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(54) **CATHETERIZATION PACKAGES AND METHODS THEREOF**

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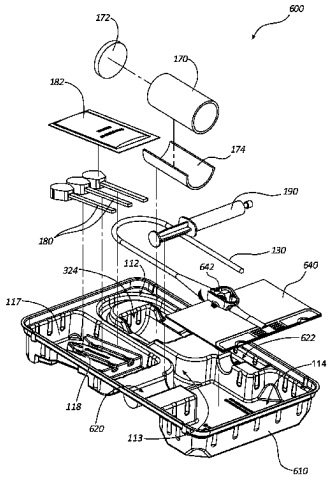
(57) **ABSTRACT**

An intermittent catheter package including a plurality of components and a catheterization tray configured to facilitate a catheterization procedure. The plurality of components include a urinary catheter fluidly connected to a urine-drainage bag and a sampling-port access device configured to fluidly connect to a urine-sampling port of the urinary catheter or the urine-drainage bag for aseptic collection of one or more urine samples.
The catheterization tray includes at least a first compartment, a second compartment, a third compartment, and a fourth compartment. The second compartment is connected to the third compartment Step-by-step surface instructions for performing the catheterization procedure are incorporated into the catheterization tray.

17 Claims, 8 Drawing Sheets



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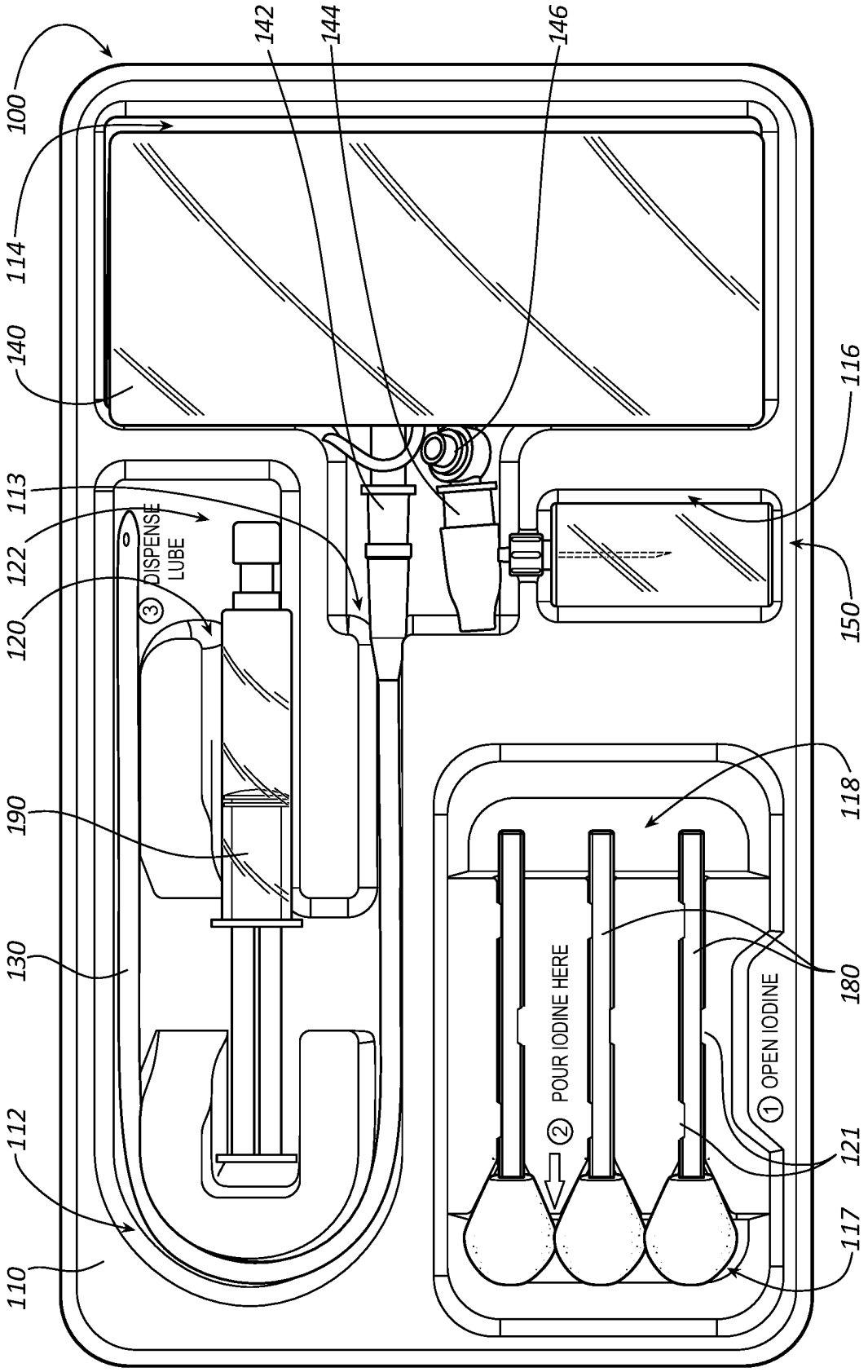
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114
140
142
144
146
116
113
122
120
150
③ DISPENSE LUBE
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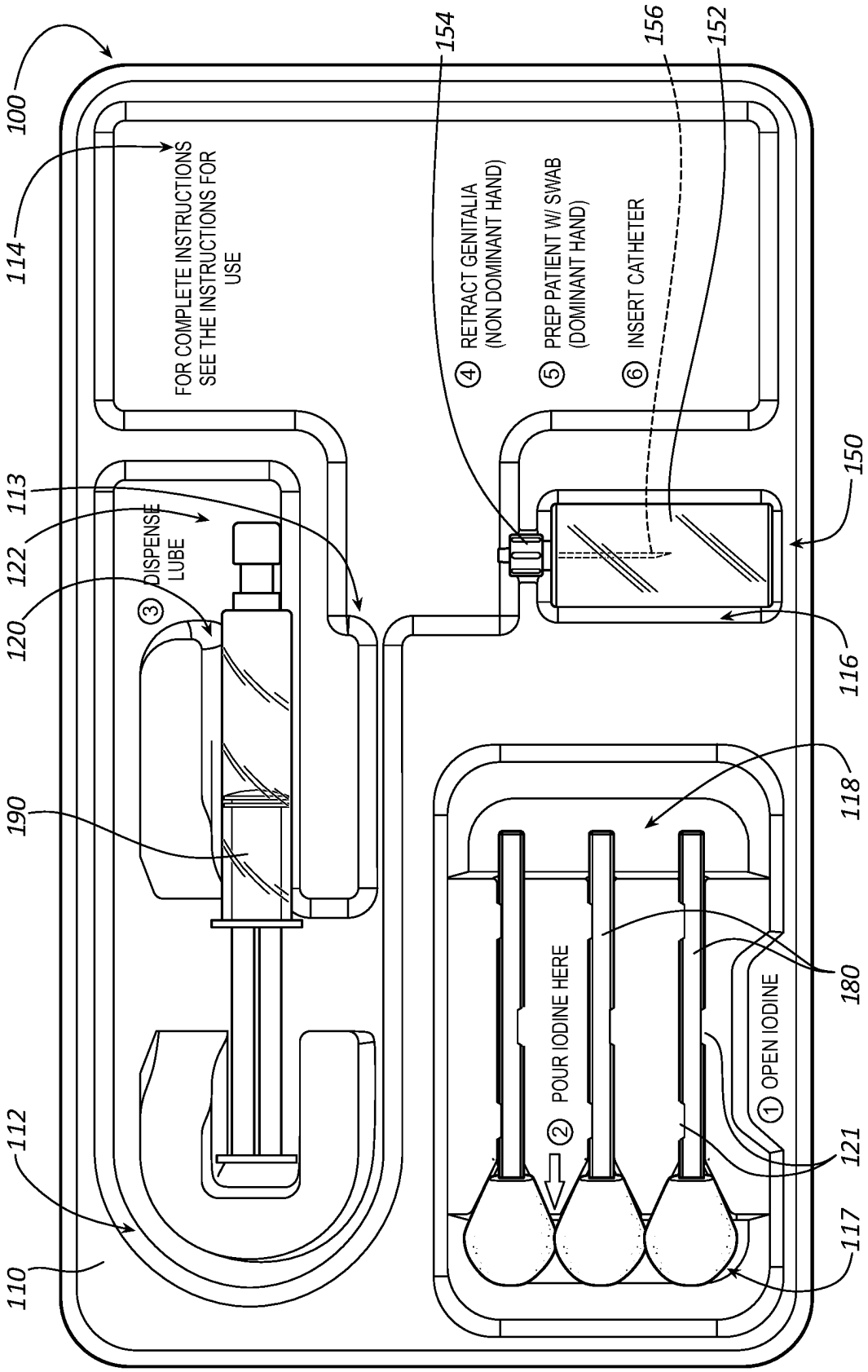
118
130
180
② POUR IODINE HERE
① OPEN IODINE
112
121
110
117

FIG. 1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114
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154
156
152
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⑤ PREP PATIENT W/ SWAB (DOMINANT HAND)
⑥ INSERT CATHETER
150
113
122
③ DISPENSE LUBE
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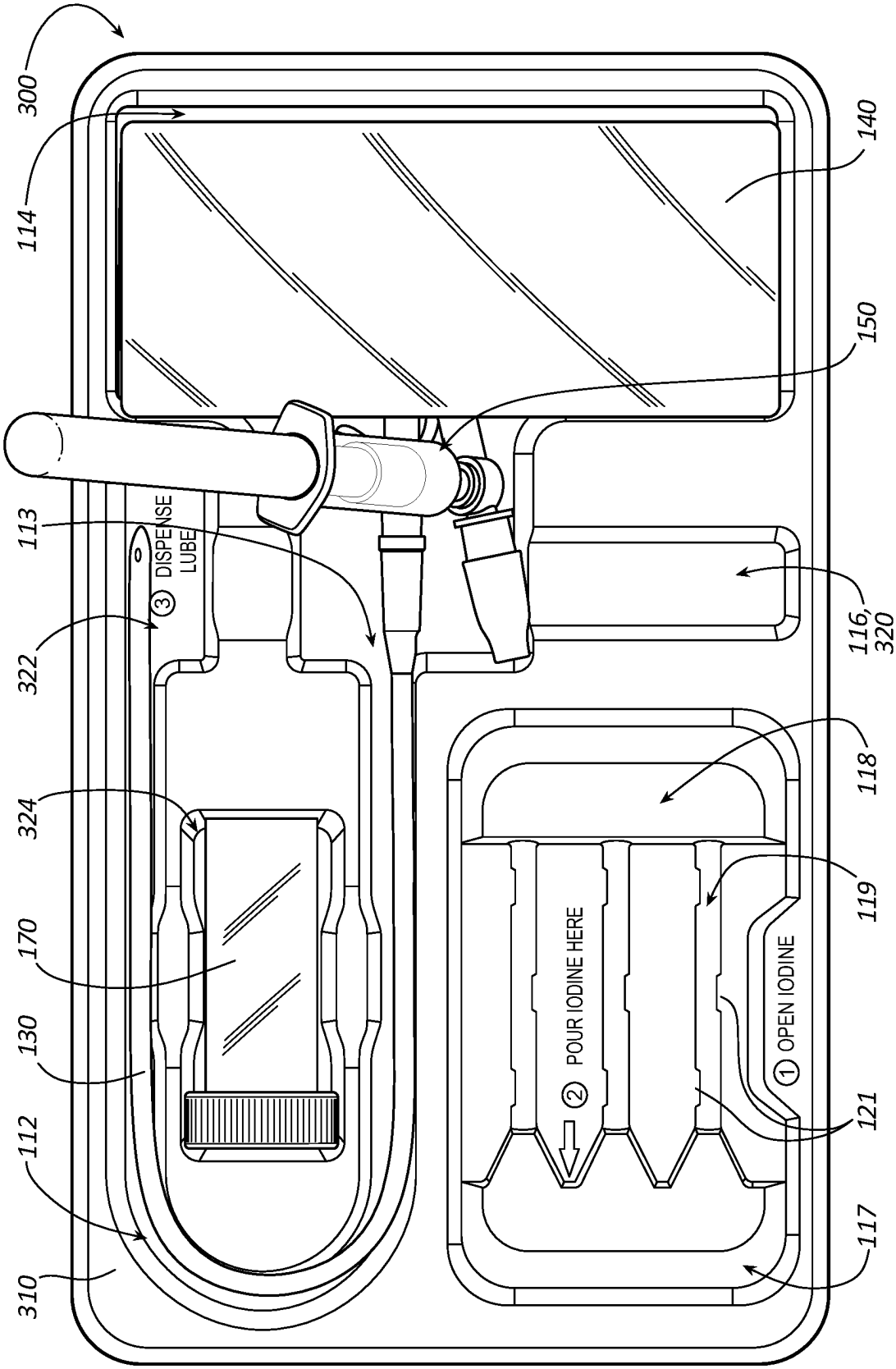
116
190
118
180
② POUR IODINE HERE
① OPEN IODINE
112
121
110
117

FIG. 2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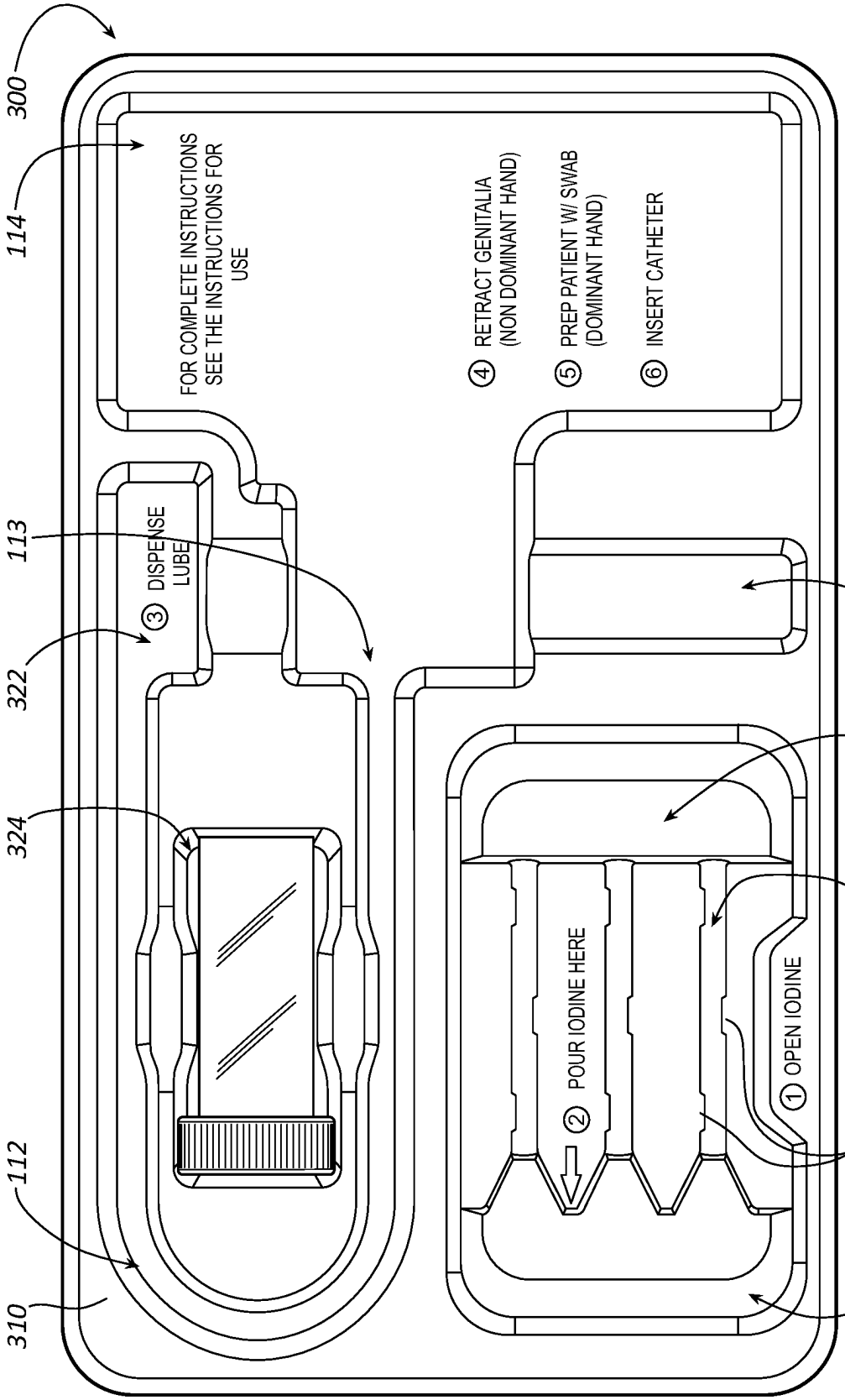
① OPEN IODINE
130
121
112
117
310

FIG. 3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⑤ PREP PATIENT W/ SWAB (DOMINANT HAND)
⑥ INSERT CATHETER
113
③ DISPENSE LUBE
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② POUR IODINE HERE
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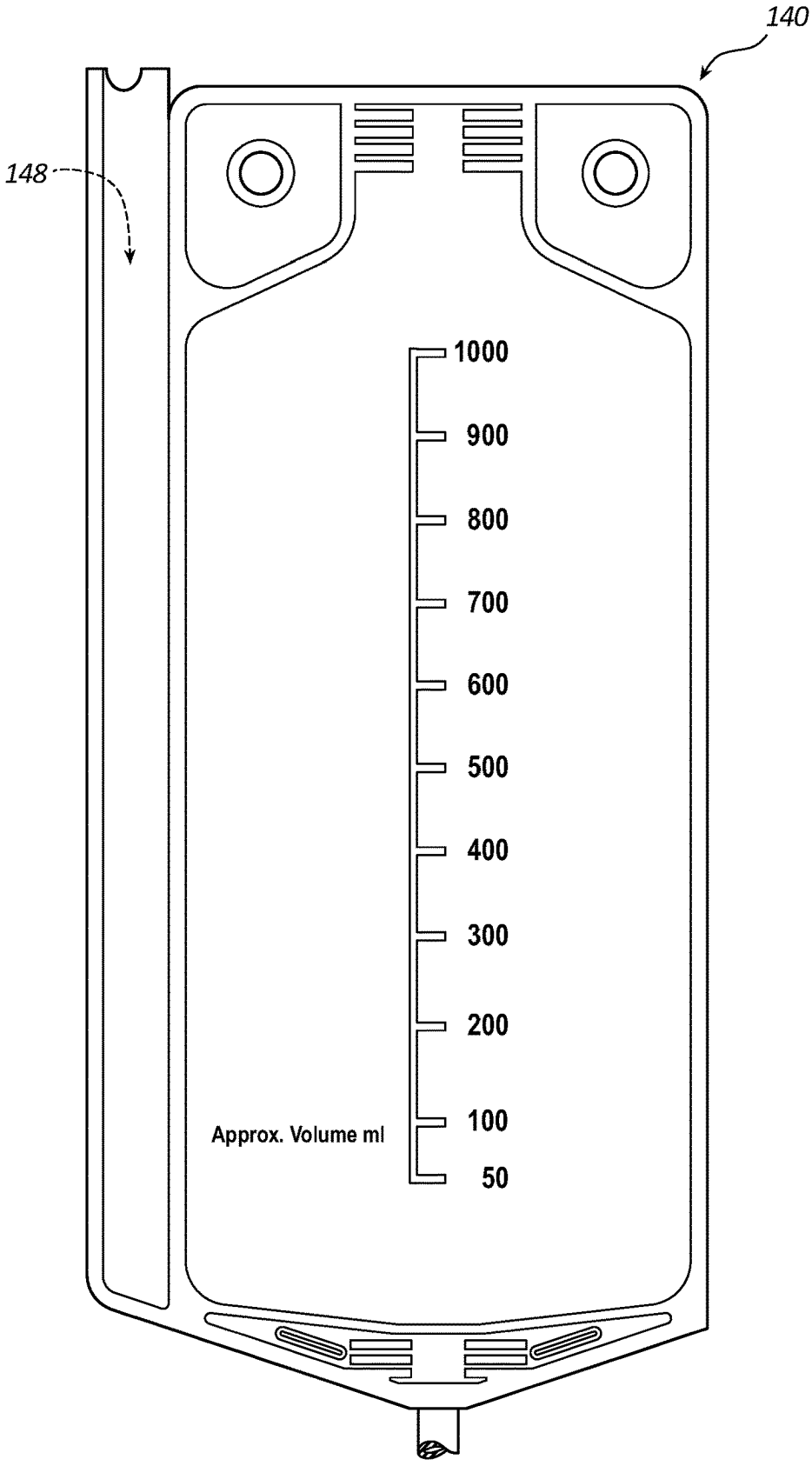
FIG. 4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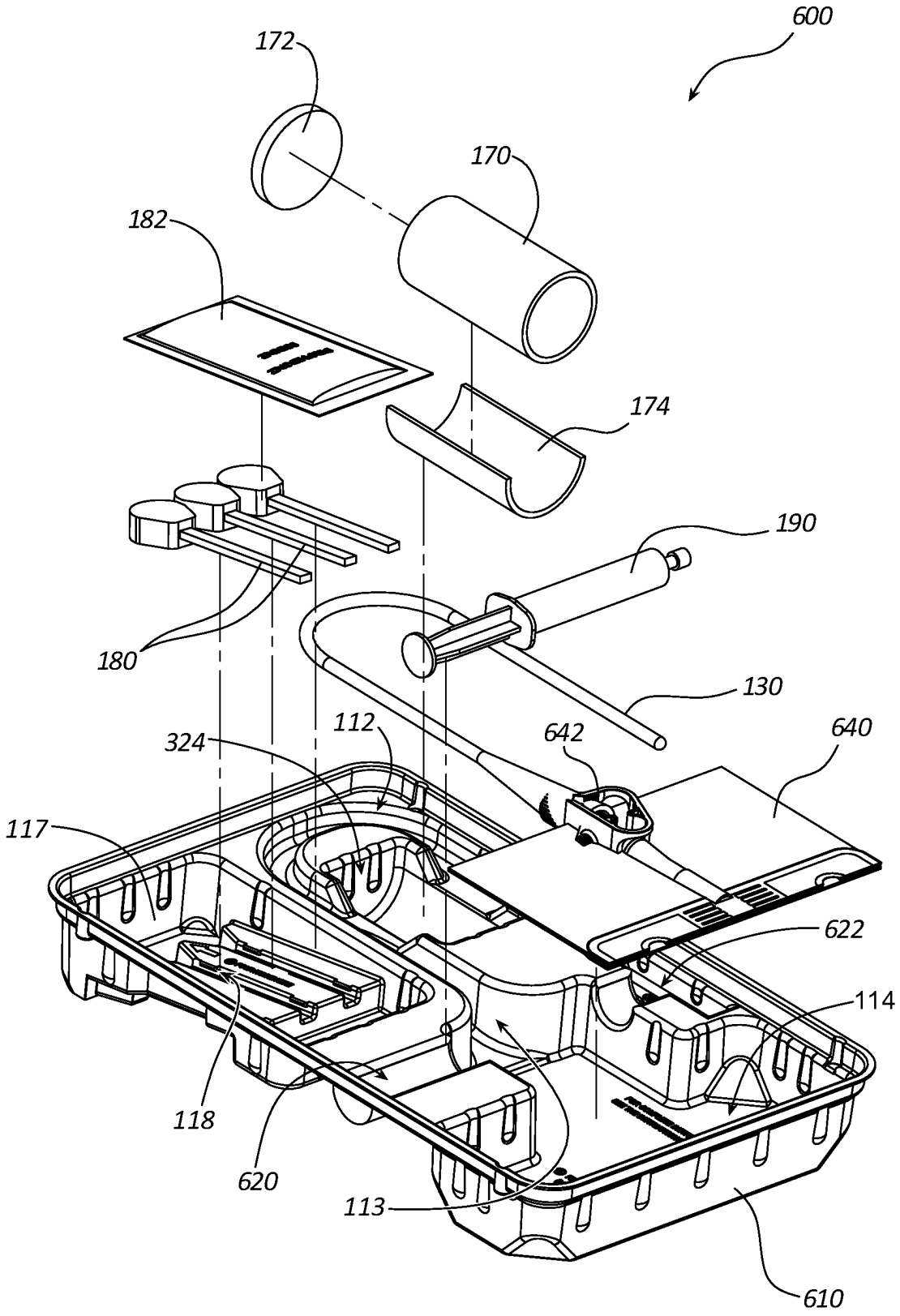
Approx. Volume ml

FIG. 5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620
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610

FIG. 6

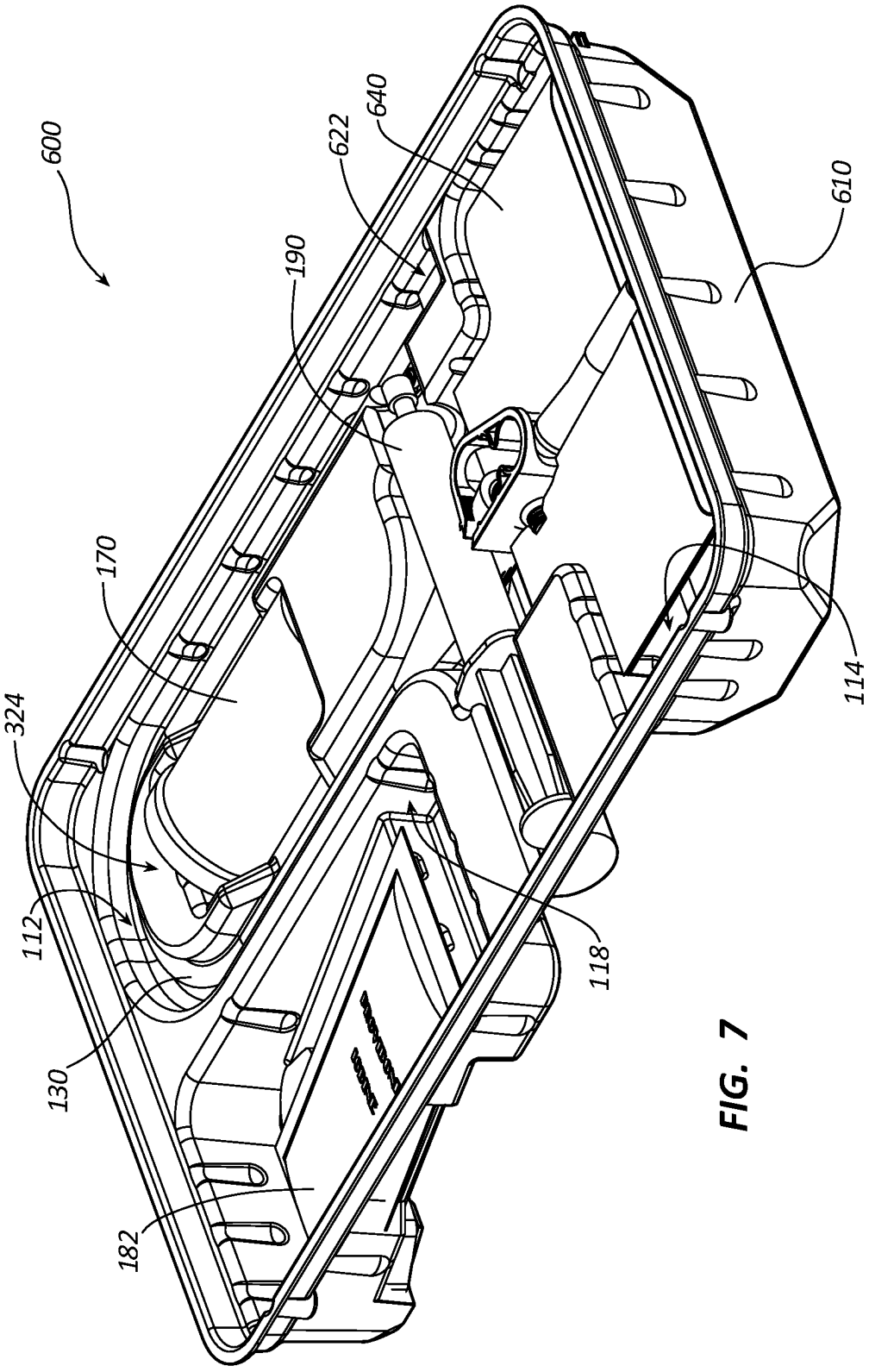
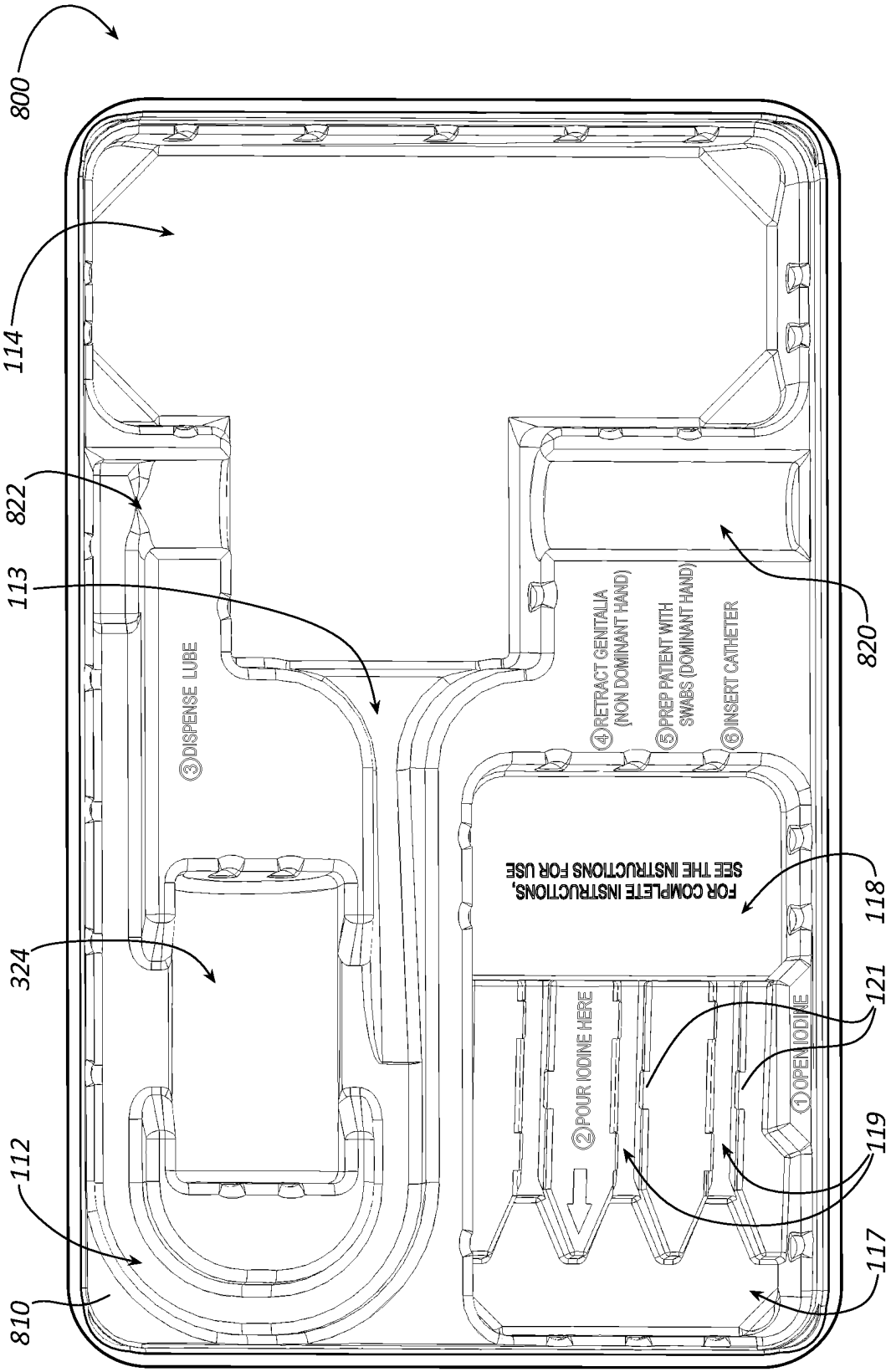


FIG. 7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324
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810
820
118
121
119
117
③DISPENSE LUBE
④RETRACT GENITALIA (NON DOMINANT HAND)
⑤PREP PATIENT WITH SWABS (DOMINANT HAND)
⑥INSERT CATHETER
FOR COMPLETE INSTRUCTIONS, SEE THE INSTRUCTIONS FOR USE
②POUR IODINE HERE
①OPEN IODINE

FIG. 8

CATHETERIZATION PACKAGES AND METHODS THEREOF

PRIORITY

This application is a continuation of U.S. patent application Ser. No. 17/982,288, filed Nov. 7, 2022, now U.S. Pat. No. 11,937,955, which is a division of U.S. patent application Ser. No. 16/639,059, filed Feb. 13, 2020, now U.S. Pat. No. 11,490,983, which is a U.S. national stage application from International Application No. PCT/US2019/028784, filed Apr. 23, 2019, which claims the benefit of priority to U.S. Provisional Patent Application No. 62/662,095, filed Apr. 24, 2018, each of which is incorporated by reference in its entirety into this application.

BACKGROUND

Catheters suitable for draining a patient's bladder include indwelling catheters. Indwelling catheters include Foley catheters, which are typically indicated for surgical and medical patients that require, at least temporarily, assisted bladder voiding. Common indications include acute or chronic urinary retention, medical procedures that may at least temporarily limit a patient's movement, a need for accurate monitoring of fluid input and urine output such as in an intensive care unit ("ICU"), benign prostatic hyperplasia, incontinence, or the effects of various surgical interventions involving the bladder or the prostate.

A standard Foley catheter design includes a balloon disposed at the distal end of the catheter to anchor the catheter in the bladder. The catheter includes at least one lumen to drain urine from the bladder and at least one lumen to inflate the balloon (e.g., with sterile water). The proximal end of the Foley catheter includes at least two ports in communication with the two lumens, a first port that is connected to the drainage lumen and has an interface with fittings for drainage and sampling, and a second port that is connected to the inflation lumen with a valve to ensure the inflation fluid remains within the lumen and balloon once filled. A tip of the standard Foley catheter extends beyond the sides of the balloon into the bladder and includes one or more apertures or "eyes" to drain fluids and debris from the bladder. This standard design has not changed in approximately 100 years, although catheters with various additions (e.g., mechanical anchors, etc.) and improvements have been proposed and investigated.

Catheters suitable for draining a patient's bladder also include intermittent catheters. A typical intermittent catheter differs from an indwelling catheter primarily in that the intermittent catheter does not have a retention balloon or an associated inflation lumen.

Rather, the intermittent catheter is typically a single-lumen device, with a plurality of drainage eyes at the distal end and a funnel at the proximal end. Intermittent catheterization is often performed in individuals with malfunctioning urinary systems (e.g., suffering from strictures and traumas), as well as disabled individuals (e.g., para- or quadriplegics) unable to voluntarily urinate. Such individuals will often self-catheterize with an intermittent catheter several times daily.

Intermittent catheters are generally catheters or tubes having a rounded, atraumatic distal tip that is inserted into the bladder of a patient. A molded funnel is typically connected to the proximal end that remains outside the body of the patient or user. The distal tip may include slots or openings on the shaft to facilitate drainage of urine therefrom once the tip is positioned inside the bladder.

Suitable non-limiting examples of urinary catheters, trays, insertion devices, and the like can be found in, for example, U.S. Pat. Nos. 8,328,792, 8,998,882, 10,758,705, and 10,905,848, the disclosures of which are incorporated herein by reference in their entirety.

Research suggests there is variation in all aspects of urine sampling including where the urine sample is taken from a collection system, how the urine-sampling area is cleaned, what device is used to take the urine sample, and how the urine sample is transferred to the lab. Nursing decision makers believe such variation and improper urine-sampling technique leads to an increased risk of contamination and, therefore, false-positive catheter-associated urinary tract infections ("CAUTIs"). Up to 70% of urine cultures reflect false-positive results leading to inaccurate CAUTI diagnoses and inappropriate antibiotic treatments, as well as artificially undermining the time and resources hospitals have dedicated toward reducing the risk of CAUTI by other means. This problem presents an ongoing challenge to those seeking to reduce CAUTI rates.

Disclosed herein are catheterization packages and methods thereof to facilitate catheterization and urine sampling in an effort to reduce CAUTIs and false-positive results leading to inaccurate CAUTI diagnoses.

SUMMARY

Disclosed herein is a catheterization package including, in some embodiments, catheterization-package components and a catheterization tray configured to facilitate a catheterization procedure. The catheterization-package components include a urinary catheter, a urine-drainage bag fluidly connected to the urinary catheter, and a sampling-port access device. The sampling-port access device is configured to fluidly connect to a urine-sampling port of the urinary catheter or the urine-drainage bag for aseptic collection of one or more urine samples. The catheterization tray includes a number of compartments configured to hold the catheterization-package components. A first compartment of the catheterization tray is configured to hold the urinary catheter. A second compartment of the catheterization tray is connected to the first compartment by an intercompartment connection. The second compartment is configured to hold the urine-drainage bag. A third compartment of the catheterization tray is configured to hold the sampling-port access device. Step-by-step instructions are incorporated into the catheterization tray to facilitate the catheterization procedure.

In some embodiments, the urine-drainage bag includes an inlet port and an outlet port. The outlet port includes the urine-sampling port integrated therein for the aseptic collection of the one or more urine samples with the sampling-port access device.

In some embodiments, the sampling-port access device includes a barrel, a tip at an end of the barrel, and a hollow needle coaxial with the barrel. The tip of the barrel is configured to fluidly connect the sampling-port access device to the urine-sampling port of the urinary catheter or the urine-drainage bag. The needle is fluidly connected to the tip of the barrel, but a tip of the needle is directed away from the tip of the barrel.

In some embodiments, the catheterization components further include one or more septum-stoppered test tubes configured for use with the sampling-port access device.

Each test tube of the one or more test tubes has an internal pressure less than atmospheric pressure. Each test tube is independently configured to include therein a formulation for urinalysis, a formulation for microbiological analysis, or no additives or preservatives.

In some embodiments, the catheterization components further include one or more swabsticks, a package of an antiseptic skin cleanser, or a package of the one or more swabsticks in the antiseptic skin cleanser.

In some embodiments, the catheterization tray further includes an isolated fourth compartment. The fourth compartment is configured to hold the one or more swabsticks, the package of the antiseptic skin cleanser, or the package of the one or more swabsticks in the antiseptic skin cleanser.

In some embodiments, the fourth compartment includes a well and one or more channels with snap-in tabs configured to hold the one or more swabsticks respectively therein. The one or more channels are angled with respect to a top or a bottom of the catheterization tray such that one or more swab heads respectively of the one or more swabsticks are disposed in the well when snapped-in to the one or more channels.

In some embodiments, the catheterization components further include a container containing a lubricant configured for lubricating the urinary catheter in accordance with the catheterization procedure.

In some embodiments, the catheterization tray further includes a fifth compartment at least partially surrounded by the first compartment. The fifth compartment is configured to a hold the container containing the lubricant. The fifth compartment is also configured to a hold the lubricant dispensed therefrom.

In some embodiments, the catheterization components further include a specimen container configured for at least clean collection of one or more urine samples from the urine-drainage bag.

In some embodiments, the catheterization tray further includes a fifth compartment at least partially surrounded by the first compartment. The fifth compartment is configured to a hold the specimen container.

In some embodiments, the catheterization components further include a pair of examination gloves and an underpad.

In some embodiments, the catheterization package further includes packaging for the catheterization package. The packaging includes a piece of paper or paperboard, central supply room ("CSR") wrap, and an outer packaging of the catheterization package. The piece of paper or paperboard is configured to cover the catheterization tray and the catheterization components therein. The CSR wrap is configured to preserve a sterile state of the contents of the catheterization package while the CSR wrap is wrapped around the catheterization tray and the catheterization components therein. The outer packaging is configured to prevent a loss of contents of the catheterization package from a point of assembling the catheterization package to a point of using the catheterization package. The outer packaging is also configured to prevent contamination of the contents of the catheterization package from a point of ethylene-oxide sterilization of the catheterization package to the point of using the catheterization package.

Disclosed herein is a catheterization package including, in some embodiments, catheterization-package components and a molded catheterization tray configured to facilitate a catheterization procedure. The catheterization-package components include a urinary catheter, a urine-drainage bag fluidly connected to the urinary catheter, a sampling-port access device configured to fluidly connect to a urine-sampling port integrated in an outlet port of the urine-drainage bag for aseptic collection of one or more urine samples, one or more swabsticks configured for use with an antiseptic skin cleanser, and a container containing a lubricant configured for lubricating the urinary catheter. The catheterization tray includes a number of compartments configured to hold the catheterization-package components. A urinary-catheter compartment of the catheterization tray is configured to hold the urinary catheter. A urine-drainage-bag compartment of the catheterization tray is connected to the urinary-catheter compartment by an intercompartment connection. The urine-drainage-bag compartment is configured to hold the urine-drainage bag. A sampling-port-access-device compartment of the catheterization tray is configured to hold the sampling-port access device. An isolated skin-cleansing compartment is configured to hold the one or more swabsticks. A catheter-lubrication compartment is substantially surrounded by the urinary-catheter compartment. The catheter-lubrication compartment is configured to a hold the container containing the lubricant. The catheter-lubrication compartment is also configured to hold the lubricant dispensed from the container containing the lubricant. Step-by-step instructions to facilitate the catheterization procedure are embossed on the catheterization tray, printed on the catheterization tray, or embossed on the catheterization tray and printed on the catheterization tray. At least some of the step-by-step instructions for the catheterization procedure are revealed as the catheterization-package components are removed from the catheterization tray.

Also disclosed herein is a method for manufacturing a catheterization package including molding a catheterization tray configured to facilitate a catheterization procedure; incorporating step-by-step instructions into the catheterization tray for the catheterization procedure; and placing catheterization-package components in the catheterization tray. The molding includes molding a urinary-catheter compartment; molding a urine-drainage-bag compartment connected to the urinary-catheter compartment with an intercompartment connection; and molding a sampling-port-access-device compartment. Placing the catheterization-package components in the catheterization tray includes placing a urinary catheter in the urinary-catheter compartment; placing a urine-drainage bag in the urine-drainage-bag compartment; and placing a sampling-port access device in the sampling-port-access-device compartment, wherein the sampling-port access device is configured to fluidly connect to a urine-sampling port of the urinary catheter or the urine-drainage bag for aseptic collection of one or more urine samples. The urine-drainage bag is fluidly connected to the urinary catheter such that when placing the urinary catheter and the urine-drainage bag respectively in the urinary-catheter compartment and the urine-drainage-bag compartment, the urinary catheter is placed across the intercompartment connection.

In some embodiments, placing the catheterization-package components in the catheterization tray further includes placing one or more septum-stoppered test tubes configured for use with the sampling-port access device either over or under the urine-drainage bag in the urine-drainage-bag compartment.

In some embodiments, molding the catheterization tray further includes molding an isolated skin-cleansing compartment.

In some embodiments, placing the catheterization-package components in the catheterization tray further includes placing one or more swabsticks in the skin-cleansing com-

partment, a package of an antiseptic skin cleanser in the skin-cleansing compartment, or a package of the one or more swabsticks in the antiseptic skin cleanser in the skin-cleansing compartment.

In some embodiments, molding the catheterization tray further includes molding a catheter-lubrication compartment at least partially surrounded by the urinary-catheter compartment.

In some embodiments, placing the catheterization-package components in the catheterization tray further includes placing a container containing a lubricant in the catheter-lubrication compartment.

In some embodiments, placing the catheterization-package components in the catheterization tray further includes placing a pair of examination gloves either in or over one or more of the compartments of the catheterization tray; and folding an underpad and placing the underpad over the pair of examination gloves.

In some embodiments, the method further includes placing a piece of paper or paperboard over the catheterization tray including the catheterization components therein to form a paper- or paperboard-covered catheterization tray; wrapping CSR wrap around the paper- or paperboard-covered catheterization tray to form a CSR-wrapped catheterization tray;

placing the CSR-wrapped catheterization tray in an outer packaging to form the catheterization package; and sterilizing the catheterization package by way of ethylene-oxide sterilization.

These and other features of the concepts provided herein will become more apparent to those of skill in the art in view of the accompanying drawings and following description, which disclose particular embodiments of such concepts in greater detail.

BRIEF DESCRIPTION OF DRAWINGS

FIG. **1** illustrates at least a portion of a first catheterization package in accordance with some embodiments.

FIG. **2** illustrates some catheterization components removed from a catheterization tray of the first catheterization package in accordance with some embodiments.

FIG. **3** illustrates at least a portion of a second catheterization package in accordance with some embodiments.

FIG. **4** illustrates some catheterization components removed from a catheterization tray of the second catheterization package in accordance with some embodiments.

FIG. **5** illustrates at least a portion of a urine-drainage bag in accordance with some embodiments.

FIG. **6** illustrates an exploded view of a third catheterization package in accordance with some embodiments.

FIG. **7** illustrates at least a portion of the third catheterization package in accordance with some embodiments.

FIG. **8** illustrates at least a portion of a fourth catheterization package in accordance with some embodiments.

DESCRIPTION

Before some particular embodiments are disclosed in greater detail, it should be understood that the particular embodiments disclosed herein do not limit the scope of the concepts provided herein. It should also be understood that a particular embodiment disclosed herein can have features that can be readily separated from the particular embodiment and optionally combined with or substituted for features of any of a number of other embodiments disclosed herein.

Regarding terms used herein, it should also be understood the terms are for the purpose of describing some particular embodiments, and the terms do not limit the scope of the concepts provided herein. Ordinal numbers (e.g., first, second, third, etc.) are generally used to distinguish or identify different features or steps in a group of features or steps, and do not supply a serial or numerical limitation. For example, "first," "second," and "third" features or steps need not necessarily appear in that order, and the particular embodiments including such features or steps need not necessarily be limited to the three features or steps. Labels such as "left," "right," "top," "bottom," "front," "back," and the like are used for convenience and are not intended to imply, for example, any particular fixed location, orientation, or direction. Instead, such labels are used to reflect, for example, relative location, orientation, or directions. Singular forms of "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

With respect to "proximal," a "proximal portion" or a "proximal end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near a clinician when the catheter is used on a patient. Likewise, a "proximal length" of, for example, the catheter includes a length of the catheter intended to be near the clinician when the catheter is used on the patient. A "proximal end" of, for example, the catheter includes an end of the catheter intended to be near the clinician when the catheter is used on the patient. The proximal portion, the proximal end portion, or the proximal length of the catheter can include the proximal end of the catheter; however, the proximal portion, the proximal end portion, or the proximal length of the catheter need not include the proximal end of the catheter. That is, unless context suggests otherwise, the proximal portion, the proximal end portion, or the proximal length of the catheter is not a terminal portion or terminal length of the catheter.

With respect to "distal," a "distal portion" or a "distal end portion" of, for example, a catheter disclosed herein includes a portion of the catheter intended to be near or in a patient when the catheter is used on the patient. Likewise, a "distal length" of, for example, the catheter includes a length of the catheter intended to be near or in the patient when the catheter is used on the patient. A "distal end" of, for example, the catheter includes an end of the catheter intended to be near or in the patient when the catheter is used on the patient. The distal portion, the distal end portion, or the distal length of the catheter can include the distal end of the catheter; however, the distal portion, the distal end portion, or the distal length of the catheter need not include the distal end of the catheter. That is, unless context suggests otherwise, the distal portion, the distal end portion, or the distal length of the catheter is not a terminal portion or terminal length of the catheter.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by those of ordinary skill in the art.

Disclosed herein are catheterization packages and methods thereof to facilitate catheterization and urine sampling in an effort to reduce CAUTIs and false-positive results leading to inaccurate CAUTI diagnoses.

Catheterization Packages

FIG. **1** illustrates at least a portion of a first catheterization package **100** in accordance with some embodiments. FIG. **2** illustrates some catheterization components removed from a catheterization tray **110** of the first catheterization package

100 in accordance with some embodiments. FIG. 3 illustrates at least a portion of a second catheterization package 300 in accordance with some embodiments. FIG. 4 illustrates some catheterization components removed from a catheterization tray 310 of the second catheterization package 300 in accordance with some embodiments. FIG. 6 illustrates an exploded view of a third catheterization package 600 in accordance with some embodiments. FIG. 7 illustrates at least a portion of the third catheterization package 600 in accordance with some embodiments. FIG. 8 illustrates at least a portion of a fourth catheterization package 800 in accordance with some embodiments.

As shown, the catheterization package 100, 300, 600, or 800 includes the catheterization tray 110, 310, 610, or 810 and the catheterization components set forth below, both of which are configured to facilitate a catheterization procedure. The catheterization package 100, 300, 600, or 800 is configured to facilitate the catheterization procedure by way of the catheterization components included in the catheterization package 100, 300, 600, or 800 how the catheterization components are arranged in the catheterization tray 110, 310, 610, or 810, and step-by-step instructions incorporated into the catheterization tray 110, 310, 610, or 810.

Beginning with the catheterization tray 110, 310, 610, or 810 the catheterization tray110, 310, 610, or 810 includes a number of compartments configured to hold the catheterization components as set forth below.

A urinary-catheter compartment 112 of the catheterization tray 110, 310, 610, or 810 is configured to hold a urinary catheter.

A urine-drainage-bag compartment 114 of the catheterization tray 110, 310, 610, or 810 is connected to the urinary-catheter compartment 112 by an intercompartment connection 113. The urine-drainage-bag compartment 114 is configured to hold at least a urine-drainage bag.

A sampling-port-access-device compartment 116 of the catheterization tray 110 or 310 is configured to hold a sampling-port access device. Alternatively, the sampling-port-access-device compartment 116 of the catheterization tray 310 is a catheter-lubrication compartment 320 configured to a hold a container containing lubricant. The catheterization tray 610 or 810 includes a catheter-lubrication compartment 620 or 820 configured to a hold a container containing lubricant instead of a separate sampling-port-access-device compartment. The catheter-lubrication compartment 320, 620, or 820 is also configured to hold the lubricant dispensed from the container containing the lubricant in a well 322, 622, or 822 shared with the urinary-catheter compartment 112. Due to a lack of a sampling-port-access-device compartment in some embodiments of the catheterization tray 310, 610, or 810, the urine-drainage-bag compartment 114 doubles as the sampling-port-access-device compartment for the catheterization tray 310, 610, or 810 when a sampling-port access device is included in the catheterization packages 300, 600, and 800.

A skin-cleansing compartment 118 of the catheterization tray 110, 310, 610, or 810 is isolated from other compartments of the catheterization tray 110, 310, 610, or 810, which can be important in maintaining a sterile field about at least the urinary-catheter compartment 112. The skin-cleansing compartment 118 is configured to hold one or more swabsticks configured for skin cleansing with an antiseptic skin cleanser, a package of the antiseptic skin cleanser, or a package of the one or more swabsticks in the antiseptic skin cleanser. The skin-cleansing compartment 118 includes a well 117 and one or more channels 119 with snap-in tabs 121 configured to hold the one or more swabsticks respectively therein. The one or more channels 119 are angled with respect to a top or a bottom of the catheterization tray 110, 310, 610, or 810 such that one or more swab heads respectively of the one or more swabsticks are disposed in the well 117 when one or more stick members respectively of the one or more swabsticks are snapped-in to the one or more channels 119. The one or more stick members angle upwardly when snapped-in to the one or more channels 119 such that the one or more stick members can be grabbed and the one or more swabsticks respectively removed from the one or more channels 119. The well 117 is configured to hold the antiseptic skin cleanser therein. When the one or more swab heads are disposed in the well 117 including the antiseptic skin cleanser, the antiseptic skin cleanser saturates the one or more swab heads for antiseptic skin cleansing with the one or more swabsticks, respectively.

A catheter-lubrication compartment 120 of the catheterization tray 110 is at least partially to substantially surrounded by the urinary-catheter compartment 112. The catheter-lubrication compartment 120 is configured to a hold a container containing lubricant. The catheter-lubrication compartment 120 is also configured to hold the lubricant dispensed from the container containing the lubricant in a well 122 shared with the urinary-catheter compartment 112.

A specimen-container compartment 324 of the catheterization tray 310, 610, or 810 is also at least partially to substantially surrounded by the urinary-catheter compartment 112. The specimen-container compartment 324 is configured to a hold a specimen container. Because of the specimen-container compartment 324 in the catheterization tray 310, 610, or 810, the urinary-catheter compartment 112 doubles as the catheter-lubrication compartment for the catheterization tray 310, 610, or 810, which includes the well 322, 622, or 822 configured to hold the lubricant; however, the well 322, 622, or 822 is diminished in size compared to the well 122 of the catheterization tray 110.

The step-by-step instructions incorporated into the catheterization tray 110, 310, 610, or 810 for the catheterization procedure can be incorporated into any of the compartments of the catheterization tray 110, 310, 610, or 810, adjacent any of the compartments of the catheterization tray 110, 310, 610, or 810, or a combination thereof as best shown in FIGS. 2, 4, and 8. For example, a first step of the step-by-step instructions is directed to opening a container or package of an antiseptic skin cleanser such as a povidone-iodine solution, which first step is incorporated into the catheterization tray 110, 310, 610, or 810 adjacent the skin-cleansing compartment 118. A second step of the step-by-step instructions is directed to pouring the antiseptic skin cleanser in the well 117 of the skin-cleansing compartment 118, which second step is incorporated into the skin-cleansing compartment 118. A third step of the step-by-step instructions is directed to dispensing a lubricant in the well 122, 322, 622, or 822, which third step is incorporated into the well 122 of the catheter-lubrication compartment 120 of the catheterization tray 110, the well 322 or 622 of the urinary-catheter compartment 112 of the catheterization tray 310 or 610, or adjacent the well 822 of the urinary-catheter compartment 112 of the catheterization tray 810. A fourth step of the step-by-step instructions is directed to retracting genitalia of a patient, a fifth step of the step-by-step instructions is directed to preparing the patient with a swabstick saturated with the antiseptic skin cleanser, and a sixth step of the step-by-step instructions is directed to inserting a urinary catheter in the patient. Each step of the fourth step, the fifth step, and the sixth step of the step-by-step instructions is incorporated into the urine-drainage-bag compartment 114

of the catheterization tray **110**, **310**, or **610**; however, due to the relatively smaller size of the urine-drainage-bag compartment **114** of the catheterization tray **810**, each step of the fourth step, the fifth step, and the sixth step of the step-by-step instructions is incorporated between the skin-cleansing compartment **118** and the catheter-lubrication compartment **820** of the catheterization tray **810** for greater visibility.

As shown between FIGS. **1** and **2** or FIGS. **3** and **4**, at least some of the step-by-step instructions for the catheterization procedure are revealed as the catheterization components are removed from the catheterization tray **110** or **310**. While not shown, at least some of the step-by-step instructions for the catheterization procedure are also revealed as the catheterization components are removed from the catheterization tray **610** or **810**. Revealing the instructions for the catheterization procedure in this way reduces procedural information to that imminently or immediately needed, which, in turn, reduces potential for informational overload, thereby simplifying the catheterization procedure.

While the catheterization trays **110**, **310**, **610**, and **810** of FIGS. **1-4**, **6**, **7**, and **8** are particular to some catheterization-package embodiments, other embodiments can include a different combination of compartments configured to hold a different combination of catheterization components, fewer compartments configured to hold fewer catheterization components, or more compartments configured to hold more catheterization components. For example, a catheterization tray having more compartments than the catheterization tray **310** can include all three of the sampling-port-access-device compartment **116**, the catheter-lubrication compartment **320**, and the specimen-container compartment **324**. Such a configuration can include the catheterization tray **310** with the catheter-lubrication compartment **320** and the urine-drainage-bag compartment **114** shown in FIG. **3** but with an additional compartment (not shown) corresponding to the sampling-port-access-device compartment **116** between the catheter-lubrication compartment **320** and the urine-drainage-bag compartment **114**.

The catheterization tray **110**, **310**, **610**, or **810** can be formed by way of, for example, injection molding, whereby each of the compartments are simultaneously formed in the catheterization tray **110**, **310**, **610**, or **810**; however, the catheterization tray **110**, **310**, **610**, or **810** is not limited to being formed by injection molding or even molding itself. If molding is used to form the catheterization tray **110**, **310**, **610**, or **810**, the step-by-step instructions can also be simultaneously formed in or on catheterization tray **110**, **310**, **610**, or **810** as embossed step-by-step instructions. The step-by-step instructions can also be printed on the catheterization tray **110**, **310**, **610**, or **810**, either in the absence of the embossed step-by-step instructions or over the embossed step-by-step instructions to improve a contrast of the step-by-step instructions with respect to the catheterization tray **110**, **310**, **610**, or **810**.

Adverting to the catheterization components for which the catheterization tray **110**, **310**, **610**, or **610** is configured, the catheterization components can include, but are not limited to a urinary catheter **130**, a urine-drainage bag **140** or **640**, a sampling-port access device **150**, one or more septum-stoppered test tubes **160**, a specimen container **170**, one or more swabsticks **180**, a container containing a lubricant **190**, or a combination thereof as set forth below.

The urinary catheter **130** can be an indwelling catheter such as a Foley catheter or an intermittent catheter as shown, description for each of which is set forth above. The urinary catheter **130** is optionally already fluidly connected to the urine-drainage bag **140** or **640** in the catheterization package **100**, **300**, **600**, or **800**, which simplifies the catheterization procedure and reduces risk of inadvertently contaminating the urinary catheter **130** such as by connecting the urinary catheter **130** to the urine-drainage bag **140** or **640**.

FIG. **5** illustrates at least a portion of the urine-drainage bag **140** in accordance with some embodiments.

The urine-drainage bag **140** includes an inlet port **142** and an outlet port **144**. The outlet port **144** includes a urine-sampling port **146** integrated therein for aseptic collection of one or more urine samples with the sampling-port access device **150**. As shown in FIG. **5**, the urine-drainage bag **140** also includes an optional channel **148** configured to receive an intermittent catheter such as the urinary catheter **130** following use thereof for disposing the intermittent catheter with the urine-drainage bag **140**.

The urine-drainage bag **640** is different than the urine-drainage bag **140** with respect to at least the arrangement of the urine-sampling port, which is integrated in the inlet port of the urine-drainage bag **640** instead of the outlet port like the urine-drainage bag **140**. In addition, a tubing clamp **642** is integrated with the urine-drainage bag **640** such that the tubing clamp **642** is configured to clamp the inlet port between the urine-sampling port and a bag portion of the urine-drainage bag **640**, thereby preventing any urine already present in the urine-drainage bag **640** from being sampled through the urine-sampling port. Such a configuration for the urine-drainage bag **640** ensures urine samples from the urine-sampling port are fresh from the urinary catheter **130**.

The sampling-port access device **150** is configured to fluidly connect to a urine-sampling port of the urinary catheter **130** (e.g., a urine-sampling port of a Foley catheter) or the urine-sampling port **146** of the urine-drainage bag **140** for the aseptic collection of one or more urine samples. The sampling-port access device **150** includes a barrel **152**, a tip **154** at an end of the barrel **152**, and a hollow needle **156** coaxial with the barrel **152**. The tip **154** of the barrel **152** is configured to fluidly connect the sampling-port access device **150** to the urine-sampling port of the urinary catheter or the urine-sampling port **146** of the urine-drainage bag **140**. (See FIG. **3** for the sampling-port access device **150** fluidly connected to the urine-sampling port **146** of the urine-drainage bag **140**.) The needle **156** is fluidly connected to the tip **154** of the barrel **152**, but a tip of the needle **156** is directed away from the tip **154** of the barrel **152**.

The one or more septum-stoppered test tubes **160** are configured for use with the sampling-port access device **150**. Each test tube of the one or more test tubes **160** has an internal pressure less than atmospheric pressure such that urine from the urine-sampling port of the urinary catheter **130** or the urine-sampling port **146** of the urine-drainage bag **140** aspirates into the test tube when certain conditions are met. For example, urine aspirates into the test tube when the urine drainage bag **140** is at least partially filled with urine, the tip **154** of the sampling-port access device **150** is fluidly connected to the urine-sampling port **146** of the urine-drainage bag **140**, and a septum stopper of the test tube is punctured by the needle **156** of the sampling-port access device **150**. Each test tube is independently configured to include therein a formulation for urinalysis, a formulation for microbiological analysis, or no additives or preservatives.

The specimen container **170** is configured for at least clean collection of one or more urine samples from the urine-drainage bag **140** or **640** such as through the outlet port **144** of the urine-drainage bag **140**, thereby providing an

alternative to the aseptic collection of the one or more urine samples as wanted or needed. As shown in at least FIG. **6**, the specimen container **170** includes a cap **172** configured to seal a urine sample in the specimen container **170**. A label **174** is optionally included in the catheterization package **100**, **300**, **600**, or **800** for labeling the specimen container **170** in accordance with any urine sample therein. The clean collection of the one or more urine samples makes use of the outlet port **144** of the urinary-drainage bag **140** and the specimen container **170** to reduce the transfer of microorganisms from health care personnel and the environment to the one or more urine samples. However, the aseptic collection of the one or more urine samples requires use of the sampling port of the urinary catheter or the sampling port **146** of the urine-drainage bag **140**, the sampling-port access device **150**, and the one or more test tubes **160** to not only reduce but prevent the transfer of microorganisms from health care personnel and the environment to the one or more urine samples.

The one or more swabsticks **180** are configured for skin cleansing with an antiseptic skin cleanser. The one or more swabsticks **180** are optionally already snapped-in to the one or more channels **119** of the skin-cleansing compartment **118** by the respective one or more stick members in the catheterization package **100**, **300**, **600**, or **800**. While only shown in FIGS. **6** and **7**, the catheterization package **100**, **300**, **600**, or **800** can include a package of an antiseptic skin cleanser **182**, the antiseptic skin cleanser being, for example, a povidone-iodine solution for pouring in the well **117** of the skin-cleansing compartment **118** to saturate one or more swab heads respectively of the one or more swabsticks **180** for the skin cleansing. Alternatively, the one or more swabsticks **180** are packaged in the package of the antiseptic skin cleanser **182**.

The container containing the lubricant **190** can be a syringe of a lubricating jelly configured to facilitate lubricating the urinary catheter **130** in the well **122** of the catheter-lubrication compartment **120** of the catheterization tray **110** or the well **322**, **622**, or **822** of the urinary-catheter compartment **112** of the catheterization tray **310**, **610**, or **810** in accordance with the catheterization procedure.

While not shown, the catheterization components for which the catheterization tray **110**, **310**, **610**, or **810** is configured can further include, but are not limited to, one or more pairs of examination gloves and an underpad. The one or more pairs of gloves and the underpad are configured for use during the catheterization procedure such as during the skin cleansing with the antiseptic skin cleanser, lubricating the urinary catheter **130** with the lubricant in the container containing the lubricant **190**, insertion of the urinary catheter **130** in the patient, or the like. The one or more pairs of gloves can be disposed in or over any of the compartments of the catheterization tray **110**, **310**, **610**, or **810**. The underpad can be folded and placed under the one or more pair of gloves, between the one or more pair of gloves, or over the one or more pairs of gloves.

While not shown, the catheterization package **100**, **300**, **600**, or **800** further includes packaging for the catheterization package **100**, **300**, **600**, or **800**. The packaging includes a piece of paper or paperboard, CSR wrap, and an outer packaging of the catheterization package **100**, **300**, **600**, or **800**.

The piece of paper or paperboard is configured to cover the catheterization tray **110**, **310**, **610**, or **810** and the catheterization components therein. FIGS. **1-4**, **6**, and **7** illustrate a lip around the catheterization tray **110**, **310**, **610**, or **810**, upon which lip the piece of paper or paperboard is configured to sit. Optionally, the piece of paper or paperboard includes product information or additional instructions to the step-by-step instructions printed thereon.

The CSR wrap is configured to preserve a sterile state of at least the catheterization components of the catheterization package **100**, **300**, **600**, or **800** while the CSR wrap is wrapped around the catheterization tray **110**, **310**, **610**, or **810** and the catheterization components therein.

The outer packaging is configured to prevent a loss of contents of the catheterization package **100**, **300**, **600**, or **800** from a point of assembling the catheterization package **100**, **300**, **600**, or **800** to a point of using the catheterization package **100**, **300**, **600**, or **800**. The outer packaging is also configured to prevent contamination of the contents of the catheterization package **100**, **300**, **600**, or **800** from a point of ethylene-oxide sterilization of the catheterization package **100**, **300**, **600**, or **800** to the point of using the catheterization package **100**, **300**, **600**, or **800**.

Methods

A method for manufacturing the catheterization package **100**, **300**, **600**, or **800** includes molding the catheterization tray **110**, **310**, **610**, or **810**; incorporating the step-by-step instructions into the catheterization tray **110**, **310**, **610**, or **810** for the catheterization procedure; and placing the catheterization components in the catheterization tray **110**, **310**, **610**, or **810**. The molding includes molding the urinary-catheter compartment **112**; molding the urine-drainage-bag compartment **114** connected to the urinary-catheter compartment **112** with the intercompartment connection **113**; and, for at least the catheterization tray **110** and some embodiments of the catheterization tray **310**, molding the sampling-port-access-device compartment **116**. Placing the catheterization components in the catheterization tray **110**, **310**, **610**, or **810** includes placing the urinary catheter **130** in the urinary-catheter compartment **112**; placing the urine-drainage bag **140** in the urine-drainage-bag compartment **114**; and placing the sampling-port access device **150** in the sampling-port-access-device compartment **116** if such a compartment exists. Otherwise, the sampling-port access device **150** can be placed in the urine-drainage-bag compartment **114** as needed. The urinary catheter **130** is fluidly connected to the urine-drainage bag **140** such that when placing the urinary catheter **130** and the urine-drainage bag **140** respectively in the urinary-catheter compartment **112** and the urine-drainage-bag compartment **114**, the urinary catheter **130** is placed across the intercompartment connection **113**.

Placing the catheterization components in the catheterization tray **110**, **310**, **610**, or **810** can further include placing the one or more septum-stoppered test tubes **160** for use with the sampling-port access device **150** either over or under the urine-drainage bag **140** in the urine-drainage-bag compartment **114**.

Molding the catheterization tray **110**, **310**, **610**, or **810** can further include molding the isolated skin-cleansing compartment **118**.

Placing the catheterization components in the catheterization tray **110**, **310**, **610**, or **810** can further include placing the one or more swabsticks **180** in the skin-cleansing compartment **118**, a package of an antiseptic skin cleanser **182** in the skin-cleansing compartment **118**, or a package of the one or more swabsticks **180** in the antiseptic skin cleanser in the skin-cleansing compartment **118**.

Molding the catheterization tray **110**, **310**, **610**, or **810** can further include molding the catheter-lubrication compartment **120** at least partially surrounded by the urinary-

catheter compartment **112** or the catheter-lubrication compartment **320**, **620**, or **820** between the skin-cleansing compartment **118** and the urine-drainage-bag compartment **114**.

Placing the catheterization components in the catheterization tray **110**, **310**, **610**, or **810** can further include placing the container containing the lubricant **190** in the catheter-lubrication compartment **120**, **320**, **620**, or **820**.

Placing the catheterization components in the catheterization tray **110**, **310**, **610**, or **810** can further include placing the one or more pairs of examination gloves either in or over one or more of the compartments of the catheterization tray **110**, **310**, **610**, or **810**; and folding the underpad and placing the underpad over the one or more pairs of examination gloves.

The method can further include placing a piece of paper or paperboard over the catheterization tray **110**, **310**, **610**, or **810** including the catheterization components therein to form a paper- or paperboard-covered catheterization tray; wrapping CSR wrap around the paper- or paperboard-covered catheterization tray to form a CSR-wrapped catheterization tray; placing the CSR-wrapped catheterization tray in an outer packaging to form the catheterization package **100**, **300**, or **600**; and sterilizing the catheterization package **100**, **300**, **600**, or **800** by way of ethylene-oxide sterilization.

While some particular embodiments have been disclosed herein, and while the particular embodiments have been disclosed in some detail, it is not the intention for the particular embodiments to limit the scope of the concepts provided herein. Additional adaptations and/or modifications can appear to those of ordinary skill in the art, and, in broader aspects, these adaptations and/or modifications are encompassed as well. Accordingly, departures may be made from the particular embodiments disclosed herein without departing from the scope of the concepts provided herein.

What is claimed is:

1. A method of performing a catheterization procedure, comprising:

opening an intermittent catheter package, the intermittent catheter package comprising:

a lubricant container including a lubricant disposed therein;

a urinary catheter coupled to a urine-drainage bag; and

a catheterization tray including surface instructions for performing the catheterization procedure, the catheterization tray comprising:

a first compartment accommodating the lubricant container;

a second compartment accommodating the urinary catheter, the second compartment wrapped around the first compartment; and

a third compartment accommodating the urine-drainage bag, the third compartment connected to the second compartment; and

acting according to the surface instructions for performing the catheterization procedure in an order corresponding to the surface instructions.

2. The method according to claim **1**, wherein the catheterization tray comprises an isolated fifth compartment designed to accommodate a plurality of swabsticks, the isolated fifth compartment comprising a plurality of channels with snap-in tabs configured to hold the plurality of swabsticks respectively therein, and wherein the plurality of channels are angled with respect to a top or a bottom of the catheterization tray, the method further comprising removing one or more of the plurality of swabsticks from the plurality of channels.

3. The method according to claim **2**, wherein the isolated fifth compartment includes a well, wherein each of the plurality of swabsticks includes a swab head, wherein each swab head is disposed in the well, and wherein acting according to the surface instructions comprises opening an iodine package and pouring it into the well to contact each swab head.

4. The method according to claim **3**, further comprising cleansing an insertion area with one or more of the plurality of swabsticks prior to insertion of the urinary catheter.

5. The method according to claim **1**, wherein the first compartment is sized to accommodate a specimen container, the method further comprising collecting a urine sample from the urine-drainage bag.

6. The method according to claim **1**, wherein the intermittent catheter package further comprises a pair of examination gloves and an underpad, the method further comprising donning the examination gloves and positioning the underpad prior to acting according to the surface instructions.

7. The method according to claim **1**, wherein the intermittent catheter package further comprises paperboard covering the catheterization tray, the method further comprising removing the paperboard from the catheterization tray to reveal the first compartment, the second compartment, the third compartment, and a fourth compartment.

8. The method according to claim **7**, wherein the intermittent catheter package further comprises central supply room ("CSR") wrap around the catheterization tray and the paperboard, the method further comprising removing the CSR wrap to reveal the catheterization tray and the paperboard.

9. The method according to claim **8**, wherein the intermittent catheter package further comprises an outer packaging enclosing the catheterization tray, the paperboard, and the CSR wrap, the method further comprising opening the outer packaging and removing the catheterization tray, the paperboard, and the CSR wrap.

10. The method according to claim **1**, wherein the first compartment comprises an area designed to receive lubricant, and wherein acting according to the surface instructions comprises removing the lubricant container from the first compartment and dispensing lube in the area designed to receive lubricant.

11. The method according to claim **1**, wherein the surface instructions include directions under the urine-drainage bag, the method further comprising removing the urine-drainage bag from the third compartment of the catheterization tray to reveal the directions, wherein acting according to the surface instructions includes following the directions.

12. The method according to claim **11**, wherein the directions include:

retract genitalia (non-dominant hand);

prep patient w/swab (dominant hand); and

insert catheter.

13. The method according to claim **1**, wherein the surface instructions include a directive to consult the surface instructions for use in order to see complete instructions for performing the catheterization procedure.

14. The method according to claim **1**, further comprising a sampling-port access device, wherein the catheterization tray further comprises a fourth compartment accommodating the sampling-port access device, the method further

comprising fluidly connecting the sampling-port access device to a urine-sampling port of the urinary catheter or the urine-drainage bag.

15. The method according to claim **14**, wherein the urine-drainage bag includes an inlet port and an outlet port, the outlet port including an integrated urine-sampling port, the method further comprising collecting a urine sample with the sampling-port access device via the integrated urine-sampling port.

16. The method according to claim **15**, wherein the sampling-port access device includes a barrel, a tip at an end of the barrel configured to fluidly connect the sampling- port access device to the urine-sampling port of the urine-drainage bag, and a hollow needle coaxial with the barrel, the hollow needle fluidly connected to, but directed away from, the tip of the barrel, the method further comprising connecting the tip of the barrel to the sampling-port access device.

17. The method according to claim **16**, wherein the intermittent catheter package further comprises one or more test tubes configured for use with the sampling-port access device, each of the one or more test tubes having an internal pressure less than atmospheric pressure, wherein each of the one or more test tubes includes a formulation for urinalysis, a formulation for microbiological analysis, or no additives or preservatives, the method further comprising coupling the one or more test tubes to the sampling-port access device.

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