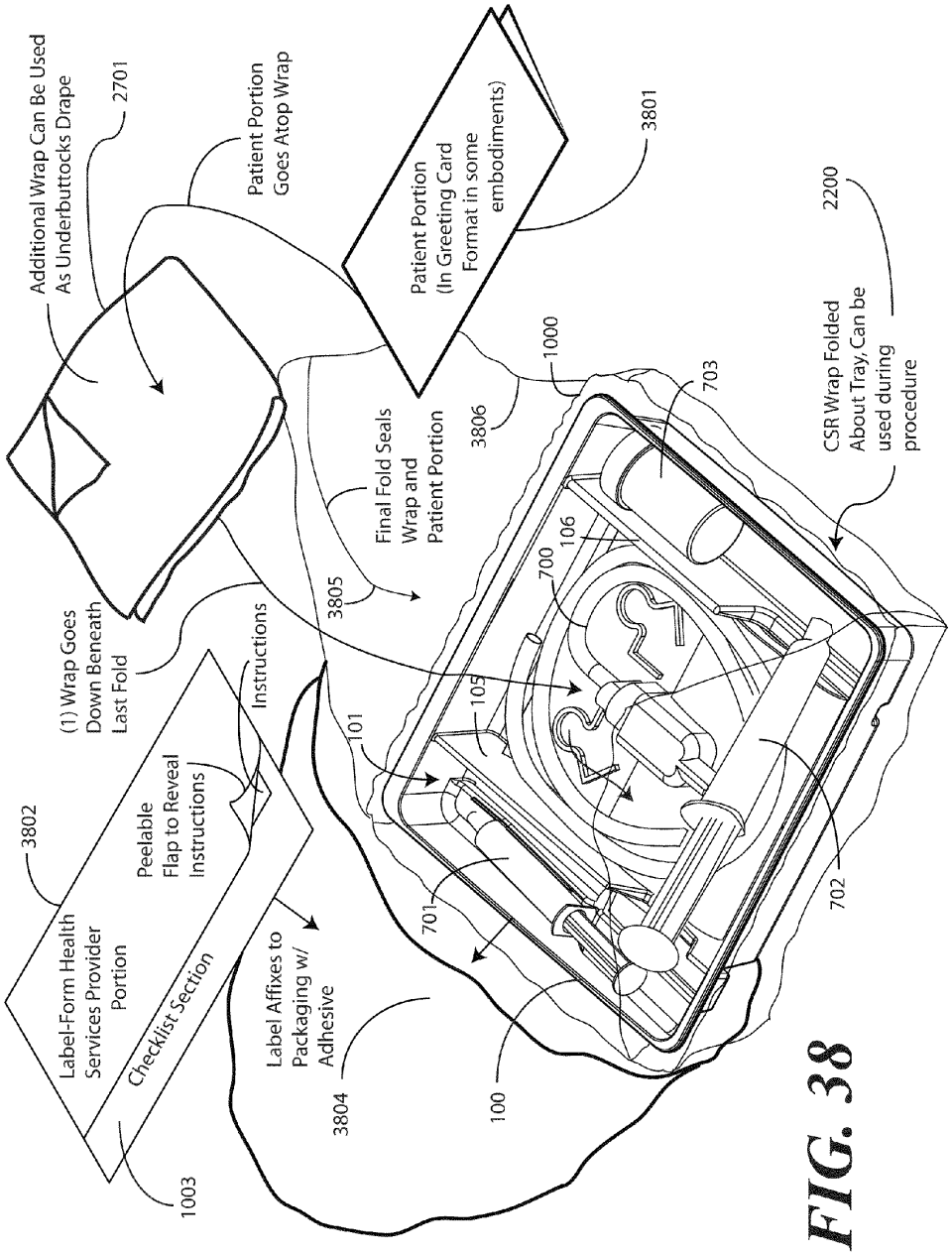


FIG. 38

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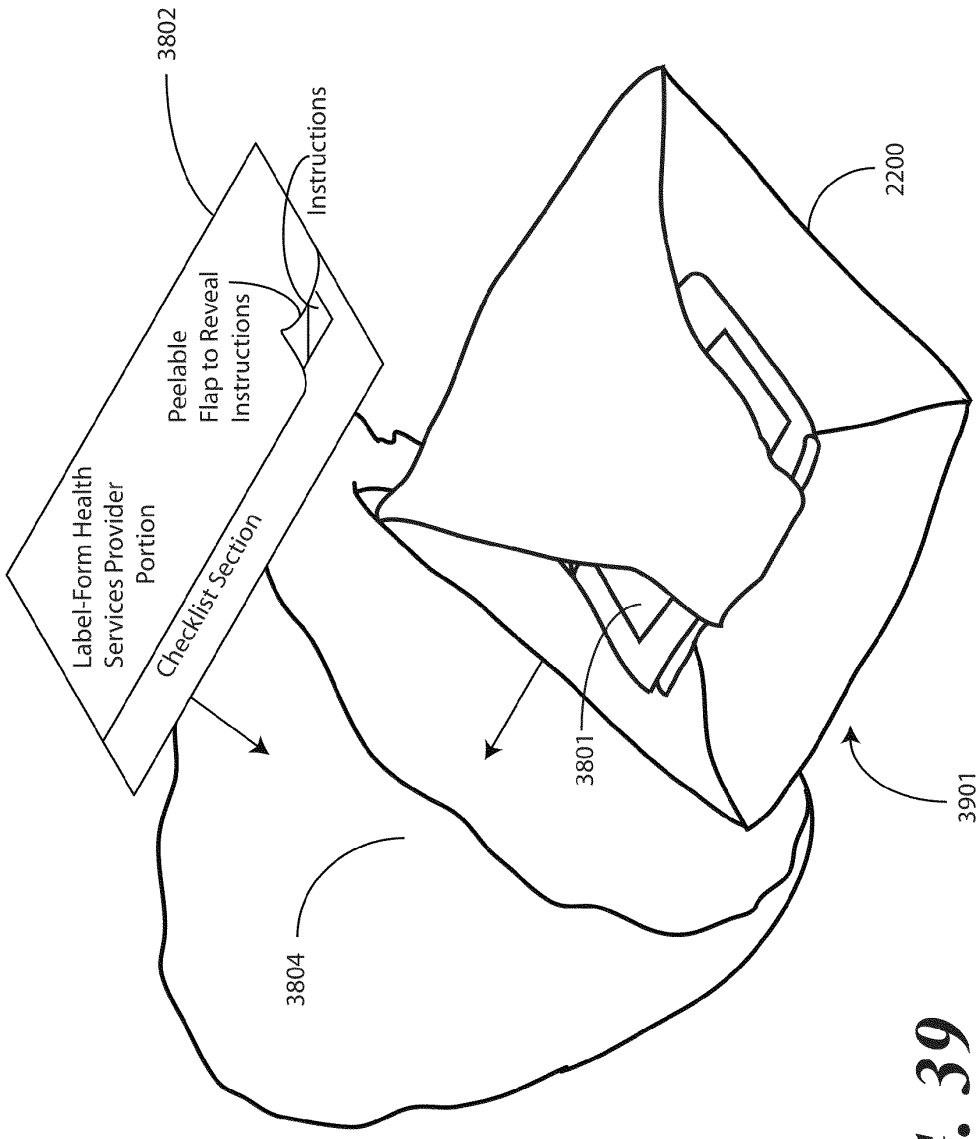

3802
Instructions
Peelable
Flap to Reveal
Instructions
Label-Form Health
Services Provider
Portion
Checklist Section
2200
3801
3901
3804

FIG. 39

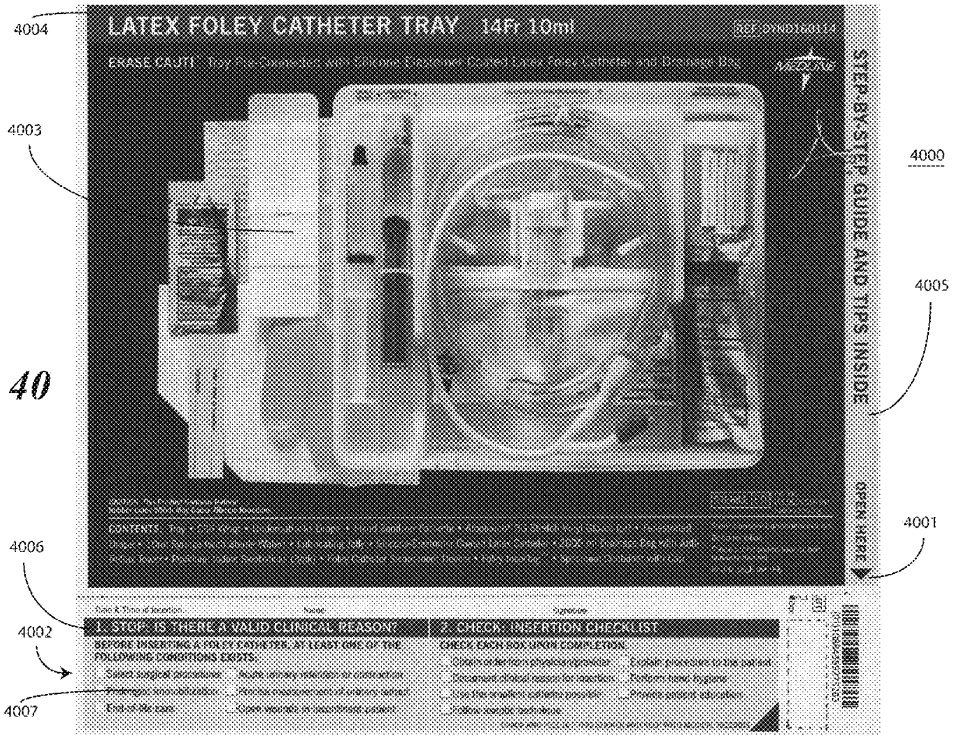

4004
LATEX FOLEY CATHETER TRAY 14Fr 10ml
4003
4000
STEP-BY-STEP GUIDE AND TIPS INSIDE
4005
OPEN HERE
4001
4006
1. STOP! IS THERE A VALID CLINICAL REASON?
2. CHECK INSERTION CHECKLIST
4002
4007

FIG. 40

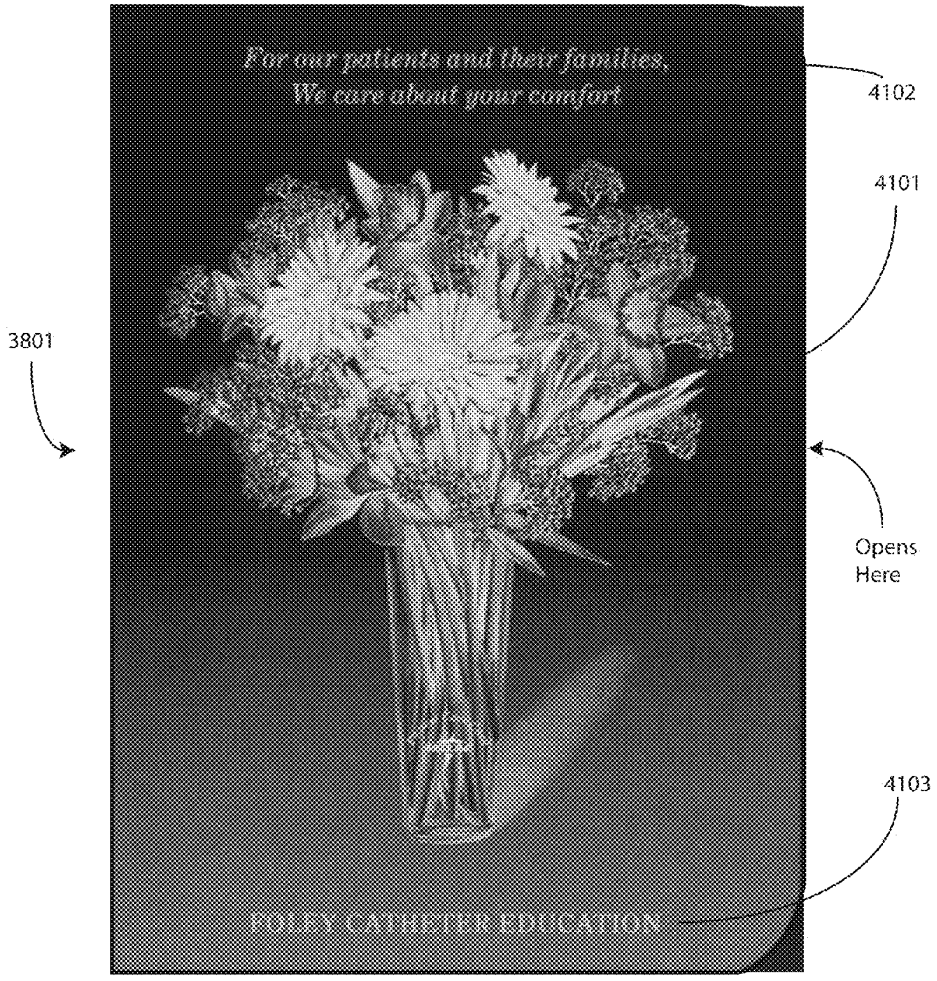

For our patients and their families.
We care about your comfort
4102
4101
3801
Opens
Here
4103
FOLEY CATHETER EDUCATION

FIG. 41

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS

CROSS REFERENCE TO PRIOR APPLICATIONS

This application 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.

This application is a continuation in part of, and therefore claims priority to the following applications, each of which is incorporated herein by reference: U.S. patent application Ser. No. 12/495,148, filed Jun. 30, 2009; U.S. patent application Ser. No. 12/647,515, filed Dec. 27, 2009; U.S. patent application Ser. No. 13/153,265, filed Jun. 3, 2011; and U.S. patent application Ser. No. 13/153,300, filed Jun. 3, 2011.

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

1. 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.

2. 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.

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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**. 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**.

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 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**.

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 nee 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 method of using a catheter package assembly, comprising:

opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein;

accessing an instruction manual;

unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly; and

placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.

2. The method of claim **1**, wherein the instruction manual comprises a health care services portion and a patient portion detachably coupled thereto.

3. The method of claim **1**, wherein the instruction manual comprises a patient portion configured as a greeting card and disposed at least partially within the one or more layers of wrap material.

4. The method of claim **3**, wherein the accessing comprises peeling a peelable flap from a health care services portion of printed instructions affixed to the thermally sealed bag.

5. The method of claim **2**, wherein the accessing comprises accessing the patient portion prior to the unfolding and accessing the health care services portion after at least some of the unfolding.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,448,786 B2
APPLICATION NO. : 13/155026
DATED : May 28, 2013
INVENTOR(S) : Tomes et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (75) Inventor is corrected to read:
-- Jennifer E. Tomes, Mundelein (IL);
Sarah Zyburt, Chicago (IL);
Susan E. Macinnes, Trout Valley (IL);
Deborah B. Adler, New York (NY) --.

Signed and Sealed this
Sixteenth Day of July, 2019

Andrei Iancu
Director of the United States Patent and Trademark Office

EXHIBIT 5

US007278987B2

(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.**

A61B 19/00	(2006.01)
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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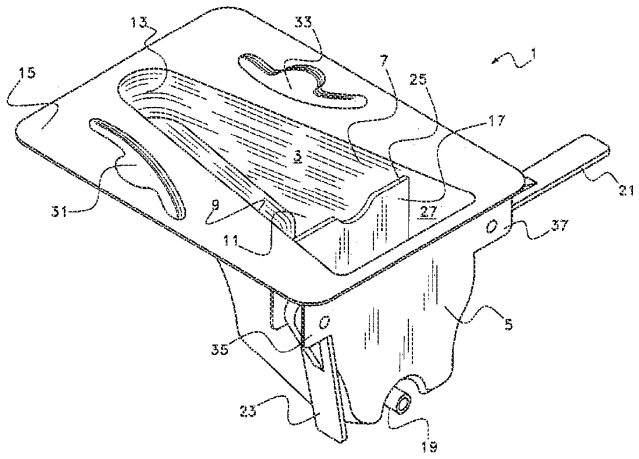
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Primary Examiner—Tatyana Zalukaeva
Assistant Examiner—Paula L. Craig
(74) *Attorney, Agent, or Firm*—Kenneth P. Glynn, Esq.

(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



Bard Exhibit 1004.0756

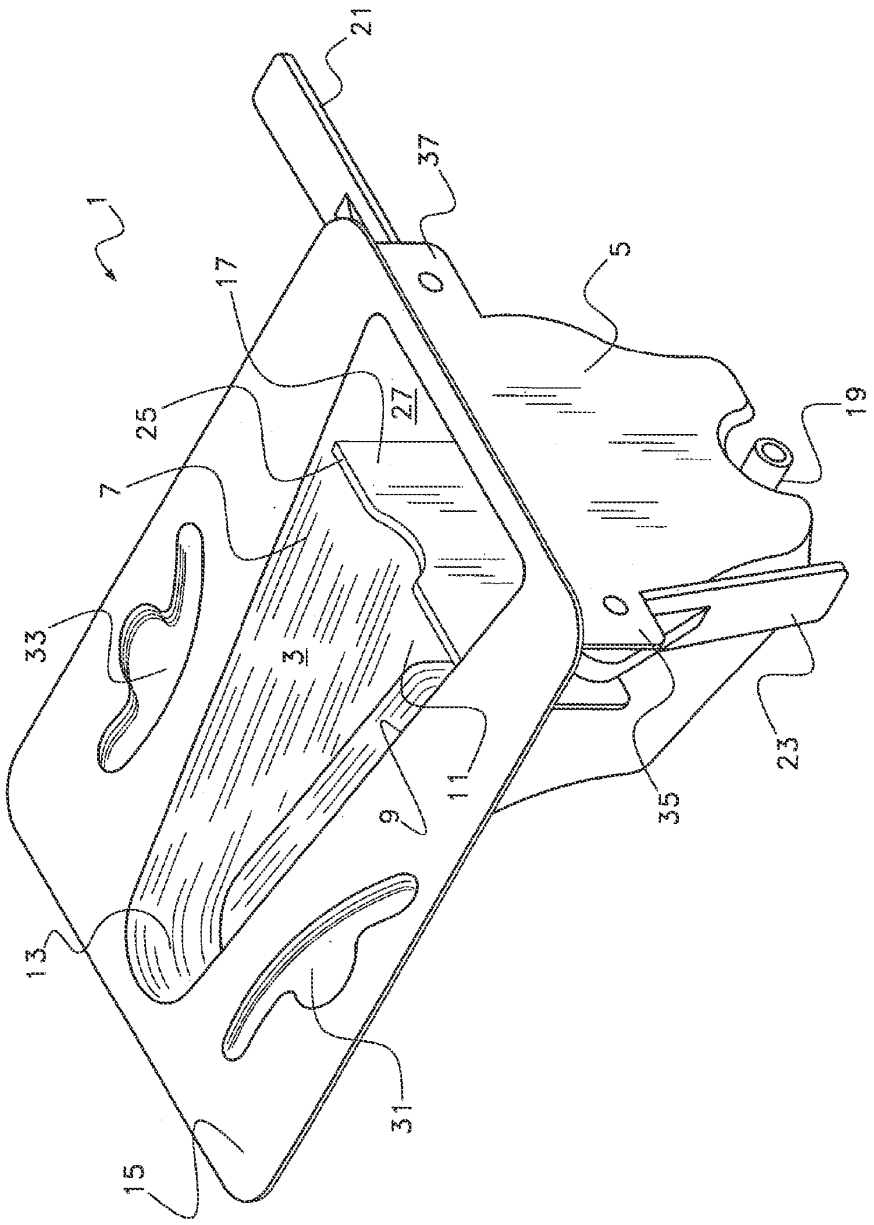


Fig. 1

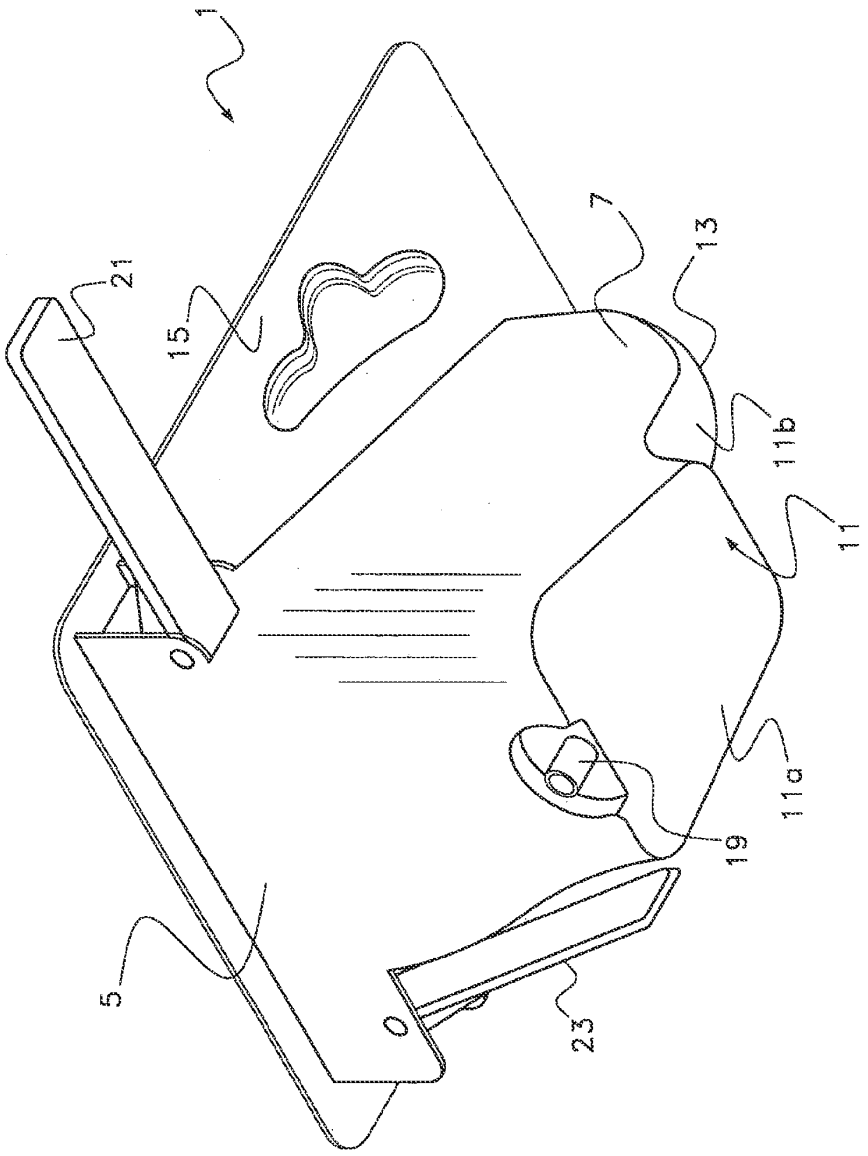
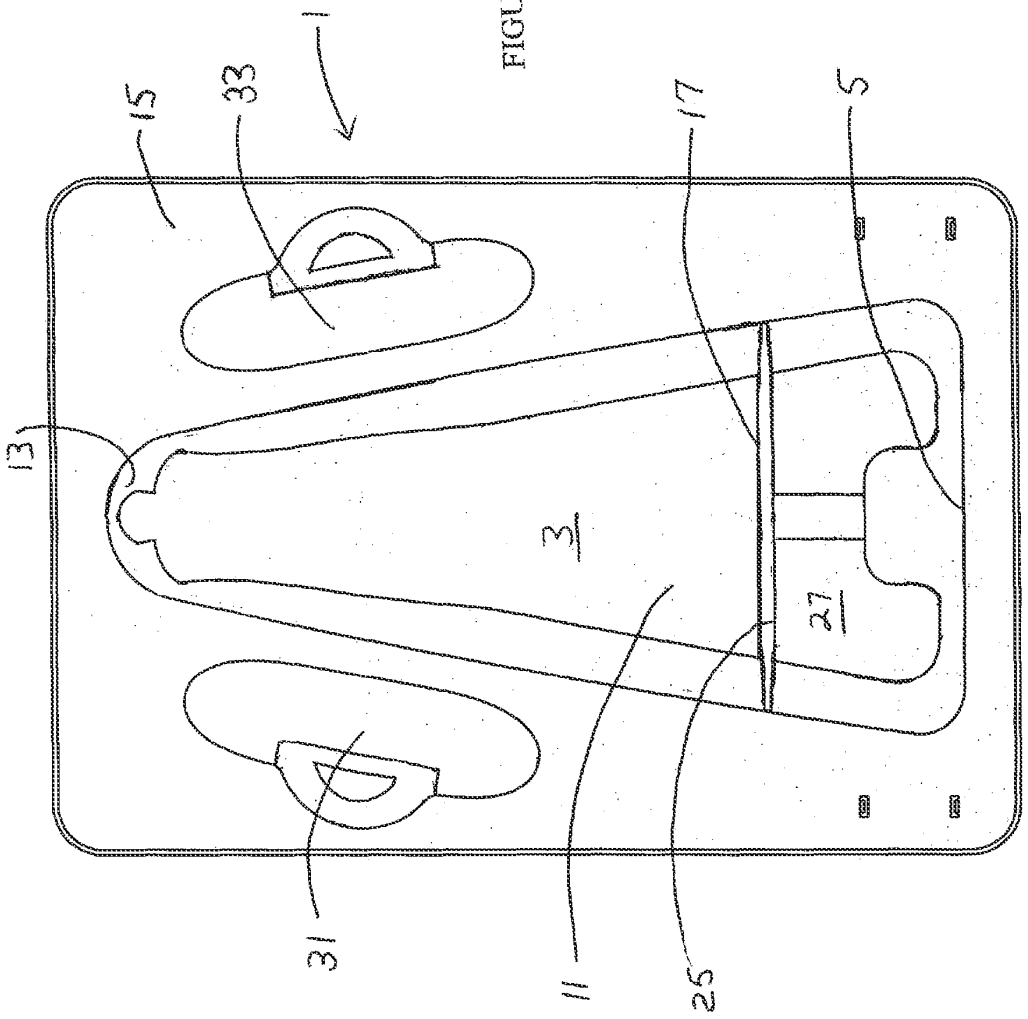


Fig. 2

FIGURE 3



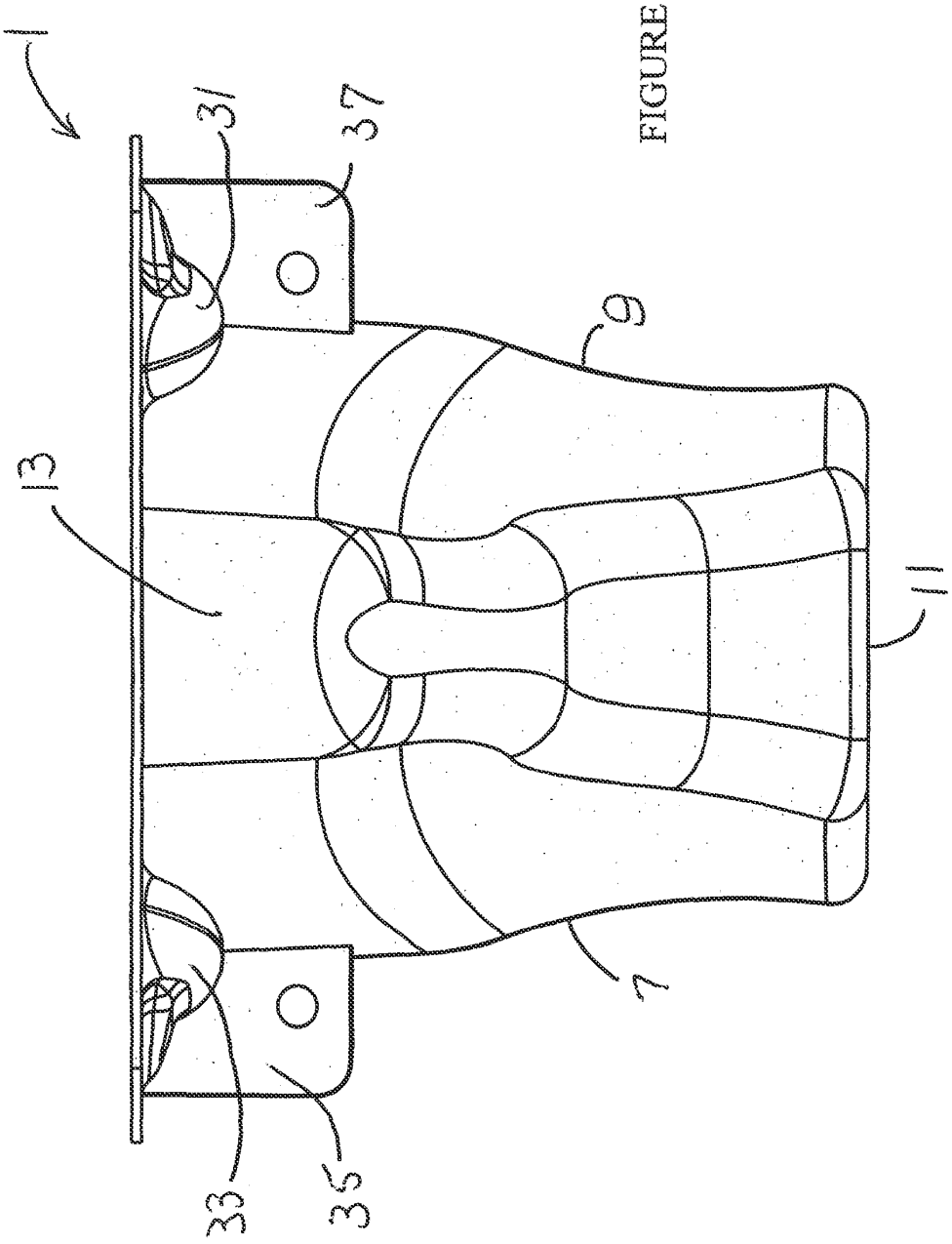


FIGURE 4

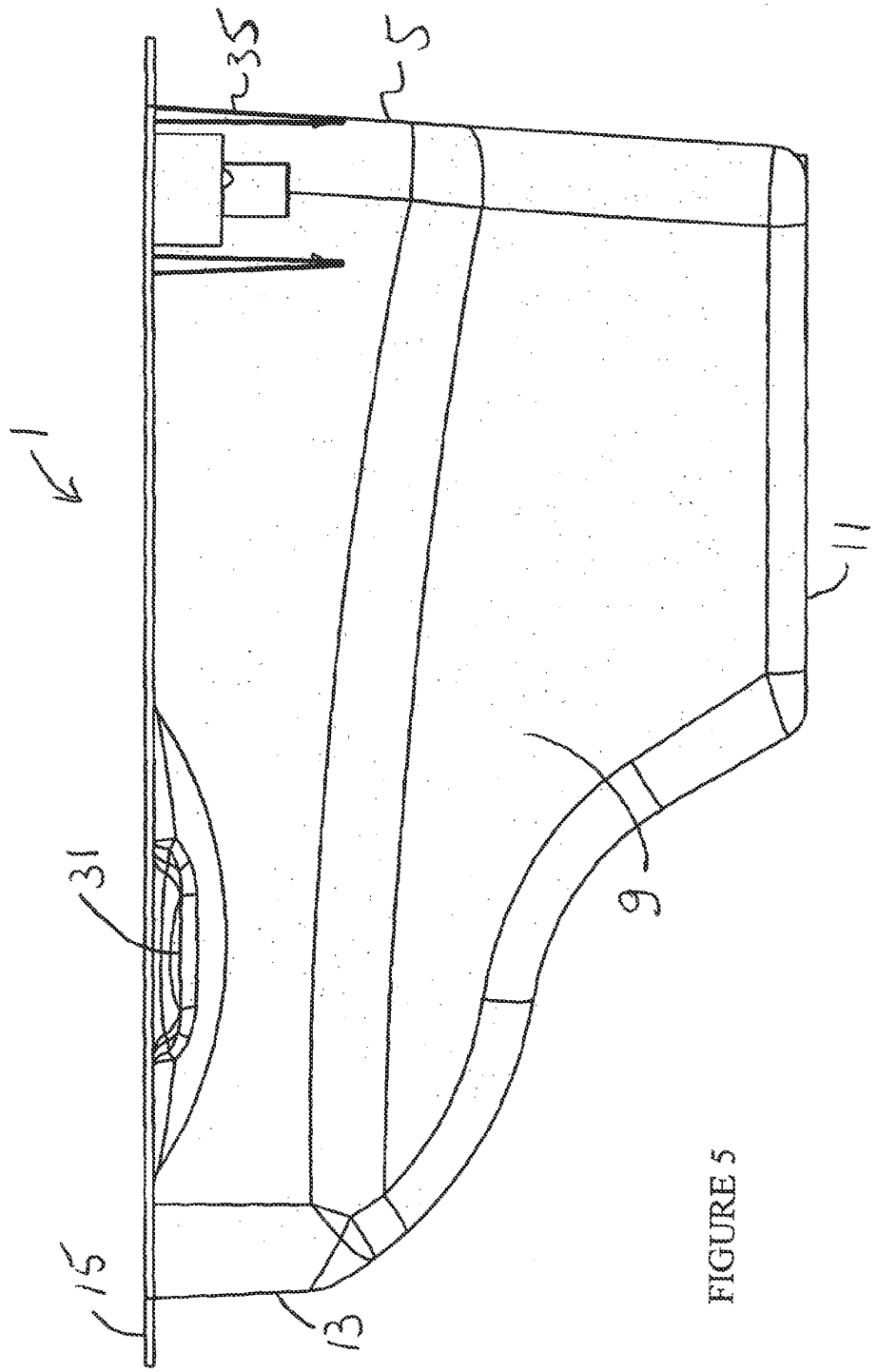


FIGURE 5

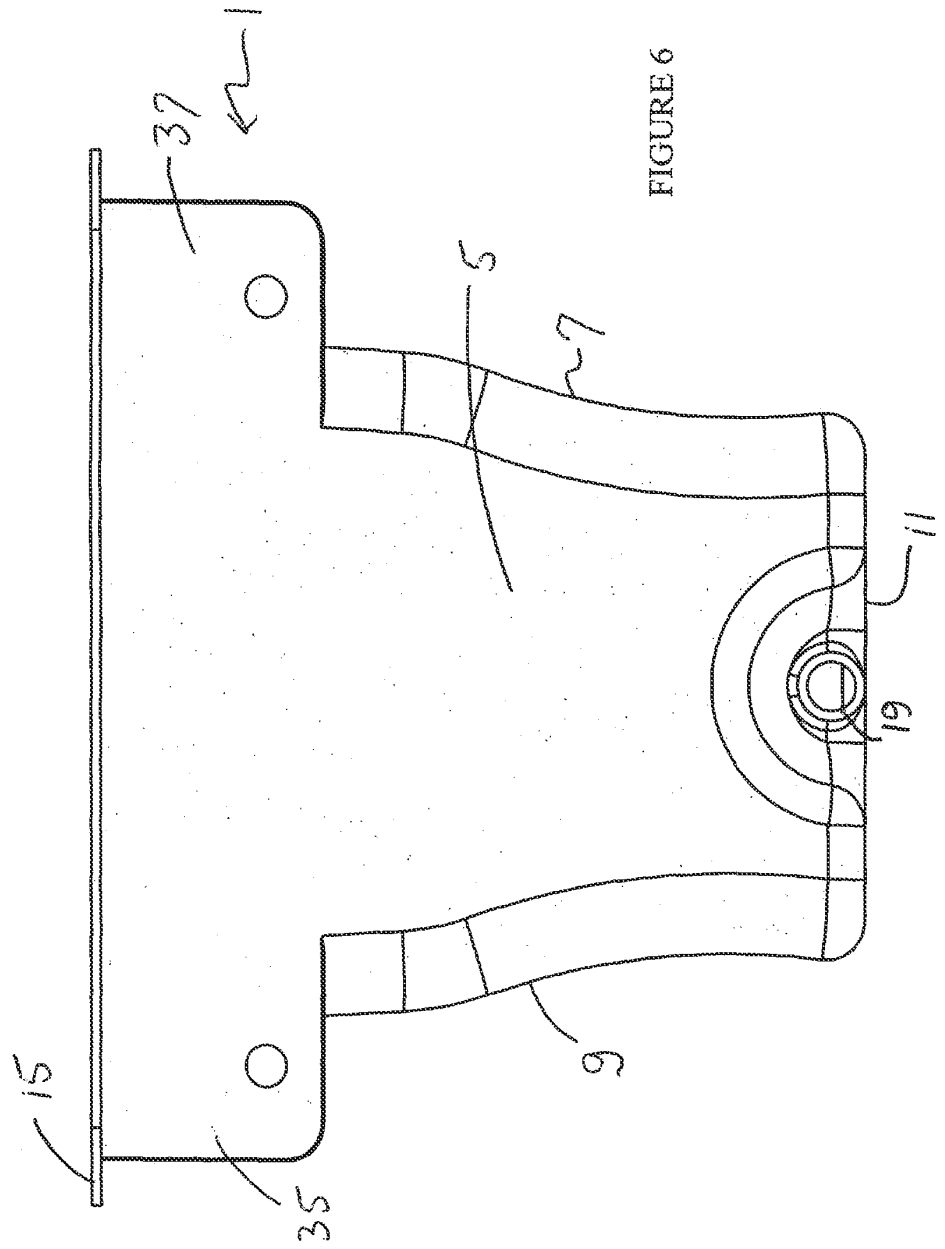


FIGURE 6

FIGURE 7

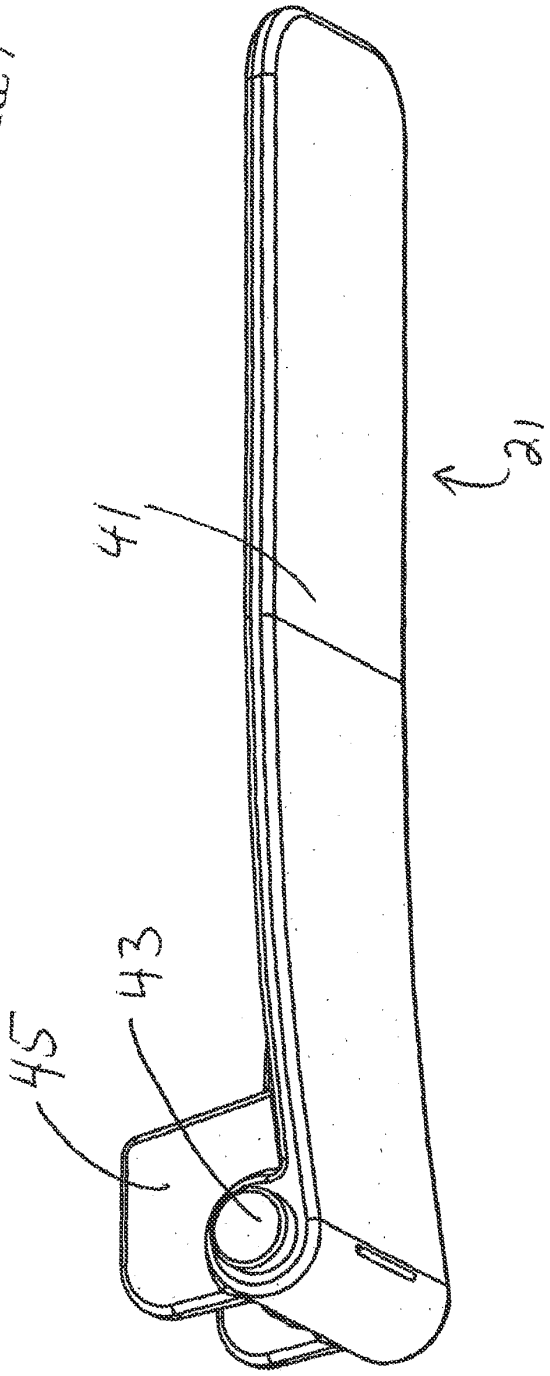
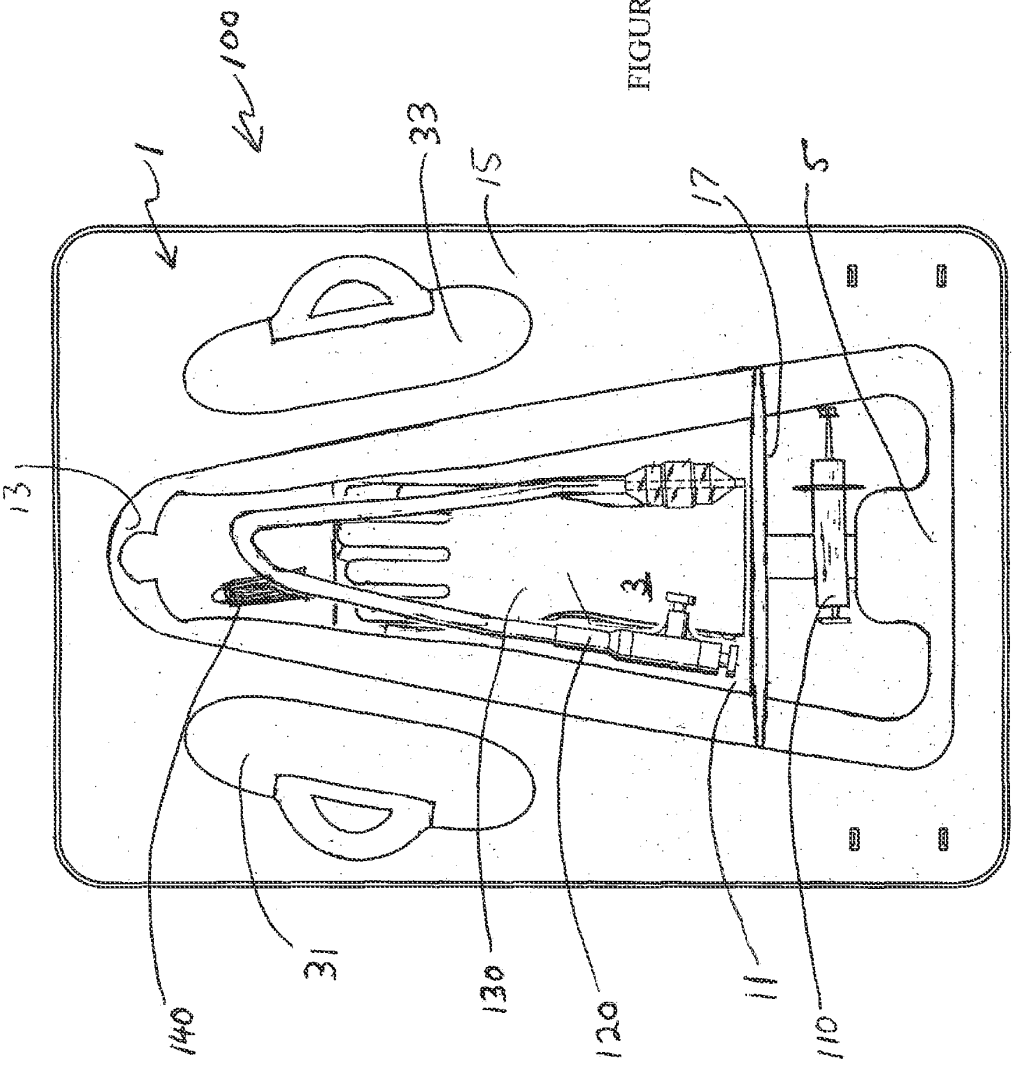


FIGURE 8



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

Bard Exhibit 1004.0765

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

Bard Exhibit 1004.0766

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.

* * * * *

EXHIBIT 7

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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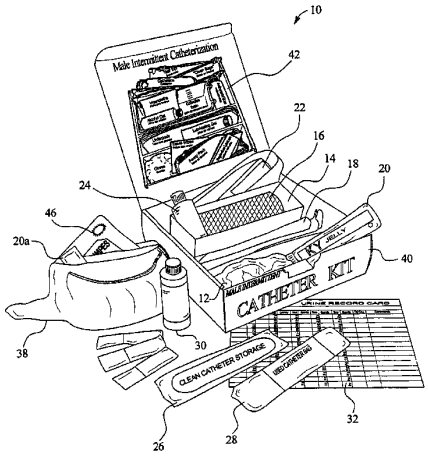
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Primary Examiner—Luan K. Bui
(74) *Attorney, Agent, or Firm*—Bell, Boyd & Lloyd LLC

(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



Bard Exhibit 1004.0769

FIG. 1

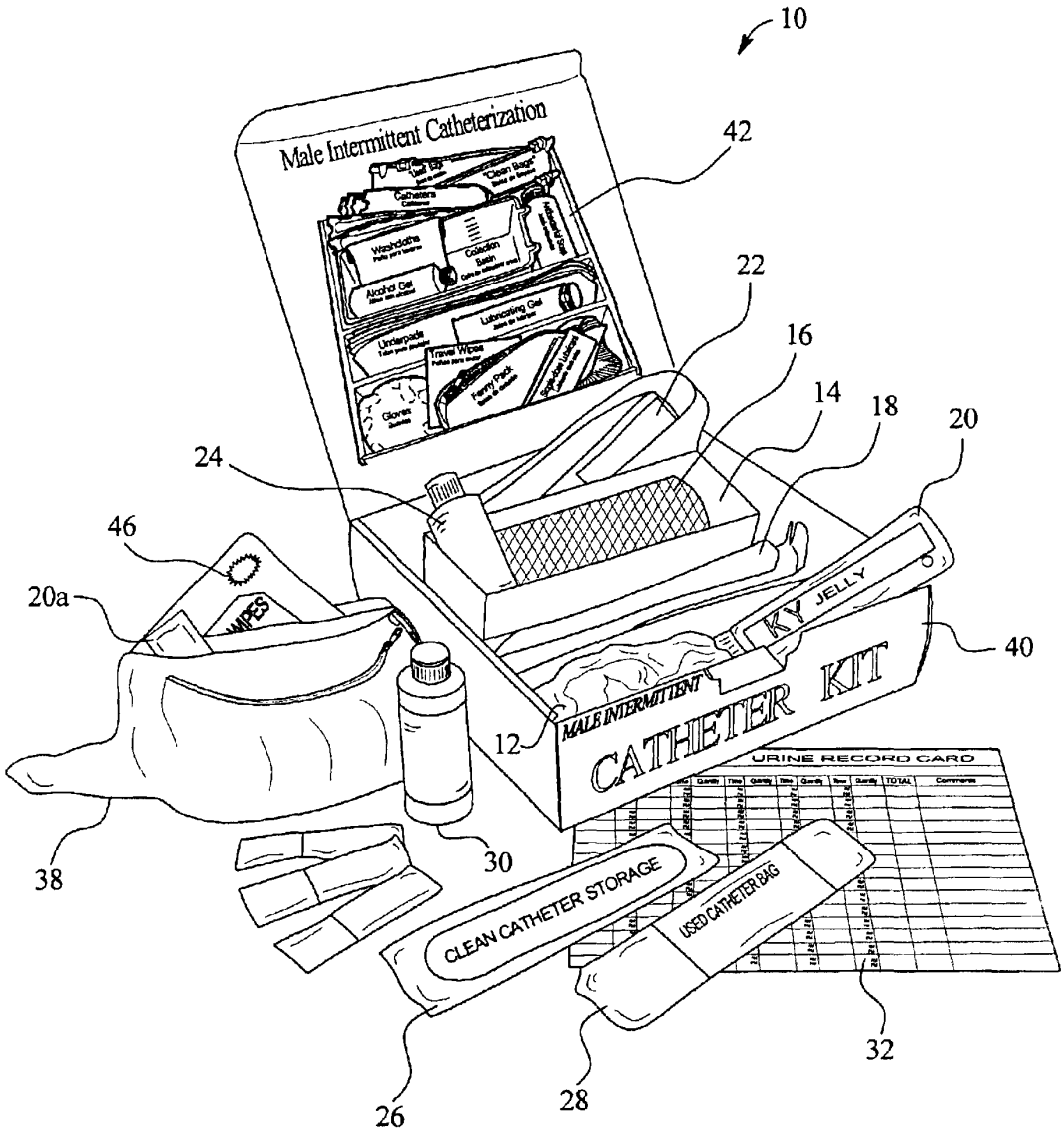

10
Male Intermittent Catheterization
42
22
16
14
18
20
24
46
20a
WIPES
KY JELLY
40
MALE INTERMITTENT
CATHETER KIT
12
URINE RECORD CARD
38
30
CLEAN CATHETER STORAGE
USED CATHETER BAG
32
26
28

FIG. 1A

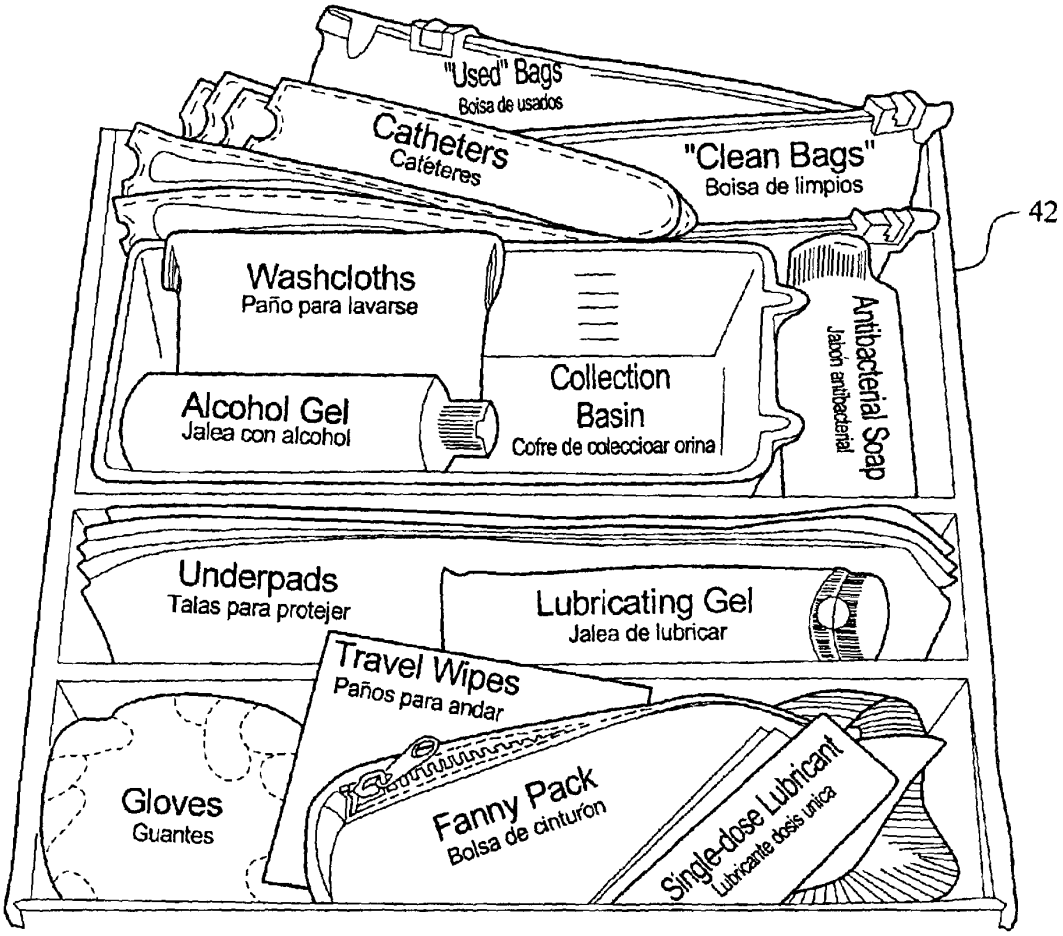

"Used" Bags
Bolsa de usados
Catheters
Catéteres
"Clean Bags"
Boisa de limpios
42
Washcloths
Paño para lavarse
Collection
Basin
Cofre de coleccioar orina
Antibacterial Soap
Jabon antibacterial
Alcohol Gel
Jalea con alcohol
Underpads
Talas para protejer
Lubricating Gel
Jalea de lubricar
Travel Wipes
Paños 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.

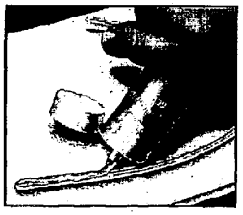


2 Wash your penis with the Paper Wash Cloth and Antibacterial Soap and warm water. Clean the head of your penis well, pulling the foreskin back if necessary.

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.

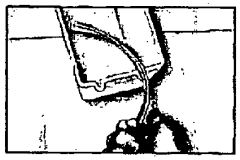
The Catheter



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.

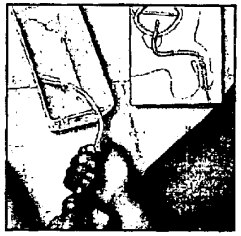


5 Lift the Catheter away from the paper towel and lay the wide end in the Collection Container. Move the Container close to your body so you do not accidentally pull the wide end of the Catheter out.



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.

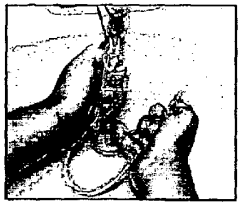
Continued on the back of this page...

FIG. 2B

34

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.



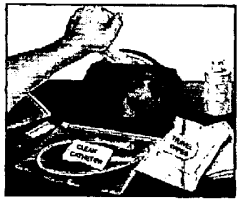
12 The Catheter should be dry by this time. Put it inside the Plastic Bag marked "Clean Catheter" and zip it closed.

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:

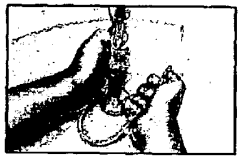
- A clean Catheter in the "Clean Catheter" Bag
- One Packet of Lubricating Jelly
- Two clean paper towels



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.

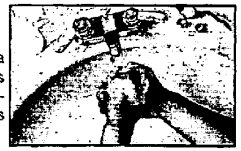
FIG. 3A

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.

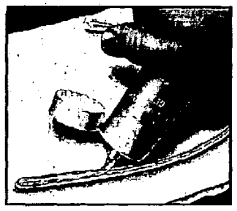


2 Lave su pene con el Paño para Lavarse, el Jabón Antibacterial, y agua tibia. Limpie la cabeza de su pene muy bien. Si Ud. no ha sido cincumcisado, mueva su piel hacia arriba para poder lavarse mejor.

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.

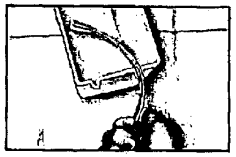
El Catétere



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.

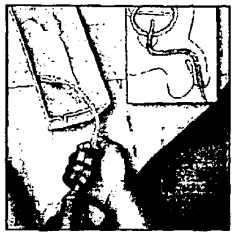


5 Recoja el Catétere de la tolla de papel y coloque la punta gruesa del Catétere en el Cofre de Coleccionar Orina. Acerque el cofre a su cuerpo para asi evitar que Ud. accidentalmente jale el Catétere fuera del cofre.



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.

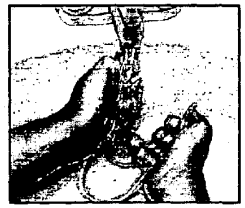
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FIG. 3B

34A

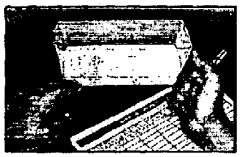
Cateterización Intermitente para el hombre *continuación...* pagina 2

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

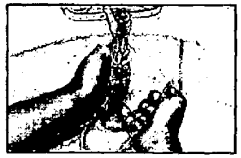
A Por cada 4 horas que Ud. este de viaje meta en la Bolsa de cinturón:
- Un Catétere limpio en la Bolsa de Limpios
- Un Paquete de Jalea para Lubricar
- Dos toallas de papel limpias



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

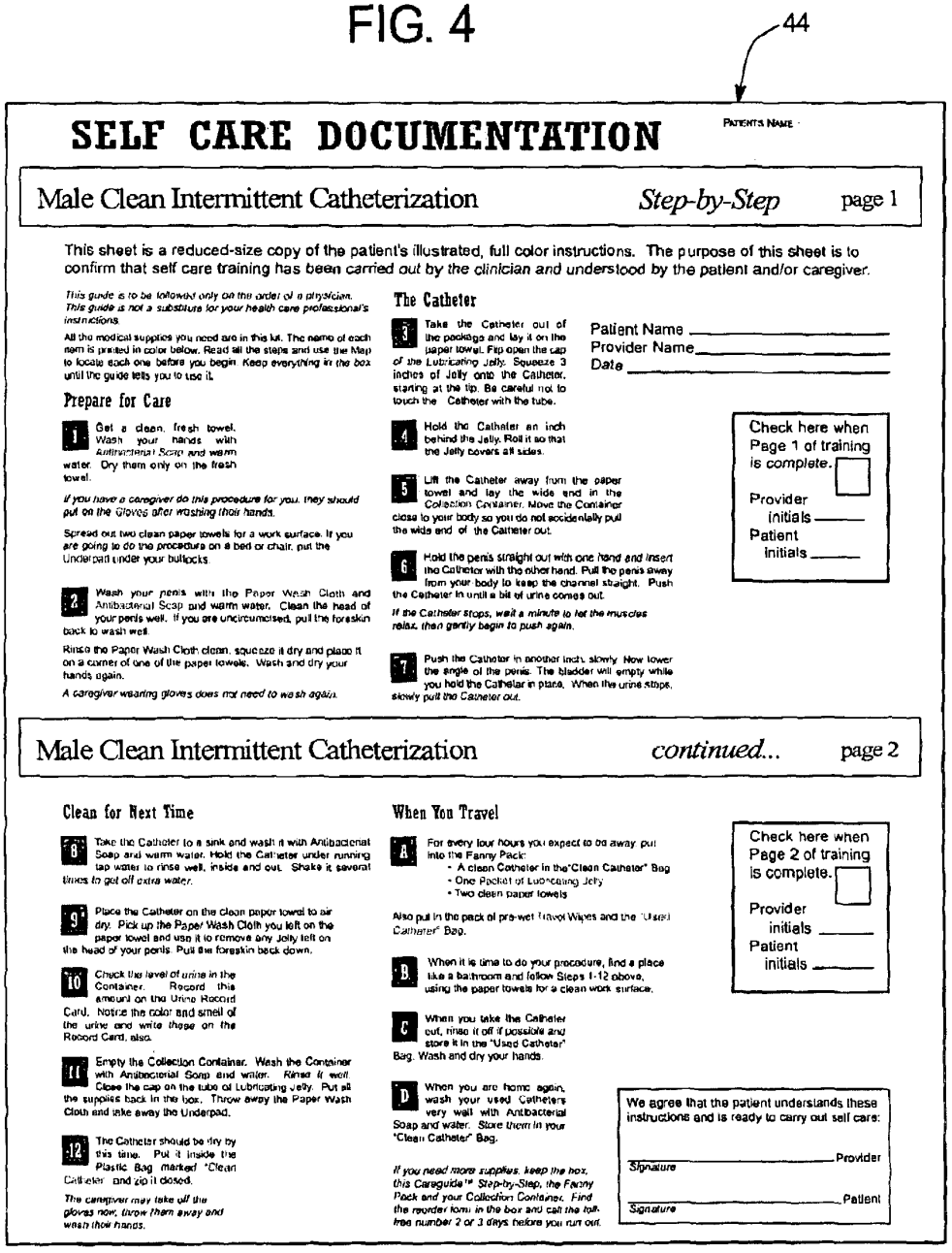

44
SELF CARE DOCUMENTATION
PATIENT'S NAME
Male Clean Intermittent Catheterization
Step-by-Step
page 1
This sheet is a reduced-size copy of the patient's illustrated, full color instructions. The purpose of this sheet is to confirm that self care training has been carried out by the clinician and understood 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			
	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			

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.

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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**.

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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**

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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;

Bard Exhibit 1004.0781

(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.

* * * * *

EXHIBIT 11

US009808400B2

(12) **United States Patent**
Tomes et al.

(10) **Patent No.: US 9,808,400 B2**
(45) **Date of Patent: *Nov. 7, 2017**

(54) **CATHETER TRAY, PACKAGING SYSTEM, AND ASSOCIATED METHODS**

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(73) Assignee: **Medline Industries, Inc.**, Mundelein, IL (US)

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(58) **Field of Classification Search**
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See application file for complete search history.

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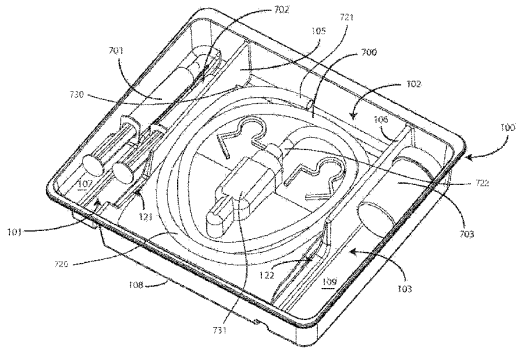
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Primary Examiner — Robert Poon

(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 1004.0784

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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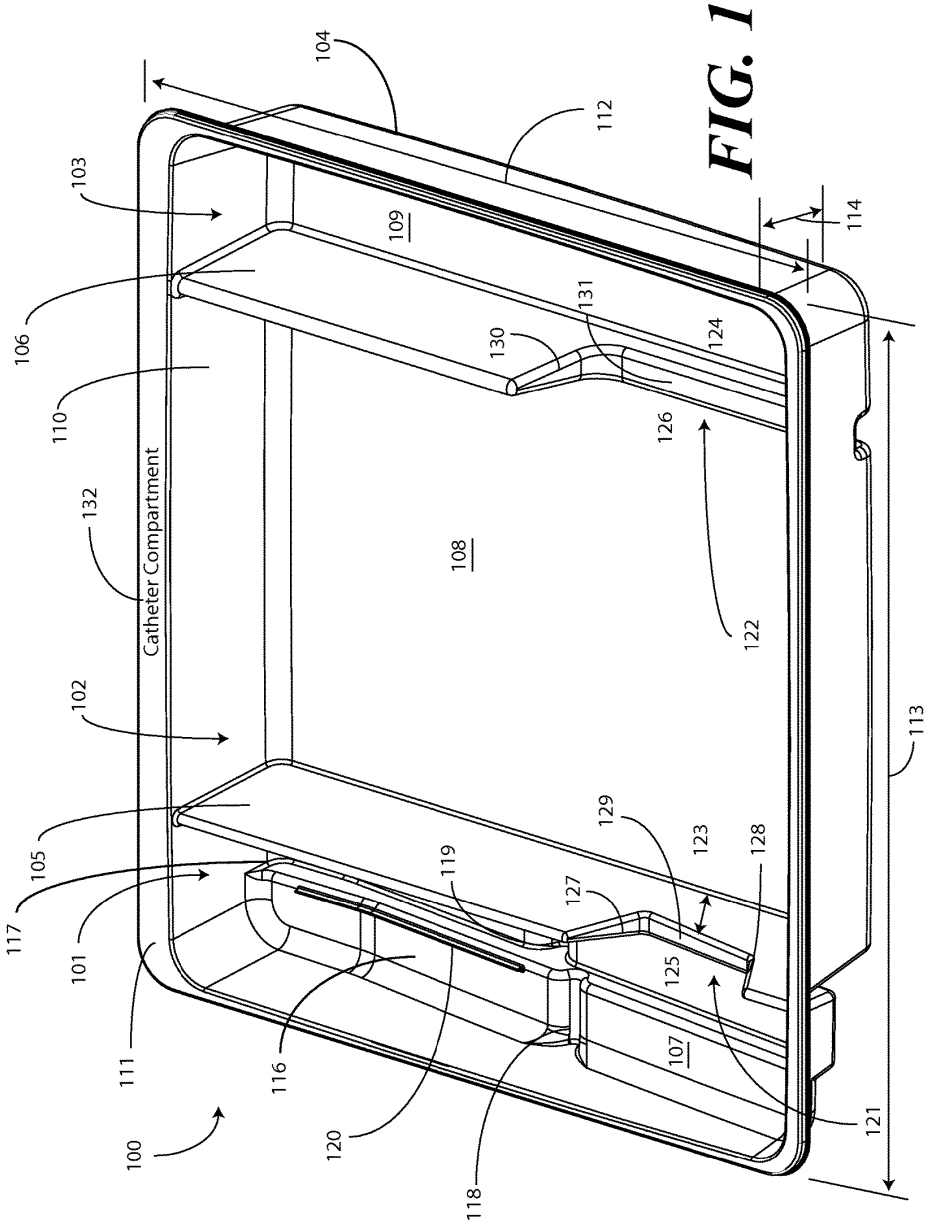


FIG. 1

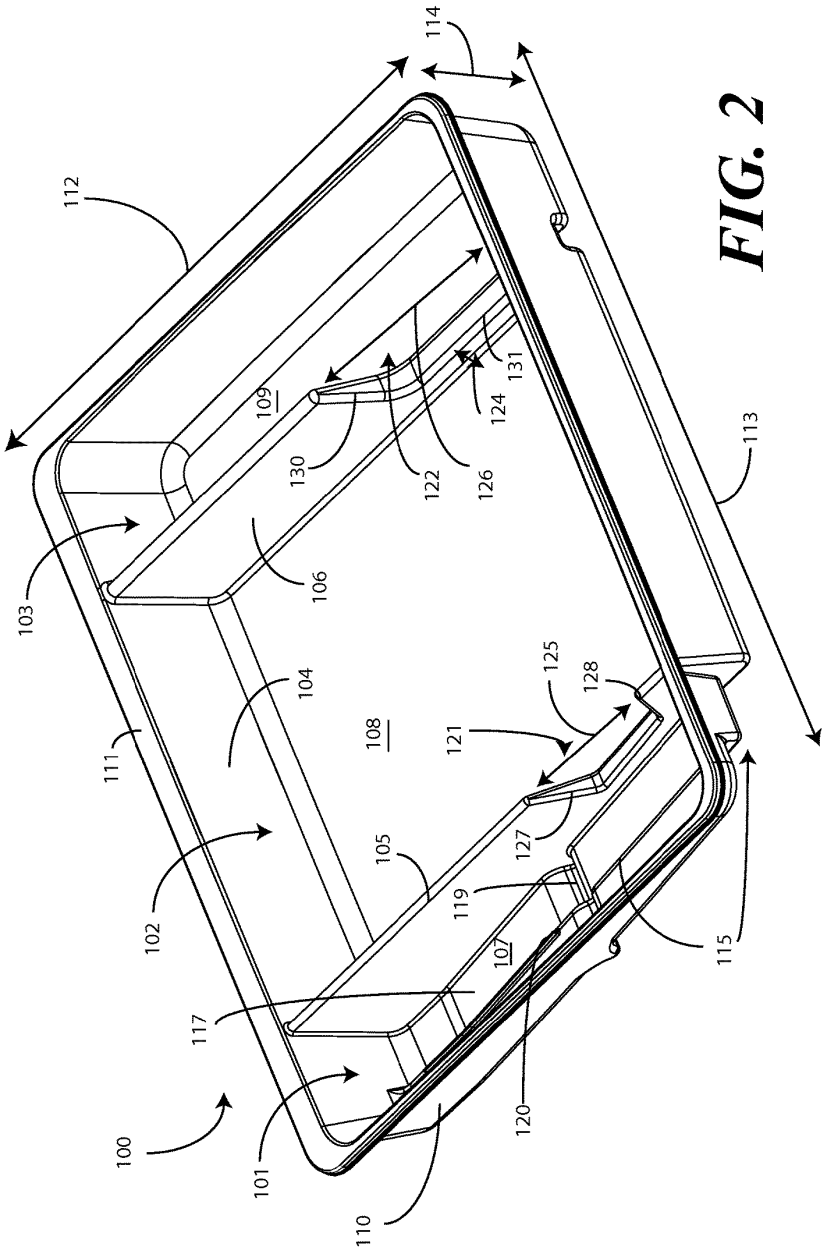

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FIG. 2

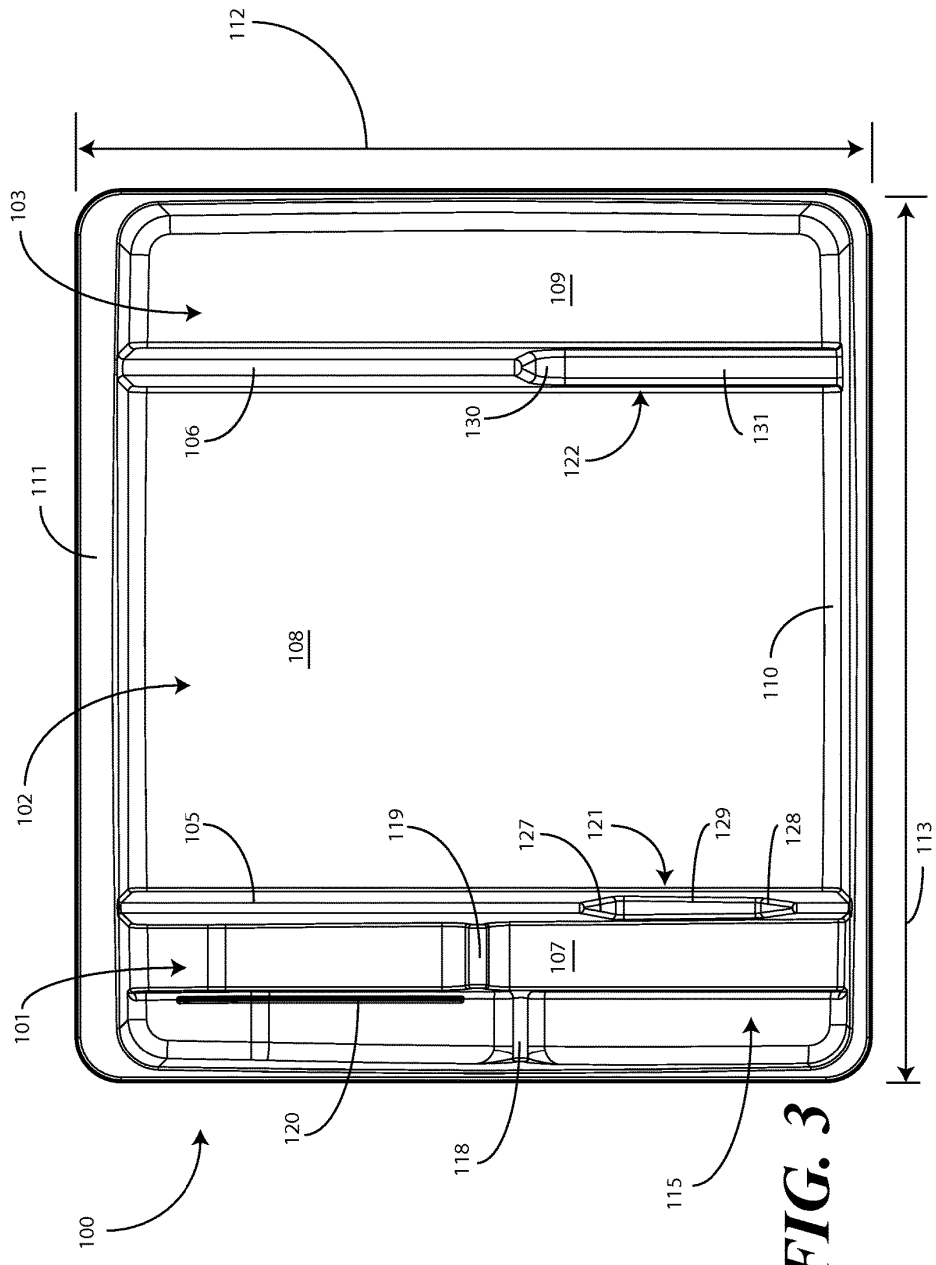

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FIG. 3

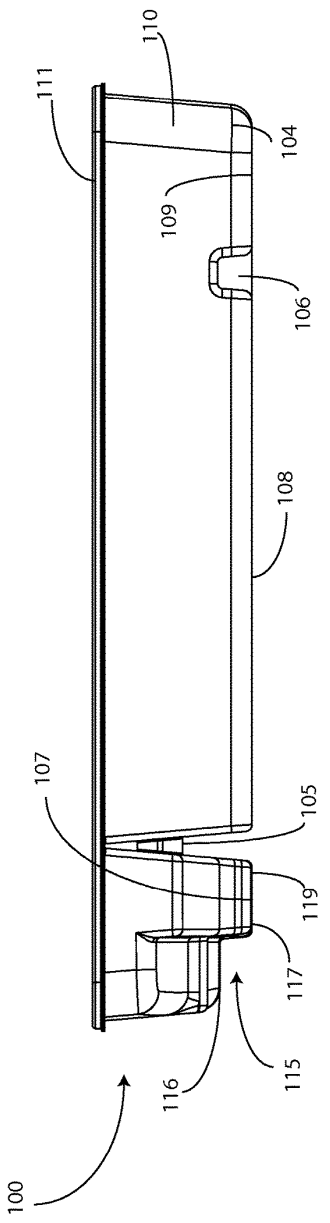

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FIG. 4

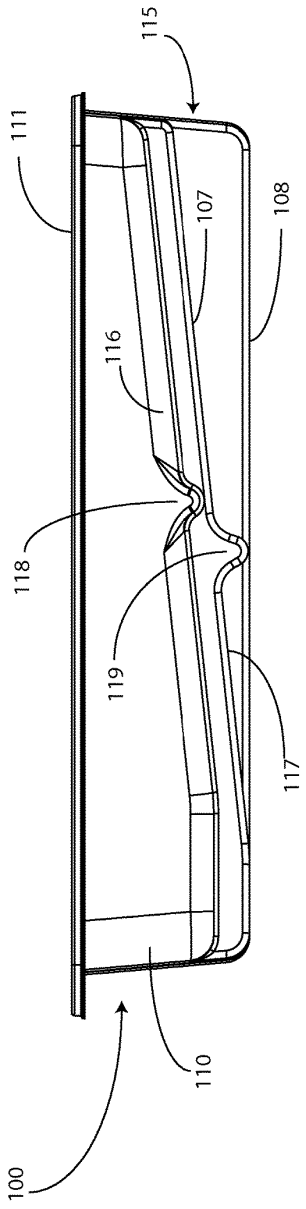

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FIG. 5

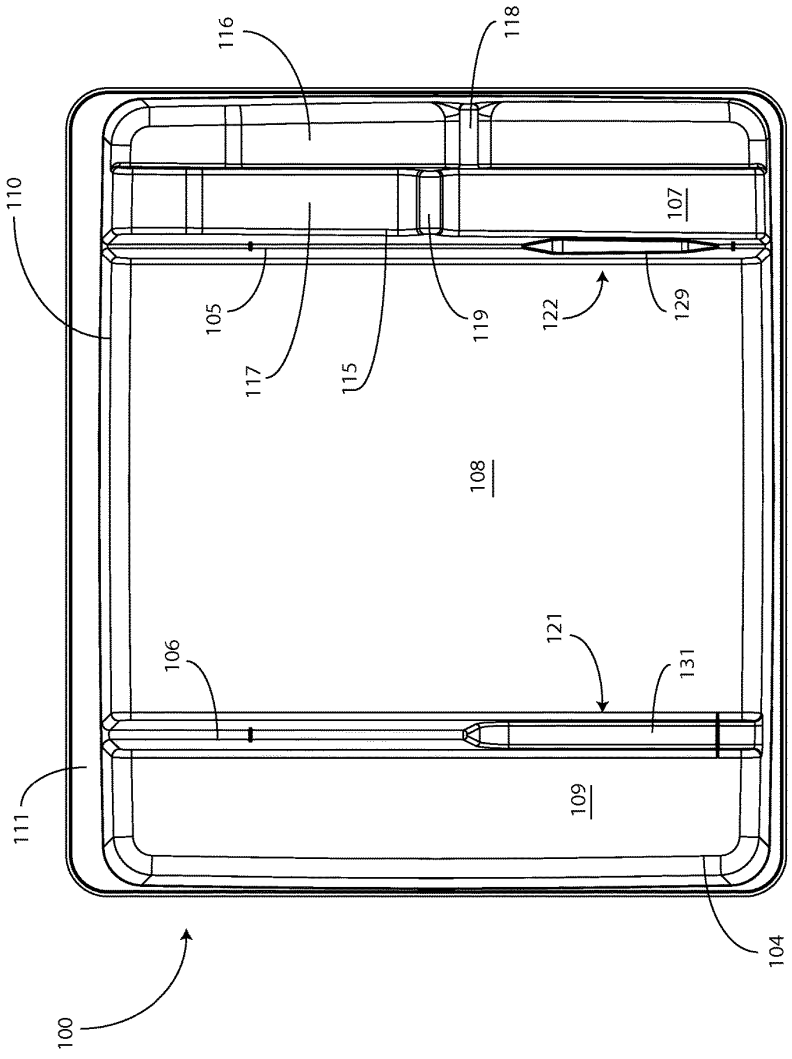

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FIG. 6

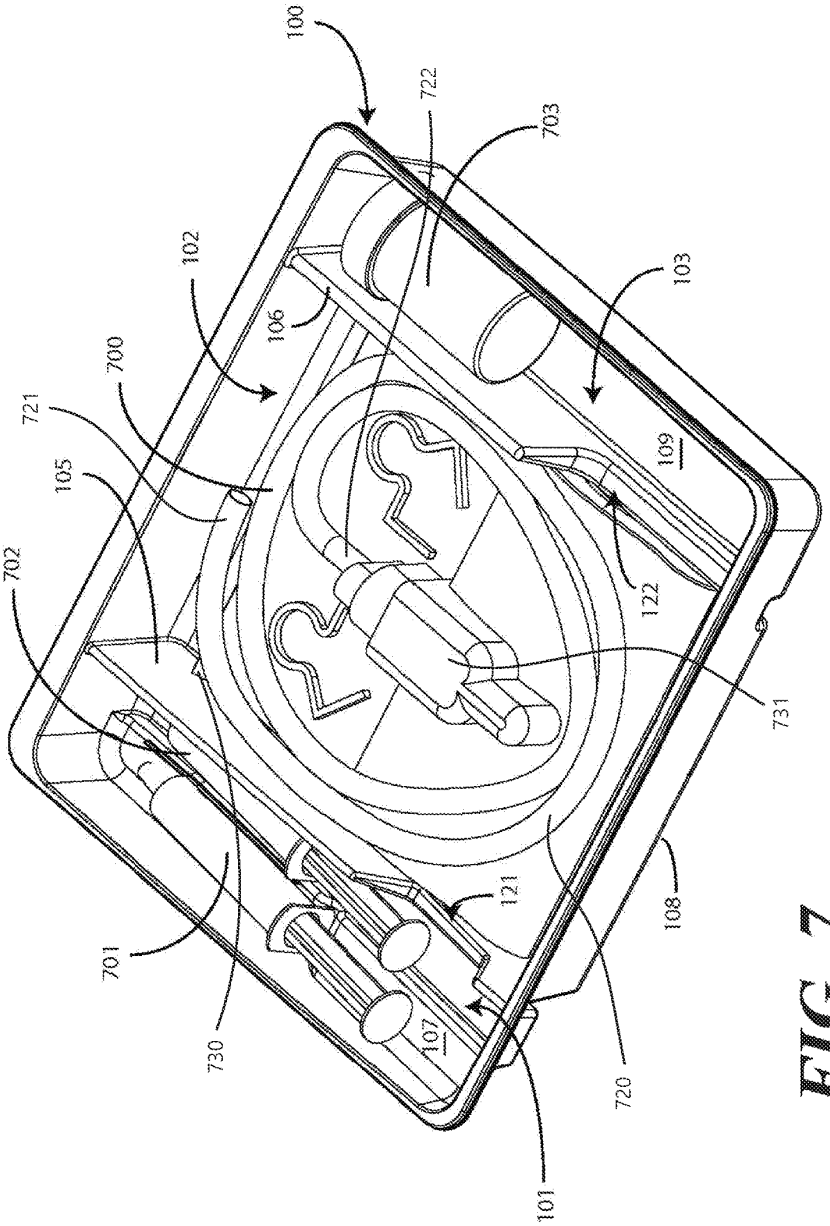

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FIG. 7

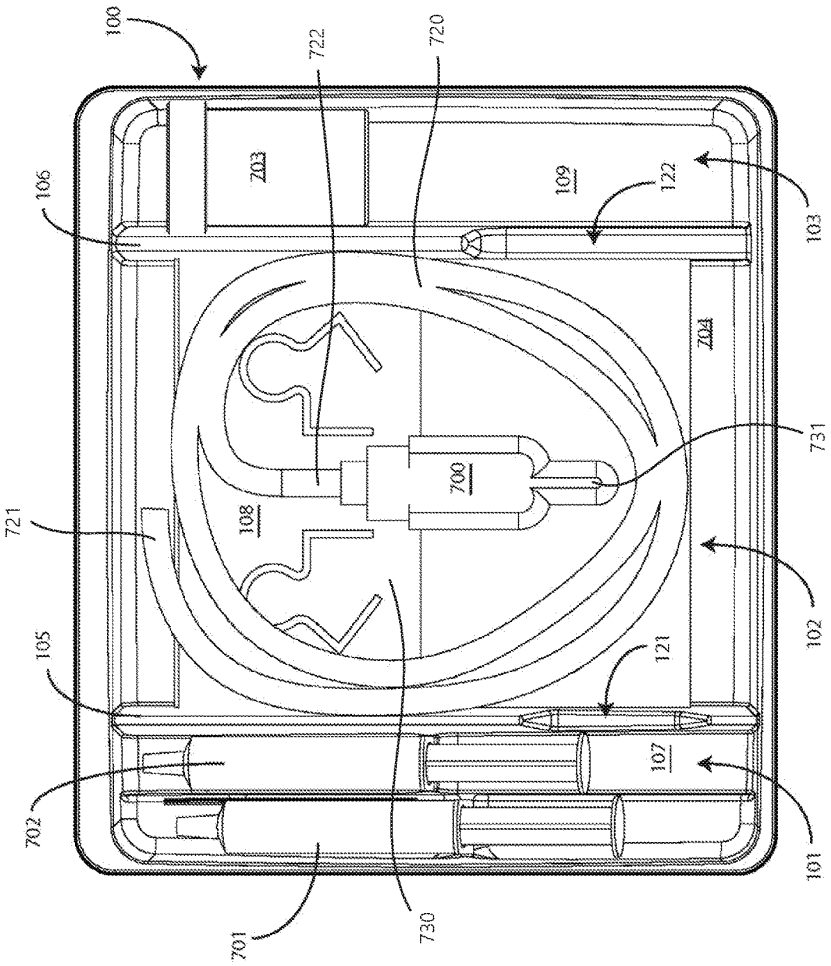

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FIG. 8

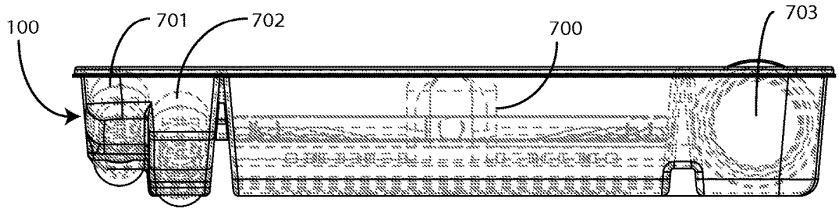


FIG. 9

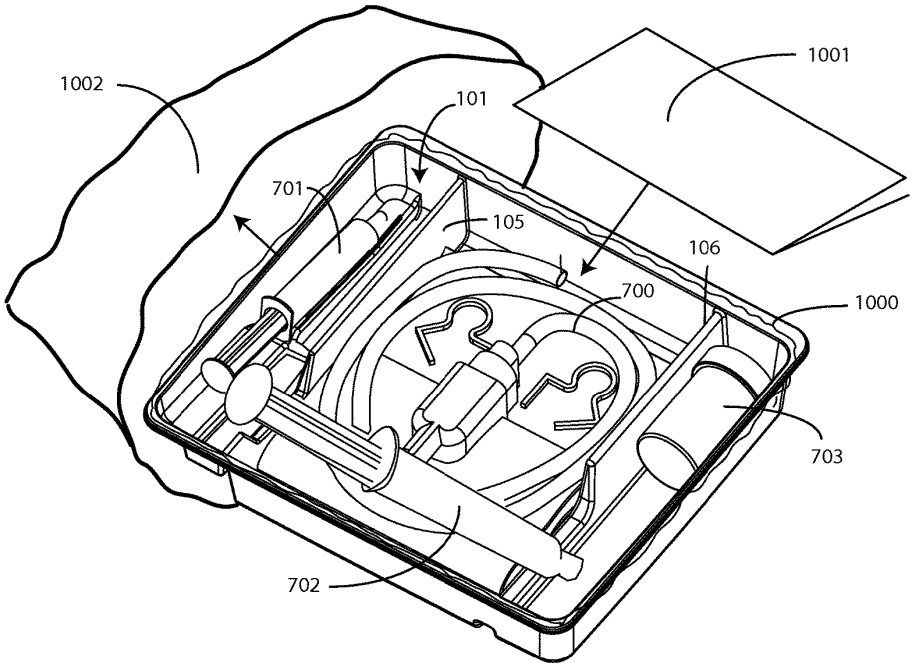


FIG. 10

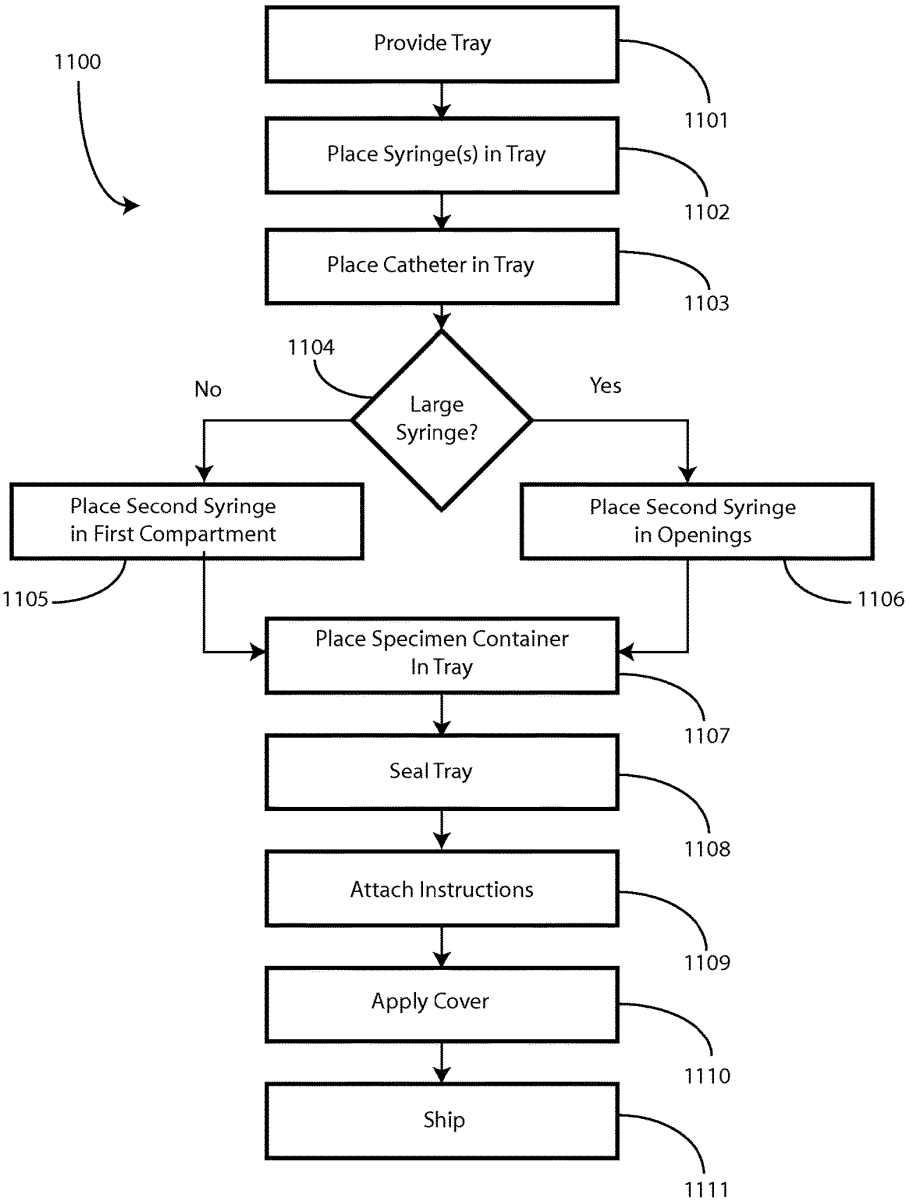

1100
Provide Tray
1101
Place Syringe(s) in Tray
1102
Place Catheter in Tray
1103
1104
Large Syringe?
No
Yes
Place Second Syringe in First Compartment
1105
Place Second Syringe in Openings
1106
Place Specimen Container In Tray
1107
Seal Tray
1108
Attach Instructions
1109
Apply Cover
1110
Ship
1111

FIG. 11

CATHETER TRAY, PACKAGING SYSTEM, AND ASSOCIATED METHODS

CROSS REFERENCE TO PRIOR APPLICATIONS

This application is a continuation from, and claims priority and benefit under 35 USC §120 from, U.S. application Ser. No. 12/846,675, filed Jul. 29, 2010, now U.S. Pat. No. 8,746,452, which application is a divisional application from and claims priority and benefit under 35 USC §121 from, U.S. application Ser. No. 12/495,148, filed Jun. 30, 2009, now U.S. Pat. No. 8,631,935, which application claims priority and benefit under 35 USC §119(e) from Provisional Application No. 61/183,629, filed Jun. 3, 2009.

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.

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.

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

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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 tray configured to accommodate a coiled medical 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 **100** configured to accommodate not only the catheter assembly **700** and fluid bag **730**, but also syringes **701**, **702** containing sterile water or lubricants. Further, the tray can accommodate a sterile specimen jar **703** or 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, printed instructions, 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**. 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**.

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.

This particular feature highlights another advantage of the "compartmentalized" structure of various embodiments of the invention. As the tray **100** includes multiple compart-

ments, 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 catheter assembly **700** includes an indwelling (or Foley) catheter coupled to a fluid bag **730** by a tube **720**. The first end portion **721** of the tube **720** is coupled to the indwelling catheter and the second end portion **722** of the tube **720** is coupled to the fluid bag **730** via an anti-reflux device **731**. 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 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. 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.

Once the necessary components are disposed within the tray 100, the tray can be sealed with a CSR wrap 1000 to keep the internal components sterile. Printed instructions 1001 can then be attached or disposed upon the tray 100. In one embodiment, the printed instructions 1001 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 730 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 the tray 100, the assembly can be sealed in a sterile wrap 1002 such as a thermally sealed bag. Inclusion of a sterile wrap allows the instructions to be included with the tray assembly, yet outside 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, however. For example, the sterile wrap 1002 can be optional. Rather than including printed instructions 1001, the instructions for use can be printed on the CSR wrap 1000, thereby making the need for a sterile wrap optional.

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. In one embodiment, as determined at decision 1104, a second syringe (702) will be disposed in the first compartment (101) at step 1105. 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 1106.

At step 1103, 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) in a third compartment (103) at step 1107, towels, drapes, printed instructions, and so forth.

At step 1108, the tray (100) is sealed. At optional step 1109, 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 1110, the manufacturer can place a sterile wrap about the tray (100) and the printed instructions (1001), where included. At step 1111, the completed assembly can be shipped to a medical services provider.

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 kit, comprising:

a single level tray defining at least a first compartment and a second compartment, the first compartment bounded by a first compartment base member of the single level tray, the second compartment bounded by a second compartment base member of the single level tray, the single level tray including a barrier separating the first compartment from the second compartment, the barrier defining an opening;

a first syringe containing an inflation fluid, the first syringe disposed within the first compartment of the single level tray;

a second syringe containing a lubricant, the second syringe disposed within the single level tray, the first syringe and the second syringe configured for use during a catheterization procedure;

an indwelling catheter; and

a coiled tube coupling the indwelling catheter to a fluid receptacle, the indwelling catheter, the coiled tube, and the fluid receptacle disposed within the second compartment of the single level tray with the coiled tube being outside of the fluid receptacle, 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.

2. The kit of claim 1, wherein:
the first syringe and the second syringe are both within the first compartment; and
the single level tray defines a third compartment configured to accommodate at least one of a specimen container or a skin cleanser.

3. The kit of claim 1, wherein the second compartment base member and the first compartment base member are substantially coplanar.

4. The kit of claim 1, wherein the opening is bounded by an opening base member and two inclined opening side members.

5. The kit of claim 1, wherein each of the first compartment and the second compartment are accessible through a top opening defined by the single level tray, the top opening opposite the second compartment base member.

6. The kit of claim 1, wherein:
the indwelling catheter includes an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient.

7. The kit of claim 6, wherein each of the first syringe and the second syringe is contained within the single level tray at different depths within the single level tray.

8. The kit of claim 6, wherein the first compartment contains the first syringe at a shallower depth within the single level tray than the second syringe.

9. The kit of claim 1, further comprising printed instructions packaged with the single level tray, the printed instructions directing a user to discharge the lubricant from the second syringe into the first compartment.

10. The kit of claim 9, wherein the printed instructions further direct the user to pass at least a portion of the indwelling catheter into the first compartment, and through the lubricant discharged from the second syringe into the first compartment.

11. The kit of claim 1, wherein the single level tray defines a top opening through which the first compartment and the second compartment can be accessed, the kit further comprising:
a sterile wrap disposed about the single level tray covering at least the top opening.

12. The kit of claim 11, wherein when the sterile wrap is unwrapped from about the top opening such that at least the first syringe, the second syringe, and the indwelling catheter are revealed.

13. A kit, comprising:
a single level tray including a first compartment base member and a second compartment base member, the single level tray defining a first compartment and a second compartment, the first compartment base member forming a portion of a boundary of the first compartment, the second compartment base member forming a portion of a boundary of the second compartment, the single level tray including a barrier separating the first compartment from the second compartment;
a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid;
a second syringe disposed within the single level tray, the second syringe containing a lubricant; and
a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient, the fluid receptacle including an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device, the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle and such that the fluid receptacle is between the second compartment base member and the coiled tube.

14. The kit of claim 13, wherein the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray with at least a portion of the fluid receptacle being beneath the coiled tube.

15. The kit of claim 13, wherein the barrier extends a length of the first compartment and defines an opening to receive a portion of the catheter assembly when a tip of the indwelling catheter is placed from the second compartment into the first compartment to lubricate the indwelling catheter.

16. The kit of claim 13, wherein the single level tray defines a top opening through which the first compartment and the second compartment can be accessed, the kit further comprising:
a sterile wrap disposed about the single level tray covering at least the top opening.

17. The kit of claim 16, wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed.

18. A kit, comprising:
a single level tray defining a first compartment and a second compartment, the single level tray including a barrier separating the first compartment from the second compartment, the barrier extending a length of the first compartment and defining an opening;
a first syringe disposed within the first compartment of the single level tray, the first syringe containing an inflation fluid;
a second syringe disposed within the single level tray, the second syringe containing a lubricant; and
a catheter assembly including a coiled tube coupling an indwelling catheter to a fluid receptacle, the indwelling catheter including an inflatable portion configured to receive the inflation fluid from the first syringe to maintain the indwelling catheter within a patient, the coiled tube and the fluid receptacle disposed within the second compartment of the single level tray with at least a portion of the coiled tube being outside of the fluid receptacle, the opening defined by the barrier sized to receive a portion of the catheter assembly when a tip of the indwelling catheter is placed from the second compartment into the first compartment to lubricate the indwelling catheter.

19. The kit of claim 18, wherein the fluid receptacle includes an anti-reflux device, an end of the coiled tube coupled to the anti-reflux device.

20. The kit of claim 19, wherein:
the single level tray includes a first compartment base member and a second compartment base member, the first compartment base member forming a portion of a boundary of the first compartment, the second compartment base member forming a portion of a boundary of the second compartment; and
the coiled tube and the fluid receptacle are disposed within the second compartment of the single level tray such that the fluid receptacle is between the second compartment base member and the coiled tube.

21. The kit of claim 18, wherein the single level tray defines a top opening through which the first compartment and the second compartment can be accessed, the kit further comprising:

a sterile wrap disposed about the single level tray covering at least the top opening.

22. The kit of claim 21, wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed.

* * * * *

(12) **INTER PARTES REVIEW CERTIFICATE** (2189th)
United States Patent
Adler et al.

(10) **Number: US 9,808,400 K1**
(45) **Certificate Issued: Jul. 7, 2021**

(54) **CATHETER TRAY, PACKAGING SYSTEM, AND ASSOCIATED METHODS**

(71) Applicants: **Deborah B. Adler**; **Alberto C. Savage**; **Earl D. Wilson**; **Jennifer E. Tomes**; **Jack E. Maze**; **Kenneth S. Chua**; **John Henry Kutsch**

(72) Inventors: **Deborah B. Adler**; **Alberto C. Savage**; **Earl D. Wilson**; **Jennifer E. Tomes**; **Jack E. Maze**; **Kenneth S. Chua**; **John Henry Kutsch**

(73) Assignee: **MEDLINE INDUSTRIES, INC.**

Trial Number:

IPR2019-00208 filed Nov. 7, 2018

Inter Partes Review Certificate for:

Patent No.: **9,808,400**
Issued: **Nov. 7, 2017**
Appl. No.: **14/265,909**
Filed: **Apr. 30, 2014**

The results of IPR2019-00208 are reflected in this inter partes review certificate under 35 U.S.C. 318(b).

AS A RESULT OF THE INTER PARTES REVIEW PROCEEDING, IT HAS BEEN DETERMINED THAT:

Claims **13**, **14**, **16** and **17** are cancelled.

* * * * *

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

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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

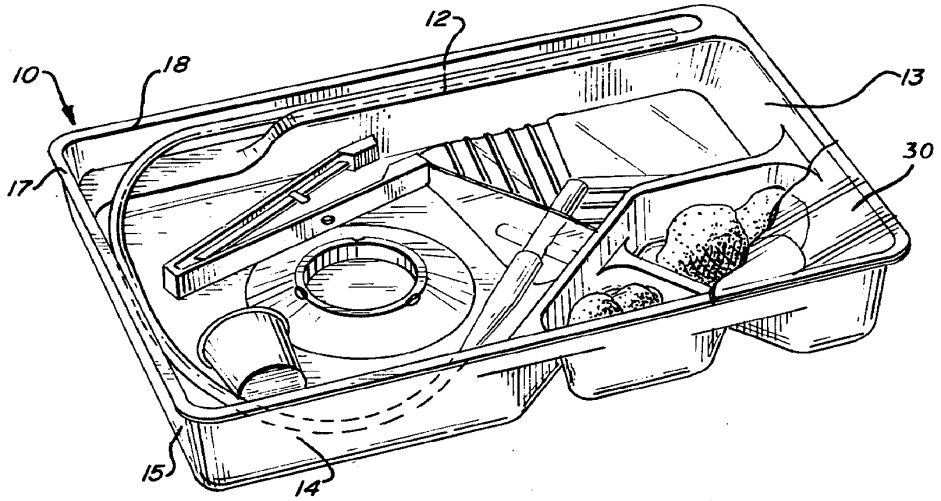
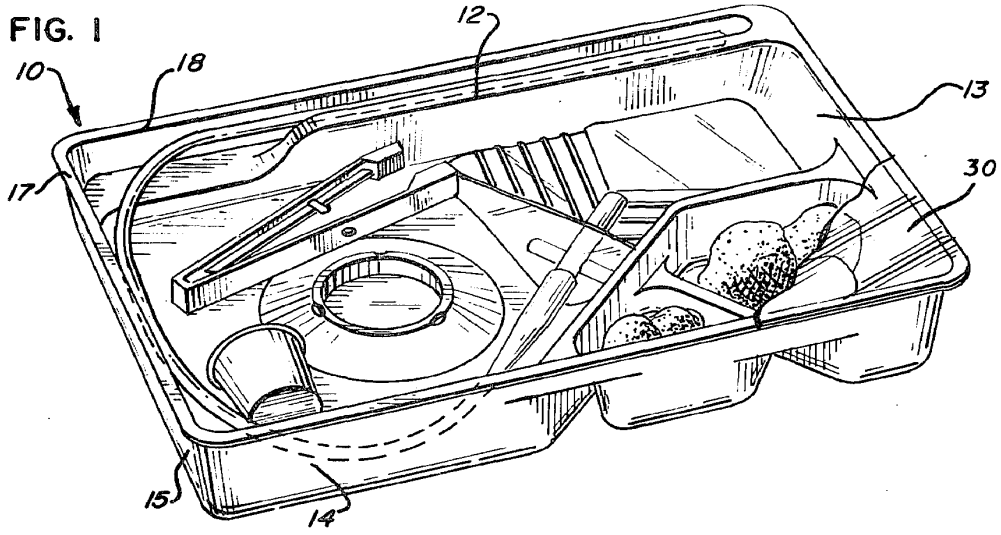


FIG. 1



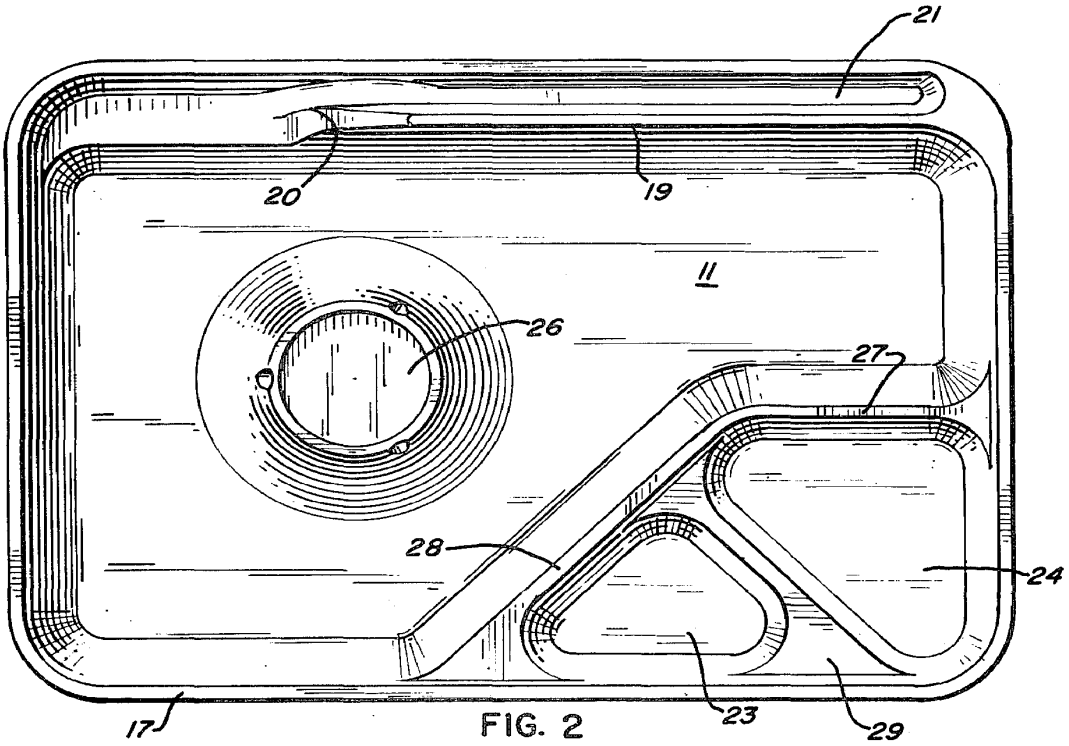
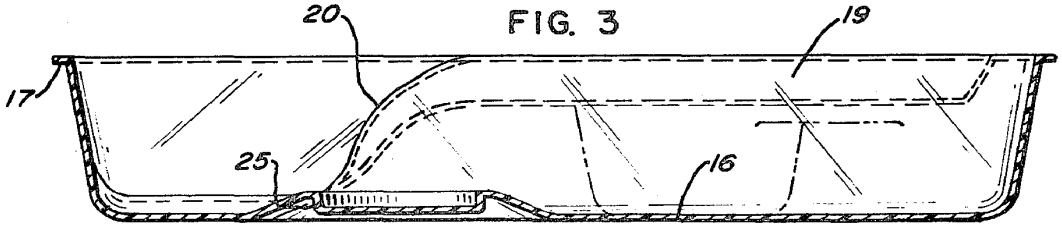


FIG. 2

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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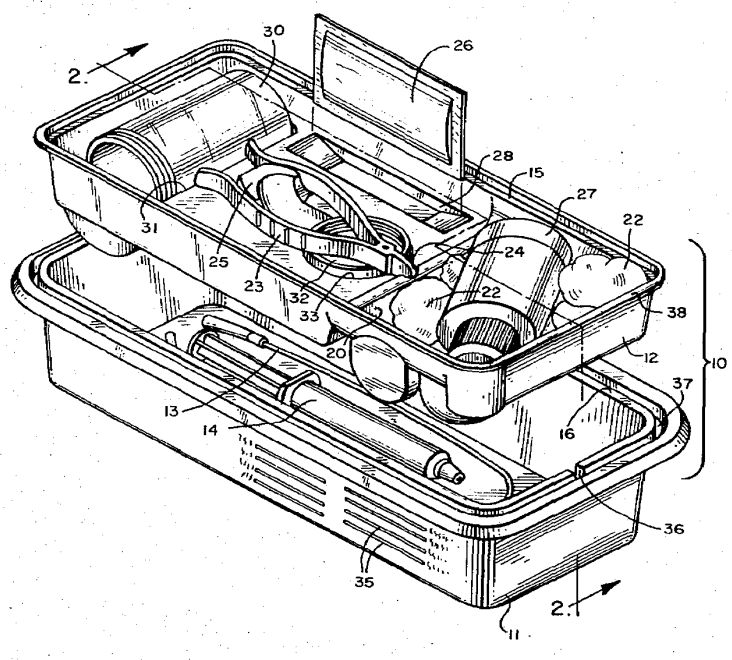
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Primary Examiner—Joseph Man-Fu Moy
Attorney, Agent, or Firm—Henry W. Collins; Eugene M. Cummings; Paul C. Flattery

[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



Bard Exhibit 1004.0814

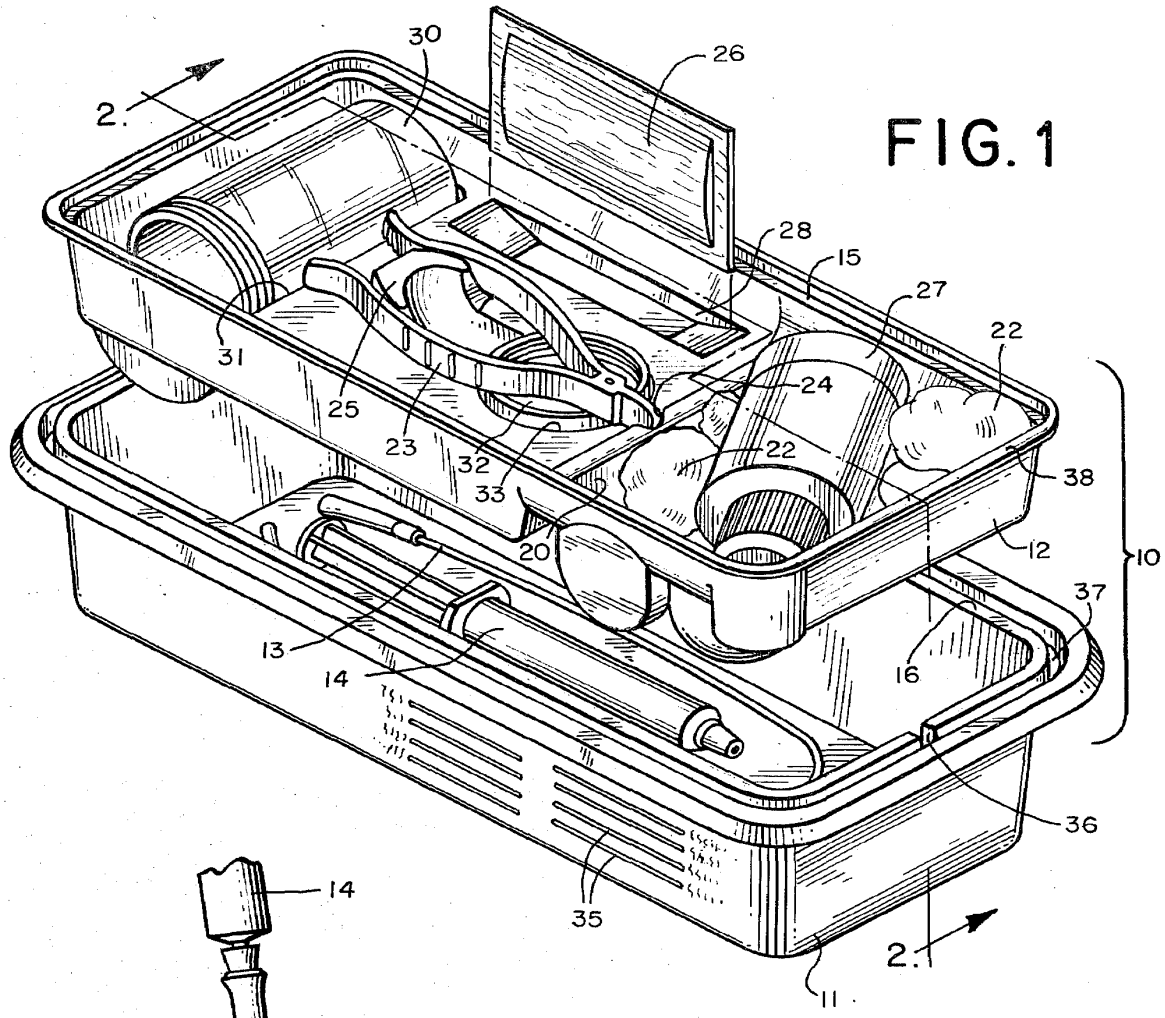

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FIG. 1

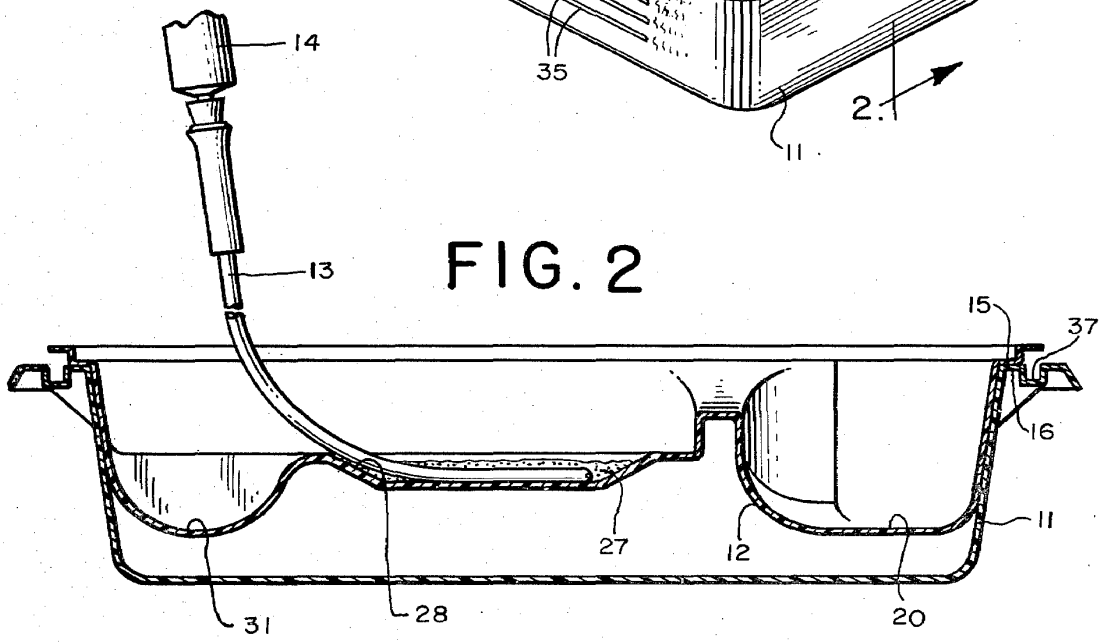

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FIG. 2

FIG. 3

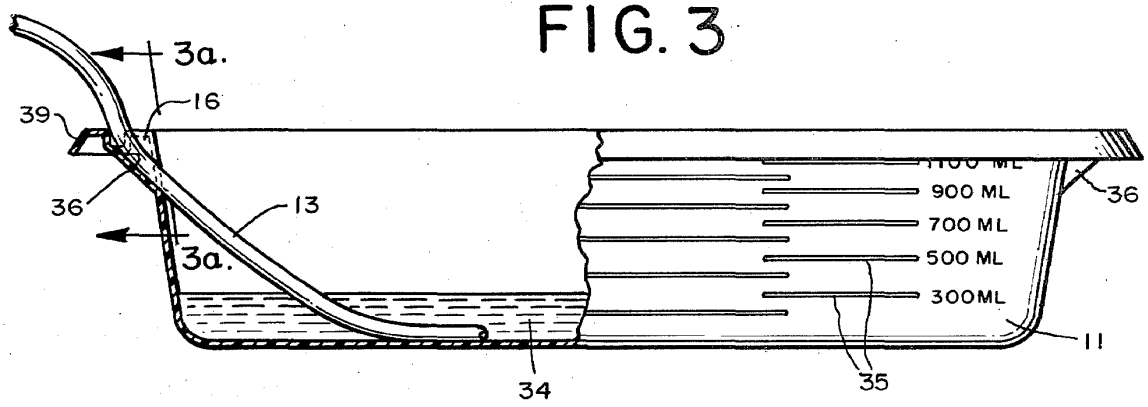


FIG. 3a

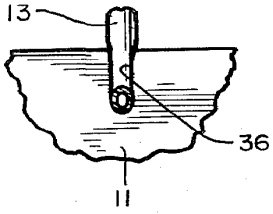
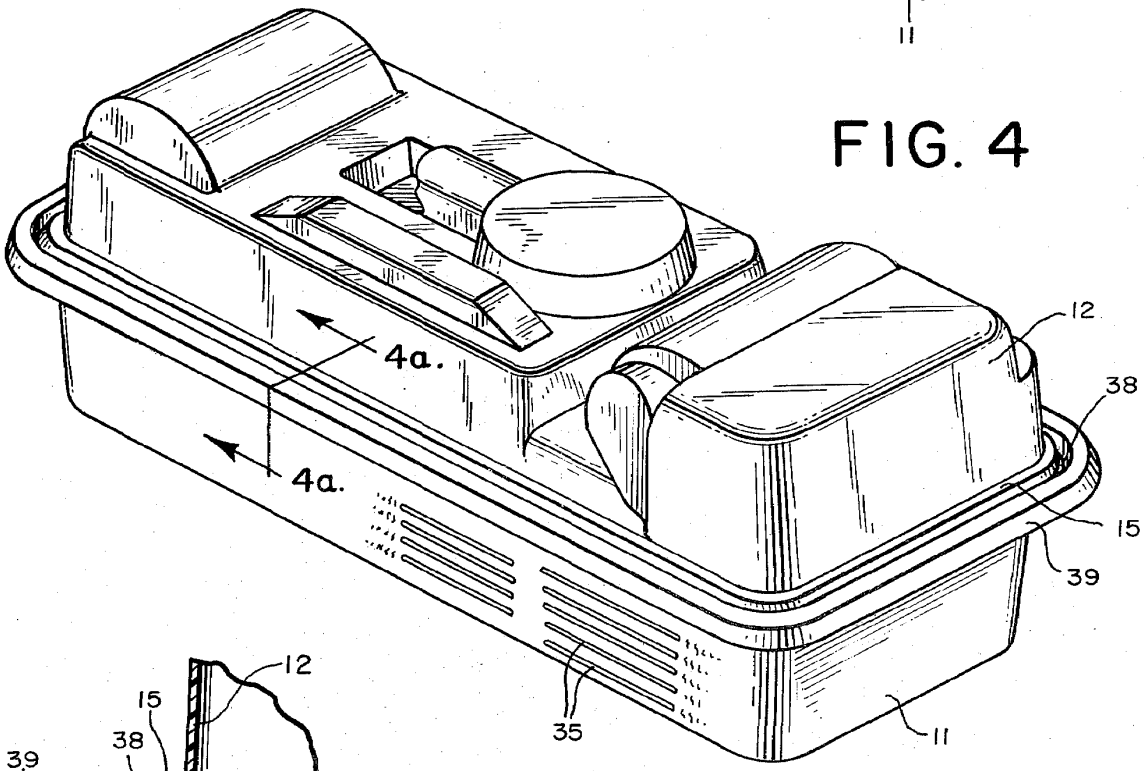


FIG. 4



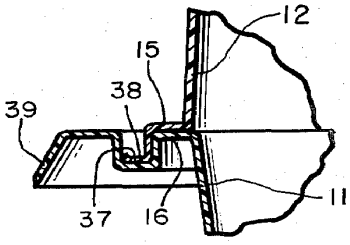


FIG. 4a

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 1004.0817

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 1004.0818

EXHIBIT 27

US008678190B2

(12) **United States Patent**
Tomes et al.

(10) **Patent No.: US 8,678,190 B2**
(45) **Date of Patent: Mar. 25, 2014**

(54) **CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS**

(75) Inventors: **Jennifer E. Tomes**, Mundelein, IL (US); **Sarah Zyburt**, Chicago, IL (US)

(73) Assignee: **Medline Industries, Inc.**, Mundelein, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 67 days.

(21) Appl. No.: **13/155,053**

(22) Filed: **Jun. 7, 2011**

(65) **Prior Publication Data**

US 2011/0290262 A1 Dec. 1, 2011

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/495,148, filed on Jun. 30, 2009, 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.

(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.**

B65D 59/00	(2006.01)
B65D 61/00	(2006.01)
A61M 27/00	(2006.01)

(52) **U.S. Cl.**

USPC **206/571**; 604/544

(58) **Field of Classification Search**

USPC 604/370, 540, 544; 206/364, 366, 438, 206/571; 220/500; 434/262

See application file for complete search history.

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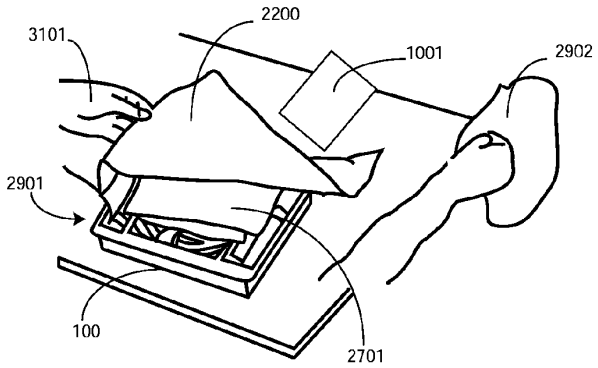
Primary Examiner — Melanie Hand

(74) *Attorney, Agent, or Firm* — David Noskowicz; 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 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**).

18 Claims, 27 Drawing Sheets



Bard Exhibit 1004.0820

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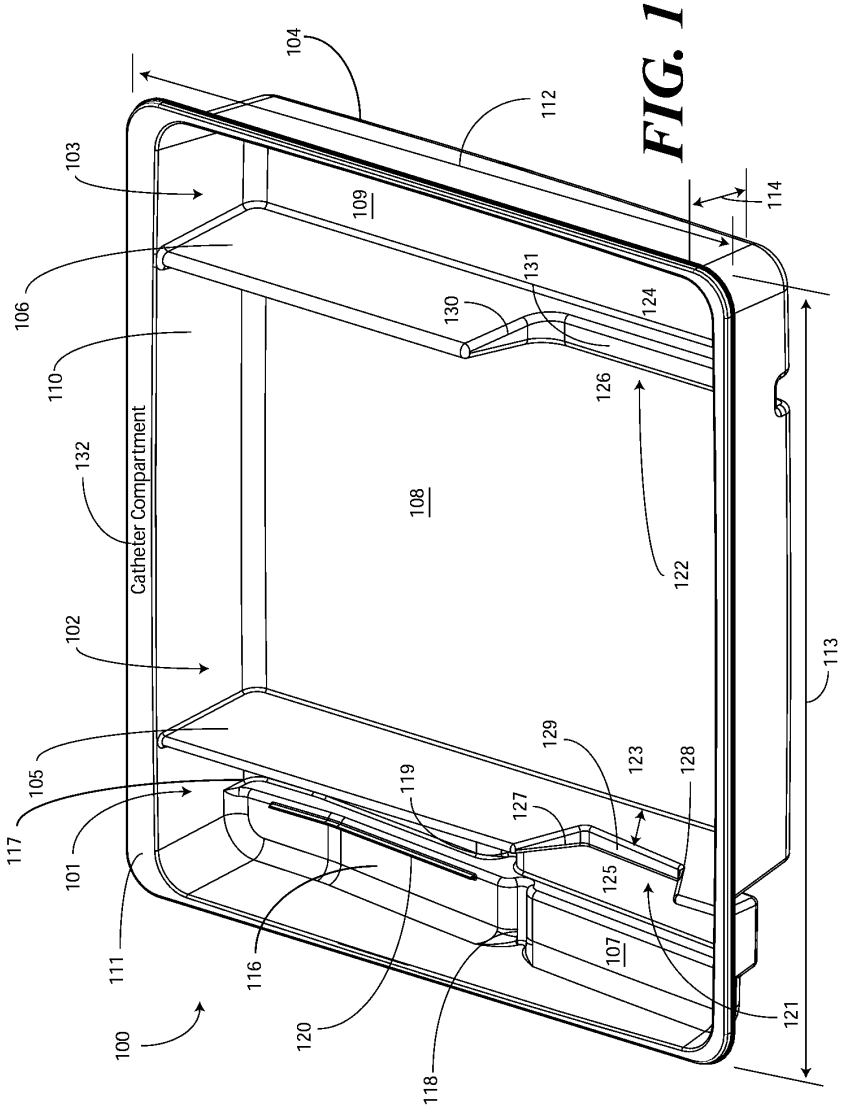


FIG. 1

Bard Exhibit 1004.0824

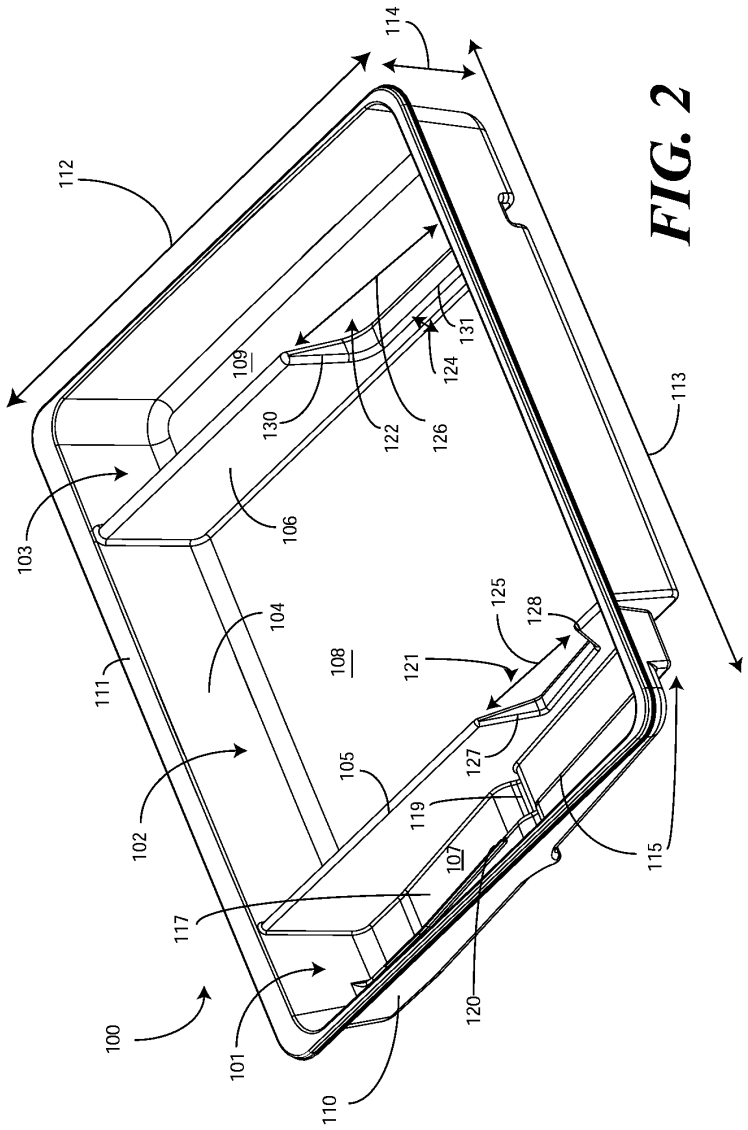


FIG. 2

Bard Exhibit 1004.0825

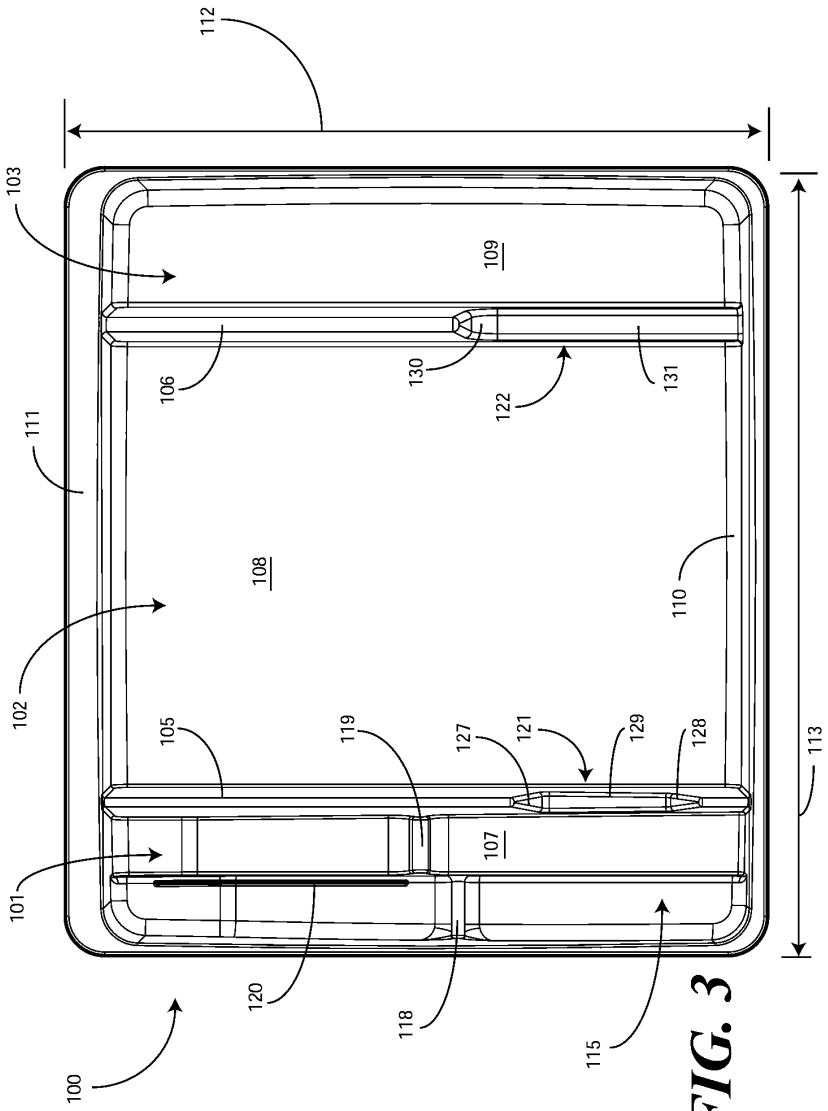


FIG. 3

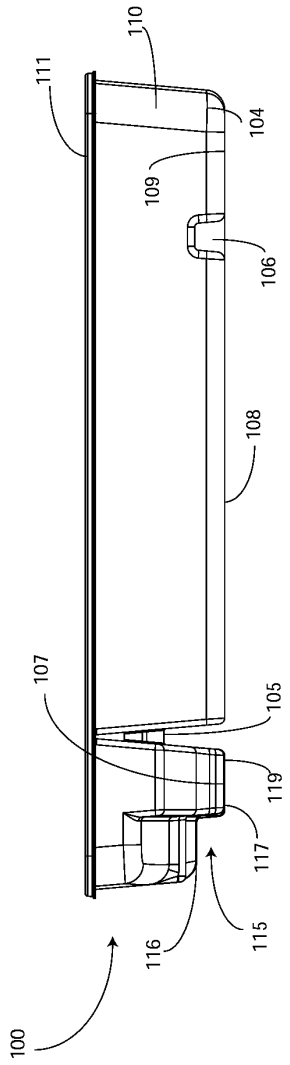

111
110
104
109
106
108
107
105
119
117
116
115
100

FIG. 4

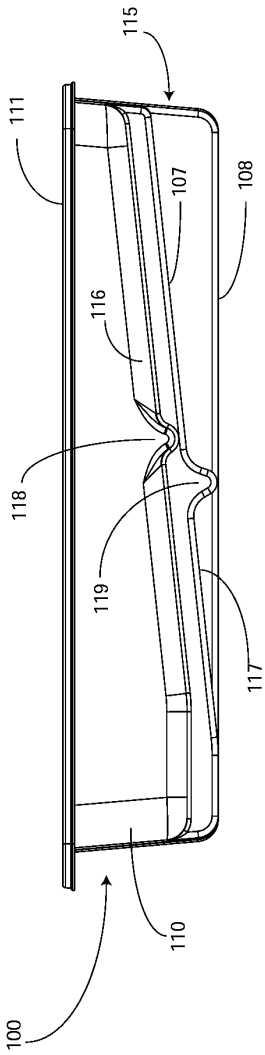

115
111
107
108
116
118
119
117
110
100

FIG. 5

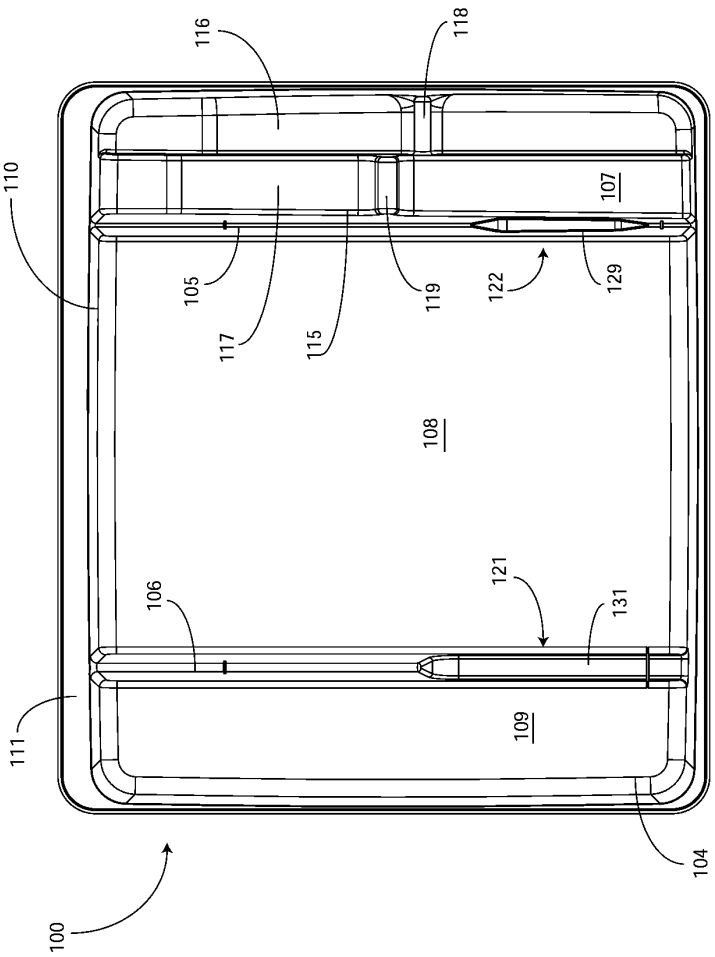

116
118
110
107
105
119
122
129
117
115
108
121
106
131
111
109
104
100

FIG. 6

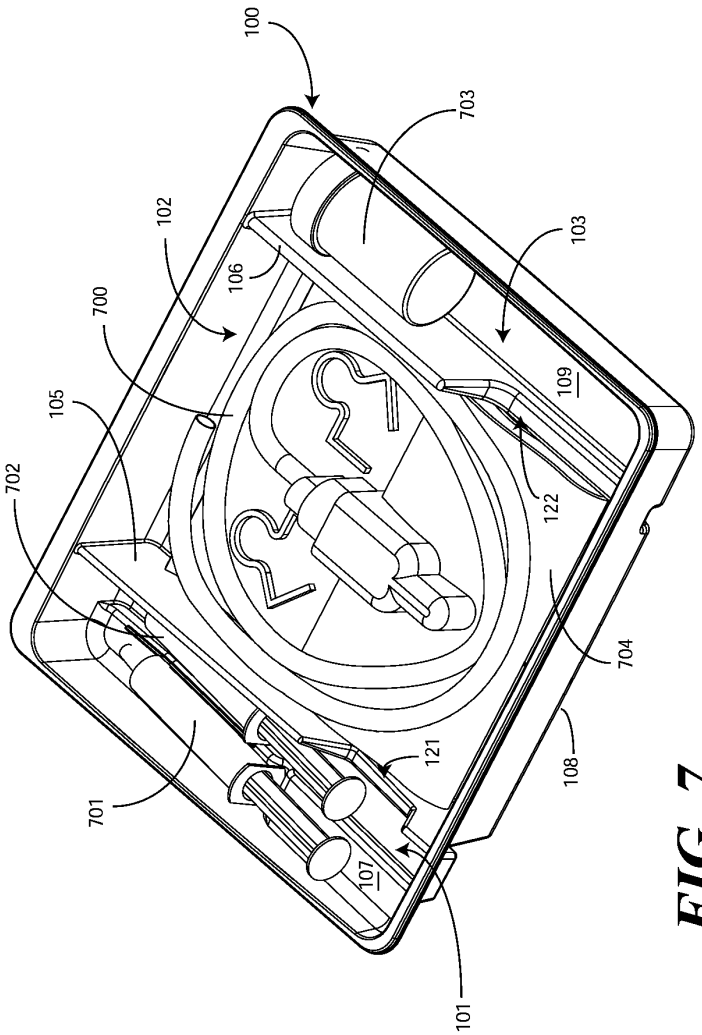


FIG. 7

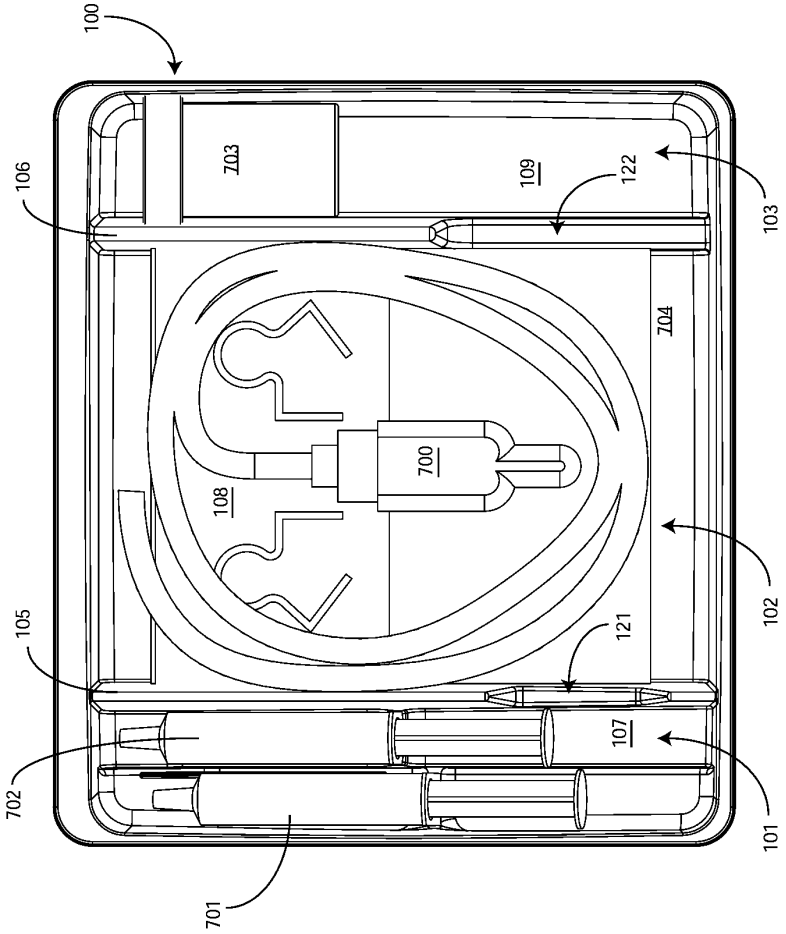


FIG. 8

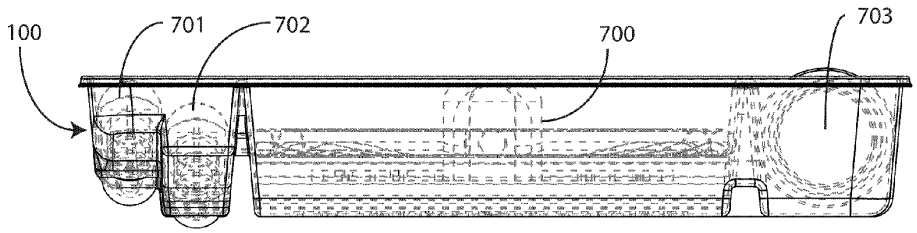

100
701
702
700
703

FIG. 9

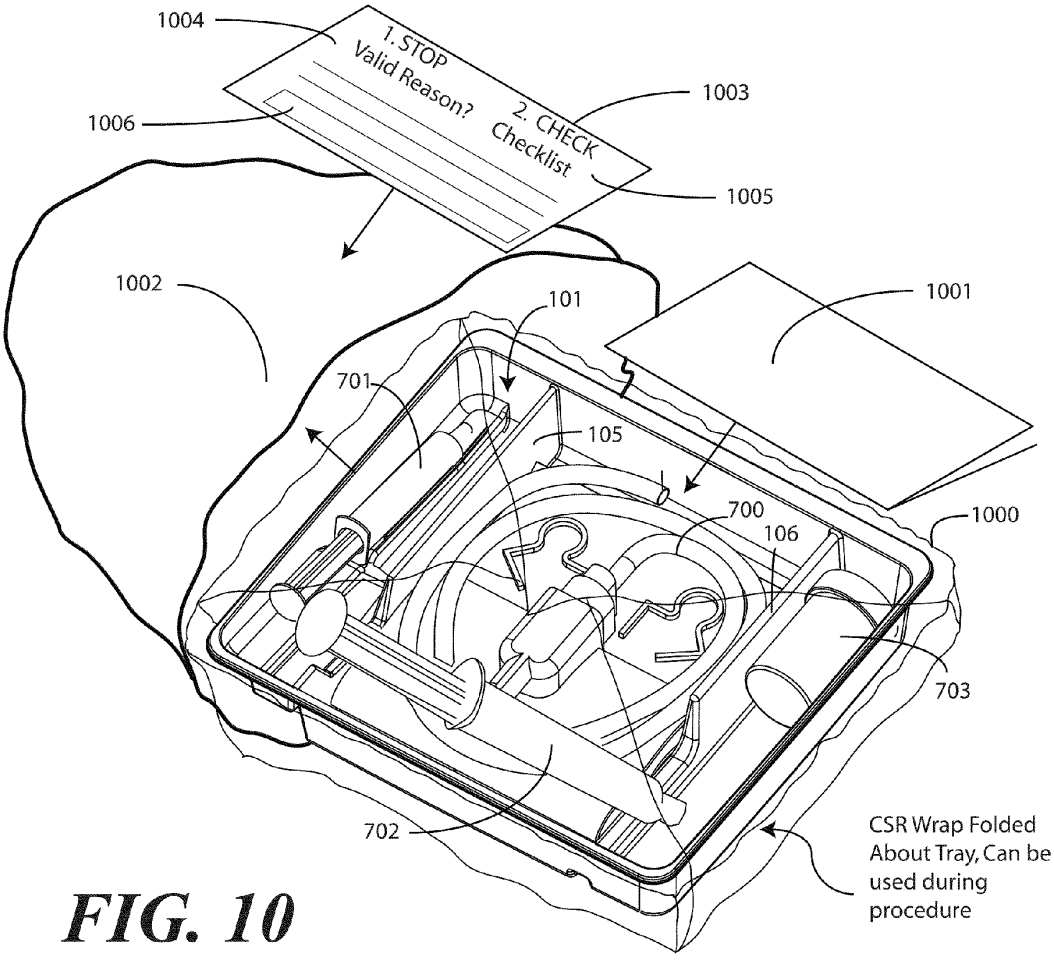

1004
1. STOP Valid Reason?
2. CHECK Checklist
1003
1006
1005
1002
101
1001
701
105
700
106
1000
703
702
CSR Wrap Folded About Tray, Can be used during procedure

FIG. 10

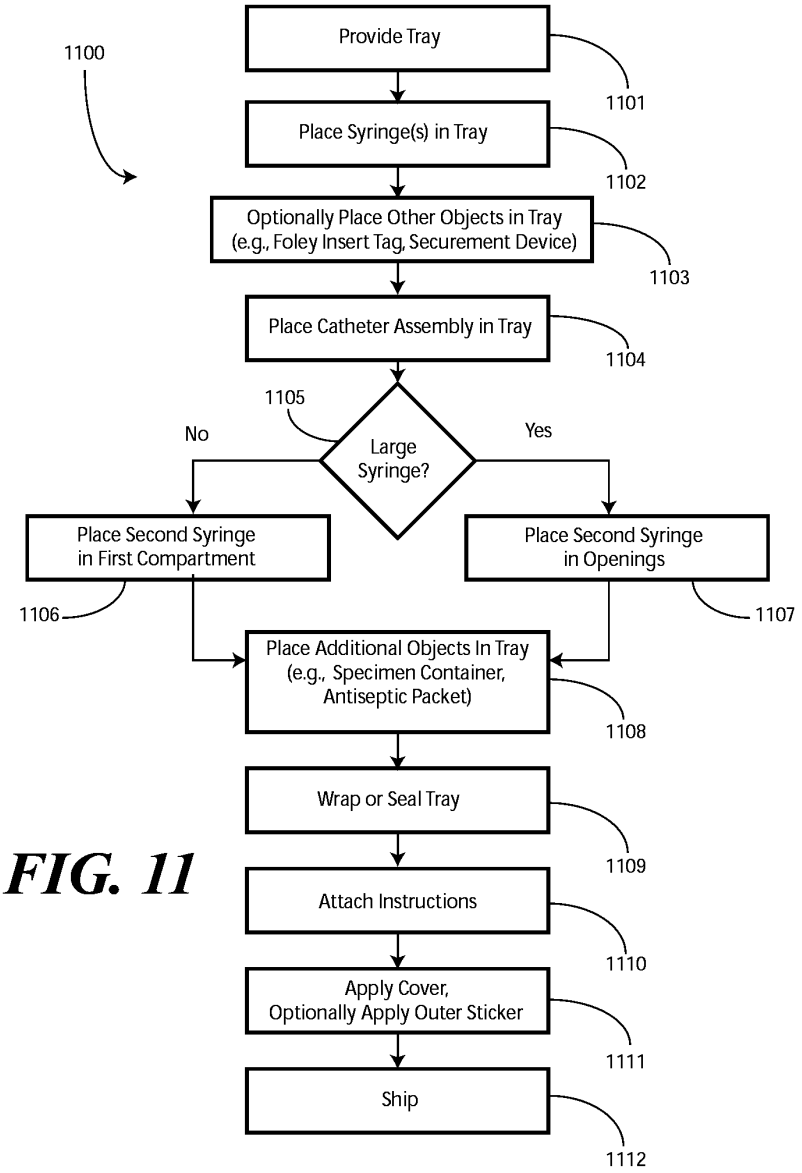

1100
Provide Tray
1101
Place Syringe(s) in Tray
1102
Optionally Place Other Objects in Tray
(e.g., Foley Insert Tag, Securement Device)
1103
Place Catheter Assembly in Tray
1104
1105
Large Syringe?
No
Yes
Place Second Syringe in First Compartment
1106
Place Second Syringe in Openings
1107
Place Additional 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

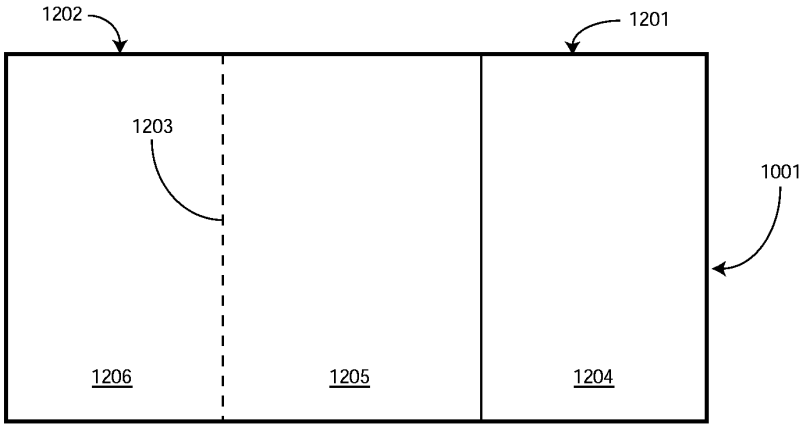

1202
1201
1203
1001
1206
1205
1204

FIG. 12

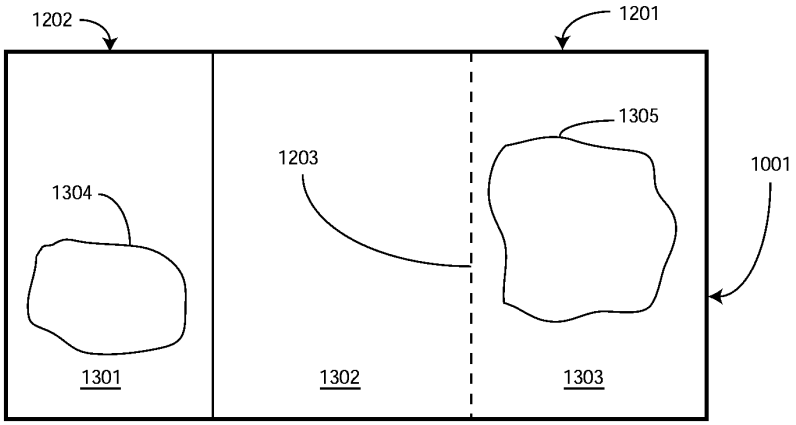

1202
1201
1305
1203
1001
1304
1301
1302
1303

FIG. 13

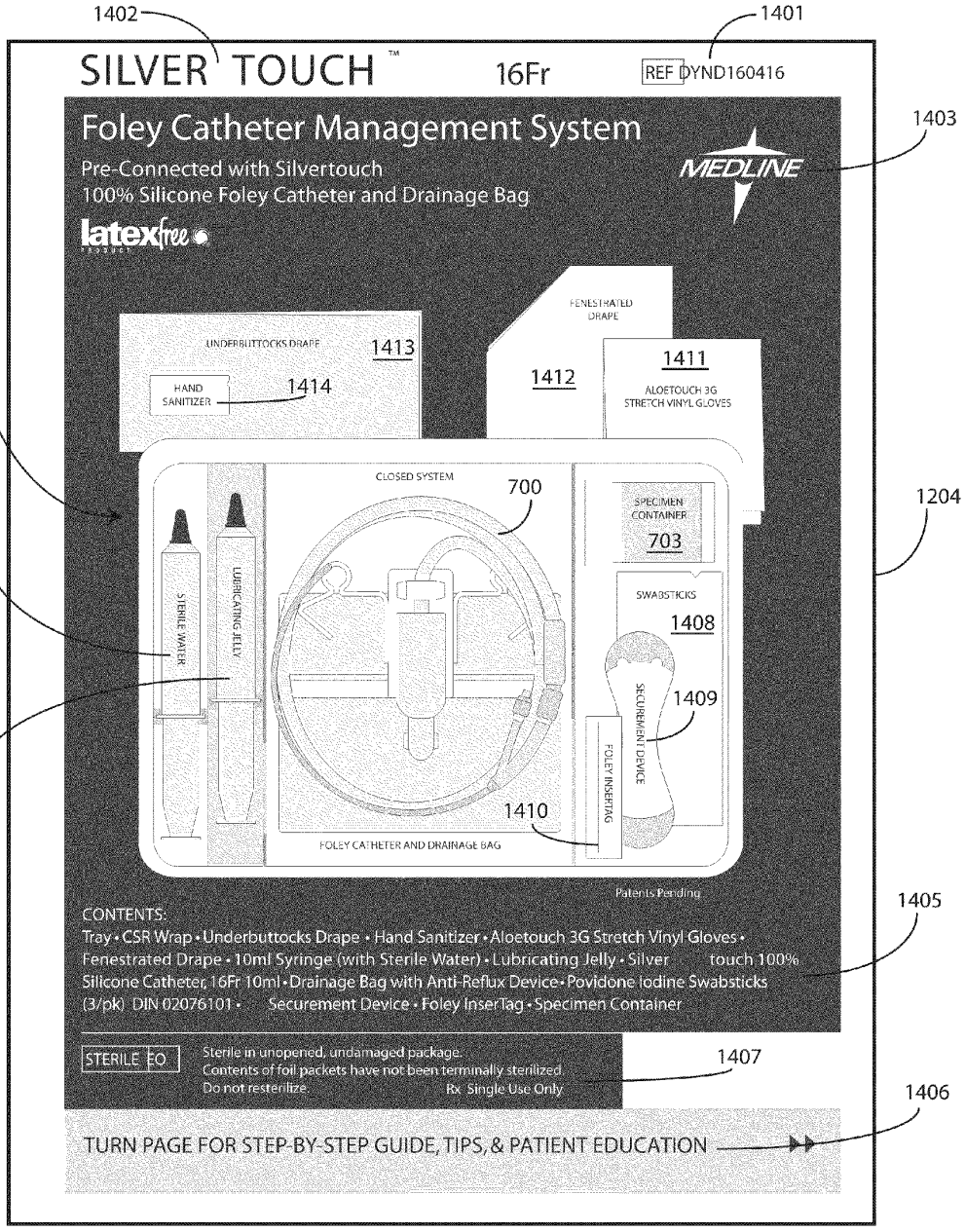

1402
1401
SILVER TOUCH™
16Fr
REF DYND160416
Foley Catheter Management System
Pre-Connected with Silvertouch
100% Silicone Foley Catheter and Drainage Bag
1403
MEDLINE
latexfree
1404
UNDERBUTTOCKS DRAPE
1413
HAND SANITIZER
1414
FENESTRATED DRAPE
1412
1411
ALOETOUCH 3G STRETCH VINYL GLOVES
CLOSED SYSTEM
700
1204
701
SPECIMEN CONTAINER
703
SWABSTICKS
1408
STERILE WATER
LUBRICATING JELLY
1409
SECUREMENT DEVICE
FOLEY INSERTAG
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 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

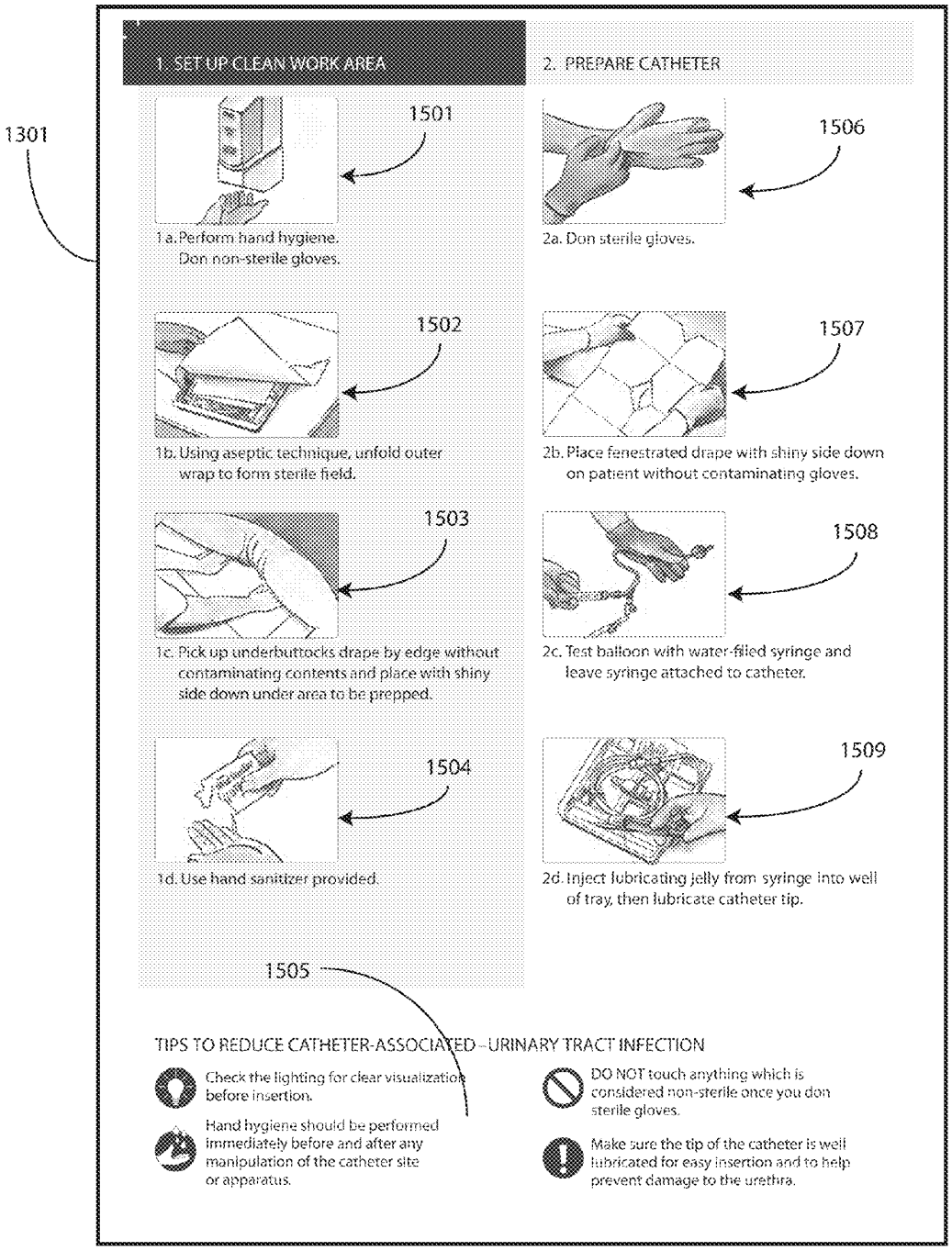

1301
1. SET UP CLEAN WORK AREA
2. PREPARE CATHETER
1501
1a. Perform hand hygiene. Don non-sterile gloves.
1502
1b. Using aseptic technique, unfold outer wrap to form sterile field.
1503
1c. Pick up underbuttocks drape by edge without contaminating contents and place with shiny side down under area to 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

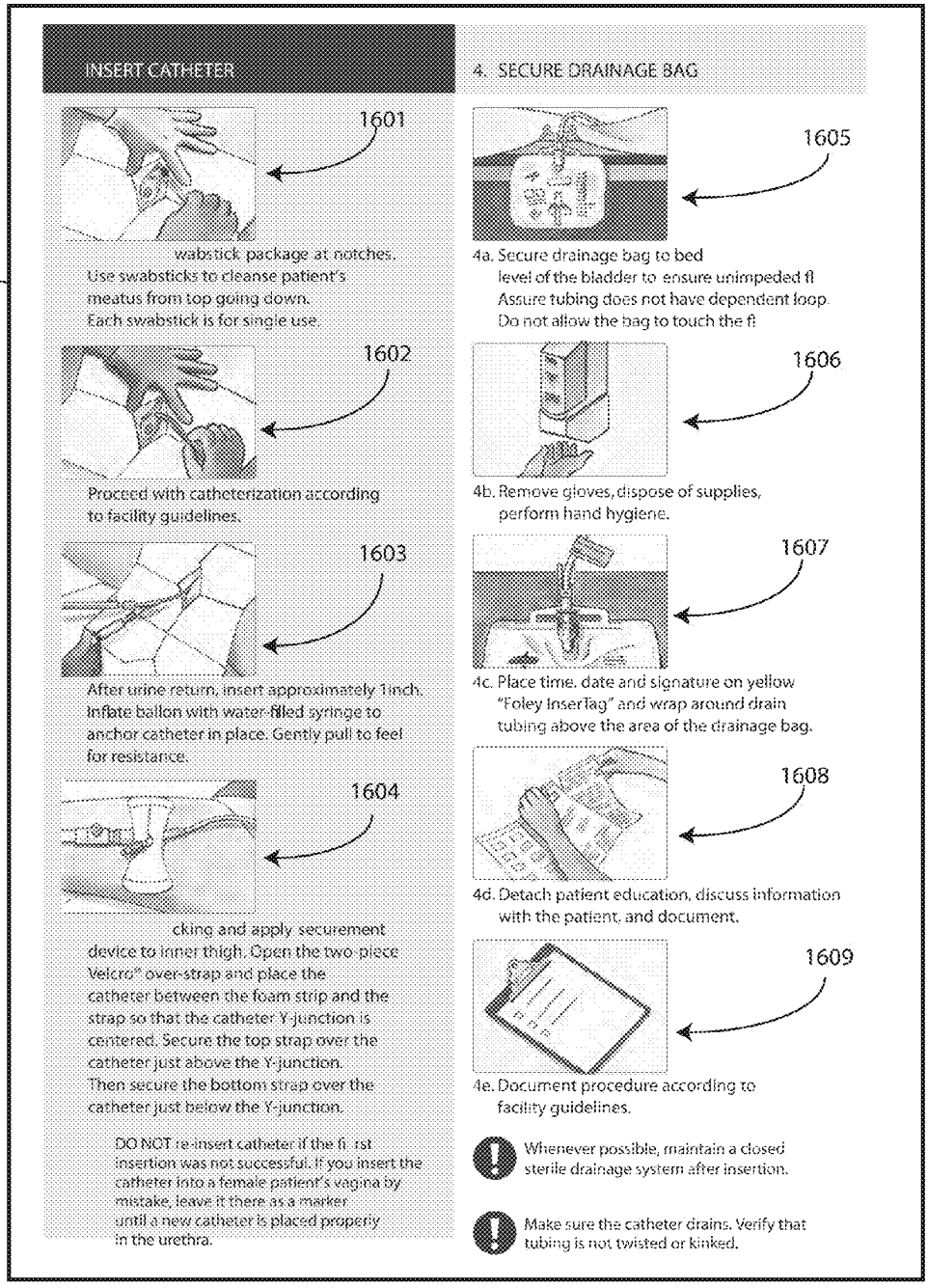

1302
INSERT CATHETER
1601
wabstick package at notches.
Use swabsticks to cleanse patient's
meatus from top going down.
Each swabstick is for single use.
1602
Proceed with catheterization according
to facility guidelines.
1603
After urine return, insert approximately 1inch.
Inflate ballon with water-filled 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

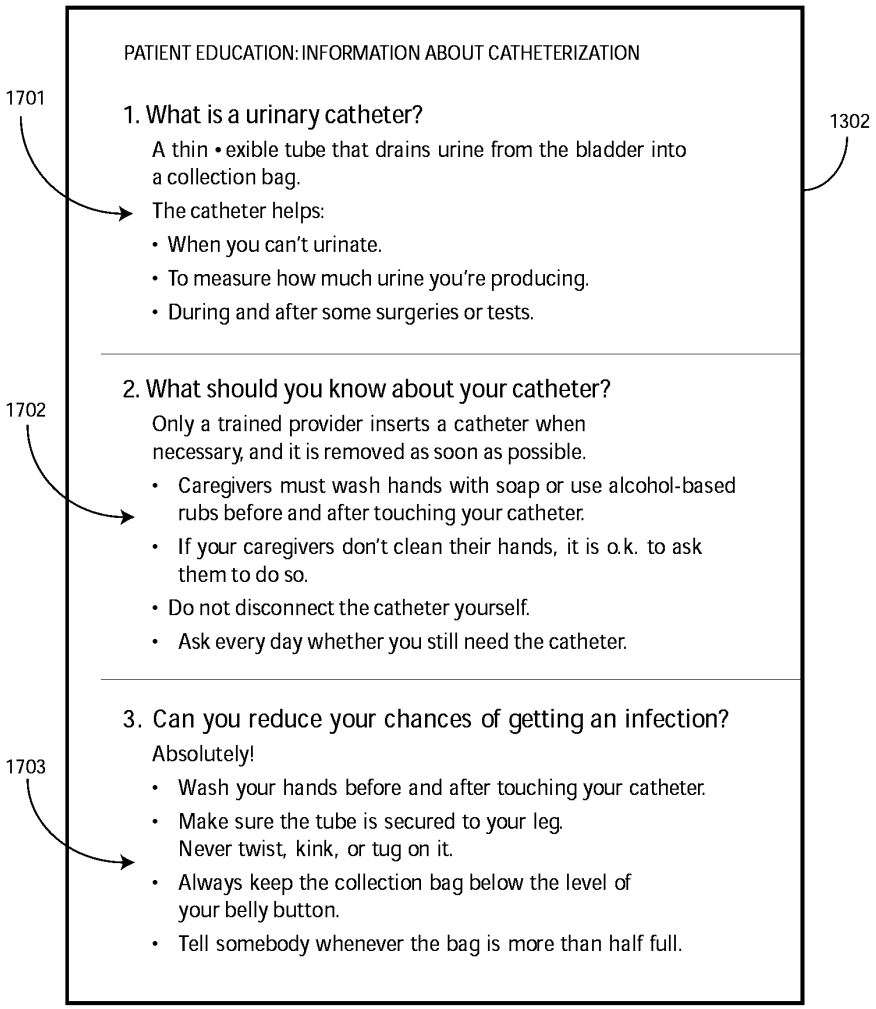

PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1701
1. What is a urinary catheter?
A thin • exible tube that drains urine from the bladder into a collection bag.
The catheter helps:
• When you can't urinate.
• To measure how much urine you're producing.
• During and after some surgeries or tests.
1302
1702
2. What should you know about your catheter?
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.
1703
3. Can you reduce your chances of getting an infection?
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

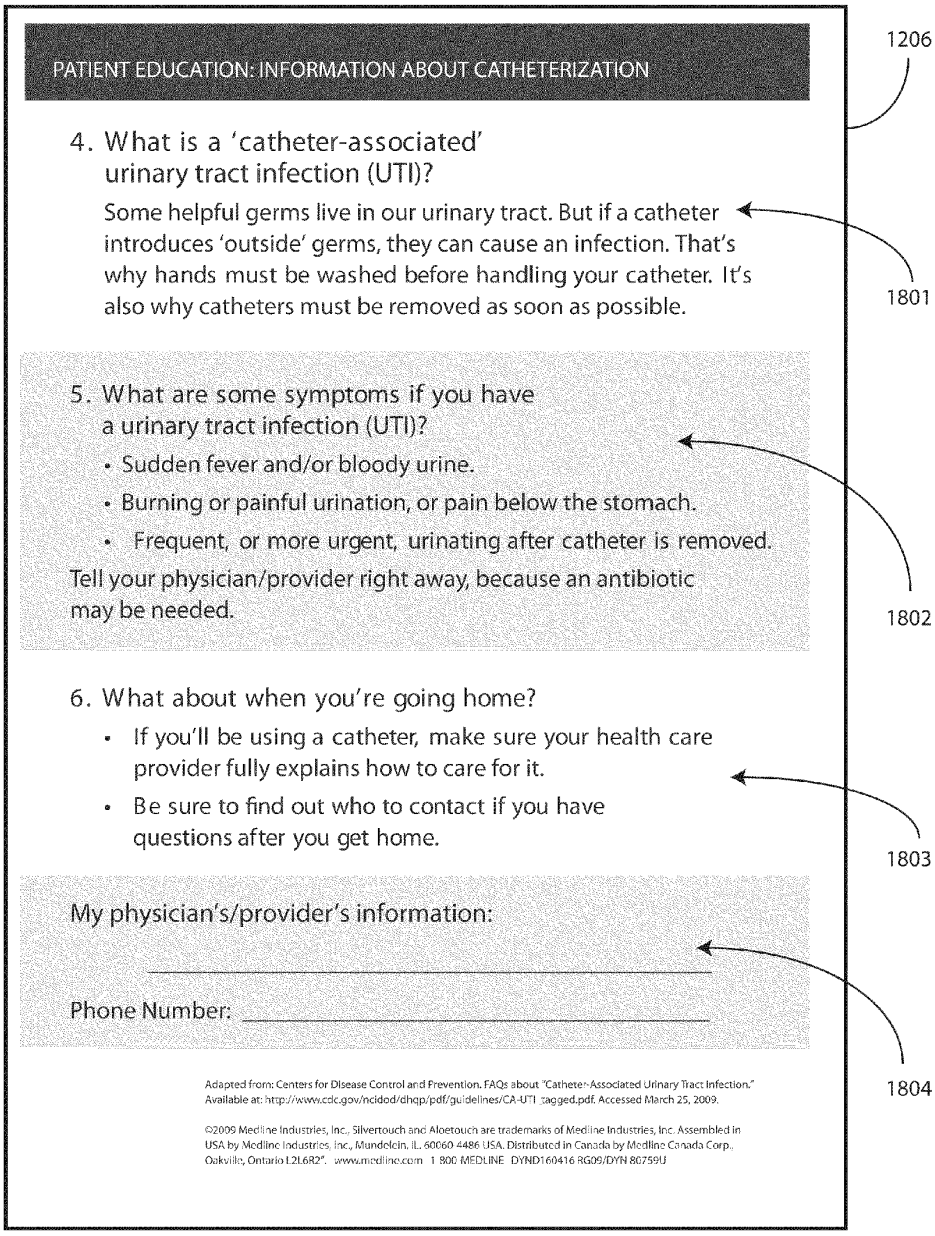

PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1206
4. What is a 'catheter-associated' urinary tract infection (UTI)?
Some helpful germs live in our urinary tract. But if a catheter introduces 'outside' germs, they can cause an infection. That's why hands must be washed before handling your catheter. 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

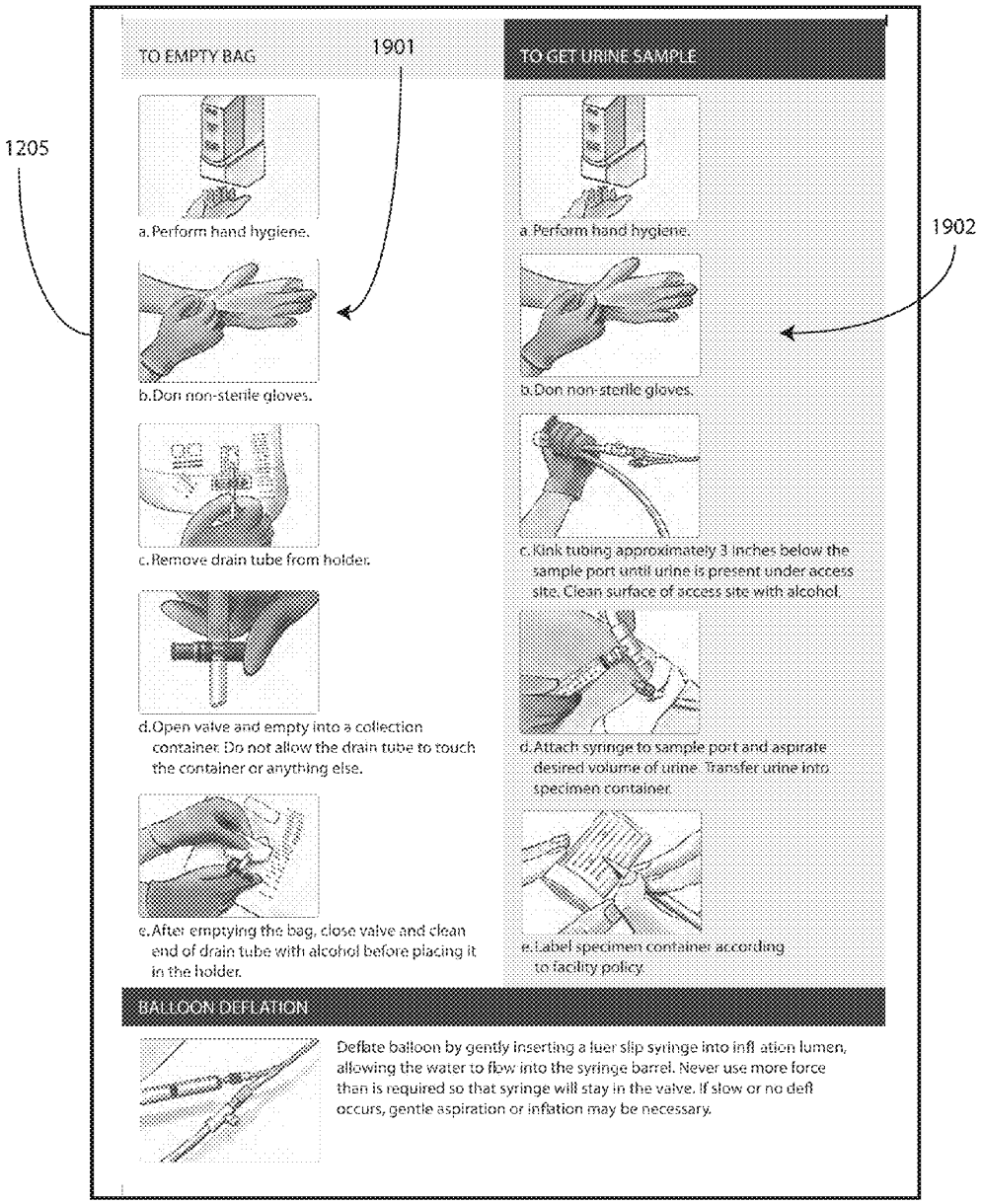

1205
1901
1902
TO EMPTY BAG
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Remove drain tube from holder.
d. Open valve and empty into a collection container. Do not allow the drain tube to touch the container or anything else.
e. After emptying the bag, close valve and clean end of drain tube 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

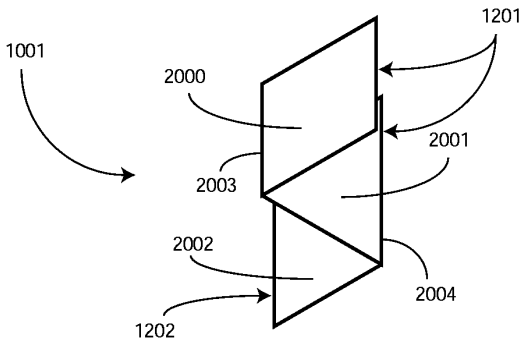

1001
1201
2000
2001
2003
2002
2004
1202

FIG. 20

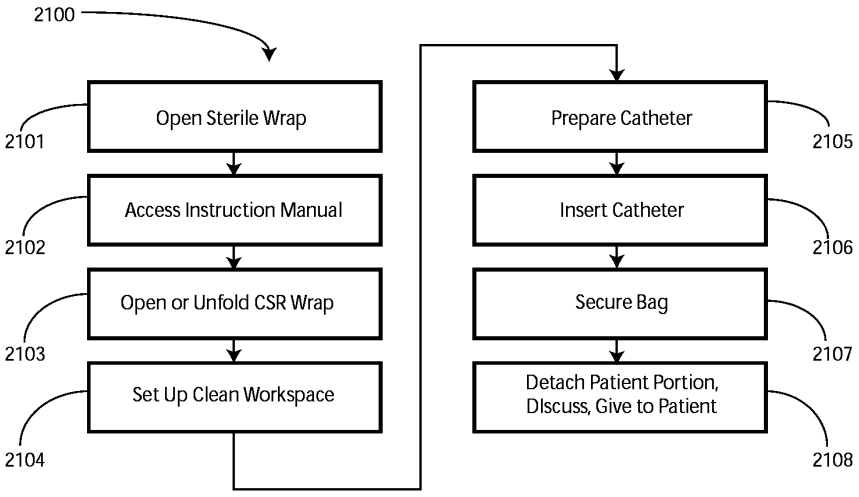

2100
Open Sterile Wrap
2101
Access Instruction Manual
2102
Open or Unfold CSR Wrap
2103
Set Up Clean Workspace
2104
Prepare Catheter
2105
Insert Catheter
2106
Secure Bag
2107
Detach Patient Portion, DIscuss, Give to Patient
2108

FIG. 21

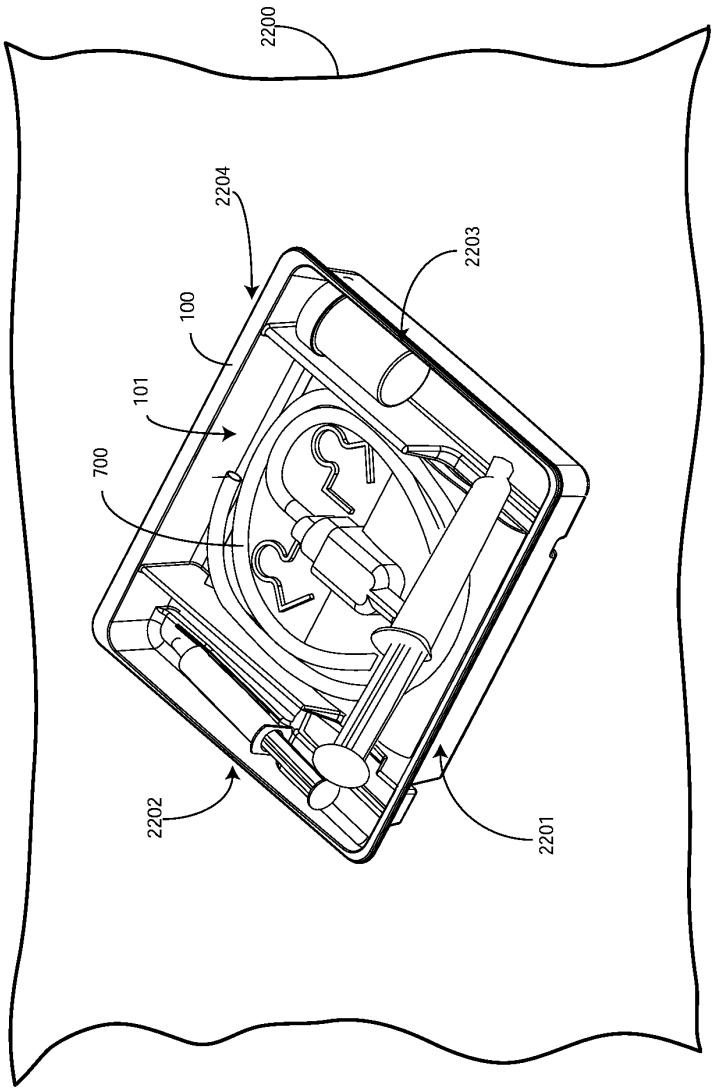


FIG. 22

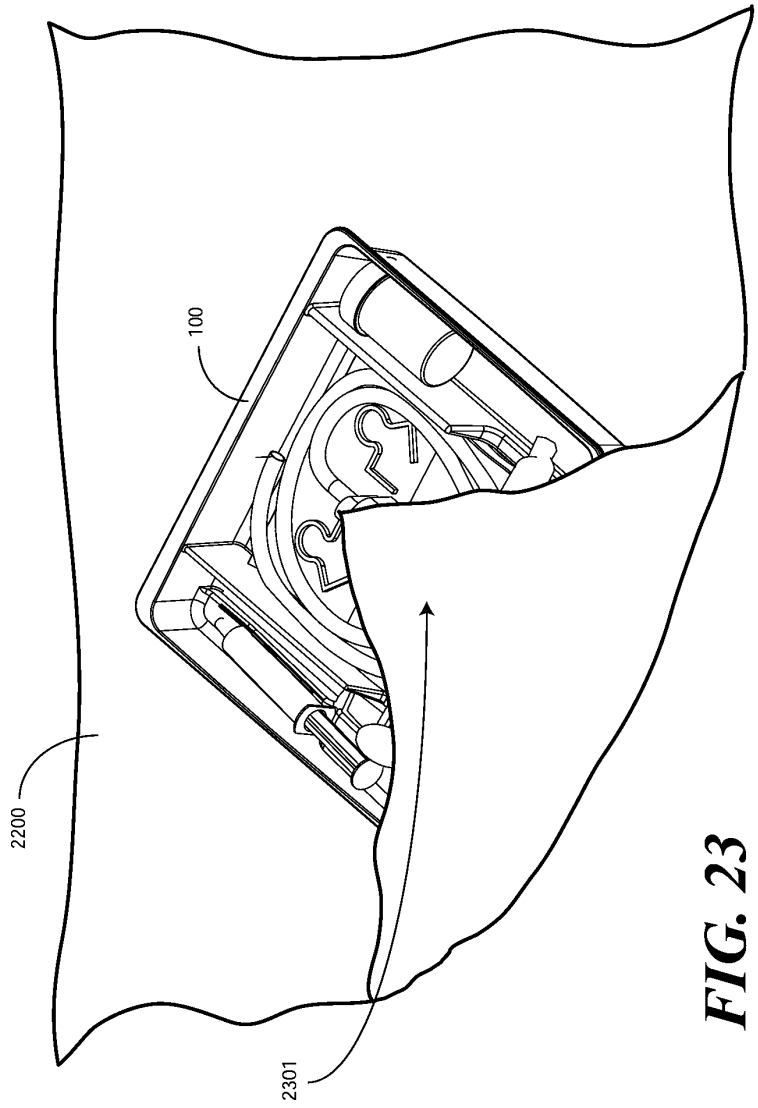


FIG. 23

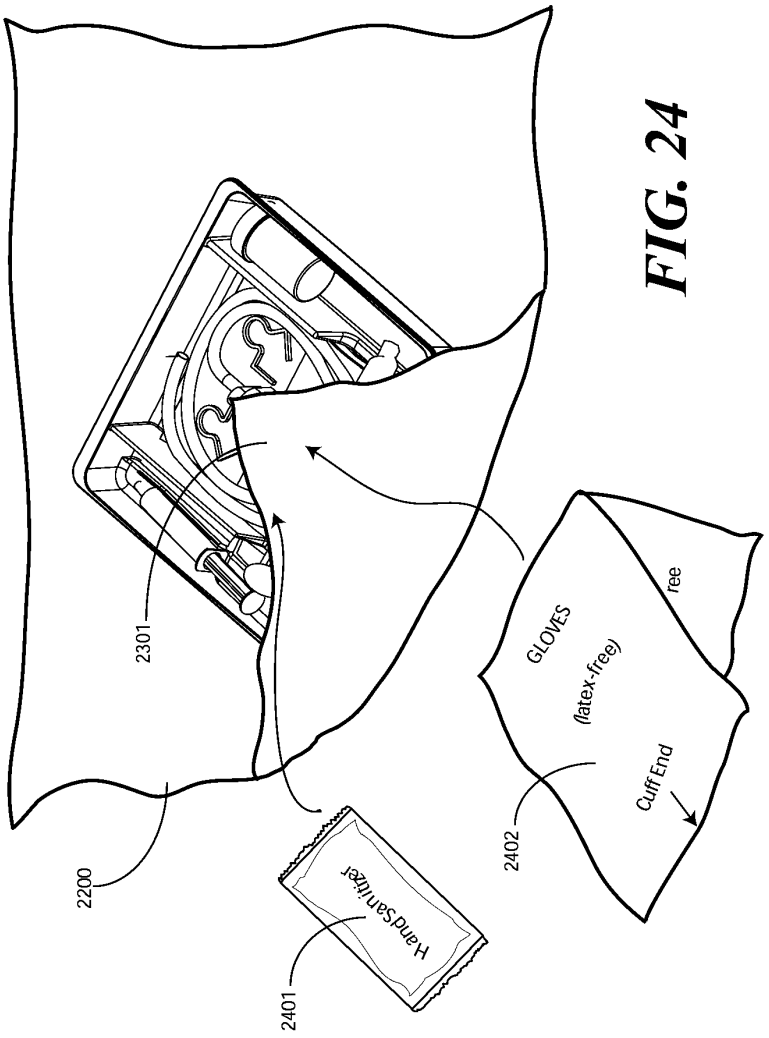

2301
2200
2401
HandSanitizer
2402
GLOVES
(latex-free)
Cuff End
ree

FIG. 24

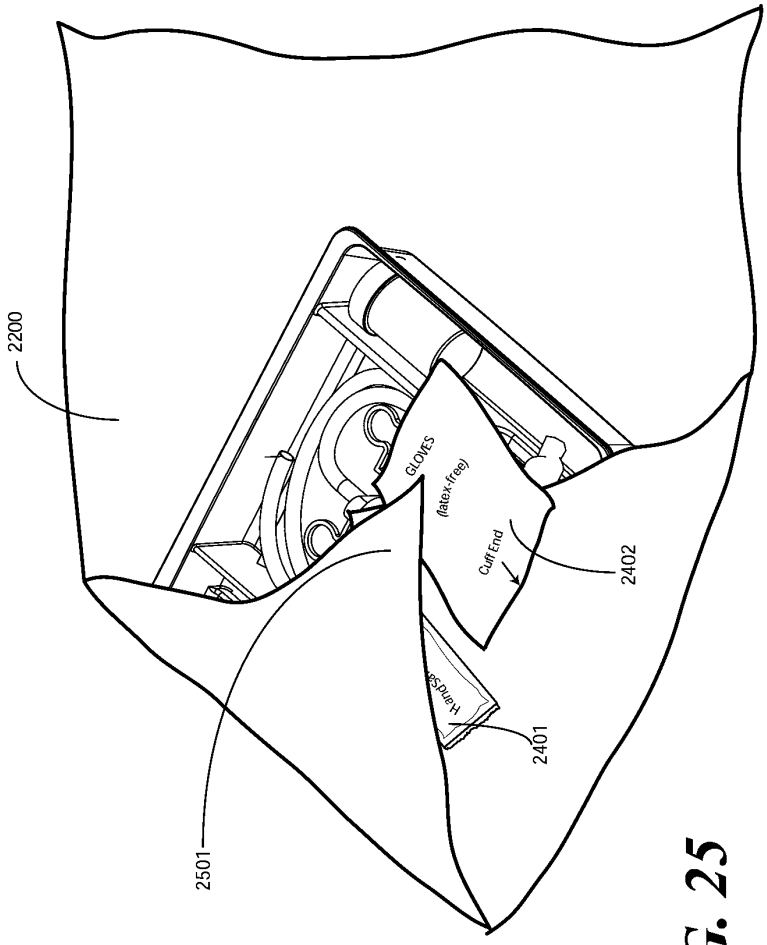


FIG. 25

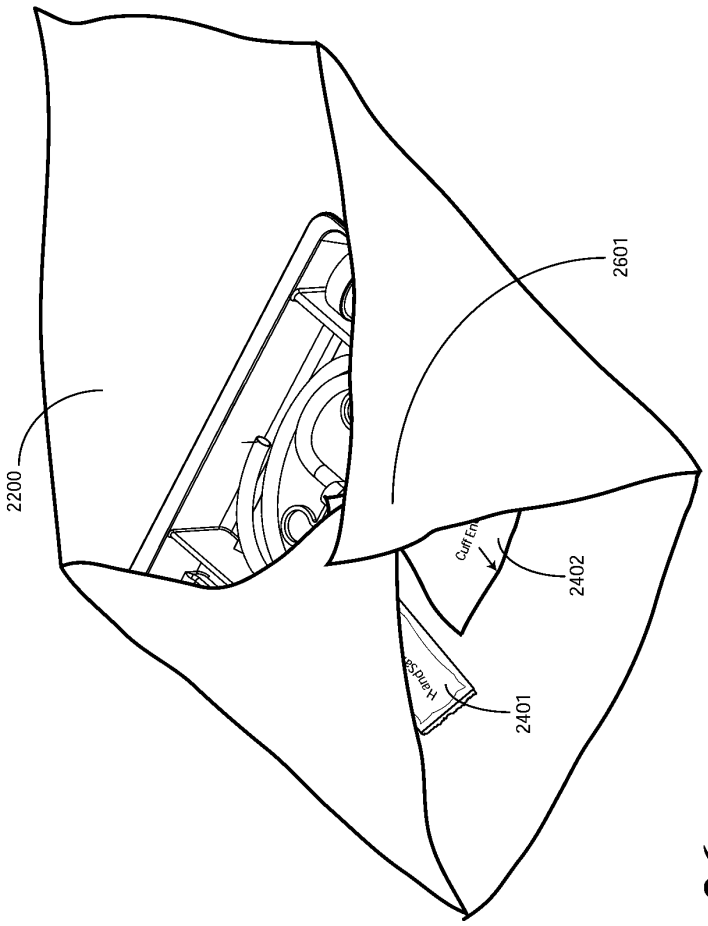


FIG. 26

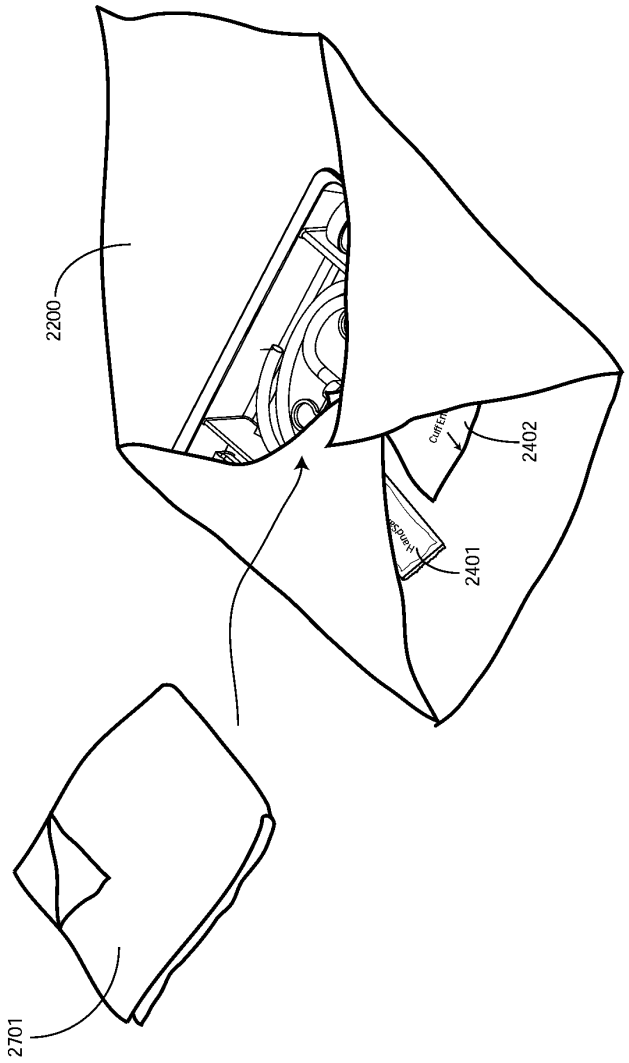


FIG. 27

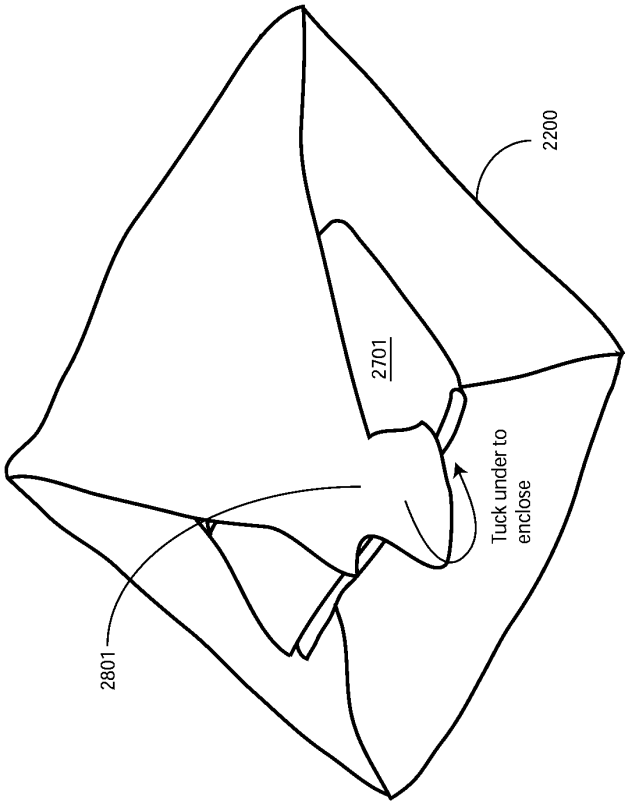


FIG. 28

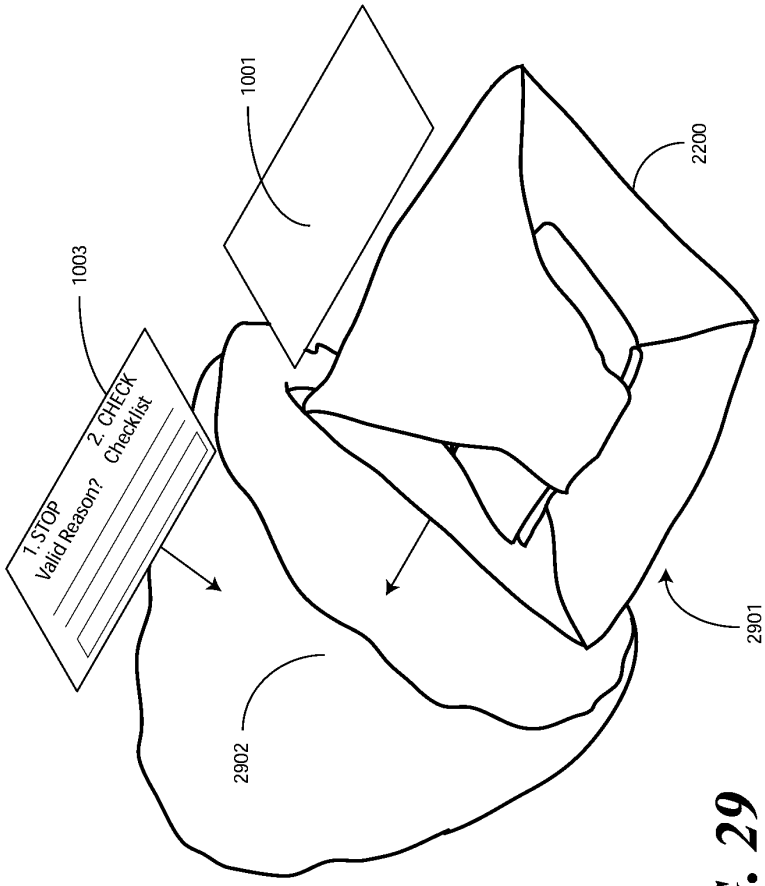

1001
2200
1003
1. STOP
Valid Reason?
2. CHECK
Checklist
2901
2902

FIG. 29

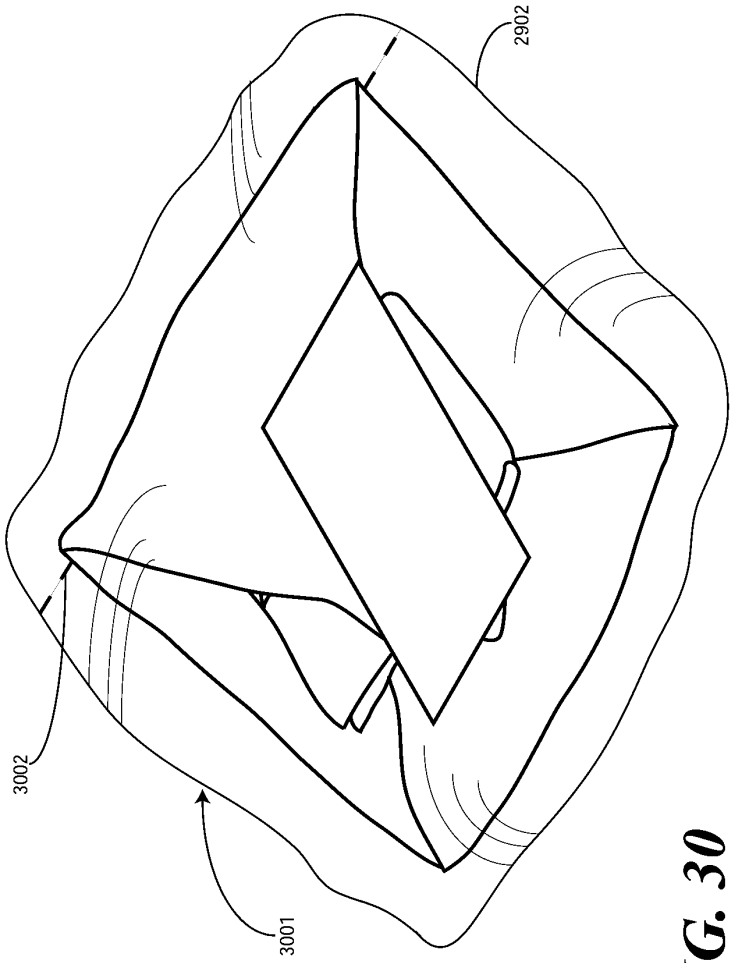


FIG. 30

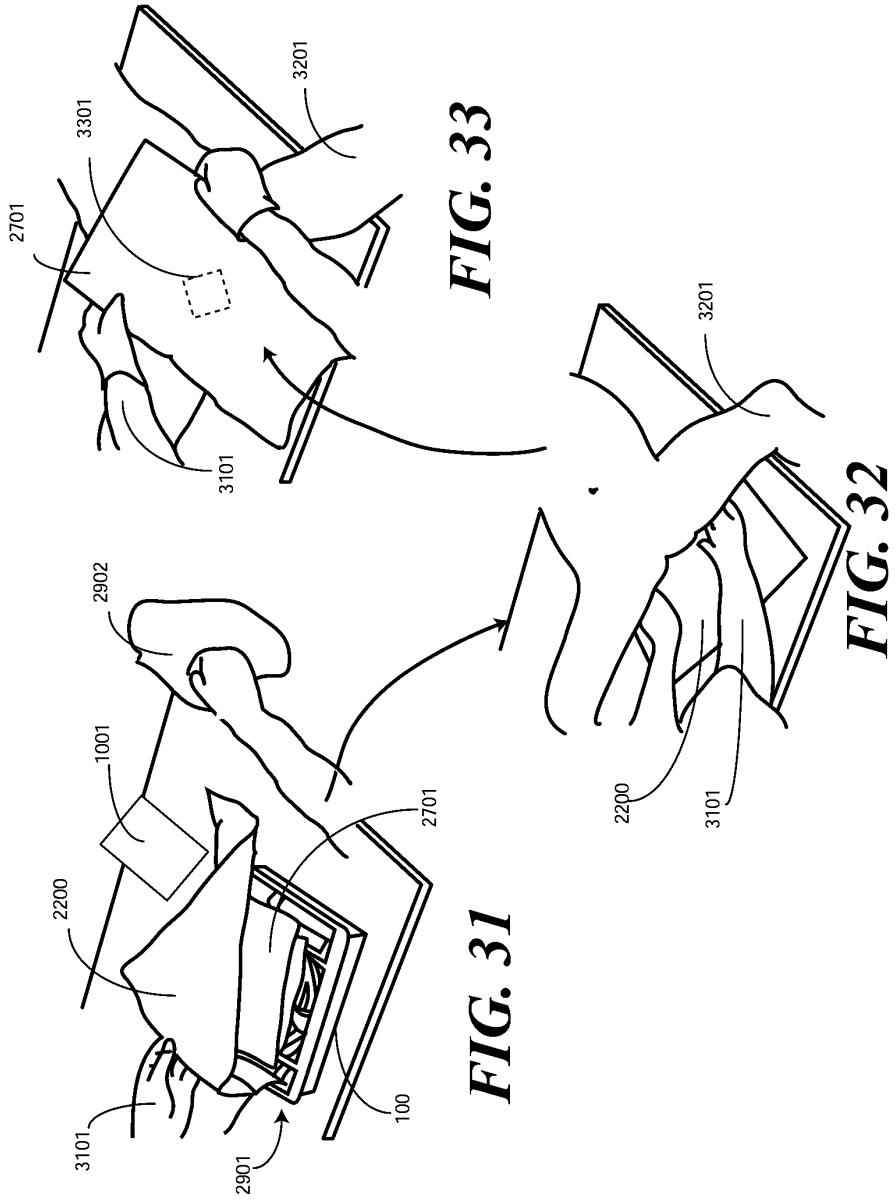


FIG. 33

FIG. 31

FIG. 32

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS

CROSS REFERENCE TO PRIOR APPLICATIONS

This application claims priority and benefit under 35 U.S.C. §119(e) from U.S. Provisional Applications: 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.

This application is a continuation in part of, and therefore claims priority to the following applications, each of which is incorporated herein by reference: U.S. patent application Ser. No. 12/495,148, filed Jun. 30, 2009; U.S. patent application Ser. No. 12/647,515, filed Dec. 27, 2009; U.S. patent application Ser. No. 13/153,265, filed Jun. 3, 2011; and U.S. patent application Ser. No. 13/153,300, filed Jun. 3, 2011.

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

1. 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.

2. 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 a method of packaging a catheter assembly and corresponding tray in accordance with embodiments of the disclosure.

FIGS. **31-33** illustrate an embodiment of a method of using a packaged catheter assembly.

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 tray configured to accommodate a coiled medical 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**. 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**.

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**.

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 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 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**. 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 embodi-

ment, 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.

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. 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.

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**).

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 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.

Once the printed instructions **1001** have been affixed to, or placed with or atop the packaged catheter assembly **2901**, 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 FIG. **30**, where 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. **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**.

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 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**.

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 configures 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. **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 sterile wrap is a sealed bag, this step **2101** can include unsealing the sealed bag. Where the sterile wrap is a thermally sealed bag, this step **2101** can include breaking through the bag or breaking the thermal seal. Where the bag is sealed with an adhesive or other type of seal, such as one including pull-tabs, this step **2101** can include pulling the pull-tabs or separating the adhesive seal. Other opening steps will be obvious to those of ordinary skill in the art having the benefit of this disclosure. Where the tray is wrapped with one more layers of wrap, such as CSR wrap, this step **2101** can reveal the one or more layers of wrap folded about the tray.

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 obtaining a package of hand sanitizer from the tray and applying or otherwise 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 obtaining a package of sterile gloves from the tray and donning the sterile gloves as shown at step (**1506**) of FIG. **15**. This may include obtaining a fenestrated drape from the tray or catheter package assembly and placing the 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 also include filling a test balloon of the catheter assembly with water from a first syringe obtained from a first compartment of the tray as shown at step (**1508**) of FIG. **15**, and injecting lubricating jelly from a second syringe, obtained from the first compartment, into the first compartment of the tray (**100**) as shown at step (**1509**) of FIG. **15**. When lubricating jelly is inserted into the first compartment, the health care services provider can pass at least a portion of the catheter assembly through an opening in the first barrier separating the second compartment from the first compartment, thereby causing the portion of the catheter assembly to pass through the lubricating jelly. Other steps can be performed as well. For example, as shown at step (**1601**) of FIG. **16**, the health care services provider can obtain one or more swabsticks from the tray and may cleanse the patients with the one or more swabsticks prior to insertion of the catheter.

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 method of using a catheter package assembly, comprising:

providing the catheter package assembly, the catheter package assembly comprising:

a tray having a catheter assembly disposed therein;

one or more layers of wrap folded about the tray so as to enclose the tray within the one or more layers of wrap; and

a sealed bag disposed about the tray;

unsealing the sealed bag disposed about the tray to reveal the one or more layers of wrap folded about the tray;

unfolding the one or more layers of wrap to create a sterile field about the tray;

accessing an instruction manual comprising a health care services portion and a patient portion detachably coupled thereto;

detaching the patient portion from the health care services portion; and

delivering the patient portion to the patient.

2. The method of claim **1**, further comprising:

obtaining an underbuttocks wrap from the catheter package assembly; and

placing the underbuttocks wrap beneath a patient.

3. The method of claim **2**, further comprising obtaining a package of liquid hand sanitizer from the catheter package assembly and applying the package of liquid hand sanitizer.

4. The method of claim **3**, further comprising obtaining a package of rubber gloves from the catheter package assembly and donning rubber gloves from the package of rubber gloves.

5. The method of claim **2**, further comprising obtaining a fenestrated drape from the catheter package assembly and placing the fenestrated drape on the patient.

6. The method of claim **5**, further comprising inserting the catheter assembly into the patient.

7. The method of claim **1**,

the health care services portion comprising instructions for using the catheter assembly and corresponding medical devices on the patient; and

the patient portion separated from the health care services portion by a perforation.

8. The method of claim **7**, further comprising writing a health care provider's name and contact information on the patient portion prior to the delivering the patient portion to the patient.

9. The method of claim **1**, further comprising:

obtaining a first syringe from a first compartment of the tray; and

forming a test balloon in the catheter assembly by injecting water from the first syringe into the catheter assembly.

10. The method of claim **9**, further comprising:

obtaining a second syringe from the first compartment of the tray;

injecting lubricating jelly from the second syringe into the first compartment of the tray; and

passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment prior to the inserting the catheter assembly into the patient.

11. The method of claim **1**, further comprising:

obtaining one or more swabsticks from a third compartment of the tray; and

cleansing the patient with the one or more swabsticks prior to the inserting the catheter assembly into the patient.

12. The method of claim **2**, further comprising:

obtaining a package of liquid hand sanitizer from the catheter package assembly and applying the package of liquid hand sanitizer; and

obtaining a package of rubber gloves from the catheter package assembly and donning rubber gloves from the package of rubber gloves;

wherein the obtaining the package of liquid hand sanitizer and the obtaining the package of rubber gloves occurs after the obtaining the underbuttocks wrap and the placing the underbuttocks wrap.

13. The method of claim **1**, further comprising obtaining a fenestrated drape from the catheter package assembly.

14. The method of claim **2**, further comprising:

removing at least one syringe from a first compartment in the tray;

injecting lubricating jelly from the at least one syringe into the first compartment of the tray; and

passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment, thereby passing the at least the portion of the catheter assembly through the lubricating jelly.

15. A method, comprising:

providing a catheter package assembly, the catheter package assembly comprising:

a tray having a catheter assembly disposed therein;

one or more layers of wrap folded about the tray so as to enclose the tray within the one or more layers of wrap; and

a sealed bag disposed about the tray;

unsealing the sealed bag disposed about the tray to reveal the one or more layers of wrap folded about the tray;

unfolding the one or more layers of wrap to create a sterile field about the tray;

removing at least one syringe from a first compartment in the tray;

injecting lubricating jelly from the at least one syringe into the first compartment of the tray; and

passing at least a portion of the catheter assembly from a second compartment of the tray through an opening in a first barrier separating the first compartment from the second compartment, thereby passing the at least the portion of the catheter assembly through the lubricating jelly.

16. The method of claim 15, further comprising delivering a patient portion of an instruction manual to a patient.

17. The method of claim 16, further comprising detaching the patient portion from a health care services portion.

18. The method of claim 15, further comprising accessing a catheter assembly.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,678,190 B2
APPLICATION NO. : 13/155053
DATED : March 25, 2014
INVENTOR(S) : Tomes et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Item (75) Inventor is corrected to read:
-- Jennifer E. Tomes, Mundelein, IL;
Sarah Zyburt, Chicago, IL;
Susan E. Macinnes, Trout Valley, IL;
Deborah B. Adler, New York, NY;
Jack E. Maze, Long Grove, IL --.

Signed and Sealed this
Third Day of September, 2019



Andrei Iancu
Director of the United States Patent and Trademark Office

(12) **INTER PARTES REVIEW CERTIFICATE** (845th)
United States Patent
Tomes et al.

(10) **Number: US 8,678,190 K1**
(45) **Certificate Issued: Feb. 21, 2018**

(54) **CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS**

(75) Inventors: **Jennifer E. Tomes**; **Sarah Zyburt**

(73) Assignee: **MEDLINE INDUSTRIES, INC.**

Trial Number:

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Patent No.: **8,678,190**
Issued: **Mar. 25, 2014**
Appl. No.: **13/155,053**
Filed: **Jun. 7, 2011**

The results of IPR2015-00514 are reflected in this inter partes review certificate under 35 U.S.C. 318(b).

AS A RESULT OF THE INTER PARTES REVIEW PROCEEDING, IT HAS BEEN DETERMINED THAT:

Claims **1-7**, **9**, **11-13** are cancelled.

* * * * *

EXHIBIT 30

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**

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(*) 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**

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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)

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CPC ***B65B 11/00*** (2013.01); ***A61B 50/30*** (2016.02); ***A61B 50/33*** (2016.02); ***A61M 25/00*** (2013.01);
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CPC A61B 2050/3008; A61B 2050/3015; A61B 42/00; A61B 46/00; A61B 50/30;
(Continued)

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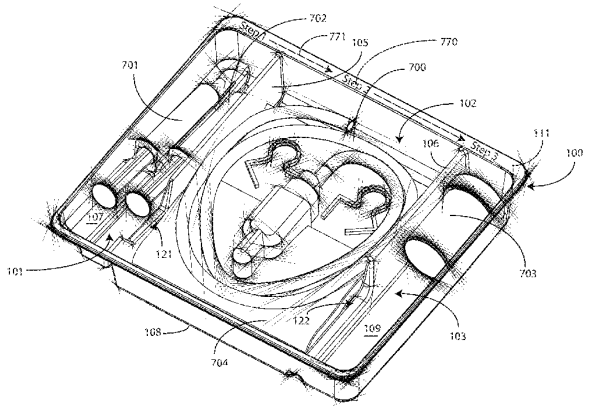
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(57) **ABSTRACT**

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. Printed instructions (**1001**) can be included with the tray (**100**). One or more layers of wrap material (**2200**) can be
(Continued)



Bard Exhibit 1004.0866

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.

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A61B 50/30	(2016.01)
A61B 42/00	(2016.01)
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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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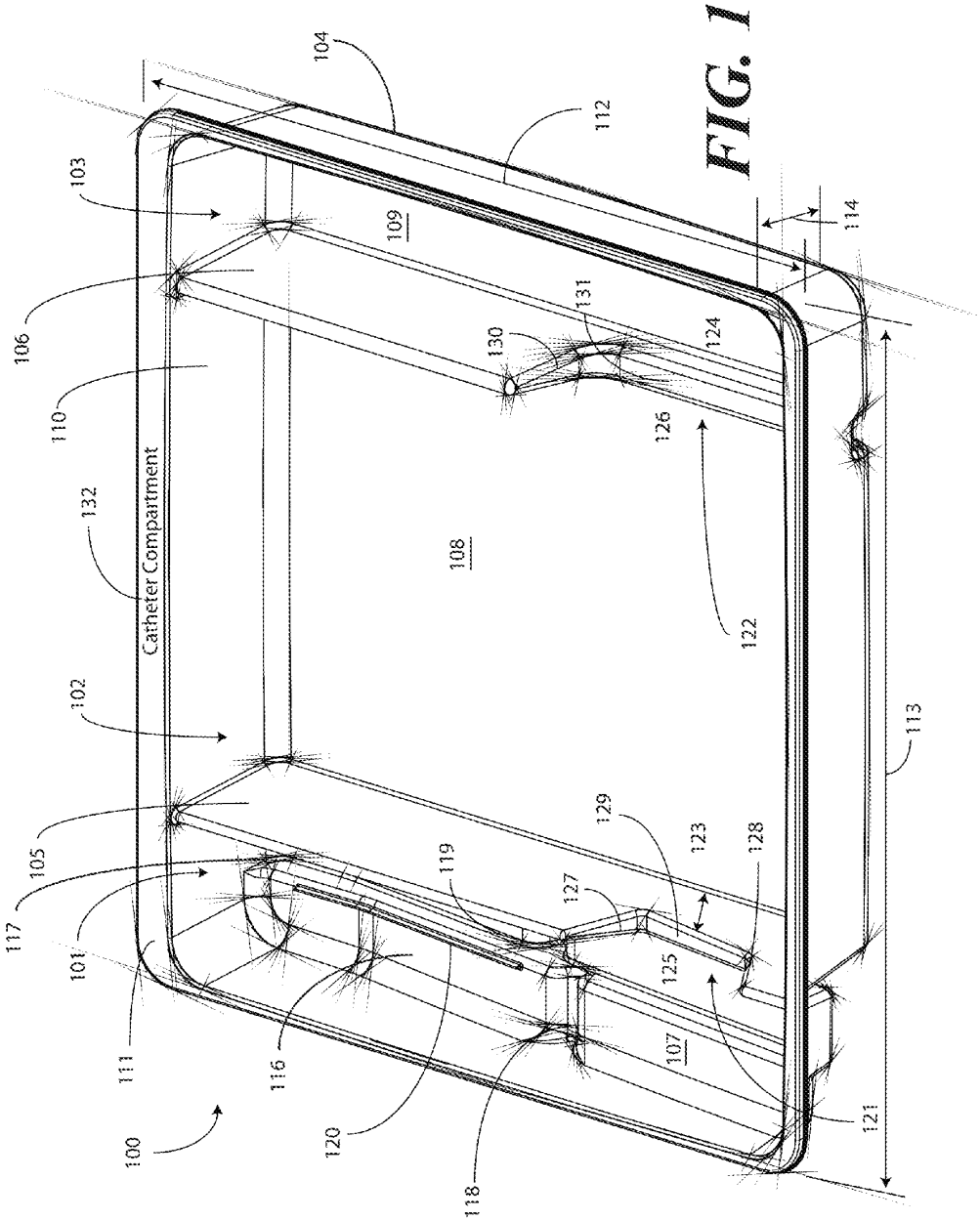


FIG. 1

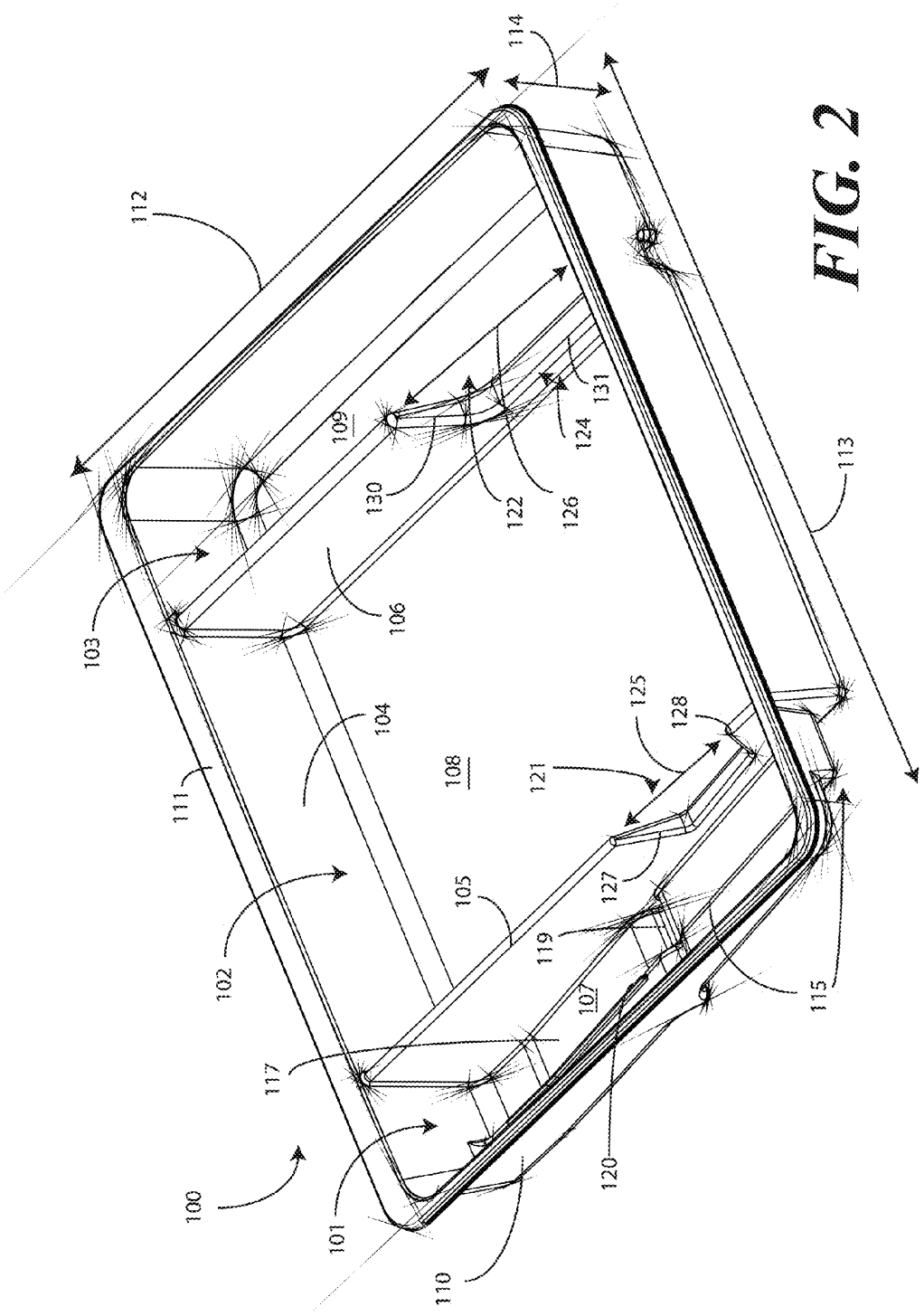

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FIG. 2

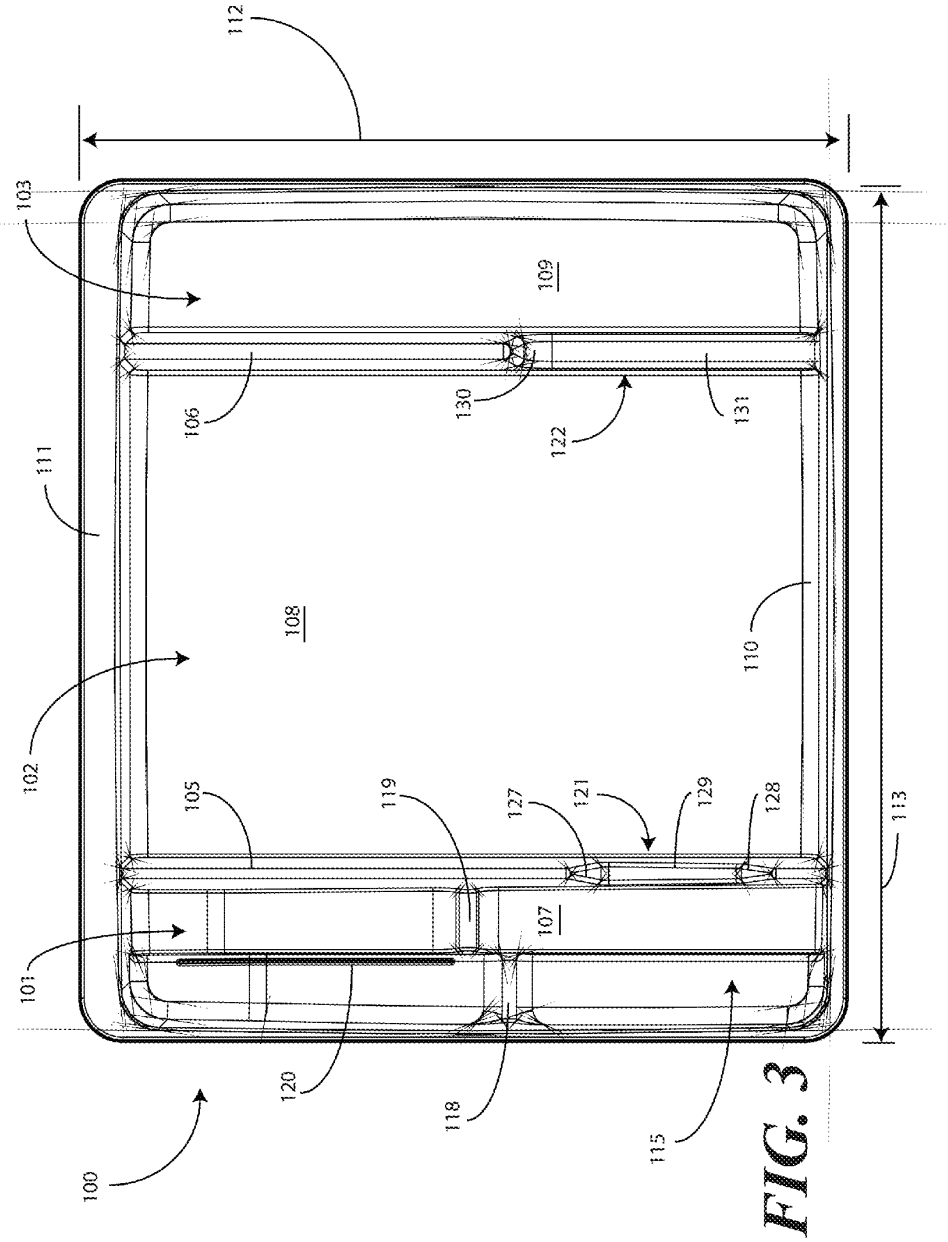

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FIG. 3

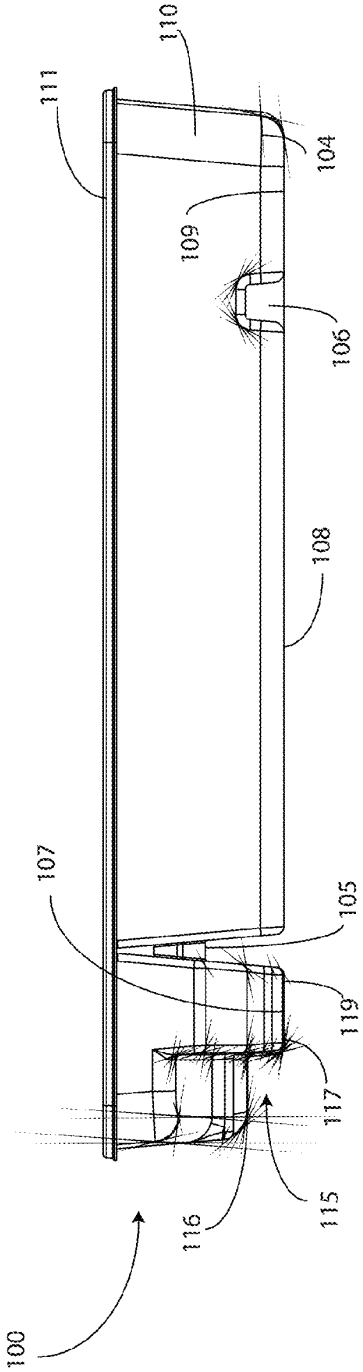

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FIG. 4

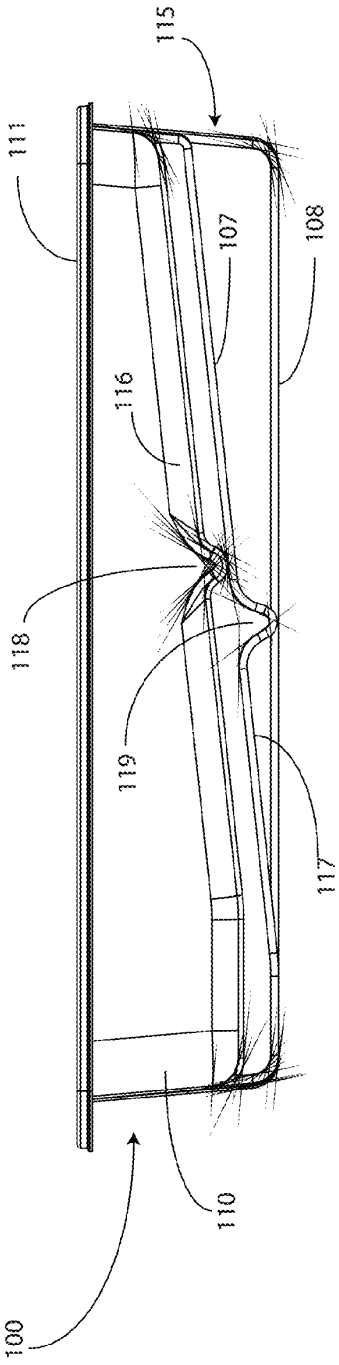

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FIG. 5

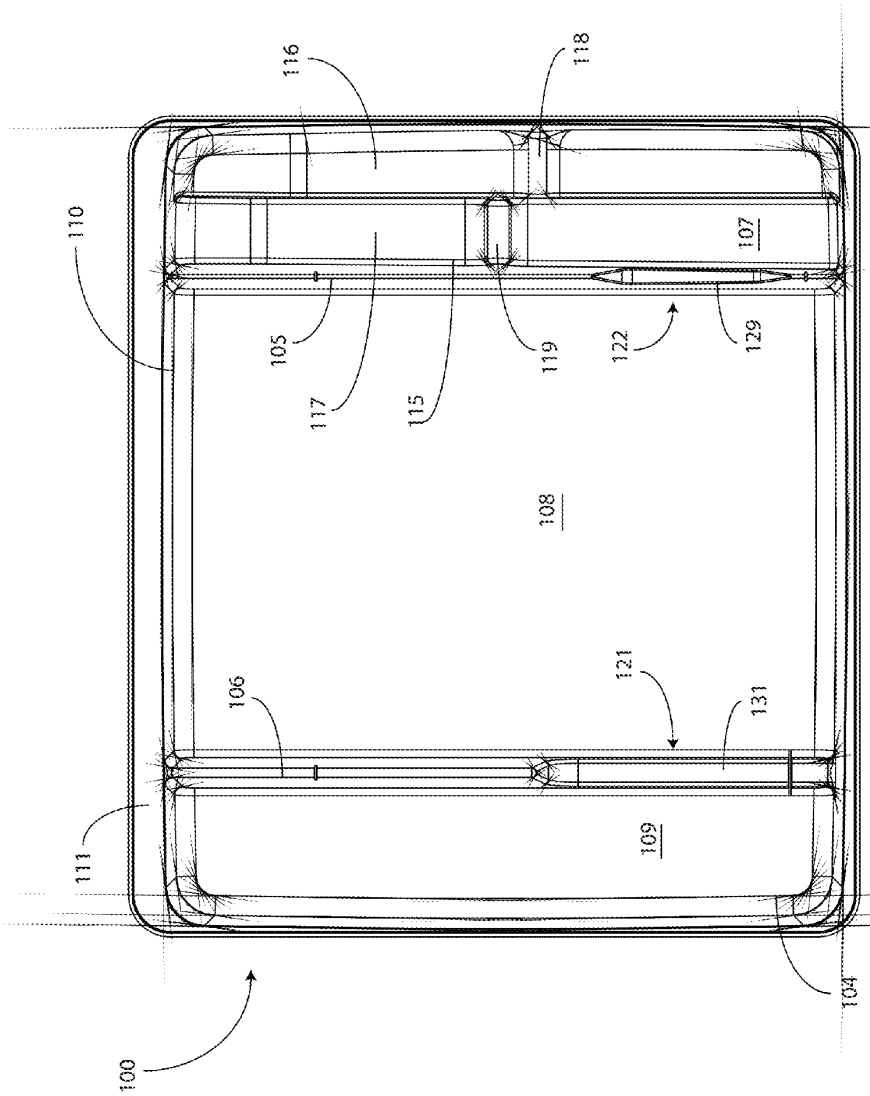

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FIG. 6

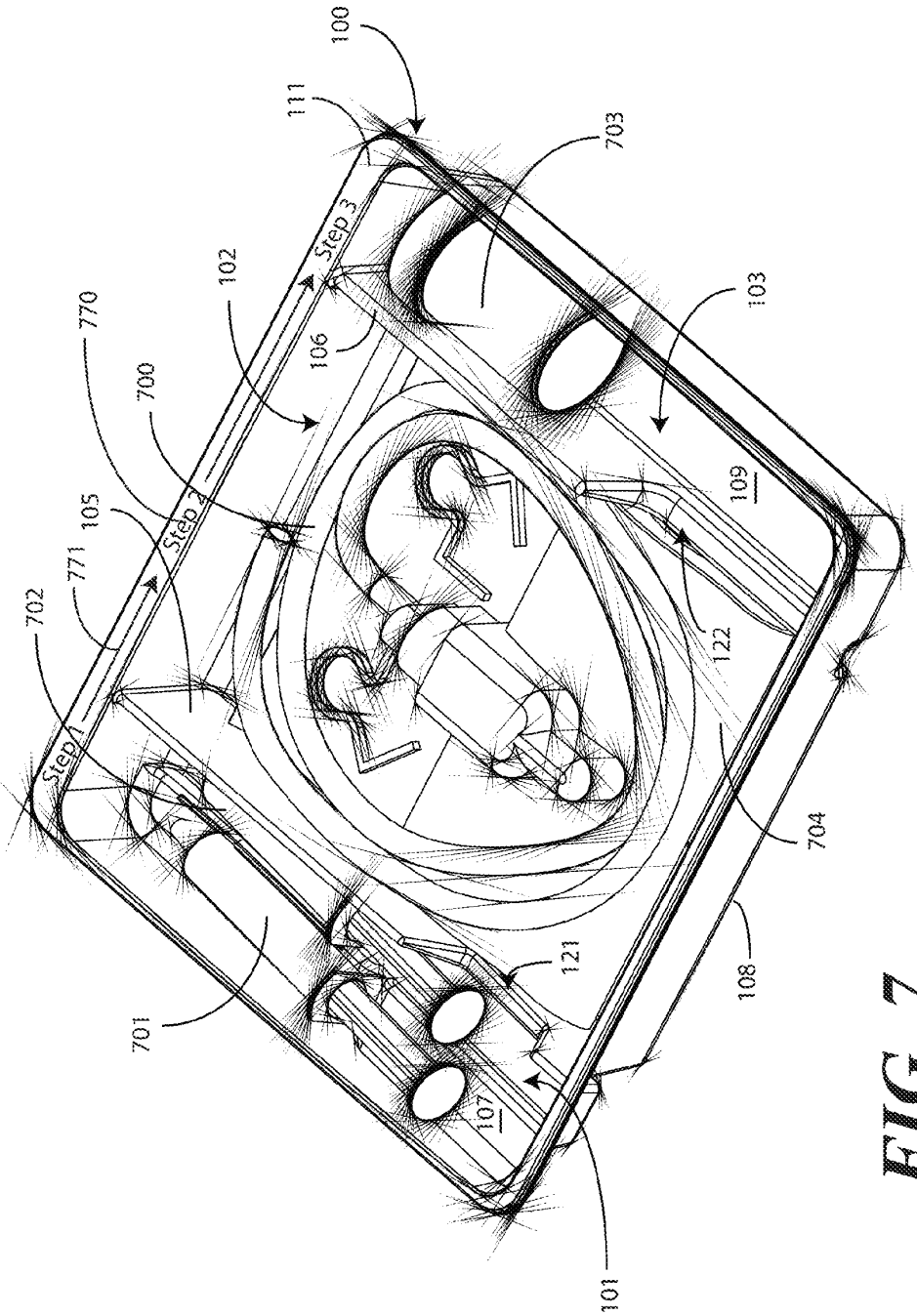

100
111
703
Step 3
102
106
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700
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702
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FIG. 7

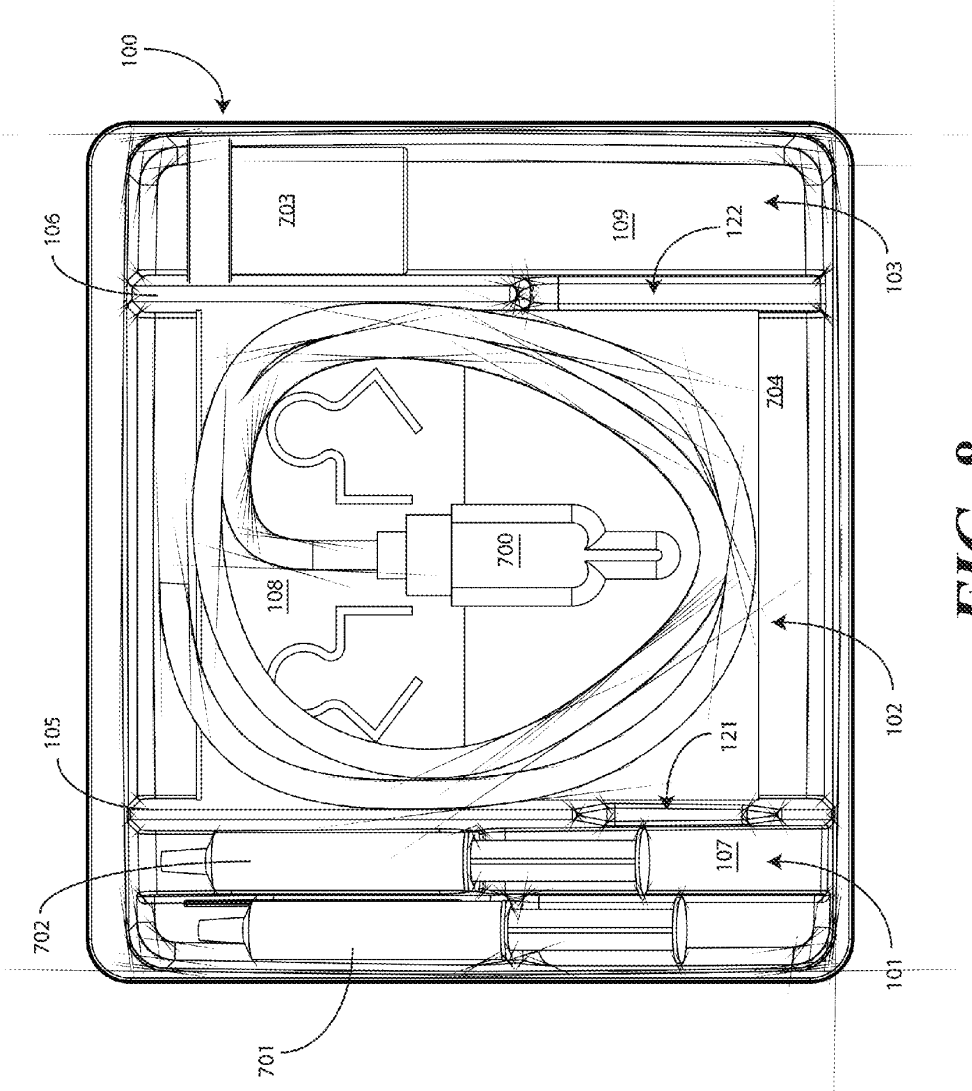


FIG. 8

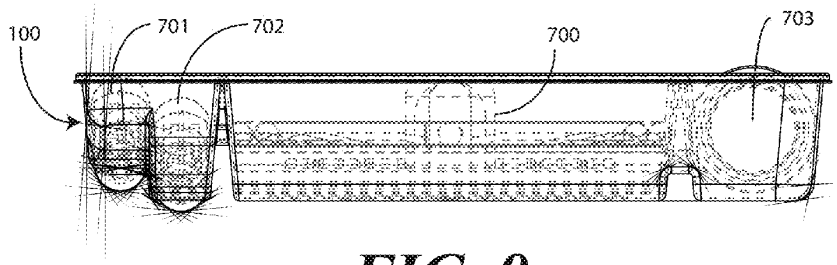

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FIG. 9

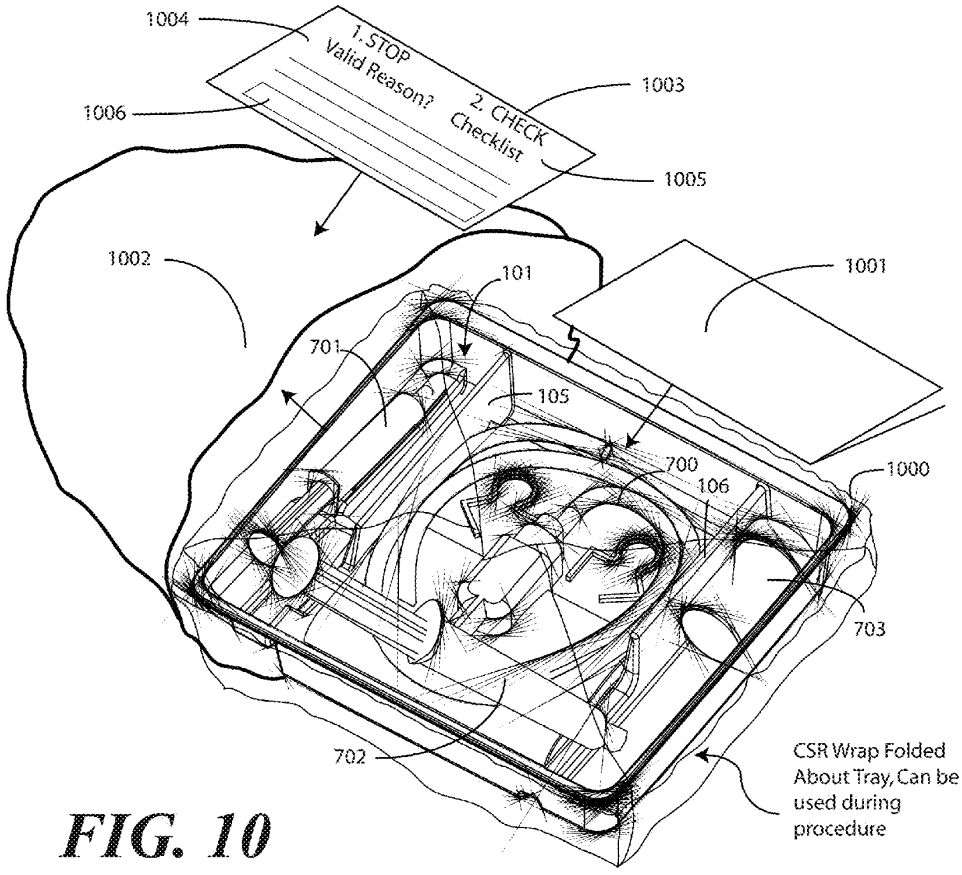

1004
1. STOP Valid Reason?
2. CHECK Checklist
1003
1006
1005
1002
101
1001
701
105
700
106
1000
703
702
CSR Wrap Folded About Tray, Can be used during procedure

FIG. 10

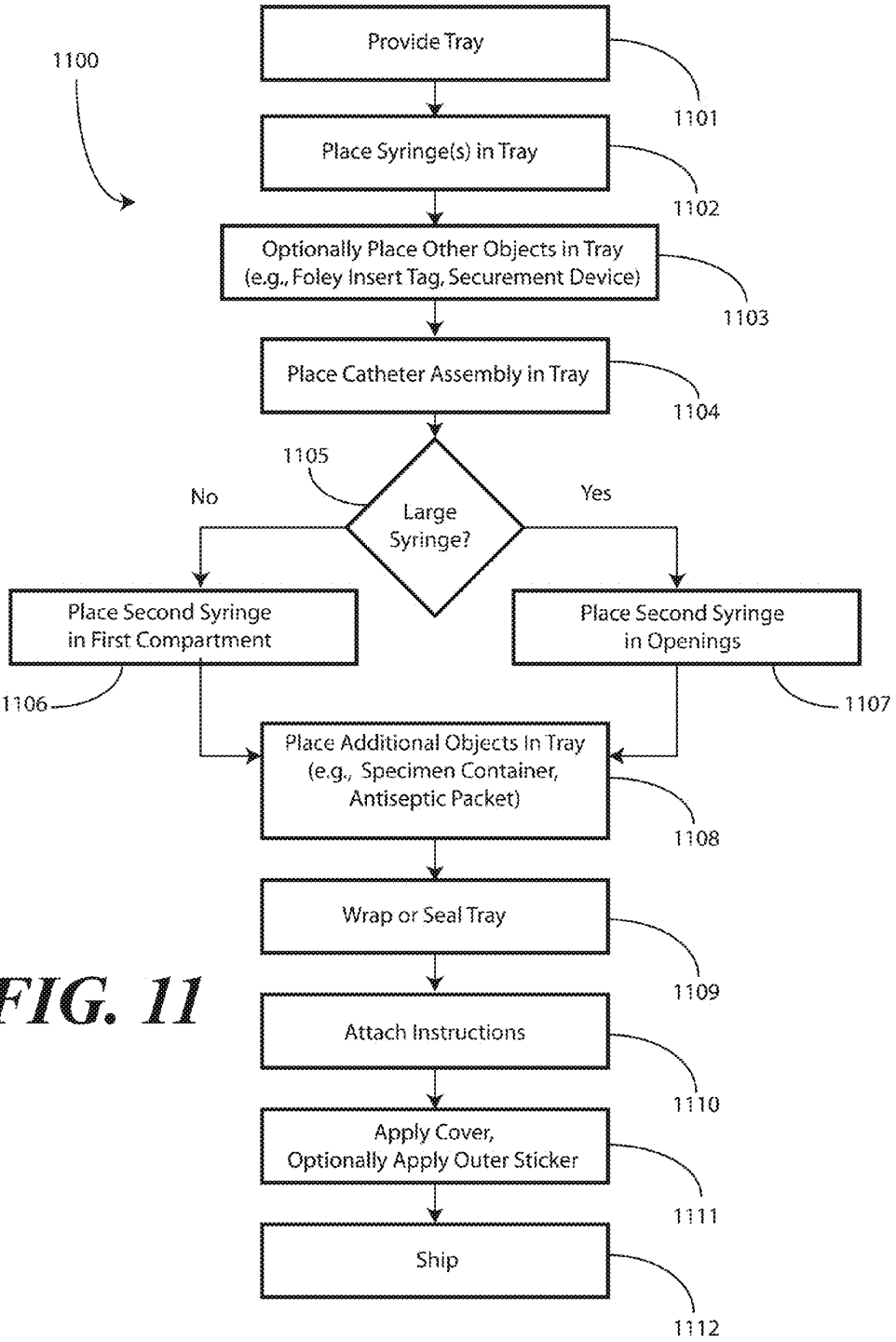

1100
Provide Tray
1101
Place Syringe(s) in Tray
1102
Optionally Place Other Objects in Tray
(e.g., Foley Insert Tag, Securement Device)
1103
Place Catheter Assembly in Tray
1104
1105
Large Syringe?
No
Yes
Place Second Syringe in First Compartment
1106
Place Second Syringe in Openings
1107
Place Additional 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

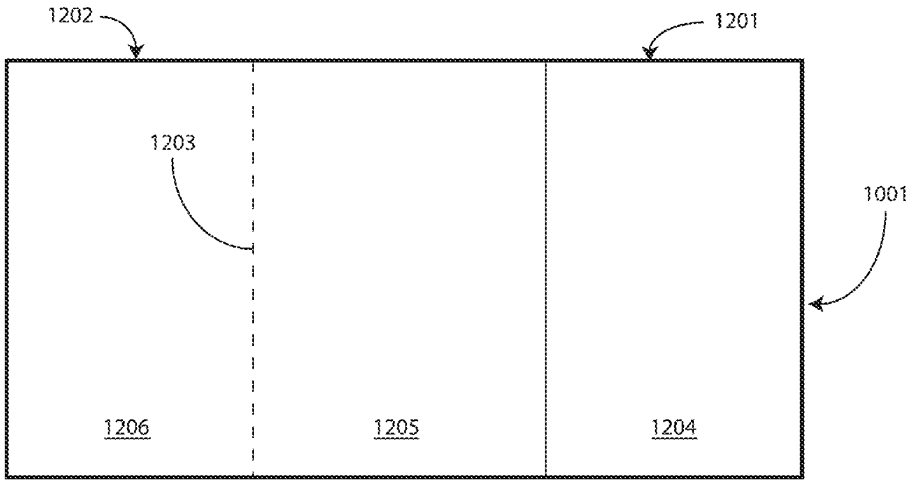

1202
1201
1203
1001
1206
1205
1204

FIG. 12

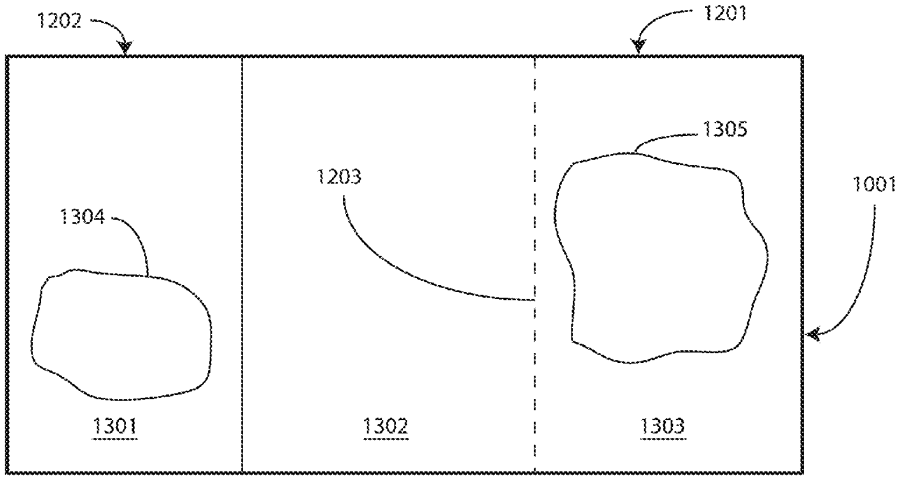

1202
1201
1305
1203
1001
1304
1301
1302
1303

FIG. 13

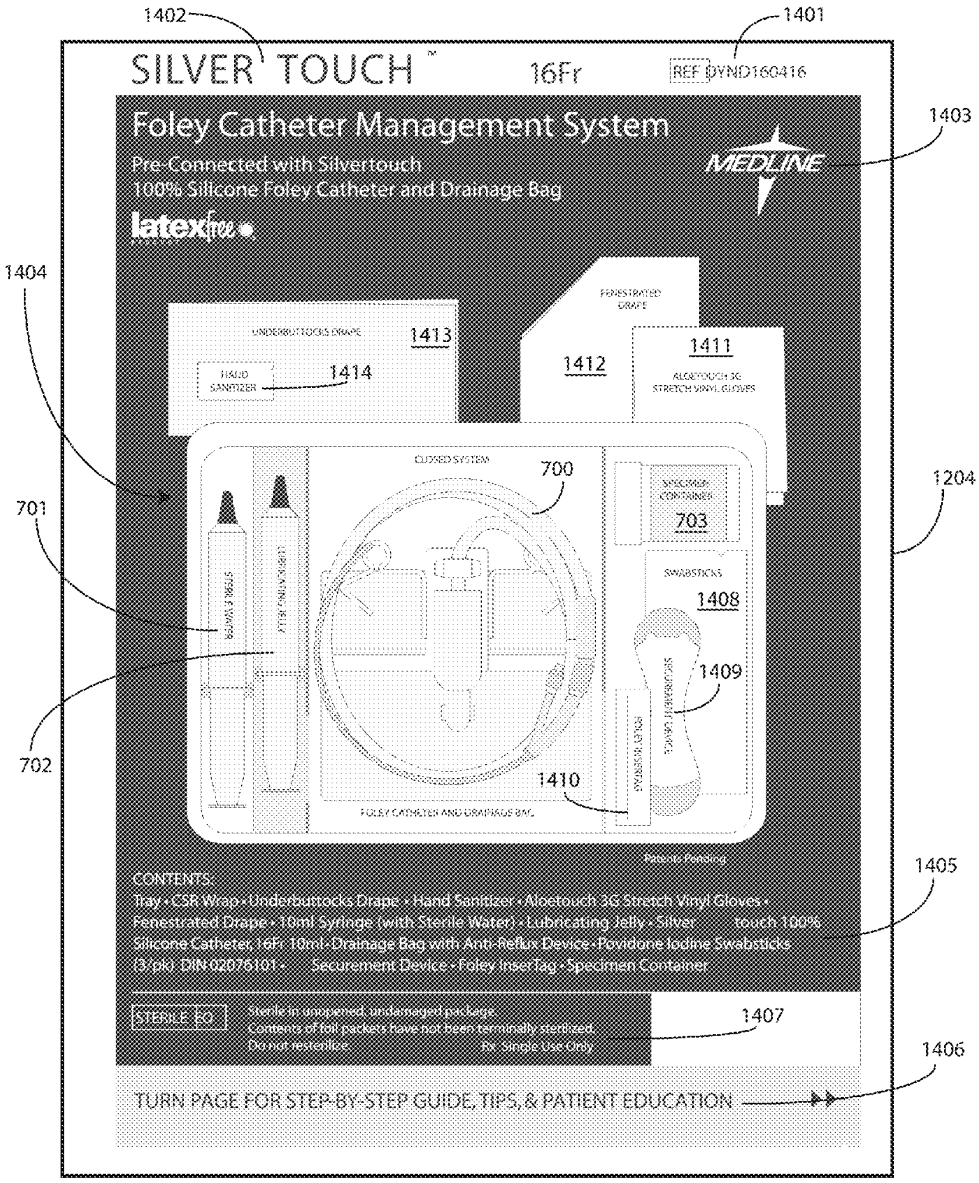

1402
1401
SILVER TOUCH
16Fr
REF DYND160416
Foley Catheter Management System
Pre-Connected with Silvertouch
100% Silicone Foley Catheter and Drainage Bag
latex free
MEDLINE
1403
1404
1413
1414
1412
1411
700
701
1204
703
1408
1409
702
1410
1405
CONTENTS:
Tray • CSR Wrap • Underbuttocks Drape • Hand Sanitizer • 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 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

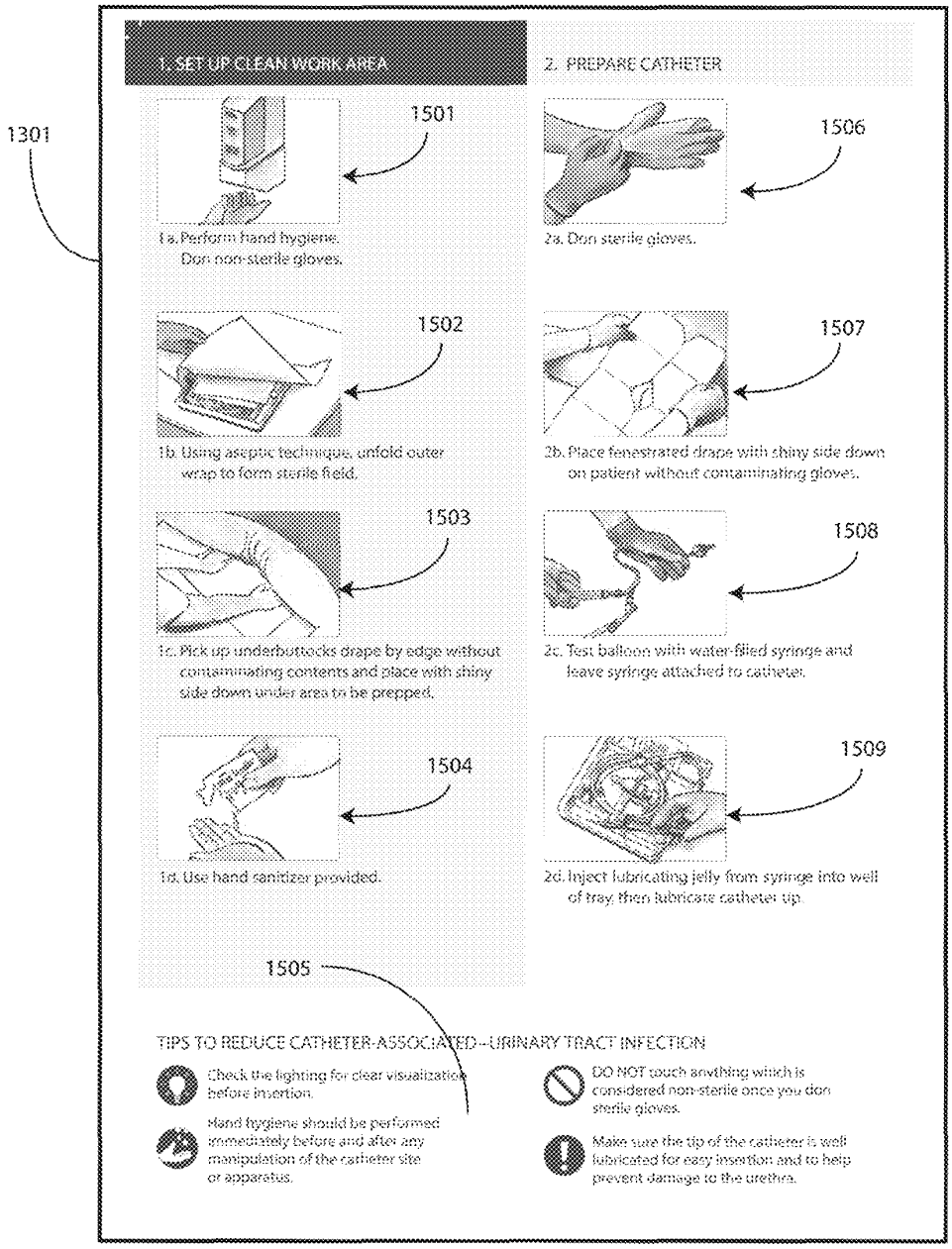

1. SET UP CLEAN WORK AREA
2. PREPARE CATHETER
1301
1501
1a. Perform hand hygiene. Don non-sterile gloves.
1502
1b. Using aseptic technique, unfold outer wrap to form sterile field.
1503
1c. Pick up underbuttocks drape by edge without contaminating contents and place with shiny side down under area to 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 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

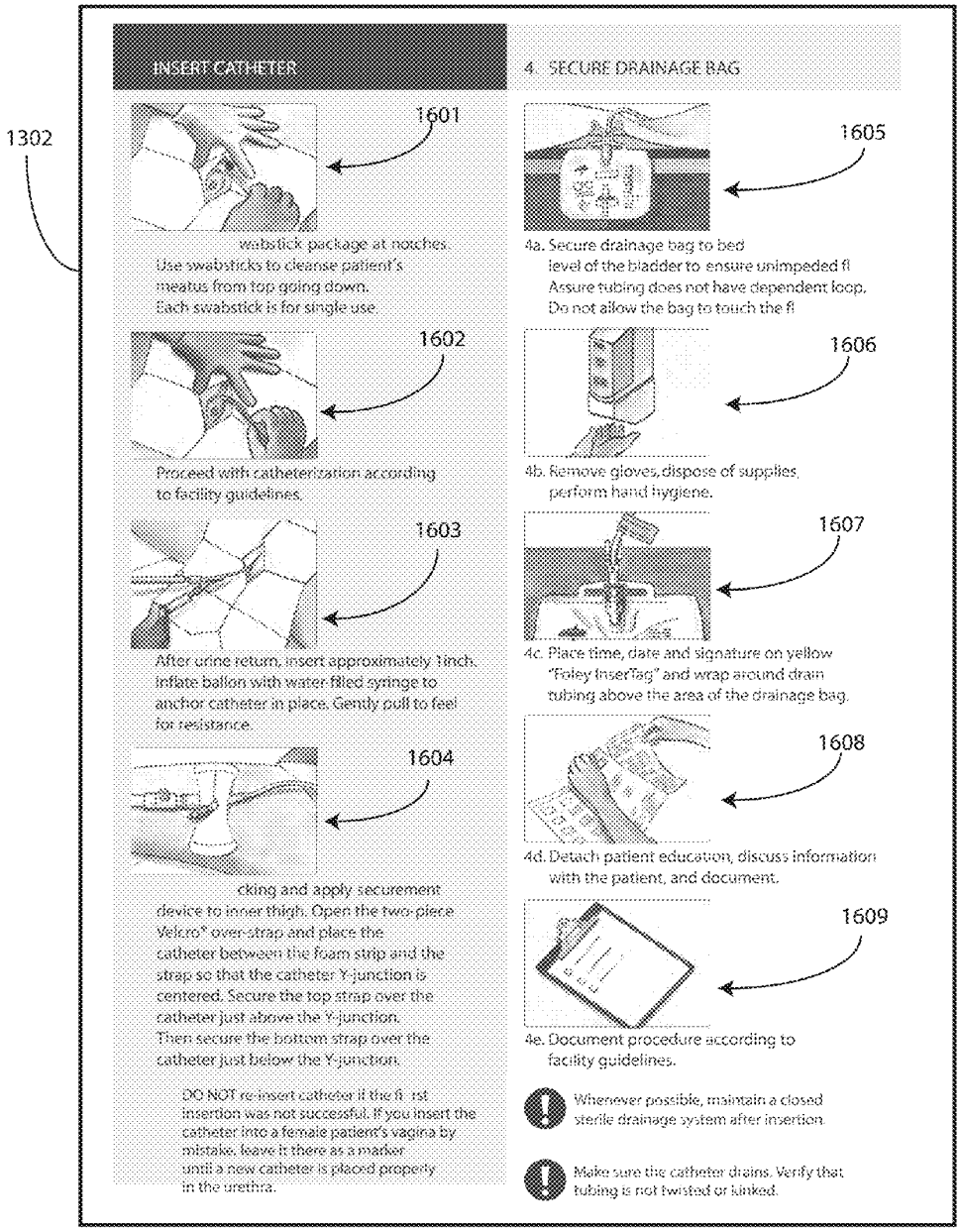

1302
INSERT CATHETER
1601
wabstick package at notches.
Use swabsticks to cleanse patient's
meatus from top going down.
Each swabstick is for single use.
1602
Proceed with catheterization according
to facility guidelines.
1603
After urine return, insert approximately 1inch.
Inflate ballon with water-filled 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

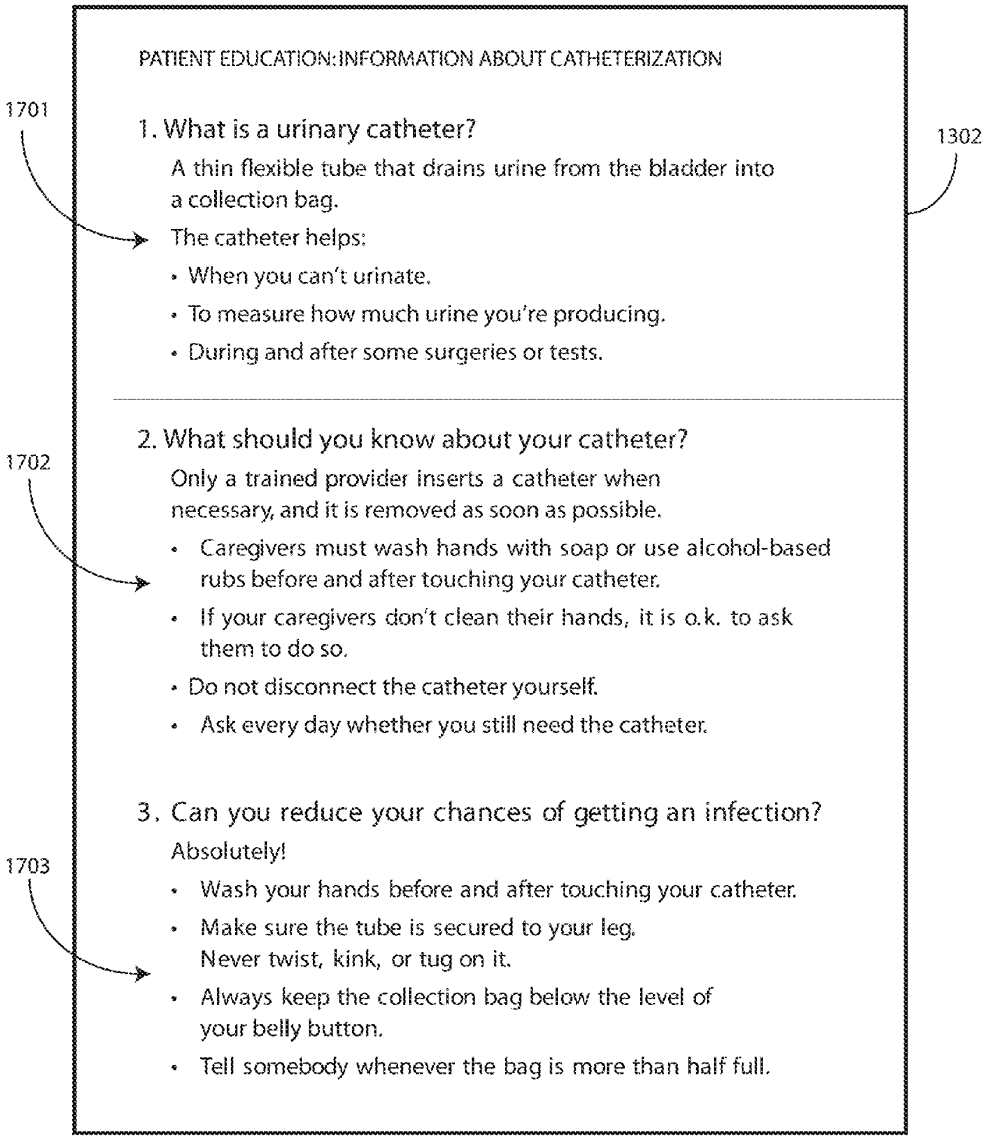

PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1701
1. What is a urinary catheter?
A thin flexible tube that drains urine from the bladder into a collection bag.
The catheter helps:
• When you can't urinate.
• To measure how much urine you're producing.
• During and after some surgeries or tests.
1302
1702
2. What should you know about your catheter?
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.
1703
3. Can you reduce your chances of getting an infection?
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

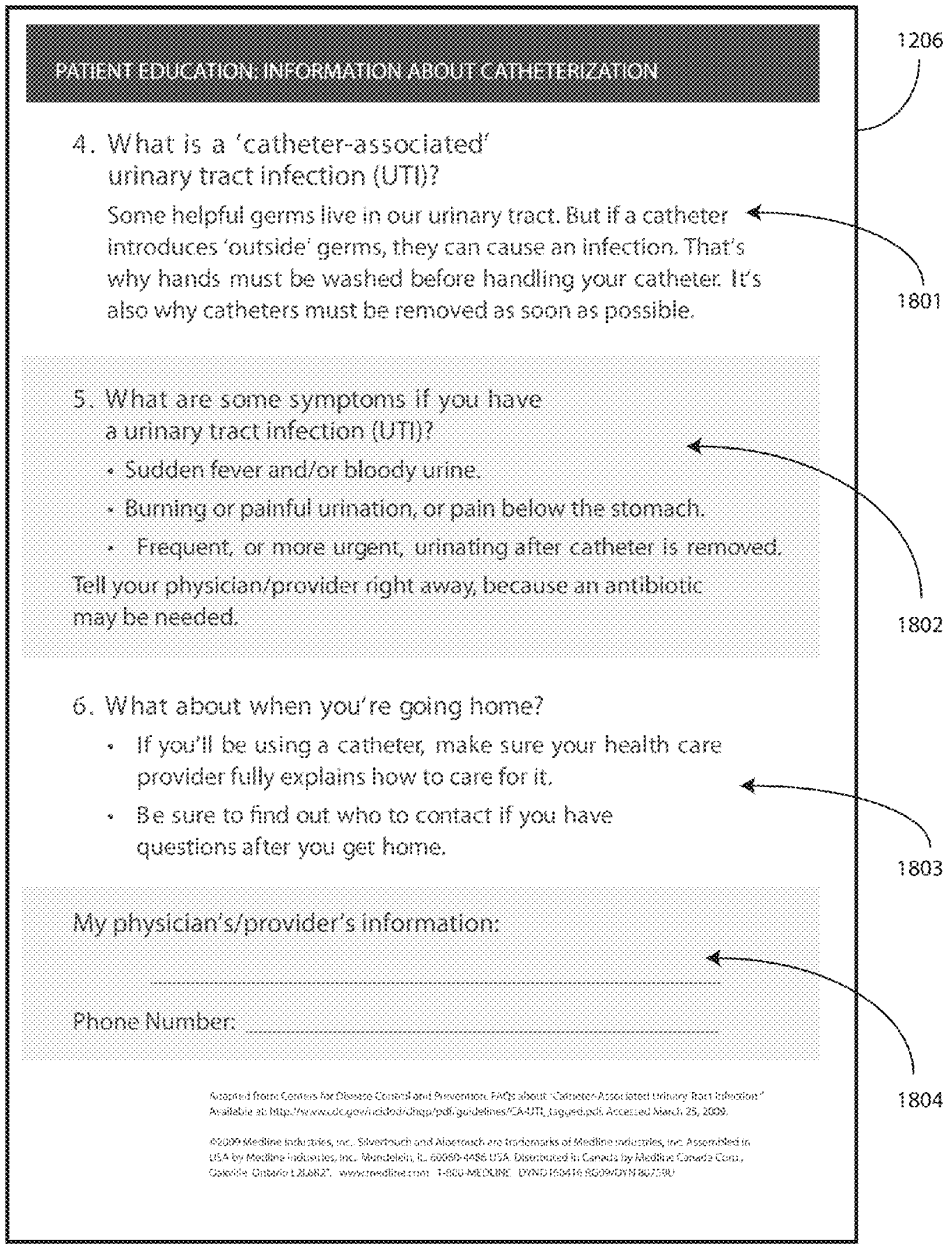

PATIENT EDUCATION: INFORMATION ABOUT CATHETERIZATION
1206
4. What is a 'catheter-associated' urinary tract infection (UTI)?
Some helpful germs live in our urinary tract. But if a catheter introduces 'outside' germs, they can cause an infection. That's why hands must be washed before handling your catheter. 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_faqued.pdf. Accessed March 25, 2009.
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FIG. 18

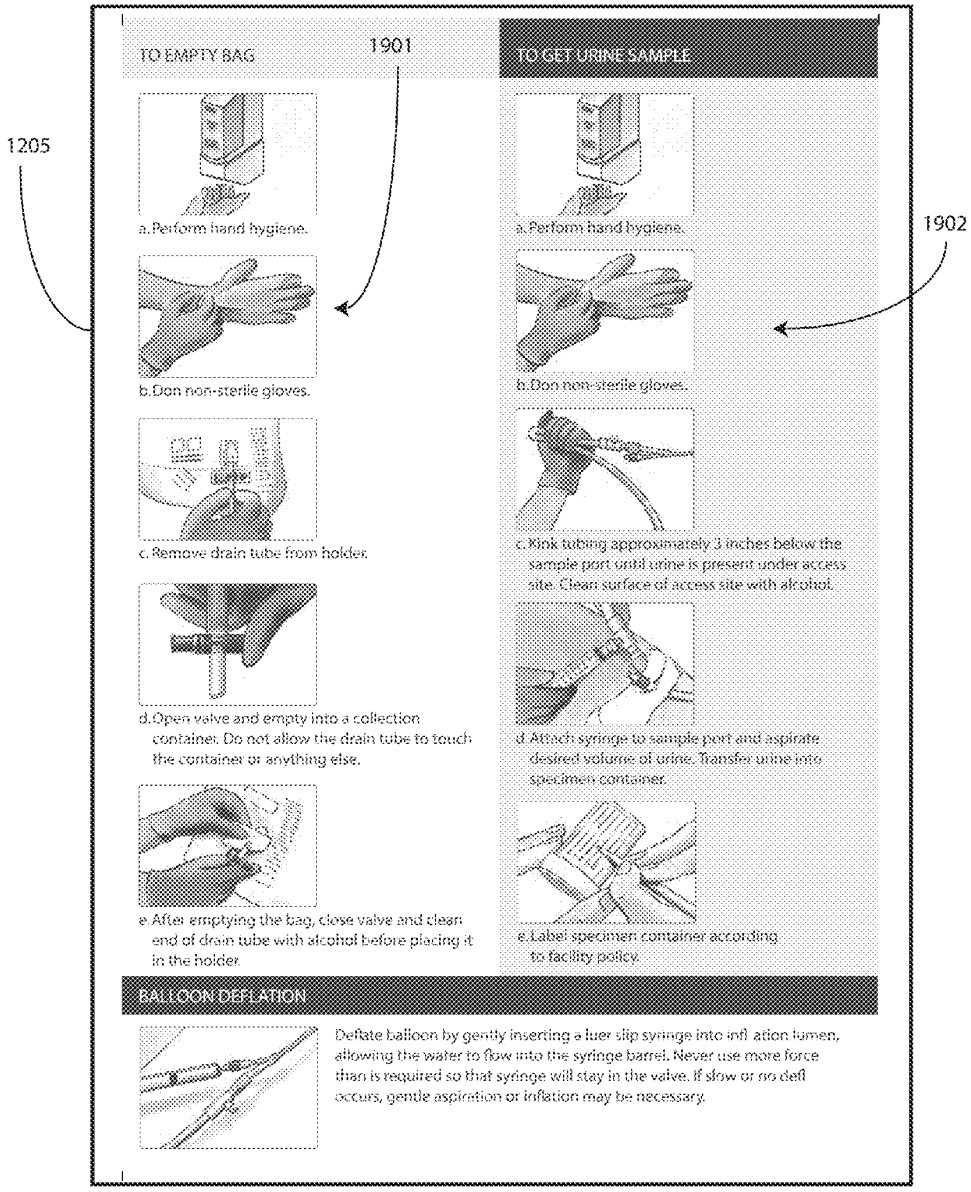

1205
1901
1902
TO EMPTY BAG
TO GET URINE SAMPLE
a. Perform hand hygiene.
b. Don non-sterile gloves.
c. Remove drain tube from holder.
d. Open valve and empty into a collection container. Do not allow the drain tube to touch the container or anything else.
e. After emptying the bag, close valve and clean end of drain tube with alcohol before placing it in the holder.
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

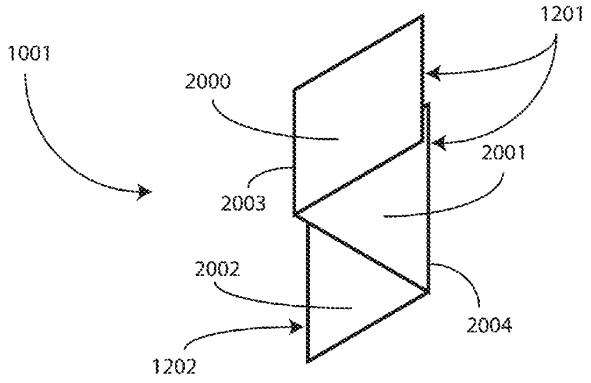

1001
1201
2000
2001
2003
2002
2004
1202

FIG. 20

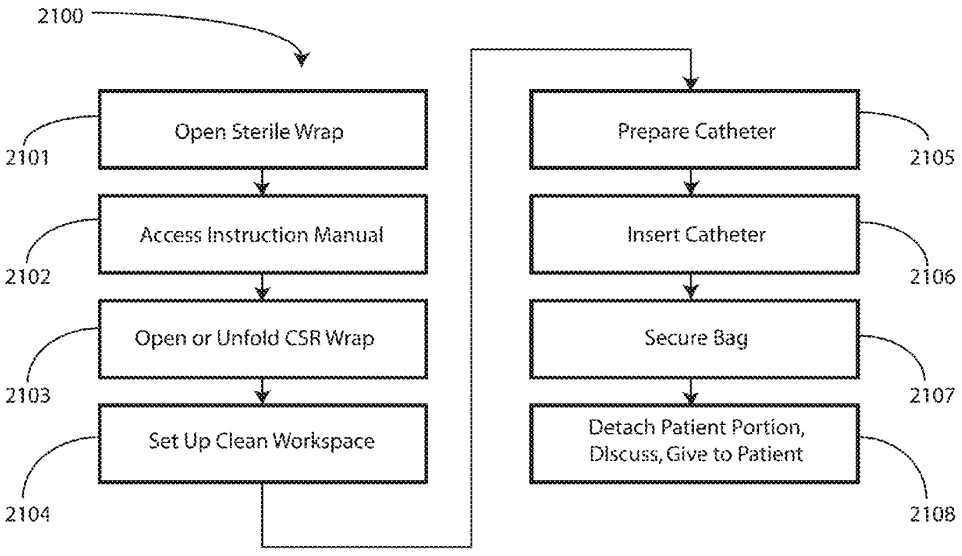

2100
Open Sterile Wrap
2101
Access Instruction Manual
2102
Open or Unfold CSR Wrap
2103
Set Up Clean Workspace
2104
Prepare Catheter
2105
Insert Catheter
2106
Secure Bag
2107
Detach Patient Portion, Discuss, Give to Patient
2108

FIG. 21

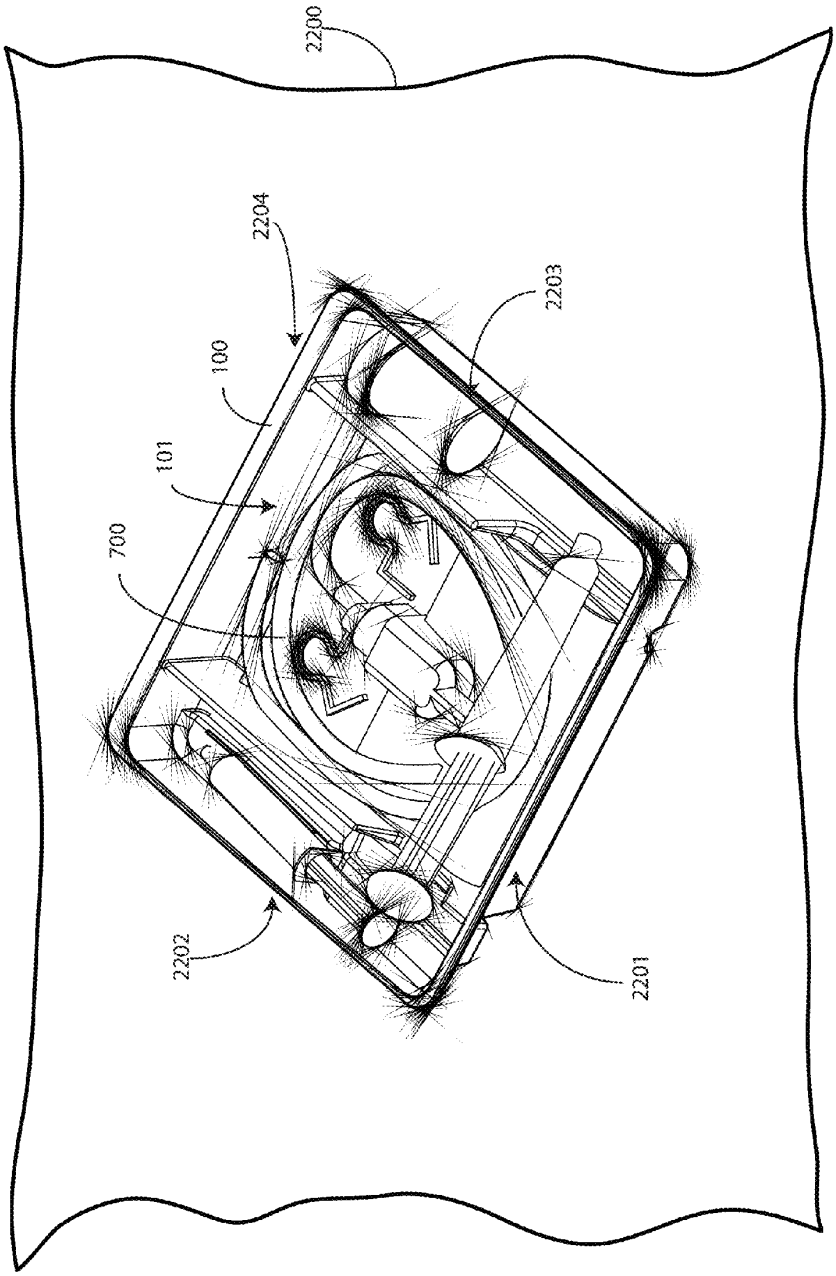


FIG. 22

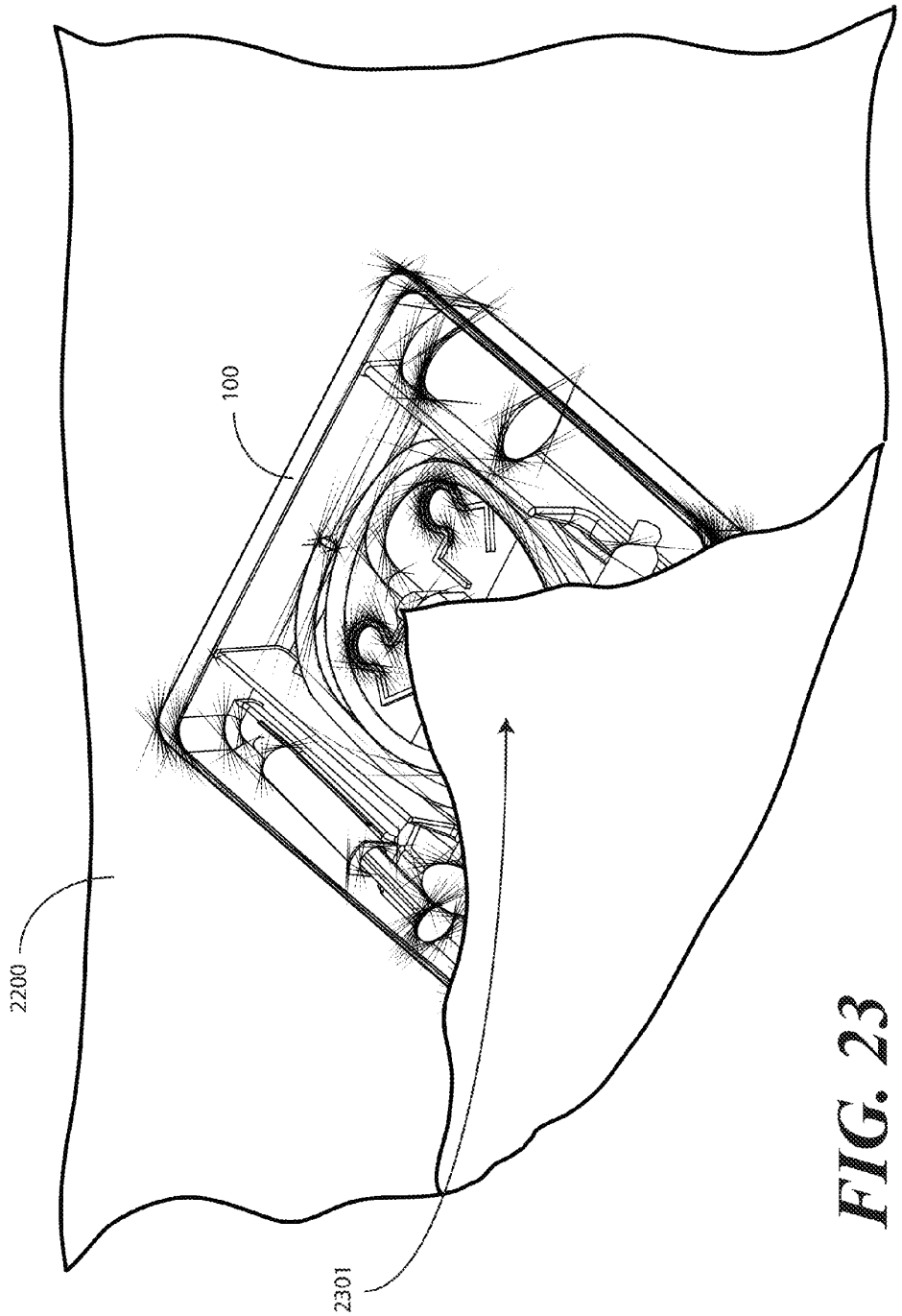


FIG. 23

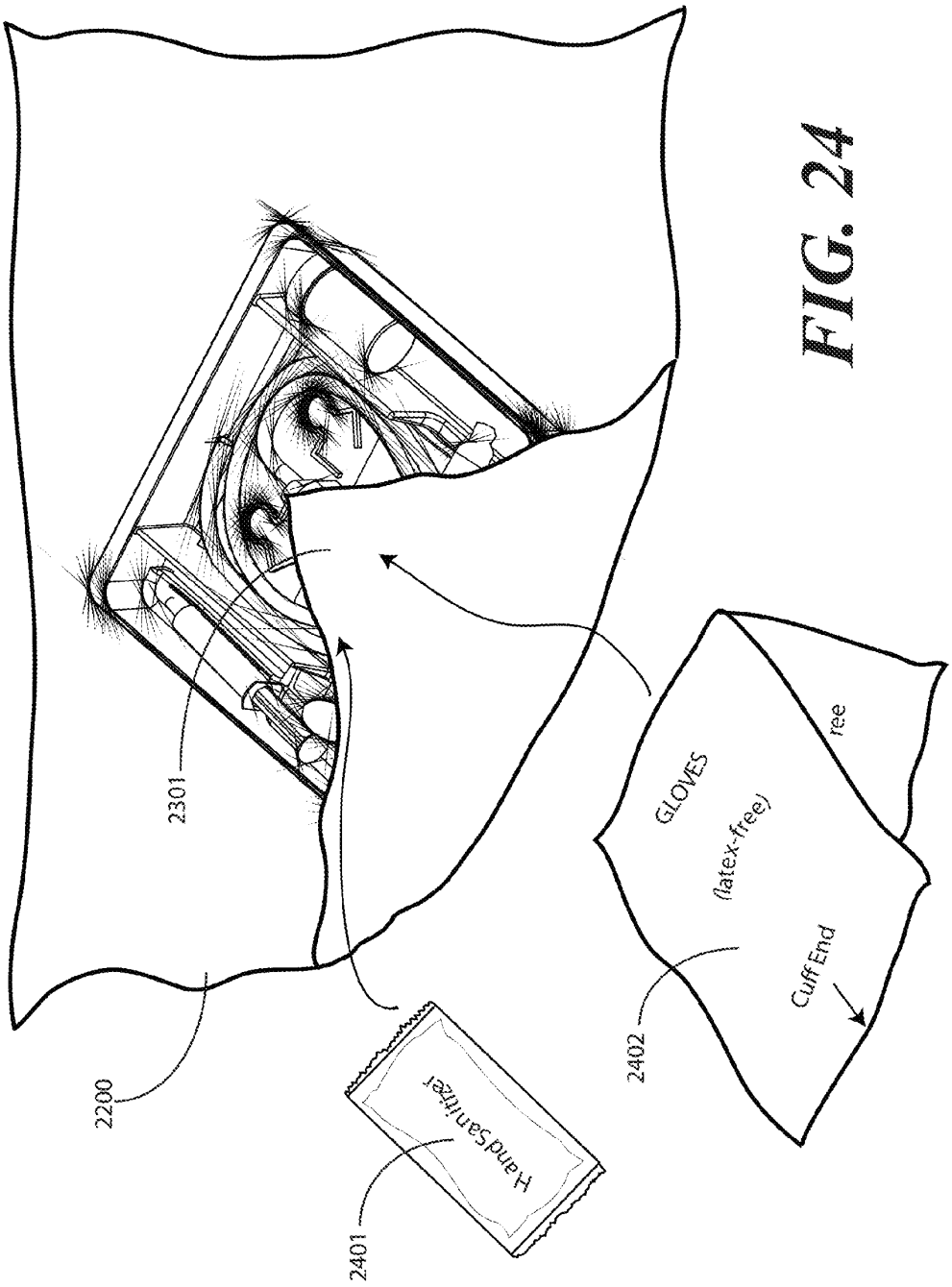

2301
GLOVES
(latex-free)
Cuff End
2402
2200
Hand Sanitizer
2401

FIG. 24

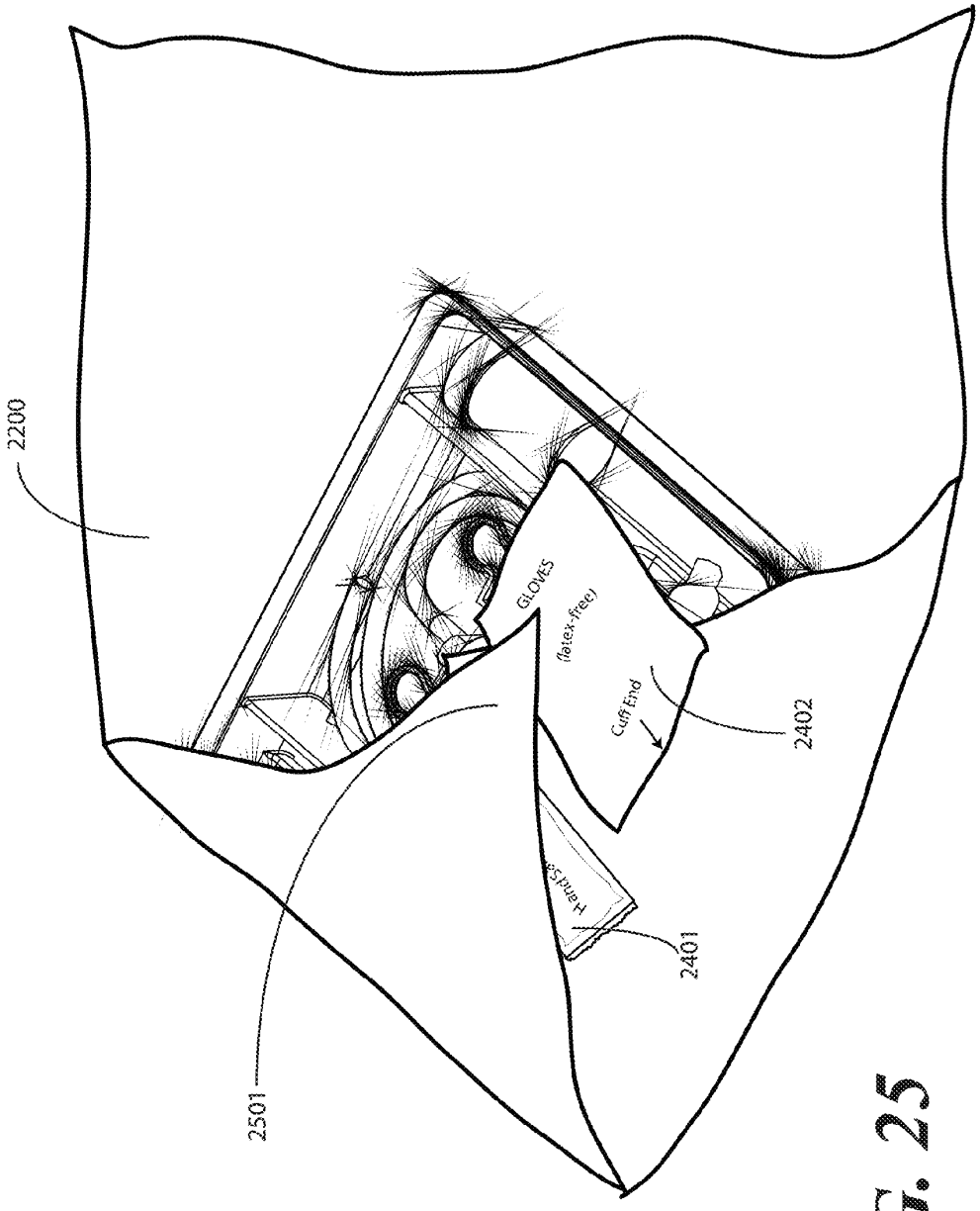


FIG. 25

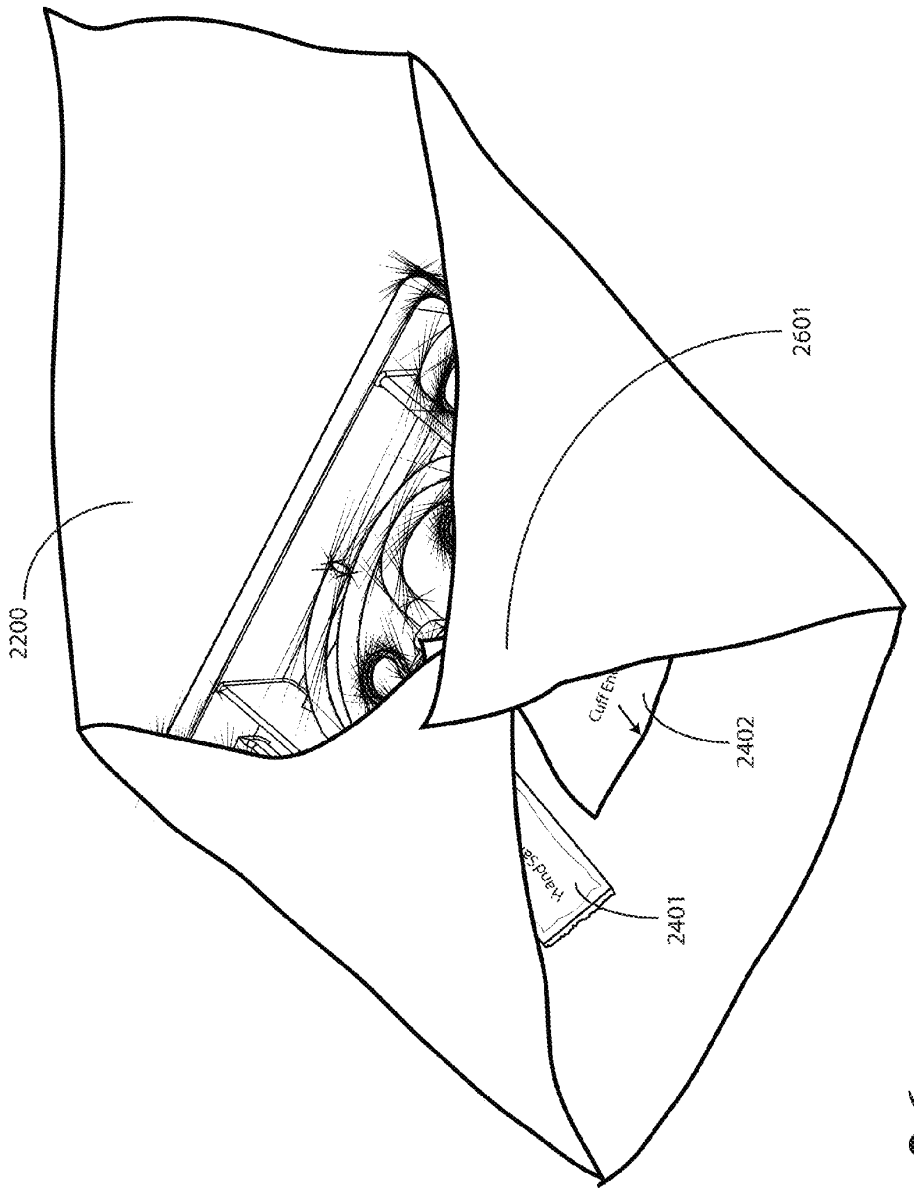


FIG. 26

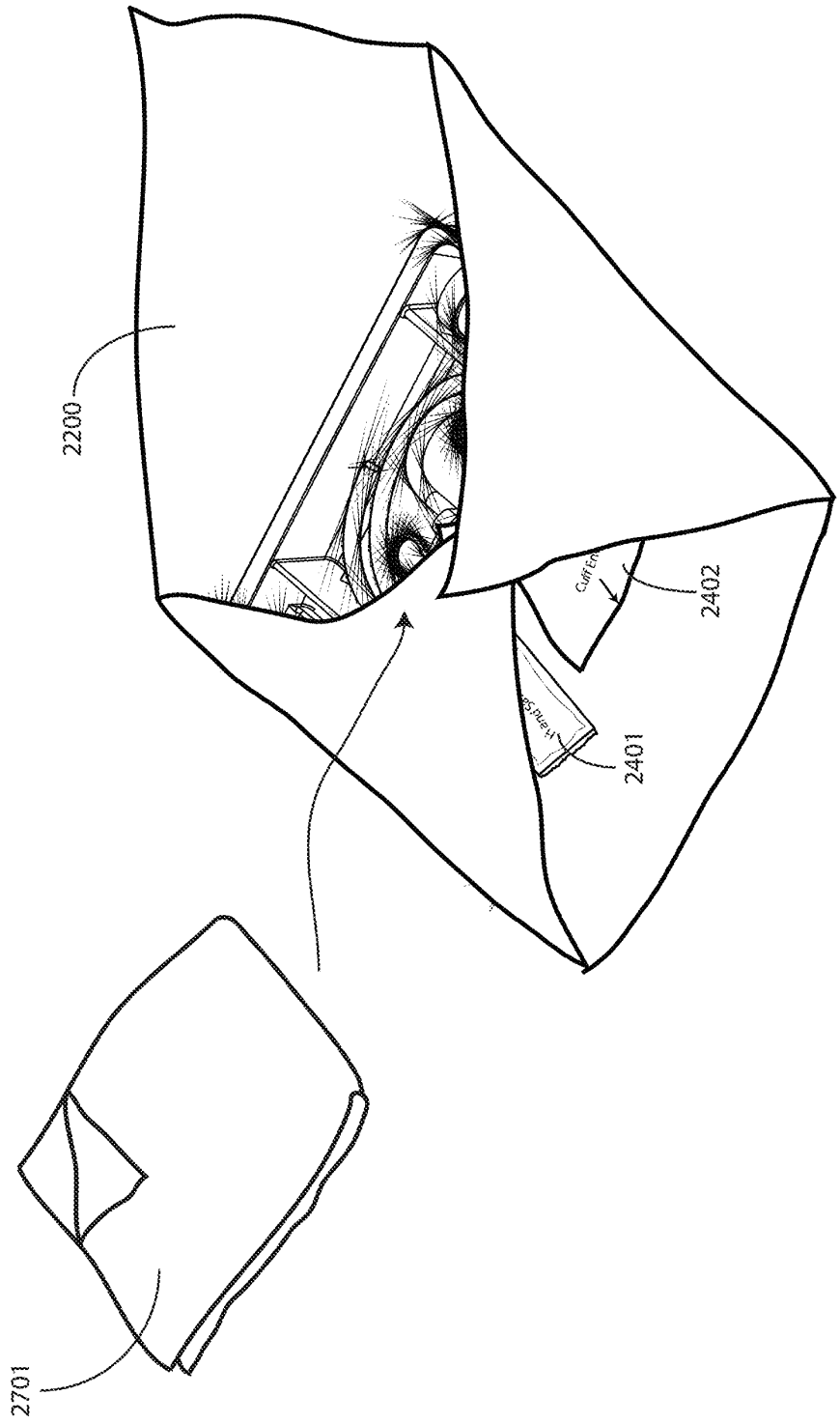


FIG. 27

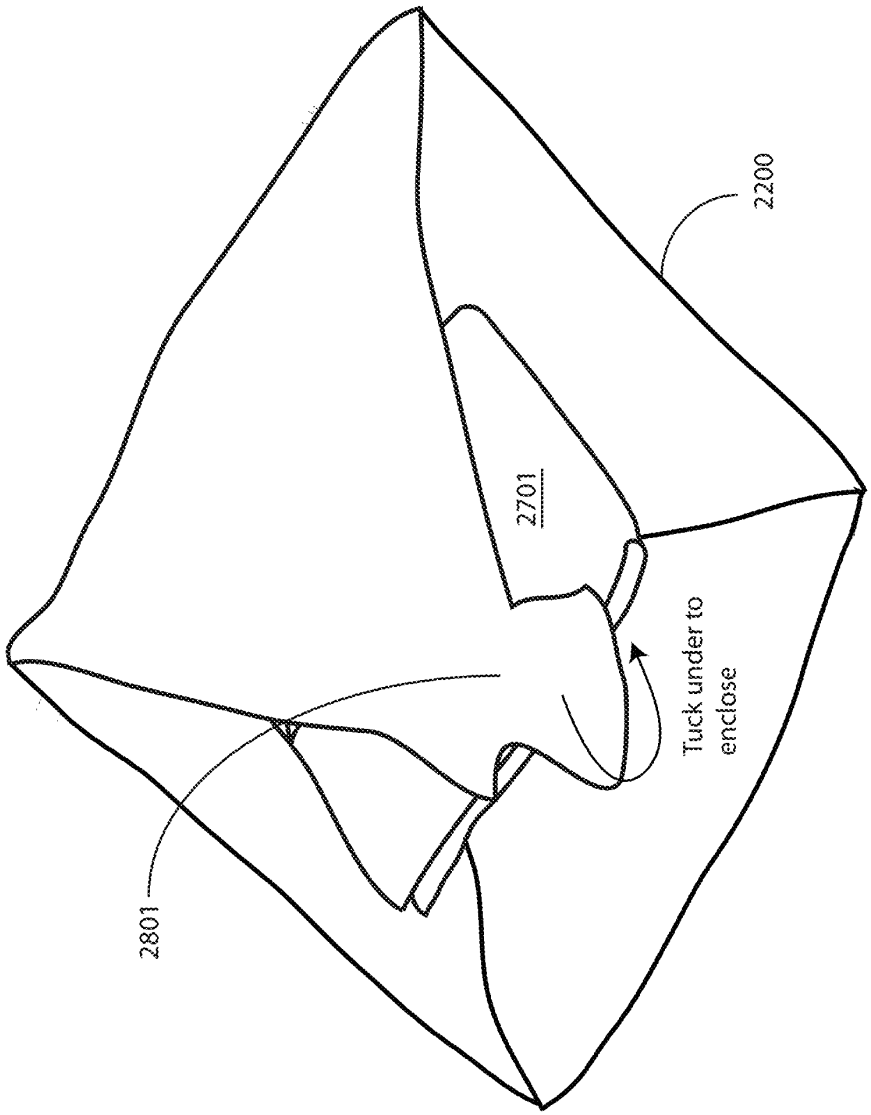


FIG. 28

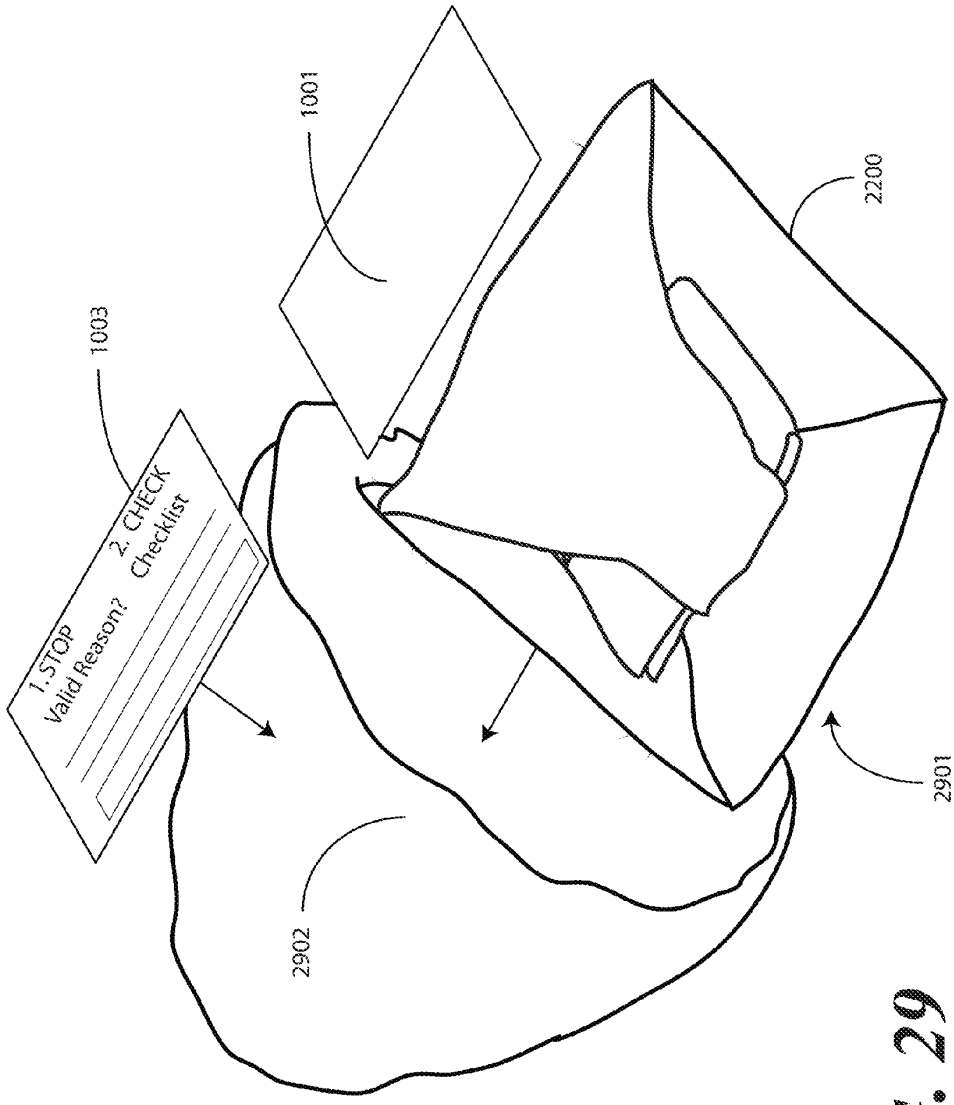

1001
2200
1003
1. STOP
Valid Reason?
2. CHECK
Checklist
2902
2901

FIG. 29

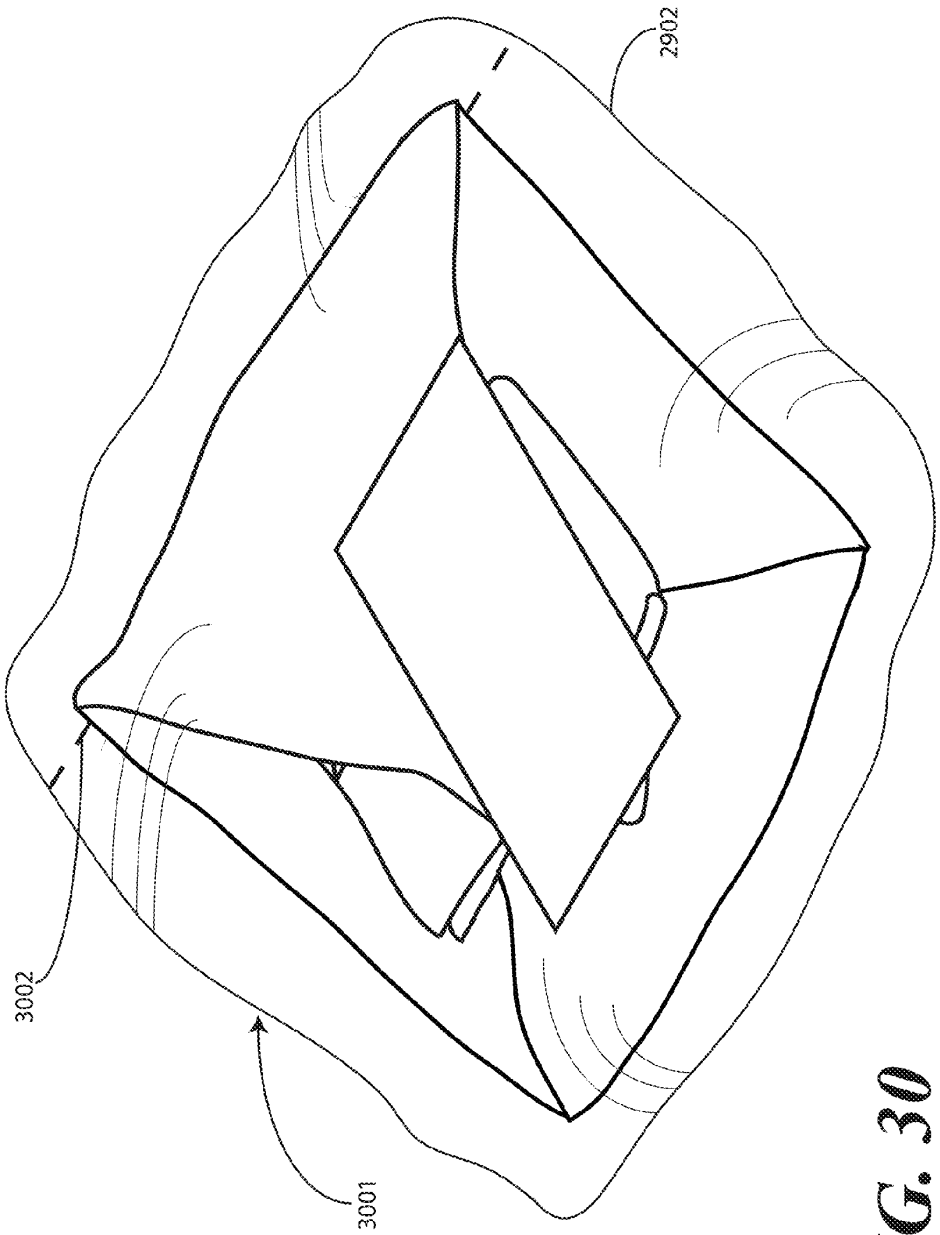


FIG. 30

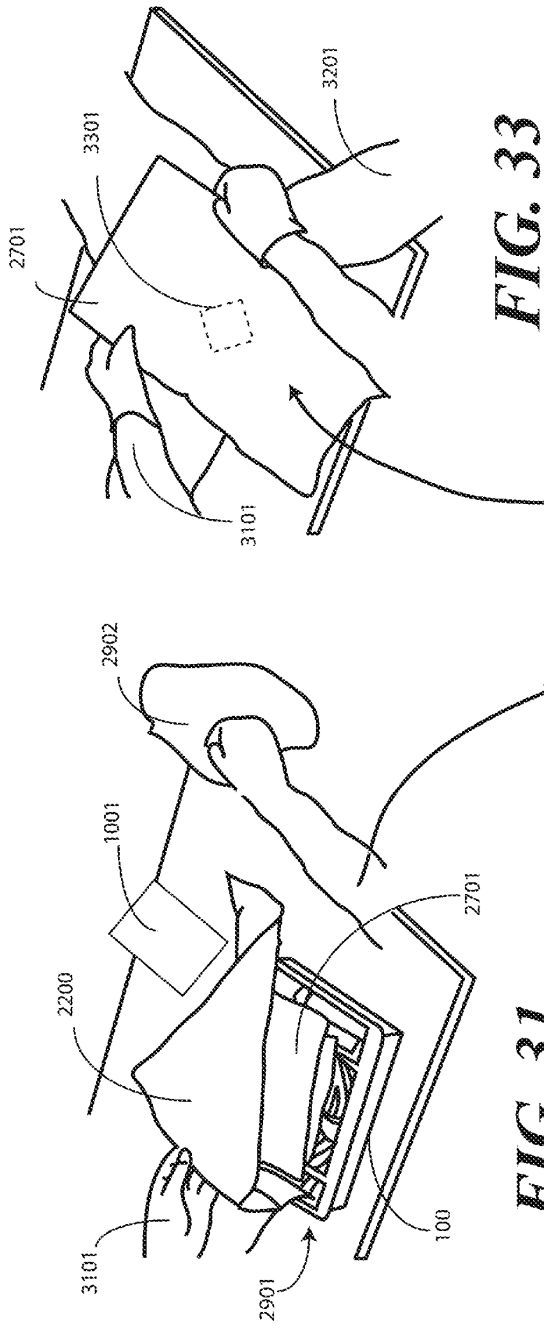


FIG. 31

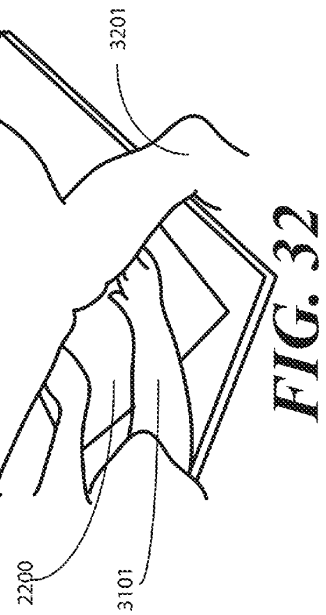


FIG. 32

FIG. 33

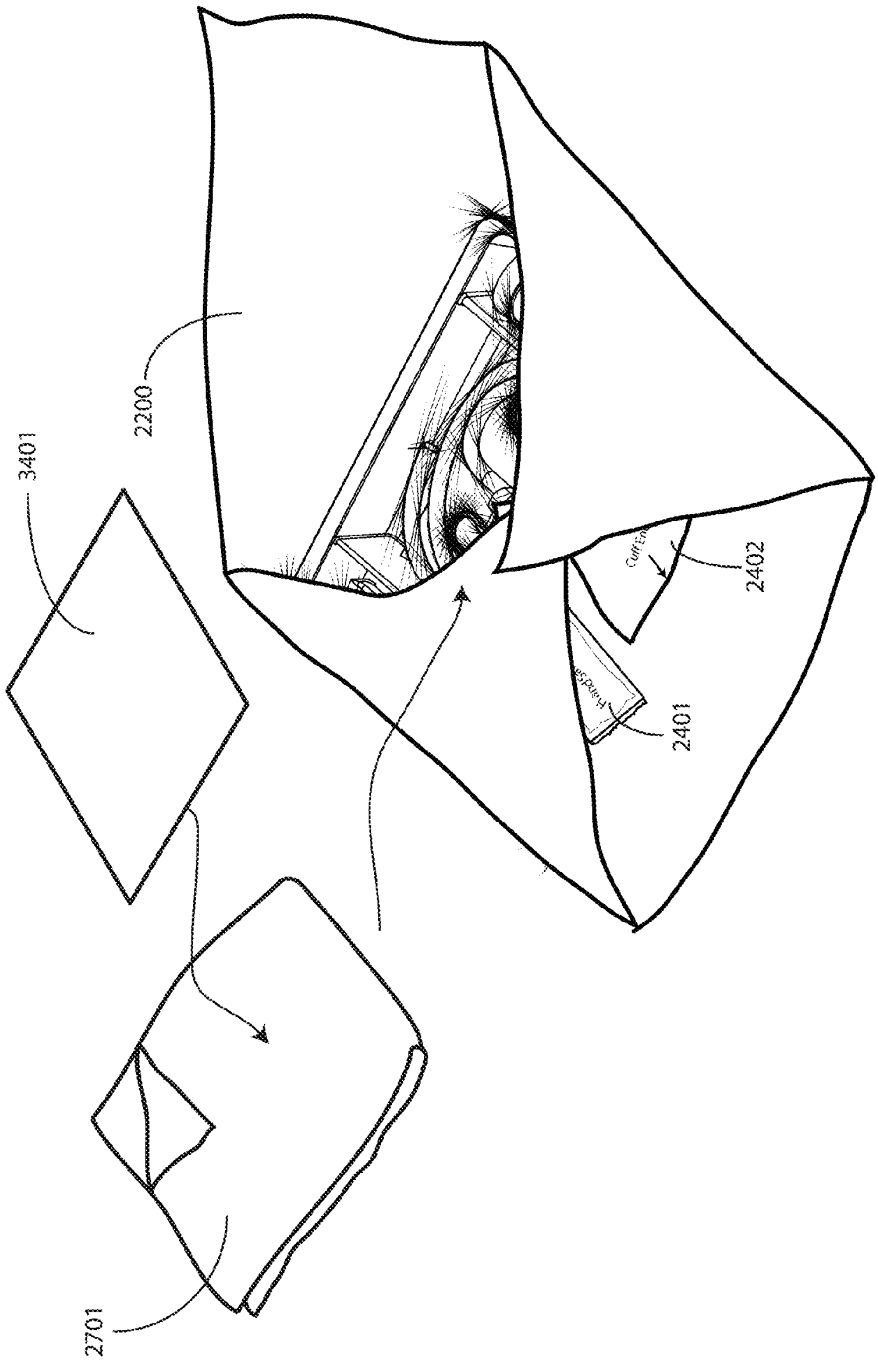


FIG. 34

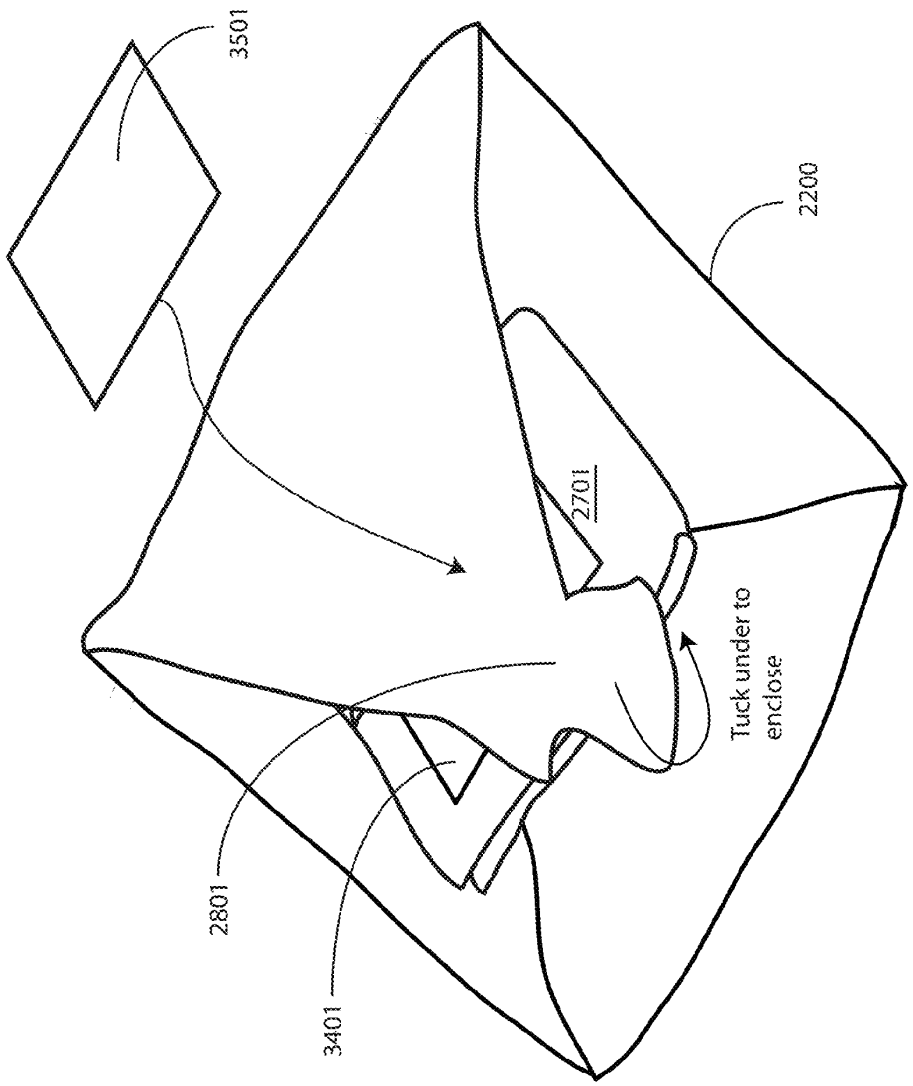


FIG. 35

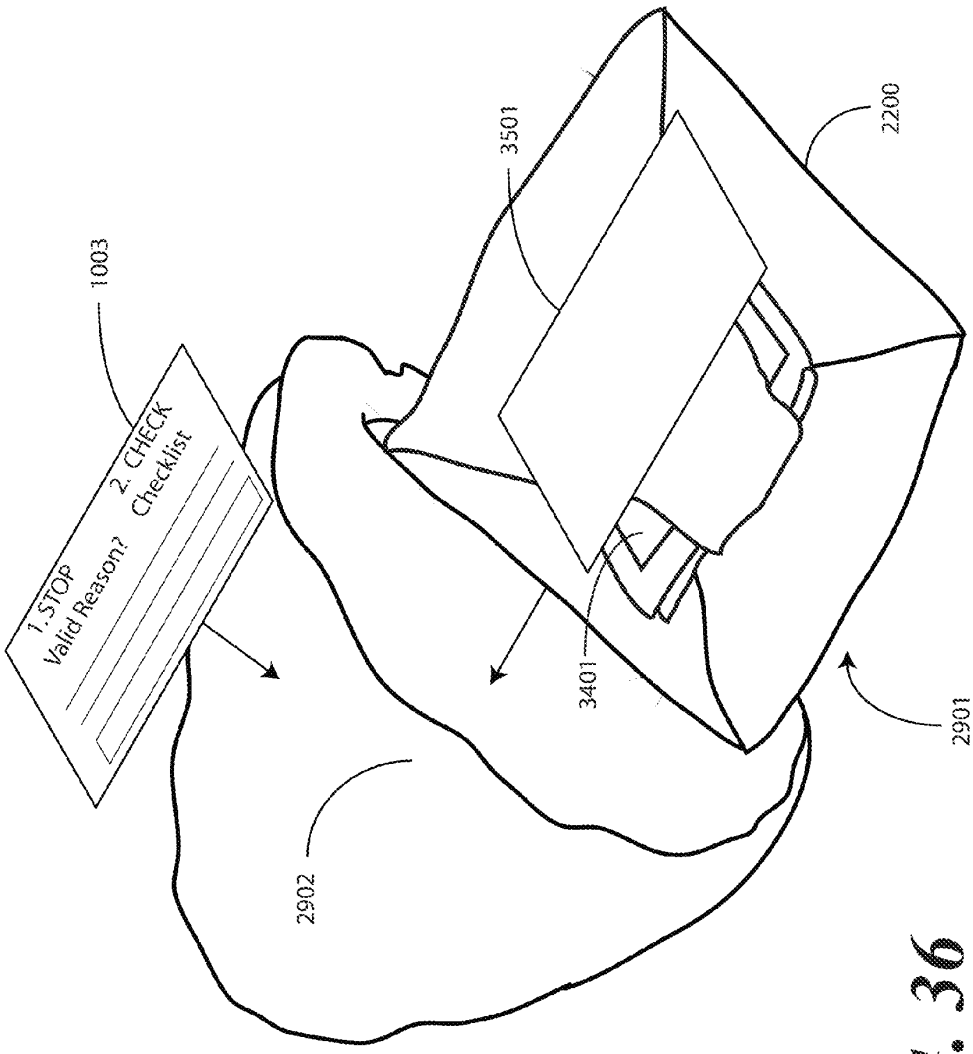

1003
1. STOP
Valid Reason?
2. CHECK
Checklist
3501
2200
3401
2901
2902

FIG. 36

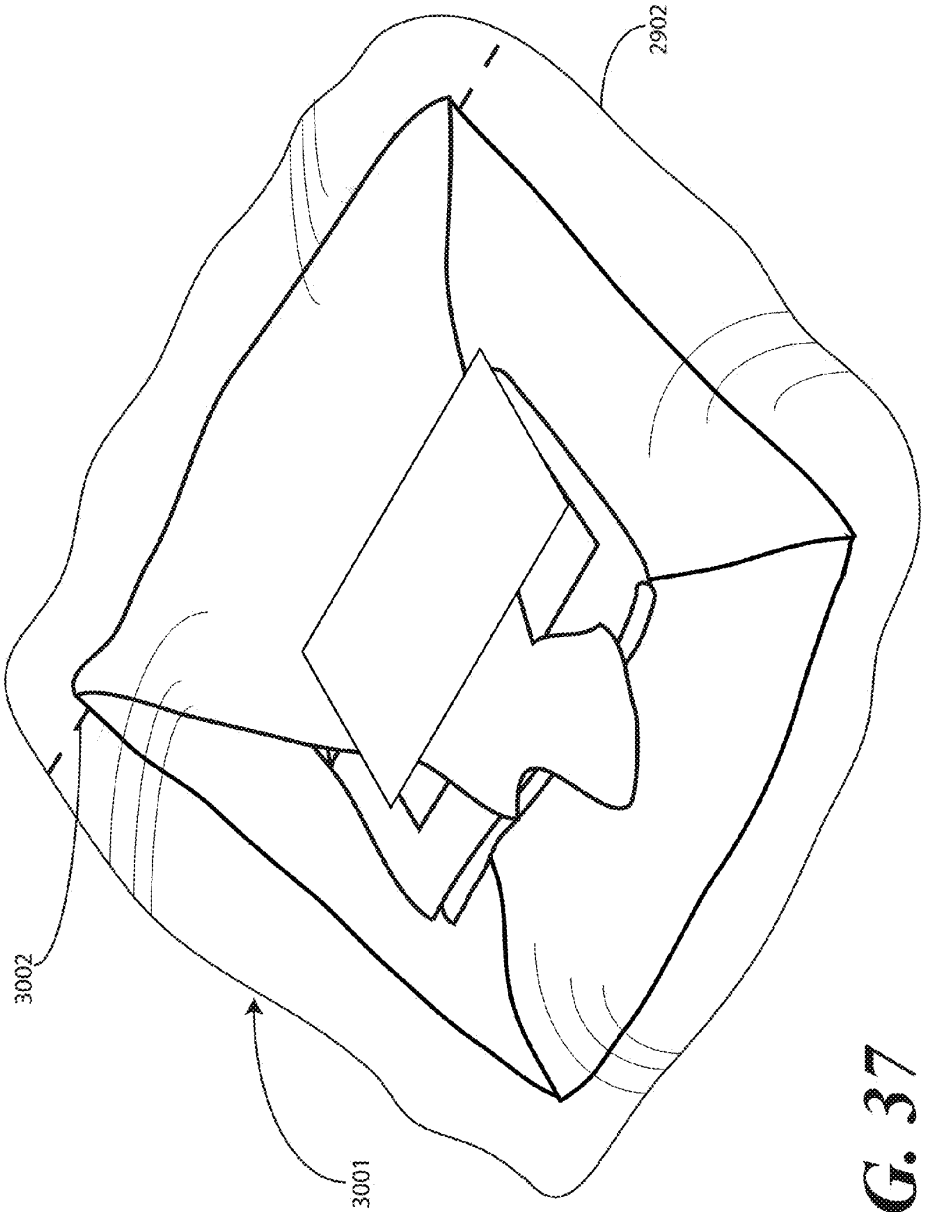


FIG. 37

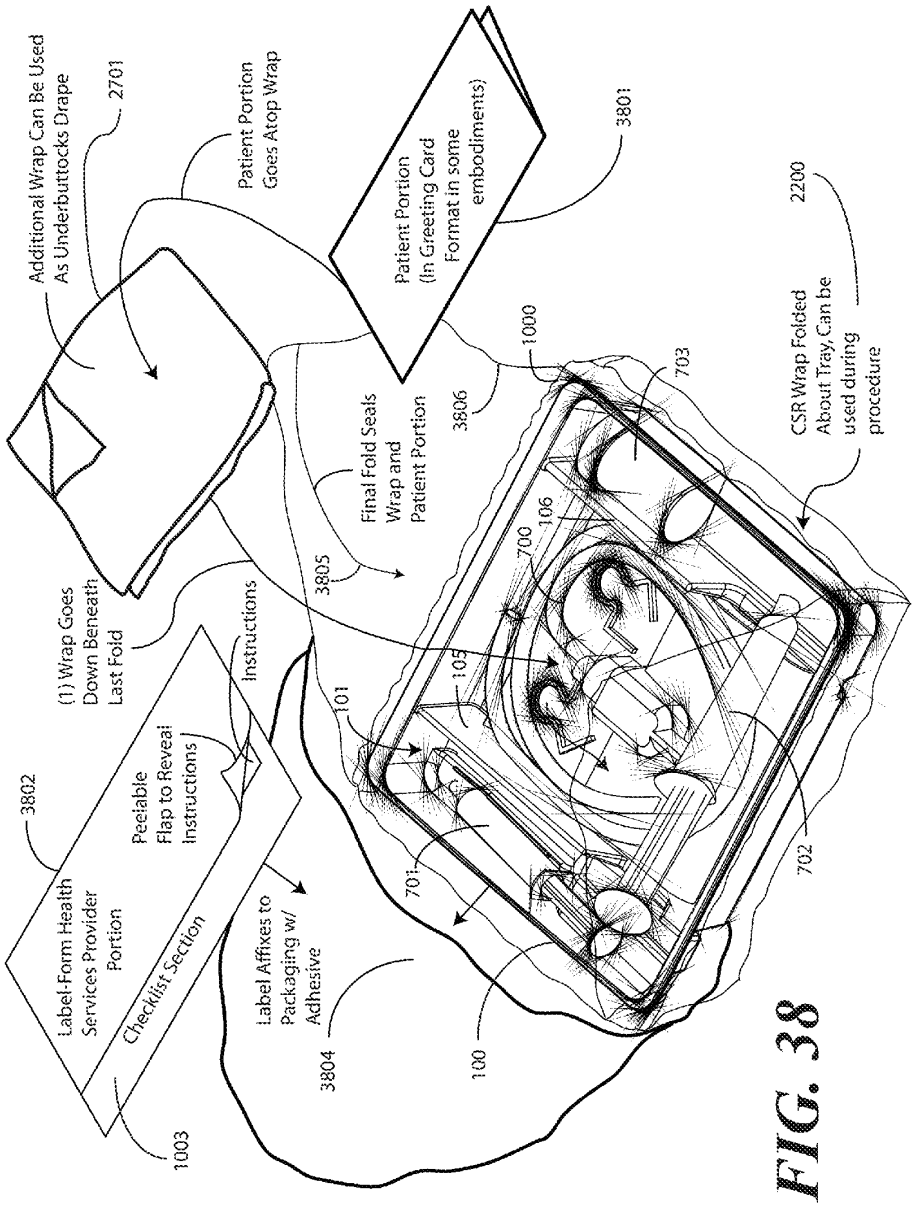


FIG. 38

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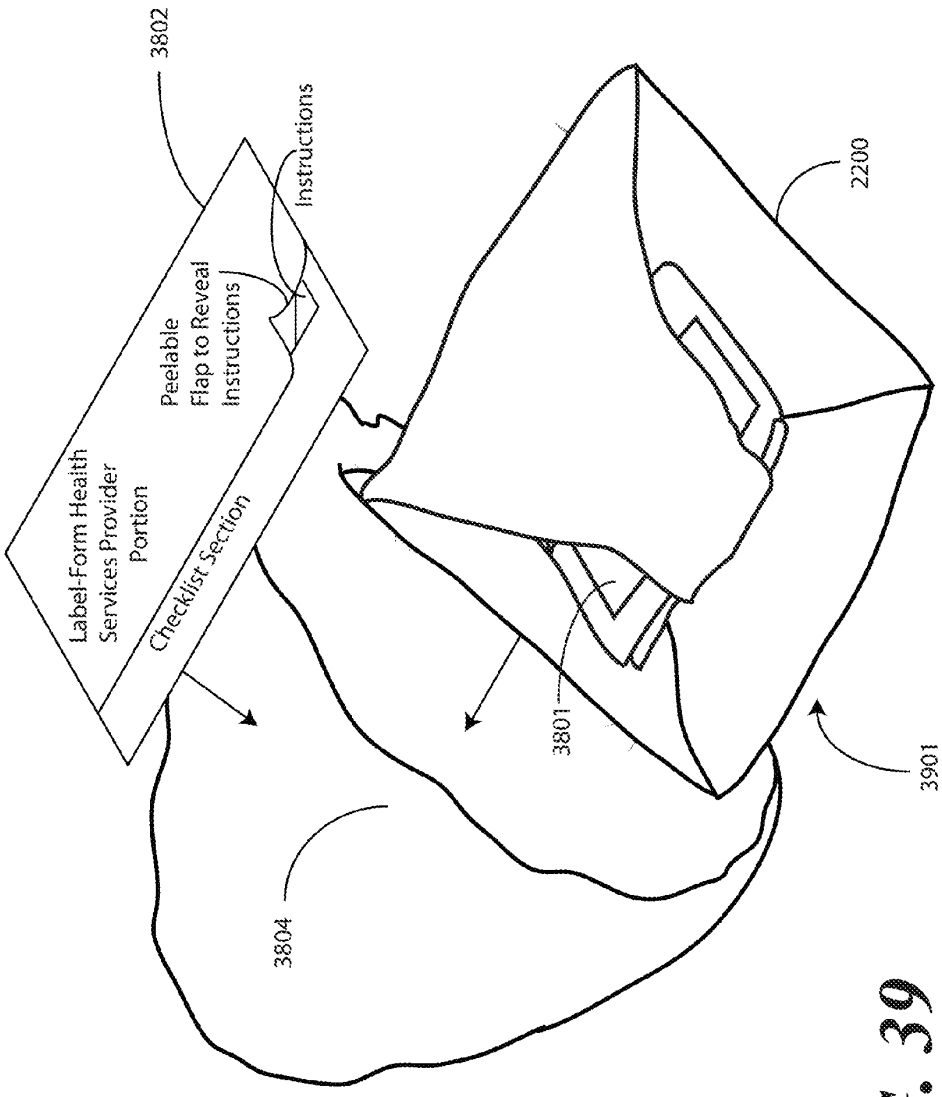

3802
Instructions
Peelable Flap to Reveal Instructions
Label-Form Heaith Services Provider Portion
Checklist Section
2200
3801
3901
3804

FIG. 39

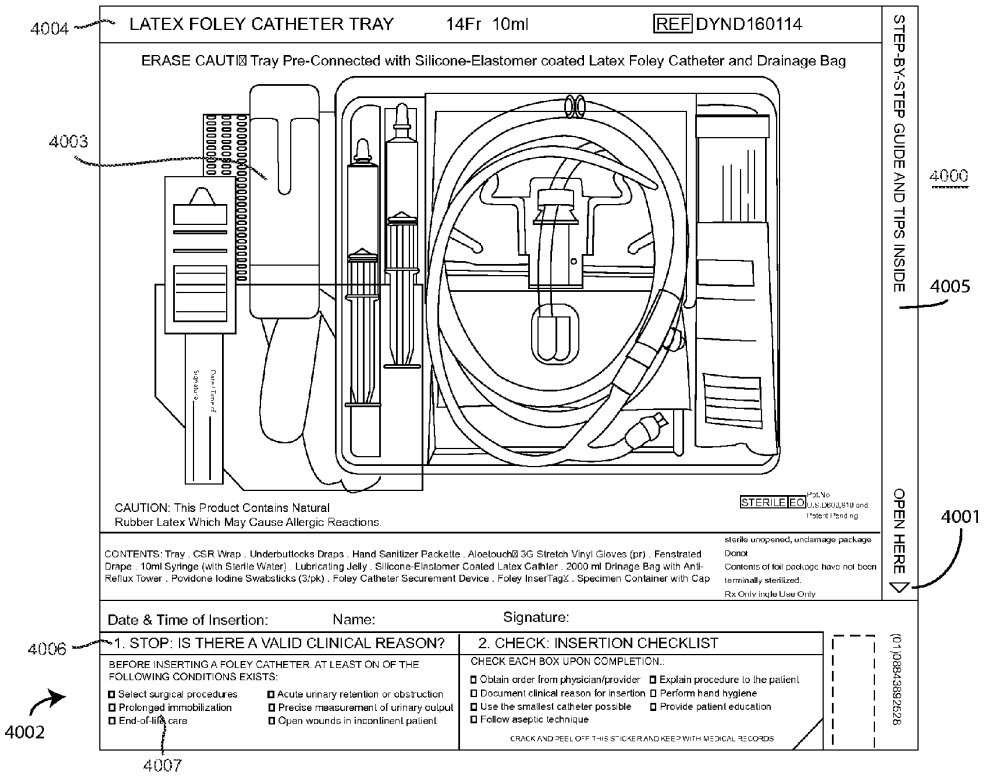

4004
LATEX FOLEY CATHETER TRAY 14Fr 10ml REF DYND160114
ERASE CAUTI Tray Pre-Connected with Silicone-Elastomer coated Latex Foley Catheter and Drainage Bag
4003
STEP-BY-STEP GUIDE AND TIPS INSIDE
4000
4005
CAUTION: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions
STERILE 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

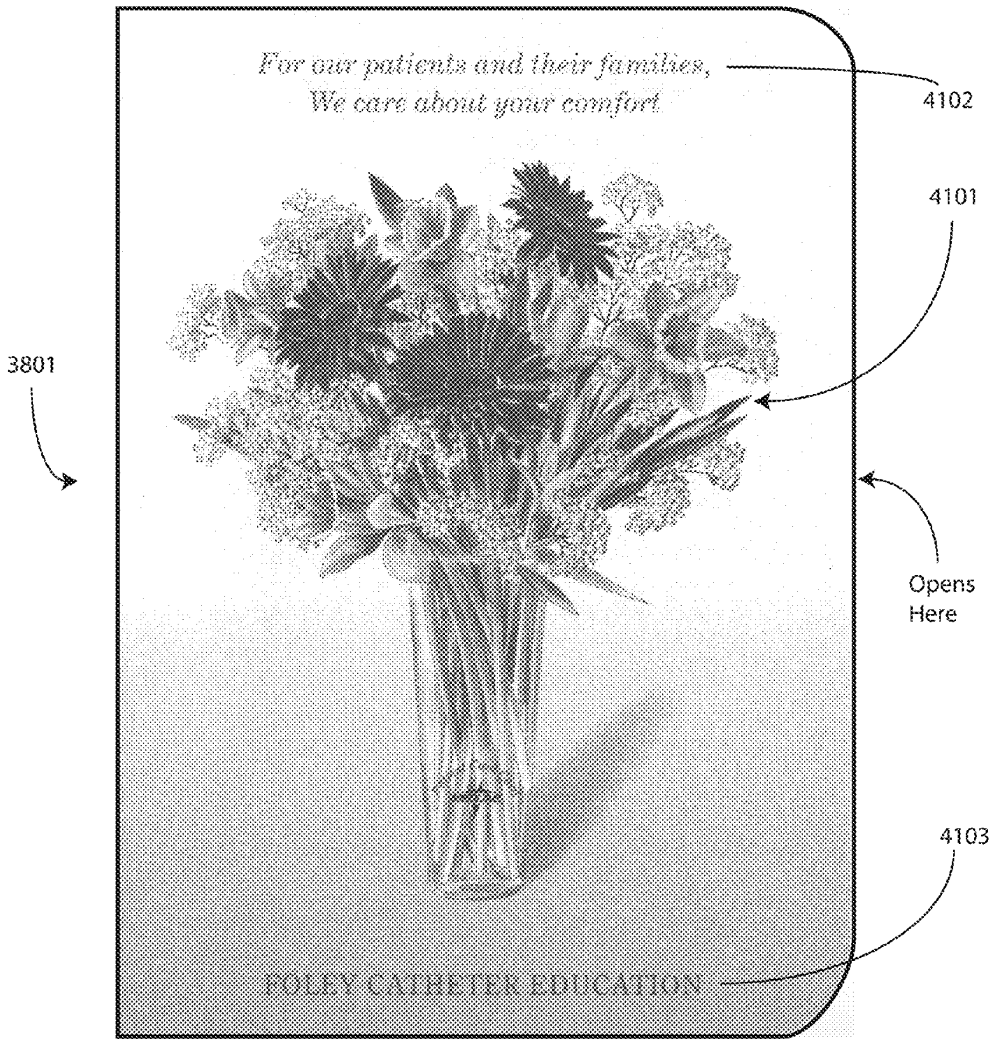

For our patients and their families,
We care about your comfort
4102
4101
3801
Opens
Here
4103
FOLEY CATHETER EDUCATION

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.

Bard Exhibit 1004.0907

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

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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 Patent Application Fee Transmittal

Application Number:	16944667
Filing Date:	31-Jul-2020
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:	10055UCIP2D1C1C1C1C1C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt	
EFS ID:	47517581
Application Number:	16944667
International Application Number:	
Confirmation Number:	8322
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
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Attorney Docket Number:	10055UCIP2D1C1C1C1C1C1
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Submitted with Payment	yes
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Payment was successfully received in RAM	$260
RAM confirmation Number	E20232CG05478918
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

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_CIP2D1C1C1C1C1C1_USA_2023-2-9_IDS.pdf	170113 e5889fe37c7240c70d35a1b4623947449870 26db	no	6
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	1037-001-03US_2022-07-05_FinalOfficeAction.pdf	858645 afb6e2155eaed288a699bf2c0a17b922a9f9433a	no	12
Warnings:					
Information:					
3	Non Patent Literature	1037-002-10US_2021-12-22_Non-FinalOfficeAction.pdf	1045235 c350b4f01f16bccd4a33a70e3cf4acc6327c79de	no	14
Warnings:					
Information:					
4	Non Patent Literature	1037-002-10US_2022-09-16_FinalOA.pdf	854555 b118908ed91ad3b8bed7f8e1a41c84b34cd0929f	no	13
Warnings:					
Information:					
5	Non Patent Literature	10055U_CIP_C2_D1_USA_2023-1-31_NonFinalOA.pdf	748254 7230c6ecd248bc633128bb097ce1013af507e638	no	11
Warnings:					
Information:					
6	Non Patent Literature	10055U_CIP2_D1_USA_2022-7-7_ReexamOrder.pdf	1263441 8f25f56811cf5a56dea3a4d34cdbd7e2efb86f34	no	19
Warnings:					

Information:					
7	Non Patent Literature	10055U_CIP2_D1C1C1C1C1_USA_2022-9-13_NonFinalOA.pdf	2070889 e3ebf598c72af1aecd2aa34b2fbe8ce14b3f27c7	no	29
Warnings:					
Information:					
8	Non Patent Literature	10055U_CIP2_USA_2022-4-19_ReexamOrder_PA.pdf	1479199 c35bcac60b756f1cbe908d0bdeef97cf4962340c	no	21
Warnings:					
Information:					
9	Non Patent Literature	10055U_CIP2_USA_2022-9-29_ReexamNonFinalOA.pdf	869682 b67bc95687c5a33f77f53d55531cd75f58fcd934	no	13
Warnings:					
Information:					
10	Non Patent Literature	10055U_CIP2D1_USA_2022-12-14_ReexamOA.pdf	815869 c0bf0db045dfe6d550c198d8437db88f1522ebbd	no	12
Warnings:					
Information:					
11	Non Patent Literature	10055U_CIP3_C1C1C1_USA_2022-10-26_NoticeOfAllowance.pdf	1409288 acda0436b1ddcca42e25f75073f82060db120619	no	16
Warnings:					
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12	Non Patent Literature	10055U_CIP3_C1C1C1_USA_2023-2-9_NoticeOfAllowance.pdf	1500492 6a551fbcb28207f34cb2df733117e2b45e4f3e1a	no	18
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13	Non Patent Literature	10055U_D1_C2_C1_C1_USA_2022-10-12_NonFinalOA.pdf	676814 49c76c3738d9c349cb332ddab6421a326499861d	no	10
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Information:					

14	Non Patent Literature	10055U_D1C2C1_USA_2021-10-7_FinalOA.pdf	792756 018d8a918d9bcdffa76abdd13b1aeb2bc977b9b2	no	11
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Information:					
15	Foreign Reference	JP2000281144A_English.pdf	3673366 265d6d2f1f4db6fc10b56db202034ba9a410ee51	no	22
Warnings:					
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16	Foreign Reference	JP2002068309A_English.pdf	2166063 b8d5b390eaa95b7f41a02ddd088022f16bcb049a	no	13
Warnings:					
Information:					
17	Foreign Reference	JP2002068309A.pdf	2168950 ef3962716d23176e8739ba473a1977aa712aa02b	no	12
Warnings:					
Information:					
18	Foreign Reference	JP2000281144A.pdf	3626337 05b08a63620f12448d43d754bfd794c012dc80df	no	20
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Information:					
19	Non Patent Literature	US_CAFC_Decision_2021-8-13.pdf	596829 6c8b865603eeb396ef90a40d8f4bad5004748c33	no	24
Warnings:					
Information:					
20	Non Patent Literature	10055U_CIP2_USA_2022-3-8_NoticeOfAssignReexamReq.pdf	194186 38816f22ad5297a1e5630098ffb2c27e85845a57	no	2
Warnings:					
Information:					

21	Non Patent Literature	10055U_CIP2_USA_2022-3-8_ReexamRequest.pdf	6853119 31480c788e8c096e8203ed788fcd01dfc93ac609	no	83
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Information:					
22	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit1.pdf	5939173 32762d39c8f35e1439c60ed031516607065a6699	no	53
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23	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit2.pdf	11651183 7e7ba682983140e96d44cc17158f0286734750fc	no	127
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Information:					
24	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit3.pdf	5521384 8ca8201ebd605a8c1fffa3910acfb28660e77e35	no	61
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Information:					
25	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit4.pdf	17773249 b3c791e0f30834ec11c31b538cc9a7dbedd35b64	no	246
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26	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit5.pdf	1205720 935f057d0f0867ac376dd04fe28862550ac4846d	no	13
Warnings:					
Information:					
27	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit6.pdf	742963 641c158c809688713bc781a1bdf20de74955d380	no	6
Warnings:					
Information:					

28	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit7.pdf	1774515 d589a738739bf8015afc0e87224d598c8081a718	no	15
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29	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit8.pdf	584697 218386e9d34372524657d8373052735e97a04077	no	5
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30	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit9.pdf	2656928 8312d525ecb9e155d1602d86a52c1409a4a6edd2	no	21
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31	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit10.pdf	1389068 8733a4e17ba9b631dd0465f038d44152756007b8	no	12
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32	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit11.pdf	2838890 16a3b44df9ad143c7d558cbc9e4a6c9298fecae8	no	25
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Information:					
33	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit12.pdf	12900434 9ded8857c8f42eef0856f7aa5d67eb72a01d60ab	no	151
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34	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit13.pdf	522830 1eb8df0b4444598d8dfeeb23193f2c2e235ccbd0	no	5
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Information:					

35	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit14.pdf	810043 e4a6d9c8e55dd2491f01b1dcf593e9350a6b7502	no	6
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36	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit15.pdf	4347492 80ebaf709e65e067d008ca5f2bd5c1b6e442faf5	no	44
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37	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit16.pdf	281178 6b9154ad7155b51b6dcae6ce72b5483c24aa583f	no	4
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38	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit17.pdf	367740 1be1334f1ca805b9c9e67f6cbd3d7d6bf74fd369	no	7
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Information:					
39	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit18.pdf	3493534 e082a373df83cdd57ce1b0e7655f6a42ac626de1	no	37
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Information:					
40	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit19.pdf	232504 775c76bcc62e7c3c05bed1a66036e19e194df2ef	no	2
Warnings:					
Information:					
41	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit20.pdf	69694 6ca8e3e7057ce8892aa85b003e06fa96203d677c	no	2
Warnings:					
Information:					

42	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit21.pdf	6084442 feb8941b33c71daad88fe5df751eb22152b945be	no	63
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Information:					
43	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit22.pdf	755977 b27b1cc5f09f114c0012b4832d44405e23e88659	no	13
Warnings:					
Information:					
44	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit23.pdf	6580333 3557b27c90dc4801550330ecea285729b419eca3	no	179
Warnings:					
Information:					
45	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit24.pdf	1230710 6b17063657331d778c9bcd3a8efe330b9701fd80	no	14
Warnings:					
Information:					
46	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit25.pdf	14867514 9c22c82a25c9ae7d9ecac313c42f0d032b08543e	no	174
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Information:					
47	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit26.pdf	3966993 b3b0242b518f4f6729d13826896e7ef6d953ebaf	no	57
Warnings:					
Information:					
48	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit27.pdf	4475966 2045c4bfbc775528bbb825c26bb7479174f4dd2c	no	46
Warnings:					
Information:					

49	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit28.pdf	2380651 f336c3eabe7708932749bc174e69eb9f8153cb50	no	23
Warnings:					
Information:					
50	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit29.pdf	262769 ed2ab413f2abfe9bd9b37d1d2d48b97329f23a4f	no	5
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Information:					
51	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit30.pdf	6645643 f542459c0409b5da13ef778034d5fd351181e1f6	no	59
Warnings:					
Information:					
52	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit31.pdf	218843 0937679f053bf3d5c1cbb3b9f03a23439f6a5070	no	4
Warnings:					
Information:					
53	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit32.pdf	1060364 8102639b1a6b8dd797edda03223b44824793dfb9	no	13
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Information:					
54	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit33.pdf	138050 56ef297cdd5d72926cea08be8c25fa071deb2275	no	2
Warnings:					
Information:					
55	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit34.pdf	3170637 637e383d604ab778fe2ef8d3f37ec6c3a0a15de6	no	30
Warnings:					
Information:					

56	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit35.pdf	1056229 47fe120b1e52bcc7718b967af97142fcc689fd0b	no	12
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Information:					
57	Fee Worksheet (SB06)	fee-info.pdf	38333 ca431d64871ac16a094452ccd53cfb7ccc53f655	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	161870755		

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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.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/944,667
	Filing Date	July 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3735
	Examiner Name	Adam Marceitch
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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
		4460360		1984-07-17	Finegold, Aaron	

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
		20110218520		2011-09-08	Andrich, Daniela	

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]
		MARCETICH, ADAM , "Notice of Allowance", USSN 16/833,575; Filed March 28, 2020; Attorney Docket No 10055UCIP2D1C1C1C1C1; Mailed February 24, 2023	

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

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/944,667
	Filing Date	July 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3735
	Examiner Name	Adam Marceitch
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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.

[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

☐ 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

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	16/944,667
	Filing Date	July 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3735
	Examiner Name	Adam Marceitch
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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)	2023-02-28
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 Patent Application Fee Transmittal

Application Number:	16944667
Filing Date:	31-Jul-2020
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:	10055UCIP2D1C1C1C1C1C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
		Total in USD ($)		**260**

Electronic Acknowledgement Receipt	
EFS ID:	47606430
Application Number:	16944667
International Application Number:	
Confirmation Number:	8322
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:	10055UCIP2D1C1C1C1C1C1
Receipt Date:	28-FEB-2023
Filing Date:	31-JUL-2020
Time Stamp:	16:06:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$260
RAM confirmation Number	E20232RG06438398
Deposit Account	
Authorized User	
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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_C1C1C1C1_USA_2023-2-24_NoticeOfAllowance.pdf	1651123 48f1b3c288dfaded11cd697cbd2881c5a4bb74f7	no	20
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2D1C1C1C1C1C1_USA_2023-2-28_IDS.pdf	136548 681f4b11c7cd242e99f60576c6299880dd9a4f0a	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Fee Worksheet (SB06)	fee-info.pdf	38333 c2f1ca511c9f8d3ebc48a3b9f871a1c5eb0e5563	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1826004		

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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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NOTICE OF ALLOWANCE AND FEE(S) DUE

189038 7590 03/02/2023

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

EXAMINER
MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
3781	

DATE MAILED: 03/02/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/944,667	07/31/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1C1	8322

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/02/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PTOL-85 (Rev. 02/11)

Bard Exhibit 1004.0943

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

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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189038 7590 03/02/2023

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

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/944,667	07/31/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1C1	8322

TITLE OF INVENTION: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/02/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3781	206-571000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1_____
2_____
3_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

Bard Exhibit 1004.0944

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/944,667	07/31/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1C1	8322

189038 7590 03/02/2023

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

EXAMINER	
MARCETICH, ADAM M	
ART UNIT	**PAPER NUMBER**
3781	

DATE MAILED: 03/02/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Bard Exhibit 1004.0945

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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 30 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. 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.

Privacy Act Statement

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 disclosure of these records is required by the Freedom of Information Act.
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 Cooperation Treaty.
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.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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.

Notice of Allowability	Application No. 16/944,667	Applicant(s) Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	AIA (FITF) Status Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 13 February 2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ 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.

3. ☑ The allowed claim(s) is/are 1-16 and 18-23 . As a result of the allowed claim(s), 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.**

4. ☐ 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)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

Bard Exhibit 1004.0947

EXAMINER'S COMMENT / AMENDMENT / REASONS FOR ALLOWANCE

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.

Examiner's Comment

The objections to claims 1, 14 and 21 for minor informalities and the rejections of claims 2, 4, 8 and 13 under 35 USC § 112 are withdrawn in view of the amendments filed 13 February 2023.

Terminal Disclaimer

The terminal disclaimer filed on 13 February 2023 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of

- Tomes; Jennifer E. et al. (US 10251812 B2)
- Tomes; Jennifer E. et al. (US 9522753 B2)
- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 9283352 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 10512752 B2)

has been reviewed and is accepted. The terminal disclaimer has been recorded.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claim 1 is amended as follows. **[[Deletions are in double brackets]]** and **additions are underlined.** Ellipsis **…** designates unchanged portions of claims which have been omitted for brevity.

Claim 1 (amended in part) "**…** a surface defining an opening allowing access to the second compartment from **[[the]] a** top of the single layer tray **…**"

Allowable Claims

Claims 1-16 and 18-23 are allowed.

Reasons for Allowance

Applicant's arguments filed 13 February 2023 have been considered and are persuasive. Examiner advances additional reasons for allowance.

Solazzo; Anthony (US 20060009742 A1), the closest art of record, lacks first and second syringes arranged in a first compartment and a medical assembly disposed in a second compartment. Instead, Solazzo discloses only one syringe, and stores lubricant in a second flexible container (¶ [0043], inflation syringe 10 … and a tube of lubricant fluid 140).

Regarding claim 8, Solazzo lacks a wrap material and outer packaging and is silent whether the tray is enclosed in any packaging. Solazzo also lacks coiled tubing and a bag, and at most discloses a catheter (¶ [0043], catheter 120).

Regarding claim 14, Solazzo discloses four compartments (Figs. 1, 3, 8, recessed area 3, compartment 27 and catheter lubricating wells 31 and 33). However, Solazzo lacks a pair of syringes and instead discloses only one syringe (inflation syringe 10). Solazzo also lacks swabsticks disposed within a third compartment. Solazzo arranges accessories including lubricant and gloves in the same compartment as the Foley catheter (Fig. 8, compartment 27 stores catheter 120, surgical gloves 130 and a tube of lubricant fluid 140). This suggests that even if Solazzo were modified to include swabsticks, they would be placed in the same compartment as the Foley catheter and not in a separate third compartment.

Regarding claim 21, Solazzo lacks a pair of syringes, swabsticks disposed within a third compartment and a wrap as discussed above.

Cornett, III; Walter G. (US 4411656 A) and Wheeler; Robert P. (US 4439184 A) were cited on recently filed IDS forms. Each of these references discloses a syringe containing a lubricant. However, neither of the references discloses a tray having a lubricating jelly application chamber. At most, Cornett and Wheeler disclose free-standing syringes and do not teach or suggest details of a tray, kit or package.

Also of record, **Blanco; Juan Carlos Aceves (US 6454097 B1)** discloses a tray comprising multiple compartments (col. 3, lines 35-40, Compartments 22, which may be

of varying sizes, are covered with lids 30 that are installed with hinges 40, preferably along the perimeter of modules 120 and 220). However, Blanco's tray lacks a Foley catheter and syringe. Instead, Blanco configures the tray as a first-aid kit containing bandages and medications to treat injuries or emergency conditions (cols. 7-8, TABLE 1 Preferred Contents).

Another cited reference, **Pilger; Nicholas J. (US 3485352 A),** discloses a package for a catheter, comprising a tray (col. 2, lines 40-45, dish portion with a bottom 2 and a generally circular upstanding wall 3), a Foley catheter (col. 2, lines 40-45, a flexible catheter 8 is held in a generally circular coil); a syringe (col. 2, lines 60-65, This balloon is inflated by a hypodermic syringe 15); and a lubricant container (col. 2, lines 50-55, lubricant packet 9).

However, Pilger lacks multiple compartments and at most discloses posts, supports or grooves that accommodate various accessories (col. 2, lines 40-45, Extending upwardly from bottom 2 are a series of posts 5, 6 and 7 which are near but spaced from the side wall 3; col. 2, lines 50-55, a series of posts 5, 11 and 12; col. 2, lines 60-70, the syringe which is filled with sterile liquid is confined between posts 6, 11, 12 and 16 in the dish portion. A ledge section 17 abuts a plunger 18 of the hypodermic syringe). The posts do not divide the tray into compartments but instead extend as islands or pegs within a single compartment of the tray (Figs. 1-5). Pilger also lacks a syringe containing lubricating jelly and instead stores lubricant in a packet (col. 2, lines 50-55, lubricant packet 9).

Also cited previously, **McMichael; Donald J. et al. (US 6896141 B2)** discloses a tray comprising multiple compartments (col. 3, lines 50-60, A plurality of recesses … are defined in the various planar surfaces 64, 66, 68, and 70). However, McMichael does not include a Foley catheter in the tray and instead configures it to hold equipment for a PEG procedure (col. 1, lines 60-65, The terms surgical "articles" or "implements" are intended to encompass any combination of devices used in a surgical procedure and may include, without limitation, scissors, clamps, forceps, medicines and drugs, syringes, needles, tubes, scalpels, snares, cannulas, and so forth; cols. 5-6, lines 65-6, The second planar surface 66 may also include a recess 94 that is adapted to hold at least a portion of a percutaneous endoscopic gastrostomy (PEG) tube 94A).

The following newly cited references fail to teach or suggest all limitations of the amended claims.

Fvlbrook; Jason D. et al. (US 20090301927 A1) discloses an organizer tray for medical equipment (¶ [0018], [0019], [0025]); comprising a tray having multiple compartments (¶ [0040] 37 A tray organizer feature common to all embodiments (first, second, and third) … recessed openings 38, 40, 42, 44, 46); and a syringe (¶ [0109] 12. Rectangular shaped recessed openings for securing appliances such as syringes, scissors … and other miscellaneous items; ¶ [0133] 13. Rectangular shaped recessed opening for securing appliances such as syringes, scissors … alcohol wipes, etc.). However, Fvlbrook lacks a Foley catheter and instead configures the tray to store accessories used by a patient at their bedside (¶ [0023], mounting the organizer tray on an IV pole or bed guard rail; ¶ [0069] organizer trays for holding/securing/locating a

plurality of expendable supplies for bed-ridden patients in hospital or home care settings).

Andrich; Daniela (US 20110218520 A1) discloses a catheterization kit including a catheter (¶ [0068], a catheter 10 having a flexible elongate shaft 12; ¶ [0095] FIG. 5 shows how the device of the invention is packaged in a sterile environment ready for use); and a syringe filled with water (¶ [0097] Additionally housed within the external wrapping 104 is a syringe 108 pre-filled with water for lubricating the guidewire 38).

However, Andrich lacks a tray having multiple compartments and instead stores the components in a pair of nested wrappings (¶ [0096] The device of the invention (not shown) is contained within a sterile internal wrapping 90, which is typically made from plastic; ¶ [0097] The internal wrapping 90 is housed within a sterile external wrapping 104, which is typically made of plastic or paper).

Finegold; Aaron N. (US 4460360 A) discloses an instrument and method of applying a local anesthetic to the urethra including a syringe containing a lubricant (col. 3, lines 20-25, The syringe body 12 contains a suitable anesthetic, such as a lidocaine hydrochloride solution or jelly). However, Finegold does not package the syringe in a tray and at most describes a freestanding syringe configured to deliver the lubricant through a lumen of a catheter (col. 3, lines 20-40, The barrel 28 is inserted into the anterior urethra 48 … the anesthetic is applied to the interior walls of first the posterior urethra 46 and then the anterior urethra 48).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

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, Nicholas Weiss can be reached at 571-270-1775. 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. 16/944,667	Applicant(s)/Patent Under Reexamination Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-4460360-A	07-1984	Finegold; Aaron N.	A61M25/00	604/288
*	B	US-20090301927-A1	12-2009	Fvlbrook; Jason D.	A61B90/57	248/304
*	C	US-20110218520-A1	09-2011	Andrich; Daniela	A61M25/0017	604/544
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*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 1004.0955

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

CPC						
Symbol					**Type**	**Version**
B65B	/	11	/	00	F	2013-01-01
A61M	/	25	/	00	I	2013-01-01
A61B	/	50	/	30	I	2016-02-01
A61B	/	50	/	33	I	2016-02-01
A61M	/	25	/	002	I	2013-01-01
A61M	/	2209	/	06	A	2013-01-01
A61M	/	5	/	002	A	2013-01-01
A61L	/	2202	/	18	A	2013-01-01
A61L	/	2202	/	182	A	2013-01-01
A61J	/	2205	/	50	A	2013-01-01
A61J	/	2205	/	40	A	2013-01-01
A61M	/	25	/	0017	A	2013-01-01
A61B	/	2050	/	3015	A	2016-02-01
A61B	/	2050	/	3008	A	2016-02-01
A61B	/	42	/	00	A	2016-02-01
A61B	/	46	/	00	A	2016-02-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	22 February 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

U.S. Patent and Trademark Office — Part of Paper No.: 20230222

Bard Exhibit 1004.0956

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

INTERNATIONAL CLASSIFICATION				
CLAIMED				
B65B11/00	/	11	/	00
A61M25/00	/	25	/	00
A61B50/30	/	50	/	30
A61B50/33	/	50	/	33
A61M5/00	/	5	/	00
A61B42/00	/	42	/	00
A61B46/00	/	46	/	00

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 22	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) 22 February 2023 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 7

U.S. Patent and Trademark Office Part of Paper No.: 20230222

Bard Exhibit 1004.0957

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	20	19										
2	2	11	11	21	20										
3	3	12	12	22	21										
4	4	13	13	15	22										
5	5	16	14	14	23										
6	6	17	15												
7	7	18	16												
8	8		17												
9	9	19	18												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	22 February 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

U.S. Patent and Trademark Office Part of Paper No.: 20230222

Bard Exhibit 1004.0958

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

CPC - Searched*		
Symbol	**Date**	**Examiner**
B65B11/00, A61B50/30, A61B50/33, A61B2050/3008	09/29/2022	AMM
A61M25/00, A61M25/002, A61M5/002, A61M25/0017, A61M2209/06	09/29/2022	AMM
A61J2205/50, A61L2202/18, A61L2202/182	09/29/2022	AMM
update search	02/22/2023	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	09/29/2022	AMM
Review cited art for related cases 16833575, 15684787, 14793455, 13860902, 13155026, 12647515, 12495148	09/29/2022	AMM
Review Inter Partes Review cases IPR2015-00509, IPR2015-00511, IPR2015-00513, IPR2019-00035, IPR2019-00036, IPR2019-00109	09/29/2022	AMM
update search	02/22/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	

Bard Exhibit 1004.0959

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	Art Unit
	Adam M Marcetich	3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	claim keyword search	02/22/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	

Bard Exhibit 1004.0960

Bibliographic Data

Application No: 16/944,667

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /Adam Marcetich/ Examiner's Signature | Initials

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

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/31/2020	206	3781	10055UCIP2D1C1C1C1C1C1
RULE			

APPLICANTS

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John Kutsch, Harvard, IL, UNITED STATES

CONTINUING DATA

This application is a CON of 16833575 03/28/2020

16833575 is a CON of 15684787 08/23/2017 PAT 10640243

15684787 is a CON of 14793455 07/07/2015 PAT 9745088

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13155026 is a CIP of 13153300 06/03/2011ABN

13155026 has PRO of 61437796 01/31/2011

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12495148 has PRO of 61183629 06/03/2009

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

08/07/2020

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FILING FEE RECEIVED

$1,720

Receipt date: 02/13/2023

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	16/944,667
	Filing Date	Jul 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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	
		4411656		1983-10-25	Cornett, Walter	
		4439184		1984-03-27	Wheeler, Robert P.	
		4554156		1985-11-19	Fischer, Herbert	
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		10512752		2019-12-24	Tomes, Jennifer	
		10946169		2021-03-16	Lockwood, Robert	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 02/13/2023

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

PTO/SB/08a (01-10)
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	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

		10946992		2021-03-16	Tomes, Jennifer	

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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
		20060011506		2006-01-19	Riley, Kimberly	
		20070197998		2007-08-23	Itou, Yasushi	
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	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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]
		2000281144	JP		2000-10-10	Shimura, Kenichi		
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		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,	
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		"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,	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

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Doc code: IDS
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PTO/SB/08a (01-10)
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	Examiner Name	Adam M Marcetich
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

		KLEIN, BENJAMIN , "Non-Final Office Action", USSN 16/688,185; Filed November 19, 2019; Attorney Docket No. BPMDL10055U P1C2D1; Mailed January 31, 2023,	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 02/13/2023

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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	Filing Date	Jul 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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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,	
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EXAMINER SIGNATURE

Examiner Signature	/Adam Marcetich/	Date Considered	02/22/2023

*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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 02/13/2023

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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	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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)	2023-02-09
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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L207	15	(12/495148 12/647515 13/153265 13/153300 13/155026 13/860902 14/793455 15/684787 16/833575).app.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 02:30 PM
L208	1394	(Medline).as. (Medline).aanm. (Jennifer near2 Tomes).in. (Sarah NEAR Dickinson).in. (Deborah NEAR Adler).in. (Jack NEAR Maze).in. (Alberto NEAR Savage).in. (Kenneth NEAR Chua).in. (Earl NEAR Wilson).in. (John NEAR Kutsch).in.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/02 02:33 PM
L209	5824	(B65B11/00 A61B50/30 A61B50/33 A61M25/00 A61M25/002 A61B2050/3008 A61J2205/50 A61L2202/18 A61L2202/182 A61M5/002 A61M25/0017 A61M2209/06).cpc. AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/02 03:59 PM
L210	12	L208 AND ((tray kit compartment chamber) near3 (lubricat$3 lubricant jelly gel)).clm.	(USPAT)	OR	ON	ON	2022/09/02 04:00 PM
L211	3	("9,745,088" "9,808,596" "9,795,761").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 09:16 AM
L212	5	("7,278,987" "3,329,261" "3,166,189").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 09:30 AM
L213	2	("2007229520").pn.	(FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA,	OR	ON	ON	2022/09/06 09:36 AM

Bard Exhibit 1004.0969

			VN, UA, VN, WO); JPO)				
L214	68	((US-3485352-A OR US-3830035-A OR US-3780857-A OR US-3750663-A OR US-3851649-A OR US-5447237-A OR US-4282972-A OR US-4226328-A OR US-6691946-B2 OR US-4170300-A OR US-4366901-A OR US-6012586-A OR US-4811847-A OR US-4925448-A OR US-4928830-A OR US-3978983-A OR US-6540078-B1 OR US-4085845-A OR US-3107786-A OR US-4523679-A OR US-5635134-A OR US-3750664-A OR US-3998221-A OR US-3225920-A OR US-5174306-A OR US-6142152-A OR US-3650393-A OR US-4051845-A OR US-5072832-A OR US-9745088-B2 OR US-11116937-B2).did. AND USPT.dbnm.) OR ((US-3542019-A OR US-2734543-A OR US-3166189-A).did. AND USOC.dbnm.) OR ((US-20080272023-A1 OR US-20070161971-A1 OR US-20040004019-A1 OR US-20170216558-A1 OR US-20030038475-A1 OR US-20060009742-A1 OR US-20060025753-A1 OR US-20030159968-A1 OR US-20060011501-A1 OR US-20110284410-A1 OR US-20090099531-A1 OR US-20090236259-A1 OR US-20040055925-A1 OR US-20070026472-A1 OR US-20040076564-A1 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 12:53 PM

Bard Exhibit 1004.0970

		20040074593-A1 OR US-20110192115-A1 OR US-20110033137-A1 OR US-20020185406-A1 OR US-20050022822-A1 OR US-20100186754-A1 OR US-20060104856-A1 OR US-20020064478-A1 OR US-20100252473-A1 OR US-20150034521-A1 OR US-20070095699-A1 OR US-20060185326-A1 OR US-20110214679-A1 OR US-20070225687-A1 OR US-20090152160-A1 OR US-20060067855-A1 OR US-20050079093-A1 OR US-20200223571-A1).did. AND PGPB.dbnm.) OR ((JP-2007229520-A).did. AND FTDB.dbnm.)					
L215	14	L214 AND (swab swabstick)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 12:53 PM
L216	55	L209 AND (tray kit package compartment chamber zone box divider divided division subdivided subdivision) near3 (lubricat$3 lubricant jelly gel)	(USPAT)	OR	ON	ON	2022/09/06 03:37 PM
L217	278	("10640243"|"20040031721"|"20170202699"|"20170216558"|"20170368302"|"20190344044"|"5289919"|"10251812"|"20020000018"|"20030000003"|"20030000007"|"20030000015"|"20030038475"|"2004000"|"20040000005"|"20040000016"|"20040000018"|"20040000019"|"20040000023"|"20050000002"|"20050000010"|"20050000022"|"20050000025"|"20050000028"|"20050241986"|"2006000"|"20060000001"|"20060000002"|"20060000008"|"20060000009"|"20060000018"|"20060000026"|	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 03:38 PM

Bard Exhibit 1004.0971

		20060000027"|"200600 00264"|"20070000002"| "20070000006"|"20070 000008"|"20070000009 "|"20070000014"|"2007 0000016"|"2007000002 0"|"20070000022"|"200 70000029"|"200800000 11"|"20080000022"|"20 080000024"|"20080000 028"|"20080000121"|"2 0080281254"|"2008028 3433"|"20090000007"|" 20090000015"|"200900 00018"|"20090000019"| "20090000023"|"20090 000031"|"20090004055 "|"20090099531"|"2010 0000027"|"2010000003 0"|"20100000031"|"201 00307941"|"201003110 26"|"20110000010"|"20 110000015"|"20110000 023"|"20110000028"|"2 0110000029"|"2011023 3079"|"20110290260"|" 20110290262"|"201200 00014"|"20120145589"| "20140000011"|"26594 85"|"2715296"|"278161 1"|"2886316"|"2947415" |"2954642"|"2959891"|" 3013656"|"3133635"|"3 166189"|"3315802"|"33 29261"|"3379339"|"348 5352"|"3542019"|"3726 281"|"3770119"|"38516 49"|"3901235"|"396590 0"|"3967728"|"3976195" |"3978983"|"3998221"|" 4011944"|"4053280"|"4 075782"|"4140127"|"41 60505"|"4170300"|"422 6328"|"4266669"|"4269 310"|"4282678"|"43075 39"|"4334537"|"445870 5"|"4501363"|"4523679" |"4530349"|"4761008"|" 4767008"|"4795441"|"4 811847"|"4828113"|"48 44259"|"4858821"|"492 5448"|"4928830"|"4991 877"|"5007535"|"50243 26"|"5031768"|"509462 1"|"5163557"|"5170804" |"5197885"|"5232369"|" 5242398"|"5244394"|"5 312287"|"5314339"|"53					

		18543"|"5324201"|"533 9955"|"5392918"|"5411 437"|"5487566"|"56659 45"|"5713778"|"572050 2"|"5778574"|"5779053" |"5795213"|"5810738"|" 5820441"|"5827262"|"5 829790"|"5872262"|"59 31303"|"5941241"|"594 7284"|"5954369"|"5975 295"|"6004136"|"60125 86"|"6068121"|"608994 3"|"6142152"|"6158437" |"6159017"|"6330427"|" 6361396"|"6382212"|"6 405863"|"6454097"|"65 79271"|"6659506"|"668 1933"|"6769546"|"6793 078"|"6840379"|"68961 41"|"6915901"|"692670 8"|"6948742"|"7048120" |"7066328"|"7264869"|" 7278987"|"7401703"|"7 434687"|"7624869"|"77 85312"|"7789873"|"844 8786"|"8628549"|"8631 935"|"8678190"|"87089 99"|"9084593"|"928335 2"|"9522753"|"9795761" |"9808400"|"D209641"|" D218077"|"D234404"|" D237315"|"D237317"|" D242654"|"D243798"|" D248871"|"D249362"|" D262995"|"D268130"|" D275886"|"D276462"|" D277508"|"D280663"|" D280933"|"D280993"|" D283051"|"D287760"|" D310896"|"D334973"|" D337830"|"D343687"|" D351661"|"D380272"|" D387177"|"D387559"|" D442697"|"D450130"|" D450391"|"D495491"|" D530920"|"D547064"|" D549454"|"D557047"|" D561473"|"D563673"|" D579662"|"D590596"|" D596311"|"D609819"|" D612153"|"D623765"|" D636894"|"D638137"|" D650912"|"D662218"|" D688461"|"D704856"|" D708347"|"D708759"|" D720470"|"D720471"|" D742028"|"D779082"|" D800337"|"D832456").P					

Bard Exhibit 1004.0973

		N.					
L218	39	L217 AND (lubricat$3 lubricant jelly gel)	(USPAT)	OR	ON	ON	2022/09/06 03:38 PM
L219	2	(10/888659).APP.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 03:47 PM
L220	79	("20060009742" "20060009742" "7278987" "20090050516" "7657953" "20110225726" "20120103840" "9283352" "9522753" "9693756" "9795761" "9808400" "10106295" "10758705" "10960260" "11116937" "8042689" "8382730" "9011563" "7866471" "8608719" "10029075" "2032593" "2563060" "2783109" "3166189" "3329261" "3532336" "3795015" "3851649" "4160505" "4226328" "4503864" "4595102" "4635913" "4752293" "4811847" "4925448" "5242398" "5339955" "5383411" "5438938" "5586163" "5697921" "5792125" "6012586" "6090075" "6485438" "20030056285" "20050205450" "2032593" "2563060" "2783109" "3166189" "3329261" "3532336" "3795015" "3851649" "4160505" "4226328" "4503864" "4752293" "4595102" "4635913" "4811847" "4925448" "5242398" "5339955" "5383411" "5438938" "5586163" "5697921" "5792125" "6012586" "6090075" "6485438" "20030056285" "20050205450" "8327480" "7657953" "7757317" "7798331" "20090050516" "9522753" "9693756" "9745088" "10512752" "9808596" "10251812" "9808400" "9283352"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 03:49 PM

Bard Exhibit 1004.0974

		"10624614" "10946992" "9795761" "20180001052" "20180057196" "10946169" "10640243" "20110225726" "10106295" "20120103840" "8584849" "10758705" "10905848" "11116937" "10960260" "20060009742" "7278987" "10449328" "6007521" "8414562" "8317775" "6004305" "20090054876" "20090024111" "8491621" "20210162169").pn.					
L221	81	("5339955" "5441152" "5706991" "5772031" "5791472" "5848693" "6012586" "6089370" "6426041" "20030073155" "20030072686" "6634513" "20040144667" "6783976" "6929926" "20050247585" "20060009742" "6998250" "20060042977" "7008777" "20060096877" "20060118444" "7119689" "20060272979" "20080237084" "7441655" "20090050516" "7660724" "20100270442" "20100311026" "20100307941" "20110017621" "7970722" "20110203957" "8195328" "8448786" "8560460" "8628155" "20140069841" "8678190" "20150021221" "9168107" "9721064" "9795761" "10106295" "20190038829" "20190167375" "10350020" "10466143"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/06 03:54 PM

Bard Exhibit 1004.0975

		"20200138536" "10758705" "11116937" "435108" "2659485" "2766919" "3133635" "3380573" "3437423" "3489268" "3601277" "3907111" "4153160" "4195734" "4655360" "5005590" "5024326" "5173273" "435108" "2659485" "2766919" "3133635" "3437423" "3380573" "3489268" "3601277" "3907111" "4655360" "4153160" "4195734" "5005590" "5024326" "5173273" "5441152" "5791472" "5772031" "5706991" "5848693" "6012586" "6634513" "6089370" "8005777" "8160988" "7970722" "6426041" "6998250" "6929926" "20030073155" "20030072686" "7008777" "6783976" "20040144667" "6902057" "7123150" "8868434" "8204620" "7126480" "7138918" "8296243" "8195328" "7119689" "7664656" "8355994" "8595021" "8560460" "7660724" "20050247585" "7278987" "20060009742" "20060042977" "8616215" "9168107" "9721064" "20060096877" "8556115" "20060118444" "7441655" "20060272979" "20080237084" "7798331" "20090050516" "9745088" "9693756" "9522753" "7980517" "20110017621" "8453977" "20100270442" "20110203957" "20100307942" "9808400" "9808596" "8631935" "9283352"					

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L222	49	("3601277" "3894649" "3897885" "4013798" "4090275" "4160505" "4304330" "4718555" "5019124" "5335787" "5339955" "5368183" "5511653" "20060113204" "20060157377" "20060172043" "20070062965" "7225927" "20090092738" "20090090648" "20090089993" "20090092719" "20090091059"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/06 04:09 PM

Bard Exhibit 1004.0977

		"20090090649" "20090200194" "20090200316" "20090200701" "20090200195" "20090200197" "20100181226" "1595356" "2738915" "3051346" "3197058" "3203573" "3353886" "1595356" "2738915" "3051346" "3203573" "3197058" "3353886" "3897885" "3894649" "4013798" "4090275" "4160505" "4304330" "4718555" "5019124" "5335787" "5339955" "5368183" "5511653" "5887749" "20060113204" "7225927" "20060157377" "20060172043" "20070062965" "7934449" "7736580" "7735651" "20090092719" "20090091059" "20090090649" "20090089993" "8006369" "20090092738" "7802684" "20090090648" "20090200194" "20090200197" "20100181226" "20090200195" "20090200701" "20090200316" "3601277" "3675811" "3366290" "3704779" "3401863" "3807622" "3955672" "3349943" "4787527" "3506154" "3261494" "3720365" "4381847" "4736977" "3146885" "3786932" "4006818" "4278197" "2946621" "3765592" "2509447" "3931888").pn. AND @Ad<"20110131"					
L223	47	("4160505" "4266669" "4479762" "4573576" "4811847" "4936448" "4989733" "5098391"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/06 04:12 PM

Bard Exhibit 1004.0978

		"5099839" "5454797" "5931303" "6405863" "20030072686" "20030073155" "20030082664" "6783976" "6929926" "20060009742" "6998250" "20060271017" "20070062965" "20080119803" "20090200196" "20090200197" "20090236259" "20120103840" "20130105344" "9283352" "9522753" "9693756" "9795761" "9808400" "10106295" "10758705" "11116937" "11399911" "2319556" "3329261" "3485352" "3601277" "3851649" "2319556" "3329261" "3485352" "3601277" "3851649" "4266669" "4479762" "4573576" "4811847" "5099839" "5356427" "4936448" "5098391" "4989733" "5454797" "5931303" "6405863" "20030082664" "20030073155" "20030072686" "6929926" "6998250" "7008777" "6783976" "20060009742" "7278987" "20080119803" "8852171" "20060271017" "7736348" "7934449" "20070062965" "9745088" "9693756" "9522753" "20090200196" "20090200197" "20090236259" "9283352" "10512752" "9808400" "9808596" "10251812" "10640243" "10624614" "10946992" "10946169" "9795761" "10106295" "20120103840" "8584849" "20130105344"					

Bard Exhibit 1004.0979

		"10758705" "10905848" "10405938" "11399911" "11116937" "4160505" "4190153" "4976726" "6012586" "5000741" "7665491" "3774609" "3851649" "4917112" "3650267" "3166189" "4988296" "5454797" "5683655" "8753355" "5361781").pn. AND @Ad<"20110131"					
L224	7	L209 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe	(USPAT)	OR	ON	ON	2022/09/06 04:22 PM
L225	2	L207 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe.clm.	(USPAT)	OR	ON	ON	2022/09/07 07:30 AM
L227	2	("3329261").pn.	(USPAT; USOCR)	OR	ON	ON	2022/09/07 07:43 AM
L228	461572	(B65B A61B A61J A61L A61M A61F).cpcl. AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/07 07:45 AM
L229	304	L228 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe	(USPAT)	OR	ON	ON	2022/09/07 07:45 AM
L230	2	(12/763687).APP.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 07:46 AM
L231	5	"9703710".pn.	(FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN, UA, VN, WO); FPRS)	OR	ON	ON	2022/09/07 07:47 AM
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
L234	13	(16/944667 16/833575 15/684787 14/793455 13/860902 13/155026	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/29 12:36 PM

Bard Exhibit 1004.0980

		12/647515 12/495148).app.					
L235	1401	(Medline).as. (Medline).aanm. (Jennifer near2 Tomes).in. (Sarah NEAR Dickinson).in. (Deborah NEAR Adler).in. (Jack NEAR Maze).in. (Alberto NEAR Savage).in. (Kenneth NEAR Chua).in. (Earl NEAR Wilson).in. (John NEAR Kutsch).in.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/29 12:37 PM
L236	85	((US-3485352-A OR US-3830035-A OR US-3780857-A OR US-3750663-A OR US-3851649-A OR US-5447237-A OR US-4282972-A OR US-4226328-A OR US-6691946-B2 OR US-4170300-A OR US-4366901-A OR US-6012586-A OR US-4811847-A OR US-4925448-A OR US-4928830-A OR US-3978983-A OR US-6540078-B1 OR US-4085845-A OR US-3107786-A OR US-4523679-A OR US-5635134-A OR US-3750664-A OR US-5072832-A OR US-3225920-A OR US-5174306-A OR US-6142152-A OR US-3650393-A OR US-4051845-A OR US-3998221-A OR US-9745088-B2 OR US-9795761-B2 OR US-7278987-B2 OR US-5339955-A OR US-5706991-A OR US-3601277-A OR US-5887749-A OR US-4160505-A OR US-4503864-A OR US-5853749-A OR US-4554156-A OR US-11116937-B2).did. AND USPT.dbnm.) OR ((US-	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/29 12:40 PM

Bard Exhibit 1004.0981

		3542019-A OR US-2734543-A OR US-3166189-A OR US-3329261-A).did. AND USOC.dbnm.) OR ((US-20080272023-A1 OR US-20070161971-A1 OR US-20040004019-A1 OR US-20170216558-A1 OR US-20030038475-A1 OR US-20060009742-A1 OR US-20060025753-A1 OR US-20030159968-A1 OR US-20060011501-A1 OR US-20110284410-A1 OR US-20090099531-A1 OR US-20090236259-A1 OR US-20040055925-A1 OR US-20070026472-A1 OR US-20040076564-A1 OR US-20040074593-A1 OR US-20110192115-A1 OR US-20110033137-A1 OR US-20020185406-A1 OR US-20050022822-A1 OR US-20100186754-A1 OR US-20060104856-A1 OR US-20020064478-A1 OR US-20070225687-A1 OR US-20100252473-A1 OR US-20150034521-A1 OR US-20070095699-A1 OR US-20060185326-A1 OR US-20110214679-A1 OR US-20090152160-A1 OR US-20060067855-A1 OR US-20050079093-A1 OR US-20200223571-A1 OR US-20120103840-A1 OR US-20110225726-A1 OR US-20050205450-A1 OR US-20110017621-A1 OR US-20060096877-A1 OR US-20060042977-A1 OR US-20100272669-A1).did.					

Bard Exhibit 1004.0982

		AND PGPB.dbnm.) OR ((JP-2007229520-A).did. AND FTDB.dbnm.)					
L237	35	L235 AND (syringe near5 (lubricating lubricant jelly gel water) AND (compartment zone area chamber) AND (tubing tube coil coiled Foley catheter)).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/09/29 02:31 PM
L238	15	L235 AND (syringe near5 (lubricating lubricant jelly gel water) AND (compartment zone area chamber) AND (tubing tube coil coiled Foley catheter)).clm.	(USPAT)	OR	ON	ON	2022/09/29 02:31 PM
L239	13	L238 AND (opening hole passage pass passed passing across through gap) near8 (tubing tube coil coiled Foley catheter barrier surface catheter).clm.	(USPAT)	OR	ON	ON	2022/09/29 02:34 PM
L240	5	(16/944667 16/833575 15/684787 14/793455 13/860902 13/155026 12/647515 12/495148).app.	(USPAT)	OR	ON	ON	2022/09/29 02:47 PM
L241	15	L238 AND (opening hole passage pass passed passing across through gap) near8 (tubing tube coil coiled Foley catheter barrier surface catheter compartment zone area chamber).clm.	(USPAT)	OR	ON	ON	2022/09/29 02:51 PM
L242	5824	(B65B11/00 A61B50/30 A61B50/33 A61M25/00 A61M25/002 A61B2050/3008 A61J2205/50 A61L2202/18 A61L2202/182 A61M5/002 A61M25/0017 A61M2209/06).cpc. AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/29 03:19 PM
L271	22	L242 AND (tray kit package box assembly) SAME (compartment	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/30 10:49 AM

Bard Exhibit 1004.0983

		chamber zone divider divided division subdivided subdivision) near3 (lubricat$3 lubricant jelly gel)					
L272	12	L236 AND (water saline inflat$3) near4 syringe AND (Bag wrap wrapper wrapping packaging box pouch)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/30 12:54 PM
L273	278	("10640243"|"20040031721"|"20170202699"|"20170216558"|"20170368302"|"20190344044"|"5289919"|"10251812"|"20020000018"|"20030000003"|"20030000007"|"20030000015"|"20030038475"|"2004000"|"20040000005"|"20040000016"|"20040000018"|"20040000019"|"20040000023"|"20050000002"|"20050000010"|"20050000022"|"20050000025"|"20050000028"|"20050241986"|"2006000"|"20060000001"|"20060000002"|"20060000008"|"20060000009"|"20060000018"|"20060000026"|"20060000027"|"20060000264"|"20070000002"|"20070000006"|"20070000008"|"20070000009"|"20070000014"|"20070000016"|"20070000020"|"20070000022"|"20070000029"|"20080000011"|"20080000022"|"20080000024"|"20080000028"|"20080000121"|"20080281254"|"20080283433"|"20090000007"|"20090000015"|"20090000018"|"20090000019"|"20090000023"|"20090000031"|"20090004055"|"20090099531"|"20100000027"|"20100000030"|"20100000031"|"20100307941"|"20100311026"|"20110000010"|"20110000015"|"20110000023"|"20110000028"|"20110000029"|"20110233079"|"20110290260"|	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/03 02:29 PM

Bard Exhibit 1004.0984

		20110290262"|"201200 00014"|"20120145589"| "20140000011"|"26594 85"|"2715296"|"278161 1"|"2886316"|"2947415" |"2954642"|"2959891"|" 3013656"|"3133635"|"3 166189"|"3315802"|"33 29261"|"3379339"|"348 5352"|"3542019"|"3726 281"|"3770119"|"38516 49"|"3901235"|"396590 0"|"3967728"|"3976195" |"3978983"|"3998221"|" 4011944"|"4053280"|"4 075782"|"4140127"|"41 60505"|"4170300"|"422 6328"|"4266669"|"4269 310"|"4282678"|"43075 39"|"4334537"|"445870 5"|"4501363"|"4523679" |"4530349"|"4761008"|" 4767008"|"4795441"|"4 811847"|"4828113"|"48 44259"|"4858821"|"492 5448"|"4928830"|"4991 877"|"5007535"|"50243 26"|"5031768"|"509462 1"|"5163557"|"5170804" |"5197885"|"5232369"|" 5242398"|"5244394"|"5 312287"|"5314339"|"53 18543"|"5324201"|"533 9955"|"5392918"|"5411 437"|"5487566"|"56659 45"|"5713778"|"572050 2"|"5778574"|"5779053" |"5795213"|"5810738"|" 5820441"|"5827262"|"5 829790"|"5872262"|"59 31303"|"5941241"|"594 7284"|"5954369"|"5975 295"|"6004136"|"60125 86"|"6068121"|"608994 3"|"6142152"|"6158437" |"6159017"|"6330427"|" 6361396"|"6382212"|"6 405863"|"6454097"|"65 79271"|"6659506"|"668 1933"|"6769546"|"6793 078"|"6840379"|"68961 41"|"6915901"|"692670 8"|"6948742"|"7048120" |"7066328"|"7264869"|" 7278987"|"7401703"|"7 434687"|"7624869"|"77 85312"|"7789873"|"844 8786"|"8628549"|"8631					

Bard Exhibit 1004.0985

		935"|"8678190"|"8708999"|"9084593"|"9283352"|"9522753"|"9795761"|"9808400"|"D209641"|"D218077"|"D234404"|"D237315"|"D237317"|"D242654"|"D243798"|"D248871"|"D249362"|"D262995"|"D268130"|"D275886"|"D276462"|"D277508"|"D280663"|"D280933"|"D280993"|"D283051"|"D287760"|"D310896"|"D334973"|"D337830"|"D343687"|"D351661"|"D380272"|"D387177"|"D387559"|"D442697"|"D450130"|"D450391"|"D495491"|"D530920"|"D547064"|"D549454"|"D557047"|"D561473"|"D563673"|"D579662"|"D590596"|"D596311"|"D609819"|"D612153"|"D623765"|"D636894"|"D638137"|"D650912"|"D662218"|"D688461"|"D704856"|"D708347"|"D708759"|"D720470"|"D720471"|"D742028"|"D779082"|"D800337"|"D832456").PN.					
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L277	11	L276 AND (lubricant lubricating gel jel jelly	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 10:11 AM

Bard Exhibit 1004.0986

		friction syringe) AND @Ad<"20110131"					
L278	2	(US-20110092958-$ | US-20140072190-$).DID.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 10:23 AM
L280	13	(16/944667 16/833575 15/684787 14/793455 13/860902 13/155026 12/647515 12/495148).app.	(US-PGPUB; USPAT)	OR	ON	ON	2023/02/22 10:32 AM
L281	1	12/647515.app.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 02:51 PM
L282	2	12/495148.app.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 02:55 PM
L283	29037	(Catheter catheterization catheterisation cannula canula cannulation urinary urine bladder) near5 (package kit tray assembly assemblage box pan) AND @ad<"20090630"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 02:58 PM
L284	925	L283 AND syringe near5 (compartment subcompartment zone chamber divider subdivider box divided area subarea chamber cell recess recessed)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 03:00 PM
L285	1277	L283 AND syringe near5 (compartment subcompartment zone chamber divider subdivider box divided area subarea chamber cell recess recessed depression depressed hollow)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 03:00 PM
L286	644	L285 AND (package kit tray assembly assemblage box pan) near5 (compartment subcompartment zone chamber divider subdivider box divided area subarea chamber cell recess recessed depression depressed hollow)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 03:01 PM
L287	34	("20060009742" "3329261" "4554156" "4411656" "4439184" "20110218520" "4460360" "4226328"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 03:58 PM

Bard Exhibit 1004.0987

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L288	298	("10512752"|"10946169"|"10946992"|"20060011506"|"20070197998"|"20080125722"|"20100272669"|"20110017621"|"20110225726"|"20110284410"|"20120267272"|"3650393"|"4085845"|"4411656"|"4439184"|"4554156"|"5887749"|"9693756"|"9745088"|"9808596"|"10640243"|"20040031721"|"20170202699"|"20170216558"|"20170368302"|"20190344044"|"5289919"|"10251812"|"20020000018"|"20030000003"|"20030000007"|"20030000015"|"20030038475"|"2004000"|"20040000005"|"20040000016"|"20040000018"|"20040000019"|"20040000023"|"20050000002"|"20050000010"|"20050000022"|"20050000025"|"20050000028"|"20050241986"|"2006000"|"20060000001"|"20060000002"|"20060000008"|"20060000009"|"20060000018"|"20060000026"|"20060000027"|"20060000264"|"2007000	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/22 04:10 PM

Bard Exhibit 1004.0988

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Bard Exhibit 1004.0989

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L289	4	(US-3485352-$ | US-	(US-PGPUB; USPAT;	OR	ON	ON	2023/02/22

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L294	2	("20110218520" "4460360").pn.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/23 09:28 AM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N213	18235	(Catheter catheterization catheterisation cannula canula cannulation urinary urine bladder) near5 (package kit tray assembly assemblage box pan).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/02/23 09:14 AM
N214	2370	N213 AND (package kit tray assembly assemblage box pan) near5 (compartment subcompartment zone chamber divider subdivider box divided area subarea chamber cell recess recessed depression depressed hollow).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/02/23 09:14 AM
N215	72	N214 AND syringe near5 (compartment subcompartment zone chamber divider subdivider box divided area subarea chamber cell recess recessed).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/02/23 09:15 AM
N216	124	N214 AND syringe WITH (compartment subcompartment zone chamber divider subdivider box divided area subarea chamber cell recess recessed).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/02/23 09:15 AM

Receipt date: 02/28/2023

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
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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/944,667
	Filing Date	July 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3735
	Examiner Name	Adam Marceitch
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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
		4460360		1984-07-17	Finegold, Aaron	

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
		20110218520		2011-09-08	Andrich, Daniela	

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]
		MARCETICH, ADAM , "Notice of Allowance", USSN 16/833,575; Filed March 28, 2020; Attorney Docket No 10055UCIP2D1C1C1C1C1; Mailed February 24, 2023	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 02/28/2023

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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	Application Number	16/944,667
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	First Named Inventor	Jennifer E. Tomes
	Art Unit	3735
	Examiner Name	Adam Marceitch
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	03/06/2023

*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.

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 02/28/2023

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	16/944,667
	Filing Date	July 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3735
	Examiner Name	Adam Marceitch
	Attorney Docket Number	10055UCIP2D1C1C1C1C1C1

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)	2023-02-28
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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
16944667	31-Jul-2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1C	8322

TITLE OF INVENTION :

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

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	3781	571000	ADAM MARCETICH

Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
$1200	$0	$1200	02-Jun-2023	$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
189038 Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC (MDL) 222 12th Street NE Suite 1803 Atlanta GA 30309 UNITED STATES 404-797-8111 BIPLaw_docketing@burrusiplaw.com	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status

Change in Entity Status

○ Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.
Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.

○ Applicant asserting small entity status. See 37 CFR 1.27.
Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

◉ Applicant changing to regular undiscounted fee status.
Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

Bard Exhibit 1004.0995

Doc Code: IFEE PTOL/85B-EFS

Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:

☒ Issue Fee

☐ I authorize USPTO to apply my previously paid issue fee to the current fees due

☐ Publication Fee

☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____

☐ If i**n addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number _____ . The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed

NOTE: If no name is listed, no name will be printed
For printing on the patent front page, list to be displayed as entered

1. Philip H. Burrus, IV
2.
3.

5.Assignee Name(s) and Residence Data To Be Printed

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

Name	City	State	Country	Category
Medline Industries, LP	Northfield	ILLINOIS	UNITED STATES	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Philip H. Burrus, IV/	**Date**	03-15-2023
Name	Philip Henry Burrus	**Registration Number**	45432

Bard Exhibit 1004.0996

Electronic Patent Application Fee Transmittal

Application Number:	16944667
Filing Date:	31-Jul-2020
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:	10055UCIP2D1C1C1C1C1C1

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 APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1200**

Electronic Acknowledgement Receipt	
EFS ID:	47688026
Application Number:	16944667
International Application Number:	
Confirmation Number:	8322
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:	10055UCIP2D1C1C1C1C1C1
Receipt Date:	15-MAR-2023
Filing Date:	31-JUL-2020
Time Stamp:	15:53:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1200
RAM confirmation Number	E20233EF53195704
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	60286 267e3c082544fc01d6a9c2746d79fdbb2926c44e	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40365 1eb1a79e4f604e0205a7ca797d680af613edf7cc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	100651		

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 NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/944,667	04/18/2023	11628958	10055UCIP2D1C1C1C1C1C1	8322

189038 7590 03/29/2023

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 322 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

Bard Exhibit 1004.1001

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Jennifer E. Tomes, Mundelein, IL;
Sarah Dickinson, Chicago, IL;
Deborah Adler, New York, NY;
Jack Maze, Long Grove, IL;
Alberto Savage, Buffalo Grove, IL;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Medline Industries, LP, Northfied, IL;

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 USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Bard Exhibit 1004.1002

Electronic Patent Application Fee Transmittal

Application Number:	16944667
Filing Date:	31-Jul-2020
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:	10055UCIP2D1C1C1C1C1C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
PETITION FEE- 37 CFR 1.17(H) (GROUP III)	1464	1	140	140
RCE- 1ST REQUEST	1801	1	1360	1360
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1500**

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Decision Date : April 6, 2023

In re Application of :

Jennifer E. Tomes

DECISION ON PETITION
UNDER CFR 1.313(c)(2)

Application No : 16944667

Filed : 31-Jul-2020

Attorney Docket No : 10055UCIP2D1C1C1C1C1C1

This is an electronic decision on the petition under 37 CFR 1.313(c)(2), filed April 6, 2023 , to withdraw the above-identified application from issue after payment of the issue fee.

The petition is **GRANTED.**

The above-identified application is withdrawn from issue for consideration of a submission under 37 CFR 1.114 (request for continued examination). See 37 CFR 1.313(c)(2).

Petitioner is advised that the issue fee paid in this application cannot be refunded. If, however, this application is again allowed, petitioner may request that it be applied towards the issue fee required by the new Notice of Allowance.

Telephone inquiries concerning this decision should be directed to the Patent Electronic Business Center (EBC) at 866-217-9197.

This application file is being referred to Technology Center AU 3781 for processing of the request for continuing examination under 37 CFR 1.114 .

Office of Petitions

Electronic Acknowledgement Receipt	
EFS ID:	47804139
Application Number:	16944667
International Application Number:	
Confirmation Number:	8322
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:	10055UCIP2D1C1C1C1C1C1
Receipt Date:	06-APR-2023
Filing Date:	31-JUL-2020
Time Stamp:	15:43:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1500
RAM confirmation Number	E202346F43158009
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	ePetition Request Form	petition-request.pdf	39938 e09235f408d6c83dec6182ab72e0cf4f415d4bc2	no	2
Warnings:					
Information:					
2	Quick Path Information Disclosure Statement	10055U_CIP2_D1_C1C1C1C1C1_USA_2023-4-6_QPIDSReq.pdf	214657 a851826ea9176f2731f642a4d4b98ed07a35a2f1	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2_D1_C1C1C1C1C1_USA_2023-4-6_IDS.pdf	194325 af1de4706c6bf0ab7ec09ab7ece17e50c05f8046	no	3
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Non Patent Literature	10055U_CIP2_D1_USA_2023-4-4_ReExamFinalOA.pdf	1009043 6b217249c6fd0167dcc30808b5dbed09cfd70a19	no	14
Warnings:					
Information:					
5	Non Patent Literature	10055U_CIP2_USA_2023-3-21_NoticeIntent_IssueReexamCertificate.pdf	382839 07a5f6bf3e161b973ca6289bac64961932f0518e	no	6
Warnings:					
Information:					
6	Request for Continued Examination (RCE)	10055U_CIP2_D1_C1C1C1C1C1_USA_2023-4-6_RCE.pdf	1349990 07caf13abe75dfa3aecb2bc3f5366f6393d1ee44	no	3
Warnings:					

Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	40607 5b6591d73f229d563e158e5933081fa1f9e112b5	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	3231399	

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

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New International Application Filed with the USPTO as a Receiving Office

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Doc Code: PET.AUTO Document Description: Petition automatically granted by EFS-Web	PTO/SB/140 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**PETITION TO WITHDRAW AN APPLICATION FROM ISSUE AFTER PAYMENT OF THE ISSUE FEE UNDER 37 CFR 1.313(c)**
Application Number	16944667
Filing Date	31-Jul-2020
First Named Inventor	Jennifer Tomes
Art Unit	3781
Examiner Name	ADAM MARCETICH
Attorney Docket Number	10055UCIP2D1C1C1C1C1C1
Title	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17(h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary.

APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c).

A grantable petition requires the following items:
(1) Petition fee; and
(2) One of the following reasons:
(a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable;
(b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or
(c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).

Petition Fee

○	Small Entity
○	Micro Entity
◉	Regular Undiscounted

Reason for withdrawal from issue

◯ One or more claims are unpatentable ◉ Consideration of a request for continued examination (RCE) (List of Required Documents and Fees) ◯ Applicant hereby expressly abandons the instant application (any attorney/agent signing for this reason must have power of attorney pursuant to 37 CFR 1.32(b)).
RCE request,submission, and fee. ☐ I certify, in accordance with 37 CFR 1.4(d)(4) that : The RCE request ,submission, and fee have already been filed in the above-identified application on ☒ Are attached.
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ◉ An attorney or agent registered to practice before the Patent and Trademark Office who has been given power of attorney in this application. ◯ An attorney or agent registered to practice before the Patent and Trademark Office, acting in a representative capacity. ◯ A sole inventor ◯ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ◯ A joint inventor; all of whom are signing this e-petition

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

Doc Code: QPIDS.REQ
Document Description: QuickPath Information Disclosure Statement

PTO/SB/09 (09-18)

CERTIFICATION AND REQUEST FOR CONSIDERATION OF AN INFORMATION DISCLOSURE STATEMENT FILED AFTER PAYMENT OF THE ISSUE FEE UNDER THE QPIDS PROGRAM

Non-Provisional Application Number:	Filing Date:
16944667	2020-07-31
First Named Inventor:	Title of Invention:
Jennifer E. Tomes	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

THE UNDERSIGNED HEREBY CERTIFIES AND REQUESTS THE FOLLOWING FOR THE ABOVE-IDENTIFIED APPLICATION.

1. Consideration is requested of the information disclosure statement (IDS) submitted herewith, which is being filed after payment of the issue fee.
2. Check the box next to the appropriate selection:

   ☐ Each item of information contained in the IDS 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 IDS. See 37 CFR 1.97(e)(1).

   OR

   ☒ No item of information contained in the IDS 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 IDS was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(2).

   OR

   ☐ See attached certification statement in compliance with 37 CFR 1.97(e).
3. Please charge the IDS fee set forth in 37 CFR 1.17(p) to Deposit Account No. 503608.
4. A Petition to Withdraw from Issue After Payment of the Issue Fee (37 CFR 1.313(c)(2)), including the petition fee set forth in 37 CFR 1.17(h), is submitted herewith as a **Web-based ePetition**. **WARNING:** Do not submit the petition as a follow-on paper via EFS-Web. Submit the petition as a Web-based ePetition by signing on to EFS-Web as a registered user, selecting the radio button next to "Existing application/patent," and then selecting the radio button next to "ePetition (for automatic processing and immediate grant, if all petitions requirements are met)." Failure to use the Web-based ePetition interface will result in automatic entry of the RCE.
5. A request for continued examination (RCE) under 37 CFR 1.114 and the RCE fee under 37 CFR 1.17(e) are submitted herewith.
6. The RCE will be treated as a "conditional" RCE. In the event the examiner determines that any item of information contained in the IDS necessitates the reopening of prosecution in the application, the undersigned understands that (i) the RCE will be processed and treated as an RCE under 37 CFR 1.114 and therefore (ii) the IDS fee under 37 CFR 1.17(p) will be returned in accordance with 37 CFR 1.97(b)(4). In the event that no item of information in the IDS necessitates reopening prosecution, the undersigned understands that the RCE will not be processed and the RCE fee under 37 CFR 1.17(e) will be returned.
7. This certification and request is being filed as a **Web-based ePetition** and is not accompanied by an amendment to the application. Inclusion of an amendment will result in automatic entry of the RCE.

Signature /Philip H. Burrus, IV/	Date 2023-04-06
Name (Print/Typed) Philip H. Burrus, IV	Practitioner Registration Number (If applicable) 45432

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.**

☐ *Total of _____ forms are submitted.

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

Privacy Act Statement

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 disclosure of these records is required by the Freedom of Information Act.
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 Cooperation Treaty.
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.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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.

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

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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/944,667
	Filing Date	Jul 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1C1C1C1C1

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]
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023	
		REIP, DAVID O. , "ReExamination Final Office Action", USSN 90/015,051; Filed June 8, 2022; Patent Under Reexam 9522753; Mailed April 4, 2023	

EXAMINER SIGNATURE

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)		
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	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1C1C1C1C1

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.

[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

☒ 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.

☒ The Director is hereby authorized to charge the fee set forth in 37 CFR 1.17 (p) to Deposit Account No. 50-3608. Additionally, the Director is hereby authorized to charge any underpayment of fees to Deposit Account No. 50-3608.

☐ 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)	2023-04-06
Name/Print	Philip H. Burrus	Registration Number	45,432

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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	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1C1C1C1C1

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.**

United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :Karen Vestal

Sale Accounting Date:04/10/2023

Sale Item Reference Number	Effective Date
16944667	04/06/2023

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I202349710129700	1806	SUBMISSION- INFORMATION DISCLOSURE STMT	$260.00	Deposit Account

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/944,667	07/31/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1C1	8322

189038 7590 04/14/2023

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

EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3781	

NOTIFICATION DATE	DELIVERY MODE
04/14/2023	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):

BIPLaw_docketing@burrusiplaw.com
pburrus@burrusiplaw.com

Corrected ***Notice of Allowability***	**Application No.** 16/944,667	**Applicant(s)** Tomes et al.	
	Examiner Adam M Marcetich	**Art Unit** 3781	**AIA (FITF) Status** Yes

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 06 April 2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ 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.

3. ☑ The allowed claim(s) is/are 1-16 and 18-23 . As a result of the allowed claim(s), 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.**

4. ☐ 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)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

Bard Exhibit 1004.1018

EXAMINER'S COMMENT / AMENDMENT / REASONS FOR ALLOWANCE

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.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 06 April 2023 has been entered.

Examiner's Comment

The objections to claims 1, 14 and 21 for minor informalities and the rejections of claims 2, 4, 8 and 13 under 35 USC § 112 are withdrawn in view of the amendments filed 13 February 2023.

Terminal Disclaimer

The terminal disclaimer filed on 13 February 2023 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of

- Tomes; Jennifer E. et al. (US 10251812 B2)
- Tomes; Jennifer E. et al. (US 9522753 B2)

- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 9283352 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 10512752 B2)

has been reviewed and is accepted. The terminal disclaimer has been recorded.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claim 1 is amended as follows. **[[Deletions are in double brackets]]** and **additions are underlined.** Ellipsis **…** designates unchanged portions of claims which have been omitted for brevity.

Claim 1 (amended in part) "**…** a surface defining an opening allowing access to the second compartment from **[[the]] a** top of the single layer tray **…**"

Allowable Claims

Claims 1-16 and 18-23 are allowed.

Reasons for Allowance

All references on the IDS filed 06 April 2023 have been considered.

The **Notice of intent to Issue Ex Parte Reexamination Certificate for case 90014964** mailed 21 March 2023 confirms claim 1 of Tomes; Jennifer E. et al. (US 8448786 B2), which describes a method of using a catheter package assembly.

Also cited on the recently filed IDS, the **Final Rejection for case 90015051** mailed 04 April 2023 cites a combination of four references (office action p. 4)

- Pilger; Nicholas J. (US 3485352 A)
- Wheeler; Robert P. (US 4439184 A)
- McMichael, Donald J. et al. (US 20030159968 A1)
- Serany; Frank J. Jr. et al. (US 3329261 A)

However, none of these references teaches or suggests a medical procedure kit comprising a single layer tray having first and second compartments containing first and second syringes and a Foley catheter. **Pilger** was discussed in the Notice of Allowance mailed 02 March 2023.

Wheeler lacks a tray and at most discloses a syringe filled with lubricant (col. 3, lines 40-45, In the preferred embodiment used for preparing a urethra for catheterization, first fluid 28 is comprised of 5 ml. of iodophor jelly, a lubricating antiseptic, and second fluid 30 is comprised of 5 ml. of lidocaine hydrochloride jelly, a lubricating anesthetic).

McMichael discloses a tray having a plurality of compartments (¶ [0024] The PEG kit 20 may include a tray 22 having a plurality of planar surfaces and a plurality of recesses; ¶ [0033], the tray 22 may include a first planar surface 64. Several recesses

are disposed in surface 64, including two recesses 76 that may be used to hold or support coiled articles and a needle recess 81; ¶ [0034] The first surface 64 may also include a recess 103 that may be configured to have elongated portions 104 and 105; ¶ [0038] A recess 110 may also be provided in the second planar surface 66, the recess 110 being adapted to hold an exterior tube retention device 110A).

However, the tray is not configured to hold a coiled tubing coupled between a fluid drain bag and a Foley catheter, and instead holds supplies for a percutaneous endoscopic gastrostomy (¶ [0005], [0023]). McMichael suggests that the tray may be used for other procedures (¶ [0023], the invention is not limited to a PEG kit or any other particular type of kit). However, McMichael does not disclose any elements from another type of kit, and does not list any examples of alternate applications.

Serany discloses a compact package containing sterile components for catheterization (col. 1, lines 25-30), including a tray (col. 1, lines 60-65, box 10 having an open top with a tray 12 mounted thereon); a syringe in one compartment of the tray (col. 3, lines 5-10, The tray 12 has a further depression 44 for a prefilled syringe 45 used to inflate the balloon on the catheter); and a Foley catheter (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).

However, Serany stores the Foley catheter in a separate compartment of the box and not inside the tray (col. 3, lines 20-25; Fig. 6).

Applicant's arguments filed 13 February 2023 have been considered and are persuasive. Examiner advances additional reasons for allowance.

Solazzo; Anthony (US 20060009742 A1), the closest art of record, lacks first and second syringes arranged in a first compartment and a medical assembly disposed in a second compartment. Instead, Solazzo discloses only one syringe, and stores lubricant in a second flexible container (¶ [0043], inflation syringe 10 … and a tube of lubricant fluid 140).

Regarding claim 8, Solazzo lacks a wrap material and outer packaging and is silent whether the tray is enclosed in any packaging. Solazzo also lacks coiled tubing and a bag, and at most discloses a catheter (¶ [0043], catheter 120).

Regarding claim 14, Solazzo discloses four compartments (Figs. 1, 3, 8, recessed area 3, compartment 27 and catheter lubricating wells 31 and 33). However, Solazzo lacks a pair of syringes and instead discloses only one syringe (inflation syringe 10). Solazzo also lacks swabsticks disposed within a third compartment. Solazzo arranges accessories including lubricant and gloves in the same compartment as the Foley catheter (Fig. 8, compartment 27 stores catheter 120, surgical gloves 130 and a tube of lubricant fluid 140). This suggests that even if Solazzo were modified to include swabsticks, they would be placed in the same compartment as the Foley catheter and not in a separate third compartment.

Regarding claim 21, Solazzo lacks a pair of syringes, swabsticks disposed within a third compartment and a wrap as discussed above.

Cornett, III; Walter G. (US 4411656 A) and Wheeler; Robert P. (US 4439184 A) were cited on recently filed IDS forms. Each of these references discloses a syringe containing a lubricant. However, neither of the references discloses a tray having a lubricating jelly application chamber. At most, Cornett and Wheeler disclose free-standing syringes and do not teach or suggest details of a tray, kit or package.

Also of record, **Blanco; Juan Carlos Aceves (US 6454097 B1)** discloses a tray comprising multiple compartments (col. 3, lines 35-40, Compartments 22, which may be of varying sizes, are covered with lids 30 that are installed with hinges 40, preferably along the perimeter of modules 120 and 220). However, Blanco's tray lacks a Foley catheter and syringe. Instead, Blanco configures the tray as a first-aid kit containing bandages and medications to treat injuries or emergency conditions (cols. 7-8, TABLE 1 Preferred Contents).

Another cited reference, **Pilger; Nicholas J. (US 3485352 A),** discloses a package for a catheter, comprising a tray (col. 2, lines 40-45, dish portion with a bottom 2 and a generally circular upstanding wall 3), a Foley catheter (col. 2, lines 40-45, a flexible catheter 8 is held in a generally circular coil); a syringe (col. 2, lines 60-65, This balloon is inflated by a hypodermic syringe 15); and a lubricant container (col. 2, lines 50-55, lubricant packet 9).

However, Pilger lacks multiple compartments and at most discloses posts, supports or grooves that accommodate various accessories (col. 2, lines 40-45, Extending upwardly from bottom 2 are a series of posts 5, 6 and 7 which are near but

spaced from the side wall 3; col. 2, lines 50-55, a series of posts 5, 11 and 12; col. 2, lines 60-70, the syringe which is filled with sterile liquid is confined between posts 6, 11, 12 and 16 in the dish portion. A ledge section 17 abuts a plunger 18 of the hypodermic syringe). The posts do not divide the tray into compartments but instead extend as islands or pegs within a single compartment of the tray (Figs. 1-5). Pilger also lacks a syringe containing lubricating jelly and instead stores lubricant in a packet (col. 2, lines 50-55, lubricant packet 9).

Also cited previously, **McMichael; Donald J. et al. (US 6896141 B2)** discloses a tray comprising multiple compartments (col. 3, lines 50-60, A plurality of recesses … are defined in the various planar surfaces 64, 66, 68, and 70). However, McMichael does not include a Foley catheter in the tray and instead configures it to hold equipment for a PEG procedure (col. 1, lines 60-65, The terms surgical "articles" or "implements" are intended to encompass any combination of devices used in a surgical procedure and may include, without limitation, scissors, clamps, forceps, medicines and drugs, syringes, needles, tubes, scalpels, snares, cannulas, and so forth; cols. 5-6, lines 65-6, The second planar surface 66 may also include a recess 94 that is adapted to hold at least a portion of a percutaneous endoscopic gastrostomy (PEG) tube 94A).

The following newly cited references fail to teach or suggest all limitations of the amended claims.

Fvlbrook; Jason D. et al. (US 20090301927 A1) discloses an organizer tray for medical equipment (¶ [0018], [0019], [0025]); comprising a tray having multiple

compartments (¶ [0040] 37 A tray organizer feature common to all embodiments (first, second, and third) … recessed openings 38, 40, 42, 44, 46); and a syringe (¶ [0109] 12. Rectangular shaped recessed openings for securing appliances such as syringes, scissors … and other miscellaneous items; ¶ [0133] 13. Rectangular shaped recessed opening for securing appliances such as syringes, scissors … alcohol wipes, etc.). However, Fvlbrook lacks a Foley catheter and instead configures the tray to store accessories used by a patient at their bedside (¶ [0023], mounting the organizer tray on an IV pole or bed guard rail; ¶ [0069] organizer trays for holding/securing/locating a plurality of expendable supplies for bed-ridden patients in hospital or home care settings).

Andrich; Daniela (US 20110218520 A1) discloses a catheterization kit including a catheter (¶ [0068], a catheter 10 having a flexible elongate shaft 12; ¶ [0095] FIG. 5 shows how the device of the invention is packaged in a sterile environment ready for use); and a syringe filled with water (¶ [0097] Additionally housed within the external wrapping 104 is a syringe 108 pre-filled with water for lubricating the guidewire 38).

However, Andrich lacks a tray having multiple compartments and instead stores the components in a pair of nested wrappings (¶ [0096] The device of the invention (not shown) is contained within a sterile internal wrapping 90, which is typically made from plastic; ¶ [0097] The internal wrapping 90 is housed within a sterile external wrapping 104, which is typically made of plastic or paper).

Finegold; Aaron N. (US 4460360 A) discloses an instrument and method of applying a local anesthetic to the urethra including a syringe containing a lubricant (col. 3, lines 20-25, The syringe body 12 contains a suitable anesthetic, such as a lidocaine hydrochloride solution or jelly). However, Finegold does not package the syringe in a tray and at most describes a freestanding syringe configured to deliver the lubricant through a lumen of a catheter (col. 3, lines 20-40, The barrel 28 is inserted into the anterior urethra 48 … the anesthetic is applied to the interior walls of first the posterior urethra 46 and then the anterior urethra 48).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

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, Sarah Al-Hashimi can be reached at 571-272-7159. 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

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

CPC - Searched*		
Symbol	**Date**	**Examiner**
B65B11/00, A61B50/30, A61B50/33, A61B2050/3008	09/29/2022	AMM
A61M25/00, A61M25/002, A61M5/002, A61M25/0017, A61M2209/06	09/29/2022	AMM
A61J2205/50, A61L2202/18, A61L2202/182	09/29/2022	AMM
update search	02/22/2023	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	09/29/2022	AMM
Review cited art for related cases 16833575, 15684787, 14793455, 13860902, 13155026, 12647515, 12495148	09/29/2022	AMM
Review Inter Partes Review cases IPR2015-00509, IPR2015-00511, IPR2015-00513, IPR2019-00035, IPR2019-00036, IPR2019-00109	09/29/2022	AMM
update search	02/22/2023	AMM
update search	04/10/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	

Bard Exhibit 1004.1029

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	Art Unit
	Adam M Marcetich	3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	claim keyword search	02/22/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	

Bard Exhibit 1004.1030

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

CPC						
Symbol					**Type**	**Version**
B65B	/	11	/	00	F	2013-01-01
A61M	/	25	/	00	I	2013-01-01
A61B	/	50	/	30	I	2016-02-01
A61B	/	50	/	33	I	2016-02-01
A61M	/	25	/	002	I	2013-01-01
A61M	/	2209	/	06	A	2013-01-01
A61M	/	5	/	002	A	2013-01-01
A61L	/	2202	/	18	A	2013-01-01
A61L	/	2202	/	182	A	2013-01-01
A61J	/	2205	/	50	A	2013-01-01
A61J	/	2205	/	40	A	2013-01-01
A61M	/	25	/	0017	A	2013-01-01
A61B	/	2050	/	3015	A	2016-02-01
A61B	/	2050	/	3008	A	2016-02-01
A61B	/	42	/	00	A	2016-02-01
A61B	/	46	/	00	A	2016-02-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	10 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

U.S. Patent and Trademark Office — Part of Paper No.: 20230410

Bard Exhibit 1004.1031

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

INTERNATIONAL CLASSIFICATION				
CLAIMED				
B65B11/00	/	11	/	00
A61M25/00	/	25	/	00
A61B50/30	/	50	/	30
A61B50/33	/	50	/	33
A61M5/00	/	5	/	00
A61B42/00	/	42	/	00
A61B46/00	/	46	/	00

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	10 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

U.S. Patent and Trademark Office — Part of Paper No.: 20230410

Bard Exhibit 1004.1032

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/944,667	Tomes et al.
	Examiner	**Art Unit**
	Adam M Marcetich	3781

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	10	10	20	19										
2	2	11	11	21	20										
3	3	12	12	22	21										
4	4	13	13	15	22										
5	5	16	14	14	23										
6	6	17	15												
7	7	18	16												
8	8		17												
9	9	19	18												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	22	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	10 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

U.S. Patent and Trademark Office Part of Paper No.: 20230410

Bard Exhibit 1004.1033

Receipt date: 04/06/2023

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
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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16/944,667
	Filing Date	Jul 31, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1C1C1C1C1

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]
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023	
		REIP, DAVID O. , "ReExamination Final Office Action", USSN 90/015,051; Filed June 8, 2022; Patent Under Reexam 9522753; Mailed April 4, 2023	

EXAMINER SIGNATURE

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 04/06/2023

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

PTO/SB/08a (01-10)
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	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1C1C1C1C1

Examiner Signature	/Adam Marcetich/	Date Considered	04/10/2023

*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.

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.

☒ The Director is hereby authorized to charge the fee set forth in 37 CFR 1.17 (p) to Deposit Account No. 50-3608. Additionally, the Director is hereby authorized to charge any underpayment of fees to Deposit Account No. 50-3608.

☐ 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)	2023-04-06
Name/Print	Philip H. Burrus	Registration Number	45,432

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Receipt date: 04/06/2023

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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	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1C1C1C1C1

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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :Simret Direta

Refund Accounting Date:04/18/2023

Effective Date	Sale Item Reference Number	Refund Total
04/06/2023	16944667	$1,360.00

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method	Account Number
I20234H022237920	1801	RCE- 1ST REQUEST	$1,360.00		**********3000

United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :Simret Direta

Sale Adjustment Accounting Date:04/18/2023

Effective Date	Sale Accounting Date	Sale Item Reference Number
04/06/2023	04/18/2023	16944667

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I20234H022237920	1801	RCE- 1ST REQUEST	$1,360.00	

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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/944,667	05/30/2023	11661220	10055UCIP2D1C1C1C1C1C1	8322

189038 7590 05/10/2023

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

The USPTO is implementing electronic patent issuance with a transition period, during which period the USPTO will mail a ceremonial paper copy of the electronic patent grant to the correspondence address of record. Additional copies of the patent (i.e., certified and presentation copies) may be ordered for a fee from the USPTO's Certified Copy Center at https://certifiedcopycenter.uspto.gov/index.html. The Certified Copy Center may be reached at (800)972-6382.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 287 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

Bard Exhibit 1004.1039

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Jennifer E. Tomes, Mundelein, IL;
Sarah Dickinson, Chicago, IL;
Deborah Adler, New York, NY;
Jack Maze, Long Grove, IL;
Alberto Savage, Buffalo Grove, IL;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Medline Industries, LP, Northfied, IL;

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 USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

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, VA 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.
16/944,667	30-MAY-23	11661220

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

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.:	11,661,220
Issue Date:	May 30, 2023
Application No:	16/944,667
Appn. Filed:	July 30, 2020
Examiner:	Marcetich, Adam M.
Art Group:	3781
Reference No.:	BPMDL0005JT CIP2 D1 C1 C1 C1 C1 C1 (10055U CIP2 D1 C1 C1 C1 C1 C1)
Applicants:	Tomes, Jennifer E. et al.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

June 11, 2023

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

REQUEST FOR A CERTIFICATE OF CORRECTION UNDER 37 CFR 1.323
(APPLICANTS MISTAKE)

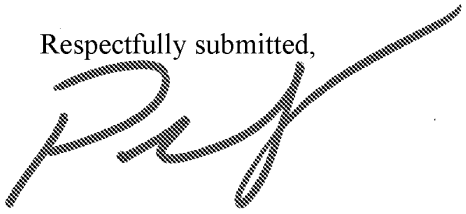
In accordance with the Provisions of 37 CFR §1.323, the Patent and Trademark Office is respectfully requested to issue a Certificate of Correction in the above-identified patent.

It is certified that a typographical error, which occurred without deceptive intent, appears in the above-identified patent in claim 12, as shown in the attached Certificate of Correction.

Applicant certifies that this inadvertent scrivener's error occurred in good faith. Since the changes necessary to correct these errors in the patent would not constitute new matter and would not require re-examination in view of the antecedent basis support for the correction found in claims 8 and 11, the similar limitations found in claims 7 and 15, and the support found in the specification at paragraph [0116] as noted in the remarks filed in this case on February 13, 2023 when the inadvertent typographical error occurred, Applicant respectfully requests for a Certificate of Correction to issue.

The fee under 37 CFR 1.20(a) is included herewith. The Director is authorized to charge any underpayments or credit any overpayments 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

PTO/SB/44 (09-07)
Approved for use through 01/31/2020. OMB 0651-0033
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.
(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,661,220

APPLICATION NO.: 16/944,667

ISSUE DATE : May 30, 2023

INVENTOR(S) : Tomes, Jennifer E.; Dickinson, Sarah; Adler, Deborah; Maze, Jack; Savage, Alberto; Chua, Kenneth; Wilson, Earl; and Kutsch, John

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In claim 12, at line 2, replace “container of water and the container of water” with -- container of water and the container of lubricating jelly --.

MAILING ADDRESS OF SENDER (Please do not use Customer Number below):
Philip H. Burrus, IV
Burrus Intellectual Property Law Group
222 12th Street NE, Suite 1803
Atlanta, Georgia 30309

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. 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 1.0 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: Attention Certificate of Corrections Branch, 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.

Privacy Act Statement

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 disclosure of these records is required by the Freedom of Information Act.
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 Cooperation Treaty.
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.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
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.

Electronic Patent Application Fee Transmittal

Application Number:	16944667
Filing Date:	31-Jul-2020
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:	10055UCIP2D1C1C1C1C1C1

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
CERTIFICATE OF CORRECTION	1811	1	160	160

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**160**

Electronic Acknowledgement Receipt	
EFS ID:	48138812
Application Number:	16944667
International Application Number:	
Confirmation Number:	8322
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:	10055UCIP2D1C1C1C1C1C1
Receipt Date:	12-JUN-2023
Filing Date:	31-JUL-2020
Time Stamp:	16:57:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$160
RAM confirmation Number	E20236BG58138299
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	10055U_CIP2D1C1C1C1C1C1_USA_2023-6-12_CertCorrectionRequest.pdf	273108 0c097e2c890f0c8e7124725081a8c2ea89d5c307	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38268 df1694ff650780d384857719948b15c238b3bfd2	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	311376		

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

CERTIFICATE OF CORRECTION

PATENT NO. : 11,661,220 B2
APPLICATION NO. : 16/944667
DATED : May 30, 2023
INVENTOR(S) : Tomes et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 29, In Claim 12, at Line 2, replace “container of water and the container of water” with -- container of water and the container of lubricating jelly --.

Signed and Sealed this
Eighteenth Day of July, 2023

Katherine Kelly Vidal

Katherine Kelly Vidal
Director of the United States Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.

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

August 30, 2023

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

PETITION CORRECT INVENTORSHIP UNDER 37 CFR §1.324 PURSUANT TO 35 USC §256

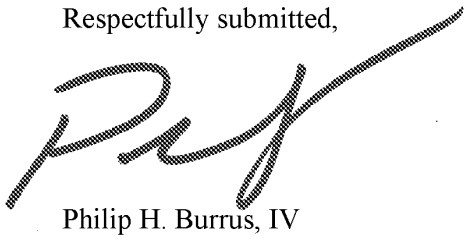
This Petition is filed under 37 CFR §1.324 to correct inventorship of US Patent No. 11,661,220. The Petition is being submitted concurrently with affidavits of the named inventors, and inventors petitioning to be named, and the assignee of record. The Petition Fee is enclosed herewith. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-3608.

Statement of Facts and Request for Relief:

Susan E. Macinnes is petitioning to be added as a named inventor. A declaration from Susan E. Macinnes, in accordance with 37 CFR 1.324(b)(1), is included herewith. Declarations from the named inventors in accordance with 37 CFR 1.324(b)(2) are included herewith. A declaration from the Assignee of record, Medline Industries, LP, in accordance with 37 CFR 1.324(b)(3) is included. The fee in accordance with 37 CFR 1.324(b)(4) is included.

As the requirements of 37 CFR 1.324 have been met, and as the inventorship error of failing to include Susan E. Macinnes as an inventor of the patent occurred without any deceptive intention on the part of Susan E. Macinnes, it is respectfully requested that Susan E. Macinnes be added to this patent via a Certificate of Correction.

Respectfully submitted,



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

Bard Exhibit 1004.1052

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16,944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF MEDLINE INDUSTRIES, LP, ASSIGNEE, PURSUANT TO 37 CFR §1.324

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

I, David S. Noskowicz, declare as follows:

1. I am Patent Counsel for Medline Industries, LP, assignee of one hundred percent (100%) interest in the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I am authorized to sign declarations on behalf of Medline Industries, LP.
3. Medline Industries, LP, is the assignee of the patent by way of an assignment from inventors Jennifer E. Tomes and Sarah Dickinson (formally Sarah Zyburt), which was recorded in the Patent Office at Reel 026750, beginning at Frame 0103 on August 15, 2011, and further by way of another assignment from Deborah Adler, Jack Maze, Alberto Savage, Earl Wilson, John Kutsch, and Kenneth S. Chua to Medline Industries, Inc., which was recorded in the

Patent Office at Reel 022895, beginning at Frame 0331, on June 30, 2009, with a subsequent corporate conversion converting Medline Industries, Inc. to Medline Industries LP, with said conversion being recorded in the Patent Office at Reel 057977, beginning at Frame 0436, on October 31, 2021.

4. Medline Industries, LP, understands that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
5. Medline Industries, LP, the assignee of record, agrees this requested change in inventorship in the patent by way of the addition of Susan E. Macinnes as an inventor.
6. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

David Noskowicz

_____ DATE: 09/20/2023

David S. Noskowicz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

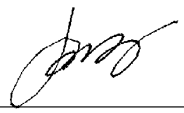
Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF JENNIFER E. TOMES, PURSUANT TO 37 CFR §1.324

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

I, Jennifer E. Tomes, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Jennifer E. Tomes

DATE: 09/27/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF SARAH DICKINSON, PURSUANT TO 37 CFR §1.324

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

I, Sarah Dickinson, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Sarah Dickinson

Sarah Dickinson DATE: 09/19/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF DEBORAH ADLER, PURSUANT TO 37 CFR §1.324

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

I, Deborah Adler, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Deborah Adler

DATE: 11/29/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF JACK MAZE, PURSUANT TO 37 CFR §1.324

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

I, Jack Maze, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Jack E Maze

Jack Maze

DATE: 09/26/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF ALBERTO SAVAGE, PURSUANT TO 37 CFR §1.324

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

I, Alberto Savage, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Alberto Savage

DATE: 09/19/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF KENNETH CHUA, PURSUANT TO 37 CFR §1.324

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

I, Kenneth Chua, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Kenneth Chua

DATE: 09/29/2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF EARL WILSON, PURSUANT TO 37 CFR §1.324

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

I, Earl Wilson, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Earl Wilson

Earl Wilson

DATE: November 17, 2023

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

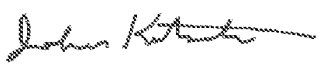
Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.
Title:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF JOHN KUTSCH, PURSUANT TO 37 CFR §1.324

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

I, John Kutsch, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



_____ DATE: 09/21/2023
John Kutsch

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	16/944,667
US Pat. No.:	11,661,220
Examiner:	Marcetich, Adam M
Art Group:	3781
Reference No.:	10055U CIP2 D1 C1 C1 C1 C1 C1
Appn. Filed:	July 31, 2020
First Inventor:	Tomes, Jennifer E.

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

AFFIDAVIT OF SUSAN E. MACINNES, PURSUANT TO 37 CFR §1.324

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

I, Susan E. Macinnes, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,220.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Susan E. Macinnes.

5. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Susan E. Macinnes

Susan E. Macinnes DATE: 09/21/2023

COMBINATION DECLARATION AND ASSIGNMENT FOR UTILITY AND DESIGN APPLICATIONS

United States Patent Rights Plus
All Foreign Rights

INVENTION TITLE:

CATHETER TRAY, PACKAGING SYSTEM, INSTRUCTION INSERT, AND ASSOCIATED METHODS

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

This declaration is directed to the application attached hereto, OR, if the application is not attached hereto, the application is as identified by the attorney docket number as set forth above and/or the following:

United States Application Number 16/944,667, now US Pat. No. 11,661,220;

Which was filed on July 31, 2020.

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 the claimed invention in the application.

I acknowledge the duty to disclose information which is material to the patentability as defined in 37 CFR 1.56, including continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

ASSIGNMENT OF RIGHTS AND AGREEMENT:

WHEREAS, as a below named inventor, I hereby declare that I have invented certain new and useful improvements described in the application identified; and

WHEREAS, Medline Industries, LP, a limited partnership organized and existing under the laws of Illinois, having its principal place of business at Three Lakes Drive, Northfield, IL 60093 (hereinafter referred to as "ASSIGNEE"), is desirous of acquiring my entire right, title and interest in and to the invention, and in and to the said application and any Letters Patent that may issue thereon;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, I do hereby sell, assign and transfer unto ASSIGNEE, its successors, assigns and legal representatives my entire right, title and interest in and to said invention and in and to said applications and all patents which may be granted therefore, and all provisionals, nonprovisionals, continuations, continuations-in-part, divisionals, designs, appeals, reissues, substitutions and extensions thereof; and I hereby authorize and request the Commissioner of Patents and Trademarks to issue all patents for said invention, or patents resulting therefrom, insofar as my interest is concerned, to the said ASSIGNEE of my entire right, title and interest.

Bard Exhibit 1004.1065

I also hereby sell and assign to said ASSIGNEE, its successors, assigns and legal representatives the full and exclusive rights, title and interest to the invention disclosed in said applications throughout the world, including the right to file applications and obtain patents, utility models, industrial models and designs for said invention in its own name throughout the world including all rights of priority, all rights to publish cautionary notices reserving ownership of said invention and all rights to register said invention in appropriate registries; and

I further agree to execute any and all powers of attorney, applications, assignments, declarations, affidavits, and any other papers in connection therewith necessary to perfect such rights, title and interest in ASSIGNEE, its successors, assigns and legal representatives. This includes executing all papers necessary in connection with this application and any continuing, divisional, conversion or reissue applications thereof, and also to execute separate assignments that may be necessary in connection with such applications, as the ASSIGNEE may deem necessary or expedient. I further agree to execute all papers and documents and to perform any act that may be necessary in connection with claims or provisions of the International Convention for the Protection of Industrial Property or similar agreements, and to perform all affirmative acts which may be necessary to obtain a grant of (a) valid United States of America patent(s) or a grant of (a) valid United States of America and any foreign patent(s) to the ASSIGNEE, and to vest all rights therein hereby conveyed to said ASSIGNEE as fully and entirely as the same would have been held by the undersigned if this Assignment and sale had not been made.

I hereby further agree that I will communicate to said ASSIGNEE, or its successors, assigns and legal representatives, any facts known to me respecting any improvements; and, at the expense of said ASSIGNEE, to testify in any legal proceedings, sign all lawful papers, execute all provisional, nonprovisional, continuation, continuation-in-part, divisional, design, appeals, reissue and substitute applications, make all lawful oaths, and generally do everything possible to vest title in said ASSIGNEE and to aid said ASSIGNEE, its successors, assigns and legal representatives to obtain and enforce proper protection for said invention in all countries.

I further authorize and direct the ASSIGNEE and its attorneys to insert above the serial number and filing date of said application now identified as Atty. Docket No. 10055U CIP2 D1 C1 C1 C1 C1 as soon as the same shall have been made known to them by the United States Patent and Trademark Office, and/or to insert any further identification which may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

The undersigned hereby covenants that no assignment, sale, agreement or encumbrance has been or will be made or entered into which would conflict with this assignment.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment of not more than five (5) years, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Bard Exhibit 1004.1066

IN WITNESS WHEREOF, I have hereunto set my hand and seal on 09/21/2023.

Susan E. Macinnes

Name: Susan E. Macinnes

Bard Exhibit 1004.1067

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/944,667	**12/01/2023 05:10:09 PM Z ET**	**10055UCIP2D1C1C1C1C1C1**

Title of Invention

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

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	11661220
CONFIRMATION #	8322	FILED BY	Kayla Burrus
PATENT CENTER #	63448097	FILING DATE	07/31/2020
CUSTOMER #	189038	FIRST NAMED INVENTOR	Jennifer E. Tomes
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Philip Burrus

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
10055U_CIP2_D1C1C1C1C1C1_USA_2023-11-30_Petition.pdf	17	Petition for review by the Technology Center Special Program Examiner(SPRE)	1605 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
10055U_CIP2_D1C1C1C1C1C1_USA_2023-11-30_Petition.pdf	BF92D9FBE7841D6C830C51EE541B86D4B8AD64E108BF0F3FB4EB3B974896A1BC792F3EFFF7E9B79150EAB92E3A230AC540E46B92A5A91620610F5A8CCC14D87F

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 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

P.O. Box 1450
Alexandria, VA 22313 - 1450
www.uspto.gov

ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/944,667	12/01/2023 05:10:09 PM Z ET	10055UCIP2D1C1C1C1C1C1

Title of Invention

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

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	11661220
CONFIRMATION #	8322	FILED BY	Kayla Burrus
PATENT CENTER #	63448097	AUTHORIZED BY	Philip Burrus
CUSTOMER #	189038	FILING DATE	07/31/2020
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Jennifer E. Tomes

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 3000	E2023B1H11135610	Kayla Burrus

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
1816	PROCESSING FEE FOR CORRECTING INVENTORSHIP IN A PATENT	160.00	1	160.00
			TOTAL AMOUNT:	$160.00

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 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.