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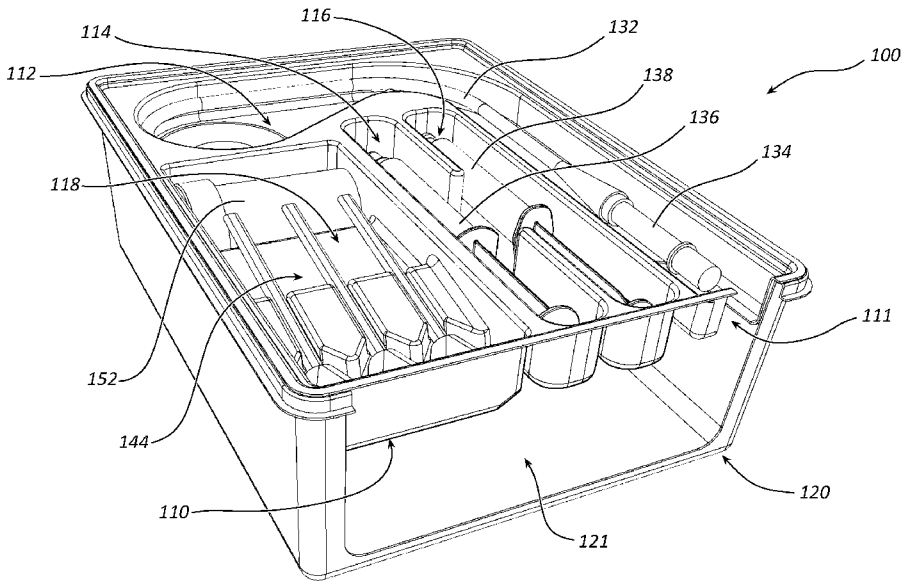


FIG. 1A

(57) Abstract: Urinary catheter-insertion kits disclosed herein can include a working tray, a storage tray, a urinary catheter, and a drainage system including drainage tubing and a drainage receptacle. The working tray can be configured to nest with the storage tray by suspending the working tray from the storage tray. At least the working tray includes a number of preformed sections configured to hold a number of components of the urinary catheter-insertion kit. At least one section of the preformed sections of the working tray includes a catheter section configured to hold the urinary catheter. The storage tray can be configured to hold the drainage system. Also disclosed herein are methods of urinary catheterization with the urinary catheter- insertion kits.

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URINARY CATHETER-INSERTION KITS WITH INTEGRATED INSTRUCTIONS FOR USE AND METHODS THEREOF

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 62/687,656, filed June 20, 2018, and to U.S. Provisional Application No. 62/724,292, filed August 29, 2018, each of which is incorporated by reference in its entirety into this application.

BACKGROUND

[0001] Urinary catheters are used in healthcare facilities such as hospitals to drain urine from patients. However, the second most common form of hospital-acquired infection ("HAI") is catheter-associated urinary tract infection ("CAUTI"). As such, hospitals are interested in ways to cut their CAUTI rates by conforming to strict aseptic techniques as part of their standard of care. But there are many factors that influence a hospital's ability to meet that standard of care. These factors include aspects of healthcare-practitioner training and experience, patient factors (e.g., general health, weight, and anatomy), environmental factors, and characteristics of urinary catheter-insertion kits including components of the kits, various layouts of the components in the kits, and instructions for use of such kits. There is a need in healthcare for an easy, safe, and reliable standard method for inserting a catheter into a patient. Disclosed herein are catheter-insertion kits, including urinary catheter insertion kits, with integrated instructions for use and methods thereof that address the foregoing.

SUMMARY

[0002] Disclosed herein is urinary catheter-insertion kit including, in some embodiments, a working tray, a storage tray, a catheter (by way of non-limiting example, a fluid drainage catheter, such as a urinary catheter), and a drainage system including drainage tubing and a drainage receptacle. The working tray is configured to nest with the storage tray by suspending the working tray from the storage tray. According to some embodiments, the working tray is fixed to the storage tray to at least substantially prevent their separation. At least the working tray includes a number of preformed sections configured to hold a number of components of the urinary catheter-insertion kit. At least one section of the preformed sections of the working tray includes a catheter section configured to hold the catheter. The storage tray is configured to hold the drainage system.

[0003] In some embodiments, suspending the working tray from the storage tray includes inserting folded-over longitudinal edges or tabs of a paperboard storage tray in a gap between longitudinal sides and an overhang of the working tray. The gap includes a number of protrusions configured to engage the folded-over longitudinal edges or tabs of the paperboard storage tray and fasten together the working tray and the storage tray.

[0004] In some embodiments, the storage tray includes a cutout in an end of the storage tray. The cutout in the end of the storage tray is configured to facilitate access to any of the components of the urinary catheter-insertion kit stored in the storage tray while working from the working tray.

[0005] In some embodiments, the working tray includes a cutout in a corner area of the catheter section formed between a bottom portion and an end portion of the catheter section. The cutout in the corner area of the catheter section is configured to allow the drainage tubing to pass from the storage tray to the working tray by way of a bottom of the cutout when the drainage tubing is stored in the storage tray. According to other embodiments, there is no cut-out but instead the working tray edge nearest the cut-out end of the storage tray is short enough to permit the drainage tubing to extend from the storage tray to the working tray.

[0006] In some embodiments, a side of the cutout in the corner area of the catheter section is configured to allow the drainage tubing to be removed from the storage tray without disconnecting the drainage tubing from the catheter when the drainage tubing and the catheter are pre-connected in the urinary catheter-insertion kit.

[0007] In some embodiments, the working tray includes a drainage-tubing constriction between the cutout in the corner area of the catheter section and a remainder of the catheter section. The drainage-tubing constriction is configured to hold a portion of the drainage tubing and maintain an initial placement of the urinary catheter in the working tray until the urinary catheter is used.

[0008] In some embodiments, the urinary catheter-insertion kit further includes a connector configured to connect the catheter to the drainage tubing. The connector is pre-connected to at least the catheter in the urinary catheter-insertion kit. The connector includes a urine-sampling port.

[0009] In some embodiments, the urinary catheter-insertion kit further includes a lubricant container including lubricant for the catheter. At least one section of the preformed sections of the working tray includes a lubricant-container section configured to hold the lubricant container.

[0010] In some embodiments, the urinary catheter-insertion kit further includes an inflatant container including an inflatant for inflating a balloon of the catheter. At least one section of the preformed sections of the working tray includes an inflatant-container section configured to hold the inflatant container.

[0011] In some embodiments, the urinary catheter-insertion kit further includes a genital-preparation kit including a package of an antiseptic and one or more swab sticks. At least one section of the preformed sections of the working tray includes a genital-preparation section configured with a well to hold the antiseptic from the package. The genital-preparation section also includes one or more angled channels to respectively hold the one or more swab sticks with their corresponding one or more absorbent heads in the well.

[0012] In some embodiments, the well is dimensioned to have a volume commensurate with an entire volume of the antiseptic from the package plus a volume of the one or more absorbent heads such that the one or more absorbent heads become saturated with the antiseptic when the antiseptic from the package is dispensed in the well.

[0013] In some embodiments, the urinary catheter-insertion kit further includes a urine-sampling container. At least one section of the preformed sections of the working tray includes a urine sampling-container section configured to hold the urine-sampling container. Alternatively, the storage tray is configured to hold the urine-sampling container instead of the working tray.

[0014] In some embodiments, the urinary catheter-insertion kit further includes step-by-step catheterization instructions imprinted directly on at least the working tray.

[0015] In some embodiments, the urinary catheter-insertion kit further includes an instruction to not separate the working tray from the storage tray along with the step-by-step catheterization instructions imprinted directly on at least the working tray.

[0016] In some embodiments, the urinary catheter-insertion kit further includes protective paperboard configured to protect at least the components of the working tray. The working tray includes a lip around a perimeter of the working tray configured to hold the paperboard.

[0017] In some embodiments, the urinary catheter-insertion kit further includes a peri-care kit. The urinary catheter-insertion kit is configured to include the peri-care kit between the paperboard and an outer packaging of the urinary catheter-insertion kit.

[0018] Also disclosed herein is urinary catheter-insertion kit including, in some embodiments, a working tray including a Foley catheter, a lubricant-filled syringe for lubricating the catheter, a saline-filled syringe for inflating a balloon of the catheter, a genital-preparation kit including a package of an antiseptic and one or more swab sticks, and a urine-sampling container; a storage tray including a drainage system including drainage tubing and a drainage receptacle; and step-by-step catheterization instructions imprinted directly on at least the working tray. At least the working tray includes a number of preformed sections holding a number of components of the urinary catheter-insertion kit. At least one section of the preformed sections of the working tray includes a catheter section including the catheter, a lubricant-syringe section including the lubricant-filled syringe, a saline-syringe section including the saline-filled syringe, and a genital-preparation section including the package of the antiseptic and the one or more swab sticks. At least one section of the preformed sections of the working tray includes a urine sampling-container section including the urine-sampling container. Alternatively, the storage tray is configured to hold the urine-sampling container instead of the working tray. The genital-preparation section is configured with a well to hold the antiseptic from the package. The genital-preparation section also includes one or more angled channels holding the one or more swab sticks with their absorbent heads in the well. The working tray is configured to nest with the storage tray by suspending the working tray from the storage tray. The working tray includes a cutout in a corner area of the catheter section formed between a bottom portion and an end portion of the catheter section. The drainage system is pre-connected to the catheter through a connector having a urine-sampling port. The cutout in the corner area of the catheter section is configured to allow the drainage tubing to pass from the storage tray where the drainage system is stored to the working tray by way of a bottom of the cutout in the corner area of the catheter section.

[0019] In some embodiments, the working tray includes a drainage-tubing constriction between the cutout in the corner area of the catheter section and a remainder of the catheter section. The drainage-tubing constriction is configured to hold a portion of the drainage tubing and maintain an initial placement of the urinary catheter in the working tray until the urinary catheter is used.

[0020] Also disclosed herein is a method of urinary catheterization with a urinary catheter-insertion kit including, in some embodiments, removing an outer packaging from the urinary catheter-insertion kit, cleaning a patient's perianal area with a peri-care kit, preparing the patient's genital area using a genital-preparation kit, and catheterizing the patient with a Foley catheter. Removing the outer packaging from the urinary catheter-insertion kit bares a working tray suspendedly nested with a storage tray with step-by-step catheterization instructions imprinted directly on at least the working tray. The working tray includes a number of preformed sections holding a number of components for the method of urinary catheterization with the urinary catheter-insertion kit. Removing the outer packaging from the urinary catheter-insertion kit also bares a protective paperboard configured to protect the components of the urinary catheter-insertion kit in the working tray under the paperboard. Cleaning the patient's perianal area with the peri-care kit includes removing the peri-care kit from between the outer packaging of the urinary catheter-insertion kit and the paperboard over the working tray. Preparing the patient's genital area using the genital-preparation kit includes using a package of an antiseptic and one or more swab sticks of the genital-preparation kit. Preparing the patient's genital area includes removing the package of the antiseptic from a genital-preparation section of the working tray and dispensing the antiseptic into a well of the genital-preparation section, thereby saturating one or more absorbent heads of one or more corresponding swab sticks respectively held in one or more angled channels of the genital-preparation section. Catheterizing the patient with the catheter includes removing the catheter from a catheter section of the working tray and a drainage system from the storage tray without disconnecting the catheter from either drainage tubing or a drainage receptacle of the drainage system.

[0021] In some embodiments, the working tray includes a cutout in a corner area of the catheter section formed between a bottom portion and an end portion of the catheter section. The cutout enables removing both the catheter from the catheter section of the working tray

and the drainage system from the storage tray without disconnecting the catheter from the drainage system.

[0022] In some embodiments, the method further includes removing the drainage tubing from a drainage-tubing constriction in the working tray between the cutout in the corner area of the catheter section and a remainder of the catheter section.

[0023] In some embodiments, dispensing the antiseptic into the well of the genital-preparation section of the working tray is in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

[0024] In some embodiments, preparing the patient's genital area includes retracting the patient's genitals using a non-dominant hand and swabbing the patient's genitals with the antiseptic using a dominant hand in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

[0025] In some embodiments, the method further includes removing a lubricant-filled syringe from a lubricant-syringe section of the working tray, dispensing the lubricant from the lubricant-filled syringe into the catheter section of the working tray, and lubricating the catheter with the lubricant dispensed in the lubricant-syringe section of the working tray. At least dispensing the lubricant into the catheter section and lubricating the catheter with the lubricant dispensed in the catheter section of the working tray are in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

[0026] In some embodiments, the method further includes removing a saline-filled syringe from a saline-syringe section of the working tray and attaching the saline-filled syringe to the catheter for inflating a balloon of the catheter. At least attaching the saline-filled syringe to the catheter is in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

[0027] In some embodiments, catheterizing the patient includes inserting the catheter into the patient's urethra and inflating the balloon with saline from the saline-filled syringe. At least inflating the balloon with saline from the saline-filled syringe is in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

[0028] 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.

DRAWINGS

[0029] FIG. 1A provides a perspective view of a urinary catheter-insertion kit including at least some components in a working tray of the urinary catheter-insertion kit in accordance with some embodiments.

[0030] FIG. 1B provides a top view of the urinary catheter-insertion kit of FIG. 1A.

[0031] FIG. 1C provides a first cross-sectional view of the urinary catheter-insertion kit of FIG. 1A.

[0032] FIG. 1D provides a second cross-sectional view of the urinary catheter-insertion kit of FIG. 1A.

[0033] FIG. 2A provides a perspective view of alternative nested trays of a urinary catheter-insertion kit in accordance with some embodiments.

[0034] FIG. 2B provides a top view of the nested trays of FIG. 2A.

[0035] FIG. 3A provides a perspective view of alternative nested trays of a urinary catheter-insertion kit in accordance with some embodiments.

[0036] FIG. 3B provides a top view of the nested trays of FIG. 3A.

[0037] FIG. 4A illustrates a perspective view of a urinary catheter-insertion kit.

[0038] FIG. 4B illustrates another view of the urinary catheter-insertion kit.

[0039] FIG. 5 illustrates a urinary catheter insertion kit in accordance with some embodiments.

[0040] FIG. 6A provides a perspective view of alternative nested trays of a urinary catheter-insertion kit in accordance with some embodiments.

[0041] FIG. 6B provides a top view of an alternative working tray of a urinary catheter-insertion kit in accordance with some embodiments.

[0042] FIG. 6C provides a top view of an unfolded paperboard precursor of an alternative storage tray of a urinary catheter-insertion kit in accordance with some embodiments.

[0043] FIG. 7 provides a cross section of a tray fastening mechanism for fastening together the alternative nested trays of FIG. 6A in accordance with some embodiments.

DESCRIPTION

[0044] 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.

[0045] 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,” “front,” “back,” “top,” “bottom,” “forward,” “reverse,” “clockwise,” “counter clockwise,” “up,” “down,” or other similar terms such as “upper,” “lower,” “aft,” “fore,” “vertical,” “horizontal,” “proximal,” “distal,” 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] Urinary catheters are used in healthcare facilities such as hospitals to drain urine from patients. However, the second most common form of hospital-acquired infection ("HAI") is catheter-associated urinary tract infection ("CAUTI"). As such, hospitals are interested in ways to cut their CAUTI rates by conforming to strict aseptic techniques as part of their standard of care. But there are many factors that influence a hospital's ability to meet that standard of care. These factors include aspects of healthcare-practitioner training and experience, patient factors (e.g., general health, weight, and anatomy), environmental factors, and characteristics of urinary catheter-insertion kits including components of the kits, various layouts of the components in the kits, and instructions for use of such kits. There is a need in healthcare for an easy, safe, and reliable standard method for inserting a urinary catheter into a patient. Disclosed herein are urinary catheter-insertion kits with integrated instructions for use and methods thereof that provide an easy, safe, and reliable standard method for inserting a urinary catheter into a patient, thereby reducing CAUTI rates.

Urinary Catheter-Insertion Kits

[0050] FIG. 1A provides a perspective view of a urinary catheter-insertion kit 100 including at least some components in a working tray 110 of the urinary catheter-insertion kit 100 in accordance with some embodiments. FIGS. 1B-1D provide different views of the urinary catheter-insertion kit 100 of FIG. 1A. Additional components not shown in FIGS. 1A-1D that are useful in the urinary catheter-insertion kit 100 can be found in U.S. Patent Publication Nos. US 2016/0228676 and US 2017/0216558, each of which is incorporated by reference in its entirety into this application. Such components can include, but are not limited to, any one or more components selected from a stabilization device (e.g., C. R. Bard, Inc.'s StatLock® Foley stabilization device), prepping balls (e.g., absorbent cotton balls), forceps, a label that can be filled out with catheterization or urine-sampling details, a fenestrated drape to place over a patient, an underpad to place under the patient, gloves (e.g., a package of latex or latex-free gloves), a sterile wrap (e.g., Central Supply Room ["CSR"] wrap) to wrap around the working and storage trays, a belly band (e.g., to hold the sterile wrap in place around the working and storage trays), hand sanitizer, moist towelettes (e.g., a package of castile-soap towelettes), additional instructions to those imprinted on at least the working tray (e.g., an instruction sheet for a clinician, an instruction pamphlet for the patient, etc.), a checklist of safety considerations, a patient information chart, an insert sheet, and a packaging label. FIGS. 2A and 2B provide different views of alternative nested trays of the urinary catheter-insertion kit 100 in accordance with some embodiments. FIGS. 3A and 3B provide different views of further alternative nested trays of the urinary catheter-insertion kit 100 in accordance with some embodiments. FIG. 6A provides a perspective view of yet further alternative trays of the urinary catheter-insertion kit 100 in accordance with some embodiments.

[0051] The urinary catheter-insertion kit 100 can include a working tray 110, a storage tray 120, a urinary catheter 132 (e.g., a Foley catheter), and a drainage system (not shown) including drainage tubing and a drainage receptacle (e.g., drainage bag, optionally including a urine meter). (*See* U.S. Patent Publication Nos. US 2016/0228676 and US 2017/0216558 for description of the drainage system, which can include a urine meter in addition to the drainage tubing and the drainage receptacle.)

[0052] The working tray 110 can be configured to nest with the storage tray 120 by suspending the working tray 110 from the storage tray 120. At least the working tray 110 can include a number of preformed sections configured to respectively hold a number of

components of the urinary catheter-insertion kit 100. For example, at least one section of the preformed sections of the working tray 110 can include a catheter section 112 configured to hold the catheter 132.

[0053] The storage tray 120 can include an opening such as a cutout 121 in an end of the storage tray 120. The opening such as the cutout 121 in the end of the storage tray 120 can be configured to facilitate access to any of the components of the urinary catheter-insertion kit 100 stored in the storage tray 120 while working from the working tray 110. For example, until needed, the drainage system can be stored in the storage tray 120 while working from the working tray 110. The opening or the cutout 121 also allows access to a bottom of the working tray 110, if needed, to lift the working tray 110 out of the storage tray 120 while supporting the bottom of the working tray 110. That said, the working tray 110 can be fixed (e.g., fastened, bonded, etc.) to the storage tray 120 in some embodiments. In such embodiments, the urinary catheter-insertion kit 100 is designed such that the working tray 110 remains fixed to the storage tray 120 throughout a catheterization procedure. Indeed, as shown in FIG. 6B, an instruction can be included along with step-by-step catheterization instructions imprinted directly on at least the working tray 110 to not separate the working tray 110 from the storage tray 120.

[0054] The storage tray 120 of FIG. 6A is a folded paperboard storage tray of the urinary catheter-insertion kit 100. FIG. 6C provides an unfolded paperboard precursor to the foregoing folded paperboard storage tray. Once the paperboard precursor is folded along the fold lines shown, the resulting storage tray 120 includes folded-over longitudinal edges configured to engage a number of protrusions (*see* FIG. 6A) molded into the working tray 110, thereby forming a portion of a fastening mechanism (*see* FIG. 7) for fastening together the working tray 110 and the storage tray 120. As an alternative to the folded-over longitudinal edges, the paperboard precursor of FIG. 6C can include a number of tabs along the longitudinal edges thereof configured to form upon folding the paperboard precursor a number of folded-over tabs configured to engage the number of protrusion molded into the working tray 110.

[0055] The working tray 110 can include a cutout 111 in a corner area of the catheter section 112 formed between a bottom portion and an end portion of the catheter section 112. The cutout 111 in the corner area of the catheter section 112 can be configured to allow, for example, the drainage tubing of the drainage system to pass from the storage tray 120 to the working tray 110 by way of a bottom of the cutout 111 when the drainage tubing is stored in

the storage tray 120. A side of the cutout 111 in the corner area of the catheter section 112 can be configured to allow the drainage tubing to be removed from the storage tray 120 without disconnecting the drainage tubing from the catheter 132 when the drainage system and the catheter 132 are pre-connected in the urinary catheter-insertion kit 100 as set forth below. In contrast, if the end portion of the catheter section 112 is intact and the cutout 111 consists of only the bottom portion of the catheter section 112 (i.e., the cutout 111 is a hole in the bottom portion of the catheter section 112), the drainage tubing and, subsequently, the catheter 132 would have to be pulled through the cutout 111 when the drainage system and the catheter 132 are pre-connected, which risks contamination of the catheter 132. Alternatively, the drainage tubing would have to be disconnected from the catheter 132 when the drainage system and the catheter 132 are pre-connected, which also risks contamination of the catheter 132 by way of either disconnecting the drainage tubing from the catheter 132 or reconnecting the drainage tubing to the catheter 132.

[0056] The working tray 110 can include a drainage-tubing constriction 113 between the cutout 111 in the corner area of the catheter section 112 and a remainder of the catheter section 112 as shown in FIG. 6B. The drainage-tubing constriction 113 can be configured to hold a portion of the drainage tubing when the drainage system and the catheter 132 are pre-connected. By holding the drainage tubing in the drainage-tubing constriction 113, an initial or as-manufactured placement of the foregoing pre-connected urinary catheter 132 in the working tray 110 can be maintained until the urinary catheter 120 is used for urinary catheterization. As shown, the drainage-tubing constriction 113 can include snap-in tabs configured to hold the drainage tubing in the drainage-tubing constriction 113.

[0057] The working tray 110 can include a number of lugs 104 projecting from a bottom side of the working tray 110. Each lug of the number of lugs 104 also forms a well in a top side of the working tray 110 as shown in FIG. 6A. Notably, while the number of lugs 104 are shown in sets of three about the working tray 110 such as the four sets of three lugs 104 respectively at or near the four corners of the working tray 110, only one lug of each set of lugs 104 is present in any particular working tray 110. For example, a first lug of each set of lugs 104 can be present in a first working tray 110, a second lug of each set of lugs 104 can be present in a second working tray 110, and a third lug of each set of lugs 104 can be present in a third working tray 110, not one of which working trays matches another on account of the number of lugs 104. Indeed, the number of lugs 104 are configured to prevent two or more

working trays including the number of lugs 104 to nest too tightly together such as after molding (e.g., thermoforming) two or more of the foregoing working trays and nesting them together.

[0058] The working tray 110 can include a number of indentations 108 in at least longitudinal sides of the working tray 110, as viewed from within a working area of the working tray 110. (*See*, for example, FIGS. 6A and 7.) The number of indentations 108 correspondingly provide a number of projections between at least the longitudinal sides of the working tray 110 and an overhang 122 (*see* FIG. 7) of the working tray 120, thereby forming another portion of the fastening mechanism for fastening together the working tray 110 and the storage tray 120. With the overhang 122, the working tray 110 is configured for insertion of the folded-over longitudinal edges or tabs of the storage tray 120 of FIG. 6A in a gap between the longitudinal sides of the working tray 110 and the overhang 122. As shown, the number of projections provided by way of the number of indentations 108 are configured to engage the folded-over longitudinal edges or tabs of the storage tray 120, thereby fastening together the working tray 110 and the storage tray 120 and preventing separation thereof. Notably, the gap between the longitudinal sides and the overhang 122 of the working tray 110 are dimensioned to provide the folded-over longitudinal edges or tabs of the storage tray 120 room to expand under a spring force within folds of the folded-over longitudinal edges or tabs created by forcing the longitudinal edges or tabs into longitudinal sides of the paperboard of the storage tray 120. In addition, the number of protrusions protrude as sharply as molding (e.g., thermoforming) allows making engaging surfaces of the number of protrusions as flat as possible for engaging the folded-over longitudinal edges or tabs of the storage tray 120. The foregoing fastening mechanism shown in FIG. 7 obviates a need for a secondary mechanism (e.g., bonding) for fastening the working tray 110 and the storage tray 120 together.

[0059] The catheter 132 can be pre-connected to the drainage system to minimize any potential failures in connecting the catheter 132 to the drainage system, which, in turn, can minimize any potential contamination. Between the catheter 132 and the drainage tubing, a connector 134 can be used to connect the catheter 132 and the drainage tubing. The connector 134 can include a urine-sampling port configured to facilitate urine sampling.

[0060] At least one section of the preformed sections of the working tray 110 can include a lubricant well 109 configured to hold lubricant dispensed into the lubricant well 109 for lubricating the catheter 132. For example, the embodiments of FIGS. 1A-1D, 3A, and 3B include the lubricant well 109 as part of the catheter section 112. Alternatively, the working tray 110 does not include the lubricant well 109 but includes another section additionally configured for lubricating the catheter 132. For example, the embodiment of FIGS. 2A and 2B do not include the lubricant well 109 as part of the catheter section 112 but include additional space in place of the lubricant well 109 to hold dispensed lubricant for lubricating the catheter 132.

[0061] The urinary catheter-insertion kit 100 can further include a lubricant container 136 (e.g., syringe, packet, pod, vial, etc.) including, containing, or filled with lubricant for the catheter 132. At least one section of the preformed sections of the working tray 110 can include a lubricant-container section 114 (e.g., lubricant-syringe section, lubricant-packet section, lubricant-pod section, lubricant-vial section, etc.) configured to hold the lubricant container 136. The lubricant-container section 114 can be preformed to accommodate the lubricant container 136; however, the lubricant-container section 114 need not conform to every feature of the lubricant container 136. For example, if the lubricant container 136 is a syringe, the lubricant-container section 114 (e.g., lubricant-syringe section) need not include a recess for a flange of the syringe. That is, the lubricant-container section 114 can have a constant width or depth commensurate with at least the flange of the syringe to accommodate the syringe. Indeed, the lubricant-container section 114 can have a constant width or depth commensurate with the greatest width or diameter of any type lubricant container 136 set forth herein.

[0062] The urinary catheter-insertion kit 100 can further include an inflatant container 138 (e.g., syringe) including, containing, or filled with an inflatant (e.g., saline) for inflating a balloon of the catheter 132. At least one section of the preformed sections of the working tray 110 can include an inflatant-container section 116 (saline-syringe section) configured to hold the inflatant container 138. The inflatant-container section 116 can be preformed to accommodate the inflatant container 138; however, the inflatant-container section 116 need not conform to every feature of the inflatant container 138. For example, if the inflatant container 138 is a syringe, the inflatant-container section 116 (e.g., saline-syringe section) need not include a recess for a flange of the syringe. That is, the inflatant-container section 116 can have a constant width or depth commensurate with at least the flange of the syringe to accommodate

the syringe. Indeed, the inflatant-container section 116 can have a constant width or depth commensurate with the greatest width or diameter of any type inflatant container 138 set forth herein.

[0063] As shown, the lubricant-container section 114 and the inflatant-container section 116 can be commensurate in shape and size. For example, the lubricant-container section 114 and the inflatant-container section 116 can have a same length, width, depth from common top surface of the working tray 110, or a combination thereof. Alternatively, each of the lubricant-container section 114 and the inflatant-container section 116 can have a different shape or size as shown in FIG. 6B. An opening between the lubricant-container section 114 and the inflatant-container section 116 as shown in each figure of FIGS. 1B, 2B, 3B, 4B, and 6B provides an access space configured for a lateral approach to scooping up the lubricant container 136 or the inflatant container 138 with one or more fingers and removing it from the working tray 110. If either container of the lubricant container 136 or the inflatant container 138 is a syringe, the lateral approach obviates handling the syringe by way of a longitudinal approach, which prevents accidental dispensation of the lubricant or the inflatant by pushing a plunger of the syringe into a barrel thereof. Since each section of the lubricant-container section 114 and the inflatant-container section 116 is commensurate with the greatest width or diameter of the lubricant container 136 or the inflatant container 138, the opening can be anywhere along a length of the foregoing sections. That is, the opening is not needed to accommodate any portion of either one of the lubricant container 136 or the inflatant container 138. However, to further prevent accidental dispensation of the lubricant or the inflatant when either the lubricant container 136 or the inflatant container 138 is a syringe, it is beneficial to have the opening around the barrel of the syringe to promote handling the syringe by the barrel.

[0064] The urinary catheter-insertion kit 100 can further include a genital-preparation kit including a package of an antiseptic (not shown) and one or more swab sticks 144. (*See* U.S. Patent Publication Nos. US 2016/0228676 and US 2017/0216558 for description of the genital-preparation kit.) At least one section of the preformed sections of the working tray 110 can include a genital-preparation section 118 configured with a well 117 to hold the antiseptic (e.g., povidone-iodine solution) from the package. The genital-preparation section 118 can also include one or more angled channels 119 to respectively hold the one or more swab sticks 144 with their corresponding one or more absorbent heads in the well 117. The well 117 is dimensioned to have a volume commensurate with an entire volume of the antiseptic from the

package plus a volume of the one or more absorbent heads such that the one or more absorbent heads become saturated with the antiseptic when the antiseptic from the package is dispensed in the well 117. As shown, the one or more angled channels 119 can include snap-in tabs 121 configured to hold the one or more swab sticks respectively in the one or more angled channels 119.

[0065] The urinary catheter-insertion kit 100 can further include a urine-sampling container 152. At least one section of the preformed sections of the working tray 110 can include a urine sampling-container section 115 configured to hold the urine-sampling container 152. (*See* the embodiments of FIGS. 1A-1D, 2A, and 2B.) Alternatively, the storage tray 120 can be configured to hold the urine-sampling container 152 instead of the working tray 110. (*See*, for example, the embodiment of FIGS. 3A and 3B, which does not include the urine sampling-container section 115 in the working tray 110.) Configuring the storage tray 120 to hold the urine-sampling container 152 instead of the working tray 110 minimizes a height of the working tray 110.

[0066] The urinary catheter-insertion kit 100 can further include step-by-step catheterization instructions 102 imprinted directly on at least the working tray 110. At least some of the instructions 102 can be placed in a location that expressly or implicitly suggests by way of the location how to perform a step of the catheterization. For example, the genital-preparation section 118 can include an express instruction in the genital-preparation section 118 such as in the well 117 for dispensing the antiseptic from the package thereof into the well 117. (*See*, for example, FIG. 2B.) For example, the catheter section 112 can include an implicit instruction in the catheter section 112 for dispensing the lubricant into the catheter section 112 for lubricating the catheter 132. (*See*, for example, the instruction on the support in the middle of the catheter section 112 of the working tray 110 of FIG. 6B.) At least some of the instructions 102 can be revealed in step with steps of the catheterization. For example, removing the package of antiseptic from the genital-preparation section 118 can reveal the instruction to dispense the antiseptic from the package into the well 117 of the genital-preparation section 118 for saturating the one or more absorbent heads of the corresponding one or more swab sticks with the antiseptic. Revealing steps of the catheterization instructions 102 in this way does not overwhelm the clinician preforming the catheterization with too many steps at once.

[0067] The urinary catheter-insertion kit 100 can further include protective paperboard (not shown) configured to protect at least the components of the working tray 110. The working

tray 110 can include a lip 101 around a perimeter of the working tray 110 configured to hold the paperboard.

[0068] The urinary catheter-insertion kit 100 can further include a peri-care kit (not shown). (*See* U.S. Patent Publication Nos. US 2016/0228676 and US 2017/0216558, each of which is incorporated by reference in its entirety herein, for description of the peri-care kit.) The urinary catheter-insertion kit 100 can be configured to include the peri-care kit between the paperboard and an outer packaging (e.g., Tyvek®) of the urinary catheter-insertion kit 100.

[0069] As such the urinary catheter-insertion kit 100 includes, in some embodiments, the working tray 110 including the urinary catheter 132, the lubricant container 136 including a lubricant for lubricating the catheter 132, the inflatant container 138 including an inflatant for inflating a balloon of the catheter 132, and a genital-preparation kit including a package of an antiseptic and the one or more swab sticks 144; the storage tray 120 including a drainage system including drainage tubing and a drainage receptacle; the step-by-step catheterization instructions 102 imprinted directly on at least the working tray 110; and an outer packaging of Tyvek® around the urinary catheter-insertion kit 100. At least the working tray 110 includes a number of preformed sections respectively holding a number of components of the urinary catheter-insertion kit 100. The preformed sections of the working tray 110 include at least the catheter section 112 including the catheter 132, the lubricant-container section 114 including the lubricant container 136, the inflatant-container section 116 including the inflatant container 138, and the genital-preparation section 118 including the package of the antiseptic and the one or more swab sticks 144. The preformed sections of the working tray 110 include the step-by-step catheterization instructions 102 imprinted directly on at least the working tray 110 without express identification on the working tray 110 of the number of components.

[0070] The catheter section 112 is configured to hold the lubricant dispensed from the lubricant container 136 when lubricating the catheter 132. The lubricant-container section 114 and the inflatant-container section 116 have the same constant depth from the common top surface of the working tray 110. The genital-preparation section 118 is configured with the well 117 to hold the antiseptic from the package. The genital-preparation section 118 also includes the one or more angled channels 119 holding the one or more swab sticks 144 with their absorbent heads in the well 118. The working tray 110 is fixed to the storage tray 120 in a nested configuration in which the working tray 110 is suspended from the storage tray 120. The working tray 110 includes the cutout 111 in the corner area of the catheter section 112

formed between a bottom portion and an end portion of the catheter section 112. The drainage system is pre-connected to the catheter 132 through the connector 134 having the urine-sampling port. The cutout 111 in the corner area of the catheter section 112 is configured to allow the drainage tubing to pass from the storage tray 120 where the drainage system is stored to the working tray 110 by way of a bottom of the cutout 111 in the corner area of the catheter section 112.

[0071] As such the urinary catheter-insertion kit 100 also includes, in some embodiments, the working tray 110 including a Foley catheter, a lubricant-filled syringe for lubricating the catheter 132, a saline-filled syringe for inflating a balloon of the catheter 132, a genital-preparation kit including a package of an antiseptic and the one or more swab sticks 144, and the urine-sampling container 152; the storage tray 120 including a drainage system including drainage tubing and a drainage receptacle; and the step-by-step catheterization instructions 102 imprinted directly on at least the working tray 110. At least the working tray 110 includes a number of preformed sections respectively holding a number of components of the urinary catheter-insertion kit 100. The preformed sections of the working tray 110 include at least the catheter section 112 including the catheter 132, a lubricant-syringe section including the lubricant-filled syringe, a saline-syringe section including the saline-filled syringe, and the genital-preparation section 118 including the package of the antiseptic and the one or more swab sticks 144. At least one section of the preformed sections of the working tray 110 includes the urine sampling-container section 115 including the urine-sampling container 152.

[0072] Alternatively, the storage tray 120 is configured to hold the urine-sampling container 152 instead of the working tray 110. The genital-preparation section 118 is configured with the well 117 to hold the antiseptic from the package. The genital-preparation section 118 also includes the one or more angled channels 119 holding the one or more swab sticks 144 with their absorbent heads in the well 118. The working tray 110 is configured to nest with the storage tray 120 by suspending the working tray 110 from the storage tray 120. The working tray 110 includes the cutout 111 in the corner area of the catheter section 112 formed between a bottom portion and an end portion of the catheter section 112. The drainage system is pre-connected to the catheter 132 through the connector 134 having the urine-sampling port. The cutout 111 in the corner area of the catheter section 112 is configured to allow the drainage tubing to pass from the storage tray 120 where the drainage system is stored to the working tray 110 by way of a bottom of the cutout 111 in the corner area of the catheter section 112.

[0073] FIG. 4A illustrates another embodiment of the present invention. Urinary catheter-insertion kit 200 includes a urine sampling container section 215, syringe compartment 214, a second syringe compartment 216, and a base 250 that separates the working tray from the storage tray. According to certain embodiments, the base 250 is configured to be secured to the working tray, *e.g.*, the base 250 is not configured to be removed. Features 260a-260e are configured to assist in securely fastening the base 250 between the working and storage trays.

[0074] FIG. 4B illustrates another embodiment of the tray of FIG. 4A, including working tray 210 and storage tray 220, which can include an opening 221 in an end of the storage tray 220.

[0075] FIG. 5 illustrates yet another embodiment of a catheter-insertion tray in accordance with the present disclosure. Base 250 has an elevated portion 252 allowing for more room in the storage tray. Moreover, feature 260c is absent according to this embodiment.

Methods

[0076] Methods of urinary catheterization with a urinary catheter-insertion kit 100 can include, in some embodiments, removing an outer packaging from the urinary catheter-insertion kit 100, cleaning a patient's perianal area with a peri-care kit, preparing the patient's genital area using a genital-preparation kit, and catheterizing the patient with the catheter 132

(e.g., a Foley catheter). Removing the outer packaging from the urinary catheter-insertion kit 100 can bare the working tray 110 suspendedly nested with the storage tray 120 with the step-by-step catheterization instructions 102 imprinted directly on at least the working tray 110. The working tray 110 can include a number of preformed sections respectively holding a number of components for the method of urinary catheterization with the urinary catheter-insertion kit 100. Removing the outer packaging from the urinary catheter-insertion kit 100 can also bare a protective paperboard configured to protect the components of the urinary catheter-insertion kit 100 in the working tray 110 under the paperboard.

[0077] Cleaning the patient's perianal area with the peri-care kit can include removing the peri-care kit from between the outer packaging of the urinary catheter-insertion kit 100 and the paperboard over the working tray 110. Preparing the patient's genital area using the genital-preparation kit can include using a package of an antiseptic and the one or more swab sticks 144 of the genital-preparation kit. Preparing the patient's genital area can include removing the package of the antiseptic from the genital-preparation section 118 of the working tray 110, opening the package of the antiseptic, and dispensing the antiseptic into the well 117 of the genital-preparation section 118, thereby saturating one or more absorbent heads of the one or more corresponding swab sticks 144 respectively held in the one or more angled channels 119 of the genital-preparation section 118. Catheterizing the patient with the catheter 132 can include removing the catheter 132 from the catheter section 112 of the working tray 110 and a drainage system from the storage tray 120 without disconnecting the catheter 132 from either drainage tubing or a drainage receptacle of the drainage system.

[0078] The working tray 110 can include the cutout 111 in the corner area of the catheter section 112 formed between a bottom portion and an end portion of the catheter section 112. The cutout 111 can enable removing both the catheter 132 from the catheter section 112 of the working tray 110 and the drainage system from the storage tray 120 without disconnecting the catheter 132 from the drainage system. If the working tray 110 includes the drainage-tubing constriction 113, removing both the catheter 132 from the working tray 110 and the drainage system from the storage tray 120 includes removing the drainage tubing from the drainage-tubing constriction 113 in the working 110.

[0079] Opening the package of the antiseptic and dispensing the antiseptic into the well 117 of the genital-preparation section 118 of the working tray 110 can be in accordance with the step-by-step catheterization instructions 102 imprinted directly on the working tray 110.

These catheterization instructions 102 are shown in FIGS. 2B and 3B as the first and second steps of the method imprinted directly on the working tray 110.

[0080] Preparing the patient's genital area can include retracting the patient's genitals using a non-dominant hand and swabbing the patient's genitals with the antiseptic using a dominant hand in accordance with the step-by-step catheterization instructions 102 imprinted directly on the working tray 110. These catheterization instructions 102 are shown in FIGS. 2B and 3B as the fifth and sixth steps of the method imprinted directly on the working tray 110.

[0081] The method can further include removing a lubricant-filled syringe from a lubricant-syringe section of the working tray 110, dispensing the lubricant from the lubricant-filled syringe into the lubricant-syringe section, the catheter section 112, or another preformed section of the working tray 110, and lubricating the catheter 132 with the lubricant dispensed in the working tray 110. At least dispensing the lubricant into a preformed section of the working tray 110 (e.g., the catheter section 112) and lubricating the catheter 132 with the lubricant dispensed in the working tray 110 can be in accordance with the step-by-step catheterization instructions 102 imprinted directly on the working tray 110. This catheterization instruction is shown in FIGS. 2B and 3B as the fourth step of the method imprinted directly on the working tray 110. Removing the lubricant-filled syringe from the lubricant-syringe section can reveal the catheterization instruction imprinted in a bottom of the lubricant-syringe section to dispense the lubricant from the lubricant-filled syringe into the catheter section 112 for lubricating the catheter 132. Revealing steps of the catheterization instructions 102 in this way keeps the clinician performing the catheterization from becoming overwhelmed by too many steps at once.

[0082] The method further can include removing a saline-filled syringe from a saline-syringe section of the working tray 110 and attaching the saline-filled syringe to the catheter 132 for inflating a balloon of the catheter 132. At least attaching the saline-filled syringe to the catheter 132 can be in accordance with the step-by-step catheterization instructions 102 imprinted directly on the working tray 110. This catheterization instruction is shown in FIGS. 2B and 3B as the third step of the method imprinted directly on the working tray 110.

[0083] Catheterizing the patient can include inserting the catheter 132 into the patient's urethra and inflating the balloon with saline from the saline-filled syringe. At least inflating the balloon with saline from the saline-filled syringe can be in accordance with the step-by-step

catheterization instructions 102 imprinted directly on the working tray 110. This catheterization instruction is shown in FIGS. 2B and 3B as the seventh step of the method imprinted directly on the working tray 110.

[0084] 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.

CLAIMS

What is claimed is:

1. A urinary catheter-insertion kit, comprising:

a storage tray;

a working tray including a plurality of preformed sections designed to hold a plurality of components of the urinary catheter-insertion kit, the working tray designed to nest with the storage tray by suspending the working tray from the storage tray;

a urinary catheter disposed in a catheter section of the plurality of preformed sections of the working tray; and

a drainage system disposed in the storage tray, the drainage system including drainage tubing and a drainage receptacle, the drainage tubing connected to the urinary catheter.

2. The urinary catheter-insertion kit according to claim 1, wherein suspending the working tray from the storage tray includes inserting folded-over longitudinal edges or tabs of a paperboard storage tray in a gap between longitudinal sides and an overhang of the working tray, the gap including a number of protrusions configured to engage the folded-over longitudinal edges or tabs of the paperboard storage tray and fasten together the working tray and the storage tray.

3. The urinary catheter-insertion kit according to either claim 1 or 2, wherein the storage tray includes a cutout in an end of the storage tray designed to facilitate access to any of the components of the urinary catheter-insertion kit stored in the storage tray while working from the working tray.

4. The urinary catheter-insertion kit according to either claim 1 or 2, wherein the working tray includes a cutout in a corner area of the catheter section formed between a bottom portion and an end portion of the catheter section, the drainage tubing connected to the urinary catheter through the cutout in the catheter section.

5. The urinary catheter-insertion kit according to claim 4, wherein a side of the cutout in the corner area of the catheter section is designed to allow the drainage tubing to be removed from the storage tray without disconnecting the drainage tubing from the urinary catheter.

6. The urinary catheter-insertion kit according to either claim 4 or 5, wherein the working tray includes a drainage-tubing constriction between the cutout in the corner area of the catheter section and a remainder of the catheter section configured to hold a portion of the drainage tubing and maintain an initial placement of the urinary catheter in the working tray until the urinary catheter is used.

7. The urinary catheter-insertion kit according to any claim of claims 1-6, further comprising a connector including a urine-sampling port configured to connect the urinary catheter to the drainage tubing, wherein the connector is pre-connected to at least the urinary catheter in the urinary catheter-insertion kit.

8. The urinary catheter-insertion kit according to any claim of claims 1-7, further comprising a lubricant container including lubricant for the catheter, wherein at least one section of the preformed sections of the working tray includes a lubricant-container section configured to hold the lubricant container.

9. The urinary catheter-insertion kit according to any claim of claims 1-8, further comprising an inflatant container including an inflatant for inflating a balloon of the catheter, wherein at least one section of the preformed sections of the working tray includes an inflatant-container section configured to hold the inflatant container.

10. The urinary catheter-insertion kit according to any claim of claims 1-9, further comprising a genital-preparation kit including a package of an antiseptic and one or more swab sticks, wherein at least one section of the preformed sections of the working tray includes a genital-preparation section configured with a well to hold the antiseptic from the package and one or more angled channels to respectively hold the one or more swab sticks with their corresponding one or more absorbent heads in the well.

11. The urinary catheter-insertion kit according to claim 10, wherein the well is dimensioned to have a volume commensurate with an entire volume of the antiseptic from the package plus a volume of the one or more absorbent heads such that the one or more absorbent heads become saturated with the antiseptic when the antiseptic from the package is dispensed in the well.

12. The urinary catheter-insertion kit according to any claim of claims 1-11, further comprising a urine-sampling container, wherein at least one section of the preformed sections of the working tray includes a urine sampling-container section configured to hold the urine-sampling container.

13. The urinary catheter-insertion kit according to any claim of claims 1-11, further comprising a urine-sampling container, wherein the storage tray is designed to hold the urine-sampling container.

14. The urinary catheter-insertion kit according to any claim of claims 1-13, further comprising step-by-step catheterization instructions imprinted directly on at least the working tray.

15. The urinary catheter-insertion kit according to claim 14, further comprising an instruction to not separate the working tray from the storage tray along with the step-by-step catheterization instructions imprinted directly on at least the working tray.

16. The urinary catheter-insertion kit according to any claim of claims 1-15, further comprising:

protective paperboard configured to protect at least the components of the working tray, wherein the working tray includes a lip around a perimeter of the working tray configured to hold the protective paperboard; and

a peri-care kit, wherein the urinary catheter-insertion kit is configured to include the peri-care kit between the protective paperboard and an outer packaging of the urinary catheter-insertion kit.

17. A urinary catheter-insertion kit, comprising:

a working tray and a storage tray,

wherein the working tray is configured to nest with the storage tray by suspending the working tray from the storage tray, and

wherein at least the working tray includes a plurality of preformed sections holding a plurality of components of the urinary catheter-insertion kit;

a Foley catheter,

wherein at least one section of the preformed sections of the working tray includes a catheter section including the catheter, and

wherein the working tray includes a cutout in a corner area of the catheter section formed between a bottom portion and an end portion of the catheter section;

a drainage system including drainage tubing and a drainage receptacle,

wherein the drainage system is pre-connected to the catheter through a connector having a urine-sampling port, and

wherein the cutout in the corner area of the catheter section is configured to allow the drainage tubing to pass from the storage tray where the drainage system is stored to the working tray by way of a bottom of the cutout;

a lubricant-filled syringe for lubricating the catheter,

wherein at least one section of the preformed sections of the working tray includes a lubricant-syringe section including the lubricant-filled syringe;

a saline-filled syringe for inflating a balloon of the catheter,

wherein at least one section of the preformed sections of the working tray includes a saline-syringe section including the saline-filled syringe;

a genital-preparation kit including a package of an antiseptic and one or more swab sticks,

wherein at least one section of the preformed sections of the working tray includes a genital-preparation section configured with a well to hold the antiseptic from the package and one or more angled channels holding the one or more swab sticks with their absorbent heads in the well;

a urine-sampling container,

wherein at least one section of the preformed sections of the working tray includes a urine sampling-container section including the urine-sampling container, or

wherein the storage tray is configured to hold the urine-sampling container instead of the working tray; and

step-by-step catheterization instructions imprinted directly on at least the working tray.

18. The urinary catheter-insertion kit according to claim 17, wherein the working tray includes a drainage-tubing constriction between the cutout in the corner area of the catheter section and a remainder of the catheter section configured to hold a portion of the drainage tubing and maintain an initial placement of the urinary catheter in the working tray until the urinary catheter is used.

19. A method of urinary catheterization with a urinary catheter-insertion kit, comprising:

removing an outer packaging from the urinary catheter-insertion kit,

wherein removing the outer packaging bares a working tray suspendedly nested with a storage tray with step-by-step catheterization instructions imprinted directly on at least the working tray, and

wherein the working tray includes a plurality of preformed sections holding a plurality of components for the method of urinary catheterization with the urinary catheter-insertion kit;

cleaning a patient's perianal area with a peri-care kit,

wherein cleaning the patient's perianal area includes removing the peri-care kit from between the outer packaging of the urinary catheter-insertion kit and a protective paperboard configured to protect the components of the urinary catheter-insertion kit in the working tray under the paperboard;

preparing the patient's genital area using a genital-preparation kit including a package of an antiseptic and one or more swab sticks,

wherein preparing the patient's genital area includes removing the package of the antiseptic from a genital-preparation section of the working tray and dispensing the antiseptic into a well of the genital-preparation

section, thereby saturating one or more absorbent heads of one or more corresponding swab sticks respectively held in one or more angled channels of the genital-preparation section; and

catheterizing the patient with a Foley catheter,

wherein catheterizing the patient includes removing the catheter from a catheter section of the working tray and a drainage system from the storage tray without disconnecting the catheter from either drainage tubing or a drainage receptacle of the drainage system.

20. The method according to claim 19, wherein:

the working tray includes a cutout in a corner area of the catheter section formed between a bottom portion and an end portion of the catheter section, and

the cutout enables removing both the catheter from the catheter section of the working tray and the drainage system from the storage tray without disconnecting the catheter from the drainage system.

21. The method according to claim 20, further comprising:

removing the drainage tubing from a drainage-tubing constriction in the working tray between the cutout in the corner area of the catheter section and a remainder of the catheter section.

22. The method according to any claim of claims 19-21, wherein dispensing the antiseptic into the well of the genital-preparation section of the working tray is in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

23. The method according to any claim of claims 19-22, wherein preparing the patient's genital area includes retracting the patient's genitals using a non-dominant hand and swabbing the patient's genitals with the antiseptic using a dominant hand in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

24. The method according to any claim of claims 19-23, further comprising:

removing a lubricant-filled syringe from a lubricant-syringe section of the working tray;

dispensing the lubricant from the lubricant-filled syringe into the lubricant-syringe section of the working tray in accordance with the step-by-step catheterization instructions imprinted directly on the working tray; and

lubricating the catheter with the lubricant dispensed in the catheter section of the working tray in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

25. The method according to any claim of claims 19-24, further comprising:

removing a saline-filled syringe from a saline-syringe section of the working tray; and

attaching the saline-filled syringe to the catheter for inflating a balloon of the catheter in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

26. The method according to claim 25, wherein catheterizing the patient includes inserting the catheter into the patient's urethra and inflating the balloon with saline from the saline-filled syringe in accordance with the step-by-step catheterization instructions imprinted directly on the working tray.

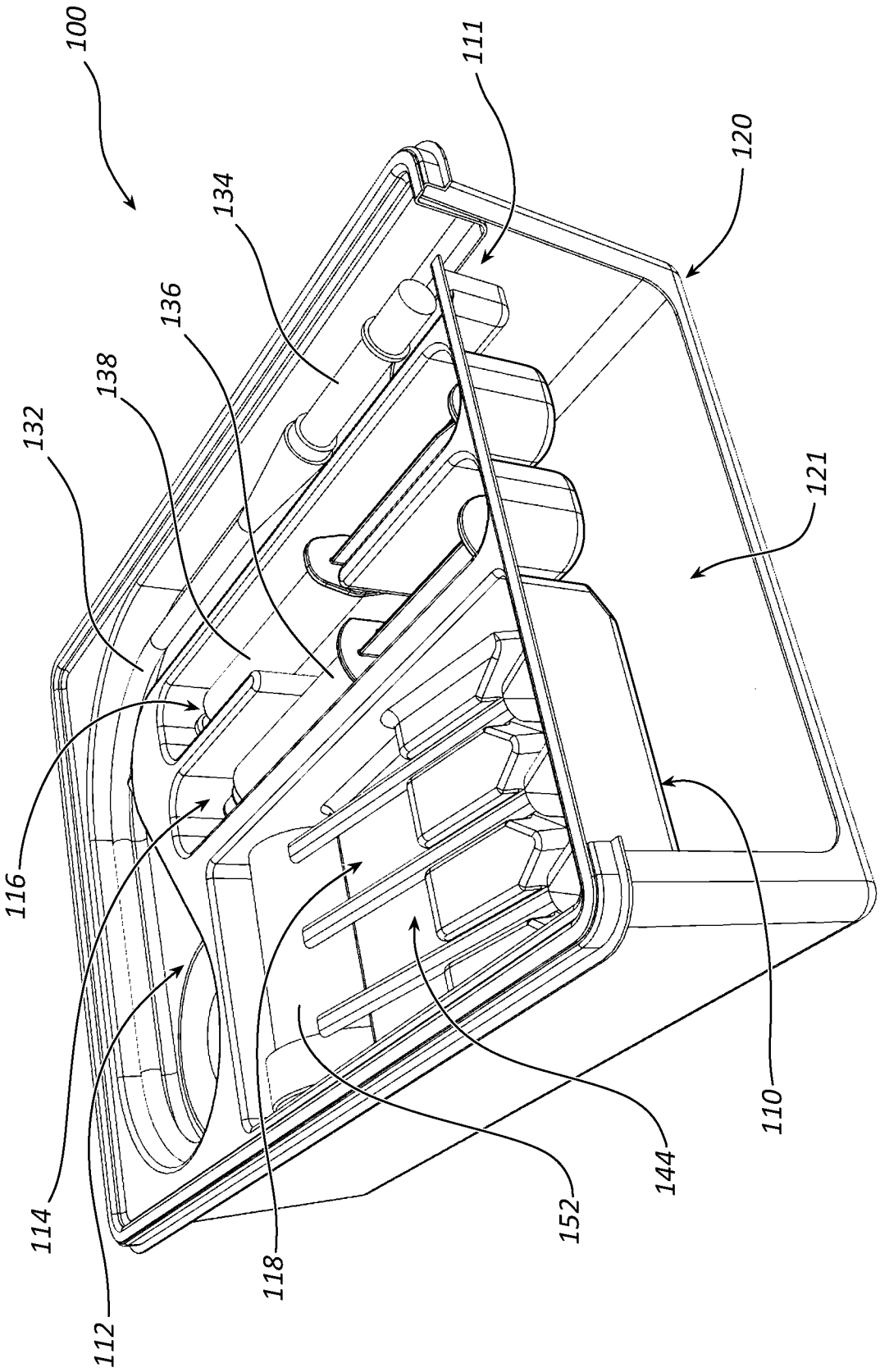


FIG. 1A

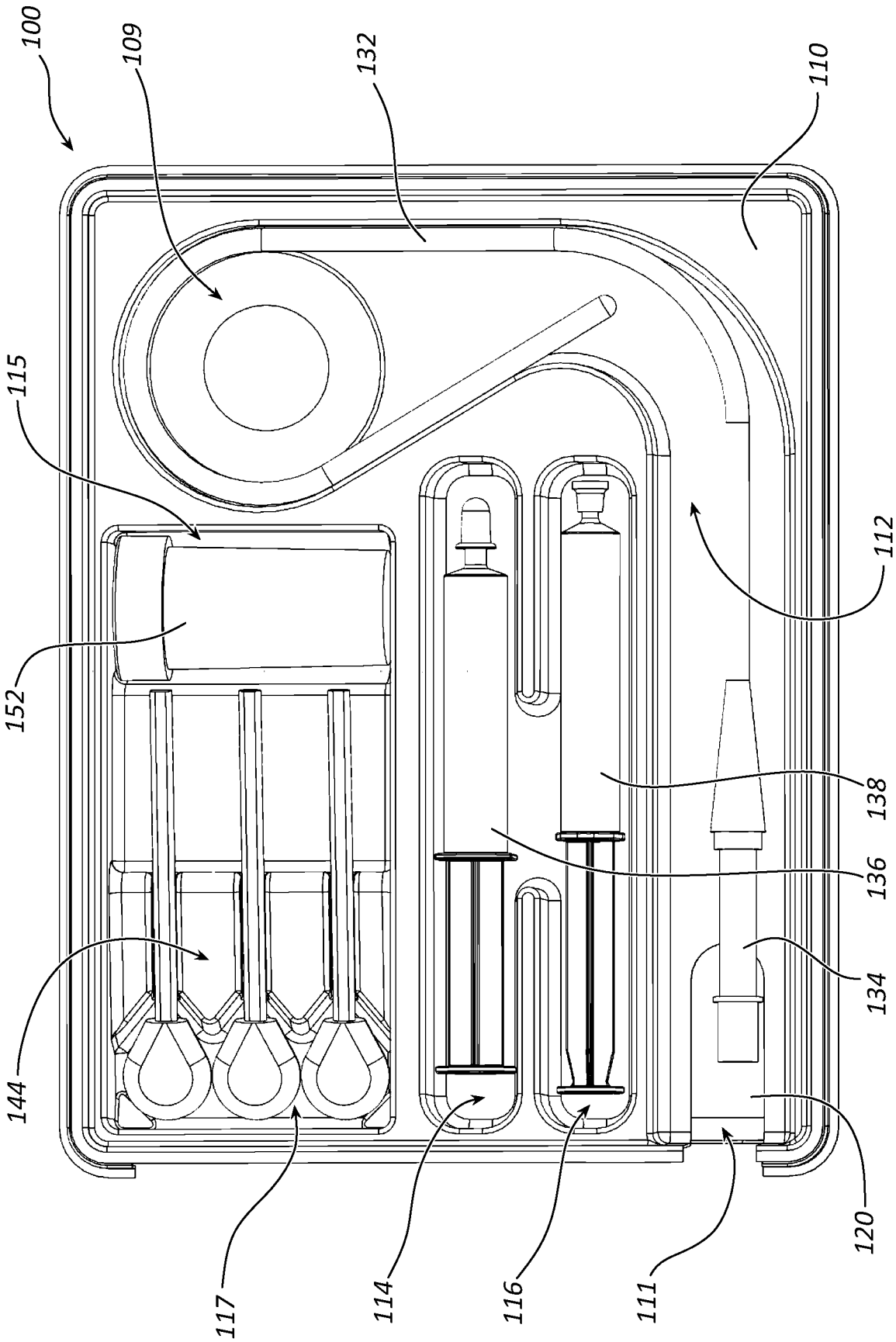


FIG. 1B

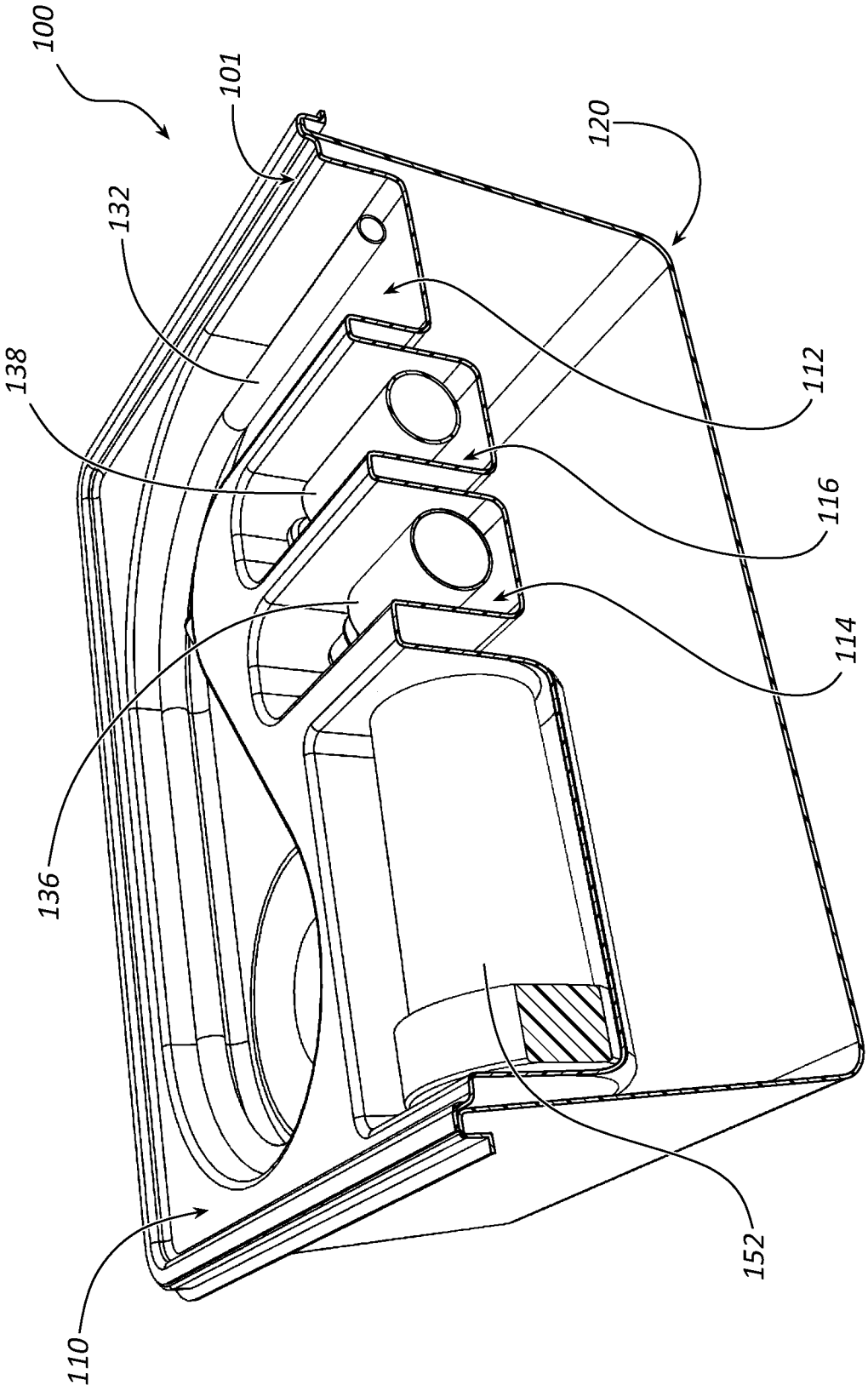


FIG. 1C

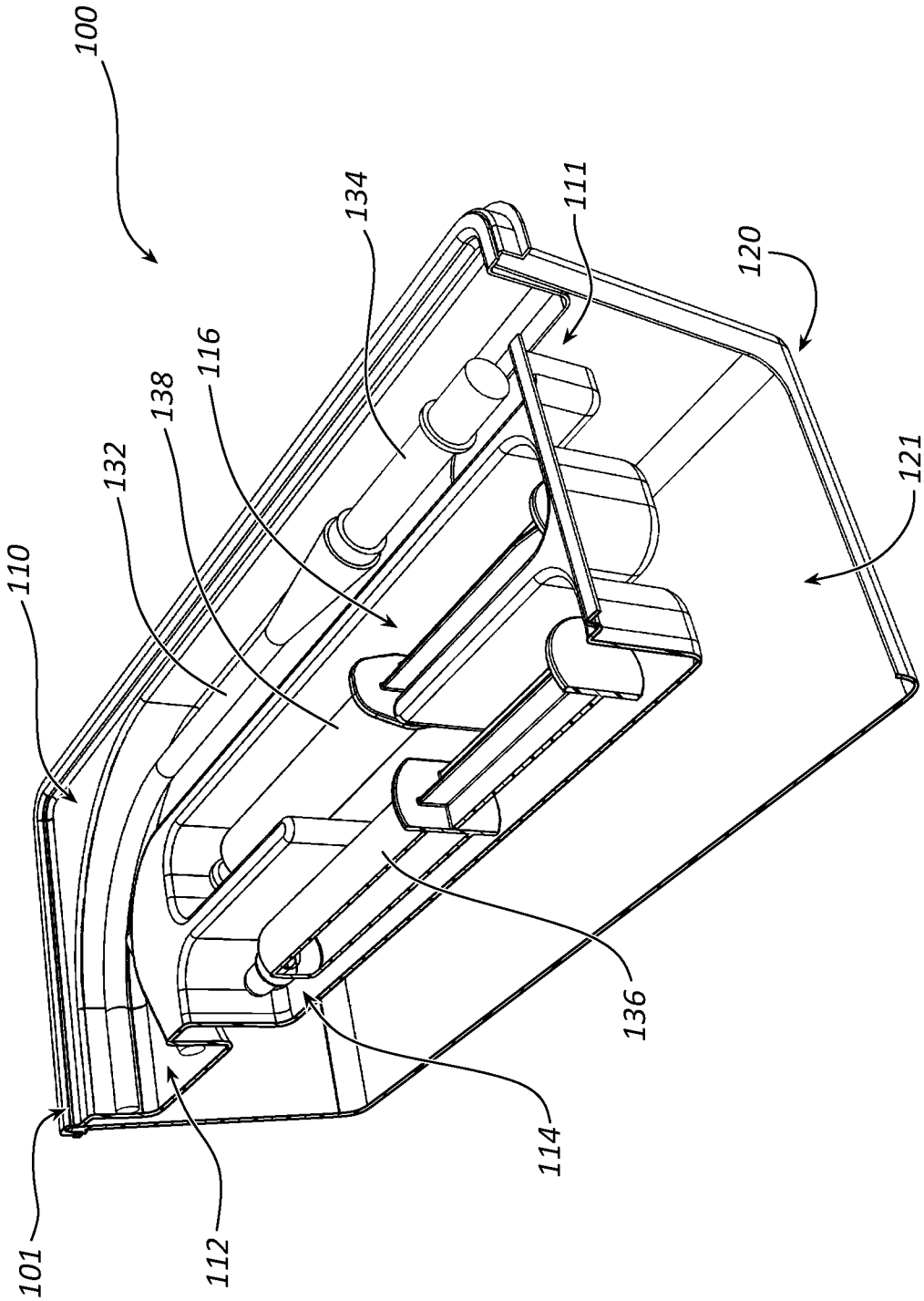


FIG. 1D

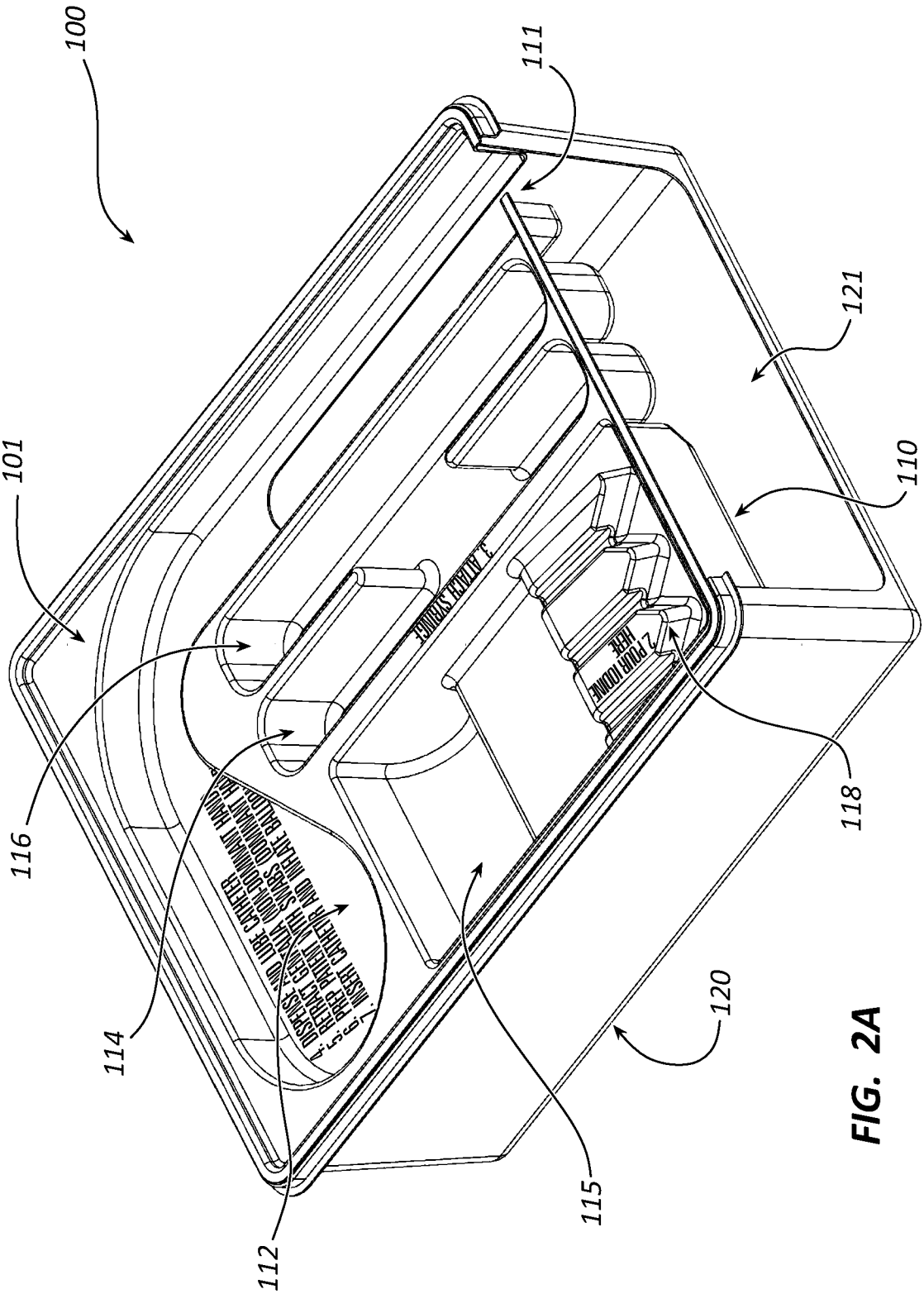

100
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118
112
115
120
3. ADDED SUGAR
2. POUR LIQUID HERE
1. PEEL BACK FILM

FIG. 2A

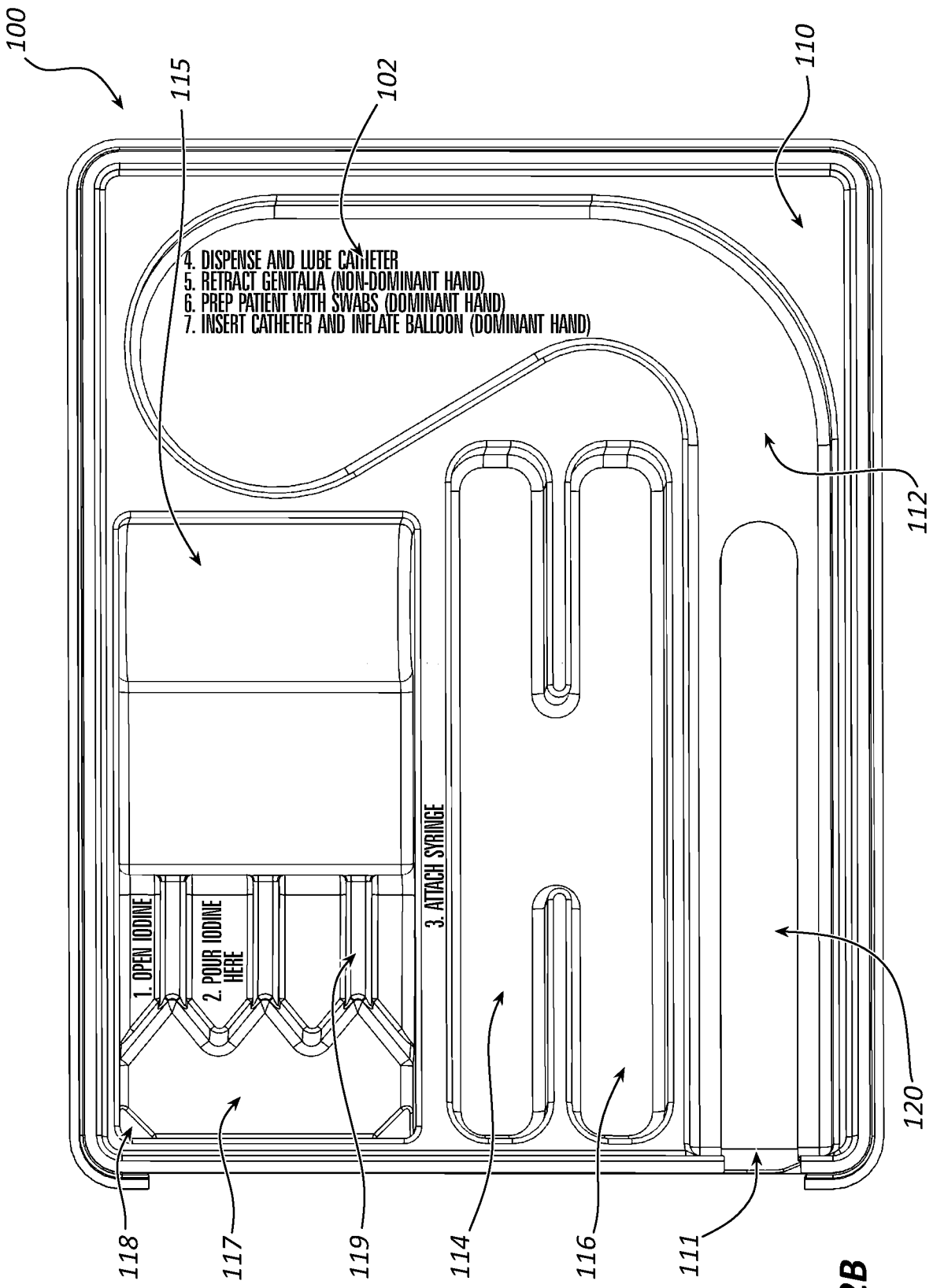

100
115
102
110
4. DISPENSE AND LUBE CATHETER
5. RETRACT GENITALIA (NON-DOMINANT HAND)
6. PREP PATIENT WITH SWABS (DOMINANT HAND)
7. INSERT CATHETER AND INFLATE BALLOON (DOMINANT HAND)
112
1. OPEN IODINE
2. POUR IODINE HERE
3. ATTACH SYRINGE
120
118
117
119
114
116
111

FIG. 2B

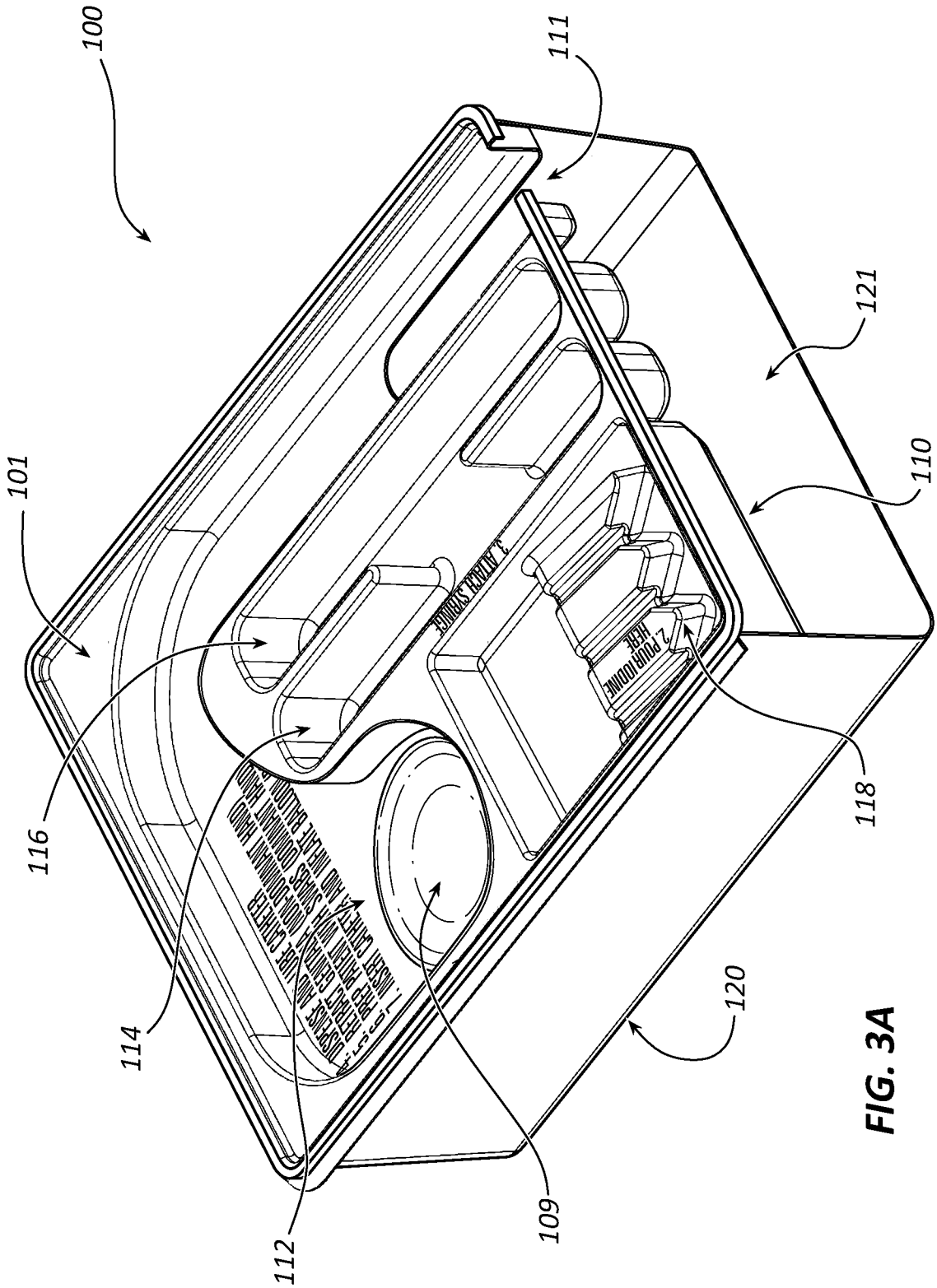

100
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114
120
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112
2. POUR ROUND HEAT
3. ADD 6 SQUARE

FIG. 3A

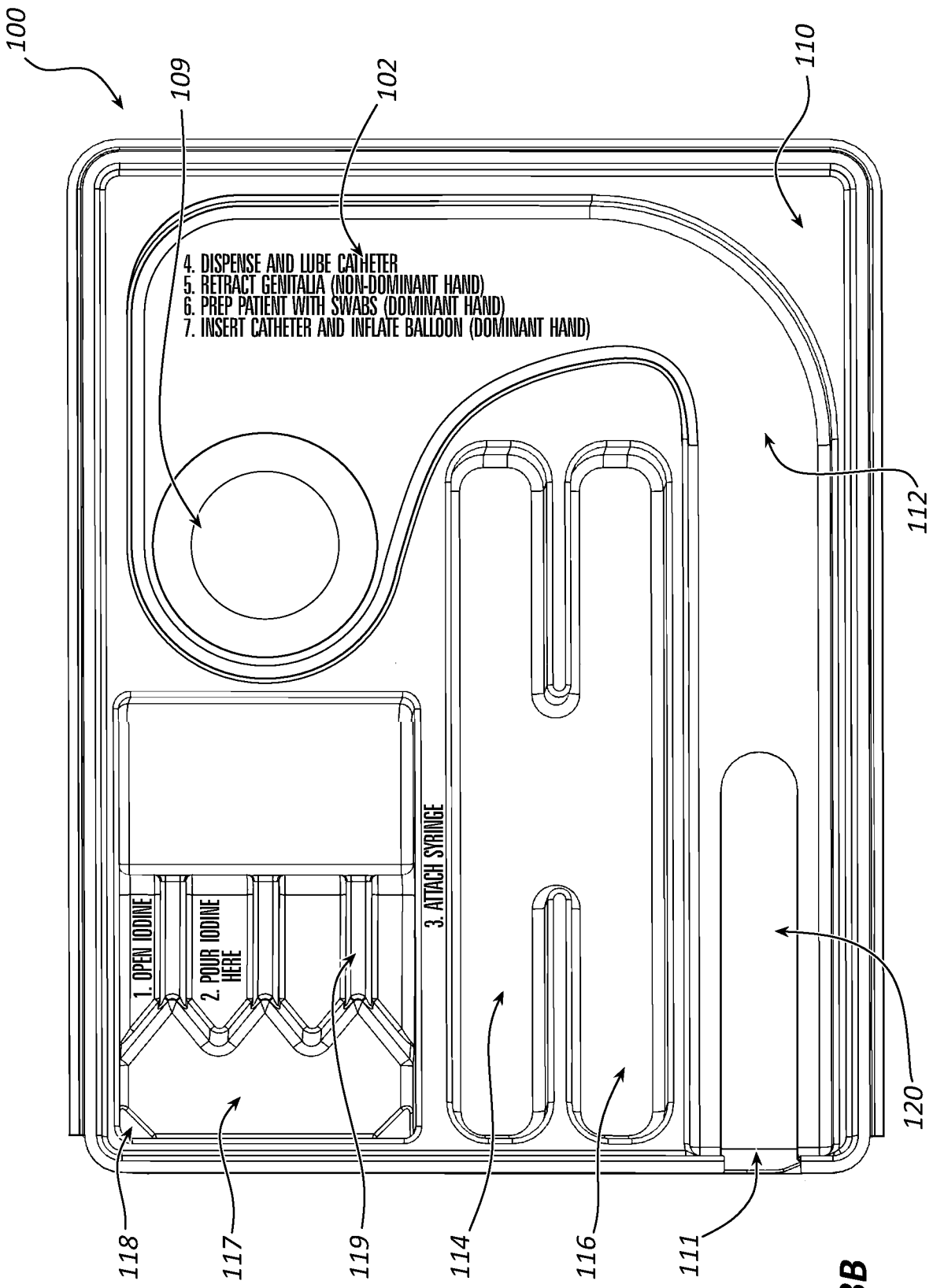

100
109
102
110
4. DISPENSE AND LUBE CATHETER
5. RETRACT GENITALIA (NON-DOMINANT HAND)
6. PREP PATIENT WITH SWABS (DOMINANT HAND)
7. INSERT CATHETER AND INFLATE BALLOON (DOMINANT HAND)
112
1. OPEN IODINE
2. POUR IODINE HERE
3. ATTACH SYRINGE
120
118
117
119
114
116
111

FIG. 3B

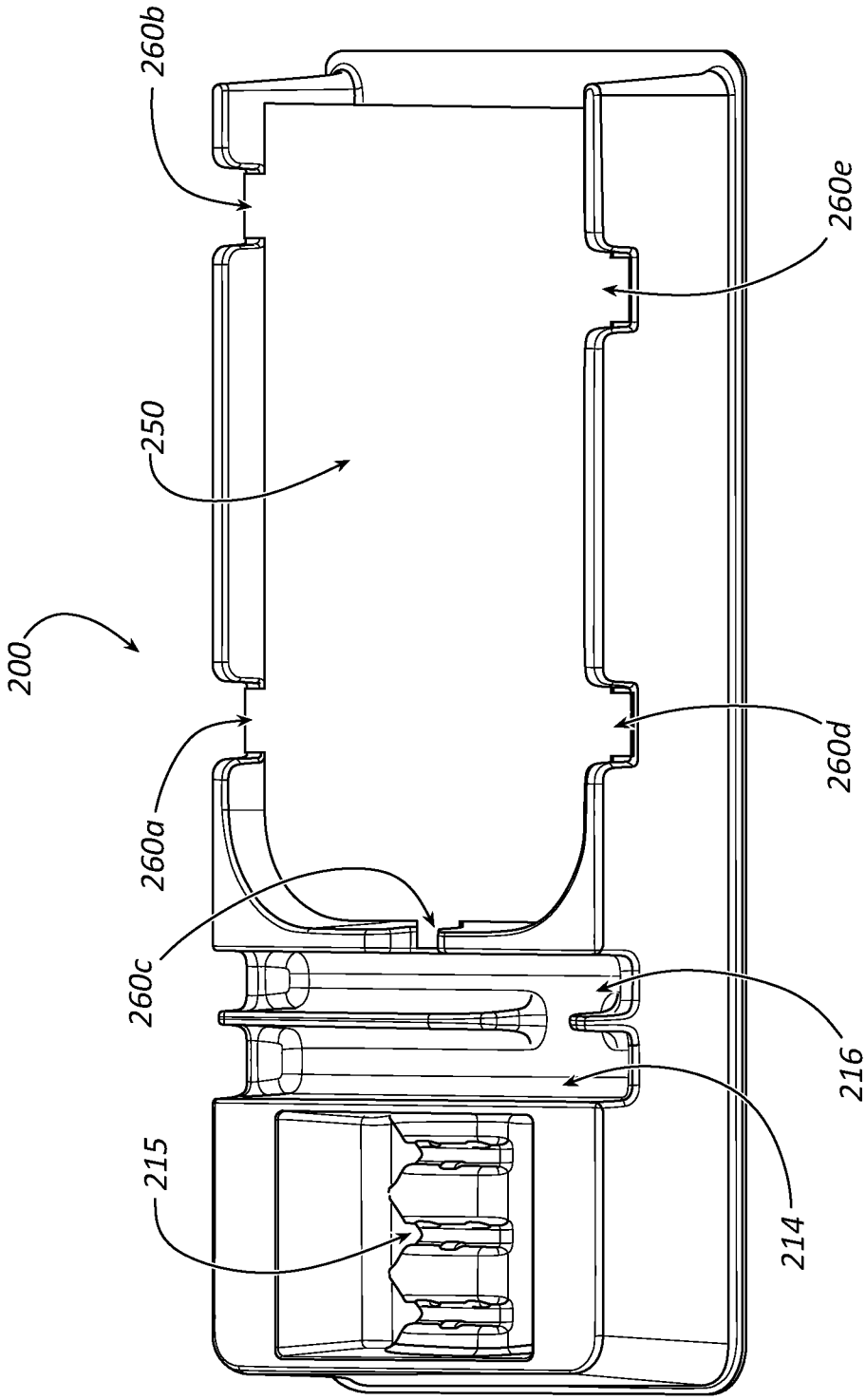


FIG. 4A

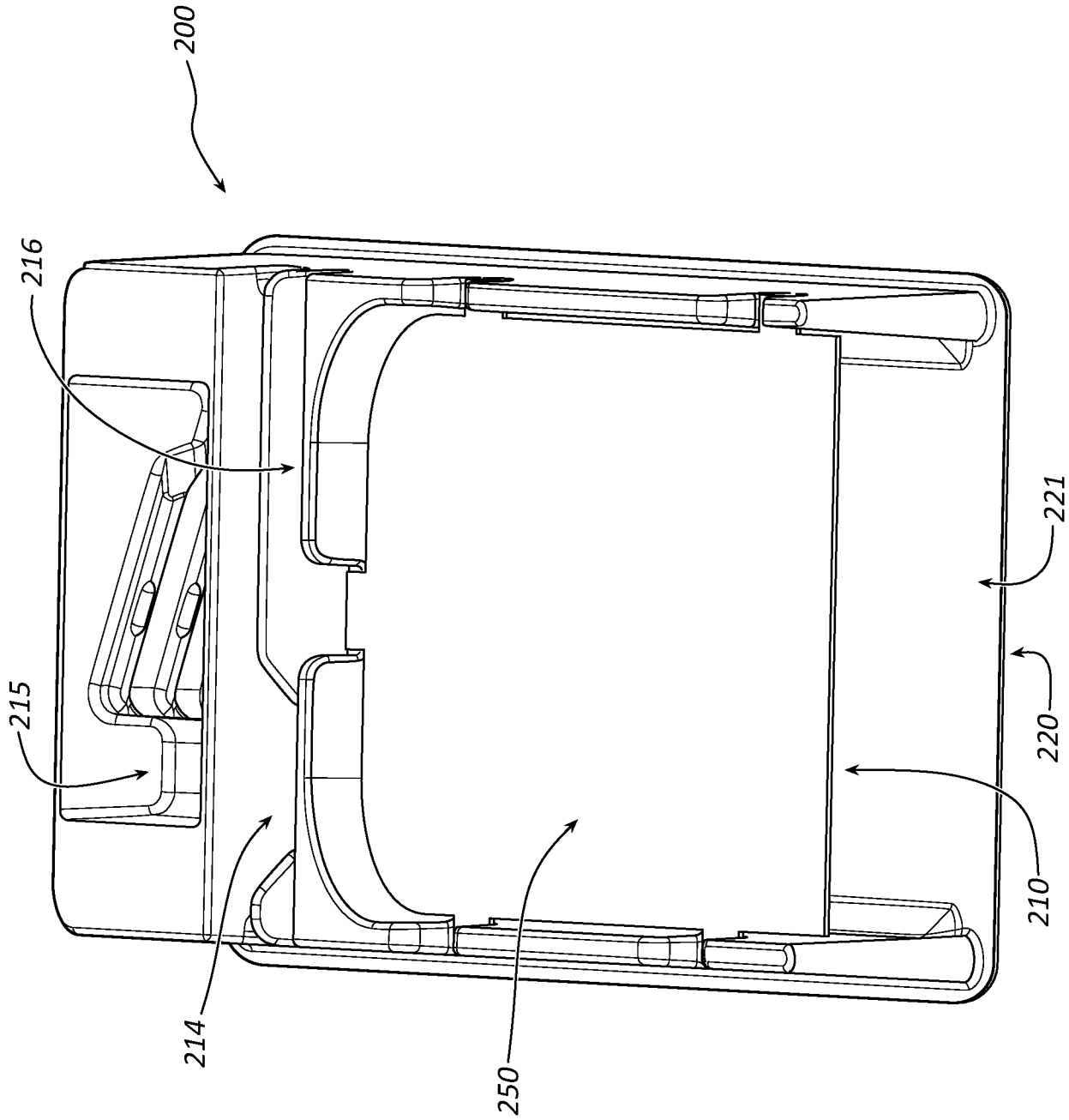


FIG. 4B

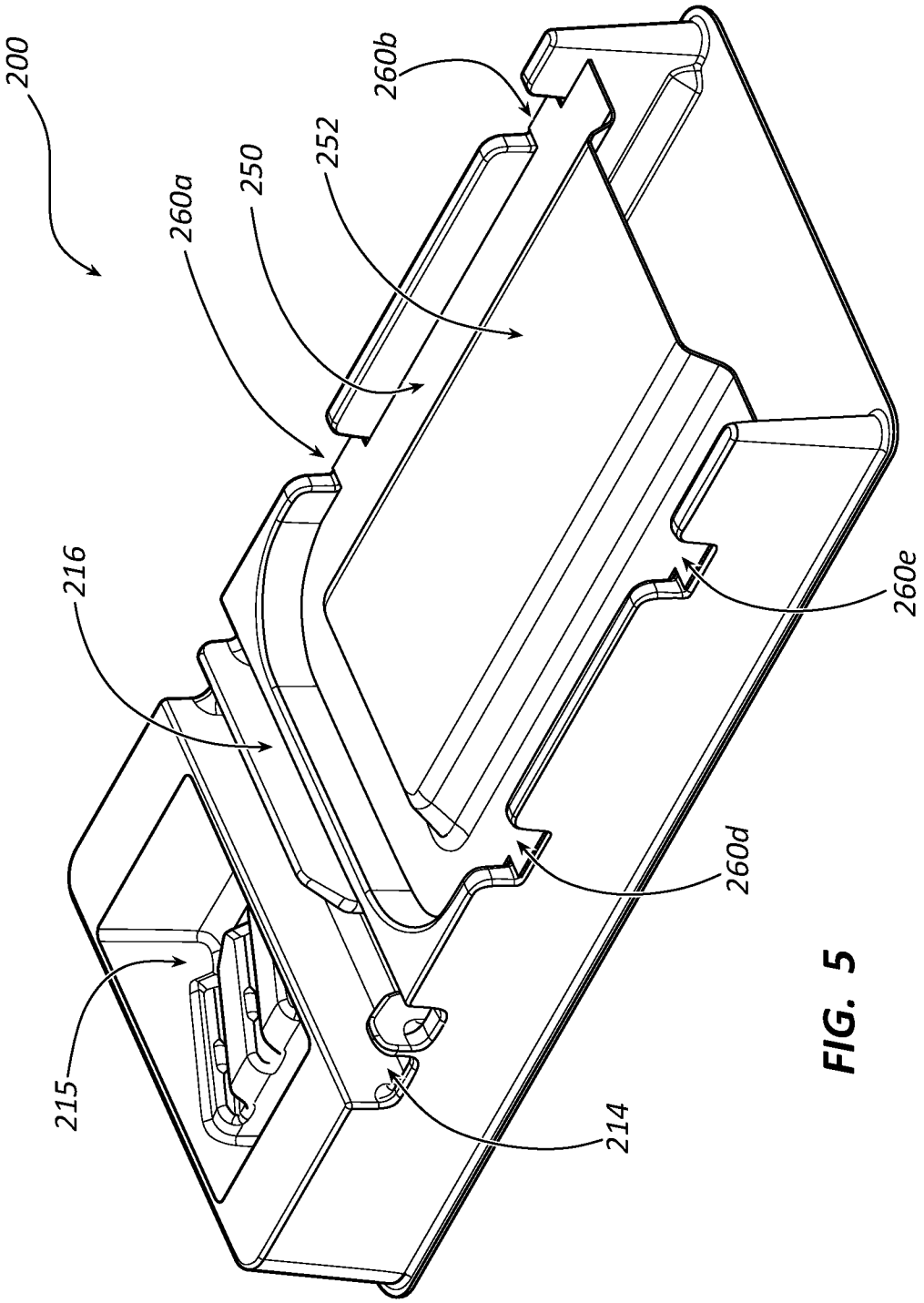


FIG. 5

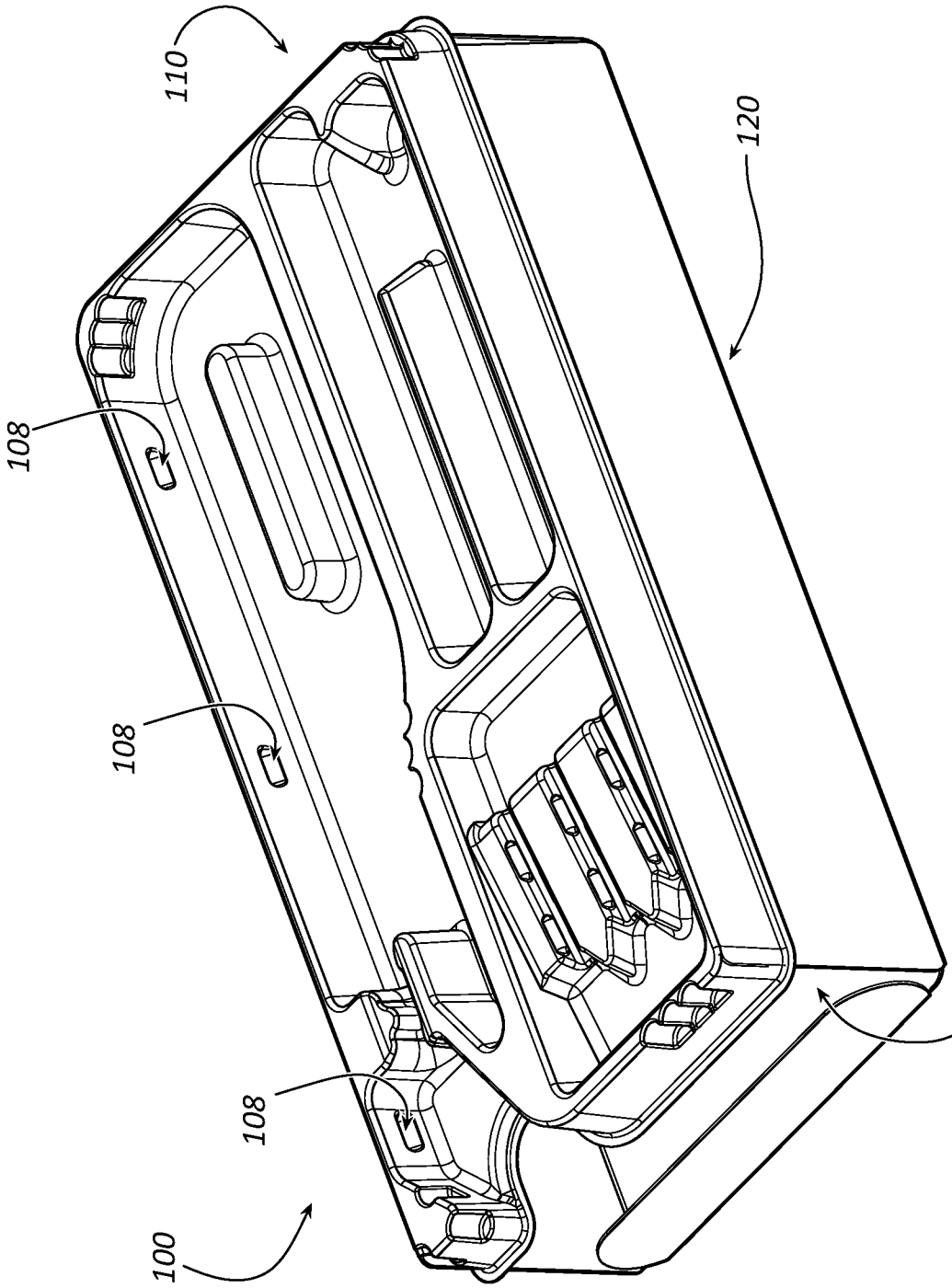


FIG. 6A

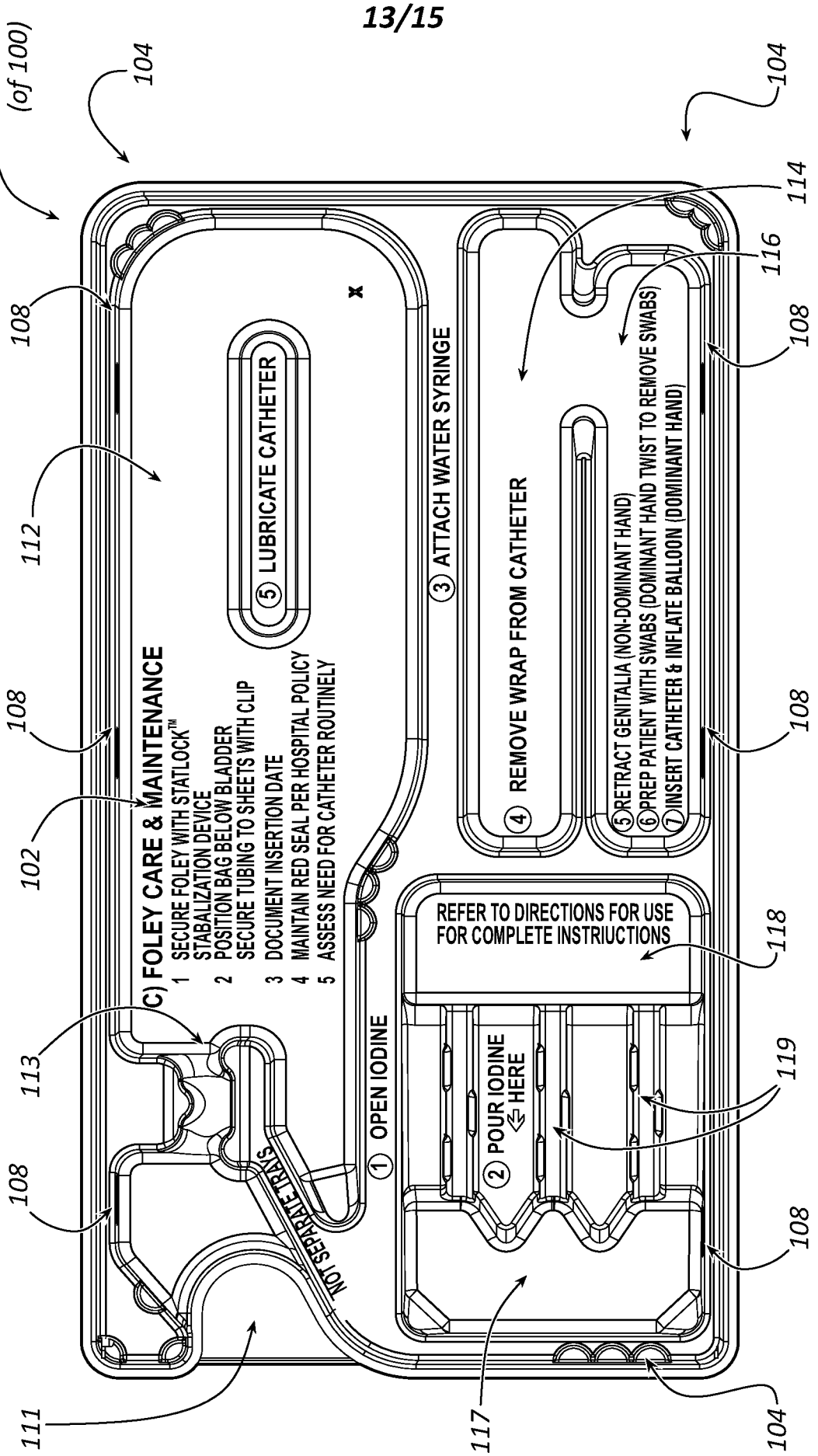

110 (of 100)
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117
104
C) FOLEY CARE & MAINTENANCE
1 SECURE FOLEY WITH STATLOCK™ STABALIZATION DEVICE
2 POSITION BAG BELOW BLADDER SECURE TUBING TO SHEETS WITH CLIP
3 DOCUMENT INSERTION DATE
4 MAINTAIN RED SEAL PER HOSPITAL POLICY
5 ASSESS NEED FOR CATHETER ROUTINELY
⑤ LUBRICATE CATHETER
③ ATTACH WATER SYSTEM
④ REMOVE WRAP FROM CATHETER
⑤ RETRACT GENITALIA (NON-DOMINANT HAND)
⑥ PREP PATIENT WITH SWABS (DOMINANT HAND TWIST TO REMOVE SWABS)
⑦ INSERT CATHETER & INFLATE BALLOON (DOMINANT HAND)
REFER TO DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS
118
① OPEN IODINE
② POUR IODINE HERE
119
NOT SEPARATE TRAYS

FIG. 6B

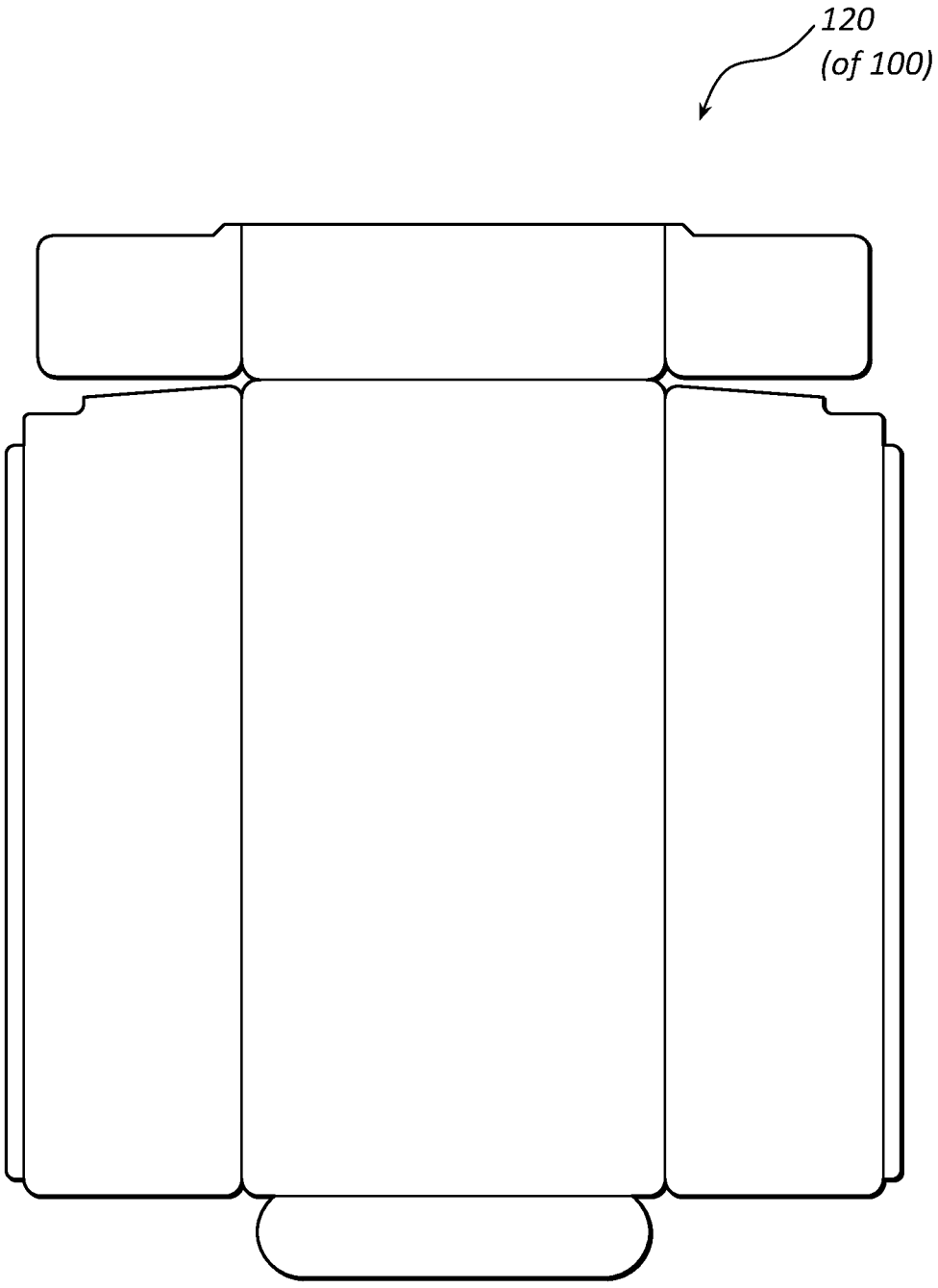


FIG. 6C

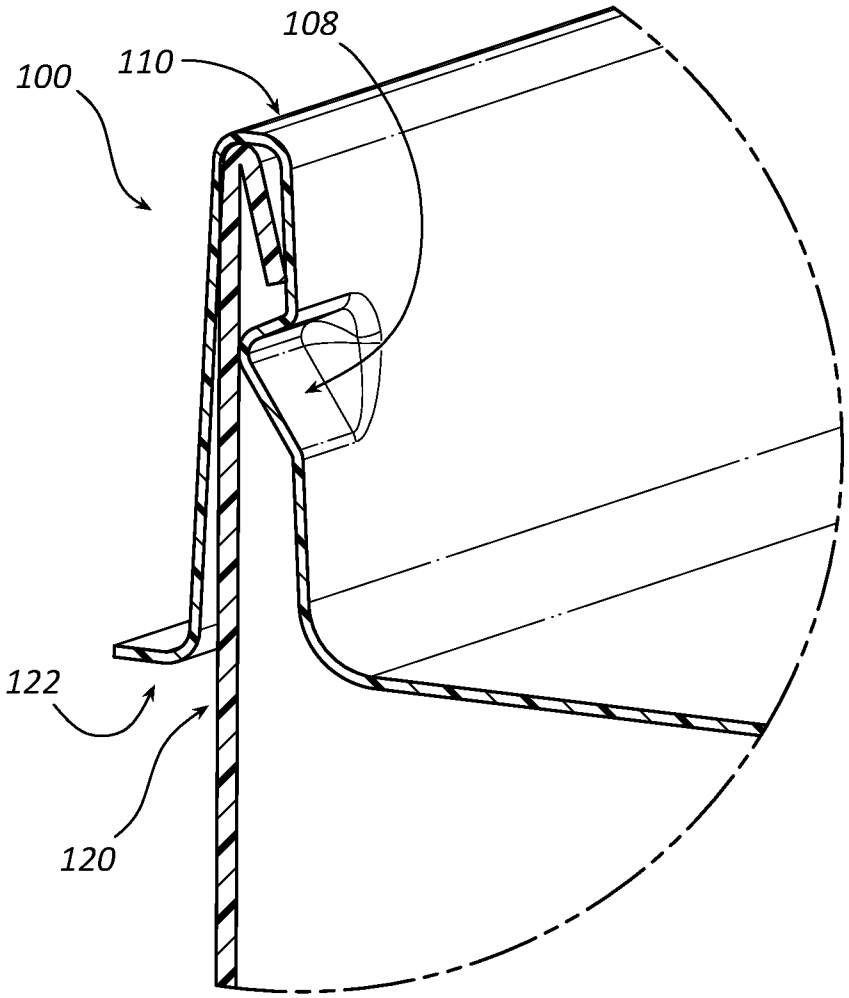


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/38051

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 50/30, 50/33; A61F 13/38; A61M 1/00, 25/00, 25/01 (2019.01)

CPC - A61M 1/0019, 25/002, 25/0111

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y --- A	US 3,329,261 A (SERANY JR., F. J. et al.) 4 July 1967, figures 5-6, column 1, lines 9-10, 60-61	1, 3/1, 17, 19, 22/19 --- 2, 3/2, 4/1-4/2, 5/4/1-5/4/2, 18, 20, 21, 21, 22/20, 22/21
Y --- A	US 2017/0216558 A1 (C. R. BARD, INC.) 3 August 2017, figures 26-29, paragraphs [0137], [0168]-[0169], [0173]-[0174]	1, 3/1, 17, 19, 22/19 --- 2, 3/2, 4/1, 5/4/1, 18, 20, 21, 22/20, 22/21
Y --- A	US 6,716,200 B2 (BRACKEN, R. L. et al.) 6 April 2004, figure 1, column 4, lines 20-21	17 --- 18
Y --- A	US 5,384,103 A (MILLER, C. H.) 24 January 1995, figure 1, column 3, line 67	17 --- 18, 20, 21, 22/20, 22/21
Y --- A	US 6,121,165 A (MACKEY, L. N. et al.) 19 September 2000, column 12, line 67, column 13, line 1	19, 22/19 --- 20, 21, 22/20, 22/21

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 August 2019 (16.08.2019)	29AUG 2019
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/38051

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/0263595 A1 (HUHTAMAKI, INC.) 18 September 2014, figures 1-2, 4, paragraph [0020]	2, 3/2, 4/2, 5/4/2
A	US 3,580,475 A (MOBLEY, O. V.) 25 May 1971, figures 1-3, column 2, lines 40-41	2, 3/2, 4/2, 5/4/2
A	US 2011/0284410 A1 (LOCKWOOD, R. A.) 24 November 2011, figure 9, paragraph [0067]	4/1, 5/4/1, 18, 20, 21, 22/20, 22/21
A	US 2006/0224086 A1 (HARTY, R. D.) 5 October 2006, figure 1, paragraph [0026]	4/1, 5/4/1
A	US 7,131,965 B1 (THORNBURY, T. R. et al.) 7 November 2006, figure 1	4/1, 5/4/1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US19/38051

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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

3. ☒ Claims Nos.: 6-16, 23-26
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

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

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

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

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.