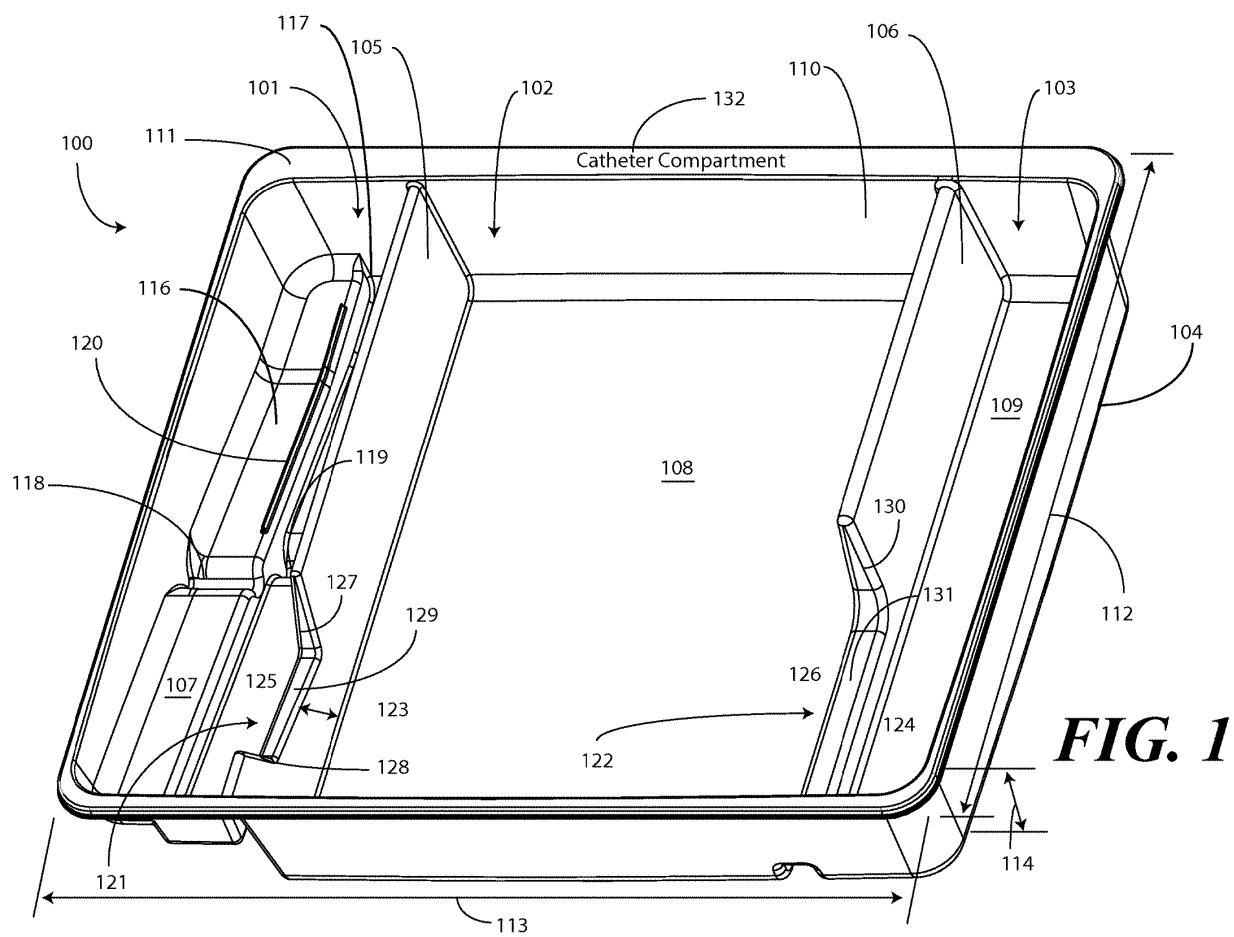




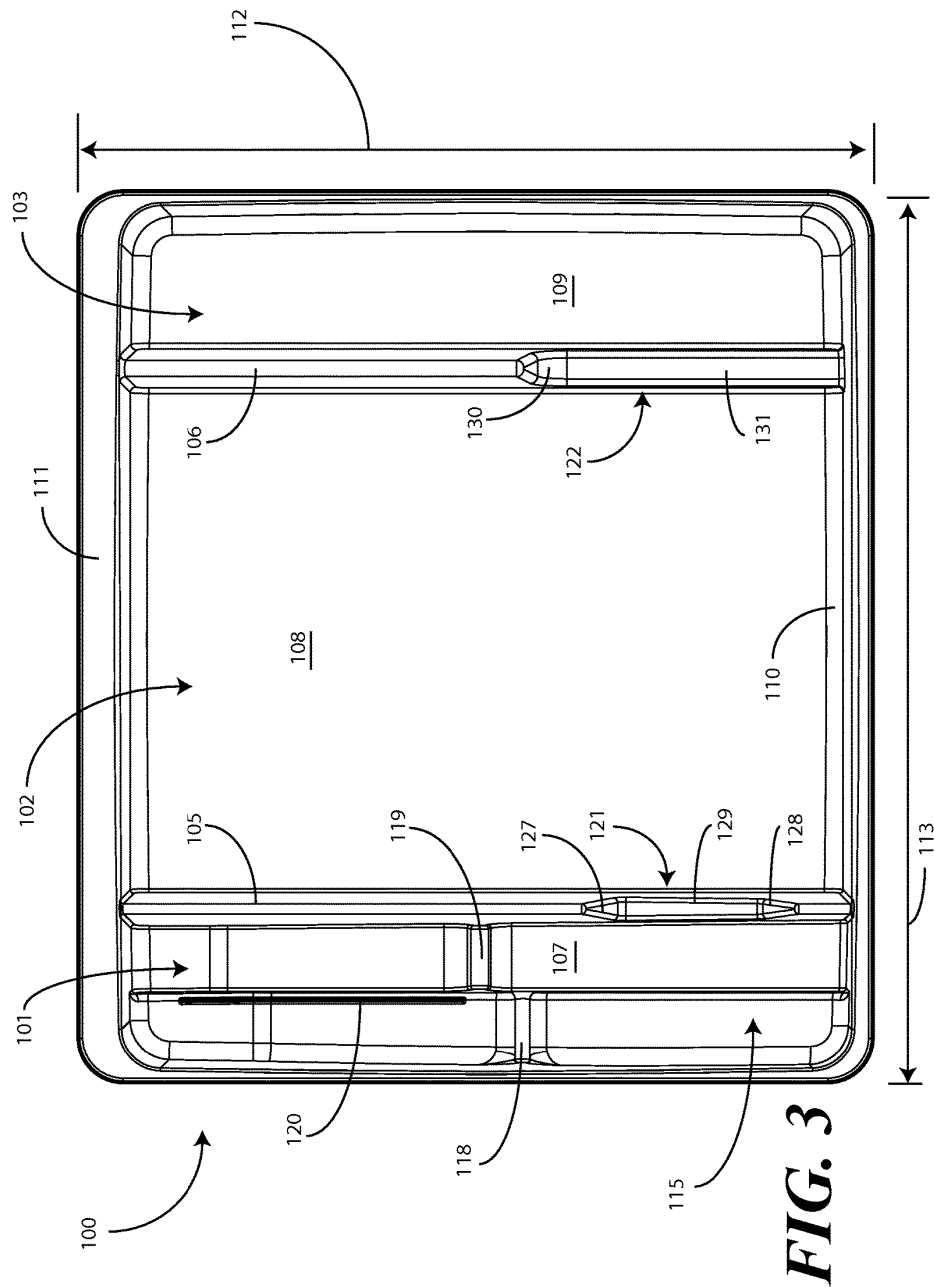


FIG. 3

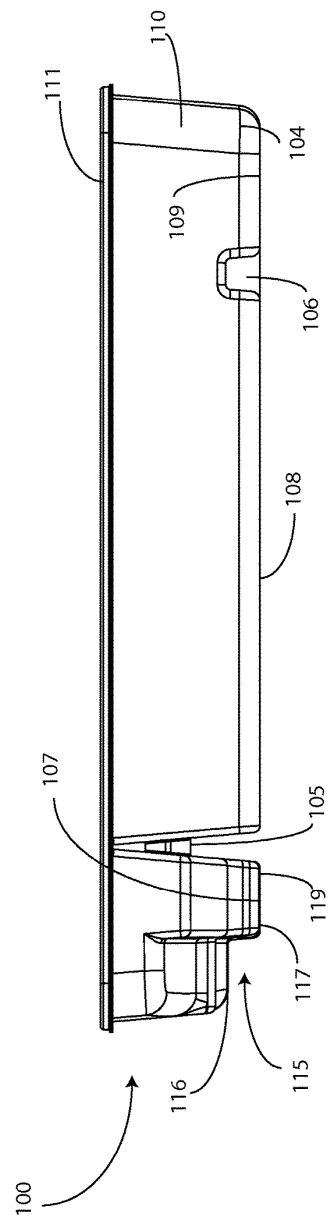


FIG. 4

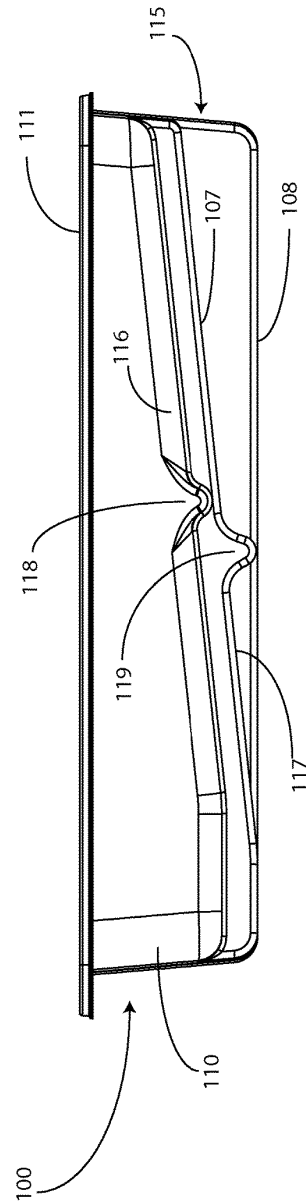


FIG. 5

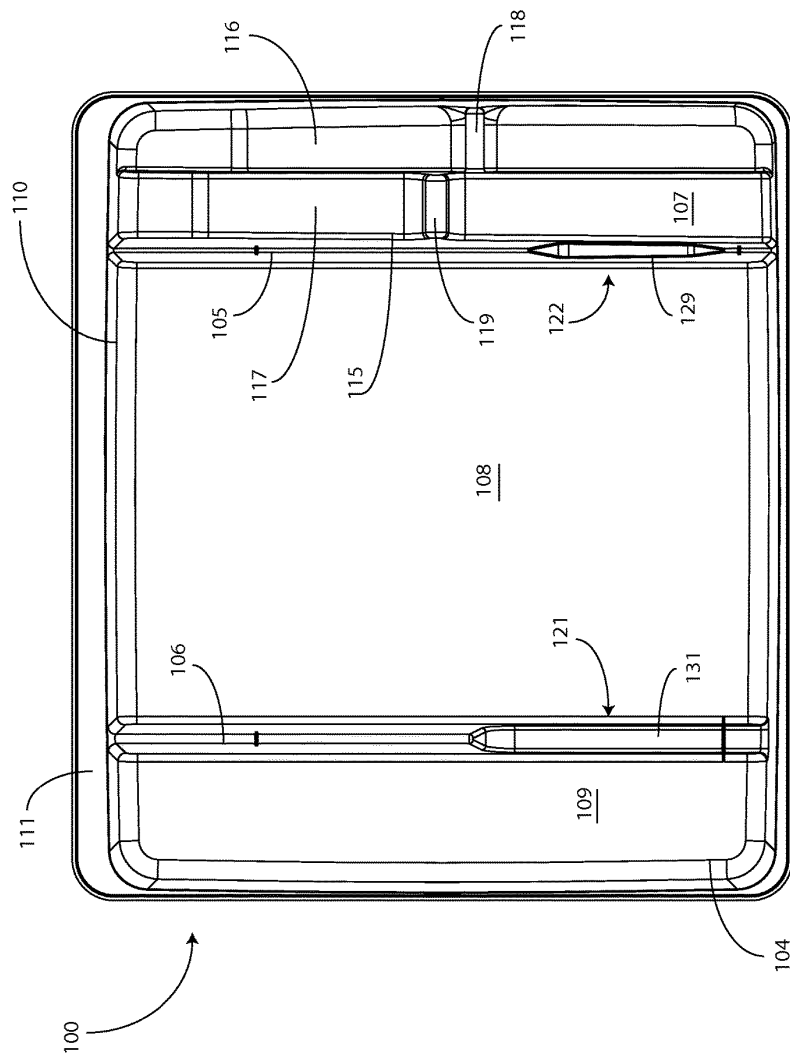


FIG. 6

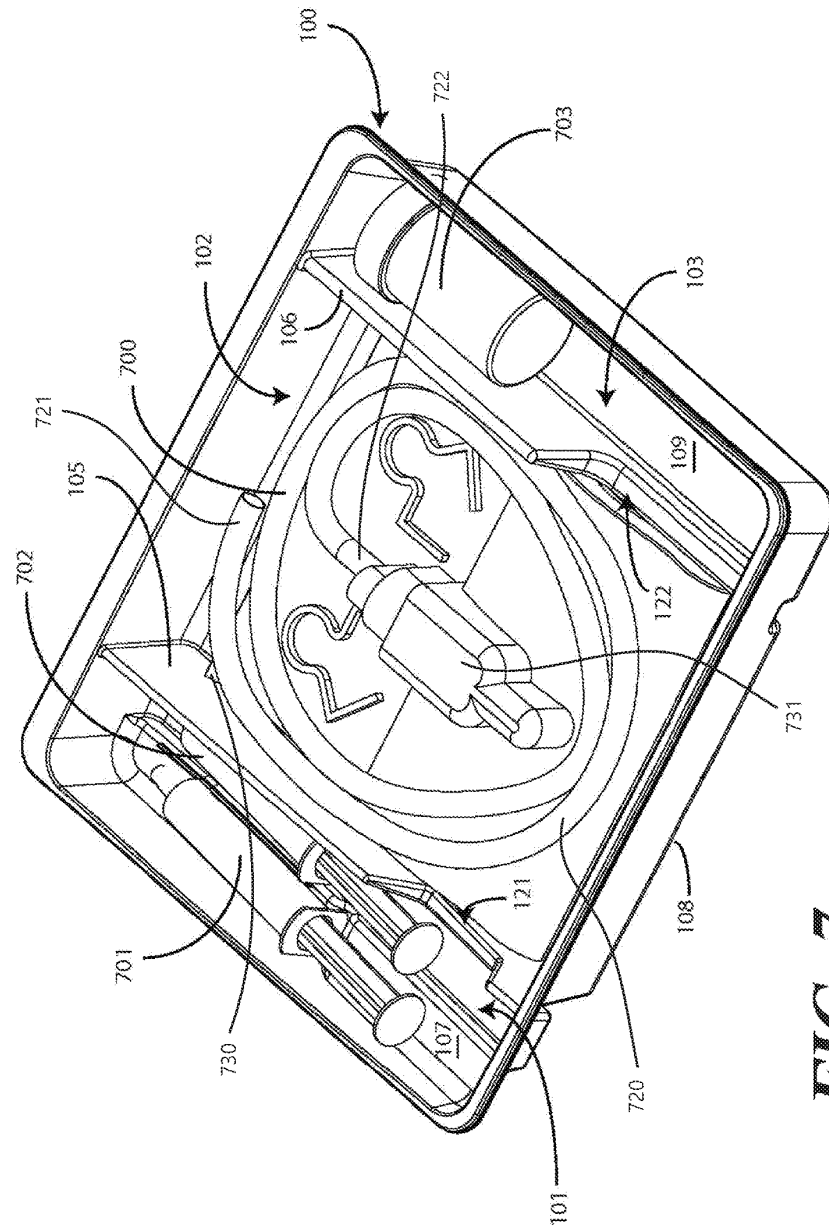


FIG. 7

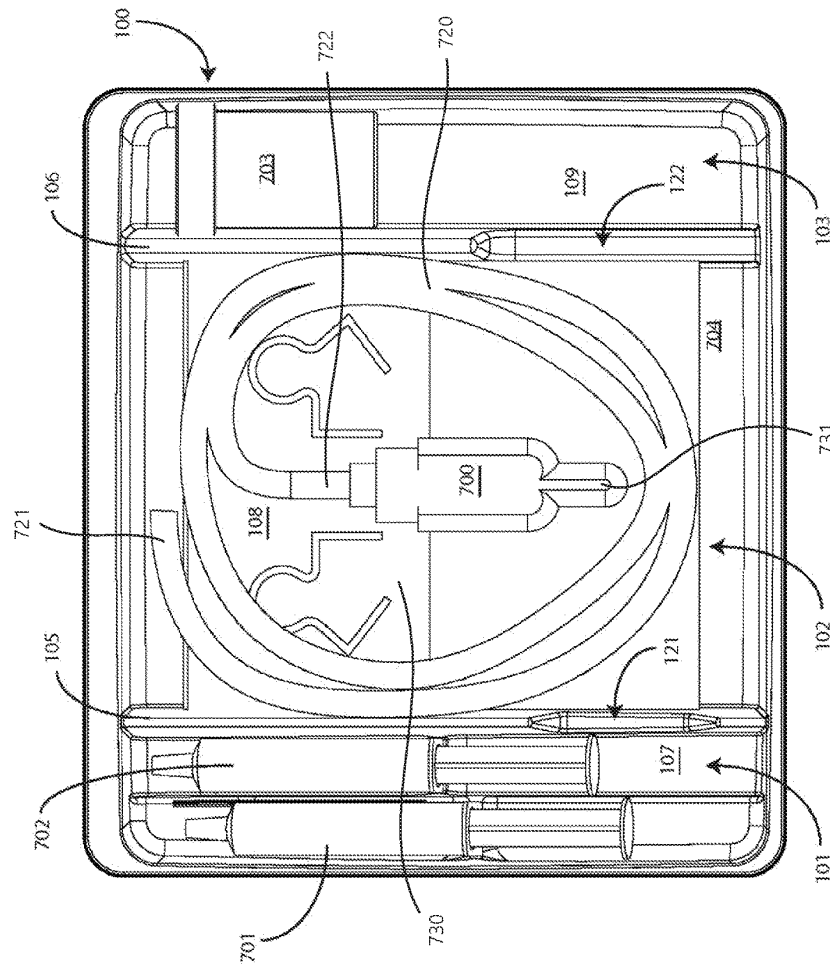


FIG. 8

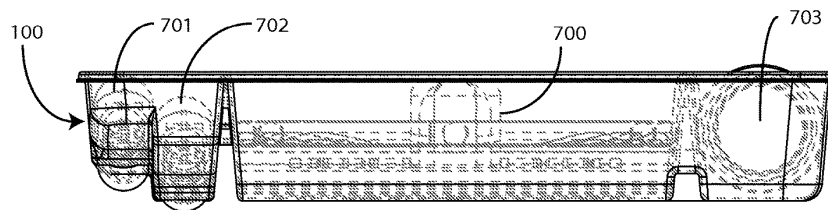


FIG. 9

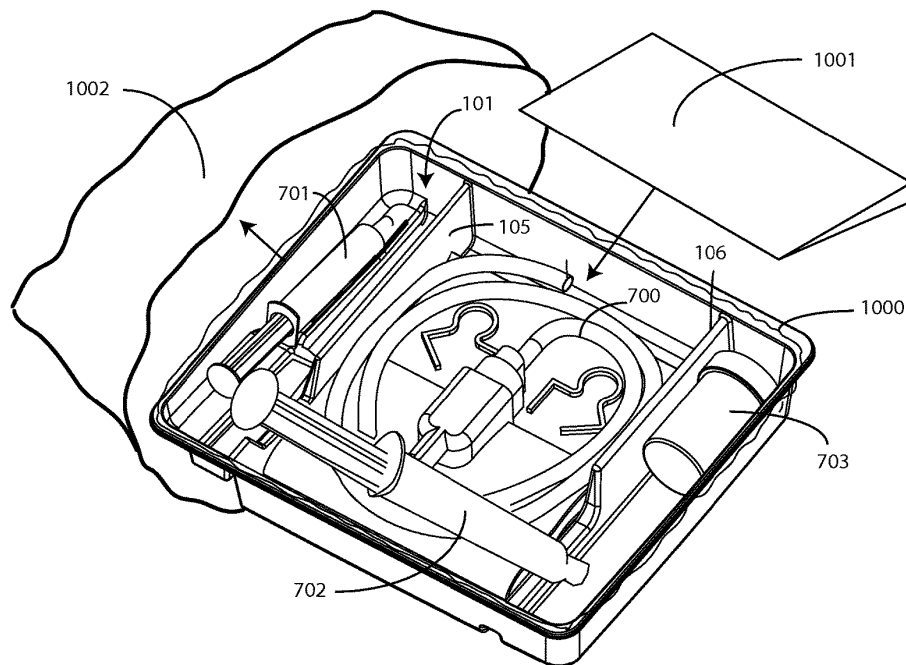
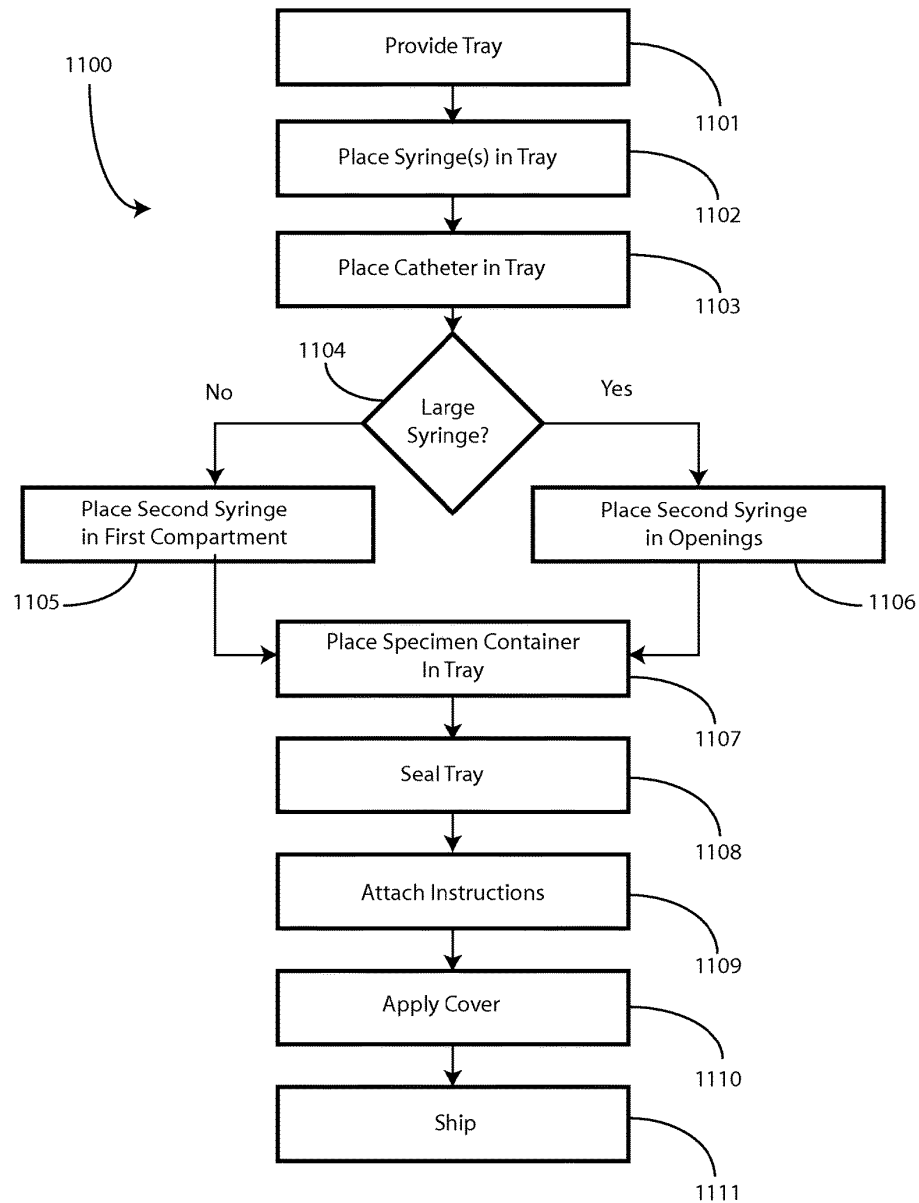


FIG. 10

**FIG. 11**

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**CATHETER TRAY, PACKAGING SYSTEM,
AND ASSOCIATED METHODS****CROSS REFERENCE TO PRIOR
APPLICATIONS**

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

BACKGROUND**Technical Field**

This invention relates generally to storage containers for medical devices, and more particularly to a storage container for a long, flexible medical implement, such as a catheter, and related medical devices.

Background Art

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

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

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

Some manufacturers have started shipping catheters and other similar devices in flat plastic trays. For example, U.S. Pat. No. 6,068,121 to McGlinch teaches one such tray. The tray has several specifically contoured loops such that one universal tray will accommodate several different sized catheters. Such packaging presents a problem, however, in that large amounts of storage space are taken with a universal tray, especially when a relatively short catheter is shipped therein. Additionally, when in use, these trays occupy large amounts of a medical service provider's sterile workspace or table, leaving little room for related components, such as lubricants, fluid bags, and so forth.

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

**DETAILED DESCRIPTION OF THE
INVENTION**

Embodiments of the invention are now described in detail. Referring to the drawings, like numbers indicate like parts throughout the views. As used in the description herein

and throughout the claims, the following terms take the meanings explicitly associated herein, unless the context clearly dictates otherwise: the meaning of “a,” “an,” and “the” includes plural reference, the meaning of “in” includes “in” and “on.” Relational terms such as first and second, top and bottom, and the like may be used solely to distinguish one entity or action from another entity or action without necessarily requiring or implying any actual such relationship or order between such entities or actions. Also, reference designators shown herein in parenthesis indicate components shown in a figure other than the one in discussion. For example, talking about a device (10) while discussing figure A would refer to an element, 10, shown in figure other than figure A.

Embodiments of the present invention provide a tray configured to accommodate a coiled medical device such as a catheter or catheter assembly. In addition to accommodating the coiled medical device, embodiments of the present invention are also configured to contain devices and materials intended for use with the coiled medical device.

Using a catheter assembly as an example, when a catheter assembly is inserted into a patient, sterile water may be used to inflate the catheter. Additionally, the catheter may be coated in a lubricating jelly prior to insertion into the patient. Fluids and other samples may then be monitored and obtained from the patient via the catheter. Embodiments of the present invention provide a single container 100 configured to accommodate not only the catheter assembly 700 and fluid bag 730, but also syringes 701, 702 containing sterile water or lubricants. Further, the tray can accommodate a sterile specimen jar 703 or capturing samples taken from the patient via the catheter.

In addition to simply accommodating these corresponding medical devices, in one embodiment the tray is configured to provide the medical services provider with mnemonic devices instructing them in which order to use each device. For example, a compartment containing syringes, in one embodiment, includes an inclined, stair-stepped bottom member to present the plungers of each syringe at an easy to reach angle and at different heights based upon order of use.

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

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

The tray 100, in one embodiment, is formed by a contoured surface 104 that defines the various features and compartments of the tray 100. The contoured surface 104 of the tray 100 can be manufactured in various ways. For example, in one embodiment, the tray 100 can be thermally formed on a mold from a soft thermoplastic, such as styrene or polystyrene. In another embodiment, the tray 100 can be injection molded. In another embodiment, the tray can be poured on a mold using a quick setting plastic, epoxy, or resin. Other methods of manufacture will be obvious to those of ordinary skill in the art having the benefit of this disclosure.

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

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

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

In one illustrative embodiment, the tray 100 is configured to hold or otherwise accommodate all of the necessary devices and materials to perform a catheter-based procedure on a patient. Said differently, the tray 100 is configured to hold not only the catheter assembly, but the medical devices corresponding to catheter use as well. Using one illustrative procedure as an example, the following devices will be used: a syringe holding sterile water, a syringe holding lubricating jelly or another equivalent lubricant, a catheter assembly, skin cleansing or preparation materials, and a specimen jar. The various compartments and features of the tray 100 shown in FIGS. 1-6 will be described for use with these devices. As will be described in more detail below, additional objects can be included with the tray, such as one or more towels, a drape to cover the patient, rubber gloves, hand sanitizing materials, printed instructions, and so forth. The syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar are used for illustration purposes only, as it will be clear that other objects may be added to or substituted for these objects. Further, subsets of these objects may be used.

In one embodiment suitable for procedures using the syringe holding sterile water, syringe holding lubricating jelly, catheter assembly, and specimen jar, in one embodiment, the tray 100 is configured such that these objects are ordered in accordance with their use during the procedure.

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For example, in one embodiment the tray **100** includes a first compartment **101** for accommodating one or more syringes, a second compartment **102** for accommodating the catheter assembly, and a third compartment **103** for accommodating the specimen jar. These devices stowed in the various compartments will be illustrated and described with respect to FIGS. 7-10 below. The discussion of FIGS. 1-6 will include the features of the tray **100** that make the tray **100** suitable for accommodating these devices.

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

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

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

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

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

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sions **120** that help to prevent the syringes from sliding laterally within the first compartment **101**.

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

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

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

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

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

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

ments, various tasks associated with a catheterization procedure can be completed while keeping the catheter within the tray **100**. The ability to keep the catheter in the tray **100** reduces the risk that the catheter or corresponding devices will be contaminated with bacteria or microbes on other objects within the procedure room. For example, when the first compartment **101** is used to apply lubricating jelly to the catheter, the lubricating jelly can be applied while the catheter is contained within the tray **100**, thereby reducing the risk that the catheter will become contaminated. This correspondingly reduces the risk of infection for the patient receiving the catheter.

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

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

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

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

Another advantage of the tray **100** is that its compartmentalized configuration helps to reduce the risk of contaminating a patient or compromising the sterile nature of the components stored in the tray **100**. Since both the catheter assembly and medical devices corresponding to catheter use are stored within the same tray **100**, the risk of cross-contamination between sterile work areas and non-

sterile spaces is minimized. Further, by having the catheter assembly and the devices corresponding to catheter use stowed in a one-level tray rather than a multi-level, stacked configuration, the medical services provider can more easily prepare and use the catheter and corresponding devices disposed within the tray **100**.

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

The illustrative catheter packaging system of FIGS. 7-9 includes a tray **100** having a first compartment **101**, a second compartment **102**, and a third compartment **103**. In this illustrative embodiment, the first compartment **101** is configured to accommodate syringes **701,702**. The second compartment **102** is configured to accommodate a coiled medical device, such as catheter assembly **700**. The catheter assembly **700** includes an indwelling (or Foley) catheter coupled to a fluid bag **730** by a tube **720**. The first end portion **721** of the tube **720** is coupled to the indwelling catheter and the second end portion **722** of the tube **720** is coupled to the fluid bag **730** via an anti-reflux device **731**. The third compartment **103** is configured to accommodate the specimen container **703**. The third compartment **103** can accommodate other materials as well, including skin sanitizers and cleansing liquids, solutions, or gels. As mentioned above, additional devices corresponding to catheter use, including towels, drapes, rubber gloves, and so forth, can be disposed in the tray **100** as well. As an illustration of this flexibility, a towel **704** is disposed beneath the catheter assembly **700**.

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

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

As noted above, some medical procedures will call for more materials than can be accommodated by a syringe capable of fitting within the first compartment **101**. For such procedures, the tray **100** can be packed with larger syringes. A large syringe (not shown) can be supported laterally within the tray **100** when it is placed across the tray **100** such that it lies within both the first opening **121** of the first barrier

105 and the second opening **122** of the second barrier **106**. Such a syringe will pass across the top of the catheter assembly **700**, but will be held in place by the side members of each opening.

Turning now to FIG. **10**, illustrated therein is an exploded view of the tray **100** having the catheter assembly **700**, a pair of syringes **701,702**, and a specimen container **703** disposed therein. In the configuration of FIG. **10**, rather than having both syringes **701,702** disposed within the first compartment **101**, one syringe **702** is disposed laterally in the first opening **121** and the second opening **122** of the first barrier **105** and second barrier **106**, respectively.

Once the necessary components are disposed within the tray **100**, the tray can be sealed with a CSR wrap **1000** to keep the internal components sterile. Printed instructions **1001** can then be attached or disposed upon the tray **100**. In one embodiment, the printed instructions **1001** can tell the medical services provider how to perform a standard catheterization procedure. For instance, in one embodiment, the tray **100** is equipped with an adhesive label that can be used to identify the patient or specimen in the specimen container **703**. Further, a label can be included to mark or otherwise identify the material in the fluid bag **730** attached to the catheter. Such labels can include pre-printed fields, such as date, time and name. Further the printed instructions **1001** can notify the medical services provider that the devices disposed within the tray **100** are ordered corresponding to use during the catheterization procedure.

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

Once the printed instructions **1001** have been affixed to or placed with the tray **100**, the assembly can be sealed in a sterile wrap **1002** such as a thermally sealed bag. Inclusion of a sterile wrap allows the instructions to be included with the tray assembly, yet outside the CSR wrap **1000**. It will be clear to those of ordinary skill in the art having the benefit of this disclosure that the invention is not so limited, however. For example, the sterile wrap **1002** can be optional. Rather than including printed instructions **1001**, the instructions for use can be printed on the CSR wrap **1000**, thereby making the need for a sterile wrap optional.

Turning now to FIG. **11**, illustrated therein is a method **1100** for manufacturing a packaged catheter assembly in accordance with embodiments of the invention. At step **1101**, the manufacturer provides a tray (**100**) having at least a first compartment (**101**) for accommodating one or more syringes (**701,702**) and a second compartment (**102**) for accommodating a flexible medical device, such as a catheter assembly (**700**). As noted above, in one embodiment the first compartment (**101**) will have a first compartment base member (**107**) having an inclined, stair-stepped contour (**115**). The first compartment (**101**) and second compartment (**102**) can be separated by a first barrier (**105**) having an opening (**121**) therein.

Once the tray (**100**) is procured, the manufacturer can dispose at least one syringe (**701**) in the first compartment (**101**) at step **1102**. In one embodiment, as determined at decision **1104**, a second syringe (**702**) will be disposed in the first compartment (**101**) at step **1105**. In another embodi-

ment, the second syringe (**702**) will be disposed laterally within the first opening (**121**) and, where present, a second opening (**122**) at step **1106**.

At step **1103**, the manufacturer will place the catheter assembly (**700**) in the second compartment (**102**). Other components may be disposed in the tray (**100**) as well, including a specimen container (**703**) in a third compartment (**103**) at step **1107**, towels, drapes, printed instructions, and so forth.

At step **1108**, the tray (**100**) is sealed. At optional step **1109**, the manufacturer can enclose printed instructions (**1001**). In one embodiment, the printed instructions (**1001**) will direct a user to discharge contents of at least one syringe into the first compartment (**101**) and to pass at least a portion of the catheter assembly (**700**) through the opening and into the contents to lubricate the catheter.

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

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

What is claimed is:

1. A kit, comprising:

- a single level tray defining at least a first compartment and a second compartment, the first compartment bounded by a first compartment base member of the single level tray, the second compartment bounded by a second compartment base member of the single level tray, the single level tray including a barrier separating the first compartment from the second compartment, the barrier defining an opening;
- a first syringe containing an inflation fluid, the first syringe disposed within the first compartment of the single level tray;
- a second syringe containing a lubricant, the second syringe disposed within the single level tray, the first syringe and the second syringe configured for use during a catheterization procedure;
- an indwelling catheter; and
- a coiled tube coupling the indwelling catheter to a fluid receptacle, the indwelling catheter, the coiled tube, and the fluid receptacle disposed within the second compartment of the single level tray with the coiled tube being outside of the fluid receptacle, the opening of the barrier sized to receive a portion of the indwelling catheter when the indwelling catheter is passed from the second compartment into the first compartment to lubricate the indwelling catheter.

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2. The kit of claim 1, wherein:
the first syringe and the second syringe are both within the
the first compartment; and
the single level tray defines a third compartment config-
ured to accommodate at least one of a specimen con-
tainer or a skin cleanser.
3. The kit of claim 1, wherein the second compartment
base member and the first compartment base member are
substantially coplanar.
4. The kit of claim 1, wherein the opening is bounded by
an opening base member and two inclined opening side
members.
5. The kit of claim 1, wherein each of the first compart-
ment and the second compartment are accessible through a
top opening defined by the single level tray, the top opening
opposite the second compartment base member.
6. The kit of claim 1, wherein:
the indwelling catheter includes an inflatable portion
configured to receive the inflation fluid from the first
syringe to maintain the indwelling catheter within a
patient.
7. The kit of claim 6, wherein each of the first syringe and
the second syringe is contained within the single level tray
at different depths within the single level tray.
8. The kit of claim 6, wherein the first compartment
contains the first syringe at a shallower depth within the
single level tray than the second syringe.
9. The kit of claim 1, further comprising printed instruc-
tions packaged with the single level tray, the printed instruc-
tions directing a user to discharge the lubricant from the
second syringe into the first compartment.
10. The kit of claim 9, wherein the printed instructions
further direct the user to pass at least a portion of the
indwelling catheter into the first compartment, and through
the lubricant discharged from the second syringe into the
first compartment.
11. The kit of claim 1, wherein the single level tray defines
a top opening through which the first compartment and the
second compartment can be accessed, the kit further com-
prising:
a sterile wrap disposed about the single level tray cover-
ing at least the top opening.
12. The kit of claim 11, wherein when the sterile wrap is
unwrapped from about the top opening such that at least the
first syringe, the second syringe, and the indwelling catheter
are revealed.
13. A kit, comprising:
a single level tray including a first compartment base
member and a second compartment base member, the
single level tray defining a first compartment and a
second compartment, the first compartment base mem-
ber forming a portion of a boundary of the first com-
partment, the second compartment base member form-
ing a portion of a boundary of the second compartment,
the single level tray including a barrier separating the
first compartment from the second compartment;
a first syringe disposed within the first compartment of the
single level tray, the first syringe containing an inflation
fluid;
a second syringe disposed within the single level tray, the
second syringe containing a lubricant; and
a catheter assembly including a coiled tube coupling an
indwelling catheter to a fluid receptacle, the indwelling
catheter including an inflatable portion configured to
receive the inflation fluid from the first syringe to
maintain the indwelling catheter within a patient, the
fluid receptacle including an anti-reflux device, an end

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- of the coiled tube coupled to the anti-reflux device, the
coiled tube and the fluid receptacle disposed within the
second compartment of the single level tray with at
least a portion of the coiled tube being outside of the
fluid receptacle and such that the fluid receptacle is
between the second compartment base member and the
coiled tube.
14. The kit of claim 13, wherein the coiled tube and the
fluid receptacle are disposed within the second compartment
of the single level tray with at least a portion of the fluid
receptacle being beneath the coiled tube.
15. The kit of claim 13, wherein the barrier extends a
length of the first compartment and defines an opening to
receive a portion of the catheter assembly when a tip of the
indwelling catheter is placed from the second compartment
into the first compartment to lubricate the indwelling cath-
eter.
16. The kit of claim 13, wherein the single level tray
defines a top opening through which the first compartment
and the second compartment can be accessed, the kit further
comprising:
a sterile wrap disposed about the single level tray cover-
ing at least the top opening.
17. The kit of claim 16, wherein when the sterile wrap is
unwrapped from about the top opening at least the first
syringe, the second syringe, and the indwelling catheter are
revealed.
18. A kit, comprising:
a single level tray defining a first compartment and a
second compartment, the single level tray including a
barrier separating the first compartment from the sec-
ond compartment, the barrier extending a length of the
first compartment and defining an opening;
a first syringe disposed within the first compartment of the
single level tray, the first syringe containing an inflation
fluid;
a second syringe disposed within the single level tray, the
second syringe containing a lubricant; and
a catheter assembly including a coiled tube coupling an
indwelling catheter to a fluid receptacle, the indwelling
catheter including an inflatable portion configured to
receive the inflation fluid from the first syringe to
maintain the indwelling catheter within a patient, the
coiled tube and the fluid receptacle disposed within the
second compartment of the single level tray with at
least a portion of the coiled tube being outside of the
fluid receptacle, the opening defined by the barrier
sized to receive a portion of the catheter assembly when
a tip of the indwelling catheter is placed from the
second compartment into the first compartment to
lubricate the indwelling catheter.
19. The kit of claim 18, wherein the fluid receptacle
includes an anti-reflux device, an end of the coiled tube
coupled to the anti-reflux device.
20. The kit of claim 19, wherein:
the single level tray includes a first compartment base
member and a second compartment base member, the
first compartment base member forming a portion of a
boundary of the first compartment, the second com-
partment base member forming a portion of a boundary
of the second compartment; and
the coiled tube and the fluid receptacle are disposed
within the second compartment of the single level tray
such that the fluid receptacle is between the second
compartment base member and the coiled tube.

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

a sterile wrap disposed about the single level tray covering at least the top opening. 5

22. The kit of claim **21**, wherein when the sterile wrap is unwrapped from about the top opening at least the first syringe, the second syringe, and the indwelling catheter are revealed. 10

* * * * *

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(12) **INTER PARTES REVIEW CERTIFICATE** (2189th)

United States Patent
Adler et al.

(10) **Number:** **US 9,808,400 K1**

(45) **Certificate Issued:** **Jul. 7, 2021**

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

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Chua; John Henry Kutsch**

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Trial Number:

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Appl. No.: **14/265,909**
Filed: **Apr. 30, 2014**

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

INTER PARTES REVIEW CERTIFICATE

U.S. Patent 9,808,400 K1

Trial No. IPR2019-00208

Certificate Issued Jul. 7, 2021

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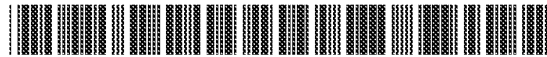
AS A RESULT OF THE INTER PARTES
REVIEW PROCEEDING, IT HAS BEEN
DETERMINED THAT:

Claims 13, 14, 16 and 17 are cancelled.

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* * * * *

EXHIBIT 12



US006158437A

United States Patent [19]

Vagley

[11] Patent Number: 6,158,437
[45] Date of Patent: *Dec. 12, 2000

[54] METHOD OF PERFORMING A SURGICAL
PROCEDURE AND ASSOCIATED SURGICAL
INSTRUMENT SUPPORT TRAY

5,059,271 10/1991 Taub 156/306.3
5,174,453 12/1992 Stoeffler 206/570
5,289,919 3/1994 Fischer 206/63.5

[76] Inventor: Richard T. Vagley, 830 15th St.,
Oakmont, Pa. 15139

Primary Examiner—Robert L. Nasser
Attorney, Agent, or Firm—David C. Jenkins; Arnold B.
Silverman; Eckert Seamans Cherin & Mellott, LLC

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[57] ABSTRACT

A method of performing a surgical procedure includes providing an instrument supporting tray having a plurality of surgical instruments positioned thereon adjacent to a plurality of instrument-identifying indicia disposed in predetermined relative positions. In performing the surgical procedure, the surgical instruments will be employed generally in the sequence in which they are positioned on the tray. The surgical instruments are identified by at least one of (a) graphics corresponding generally to the shape of the particular surgical instrument, (b) recesses conforming generally to the shape of the surgical instrument and (c) words and/or numbers providing identification thereof. In a preferred embodiment, the instrument-identifying indicia will be provided with different instruments in different sequences, depending upon the specific surgical procedure. In a further embodiment, the instrument-identifying indicia will be keyed both in terms of identity of instrument and sequence of presentation to the preference of the particular surgeon. The surgical instrument support of the present invention has a surgical instrument supporting surface for supporting a plurality of surgical instruments and instrument-identifying indicia disposed in predetermined relative position to establish a sequence which corresponds generally to the sequence in which the surgical instruments will be employed. The instrument-identifying indicia also serves to provide, by at least one of (a) graphics, (b) recesses and (c) words and/or numbers specific identification of the instrument.

[21] Appl. No.: 08/796,653

[22] Filed: Feb. 5, 1997

Related U.S. Application Data

[63] Continuation of application No. 08/417,498, Apr. 5, 1995, abandoned, which is a continuation of application No. 08/166,699, Dec. 14, 1993, abandoned.

[51] Int. Cl.⁷ B65D 85/62

[52] U.S. Cl. 128/898; 206/370; 206/570;
206/439; 206/561

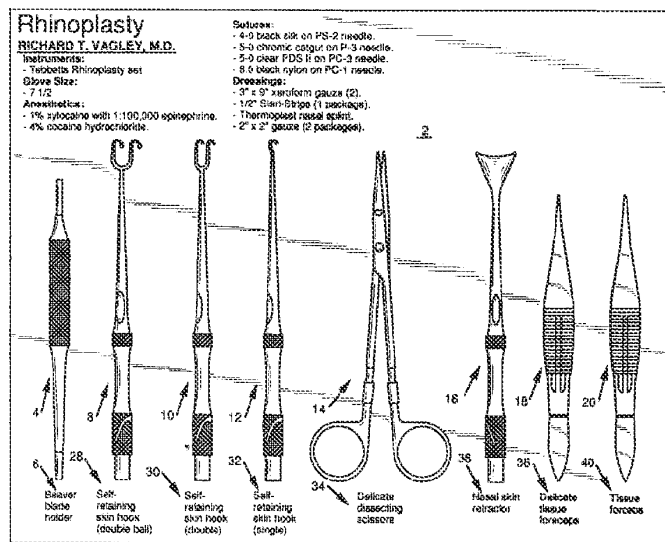
[58] Field of Search 206/369, 370,
206/438, 63, 557, 558, 562, 563, 564, 570;
433/77, 79; 128/898

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26 Claims, 3 Drawing Sheets



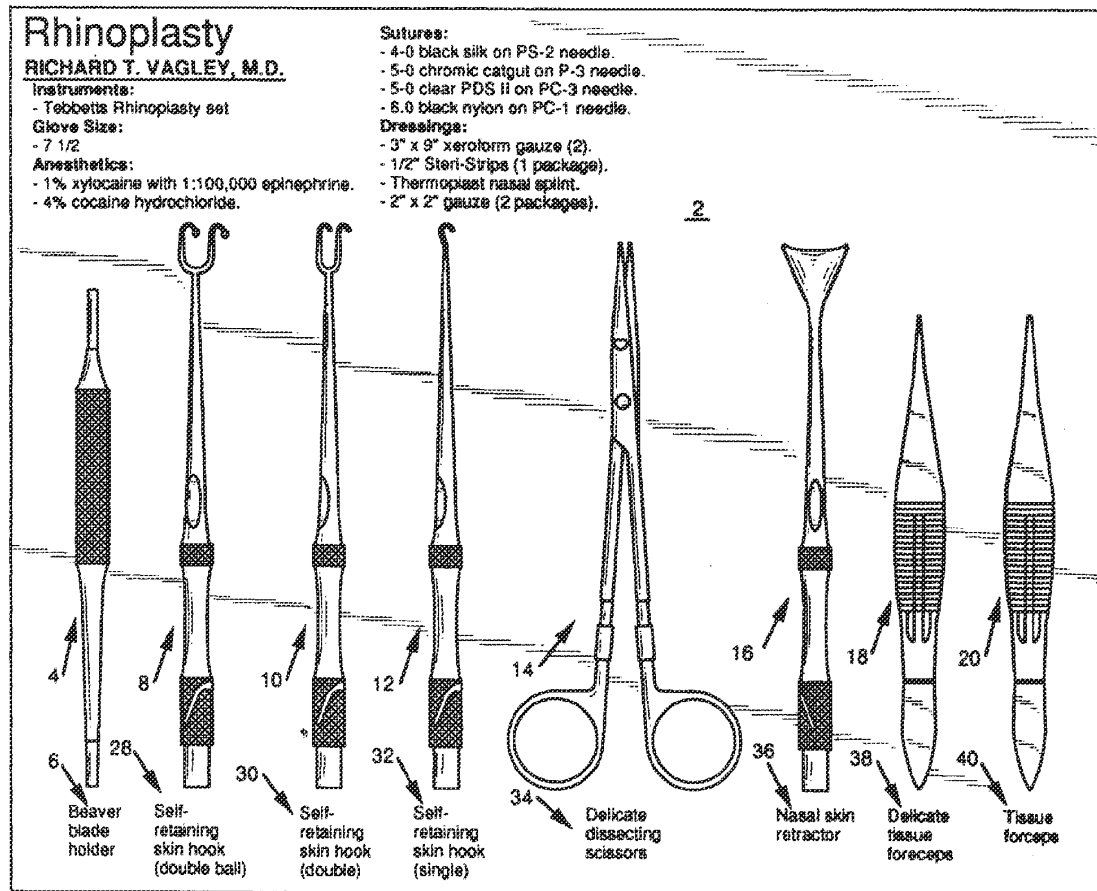


FIG. 1

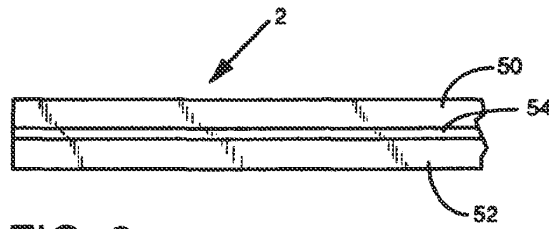


FIG. 2

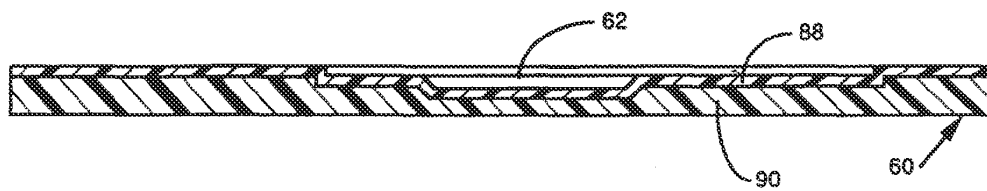
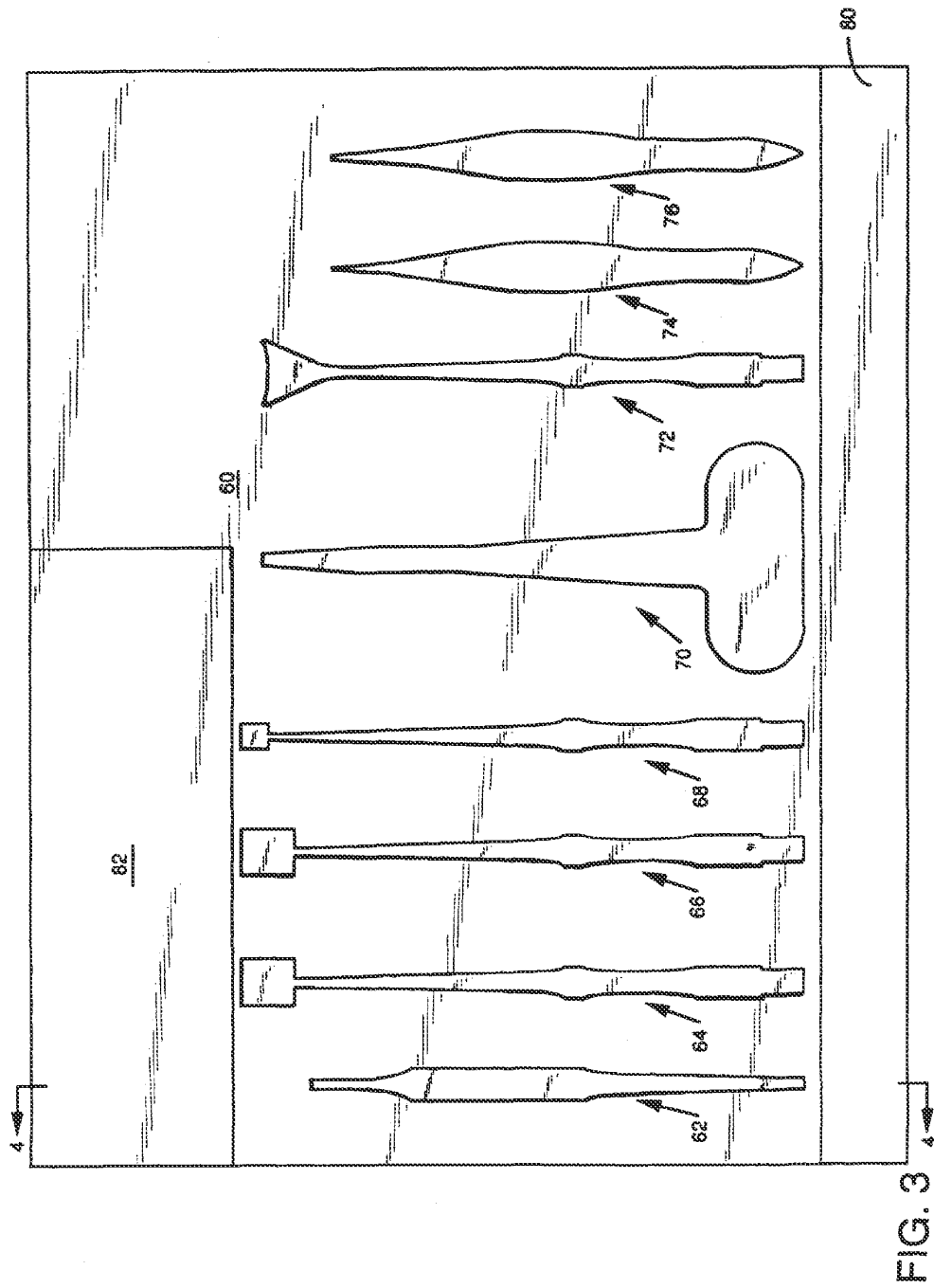


FIG. 4



METHOD OF PERFORMING A SURGICAL PROCEDURE AND ASSOCIATED SURGICAL INSTRUMENT SUPPORT TRAY

This is a continuation of U.S. patent application Ser. No. 08/417,498, filed Apr. 5, 1995, now abandoned, which is a continuation of U.S. patent application Ser. No. 08/166,699, filed Dec. 19, 1993 now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method of performing a surgical procedure and to an associated surgical instrument support tray and, more specifically, it relates to a system wherein instrument-identifying indicia are provided on a surgical instrument support tray in the general sequence in which the instruments will be employed in a particular surgical procedure.

2. Description of the Prior Art

The medical well-being of mankind has benefited tremendously in this century due to enhanced diagnostic and therapeutic equipment and procedures, improved pharmaceuticals and the enhanced skill of the surgeon.

Tremendous coordination is required in the surgical suite in order to successfully perform a surgical procedure. Not only are sterility and highly efficient coordination among the chief surgeon, assistants, nursing staff and anesthesiologists required to make a surgical procedure successful, but also efforts must be made to do no harm to the patient.

In a typical surgical procedure, a surgeon will employ a large number of hand-held surgical instruments in a specific sequence depending upon both the specific procedure being performed and the preference of the particular surgeon. As there are on the order of hundreds of different surgical instruments in general use, in addition to their being various sizes and other variations within these general categories, it becomes critical that the surgical assistants be able to deliver accurately the specific instrument called for by the surgeon in a rapid and highly reliable manner. Unfortunately, there are situations in the surgical environment wherein either experienced knowledgeable assistants make careless mistakes or assistants who are inadequately skilled are not able to identify by name the particular surgical instrument called for by a surgeon. Such errors can have a substantial detrimental impact upon the surgery.

U.S. Pat. No. 5,059,271 discloses the use of a sheet of silicone rubber with a non-slip surface with the material draped over the patient who is lying in a horizontal position. Surgical instruments are placed on this piece of material which is positioned in relatively close adjacency to the incision. It is stated that even though the surface may be inclined, the non-stick characteristics will resist undesired falling of the surgical instruments off of the sheet.

Despite the foregoing, there remains a need for improved handling of surgical instruments during surgery so as to enhance the likelihood that potentially life saving or life threatening surgical procedures can be performed with a higher degree of efficiency.

SUMMARY OF THE INVENTION

The above-described needs have been met by the present invention. The method of the present invention involves providing an instrument supporting tray having a plurality of surgical instruments positioned thereon. The tray has a plurality of instrument-identifying indicia disposed in a

predetermined relative position corresponding to the general sequence in which they will be employed in the surgical procedure. The surgeon employs the surgical instruments generally in this sequence during performance of the surgical procedure.

The instrument-identifying indicia may be one or more of the following: (a) a graphic representation corresponding in general to the appearance of the instrument, (b) a recess for at least partially receiving the instrument corresponding generally to the shape of the instrument and (c) words and/or numbers identifying the name of the instrument.

In a most preferred embodiment of the invention, the sequence of representation of the instruments by the instrument-identifying indicia will be customized to not only the particular surgical procedure which will be performed, but also to the preference of the specific surgeon who will be performing the surgery.

The surgical tray of the present invention has an instrument-supporting surface and instrument-identifying indicia disposed in a predetermined sequence so as to facilitate presentation of the instruments in the sequence in which the surgeon will be performing the surgery as well as specific identification of the instrument.

The tray of the present invention is preferably flexible such that it can be stored in a rolled or folded condition. It is also preferably sterilizable. The instrument-identifying indicia may be presented as part of a separate element secured to the tray or be imprinted directly on a tray on one or both sides thereof.

It is an object of the present invention to provide a system for enhanced surgical efficiency through presentation on a tray of the surgical instruments to be used in a particular procedure in the general sequence in which they will be employed.

It is a further object of the present invention to provide instrument-identifying indicia on the tray so as to facilitate identification of the particular instrument for delivery of the same to the surgeon and identification of the place on the tray where the instrument is to be returned after use.

It is yet another object of the present invention to provide such a system which facilitates presenting additional equipment information reflecting preferences of the particular surgeon in a readily visible manner.

It is a further object of the present invention to provide, in one embodiment, such a system which is sterilizable and readily reusable.

It is another object of the invention to present additional information on the tray related to the specific surgical procedure.

These and other objects of the invention will be more fully understood from the following description of the invention in reference to the illustrations appended hereto.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view of a form of tray of the present invention.

FIG. 2 is a partial end elevational view of a tray of the present invention showing the relative relationships of the materials.

FIG. 3 is a top plan view of a modified form of tray of the present invention wherein recesses are provided for the instruments.

FIG. 4 is a cross-sectional illustration of the tray of FIG. 3 taken through 4—4 thereof.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As employed herein, the term "patient" means a member of the animal kingdom, including humans.

As employed herein, the term "surgical procedure" means a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive.

As employed herein, "instrument-identifying indicia" means visually perceptible elements which will facilitate identification of a specific surgical instrument or its position on the tray.

FIG. 1 shows a plan view of a tray of the present invention wherein a series of eight instruments will be employed in sequence going from left to right. As used herein the reference to "generally in the sequence" refers to the individual instruments being used by the surgeon in a specific surgical procedure starting from the left and going to the right and shall embrace instances where one or more of these instruments will, during the course of the procedure, be employed more than once. Such repeat usage of the particular instruments will not be deemed to depart from the expression "employed generally" in sequence.

In this embodiment, the tray 2 has instrument-identifying indicia in the form of both graphic planar representations and words. The first instrument 4 is identified by a graphic representation of the instrument and words 6 which identify it as a Beaver blade holder. Similarly, graphic presentation of instruments 8, 10, 12, 14, 16, 18 and 20 are presented along with corresponding word identifications 28, 30, 32, 34, 36, 38, 40.

These instruments have been selected as being the instruments desired to be used by the surgeon in performing a rhinoplasty surgical procedure. By providing the instruments on the tray 2 in this sequence and identifying the instrument both graphically and textually, the efficient presentation of the instruments to the surgeon by the surgical assistant is facilitated along with enhanced facility for returning the instrument to the proper location on the tray after use. As a result, when the procedure is beginning the surgical assistant will, when asked for a Beaver blade holder, provide to the surgeon the instrument positioned over graphic component 4 and adjacent to textual legend. Subsequently, when asked for a self-retaining skin hook (double ball) the instrument positioned over graphic element 8 will be provided. This procedure will be followed throughout the surgery. As the instruments are handed back to the surgical assistant, he or she, if not certain of the identity, can look at the graphic components and text for guidance and position the same over the desired location.

In a preferred embodiment of the invention, the tray will be made of a flexible, sterilizable material which can be stored in a roll or folded without effecting meaningful damage thereto. Referring to FIG. 2, the tray may be made out of a silicone rubber material having an upper wall 50 and a lower wall 52. A pocket 54 is defined between walls 50 and 52 and may receive a plastic or paper element imprinted in the manner shown in FIG. 1. Assuming that the printed element received within pocket 54 faces upwardly, wall 50 should be transparent to facilitate ready reading of the words and viewing of the graphics. If desired, the separate element received within pocket 54 may be printed on both sides and both walls 50, 52 may be transparent thereby facilitating use of the instrument-identifying indicia in surgical procedures. In lieu of pocket 54, the separate element bearing the

instrument identifying indicia may be secured to the outer surface of wall 50 or wall 52 by any suitable means such as adhesive or tape, or frictional retention. In the alternative, the separate element may be positioned over wall 50 or wall 52 and rest thereon without securement thereto. The separate element may be made of any suitable material, such as paper, paperboard, or plastic, for example.

As the reusable tray must be sterilizable, if the separate element received in pocket 54 cannot withstand such treatment, it will be removed with the tray 2 before sterilization.

An alternative approach would be to print the material shown in FIG. 1 on the outer surface of the tray or print the same and, if desired or required, provide a protective covering thereover subsequently. If desired, printing of a pattern, such as exemplified by FIG. 1, may be provided on both surfaces of the tray with different surgical procedures represented by each printed surface. The term "printing" as employed herein refers generically to any means of applying a different colored material to the tray so as to create readily visible graphic components or the words or numbers desired.

Referred once again to FIG. 1, there is shown in the upper left hand corner a further preferred feature of the present invention. While the general concept of the present invention involves positioning instruments sequentially in the order in which they will be employed for a particular surgical procedure adjacent to their respective instrument-identifying indicia, the invention also contemplates, if desired, providing further refinements which are keyed to the preferences of a particular surgeon. For example, the description herein-before has focused upon the example of rhinoplasty. The rhinoplasty tray 2 may be keyed to the instruments which Dr. Vagley prefers to employ in the procedure in his preferred sequence. It also may provide additional information regarding equipment preferences of Dr. Vagley in performing rhinoplasty such as the particular maker of the instruments, glove size, preferred anesthetics, sutures and dressings. The present invention facilitates providing such information as well.

In general, it will be preferred that the tray have a thickness which varies depending upon the material and construction employed. The tray may be of generally rectangular configuration and have outside dimensions no greater than the dimensions of the support surface on which it will be placed. If desired, the tray may be composed of a substantially rigid material.

It will be appreciated from the foregoing that the tray may be fully sterilizable in the portion where the printed indicia, such as paint, ink or different colored material, for example, are applied. The tray may also be fully sterilizable, subject to providing (a) an insert which might bear instrument-identifying indicia and be made of plastic or paper, for example, and positioned in pocket 54, or (b) a plastic or paper element, for example, bearing instrument-identifying indicia might be positioned on top of another portion of the tray, or (c) the tray may be fully disposable, such as by employing a paper or plastic item, for example, imprinted as shown in FIG. 1, for example, supported on a rigid support which need not be a portion of the tray, or (d) the tray may have an unsterilized element bearing the instrument-identifying indicia covered by a sterile transparent drape.

One of the advantages of employing the pocket is that the benefit of the instrument-identifying indicia is provided while the non-slip characteristics of the material out of which walls 50 and 52 are made are retained.

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Referring to FIG. 3, a different embodiment of the present invention will be considered. In this embodiment, the tray 60 has a series of upwardly open recesses 62, 64, 66, 68, 70, 72, 74, 76 each being generally contoured so as to at least partially receive a specific surgical instrument. The recesses 62-76 (even numbers only) are so positioned as to provide the surgical instruments generally in the sequence in which they will be employed during the surgical procedure. In this embodiment, if desired, graphic representations of the specific instrument 62-76 (even numbers only) may be provided in addition to the recesses either within the recess or adjacent thereto. Also, textual and/or numeric identification (not shown) of the specific instruments are preferably provided within zone 80 with the words and/or numbers underlying the recess for the particular instrument. Information similar to that provided in the upper left corner of FIG. 1 may be provided in zone 82. As shown in FIG. 4, the recess 62 is upwardly open and may be formed within a molded element 88 which may form the upper portion of tray 60 which in turn may be received on any suitable underlying support member 90, such as a plastic or a metal underlying member to which it may be secured as by self-bonding or a suitable adhesive.

It will be appreciated, therefore, that the present invention not only provides for the surgical instruments to be supported on the tray in the sequence in which they will be employed during the surgical procedure, but also employs at least one of (a) graphic representation as in FIG. 1, (b) textual (or numeric) identification as in FIGS. 1 and 3 and (c) recesses as in FIGS. 3 and 4 to facilitate ready identification of the surgical instrument for purposes of delivery of the proper instrument to the surgeon in an efficient and prompt manner and returning the instrument to the proper location on the tray after use. All of this is accomplished in an economical manner employing trays which may be rigid or flexible which are sterilizable, or disposable, or are covered by a sterile drape and can be employed economically either as reusable elements or sterile, disposable elements.

As a further enhancement, the trays may be imprinted so as to not only provide a desired sequence of use and identification of the respective surgical instruments, but also be further customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All of this is directed toward enhanced efficiency in the surgical suite and more accurate and prompt delivery of the correct instrument to the surgeon and return of the same to the tray after use.

Whereas particular embodiments of the invention have been described herein, for purposes of illustration it will be evident to those skilled in the art that numerous variation of the details may be made without departing from the invention as to find in the appended claims.

I claim:

1. A method of performing a surgical procedure comprising providing a plurality of surgical instruments, each having an appearance, providing an instrument supporting tray having said plurality of surgical instruments positioned thereon, providing said tray with a plurality of instrument identifying indicia disposed in a sequence of predetermined relative positions with the identified surgical instruments positioned adjacent to said instrument identifying indicia respectively related thereto,

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performing a surgical procedure employing said surgical instruments generally in the sequence in which said instrument-identifying indicia are present, and

employing a sterilizable flexible tray having a pocket for receipt of said instrument-identifying indicia and a transparent wall whereby said instrument-identifying indicia may be seen from the exterior of said tray.

2. The method of performing a surgical procedure of claim 1

selecting and positioning said surgical instruments to correspond with the surgical procedure being performed.

3. The method of performing a surgical procedure of claim 2 including

selecting and positioning said surgical instruments according to a specific surgeon's preference.

4. The method of performing a surgical procedure of claim 2 comprising

employing as said instrument-identifying indicia at least one of (a) graphic representations corresponding generally to the appearance of said surgical instrument, (b) words, and (c) numbers.

5. The method of performing a surgical procedure of claim 4 including

establishing said instrument-identifying indicia by printing on said tray.

6. The method of performing a surgical procedure of claim 2 including

employing as said instrument-identifying indicia at least one of (a) recesses in said tray corresponding generally to the appearance of said surgical instrument, (b) words, and (c) numbers.

7. The method of performing a surgical procedure of claim 2 including

employing as said tray a flexible tray which can be rolled or folded for storage.

8. The method of performing a surgical procedure of claim 2 including

employing a sterilizable tray as said tray.

9. The method of performing a surgical procedure of claim 2 including

employing a transparent sterile drape overlying said instrument-identifying indicia.

10. The method of performing a surgical procedure of claim 1 including

employing at least some of said instruments more than once during said surgical procedure.

11. A method of performing a surgical procedure comprising:

providing a plurality of surgical instruments, each having an appearance,

providing an instrument supporting tray having said plurality of surgical instruments positioned thereon,

providing said tray with a plurality of instrument identifying indicia disposed in a sequence of predetermined relative positions with the identified surgical instruments positioned adjacent to said instrument identifying indicia respectively related thereto, and

performing a surgical procedure employing said surgical instruments generally in the sequence in which said instrument-identifying indicia are present;

employing a sterilizable flexible tray, and securing an instrument-identifying indicia bearing element to said tray;

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employing said tray having a pocket for receipt of said instrument-identifying indicia bearing element and a transparent wall whereby said instrument-identifying indicia may be seen from the exterior of said tray.

12. The method of performing a surgical procedure of claim 10 including

positioning said tray on a generally rigid support surface during said surgical procedure.

13. The method of performing a surgical procedure of claim 1 comprising

employing said process in a procedure performed on a human being by a surgeon.

14. The method of performing a surgical procedure of claim 13 including

providing on said tray identification of said surgeon and said surgeon non-instrument surgical equipment preferences.

15. The method of performing a surgical procedure of claim 1 including the step of

securing an instrument-identifying indicia bearing element to said tray.

16. A surgical instrument support tray comprising

a surgical instrument supporting surface for supporting a plurality of surgical instruments, said surgical instruments being employable in a sequence in a surgical procedure,

instrument-identifying indicia disposed in predetermined relative position generally corresponding to the sequence in which said surgical instruments will be employed,

wherein each said instrument has an appearance; and

said instrument-identifying indicia includes a visual depiction of said instruments established by a two dimensional graphics and recesses corresponding to the appearance of said instruments.

17. The surgical instrument support tray of claim 16 including

said tray having said instrument-identifying indicia identifying the instruments and relative sequence of use for a particular surgeon in a specific surgical procedure.

18. The surgical instrument support tray of claim 16 including

said tray having additional information regarding said surgeon's specific non-instrument equipment preferences.

19. The surgical instrument support tray of claim 16 including

said tray being sterilizable.

20. The surgical instrument support tray of claim 19 including

said tray being flexible so as to permit rolling or folding for storage without meaningful damage thereto.

21. The surgical instrument support tray of claim 20 including

said instrument-identifying indicia being printed on said tray.

22. The surgical instrument support tray of claim 20 including

said instrument-identifying indicia being printed on a separate element which is secured to said tray.

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23. The surgical instrument support tray of claim 16 including

a transparent sterile drape overlying the portion of said tray bearing said instrument-identifying indicia.

24. A surgical instrument support tray comprising:

a surgical instrument supporting surface for supporting a plurality of surgical instruments, said surgical instruments being employable in a sequence in a surgical procedure,

instrument-identifying indicia disposed in predetermined relative position generally corresponding to the sequence in which said surgical instruments will be employed,

said tray being sterilizable,

said tray being flexible so as to permit rolling or folding for storage without meaningful damage thereto,

said instrument-identifying indicia being printed on said tray, and

said tray having a pocket within which said separate element is secured and an adjacent transparent tray wall to permit said instrument-identifying indicia to be viewed.

25. A surgical instrument support tray comprising:

a surgical instrument supporting surface for supporting a plurality of surgical instruments, said surgical instruments being employable in a sequence in a surgical procedure,

instrument-identifying indicia disposed in predetermined relative position generally corresponding to the sequence in which said surgical instruments will be employed,

said tray being sterilizable,

said tray being flexible so as to permit rolling or folding for storage without meaningful damage thereto,

said instrument-identifying indicia being printed on a portion of said tray, and

said tray being printed with instrument-identifying indicia on a separate element which is positioned on another portion of said tray.

26. A surgical instrument support tray comprising:

a surgical instrument supporting surface for supporting a plurality of surgical instruments, said surgical instruments being employable in a sequence in a surgical procedure, and

instrument-identifying indicia disposed in predetermined relative position generally corresponding to the sequence in which said surgical instruments will be employed,

said tray being sterilizable,

said tray being flexible so as to permit rolling or folding for storage without meaningful damage thereto,

said instrument-identifying indicia being printed on a separate element which is secured to said tray,

said separate element being printed with instrument-identifying information on both sides and said tray having two said transparent walls.

* * * * *

Electronic Patent Application Fee Transmittal				
Application Number:		16833575		
Filing Date:		28-Mar-2020		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		10055UCIP2D1C1C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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

Electronic Acknowledgement Receipt	
EFS ID:	46861851
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	20-OCT-2022
Filing Date:	28-MAR-2020
Time Stamp:	16:51:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$260
RAM confirmation Number	E20220JG52013680
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2D1C1C1C1C1_USA_2022-10-5_IDS.pdf	153052	no	5
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This is not an USPTO supplied IDS fillable form					
2	Non Patent Literature	US_CAFC_Decision_2021-8-13.pdf	596829	no	24
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3	Non Patent Literature	10055U_D1C2C1_USA_2021-10-7_FinalOA.pdf	792756	no	11
			018d8a918d9bcdffa76abdd13b1aeb2bc977b9b2		
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4	Non Patent Literature	1037-001-03US_2022-07-05_FinalOfficeAction.pdf	858645	no	12
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5	Non Patent Literature	1037-002-10US_2022-09-16_FinalOA.pdf	854555	no	13
			b118908ed91ad3b8bed7f8e1a41c84b34cd0929f		
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6	Non Patent Literature	1037-002-10US_2021-12-22_Non-FinalOfficeAction.pdf	1045235	no	14
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8	Non Patent Literature	10055U_CIP2_USA_2022-4-19_ReexamOrder_PA.pdf	1479199 c35bcac60b756f1cbe908d0bdeef97cf4962340c	no	21
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9	Non Patent Literature	10055U_CIP2_USA_2022-9-29_ReexamNonFinalOA.pdf	869682 b67bc95687c5a33f77f53d55531cd75f58fcd934	no	13
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10	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit1.pdf	5939173 32762d39c8f35e1439c60ed031516607065a6699	no	53
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11	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit2.pdf	11651183 7e7ba682983140e96d44cc17158f0286734750fc	no	127
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12	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit3.pdf	5521384 8ca8201ebd605a8c1fffa3910acfb28660e77e35	no	61
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13	Non Patent Literature	10055U_CIP2_USA_2022-2-24_Exhibit4.pdf	17773249 b3c791e0f30834ec11c31b538cc9a7dbedd35b64	no	246
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56	Non Patent Literature	10055U_CIP2_D1_USA_2022-6-8_Exhibit8.pdf	590776	no	4
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Total Files Size (in bytes):			245282457		

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New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/833,575		Filing Date 03/28/2020		☐ To be Mailed	
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO									
APPLICATION AS FILED - PART I									
	(Column 1)	(Column 2)							
FOR	NUMBER FILED	NUMBER EXTRA			RATE (\$)			FEE (\$)	
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*			x \$100 =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*			x \$460 =				
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).								
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.							TOTAL		
APPLICATION AS AMENDED - PART II									
	(Column 1)	(Column 2)	(Column 3)						
AMENDMENT	02/13/2023	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(j))	* 20	Minus	** 20	= 0		x \$ 100 =	0	
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0		x \$ 480 =	0	
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE	0		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(j))	*	Minus	**	=		x \$ 0 =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x \$ 0 =		
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/NICOLE L NICHOLSON/			
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".									
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.									

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

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Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	16833575	
Filing Date	28-Mar-2020	
First Named Inventor	Jennifer Tomes	
Attorney Docket Number	10055UCIP2D1C1C1C1C1	
Title of Invention	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
Medline Industries LP	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 9745088 9522753 10251812 9808400 9808596 9283352 10946992 10640243		

as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.

Applicant claims the following fee status:

- ☐ Small Entity
- ☐ Micro Entity
- ☒ Regular Undiscounted

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES

I certify, in accordance with 37 CFR 1.4(d)(4) that I am:

☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application

Registration Number 45432

☐ A sole inventor

☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application

☐ A joint inventor; all of whom are signing this request

Signature

/Philip H. Burrus, IV/

Name

Philip H. Burrus, IV

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal				
Application Number:		16833575		
Filing Date:		28-Mar-2020		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		10055UCIP2D1C1C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				170

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16833575

Filing Date: 28-Mar-2020

Applicant/Patent under Reexamination: Tomes

Electronic Terminal Disclaimer filed on February 13, 2023

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	47516974
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	13-FEB-2023
Filing Date:	28-MAR-2020
Time Stamp:	15:55:19
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$170
RAM confirmation Number	E20232CF55158488
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	44143	no	3
			93ef0e78ae0cd17da869f1386d021c67f05650bc		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38140	no	2
			a79557345b1b75523a70623945a729c52874d213		
Warnings:					
Information:					
Total Files Size (in bytes):			82283		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
Examiner: Marcetich, Adam M.
Art Group: 3781
Reference No.: BPMDL0005JT CIP2 D1 C1 C1 C1 C1
(10055U CIP2 D1 C1 C1 C1 C1)
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

February 9, 2023

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

This paper is in response to an Office Action mailed September 13, 2022, a response thereto being due on or before December 13, 2022, and accompanies a Petition for Extension of Time for Response and the appropriate fees. In view of the remarks herein, Applicants respectfully request reconsideration of the above-identified patent application.

CLAIMS:

Listing of the Claims:

1. (Currently Amended) A medical procedure kit, comprising:
 - a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber, ~~and an opening allowing access to the lubricating jelly application chamber;~~
 - a container of lubricating jelly disposed within the single layer tray; and
 - a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit;wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly;
the container of lubricating jelly comprising a syringe containing the lubricating jelly; and
the syringe situated within the lubricating jelly application chamber.
2. (Currently Amended) The medical procedure kit of claim 1, further comprising one or more swabsticks disposed within the single layer tray.
3. (Currently Amended) The medical procedure kit of claim 1, further comprising a syringe containing water disposed within the single layer tray, wherein the syringe is at least partially disposed in the compartment with the Foley catheter.

4. (Currently Amended) The medical procedure kit of claim [[1]] 3, wherein the syringe containing the lubricating jelly and the syringe containing the water are arranged within the single layer tray in a left-to-right configuration opening defined by an opening depth.
5. (Currently Amended) The medical procedure kit of claim [[1]] 4, wherein left-to-right configuration comprises a left-to-right usage configuration the container of lubricating jelly comprising a syringe containing the lubricating jelly.
6. (Currently Amended) The medical procedure kit of claim [[5]] 3, wherein the syringe containing the lubricating jelly and the syringe containing the water are arranged within the single layer tray in accordance with an order with which they syringe containing the lubricating jelly and the syringe containing the water are removed from the single layer tray situated within the lubricating jelly application chamber.
7. (Currently Amended) The medical procedure kit of claim [[6]] 1, further comprising a second syringe disposed within the single layer tray, wherein the syringe containing the lubricating jelly and the second syringe are arranged within the single layer tray in accordance with an order with which the syringe containing the lubricating jelly and the second syringe are drawn out of the single layer tray.
8. (Original) The medical procedure kit of claim 7, the second syringe at least partially situated in the compartment.
9. (Currently Amended) The medical procedure kit of claim 7, the second syringe containing water is for attachment to the Foley Catheter.

10. (Original) The medical procedure kit of claim 9, wherein the water comprises sterile water.
11. (Currently Amended) The medical procedure kit of claim 7, wherein the syringe and the second syringe are arranged in the single layer tray in accordance with an ~~[[their]]~~ order of use during a Foley catheterization procedure.
12. (Original) The medical procedure kit of claim 11, the lubricating jelly application chamber comprising one or more contours for accommodating flanges of one or more of the syringe or the second syringe.
13. (Currently Amended) A medical procedure kit, comprising:
 - a first syringe and a second syringe;
 - a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter;
 - a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly, ~~and an opening~~ the medical procedure kit allowing passage of at least some of the Foley catheter ~~medical assembly~~ into a lubricating jelly application chamber; and
 - an outer packaging disposed about the single layer tray;wherein:
 - one of the first syringe or the second syringe contains lubricating jelly;
 - another of the first syringe or the second syringe contains water;
 - the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of

the single layer tray ~~with their use~~ during a Foley catheterization procedure; and

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

14. (Currently Amended) The medical procedure kit of claim 13, wherein the second syringe is attachable to the Foley catheter ~~at least some of the medical assembly comprises at least some of the Foley catheter~~.
15. (Currently Amended) The medical procedure kit of claim 14, wherein the single layer tray comprises a third compartment containing one or more swabsticks.
16. (Currently Amended) The medical procedure kit of claim 15, wherein ~~the opening is defined by~~ a boundary surface ~~[[of]]~~ defines the lubricating jelly application chamber.
17. (Currently Amended) The medical procedure kit of claim 16, wherein the medical procedure kit opening allows passage of at least some of the coiled tubing into the lubricating jelly application chamber.
18. (Currently Amended) A medical procedure kit, comprising:
- a Foley catheter coupled to a fluid drain bag via a coiled tubing, a first syringe and a second syringe, one or more swabsticks, a specimen container, and a surface defining a single layer tray having a lubricating jelly application chamber with the first syringe and the second syringe disposed within a single compartment and the one or more swabsticks disposed within another compartment;
- wherein:

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

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

19. (Currently Amended) The medical procedure kit of claim 18, wherein the one or more swabsticks are disposed within the single layer tray.

20. (Previously Presented) The medical procedure kit of claim 19, further comprising a wall situated between the single compartment and the lubricating jelly application chamber.

REMARKS – General

Claim Amendments:

Claims 1-3, 7, 11, 13, 15, and 18-19 have been amended with support found in claim 1 as originally filed. Claim 1 has further been amended with support found in claim 6 as previously pending. Claims 4-5 have been amended with support found in the specification at paragraph [046]. Claim 6 has been amended with support found in the specification at paragraph [048] and in the figures at FIG. 15, steps 1508 and 1509. Claims 7 and 13 have further been amended with support found in the specification at paragraph [0116]. Claims 9 and 14 have been amended with support found in the figures at FIG. 15, element 1508.

Claim Rejections under 35 USC §112:

The Office Action rejects claims 14-17 under 35 USC §112(b) as being indefinite because claim 14 recites “wherein ***the at least some of*** the medical assembly comprises ***at least some of*** the Foley catheter.” Office Action, page two. Examiner’s original emphasis. The Office Action submits this is ambiguous “because it defines the medical assembly in terms of overlapping and intermediate degrees of both the medical assembly and the Foley catheter.” *Id.* The Examiner kindly suggests removing the “at least some” qualifiers in set forth in the claim.

Claim depends from claim 13. Claim 13 recites *inter alia* a medical procedure kit comprising “a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter.” The claim also recites that an opening of the lubricating jelly application chamber allows “***at least some***” of that medical assembly to pass into the lubricating jelly application chamber. Emphasis added.

Claim 14 then makes clear that the “at least some” of the medical assembly that passes into the lubricating jelly application chamber is indeed “at least some” of the ***Foley catheter*** and not the coiled tubing or the fluid drain bag.

Since the Office Action takes issue with the wording of this claim, solely in the interest of expediting prosecution Applicant has voluntarily canceled the limitations in question from claim 14. Reconsideration of the rejection is respectfully requested.

Claim Rejections under 35 USC §103:

The Office Action rejects claims 1-3 as being obvious in view of Solazzo, US Published Patent Application No. 2006/0009742, combined with Serany, US Pat. No. 3,329,261. Claim 5 is rejected as being obvious in view of Solazzo and Serany, further combined with Fischer, US Pat. No. 4,554,156. Applicant respectfully traverses the rejections.

Claim 1 as amended, from which claims 2-3 and 5 depend, recites *inter alia* a medical procedure kit comprising:

- a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber configured to receive lubricating jelly from a container of lubricating jelly for lubricating at least a portion of a Foley catheter with the lubricating jelly;
- where the container comprises a syringe of lubricating jelly situated within the lubricating jelly application chamber.

For a proper rejection of a claim under §103, the cited combination of references must disclose, teach, or suggest all of the elements of an applicant's claim. See, e.g., *In re Dow Chemical*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988) and *In re Keller*, 208 USPQ2d 871,881 (CCPA 1981). It is respectfully submitted that neither the combination of Solazzo and Serany nor the combination of Solazzo, Serany, and Fischer teaches or suggests these limitations. Reconsideration of the rejections to claims 1-3 and 5 is respectfully requested.

Double Patenting:

Claims 1, 3, and 18 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,808,400 to Tomes.

Claims 1 and 13 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 10,251,812 to Tomes.

Claim 18 is rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 10,251,812 to Tomes combined with Jamie Glen, US Published Patent Application No. 2007/0225687.

Claims 1 and 13 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,522,753 to Tomes.

Claim 18 is rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,522,753 to Tomes combined with Jamie Glenn.

Claims 1-2, 4-13, and 16-20 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,745,088 to Tomes.

Claims 1, 13, and 18 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 10,640,243 to Tomes.

Claims 1, 13, and 18 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 10,946,992 to Tomes.

Claims 1 and 13 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,283,352 to Tomes.

Claims 1, 3, and 18 are rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,808,596 to Tomes.

Claim 18 is rejected under the judicially created, non-statutory, obviousness-type double patenting doctrine in view of commonly assigned US Pat. No. 9,808,596 to Tomes combined with Jamie Glen.

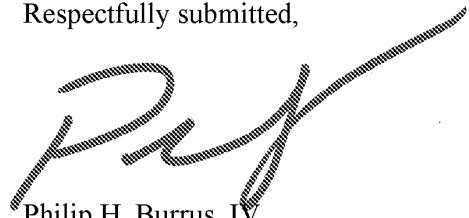
U.S.S.N. 16/833,575

As noted by the Office Action at page eight, a timely filed terminal disclaimer in compliance with 37 CFR §§1.321(c) or (d) will obviate these rejections. Applicant includes herewith eight such terminal disclaimers, along with the appropriate fee. Reconsideration of the rejections is respectfully requested.

CONCLUSION

For the above reasons, Applicant believes the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Applicant believes this application is now in condition for allowance, for which it respectfully submits.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. Burrus, IV", with a long, sweeping horizontal stroke extending to the right.

Philip H. Burrus, IV

Attorney for Applicant

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U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
Examiner: Marcetich, Adam M.
Art Group: 3781
Reference No.: BPMDL0005JT CIP2 D1 C1 C1 C1 C1
(10055U CIP2 D1 C1 C1 C1 C1)
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

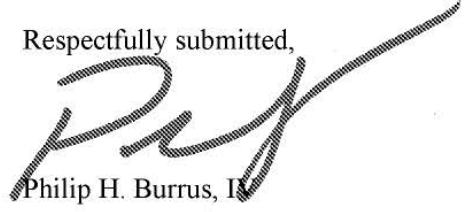
February 9, 2023

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

Petition for Extension of Time for Response

Applicant hereby respectfully requests an extension of time for response. The appropriate fees are included herewith. The Director is hereby authorized to debit any underpayments or credit any overpayments to Deposit Account No. 503608.

Respectfully submitted,


Philip H. Burrus, II

Attorney for Applicant

Registration No.: 45,432

404-797-8111

PACKAGING BODY

DOCUMENT ID

JP-2000281144-A

DATE PUBLISHED

2000-10-10

INVENTOR INFORMATION

NAME	CITY	STATE	ZIP CODE	COUNTRY
SHIMURA KENICHI	N/A	N/A	N/A	N/A
NAKAGAWA YUJI	N/A	N/A	N/A	N/A
IMAI MASAOMI	N/A	N/A	N/A	N/A

DATE FILED

1999-03-26

CPC CURRENT

TYPE	CPC	DATE
CPCI	A61M25/002	2013-01-01

Abstract

PROBLEM TO BE SOLVED: To manufacture a packaging body bringing an instrument into contact with a liquid simply and sterily and preventing the dissipation of odor to the outside, pollution, infection and the like after the use of the instrument. **SOLUTION:** A packing material 2 for a packaging body 1 is manufactured by being fusion bonded with a sheet material, and a first space 4 and a second space 5 parted by a partition 22 are formed therein. A weak sealing section 23 is formed on the partition 22. A catheter 7 and a deodorizing agent 8 stored in a container 81 provided with breathability are stored in the first space 4. A fluid substance 10 is stored in the second space 5. When the seal sealing section 23 is peeled off and the fluid substance 10 is made to flow into the first space 4 and brought into contact with the catheter 7, the surface of the catheter 7 is wetted to reduce the friction resistance.

Description

DETAILED DESCRIPTION OF THE INVENTION

[0001]

BACKGROUND OF THE INVENTION 1. Field of the Invention The present invention relates to a package for packaging a device such as a catheter.

[0002]

2. Description of the Related Art Catheters to be inserted into trachea, digestive tract, urethra, blood vessels, other body cavities, various organs, living tissues, etc.

On the surface of a medical device such as a guide wire inserted into the catheter, a large number of thrombus, tissue adhesion or foreign body reaction is generally confirmed. Therefore, it is necessary to reduce the damage to the living tissue and securely insert it into the target site. Further, in order to suppress mucosal inflammation and mucosal damage during indwelling in a living tissue, it is necessary to impart lubricity to the device surface.

For this reason, a low friction material is used as a base material, or water, a physiologically isotonic liquid or a lubricant is applied to the surface of the device prior to use. To elaborate,

The base material of the catheter has a multilayer laminated structure, and the outermost layer (or innermost layer) is made of a low friction material such as fluororesin or polyethylene resin, and the surface of the device is lubricated with water, physiological isotonic solution, glycerin, oil, etc. Agent is applied.

However, in selecting the material of the catheter base material, there is a limit in improving the slidability, and it is difficult to reach a satisfactory level.

[0005] Further, when a lubricant or the like is applied, if the product is to be commercialized while being brought into contact with the medical device, the lubricant may be used for a long time before the medical device is used. There is concern about deterioration, deterioration, peeling off from the surface of the medical device, etc., and there have been problems in terms of stability (preservability) and associated safety.

Further, it is very difficult to aseptically contact a medical device and a lubricant during use, and there is a problem that bacterial infection or the like may occur.

In an emergency, since maintaining the life of the patient is the highest priority, the operation of applying the lubricant becomes troublesome. In some cases, the lubricant is not applied and the surface is kept dry. May be used in

[0008] As a method for causing a compound which exhibits lubricity when wetted on the surface of a medical device to be present, an international application WO 9

In 001344, at least one of an alkali metal alcoholate, an amino group, an alkali metal amide group, a carboxylic acid group, a sulfonic acid group, a magnesium halide group and a fluorine-boron complex group is introduced into the polyurethane surface by a coating operation. By operation,

A technique for immobilizing a hydrophilic polymer that can react with these functional groups on the surface is disclosed.

[0009] Similarly, a method of causing a compound which exhibits lubricity when wetted on the surface of a medical device to be present is disclosed in Japanese Patent Publication No. 6-32652, Japanese Patent Application Laid-Open No. 6-7426, International Application WO9219289, Japanese Patent Application Publication No. -502854, Tokiohei 10-502855, Tokiohei 10-502856

No., etc. are also disclosed.

[0010] However, in these methods, lubricating properties are not exhibited by drying, and the medical device is taken out of the packaging material at the time of use, and a liquid such as water or a physiologically isotonic solution is put on the surface of the medical device. The operation of supplying and contacting is essential. Moreover, it is very difficult to perform this operation aseptically, except when using special operations or facilities.

For this reason, as described above, there is a risk of infection, and in an emergency, it may be inserted directly into the trachea, digestive tract, urethra, blood vessels, etc. in a dry state, and there is concern that mucous membranes may be damaged. Was to be done.

On the other hand, when blood comes in contact with foreign substances other than vascular endothelial cells, adhesion of plasma proteins and platelets and blood coagulation are induced on the surface of the foreign substances, and thrombus is formed. This thrombus formation becomes a problem when using medical devices such as catheters and guide wires.

For this reason, blood anticoagulants such as heparin are administered to blood, or blood anticoagulants are applied to the surface of medical instruments, or antithrombotic materials are used as base materials. Have been done.

[0013] However, in the former case, harmful effects such as bleeding tendency are caused to the patient, and in the latter case, a contact operation with a liquid is required at the time of use. , As described above, in that it is very difficult.

Further, in an emergency, since maintaining the life of the patient is the highest priority, the patient may be directly used without performing an anticoagulant operation, and there is a concern that there may be an adverse effect due to thrombus formation.

After use of these medical instruments, they are discarded as medical waste. Usually, inactivation operations (disinfection / sterilization operations) of bacteria, viruses and the like in body fluids and blood are performed.

It was discarded without infective or deodorizing operations, while remaining infectious or allowing odor release.

[0016] For this reason, after the medical device is used and before it is incinerated, the odor may be radiated or body fluids such as urine and blood may leak out, resulting in contamination or infection of the surroundings.

[0017]

SUMMARY OF THE INVENTION The present invention has been made in view of the above-mentioned problems, and an object of the present invention is to enable simple and aseptic contact between an instrument and a liquid, and to use the instrument. It is another object of the present invention to provide a package capable of preventing the emission of odor to the outside, contamination, infection and the like.

[0018]

This and other objects are achieved by the present invention which is defined below as (1) to (15).

(1) A packaging material having a first space and a second space which are separated from each other by a partition portion and can communicate with each other when necessary, and are stored in the first space and inserted or attached to a living body for use. A device that is stored in the first space and eliminates or reduces odor, and a flow that is stored in the second space and can contact the surface of the device and reduce its frictional resistance. A package comprising: a conductive substance.

(2) The package according to the above (1), wherein the main component of the substance that extinguishes or reduces the odor is titanium oxide.

(3) A packaging material having a first space and a second space which are separated from each other by a partition portion and can communicate with each other when necessary, and are stored in the first space and inserted or attached to a living body for use. A device that is stored in the first space and has a function of suppressing at least the growth of microorganisms; and a device that is stored in the second space and contacts the surface of the device to reduce its frictional resistance. And a flowable substance.

(4) The package according to (3), wherein the main component of the substance having a function of suppressing the growth of microorganisms is titanium oxide.

(5) A packaging material having a first space, a second space, and a third space which are separated from each other by a partition portion and can communicate with each other when necessary, and are housed in the first space and inserted into a living body. Or a device to be mounted and used, a fluid substance stored in the second space, which can be brought into contact with the surface of the device to reduce its frictional resistance, and a fluid material stored in the third space, A substance capable of absorbing and retaining a liquid.

(6) A packaging material having a first space, a second space, and a third space which are separated from each other by a partition portion and can communicate with each other when necessary, and a packaging material which is housed in the first space and inserted into a living body. Alternatively, it is characterized by comprising a device to be worn and used, a blood anticoagulant stored in the second space, and a substance stored in the third space and capable of absorbing and retaining a liquid. Packaging.

(7) The above (5), wherein the first space and the second space are formed adjacent to each other, and the first space and the third space are formed adjacent to each other.) Or the package according to (6).

(8) The package according to any one of (1) to (7), wherein the second space is formed inside the first space.

(9) The package according to any one of the above (1) to (8), wherein the partition portion is constituted by a seal portion formed by fusing a sheet material constituting the packaging material.

(10) The package according to any one of the above (1) to (9), wherein at least a part of the partition portion is constituted by a weak seal portion having a lower joint strength than other portions.

(11) The above-mentioned (1) to (1), further comprising an opening portion for taking out the device from the first space, and sealing means for sealing the opening after opening the opening portion.

0) The package according to any one of the above.

(12) The package according to any one of the above (1) to (11), wherein the packaging material has a steam barrier property.

(13) The package according to any one of (1) to (12), wherein the device is a catheter or a guide wire.

(14) The package according to any one of (1) to (12) above, wherein the device is a catheter used by being inserted into the urethra.

(15) The package according to any one of the above (1) to (14), wherein a compound that develops lubricity by wetting is provided on at least a part of the surface of the device.

[0034]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS Hereinafter, a package according to the present invention will be described in detail based on preferred embodiments shown in the accompanying drawings.

FIG. 1 is a plan view (an internal perspective view) showing a first embodiment of the package of the present invention. As shown in FIG. 1, a package 1 includes a packaging material 2 having a first space and a second space.

have.

The packaging material 2 is a bag-like material obtained by sealing a sheet material as described later in a desired pattern by fusing (or bonding). A band-shaped seal portion 21 is formed on the outer peripheral portion of the packaging material 2 and the like.

A partition 22 is formed in the middle of the packaging material 2. The partition 22 is formed by fusing (or adhering) a sheet material in a band shape similarly to the seal portion 21. The partition 22 divides the inside of the packaging material 2 into a first space 4 and a second space 5 (isolated from each other).

As shown by hatching in FIG.

A part of 2 is composed of a weak seal part (easy peel seal part) 23 having lower bonding strength (peeling strength) than the other part (seal part 21). By peeling (breaking) the weak seal portion 23, the first space 4 and the second space 5 are separated.

Communicates with

The sealing portion 21 has a completely joined state in which the opposing sheet materials are completely fused together, while the weak sealing portion 23 has a structure in which the opposing sheet materials are fused at a lower temperature. The state is such that the fusion between them is incomplete to some extent. However, the liquid tightness (airtightness) is ensured also in the weak seal portion 23. And the effect lasts over time.

To peel (break) the weak seal portion 23,

Pressing (pressing) a portion of the packaging material 2 that defines the second space 5

However, it becomes possible by increasing the internal pressure of the second space 5. In addition, the weak seal portion 23 may be rubbed and loosened by hand, or these methods may be used in combination. Thus, the first space 4 and the second space 5 can be communicated with each other with a very simple operation.

It should be noted that the weak seal portion 23 is connected to the partition

Or may be formed at more than

2 may be formed over almost the entirety.

The sealing portion 2 at the upper end of the packaging material 2 in FIG.

1, a weak seal portion (opening portion) 24 similar to the weak seal portion 23 is formed. The weak seal portion 24 is peeled (ruptured), the packaging material 2 is opened, and the stored items in the first space 4 can be taken in and out.

A zipper (sealing means) 3 which can be opened and closed is provided near the upper end side of the weak seal portion 24 in FIG. Even after the weak seal portion 24 has been peeled (ruptured) and the packaging material 2 has been opened, the zipper 3 can be closed to seal the opening. When the zipper 3 is opened, the opening can be opened again.

The zipper 3 may be of any known configuration, such as a zipper formed of grooves and projections that fit together.

The first space 4 contains a device to be inserted into or attached to a living body, and a substance for eliminating or reducing odor. A catheter or a guide wire is preferably used as an instrument to be inserted or attached to a living body. In the present embodiment, a catheter 7 and a deodorant (deodorant) 8 are housed in the first space 4. I have.

The catheter 7 is inserted into, for example, the trachea, digestive tract, urethra, vagina, blood vessels, lymph vessels, bile ducts, other body cavities, various organs such as lungs, hearts, kidneys, and other living tissues. Although various catheters and balloon catheters can be mentioned, catheters (urethral catheters, urinary catheters) used by inserting into the urethra are particularly preferable.

The urinary drainage method for dysuria is preferably an aseptic intermittent urinary drainage method instead of an indwelling catheter. In recent years, self-urinary drainage, in which a patient himself discharges urine using a catheter, has become widespread as an effective treatment method. . Urinary dysfunction is caused by obstruction of the urethra due to benign prostatic hyperplasia, stones, tumors, and neuropathic bladder caused by disorders of the brain, spinal cord, and pelvic nerves. It is necessary to drain urine regularly because the internal pressure increases and places a burden on the kidneys. The self-guided urinary method performed at this time has the advantages of completely excreting urine at low pressure, reducing existing urinary infections, relieving urinary frequency, urinary incontinence, and not burdening the bladder and kidneys. The patient inserts a catheter into the bladder through the urethra about 4 to 6 times a day, and removes the urine when the urine has been discharged. The frequency is, for example, 4 Every 5 hours, the night is before bedtime.

The surface of the catheter 7 is preferably provided with, for example, a substance which exhibits lubricity when wet. Examples of such a substance include, for example, JP-A-60-2 59269 and Japanese Patent Application Laid-Open No. 1-195863. Further, for example, Japanese Patent Publication No. 6-32652, Japanese Patent Application Laid-Open No. 6-7426, International application WO8802623, International application WO89075 21, international application WO8909246, international application WO90 01344, International application WO9219289, International application W O9311751, International application WO9529722, JP-T10-502854, JP-T10-502855

And the materials and methods disclosed in JP-A-10-502856. Such a substance exists on the surface of the catheter 7 in a non-wetting state (dry state).

Such a substance is a polymer chemically bonded to the surface of the base material of the catheter 7, and peeling from the surface of the base material of the catheter 7 is caused by elution into water, a physiological isotonic solution, other lubricants, or the like. Are less likely to occur from the viewpoints of lubricity continuity and safety.

As the deodorant (deodorant) 8, any of commercially available deodorants, deodorants, fragrances and the like may be used. In this case, the odor removing mechanism of the deodorant 8 also includes a physical deodorizing method (porous substances such as activated carbon and zeolite) and a chemical deodorizing method (various organic and inorganic compounds, plant extracts, ozone, noble metal-based oxidation). Catalyst), biological deodorization method (microorganisms, artificial enzymes), sensory deodorization method (aromatic compounds, vegetable oil)

For example, any device that can be stored in the first space 4 may be used.

A particularly preferred deodorizing agent 8 is titanium oxide (TiO_2). This titanium oxide has the following advantages.

1) It is a harmless inorganic oxide and can be harmonized with the environment. 2) As a result of ultraviolet light excitation, it has strong oxidizing power and can decompose the adsorbed organic matter at room temperature. 3) The adsorbed oxygen is changed into oxygen radicals, and the organic substances adsorbed by the radicals can be decomposed at room temperature. 4) The effects of 2) and 3) above are caused by the illumination light of the daily living space.

Due to such excellent functions of titanium oxide, not only a deodorizing effect but also an antibacterial and antifungal effect can be obtained. Preferably, such titanium oxide is supported on a base material of organic synthetic fibers such as paper and nonwoven fabric, and fibers composed of an organic compound such as pulp.

The deodorant 8 is contained in a container (packaging material) 81 having air permeability. The container 81 is preferably made of a material that allows gas to permeate but does not allow liquid to permeate. Such a container 8

Examples of the constituent material 1 include a water-impermeable porous body such as a polyethylene nonwoven fabric and a polytetrafluoroethylene porous body.

The second space 5 contains (fills) a flowable substance (liquid or semi-liquid substance) 10 which can come into contact with the surface of the catheter 7 and reduce its frictional resistance.

Examples of the fluid substance 10 include water, physiologically isotonic solutions (physiological saline), oils such as glycerin, silicone oil and olive oil, xylocaine jelly and the like (hereinafter, these are collectively referred to as "lubricating oil"). Agent ").

In the case where the surface of the catheter 7 is provided with a substance that exhibits lubricity by wetting as described above, the fluid substance 10 may be any substance that can wet this substance. Typical examples thereof include water, physiologically isotonic solution (physiological saline), glycerin aqueous solution, and the like.

The packaging material 2 (preferably the entire packaging material 2) is

It preferably has air barrier properties. Here, the steam bath

The term "rear" means that the water vapor permeability is preferably 30 g / m².

.sup.Two 24hrs 25μm thickness 40 °C 90% RH or less

Below, more preferably 10 g / m².sup.Two 24hrs 25μ

m thickness 40 °C 90% RH or less, more preferably 1g

/ M.sup.Two 24hrs 25μm thickness 40 °C 90% RH

Say that: This water vapor permeability is measured according to JIS

It is measured by the method described in K7129 (Method A).

As described above, since the packaging material 2 has a water vapor barrier property, evaporation of moisture from the interior of the packaging material 2, particularly from the second space 5, can be prevented. As a result, it is possible to prevent the liquid material (fluid substance 10 and the like) in the second space 5 from being reduced and concentrated, and the amount of the liquid material is required to be a minimum necessary amount. Weight can be reduced. In addition, it is possible to prevent water vapor from entering the first space 4 from the outside of the packaging material 2 or from the second space 5.

A sheet material (film) constituting the packaging material 2;

In particular, as the sheet material having the steam barrier property,

For example, polyethylene, polypropylene and other polyolefin resins, blended resins of these polyolefin resins,

Polyester resins such as polyethylene terephthalate, polyvinylidene chloride, single-layer films such as vinyl chloride-vinylidene chloride copolymer, aluminum and silica vapor-deposited on these films, aluminum films, A metal foil such as an aluminum laminate film or a film containing a metal foil can be used. Moreover, Those obtained by laminating two or more of these films can also be used.

In the weak seal portions 23 and 24,

The layer (sealant layer) directly involved in fusion is composed of a blend resin of two or more incompatible polyolefin resins or a random or block copolymer having two or more incompatible polyolefins in segments. Is preferred.

In the present invention, it is preferable that the entire packaging material 2 or at least a portion defining the second space 5 of the packaging material 2 is formed of a sheet material having a water vapor barrier property.

Such sheet materials include, for example, [1] a single-layer film composed of one kind of polyolefin resin, [2] a single-layer film composed of a blend resin of two or more incompatible polyolefin resins, [3] A multilayer film of a polyolefin resin or polyester resin using a polyolefin resin (a blended resin of a polyolefin resin can also be used) for the sealant layer (layer involved in fusion).

In order to obtain a higher water vapor barrier property, for example, [4] a film in which the sealant layer is composed of a polyolefin resin (a blended resin of a polyolefin resin can also be used), and a polyolefin or polyester whose outer layer is coated with polyvinylidene chloride Multilayer film composed of films, etc., [5] Sealant layer composed of polyolefin resin (blend resin of polyolefin resin can also be used), Polyolefin film or polyester film with outer layer deposited by aluminum or silica Multilayer film.

Further, in order to obtain an extremely high water vapor barrier property, for example, [6] the sealant layer is made of a polyolefin resin (a blended resin of a polyolefin resin can also be used).

A multilayer film composed of an aluminum film as the intermediate layer and a polyester film as the outermost layer. In this case, one of the pair of sheet materials facing each other is an opaque aluminum film,

The other is preferably a transparent water vapor barrier film such as a vapor-deposited silica film, because the contents of the packaging material 2 can be visually confirmed. The aluminum film may be partly or wholly removable if necessary.

The thickness of the sheet material (single-layer or multi-layer laminate) constituting the packaging material

2 depends on the layer structure and the characteristics (flexibility, strength, water vapor permeability, heat resistance, etc.) of the material used. It is determined appropriately and is not particularly limited, but is usually preferably about 60 to 700 μm ,

More preferably, it is about 500 μm .

The sheet material constituting such a packaging material 2 is as follows:

For example, inflation method, T-die method, blow molding method, dry lamination method, hot melt lamination method,

It can be manufactured by various methods such as a coextrusion inflation method, a coextrusion T-die method, and a hot press method.

Next, a second embodiment of the package of the present invention will be described focusing on differences from the first embodiment, and the description of the same items will be omitted.

In the package of the second embodiment, in place of the deodorant 8 in the package 1 shown in FIG. 1, at least a substance having a function of suppressing the growth (propagation) of microorganisms (bacteria, viruses, etc.) is stored. Things. A typical example of this substance is an antibacterial agent, which will be described below. Here, the antimicrobial agent is a general term for substances having a sterilizing, disinfecting, disinfecting, antibacterial or bacteriostatic action.

The antibacterial agent may be either an organic antibacterial agent or an inorganic antibacterial agent. However, from the viewpoint of giving more importance to safety such as prevention of emergence of resistant bacteria, for example, metals, metal oxides, various antibacterial agents, etc. Inorganic antibacterial agents such as ceramics are preferred.

Antibacterial agents can be classified into cell wall synthesis inhibition, cell membrane disorder, protein synthesis inhibition, DNA synthesis disorder, intracellular metabolism disorder, etc. based on their mechanism of action. May be.

[0071] Such antibacterial agents are particularly preferred.

The above-mentioned titanium oxide (TiO_2).sub.Two).

This titanium oxide is as described above.

The antibacterial agent is housed in a container (packing material) made of, for example, woven fabric, mesh (net-like body) or the like, which has air permeability and liquid permeability, or the container (packaging material) 81 described above. It is preferable that it is housed in the first space 4 in a state where it is closed.

FIG. 2 is a plan view (an internal perspective view) showing a third embodiment of the package of the present invention. Hereinafter, the package of the third embodiment will be described focusing on the differences from the first embodiment, and the description of the same items will be omitted.

As shown in FIG. 2, the package 1 of the third embodiment

Is a sheet-shaped antibacterial agent, that is, an antibacterial sheet 9 stored as an antibacterial agent (at least a substance having a function of suppressing the growth of microorganisms) in the first space 4 of the packaging material 2.

As the antibacterial sheet 9, for example, a sheet,

A material in which an organic antibacterial agent, an antibacterial agent such as a metal having antibacterial activity such as silver, copper or zinc, or an antibacterial agent such as ceramics is supported on a base material such as a porous body. In particular, an inorganic antibacterial agent that is less likely to cause resistant bacteria is preferred.

In the illustrated configuration, the antibacterial sheet 9

Although disposed in a part of the first space 4, an antibacterial sheet sized to cover almost the entire area of the first space 4 can be used. Also, a plurality of antibacterial sheets 9 may be stored.

As in the second and third embodiments, since the antibacterial agent is stored in the first space 4, the used catheter can be used as well as the catheter 7 before or after the packaging material 2 is opened. Even when the catheter 7 is returned to the first space 4, the antibacterial effect can be exerted on the catheter 7, and the transportation and disposal until disposal can be performed sanarily and safely.

FIG. 3 is a plan view (an internal perspective view) showing a fourth embodiment of the package of the present invention. Hereinafter, the package of the fourth embodiment will be described focusing on the differences from the first embodiment, and the description of the same items will be omitted.

As shown in FIG. 3, the package 1 of the fourth embodiment

Is such that the second space 5 is formed inside the first space 4. That is, the packaging material 2 has a first space 4 in which the catheter 7 and the deodorant 8 (Or an antibacterial agent) and a parcel material (bag) 11 are stored.

The small wrapping material 11 is formed by laminating the same sheet material as the above-mentioned wrapping material 2 and sealing the outer peripheral portion by fusion (or adhesion) to form a bag. , A second space 5 is formed. The fluid substance 10 described above is stored (filled) in the second space 5. The seal portion on the outer periphery of the parcel material 11 constitutes a partition portion 22 for dividing the second space 5 and the first space 4. A weak seal portion 23 similar to the above is formed in a part of the partition portion 22. By peeling (breaking) the weak seal portion 23, the first space 4 and the second space 5 are separated.

And the fluid substance 10 can flow into the first space 4.

The package 1 having such a structure has the following effects (advantages). First, by selecting the volume of the parcel material 11 to be put into the first space 4, the amount and weight of the contents (such as the fluid substance 10) of the parcel material 11 can be easily set. Secondly, since the parcel material 11 is movable in the first space 4, an operation of peeling (breaking) the weak seal portion 23 and an operation of pushing out the fluid substance 10 and the like from the inside of the parcel material 11 are performed. It can be done easily.

Third, because of the double packaging, the required level of the steam barrier property of the parcel material 11, which is a container of the fluid substance 10, may be lower than that of the first to third embodiments. Thus, the degree of freedom in selecting the constituent material of the package material 11 is increased, and the sheet thickness can be reduced, which is advantageous in manufacturing.

Fourth, since the parcel material 11 can be manufactured independently, manufacturing and management are easy.

In the case of the package 1 of the fourth embodiment, only the small package material 11 may have a steam barrier property.

Next, the method of use (operation) of each package 1 described above will be described.

For example, when the weak seal portion 23 is peeled (ruptured) by the above-described method, the first space 4 and the second space 5 communicate with each other, and the fluidity stored in the second space 5 is removed. The substance 10 flows into the first space 4 and contacts the surface of the catheter 7.

Thereby, lubricity is expressed on the surface of the catheter 7, and the frictional resistance is reduced. After peeling (breaking) the weak seal portion 23, if necessary, pressing (pressing) the outside of the packaging material 2 by hand or the like to squeeze out the fluid substance 10 or the like from the second space 5 is performed. May go.

The first space 4 and the second space 5 are sterilized in advance, and the operation of developing the lubricity on the surface of the catheter 7 is performed in the inside of the sealed packaging material 2. Is performed without contact with the outside air, the catheter 7 can maintain sterility.

Since the flowable substance 10 flowing into the first space 4 cannot pass through the container 81, the deodorant 8 in the container 81 does not get wet with the flowable substance 10, so that A decrease in the deodorizing function (deodorizing function) is prevented.

Conventionally, in order to prevent bacterial infection, an operation of immersing a catheter in a disinfecting solution such as a 1% povidone iodoglycerin solution to disinfect the catheter before inserting the catheter into a living body has been performed. However, in many cases, the adjustment of the disinfecting solution is very complicated, and in many cases, it is difficult to obtain the disinfecting solution itself, so that the burden on the patient himself is large and the safety is not sufficiently ensured. Also, for the same catheter, When used repeatedly for multiple times after repeated disinfection, it may become a breeding ground for bacterial propagation due to the formation of a biofilm on the catheter surface and the like. On the other hand, in the present invention, as described above, the catheter 7 can be brought into a usable state (low friction state) without opening the packaging material 2 and the catheter 7 is kept sterile. Since such a state can be obtained, such a conventional problem is solved.

When the operation of developing the lubricity on the surface of the catheter 7 is completed, the weak seal portion 24 is peeled (ruptured),

The zipper 3 is opened, the catheter 7 in the first space 4 is taken out, and inserted or attached to a target part of the living body. When the catheter 7 is a urethral catheter (urinary catheter), the catheter 7 is inserted

into the urethra and the bladder,

Urination is performed via the catheter 7. At this time, the insertion of the catheter 7 can be performed smoothly and safely because the surface of the catheter 7 has lubricity. When urination is completed, the catheter 7 is withdrawn from the urethra.

Although the used catheter 7 is discarded, instead of discarding the catheter 7 alone, the catheter 7 is returned to the first space 4 of the packaging material 2 again, the zipper 3 is closed, and the packaging material is closed. It is preferable to discard every two.

In particular, in the case of self-urination by a patient, it is difficult to use the catheter 7 in the private room of the toilet when going out and then throw it away in the installed trash box.

I would like to take it home and discard it.

In addition, it is not preferable that urine odor emitted from the used catheter 7 leaks to the outside during returning home (during transportation). Furthermore, there is a concern that bacteria, viruses and the like in the urine may propagate due to urine remaining in the catheter 7, which is not hygienic.

In the present invention, when the used catheter 7 is stored in the first space 4 of the packaging material 2, the deodorant 8 eliminates or reduces odors such as urine odor emitted from the catheter 7. Antibacterial agents (titanium oxide, antibacterial sheet 9 etc.)

Inhibits the growth of bacteria, viruses and the like. Thereby, the above-mentioned problems are solved, and the used catheter 7 can be hygienically conveyed without emitting odor.

FIG. 4 is a plan view (internal perspective view) showing a fifth embodiment of the package of the present invention. Hereinafter, the package according to the fifth embodiment will be described focusing on differences from the first embodiment and the like, and description of the same items will be omitted.

As shown in FIG. 4, the package 1 of the fifth embodiment

Has a first space 4, a second space 5, and a third space 6 partitioned by a partition portion 25 in the packaging material 2.

On the outer peripheral portion of the packaging material 2 and the like, a band-shaped sealing portion 21 in which a sheet material constituting the packaging material 2 is fused (or bonded).

Are formed.

The partition 25 is formed by fusing (or adhering) a sheet material in a band shape like the seal portion 21, and has a T-shape. Due to this partition part 25, the inside of the packaging material 2

A first space 4, which is independent (isolated from each other) 4,

It is partitioned into a second space 5 and a third space 6.

In this case, the first space 4, the second space 5, and the third space 6 are arranged adjacent to each other.

Therefore, the second space 5 to the first space 4 as described later

Of liquid to the first space 4 to the third space 6

Can be quickly and reliably performed.

The partition 22 has weak seals 26 and 27 similar to the weak seal 23. By peeling (breaking) the weak seal portion 26, the first space 4 and the second space 5 communicate with each other. By peeling (breaking) the weak seal portion 27, the first space 4 and the third space 3 are broken. Space 6

Communicates with

In the first space 4, the above-mentioned catheter 7 is stored, and in the second space 5, the above-mentioned fluid substance 10 is stored.

The third space 6 contains a water-absorbing material 12 as a substance capable of absorbing and retaining a liquid. Examples of the water absorbing material 12 include a polyacrylate, a polyvinyl alcohol, a polyacrylamide,

Preferred are synthetic polymers such as polyoxyethylene-based or maleic acid-based materials, and polymeric water-absorbing materials such as natural materials such as polysaccharide materials such as starch, cellulose, and alginic acid. In addition, other, for example, sponge,

Examples thereof include cotton, gauze, nonwoven fabric, and those in which the above-mentioned polymer water-absorbing material is supported (for example, those used for diapers, sanitary products, and the like).

These water absorbing materials 1

2 can take various forms such as, for example, powder, film, sheet, and fiber (aggregate of fibers).

The first space 4 or the third space 6

In addition, the above-mentioned deodorant and / or antibacterial agent may be stored. In particular, when these are stored in the third space 6, a configuration in which the deodorant (a component having a deodorizing function) and / or an antibacterial agent (a component having an antibacterial function) is carried on the water absorbing material 12 as described above. It is preferable that

FIG. 5 is a plan view (internal perspective view) showing a sixth embodiment of the package of the present invention. Hereinafter, the package of the sixth embodiment will be described focusing on the differences from the fifth embodiment and the like, and the description of the same items will be omitted.

As shown in FIG. 5, the package 1 of the sixth embodiment

The first space 4 and the third space 6 are separated by a partition portion 25 having a weak seal portion 27, and the second space 5 is

Is formed inside the space 4. That is, in the first space 4 of the packaging material 2, the above-described catheter 7 and the same small packaging material (bag body) 11 as described above are stored.

The outer peripheral portion of the package material 11 is constituted by a partition portion 22 having a weak seal portion 23, and a second space 5 is formed inside the partition portion 22. The fluid substance 10 described above is stored (filled) in the second space 5. By peeling (breaking) the weak seal portion 23, the first space 4 and the second space 5 communicate with each other, and the fluid substance 10 can flow into the first space 4.

Further, in the third space 6, the same water-absorbing material (substance capable of absorbing and retaining a liquid) 12 as described above is accommodated.

The package 1 having such a structure has the same effect (advantage) as the package 1 of the fourth embodiment.

FIG. 6 is a plan view (an internal perspective view) showing a seventh embodiment of the package of the present invention. Hereinafter, the package of the seventh embodiment will be described focusing on the differences from the fifth embodiment, the sixth embodiment, and the like, and the description of the same items will be omitted.

As shown in FIG. 6, the package 1 of the seventh embodiment

Is such that the second space 5 and the third space 6 are respectively formed inside the first space 4. That is,

In the first space 4 of the packaging material 2, the catheter 7 described above is provided.

And a parcel material (bag body) 14 are stored.

The small packaging material 14 is formed by stacking the same sheet material as the above-described packaging material 2 and sealing the outer periphery and the middle thereof by fusion (or adhesion) to form a bag. Inside, a second space 5 and a third space 6 are formed via a partition 28.

In the second space 5, the above-mentioned fluid substance 1

0 is stored (filled), and the above-described water-absorbing material (substance capable of absorbing and holding a liquid) 12 is stored in the third space 6.

The outer peripheral portion of the package material 14 and the seal portion crossing the middle thereof constitute a partition portion 28 for isolating (partitioning) the first space 4, the second space 5 and the third space 6. A weak seal portion 26 for opening the second space 5 and a weak seal portion 27 for opening the third space 6 are formed in a part of the partition portion 28. In this embodiment,

The weak seal portions 27 are provided at two places.

The package 1 having such a structure has the following effects (advantages). First, by selecting the capacity of the parcel material 14 to be put in the first space 4 (the respective capacities of the second space 5 and the third space 6), the contents (fluidity) of the parcel material 14 are selected. Substance 10 and water absorbing material 12)

Amount and weight can be easily set. Secondly, since the parcel material 14 is movable in the first space 4, an operation of peeling (breaking) the weak seal portions 26 and 27 or squeezing out the fluid substance 10 or the like from the second space 5. The operation and the operation of collecting the liquid into the third space 6 can be easily performed (at an appropriate position). The same applies to the third and fourth advantages of the above-described parcel material 11.

In this embodiment, the second space 5 and the third space 6 are formed in one parcel material 14.

The present invention is not limited to this. Two separated parcels are stored in the first space 4, and the second parcels 5

And the third space 6 may be formed.

With this configuration, the same effect as described above can be obtained.

FIG. 7 is a plan view (internal perspective view) showing an eighth embodiment of the package of the present invention. Hereinafter, the package of the eighth embodiment will be described focusing on differences from the fifth embodiment and the like, and the description of the same items will be omitted.

As shown in FIG. 7, the package 1 of the eighth embodiment

Has a U-shaped second space 5 on the lower end side, and the above-mentioned fluid substance 10 is stored (filled) in the second space 5.

A third space 6 is formed inside the second space 5 (on the center side of the packaging material 2) via a U-shaped partition portion 29, and is formed in the third space 6. Contains the water-absorbing material (substance capable of absorbing and retaining a liquid) 12 described above.

The partition 25 separates the first space 4 from the second space 5 and the first space 4 from the third space 6, respectively. The partition 25 has a weak seal 27 for opening the third space 6.

On one side of the partition 25, a sealing member 13 which can be broken and opened is provided. The sealing member 13 is fused to the partition 25 so as to intersect with the partition 25. Hereinafter, the configuration of the sealing member 13 will be described.

FIG. 8 is a longitudinal sectional view showing an example of the structure of the sealing member 13. As shown in FIG. As shown in the figure, a sealing member 13 is composed of a short tube 131 made of a flexible resin such as soft polyvinyl chloride,

1 and a cylindrical body 132 whose one end is closed by a solid columnar portion 133.

The upper end of the short tube 131 in FIG.

8 and the lower end of the cylindrical body 132 in FIG.

Space 5.

A thin and fragile breaking portion 134 is formed on the outer periphery in the middle of the cylindrical body 132. The internal flow path of the sealing member 13 is opened by bending the solid columnar portion 133 together with the short tube 131 from the outside of the short tube 131 by the finger or the like to break the broken portion 134 and separate the solid columnar portion 133. . Thereby, the first space 4 and the second space 5

And the fluid substance 10 in the second space 5 can flow into the first space 4.

As a constituent material of the cylindrical body 132, for example,

Hard materials such as hard polyvinyl chloride, polycarbonate, and polyester are exemplified.

The upper end 135 of the solid columnar portion 133 is also provided.

Has a wedge shape (flat shape). Thereby, after the solid columnar part 133 is fractured and separated, the solid columnar part 133 is separated.

However, the short tube 131 is not closed, and a sufficient liquid flow can be secured.

The inner diameter of the upper end of the short tube 131 in FIG. 8 is reduced, so that the solid columnar portion 133 after breaking and separation cannot pass through the reduced diameter portion 136. I have.

Thus, the solid columnar portion 133 that has been broken and separated can be prevented from entering the first space 4 and freely moving in the first space 4.

In the fifth, sixth, seventh, and eighth embodiments, the second space 5 contains the fluid substance 10, but in each of these embodiments, Instead of the fluid substance 10, a liquid containing a blood anticoagulant (antithrombotic) may be stored in the second space 5. Thereby, when using the catheter 7, a blood anticoagulant function can be provided to the catheter 7.

Examples of the blood anticoagulant include those shown in Table 1 below.

[0126]

[Table 1]

In each of the above embodiments, the packaging material 2 is made of a flexible sheet material. However, the present invention is not limited to this. For example, a part of the packaging material 2 is made of a relatively hard material. May be used. A specific example thereof is a so-called blister container. The blister container is made of a relatively hard material, and includes a main body having a recess forming a storage space (for example, a first space), and a film for hermetically sealing an opening of the recess.

The film is opened by peeling off the film.

Next, the method of use (operation) of each package 1 of the fifth to eighth embodiments will be described.

When the weak seal portion 23 or 26 is peeled (ruptured) (in the case of the eighth embodiment, When the solid columnar portion 133 of the sealing member 13 is broken and separated), The first space 4 and the second space 5 communicate with each other, and the second space 5 The fluid substance 10 stored therein flows into the first space 4 and comes into contact with the surface of the catheter 7. This allows Lubricity is developed on the surface of the catheter 7, and frictional resistance is reduced. If necessary, the fluid substance 10 is pressed from the outside of the packaging material 2 by hand (pressing) from the second space 5.

For example, an operation of ironing out may be performed.

The first space 4 and the second space 5 have been sterilized in advance, and the operation of developing the lubricity on the surface of the catheter 7 is performed in the inside of the sealed packaging material 2. Is performed without contact with the outside air, the catheter 7 can maintain sterility. As described above, the catheter 7 can be used without opening the packaging material 2 (low friction state), and such a state can be achieved while maintaining the sterility of the catheter 7. Therefore, the conventional problem described above is solved.

When the operation for developing the lubricity on the surface of the catheter 7 is completed, the weak seal portion 24 is peeled off (ruptured).

The zipper 3 is opened, the catheter 7 in the first space 4 is taken out, and inserted or attached to a target part of the living body. When the catheter 7 is a urethral catheter (urinary catheter), the catheter 7 is inserted into the urethra and the bladder,

Urination is performed via the catheter 7. At this time, the insertion of the catheter 7 can be performed smoothly and safely because the surface of the catheter 7 has lubricity. When urination is completed, the catheter 7 is withdrawn from the urethra.

Although the used catheter 7 is discarded, instead of discarding the catheter 7 alone, the catheter 7 is returned to the first space 4 of the packaging material 2 again, the zipper 3 is closed, and the packaging material is closed. It is preferable to discard every two.

At this time, the weak seal portion 27 is peeled (ruptured) and opened by the method described above. As a result, the first space 4 and the third space 6 communicate with each other, and bodily fluids such as urine adhered to the surface of the catheter 7 or remaining in the catheter 7 are stored in the third space 6. Can be absorbed and retained by the water-absorbing material 12. As a result, leakage of bodily fluids such as urine can be more reliably prevented, and the used catheter 7 can be conveyed hygienically with the packaging material 2 and discarded.

In particular, when the water-absorbing material 12 carries a deodorant (a component having a deodorizing function) and / or an antibacterial agent (a component having an antibacterial function), it emits odor and prevents bacteria, viruses and the like. Proliferation can be suppressed, and more hygienic and safe transport and disposal can be performed.

As described above, according to the package 1 of the present invention, it is possible to easily and aseptically contact the lubricant, blood anticoagulant, etc. with the catheter, and also to carry and unpack the patient. Not only is it simple, but it can also be transported and disposed of hygienically and safely after use of the catheter.

[0135] In the present invention, examples of instruments housed in the first space 4 include the following.

Oral or nasal such as gastric tube catheter, feeding catheter, tube for tube feeding, oxygen catheter, oxygen cannula, tube and cuff for endotracheal tube, tube and cuff for tracheostomy tube, intratracheal suction catheter, etc. Catheters to be inserted and detained.

Catheters to be inserted and placed in various body cavities, organs, and tissues such as suction catheters, drainage catheters, peritoneal catheters, rectal catheters, and trocars.

Catheters to be inserted and placed in blood vessels such as angiographic catheters, PTCA balloon catheters, IABP balloon catheters, indwelling catheters, and arterial infusion catheters.

Various guidewires used alone or with each of the catheters described above. Artificial blood vessels, stents, colostomy, artificial bones, artificial joints, prostheses, artificial eyes. Injection needle, indwelling needle, sheath, catheter introducer.

An endoscope, a cardiac output measuring instrument, an ultrasonic measuring / diagnosing instrument, an ultrasonic crushing probe, a pacemaker,

Thermometer. Thread for suture or ligature Enema Contact lens Contraceptive device such as condom
In the present invention, the arrangement of the first space 4, the second space 5, and the third space 6 is not limited to that of each of the illustrated embodiments. And the third space may be arranged in a line in this order. Further, the packaging material may further have a fourth space.

The first space 4, the second space 5, and the third space 6 may each contain any other than the above.
[0143]

The present invention will be specifically described below with reference to examples.

Example 1A Polypropylene (XF18)

00, manufactured by Chisso Corporation and 60 parts by weight and a styrene-based elastomer (Hybra HVS-3, manufactured by Kuraray Co., Ltd.), 40 parts by weight, are used to form an inflation sheet (thickness: 300 μ m, water vapor permeability: 15 g) by co-extrusion molding. / m .sup.2 .Math. 24 hrs, 25 μ m thickness, 40 ° C., 90% RH). This sheet was sealed by heat sealing to form a packaging material having the configuration shown in FIG.

In the first space of the packaging material, a Neraton catheter (Safide, 14Fr, manufactured by Terumo Corporation) as a catheter used by being inserted into the urethra, and a water-impermeable porous material made of polyethylene Non-woven fabric (trade name: TYPEC, Asahi DuPont Flash Span Products Co., Ltd.) Deodorant / air freshener (trade name: Airnip, manufactured by Tact Co., Ltd.). In addition, as for this Neraton catheter, the surface has a 0.2 wt% polyvinylpyrrolidone-chloroform solution (trade name: Kolydone K).

30, BASF Japan Co., Ltd.) coated with a layer of a hydrophilic polymer material. Also, in the second space of the packaging material, put 10 ml of water,
Sealed.

Sealing part of packaging material (part other than weak sealing part)

Was heat-sealed at 200 ° C. for 4 seconds and 0.25 kgf / cm .sup.2 , and the weakly sealed portion was heat-sealed at 105 ° C. for 4 seconds and 0.25 kgf / cm .sup.2 and subjected to high-pressure steam sterilization at 110 ° C. for 60 minutes. .

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between water and the catheter.

Next, when the packaging material was pressed and pressed by hand to apply a load to the weak seal portion 23, only the weak seal portion 23 was peeled off, and water in the second space was introduced into the first space. It spilled and came into contact with the catheter. Thereby, it was confirmed that the water and the catheter can be easily and aseptically contacted with each other.

After contact of the catheter with water, the weak seal portion 24 was opened, and the catheter was taken out and rubbed against the surface. As a result, the surface showed lubricity, the frictional resistance was reduced, and It was suggested that the operability of the insertion operation was improved.

Thereafter, the catheter was immersed in artificial urine having the components shown in Table 2 below for 30 seconds. Then, the catheter was returned to the first space of the packaging material, and the zipper was closed and sealed, and left for a predetermined time. The face was brought close to the packaging material, but no unpleasant sensation such as urine odor was observed.

Therefore, after using the catheter, the patient can easily take the catheter home without hesitation around, and can not only be relieved from the mental burden but also have a urinary odor to the outside air. Does not leak,

It was suggested that it was also favorable for hygiene.

[0152]

[Table 2]

(Examples 2A, 3A and 4A) The same inflation sheet as in Example 1A was sealed by heat sealing to form a packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter (without surface coating) as described above was placed, and in the second space, a lubricant having the composition shown in Table 3 below was placed, and each was hermetically sealed. did. In the first space, a deodorant, an fragrance, and the like packaged with a water-impermeable porous body shown in Table 3 below were placed.

[0155]

[Table 3]

Sealing part of packaging material (part other than weak sealing part)

Was heat-sealed at 200 ° C. for 4 seconds and 0.25 kgf / cm .sup.2 , and the weakly sealed portion was heat-sealed at 105 ° C. for 4 seconds and 0.25 kgf / cm .sup.2 and subjected to high-pressure steam sterilization at 110 ° C. for 60 minutes. .

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between the liquid in the second space and the catheter.

Next, when the packaging material was pressed and pressed by hand and a load was applied to the weak seal portion 23, only the weak seal portion 23 was peeled off, and the liquid in the second space was introduced into the first space. It spilled and came into contact with the catheter. Thereby, it was confirmed that the liquid and the catheter can be easily and aseptically contacted with each other.

After the contact between the liquid in the second space and the catheter, the weak seal portion 24 was opened, and the catheter was taken out and rubbed against the surface. The sliding resistance value on the surface has been reduced,

The improvement of the operability of the insertion operation into the body cavity was suggested.

Thereafter, the catheter was immersed in artificial urine having the components shown in Table 2 for 30 seconds. Then, the catheter was returned to the first space of the packaging material, and the zipper was closed and sealed, and left for a predetermined time. I brought my face close to the packaging material, but I felt a urine odor.

No unpleasant feeling was observed.

Therefore, after using the catheter, the patient can easily take the catheter home without hesitation around, and can not only be relieved from the mental burden, but also have a urinary odor to the outside air. Does not leak,

It was suggested that it was also favorable for hygiene.

(Examples 5A and 6A) The same inflation sheet as in Example 1A was sealed by heat sealing to form a packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter (without surface coating) as described above was placed, and in the second space, a lubricant having the composition shown in Table 4 below was placed, and each was hermetically sealed. did. In the first space, an antimicrobial sheet shown in Table 4 below was placed.

[0164]

[Table 4]

Sealing part of packaging material (part other than weak sealing part)

Was heat-sealed at 200 ° C. for 4 seconds and 0.25 kgf / cm .sup.2 , and the weakly sealed portion was heat-sealed at 105 ° C. for 4 seconds and 0.25 kgf / cm .sup.2 and subjected to high-pressure steam sterilization at 110 ° C. for 60 minutes. .

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between the liquid in the second space and the catheter.

Next, when the packaging material was pressed and pressed by hand to apply a load to the weak seal portion 23, only the weak seal portion 23 was peeled off, and the liquid in the second space was introduced into the first space. It spilled and came into contact with the catheter. Thereby, it was confirmed that the liquid and the catheter can be easily and aseptically contacted with each other.

After the liquid in the second space and the catheter came into contact with each other, the weak seal portion 24 was opened, the catheter was taken out, and the surface was rubbed. The sliding resistance value on the surface has been reduced,

The improvement of the operability of the insertion operation into the body cavity was suggested.

Thereafter, the catheter was immersed in artificial urine having the components shown in Table 2 for 30 seconds. Then, the catheter was returned to the first space of the packaging material, and the zipper was closed and sealed, and left for a predetermined time. I brought my face close to the packaging material, but I felt a urine odor.

No unpleasant feeling was observed. Furthermore, the antibacterial action of the antibacterial sheet suppressed the proliferation of urinary bacteria, viruses and the like adhering to and remaining on the catheter.

[0170] Therefore, after using the catheter, the patient can easily take the catheter home without hesitating to the surroundings, and not only can be released from the mental burden, but also can have urinary odor to the outside air. It was suggested that it was preferable from the viewpoint of hygiene, because there was no possibility of leakage and no possibility of bacterial infection.

(Example 7A) The same inflation sheet as in Example 1A was sealed by heat sealing to form a packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter (having the same surface as in Example 1A) was placed, and in the second space, 10 ml of water was placed.

And sealed each. In the first space,

Deodorizing and antibacterial sheet containing titanium oxide (trade name: PM-I N-CD, manufactured by Mitsubishi Paper Mills).

Sealing part of packaging material (part other than weak sealing part)

Was heat-sealed at 200 ° C. for 4 seconds and 0.25 kgf / cm², and the weakly sealed portion was heat-sealed at 105 ° C. for 4 seconds and 0.25 kgf / cm² and subjected to high-pressure steam sterilization at 110 ° C. for 60 minutes. .

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between the liquid in the second space and the catheter.

Next, when the packaging material was pressed and pressed by hand and a load was applied to the weak seal portion 23, only the weak seal portion 23 was peeled off, and water in the second space was introduced into the first space. It spilled and came into contact with the catheter. Thereby, it was confirmed that the water and the catheter can be easily and aseptically contacted with each other.

After the water in the second space came into contact with the catheter, the weak seal portion 24 was opened, and the catheter was taken out and rubbed against the surface. The sliding resistance on the surface was significantly reduced, suggesting improved operability of the insertion operation into the body cavity.

Thereafter, the catheter was immersed in artificial urine having the components shown in Table 2 for 30 seconds. Then, the catheter was returned to the first space of the packaging material, the zipper was closed and sealed, and left for a predetermined time. I brought my face close to the packaging material, but I felt a urine odor.

No unpleasant feeling was observed. Furthermore, the antibacterial action of the deodorizing / antibacterial sheet suppressed the proliferation of bacteria, viruses, and the like in the urine that had adhered to and remained on the catheter.

Therefore, after using the catheter, the patient can easily take the catheter home without hesitating to the surroundings, and can not only be relieved from the mental burden, but also can have urinary odor to the outside air. It was suggested that it was preferable from the viewpoint of hygiene, because there was no possibility of leakage and no possibility of bacterial infection.

(Example 8A) The same inflation sheet as in Example 1A was sealed by heat sealing to form a packaging material containing a small packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter and the small packaging material as in Example 1A were put and sealed.

The second space of the parcel material was filled with 20 ml of water and sealed. In the first space, a deodorant / fragrance (trade name) packaged by a polyethylene nonwoven fabric (trade name: TYPEC, manufactured by Asahi DuPont Flash Spun Products Co., Ltd.) which is a water-impermeable porous body : Air Nip, manufactured by Tact Co., Ltd.).

The sealing part (the part other than the weak sealing part) of the packaging material and the small packaging material is 200 ° C., 4 seconds, 0.25 kgf / cm², and the weak seal portion, 105 ° C., 4 seconds, 0.25 kgf / cm² at 110 ° C, 60

The autoclave was autoclaved for a minute.

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between the liquid in the second space and the catheter.

Next, when the small packaging material was pressed and pressed by hand from above the packaging material to apply a load to the weak seal portion 23, only the weak seal portion 23 was peeled off, and the

water in the second space was removed from the second space. 1 and came into contact with the catheter. Thereby, it was confirmed that the water and the catheter can be easily and aseptically contacted with each other. In addition, since this operation was performed by moving the small package material to a suitable position in the package material, the opening operation of the small package material could be performed more easily and reliably.

After the water in the second space came into contact with the catheter, the weak seal portion 24 was opened, and the catheter was taken out and rubbed against the surface. The sliding resistance on the surface was significantly reduced, suggesting improved operability of the insertion operation into the body cavity.

Thereafter, the catheter was immersed in artificial urine having the components shown in Table 2 for 30 seconds. Then, the catheter was returned to the first space of the packaging material, the zipper was closed and sealed, and the container was left for a predetermined time. I brought my face close to the packaging material, but I felt a urine odor.

No unpleasant feeling was observed. Further, the antibacterial action of the deodorizing / antibacterial agent suppressed the proliferation of bacteria and viruses in urine attached to and remaining on the catheter. Therefore, after using the catheter, the patient can easily take the catheter home without hesitating to the surroundings, and can not only be relieved from the mental burden, but also have a urinary odor to the outside air. It was suggested that it was preferable from the viewpoint of hygiene, because there was no possibility of leakage and no possibility of bacterial infection.

Example 1B Polypropylene (XF18)

00, manufactured by Chisso Corporation and 60 parts by weight and a styrene-based elastomer (Hybra HVS-3, manufactured by Kuraray Co., Ltd.), 40 parts by weight, are used to form an inflation sheet (thickness: 300 μm , water vapor permeability: 15 g) by co-extrusion molding. / m .sup.2 .Math. 24 hrs, 25 μm thickness, 40 ° C., 90% RH). This sheet was sealed by heat sealing to form a packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter as in Example 1A was placed, in the second space, 10 ml of water was placed, and in the third space, a cross-linking material, which was a water-absorbing material, was placed. Sodium polyacrylate (trade name: Aquaric, 1 g of Nippon Shokubai Kagaku Kogyo Co., Ltd.) was added, and each was sealed.

Sealing part of packaging material (parts other than weak seal part)

Was heat-sealed at 200 ° C. for 4 seconds at 0.25 kgf / cm .sup.2 , and the weakly sealed portion was heat-sealed at 105 ° C. for 4 seconds at 0.25 kgf / cm .sup.2 , and γ -ray sterilized at .sup.2 Mrad.

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between water and the catheter and no contact between water and the water-absorbing material.

Next, when the packaging material was pressed and pressed by hand and a load was applied to the weak seal portion 26, only the weak seal portion 26 was peeled off, and the water in the second space was introduced into the first space. It spilled and came into contact with the catheter. Thereby, it was confirmed that the water and the catheter can be easily and aseptically contacted with each other.

After contact of the catheter with water, the weak seal portion 24 was opened, and the catheter was taken out and rubbed against the surface. As a result, the surface showed lubricity, reduced frictional resistance, and reduced the body cavity. It was suggested that the operability of the insertion operation was improved. Thereafter, the catheter was soaked in bovine blood for 30 seconds, and then the catheter was returned to the first space of the packaging material, and the zipper was closed and sealed.

Next, when the weak seal portion 27 was opened to make the first space and the third space communicate with each other and the packaging material was vibrated, the blood adhering and remaining on the surface and inside of the catheter was removed. The water was absorbed and retained by the water-absorbing material in the third space. Therefore, even if the zipper was opened, blood did not leak.

Therefore, even if the used catheter is transported in a packaging material and discarded together with the packaging material, there is no blood leakage during that time, blood contamination and infection are prevented, and high safety is suggested. Was done.

(Example 2B) The same inflation sheet as in Example 1B was sealed by heat sealing to form a packaging

material containing a small packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter and guide wire (inserted into the lumen of the catheter) as in Example 1A and a small packaging material are placed.

Sealed. In the second space of the package material, 18 ml of the CPDA-1 solution shown in Table 1 above was placed as a blood anticoagulant solution and sealed. In a third space of the packaging material, 2 g of crosslinked sodium polyacrylate (trade name: Aquaric, manufactured by Nippon Shokubai Chemical Industry Co., Ltd.) as a water-absorbing material was placed and sealed.

The sealing part (the part other than the weak sealing part) of the packaging material and the small packaging material is 200 ° C., 4 seconds, 0.25 kgf / c

m .sup.2, and the weak seal portion, 105 ° C., 4 seconds, 0.25 kg

heat seal at f / cm .sup.2 and γ at .sup.2 Mrad

X-ray sterilization was performed.

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between the anticoagulant solution and the catheter and between the anticoagulant solution and the water absorbent material. .

Next, when the small package material was pressed and pressed by hand from above the package material to apply a load to the weak seal portion 23, only the weak seal portion 23 was peeled off, and the anticoagulant in the second space was removed. The liquid is first

Out of the space and contacted the catheter. Thereby, it was confirmed that the anticoagulant solution and the catheter can be easily and aseptically contacted with each other. In addition, since this operation was performed by moving the small package material to a suitable position in the package material, the opening operation of the small package material could be performed more easily and reliably.

After contact between the anticoagulant solution and the catheter, the weak seal portion 24 was opened, the catheter was taken out, and the surface was rubbed. The catheter surface showed lubricity due to the moisture of the anticoagulant solution. , The frictional resistance has been reduced,

The improvement of the operability of the insertion operation into the body cavity was suggested. Also, Since the anticoagulant is attached to the surface of the catheter,

It is considered that when inserted into a blood vessel, an excellent anticoagulant effect is exhibited.

Thereafter, the catheter was soaked in bovine blood for 30 seconds, and then the catheter was returned to the first space of the packaging material, and the zipper was closed and sealed.

Next, when the weak seal portion 27 is opened to make the first space and the third space communicate with each other and the packaging material is vibrated, the blood adhering and remaining on the surface and inside of the catheter is removed. The water was absorbed and retained by the water-absorbing material in the third space. Therefore, even if the zipper was opened, blood did not leak.

Therefore, even if the used catheter is transported in a packaging material and discarded together with the packaging material, there is no leakage of blood during that time, blood contamination and infection are prevented, and safety is high. Was done.

Example 3B An inflation sheet similar to that of Example 1B was sealed by heat sealing to form a packaging material containing a small packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter and guide wire (in the state inserted into the lumen of the catheter) and the small packaging material as in Example 1A were placed.

Sealed. In the second space of the parcel material, 18 ml of the heparin solution shown in the above Table 1 was put as a blood anticoagulant solution, and in the third space, crosslinked sodium polyacrylate (trade name: Aquaric), which is a water-absorbing material. , Nippon Shokubai Chemical Industry Co., Ltd. 2 g) were sealed and each was sealed.

The sealing part (the part other than the weak sealing part) of the packaging material and the small packaging material is 200 ° C., 4 seconds, 0.25 kgf / c.

m .sup.2, and the weak seal portion, 105 ° C., 4 seconds, 0.25 kg

heat seal at f / cm .sup.2 and γ at .sup.2 Mrad

X-ray sterilization was performed.

After sterilization, the package was vibrated violently, but peeling of the weak seal was not observed, and there was no contact between the anticoagulant solution and the catheter and no contact between the

anticoagulant solution and the water absorbent material. .

Next, when the upper half of the small packaging material in FIG. 6 was pressed and pressed by hand from above the packaging material to apply a load to the weak seal portion 26, only the weak seal portion 26 was peeled off, and the second The anticoagulant liquid in the space flowed out into the first space and came into contact with the catheter. Thereby, it was confirmed that the anticoagulant solution and the catheter can be easily and aseptically contacted with each other. In addition,

Since this operation was performed by moving the small packaging material to a suitable position within the packaging material, the operation of opening the weak seal portion 26 could be performed more easily and reliably.

After the anticoagulant solution was brought into contact with the catheter, the weak seal portion 24 was opened, the catheter was taken out, and the surface was rubbed. The catheter surface showed lubricity due to the moisture of the anticoagulant solution. , The frictional resistance has been reduced,

The improvement of the operability of the insertion operation into the body cavity was suggested. Also,

Since the anticoagulant is attached to the surface of the catheter,

It is considered that when inserted into a blood vessel, an excellent anticoagulant effect is exhibited.

Thereafter, the catheter was dipped in bovine blood for 30 seconds, and then the catheter and the guide wire were returned to the first space of the packaging material, and the zipper was closed and sealed.

Next, the weak seal portion 27 of the parcel material is opened to make the first space and the third space communicate with each other, and when the wrapping material is vibrated, it adheres and remains on the surface and inside of the catheter. The collected blood was absorbed and retained by the water-absorbing material in the third space. Therefore, even if the zipper was opened, blood did not leak. In addition, since this operation was performed by moving the small packaging material to a suitable position in the packaging material, the opening operation of the weak seal portion 27 and the absorption of the remaining blood could be performed more easily and reliably.

Therefore, even if the used catheter is transported in a packaging material and discarded together with the packaging material, there is no blood leakage during that time, thereby preventing contamination and infection, and suggesting high safety. Was done.

(Examples 4B, 5B, 6B) The same inflation sheet as in Example 1B was sealed by heat sealing to form a packaging material having the structure shown in FIG.

In the first space of the packaging material, the same Neraton catheter as in Example 1B (without surface coating)

, And a lubricant having the composition shown in Table 5 below was placed in the second space, and each was sealed. The third space was filled with a water-absorbing material shown in Table 5 below and sealed.

[0216]

[Table 5]

Sealing part of packaging material (part other than weak sealing part)

Was heat-sealed at 200 ° C. for 4 seconds at 0.25 kgf / cm .sup.2 , and the weakly sealed portion was heat-sealed at 105 ° C. for 4 seconds at 0.25 kgf / cm .sup.2 , and y-ray sterilized at .sup.2 Mrad.

After sterilization, the package was vibrated violently, but no peeling of the weak seal portion or breakage of the sealing member was observed.

There was no contact between the lubricant and the catheter and no contact between the lubricant and the water-absorbing material.

Next, the sealing member (the structure shown in FIG. 8) is bent by hand from the outside of the packaging material, the solid columnar portion is broken and separated at the breaking portion, and the portion of the second space of the packaging material is pressed. As a result, the lubricant in the second space flowed into the first space and came into contact with the catheter. Thereby, it was confirmed that the lubricant can be easily and aseptically contacted with the catheter.

[0220] After contact between the lubricant and the catheter, the weak seal portion 24 was opened, and the catheter was taken out and rubbed against the surface. As a result, the surface showed lubricity and the frictional resistance was reduced. It was suggested that the operability of the insertion operation into the device was improved.

Thereafter, the catheter was immersed in artificial urine having the components shown in Table 2 for 30 seconds, and then the catheter was returned to the first space of the packaging material, and the zipper was

closed and sealed.

Next, the weak seal portion 27 was opened to make the first space and the third space communicate with each other, and when the packaging material was vibrated, the artificial urine adhering and remaining on the surface and inside of the catheter was removed. Was absorbed and retained by the water-absorbing material in the third space. Therefore, even if the zipper was opened, leakage of artificial urine did not occur. Therefore, even if the used catheter is transported in a packaging material and discarded together with the packaging material, there is no leakage of bodily fluids such as urine during that time, thereby preventing contamination and infection and high safety. It has been suggested.

(Example 1C) As a sheet constituting a packaging material, polypropylene (manufactured by Mitsubishi Chemical Corporation, SPX960)

0) monolayer film (film thickness 300 μm , water vapor transmission rate 21 $\text{g} / \text{m}^2 \cdot 24 \text{ hrs}$ at 25 μm thickness, 40 ° C, 90% RH).

A package having the configuration shown in FIG. 1 was manufactured in the same manner as in Example 1A except that 90% RH) was used. The items stored in the first space and the second space of the packaging material are the same as those in the embodiment 1A.

(Example 2C) A linear low-density polyethylene (Nippon Polychem Co., Ltd.)

Monolayer film (film thickness 30) made of a polymer blend of Novatec LL UF340 manufactured by Novotech Co., Ltd. and polypropylene (Chisso Polypro K7714 manufactured by Chisso Corp.)

0 μm , water vapor transmission rate 18 $\text{g} / \text{m}^2 \cdot 24 \text{ hrs}$ at 25 μm

Example 1 except that m-thickness / 40 ° C./90% RH) was used.

A package having the configuration shown in FIG. 1 was manufactured in the same manner as in A.

The items stored in the first space and the second space of the packaging material are the same as those in the embodiment 1A.

(Example 3C) As a sheet constituting a packaging material, a two-layer composed of a first layer made of a polymer blend film of linear low-density polyethylene and polypropylene and a second layer made of a silica-deposited polyethylene terephthalate film Laminated film (Dai Nippon Printing Co., Ltd.

Film thickness 300 μm , water vapor permeability 0.6 $\text{g} / \text{m}^2 \cdot 24 \text{ hrs}$ at 25 μm thickness, 40 ° C., 90% RH)

A package having the configuration shown in FIG. 1 was manufactured in the same manner as in Example 1A, except that the layers were used so as to be joined to each other. The storage items in the first space and the second space of the packaging material are also the same as those of the first embodiment.

Same as A.

(Example 4C) As sheets constituting the packaging material, the first layer of a polymer blend film of linear low-density polyethylene and polypropylene, the second layer of an aluminum film, and the third layer of a polyethylene terephthalate film Constructed three-layer laminated film (Toyo Aluminum Co., Ltd., film thickness 300 μm)

m, water vapor transmission rate 0.3 $\text{g} / \text{m}^2 \cdot 24 \text{ hrs}$ at 25 μm thickness, 40 ° C., 90% RH) in the same manner as in Example 1A, except that the first layers were joined to each other.

Was manufactured. The items stored in the first space and the second space of the packaging material are also the same as those in Example 1A.

Example 5C Example 4C was repeated except that the liquid stored in the second space was 10 ml of an aqueous glycerin solution (manufactured by Kenei Pharmaceutical Co., Ltd., glycerin concentration: 84 to 87%).

A package similar to the above was produced.

<Test 1> Each package of Examples 1C to 5C was left for 4 weeks in an environment of a temperature of 40 ° C. and a humidity of 75% RH.

After one week, two weeks and four weeks, the second

The change over time in the rate of decrease of the liquid stored in the space was examined. The results are shown in Table 6 below. Here, the reduction rate of the liquid was calculated by the following equation.

Reduction rate (%) = $(W_0 - W) / W_0 \times 100$ where W_0 : the total weight

of the liquid at the start of the test (10 g) W: each liquid after 2, 4 and 4 weeks Weight of

[0231]

[Table 6]

As shown in Table 6, in all of the packages of Examples 1C to 5C, since the packaging material had a steam barrier property, the reduction rate of the liquid was low. It was confirmed that the reduction and concentration could be prevented, and the invasion of water vapor into the first space could be prevented.

In particular, the water vapor permeability is $1 \text{ g} / \text{m} \cdot \text{sup.2} \cdot \text{Math. 24 h}$

Example 3 rs, 25 μm thickness, 40 ° C., 90% RH or less

The package of C to 5C has a very small reduction rate of the liquid, and such an effect is more remarkably exhibited. Example 5C

In, the liquid stored in the second space was an aqueous glycerin solution having a lower volatility than water, so that the liquid hardly decreased.

<Test 2> Each of the packages of Examples 1C to 5C was left in the above environment for another 4 weeks. However, peeling of the weak seal portions 23 and 24 was not observed, and water from the second space was not observed. No leakage occurred.

After that, when the portion forming the second space of the packaging material was pressed and pressed by hand, the weak seal portion 23 could be easily and reliably peeled off from any of the packages, and it was confirmed that peel sealability was ensured.

<Study of Effective Storage Period of Package> In the package according to the present embodiment, when the liquid stored in the second space is reduced by evaporation and its weight becomes about half or less,

It becomes difficult to open (peel) the weak seal portion by applying pressure. Therefore, the time required for the amount of liquid stored in the second space to decrease by half under the test conditions was calculated by the following equation.

Time (year) = $(5 \text{ g} / \Delta W) \times (28 \text{ days} / 365 \text{ days})$ Here, ΔW : reduction amount of liquid after 4 weeks $\Delta W = 10 \text{ g} \times (\text{rate of reduction of liquid after 4 weeks} / 100)$

As a result, 1.9 years was obtained in Example 1C, 2.2 years in Example 2C, 5.4 years in Example 3C, and 1 year in Example 4.

It is 2.7 years and 38.0 years in Example 5C.

From the above results, by using a packaging material having a steam barrier property as in Examples 1C to 5C,

It has been found that it is possible to suppress a decrease in the stored liquid and to hold the liquid for a long time.

[0240]

As described above, according to the present invention, a device such as a catheter can be easily and aseptically contacted with a liquid. In particular, the communication operation between the isolated spaces in the packaging material and the opening operation of the packaging material can be performed easily and reliably.

The type of liquid stored in the second space,

By selecting the composition, amount, etc., various functions are imparted to the device, in particular, advantageous functions such as surface lubrication and anticoagulation (antithrombotic) when inserting or attaching the device to a living body. Can be.

In addition, by storing used equipment in a packaging material, it is possible to prevent the emission of odors to the outside, the growth of microorganisms, or the prevention of contamination and infection due to leakage of liquid adhering or remaining on the equipment. And contribute to the improvement of safety. It is also advantageous for downsizing the package. Therefore, it is advantageous for the disposal of used equipment or for transportation and storage until disposal.

In particular, in the case of self-urination in which the patient himself urinates using a catheter, labor and mental burden are reduced in transporting and disposing of the used catheter when going out, so that the patient's comfortable life (quality Of life).

[Brief description of the drawings]

FIG. 1 is a plan view (an internal perspective view) showing a first embodiment of a package of the present invention.

FIG. 2 is a plan view (an internal perspective view) showing a third embodiment of the package of the present invention.

FIG. 3 is a plan view (an internal perspective view) showing a fourth embodiment of the package of the present invention.

FIG. 4 is a plan view (an internal perspective view) showing a fifth embodiment of the package of the present invention.

FIG. 5 is a plan view (an internal perspective view) showing a sixth embodiment of the package of the present invention.

FIG. 6 is a plan view (an internal perspective view) showing a seventh embodiment of the package of the present invention.

FIG. 7 is a plan view (an internal perspective view) showing an eighth embodiment of the package of the present invention.

FIG. 8 is a longitudinal sectional view illustrating a configuration example of a sealing member.

[Explanation of symbols]

DESCRIPTION OF SYMBOLS 1 Package 2 Packaging material 21 Seal part 22 Partition part 23, 24 Weak seal part 25 Partition part 26, 27 Weak seal part 28, 29 Partition part 3 Zipper 4 1st space 5 2nd space 6 3rd space 7 Catheter 8 Deodorant 81 Container 9 Antibacterial sheet 10 Fluid substance 11 Small packaging material 12 Water-absorbing material 13 Sealing member 131 Short tube 132 Cylindrical body 133 Solid columnar part 134 Breaking part 135 Upper end part 136 Reduced diameter part 14 Small packaging material

Continuation of front page (72)

Inventor Masaomi Imai 2-44-1, Hatagaya, Shibuya-ku, Tokyo Terumo Corporation F-term (reference) 3E067 AA03 AA11 AB83 AB96 AB97 AC06 BB12A BB14A BB15A BB16A BB25A CA05 CA09 CA24 EA06 EA25 EB17 EE21 GB15 GC05 GD08

Claims

1. A packaging material having a first space and a second space which are separated from each other by a partition portion and can communicate with each other when necessary. The packaging material is housed in the first space and inserted or attached to a living body for use. A device that is contained in the first space and eliminates or reduces odor; and a fluidity that is contained in the second space and is capable of contacting the surface of the device and reducing its frictional resistance. And a substance.
2. The package according to claim 1, wherein a main component of the substance that extinguishes or reduces the odor is titanium oxide.
3. A packaging material having a first space and a second space which are separated from each other by a partition portion and can communicate with each other when necessary, and which is stored in the first space and inserted or attached to a living body for use. A device that is stored in the first space and has a function of suppressing at least the growth of microorganisms; and a device that is stored in the second space and contacts the surface of the device to reduce its frictional resistance. And a flowable substance.
4. The package according to claim 3, wherein a main component of the substance having a function of suppressing the growth of microorganisms is titanium oxide.
5. A packaging material having a first space, a second space, and a third space which are separated from each other by a partition portion and can be communicated when necessary, and a packaging material which is housed in the first space and inserted into a living body or A device that is mounted and used; a fluid material that is stored in the second space and that can contact the surface of the device and reduce its frictional resistance; and a fluid that is stored in the third space and Characterized by comprising a substance capable of absorbing and retaining the compound.
6. A packaging material having a first space, a second space, and a third space which are separated from each other by a partition portion and can communicate when necessary, and a packaging material which is housed in the first space and inserted into a living body or A package comprising: a device to be mounted

and used; a blood anticoagulant stored in the second space; and a substance stored in the third space and capable of absorbing and holding a liquid. body.

7. The device according to claim 5, wherein the first space and the second space are formed adjacent to each other, and the first space and the third space are formed adjacent to each other. 7. The package according to 6.

8. The package according to claim 1, wherein the second space is formed inside the first space.

9. The partition section is formed of a sealing section formed by fusing sheet materials constituting the packaging material.

9. The package according to any one of items 1 to 8.

10. The package according to claim 1, wherein at least a part of the partition part is formed by a weak seal part having a lower joining strength than other parts.

11. The apparatus according to claim 1, further comprising: an opening for removing the device from the first space; and sealing means for sealing the opening after opening the opening. The package as described.

12. The package according to claim 1, wherein the packaging material has a steam barrier property.

13. The package according to claim 1, wherein the device is a catheter or a guide wire.

14. The package according to claim 1, wherein the device is a catheter used by being inserted into the urethra.

15. On at least a part of the surface of the device,

The package according to any one of claims 1 to 14, further comprising a compound exhibiting lubricity when wetted.

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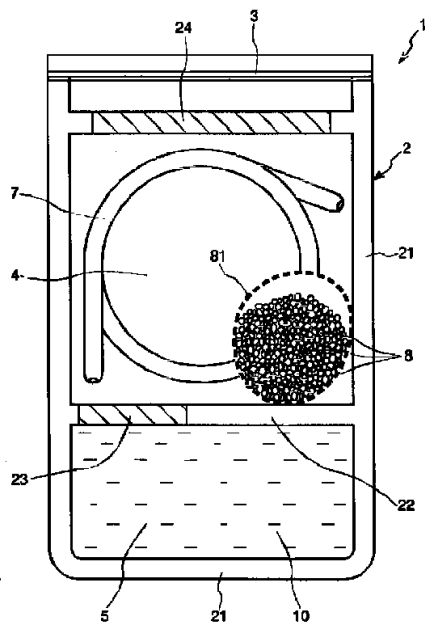
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(54) 【発明の名称】 包装体

(57) 【要約】

【課題】簡便にかつ無菌的に器具と液体との接触を可能にし、器具の使用後、外部への臭気の放散や、汚染、感染等を防止することができる包装体を提供すること。

【解決手段】包装体1の包材2は、シート材と融着して得られたものであり、その内部には、仕切部22で区画された第1の空間4と第2の空間5とが形成されている。仕切部22には、弱シール部23が形成されている。第1の空間4内には、カテーテル7と、通気性を有する容器81に入れられた脱臭剤8とが収納されている。また、第2の空間5には、流動性物質10が収納されている。弱シール部23が剥離され、流動性物質10が第1の空間4内に流入し、カテーテル7と接触すると、カテーテル7の表面は、湿润して摩擦抵抗が低減する。



【特許請求の範囲】

【請求項1】 仕切部により互いに隔離され、必要時に連通可能な第1の空間および第2の空間を有する包材と、

前記第1の空間に収納され、生体に挿入または装着して使用される器具と、

前記第1の空間に収納され、臭気を消滅または低減させる物質と、

前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【請求項2】 前記臭気を消滅または低減させる物質の主成分が酸化チタンである請求項1に記載の包装体。

【請求項3】 仕切部により互いに隔離され、必要時に連通可能な第1の空間および第2の空間を有する包材と、

前記第1の空間に収納され、生体に挿入または装着して使用される器具と、

前記第1の空間に収納され、少なくとも微生物の増殖を抑制する機能を有する物質と、

前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【請求項4】 前記微生物の増殖を抑制する機能を有する物質の主成分が酸化チタンである請求項3に記載の包装体。

【請求項5】 仕切部により互いに隔離され、必要時に連通可能な第1の空間、第2の空間および第3の空間を有する包材と、

前記第1の空間に収納され、生体に挿入または装着して使用される器具と、

前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質と、前記第3の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【請求項6】 仕切部により互いに隔離され、必要時に連通可能な第1の空間、第2の空間および第3の空間を有する包材と、

前記第1の空間に収納され、生体に挿入または装着して使用される器具と、

前記第2の空間に収納された血液抗凝固剤と、

前記第3の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【請求項7】 前記第1の空間と前記第2の空間とが隣接して形成され、かつ、前記第1の空間と前記第3の空間とが隣接して形成されている請求項5または6に記載の包装体。

【請求項8】 前記第2の空間は、前記第1の空間の内側に形成されている請求項1ないし7のいずれかに記載の包装体。

【請求項9】 前記仕切部は、前記包材を構成するシート材を融着してなるシール部で構成されている請求項1ないし8のいずれかに記載の包装体。

【請求項10】 前記仕切部の少なくとも一部が、他の部分より接合強度が弱い弱シール部で構成されている請求項1ないし9のいずれかに記載の包装体。

【請求項11】 前記第1の空間から前記器具を取り出すための開封部と、該開封部を開封後、その開封口を封止する封止手段とを有する請求項1ないし10のいずれかに記載の包装体。

【請求項12】 前記包材は、水蒸気バリア性を有するものである請求項1ないし11のいずれかに記載の包装体。

【請求項13】 前記器具は、カテーテルまたはガイドワイヤーである請求項1ないし12のいずれかに記載の包装体。

【請求項14】 前記器具は、尿道に挿入して使用されるカテーテルである請求項1ないし12のいずれかに記載の包装体。

【請求項15】 前記器具の少なくとも一部の表面に、湿潤により潤滑性が発現する化合物が付与されている請求項1ないし14のいずれかに記載の包装体。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、例えばカテーテルのような器具を包装した包装体に関する。

【0002】

【従来の技術】気管、消化管、尿道、血管、その他の体腔や、各種臓器、生体組織等へ挿入されるカテーテル、該カテーテルに挿入されるガイドワイヤー等の医療用器具の表面は、一般に、血栓、組織接着または異物反応が数多く確認される。従って、生体組織への損傷を低減し、目的部位へ確実に挿入することが必要となる。また、生体組織内での留置の際の粘膜炎症や粘膜損傷を抑制するために、器具表面に潤滑性を持たせることが必要とされる。

【0003】このため、低摩擦材料を基材として用いたり、使用に先立ち、器具表面に水、生理等張液もしくは潤滑剤を塗布したりしている。より詳しく説明すると、カテーテルの基材を多層積層構造とし、その最外層（または最内層）に、フッ素樹脂やポリエチレン樹脂等の低摩擦素材を用いたり、器具表面に水、生理等張液、グリセリン、オイル等の潤滑剤を塗布したりしている。

【0004】しかしながら、カテーテル基材の材質の選択では、摺動性の向上に限界があり、満足できるレベルに到達することが困難である。

【0005】また、潤滑剤等を付与する場合、これらを医療用器具と接触させた状態で製品化を行おうとすれば、医療用器具が使用されるまでの長時間の間に、潤滑剤の変質、劣化や、医療用器具表面からの剥離等が懸念

され、安定性（保存性）およびこれに伴う安全性の面で課題があった。

【0006】さらに、使用時に医療用器具と潤滑剤とを無菌的に接触させることは非常に困難であり、細菌感染等のおそれがあるという問題もある。

【0007】また、緊急時には、患者の生命を維持することが最優先であるため、潤滑剤の塗布の作業が煩わしいものとなり、場合によっては、潤滑剤を塗布せず、表面が乾燥状態のまま使用されることがある。

【0008】医療用器具の表面に湿潤すると潤滑性を発現する化合物を存在させる方法として、国際出願W09001344には、ポリウレタン表面にコーティング操作により、アルカリ金属アルコラート、アミノ基、アルカリ金属アミド基、カルボン酸基、スルホン酸基、マグネシウムハライド基およびフッ素ホウ素系錯体基の少なくとも一つを導入し、さらにコーティング操作により、これら官能基と反応しうる親水性ポリマーを表面に固定化する技術が開示されている。

【0009】また、同様に、医療用器具の表面に湿潤すると潤滑性を発現する化合物を存在させる方法は、特公平6-32652号、特開平6-7426号、国際出願W09219289、特表平10-502854号、特表平10-502855号、特表平10-502856号等にも開示されている。

【0010】しかしながら、これらの方法では、乾燥では潤滑性を発現することはなく、使用時には、医療用器具を包材から取り出し、その医療用器具の表面に水、生理等張液等の液体を供給し、接触させる操作が必須である。しかも、この操作を無菌的に行うことは、特別な操作や施設を利用する場合を除き、非常に困難であった。そのため、前述したように、感染のおそれを免れず、また、緊急時に、表面が乾燥状態のまま、直接、気管、消化管、尿道、血管等へ挿入することもあり、粘膜等の損傷が懸念されるものであった。

【0011】一方、血液が血管内皮細胞以外の異物と接触すると、異物表面に血漿タンパク、血小板の粘着、血液凝固が惹起され、血栓が生成される。この血栓形成は、カテーテル、ガイドワイヤー等の医療用器具の使用時において問題となる。

【0012】そのため、血液中にヘパリン等の血液抗凝固剤を投与するか、あるいは医療用器具の表面に血液抗凝固剤等を付与したり基材として抗血栓性材料を用いたりすることが行われている。

【0013】しかしながら、前者の場合には、患者に出血傾向等の弊害をもたらし、また、後者の場合には、使用時に液体との接触操作が必要であり、この操作を無菌的に行うことは、非常に困難であるという点で、前記と同様である。

【0014】さらに、緊急時には、患者の生命を維持することが最優先であるため、抗凝固操作を行わずに直接

使用することもあり、血栓形成による弊害が懸念されるものであった。

【0015】また、これら医療用器具の使用後は、医療廃棄物として廃棄処理されるが、通常は、体液や血液中の細菌、ウイルスなどの不活化操作（消毒・殺菌操作）や脱臭操作を施さずに、感染性を有したまま、あるいは臭気の放出を許容したままの状態に廃棄されていた。

【0016】そのため、医療用器具の使用後、焼却処分されるまでの間に、臭気が放散されたり、尿や血液等の体液が漏れ出し、周囲の汚染や感染を生じることがあった。

【0017】

【発明が解決しようとする課題】本発明は、上述した問題点を鑑みてなされたもので、その目的は、簡便にかつ無菌的に器具と液体との接触を可能にし、また、器具の使用後、外部への臭気の放散や、汚染、感染等を防止することができる包装体を提供することにある。

【0018】

【課題を解決するための手段】このような目的は、下記（1）～（15）の本発明により達成される。

【0019】（1）仕切部により互いに隔離され、必要時に連通可能な第1の空間および第2の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第1の空間に収納され、臭気を消滅または低減させる物質と、前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【0020】（2）前記臭気を消滅または低減させる物質の主成分が酸化チタンである上記（1）に記載の包装体。

【0021】（3）仕切部により互いに隔離され、必要時に連通可能な第1の空間および第2の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第1の空間に収納され、少なくとも微生物の増殖を抑制する機能を有する物質と、前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質とを備えることを特徴とする包装体。

【0022】（4）前記微生物の増殖を抑制する機能を有する物質の主成分が酸化チタンである上記（3）に記載の包装体。

【0023】（5）仕切部により互いに隔離され、必要時に連通可能な第1の空間、第2の空間および第3の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第2の空間に収納され、前記器具の表面と接触してその摩擦抵抗を低減させることができる流動性物質と、前記第3の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【0024】(6) 仕切部により互いに隔離され、必要時に連通可能な第1の空間、第2の空間および第3の空間を有する包材と、前記第1の空間に収納され、生体に挿入または装着して使用される器具と、前記第2の空間に収納された血液抗凝固剤と、前記第3の空間に収納され、液体を吸収、保持し得る物質とを備えることを特徴とする包装体。

【0025】(7) 前記第1の空間と前記第2の空間とが隣接して形成され、かつ、前記第1の空間と前記第3の空間とが隣接して形成されている上記(5)または(6)に記載の包装体。

【0026】(8) 前記第2の空間は、前記第1の空間の内側に形成されている上記(1)ないし(7)のいずれかに記載の包装体。

【0027】(9) 前記仕切部は、前記包材を構成するシート材を融着してなるシール部で構成されている上記(1)ないし(8)のいずれかに記載の包装体。

【0028】(10) 前記仕切部の少なくとも一部が、他の部分より接合強度が弱い弱シール部で構成されている上記(1)ないし(9)のいずれかに記載の包装体。

【0029】(11) 前記第1の空間から前記器具を取り出すための開封部と、該開封部を開封後、その開封口を封止する封止手段とを有する上記(1)ないし(10)のいずれかに記載の包装体。

【0030】(12) 前記包材は、水蒸気バリア性を有するものである上記(1)ないし(11)のいずれかに記載の包装体。

【0031】(13) 前記器具は、カテーテルまたはガイドワイヤーである上記(1)ないし(12)のいずれかに記載の包装体。

【0032】(14) 前記器具は、尿道に挿入して使用されるカテーテルである上記(1)ないし(12)のいずれかに記載の包装体。

【0033】(15) 前記器具の少なくとも一部の表面に、湿潤により潤滑性が発現する化合物が付与されている上記(1)ないし(14)のいずれかに記載の包装体。

【0034】

【発明の実施の形態】以下、本発明の包装体を添付図面に示す好適実施例に基づいて詳細に説明する。

【0035】図1は、本発明の包装体の第1実施例を示す平面図(内部透視図)である。同図に示すように、包装体1は、第1の空間および第2の空間を有する包材2を有している。

【0036】包材2は、後述するようなシート材を融着(または接着)により所望のパターンにシールして袋状としたものである。包材2の外周部等には、帯状のシール部21が形成されている。

【0037】また、包材2の途中には、仕切部22が形

成されている。この仕切部22は、前記シール部21と同様にシート材を帯状に融着(または接着)したものである。この仕切部22により、包材2内は、それぞれ独立した(互いに隔離された)第1の空間4および第2の空間5に区画されている。

【0038】図1中斜線を施して示すように、仕切部22の一部は、他の部分(シール部21)より接合強度(剥離強度)が弱い弱シール部(イージーピールシール部)23で構成されている。この弱シール部23を剥離(破断)することにより、第1の空間4と第2の空間5とが連通する。

【0039】シール部21は、対向するシート材同士が完全に融着され、強固な接合状態であるのに対し、弱シール部23は、それより低温で融着する等により、対向するシート材同士の融着がある程度不完全であるような状態とされる。ただし、弱シール部23においても、液密性(気密性)は、確保されている。そして、その効果は、経時的に持続する。

【0040】弱シール部23を剥離(破断)するには、包材2の第2の空間5を画成する部分を押圧(圧迫)し、第2の空間5の内圧を高めることにより可能となる。また、その他、弱シール部23を手で揉みほぐしてもよく、さらには、これらの方法を併用してもよい。このように、極めて簡単な操作で、第1の空間4と第2の空間5とを連通させることができる。

【0041】なお、弱シール部23は、仕切部22の2箇所以上に形成されていてもよく、あるいは、仕切部22のほぼ全体にわたって形成されていてもよい。

【0042】また、包材2の図1中上端部のシール部21にも、前記弱シール部23と同様の弱シール部(開封部)24が形成されている。この弱シール部24を剥離(破断)して包材2を開封し、第1の空間4内の収納物を出し入れすることができる。

【0043】また、弱シール部24の図1中上端側の近傍には、開閉可能なジッパー(封止手段)3が設けられている。弱シール部24を剥離(破断)して包材2を開封した後でも、このジッパー3を閉じることにより、この開封口を封止することができる。また、ジッパー3を開ければ、再び開封口を開放することができる。

【0044】なお、ジッパー3としては、例えば、互いに嵌合する溝および突条で構成されたもの等、公知の任意の構成のものが使用可能である。

【0045】第1の空間4には、生体に挿入または装着して使用される器具と、臭気を消滅または低減させる物質とが収納されている。生体に挿入または装着して使用される器具としては、カテーテルまたはガイドワイヤーが好ましく、本実施例では、第1の空間4内に、カテーテル7と脱臭剤(消臭剤)8とが収納されている。

【0046】カテーテル7としては、例えば、気管、消化管、尿道、膣、血管、リンパ管、胆管、その他の体腔

や、例えば肺、心臓、腎臓等の各種臓器、その他の生体組織等へ挿入される種々のカテーテル、バルーンカテーテルが挙げられるが、特に、尿道に挿入して使用されるカテーテル（尿道カテーテル、導尿カテーテル）が好ましい。

【0047】排尿障害における導尿法は、留置カテーテルではなく無菌間歇導尿法が好ましいが、近年、患者自身がカテーテルを使って尿を排出する自己導尿が有効な治療方法として普及してきている。排尿障害は、前立腺肥大症、結石、腫瘍などによる尿道閉塞や、脳・脊髄および骨盤神経などの障害により見られる神経因性膀胱によって起こるが、尿を完全に出しきれない状態になると、尿路内圧が上がって腎臓に負担をかけるので、定期的に尿を排出する必要がある。この際に行われる自己導尿法は、低圧で完全に尿を排出できるので、既にある尿感染が低減する、頻尿、尿失禁が治る、膀胱と腎臓に負担をかけない等の利点があり、患者自身が1日4～6回程度、尿道から膀胱内にカテーテルを挿入し、尿の排出が終了したら抜去する。その頻度は、例えば、昼間は4～5時間毎、夜間は就寝前とされる。

【0048】カテーテル7の表面には、例えば、湿潤により潤滑性を発現する物質が付与されているのが好ましい。このような物質としては、例えば、特開昭60-259269、特開平1-195863号公報に記載されているような親水性ポリマーが挙げられる。また、例えば、特公平6-32652号、特開平6-7426号、国際出願WO8802623、国際出願WO8907521、国際出願WO8909246、国際出願WO9001344、国際出願WO9219289、国際出願WO9311751、国際出願WO9529722、特表平10-502854号、特表平10-502855号、特表平10-502856号に開示されている物質や方法を用いてもよい。このような物質は、カテーテル7の表面に、湿潤していない状態（乾燥状態）で存在している。

【0049】このような物質は、カテーテル7の基材表面に化学結合されたポリマーであって、カテーテル7の基材表面からの剥離は、水、生理等張液、その他潤滑剤等への溶出が生じ難いものが、潤滑性の持続性、安全性の点から好ましい。

【0050】脱臭剤（消臭剤）8は、市販されている脱臭剤、消臭剤、芳香剤等、いずれのものを使用してもよい。この場合、脱臭剤8の臭気除去機構においても、物理的消臭法（活性炭、ゼオライト等の多孔性物質）、化学的消臭法（各種有機・無機化合物、植物抽出物、オゾン、貴金属系酸化触媒）、生物学的消臭法（微生物、人工酵素）、感覚的消臭法（芳香系化合物、植物製油）等、第1の空間4に収納可能であればいかなるものでもよい。

【0051】脱臭剤8として特に好ましいものとして

は、酸化チタン（ TiO_2 ）が挙げられる。この酸化チタンは、次のような利点を有する。

【0052】1）無害な無機酸化物であり、環境との調和が可能である。

2）紫外光励起の結果、強力な酸化力を有し、吸着した有機物の常温分解が可能である。

3）吸着した酸素を酸素ラジカルに変化させ、このラジカルにより吸着した有機物の常温分解が可能である。

4）上記2）3）の効果が、日常生活空間の照明光で惹起される。

【0053】このような酸化チタンの持つ優れた機能により、脱臭効果のみならず、抗菌、抗カビ効果も得られる。このような酸化チタンは、好ましくは、紙、不織布などの有機合成繊維や、パルプなどの有機化合物から構成される繊維の基材に担持させたものが好ましい。

【0054】このような脱臭剤8は、通気性を有する容器（包材）81に収納された状態とされている。この容器81は、気体は透過するが液体は透過できないような材料で構成されているのが好ましい。このような容器81の構成材料としては、例えば、ポリエチレン製不織布、ポリテトラフルオロエチレン製多孔質体のような水不透過性多孔質体が挙げられる。

【0055】第2の空間5には、前記カテーテル7の表面と接触してその摩擦抵抗を低減させることができる流動性物質（液状または半液状物）10が収納（充填）されている。

【0056】この流動性物質10の例としては、水、生理等張液（生理食塩水）、グリセリン、シリコーンオイル、オリーブオイル等のオイル類、キシロカインゼリー等（以下、これらを総称して「潤滑剤」と言う）が挙げられる。

【0057】カテーテル7の表面に前述したような湿潤により潤滑性を発現する物質が付与されている場合、流動性物質10は、この物質を湿潤させることができるものであればいかなるものでもよく、その典型例としては、水、生理等張液（生理食塩水）、グリセリン水溶液等が選択される。

【0058】包材2（好ましくは包材2全体）は、水蒸気バリア性を有するのが好ましい。ここで、水蒸気バリア性とは、水蒸気透過度が、好ましくは $30\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、より好ましくは $10\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、さらに好ましくは $1\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下であることを言う。この水蒸気透過度は、JIS K7129（A法）に記載の方法により測定される。

【0059】このように包材2が水蒸気バリア性を有することにより、包材2の内部、特に第2の空間5からの水分の蒸散が防止できる。その結果、第2の空間5内の液剤（流動性物質10等）の減少、濃縮を防止するこ

とができるとともに、該液剤の量が必要最少限の量で済み、包装体1全体の容積や重量を小さくすることができる。また、包材2の外部や第2の空間5からの第1の空間4内への水蒸気の侵入も防止することができる。

【0060】包材2を構成するシート材（フィルム）、特に前記水蒸気バリア性を有するシート材としては、例えば、ポリエチレン、ポリプロピレン等のポリオレフィン樹脂、これらポリオレフィン樹脂のブレンド樹脂、ポリエチレンテレフタレート等のポリエステル樹脂、ポリ塩化ビニリデン、塩化ビニル-塩化ビニリデン共重合体等の単層フィルム、これらのフィルムにアルミニウム、シリカ等を蒸着したもの、アルミニウムフィルム、アルミニウムラミネートフィルム等の金属箔または金属箔を含むフィルムを使用することができる。さらには、これら各フィルムを2層以上積層したものをを用いることもできる。

【0061】なお、弱シール部23、24においては、直接融着に関与する層（シーラント層）が2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂、もしくは2種以上の互いに相溶しないポリオレフィン樹脂をセグメントに有するランダムもしくはブロック共重合体で構成されていることが好ましい。

【0062】本発明では、包材2全体または包材2の少なくとも第2の空間5を画成する部分が、水蒸気バリア性を有するシート材で構成されているのが好ましい。このようなシート材は、例えば、[1]1種のポリオレフィン樹脂で構成される単層フィルム、[2]2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂より構成される単層フィルム、[3]シーラント層（融着に関与する層）にポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）を用いたポリオレフィン樹脂もしくはポリエステル樹脂の多層フィルム、等が挙げられる。

【0063】より高い水蒸気バリア性を得るには、例えば、[4]シーラント層がポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）より構成されるフィルム、外層がポリ塩化ビニリデンをコーティングしたポリオレフィンまたはポリエステルフィルム等で構成される多層フィルム、[5]シーラント層がポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）より構成されるフィルム、外層がアルミ蒸着もしくはシリカ蒸着されたポリオレフィンフィルムまたはポリエステルフィルム等で構成される多層フィルム、が挙げられる。

【0064】さらに、極めて高い水蒸気バリア性を得るには、例えば、[6]シーラント層がポリオレフィン樹脂（ポリオレフィン樹脂のブレンド樹脂も使用可能）より構成されるフィルム、中間層がアルミニウムフィルム、最外層がポリエステルフィルム等で構成される多層フィルム、が挙げられる。この場合、対向する一対のシ

ート材のうちの一方を不透明なアルミニウムフィルム、他方をシリカ蒸着フィルム等の透明な水蒸気バリア性フィルムとすれば、包材2の内容物の視認による確認が行えるので、さらに好ましい。なお、アルミニウムフィルムは、必要に応じその一部もしくは全部が剥離除去可能であってもよい。

【0065】包材2を構成するシート材（単層または多層積層体）の厚さは、その層構成や用いる素材の特性（柔軟性、強度、水蒸気透過性、耐熱性等）等に応じて適宜決定され、特に限定されるものではないが、通常は、60～700 μ m程度であるのが好ましく、100～500 μ m程度であるのがより好ましい。

【0066】このような包材2を構成するシート材は、例えば、インフレーション法、Tダイ法、ブロー成型法、ドライラミネート法、ホットメルトラミネート法、共押出インフレーション法、共押出Tダイ法、ホットプレス法等の種々の方法により製造することができる。

【0067】次に、本発明の包装体の第2実施例について、前記第1実施例との相違点を中心に説明し、同様の事項の説明は省略する。

【0068】第2実施例の包装体は、図1に示す包装体1において、脱臭剤8に代え、少なくとも微生物（細菌、ウイルス等）の増殖（繁殖）を抑制する機能を有する物質を収納したものである。この物質の代表的なものとしては、抗菌剤が挙げられ、以下、この抗菌剤が代表的に説明する。ここで、抗菌剤とは、殺菌、消毒、除菌、抗菌または制菌作用を有する物質の総称を言う。

【0069】抗菌剤としては、有機系抗菌剤、無機系抗菌剤のいずれでもよいが、耐性菌の出現の防止等、安全性をより重視するという点では、例えば、金属、金属酸化物、各種セラミックス等の無機系抗菌剤が好ましい。

【0070】また、抗菌剤は、その作用機序から、細胞壁合成阻害、細胞膜障害、蛋白合成阻害、DNA合成障害、細胞内代謝障害等に分類できるが、本発明では、いかなる作用機序のものでもよい。

【0071】このような抗菌剤の特に好ましいものとしては、前述した酸化チタン（TiO₂）が挙げられる。この酸化チタンについては、前述した通りである。

【0072】また、抗菌剤は、例えば、織布、メッシュ（網状体）等で構成された通気性および通液性を有する容器（包材）、あるいは前述した容器（包材）81に収納された状態で、第1の空間4内に収納されているのが好ましい。

【0073】図2は、本発明の包装体の第3実施例を示す平面図（内部透視図）である。以下、第3実施例の包装体について、前記第1実施例との相違点を中心に説明し、同様の事項の説明は省略する。

【0074】図2に示すように、第3実施例の包装体1は、包材2の第1の空間4内に抗菌剤（少なくとも微生物の増殖を抑制する機能を有する物質）として、シート

状の抗菌剤、すなわち、抗菌シート9を収納したものである。

【0075】抗菌シート9としては、例えば、シート、多孔質体等の基材に、有機系抗菌剤、銀、銅、亜鉛などの抗菌活性を有する金属、セラミックス等の抗菌剤を担持させたものが挙げられる。特に、耐性菌の出現の懸念の少ない無機系抗菌剤が好ましい。

【0076】なお、図示の構成では、抗菌シート9は、第1の空間4の一部分に配置されているが、第1の空間4のはば全域をカバーするような大きさの抗菌シートを用いることもできる。また、抗菌シート9は、複数枚収納されていてもよい。

【0077】第2および第3実施例のように、第1の空間4内に抗菌剤を収納したことにより、包材2の開封前または開封後のカテーテル7は勿論のこと、使用済みのカテーテル7を第1の空間4内へ戻した際にも、カテーテル7に対し抗菌作用を発揮することができ、廃棄までの間の運搬や廃棄処理を衛生的で安全に行うことができる。

【0078】図3は、本発明の包装体の第4実施例を示す平面図（内部透視図）である。以下、第4実施例の包装体について、前記第1実施例との相違点を中心に説明し、同様の事項の説明は省略する。

【0079】図3に示すように、第4実施例の包装体1は、第2の空間5が第1の空間4の内側に形成されているものである。すなわち、包材2は、第1の空間4を有し、その中には、前述したカテーテル7と、脱臭剤8（または抗菌剤）と、小包材（袋体）11とが収納されている。

【0080】小包材11は、前述した包材2を構成するシート材と同様のシート材を重ね、その外周部を融着（または接着）によりシールして袋状としたものであり、その内部には、第2の空間5が形成される。この第2の空間5には、前述した流動性物質10が収納（充填）されている。

【0081】小包材11の外周のシール部は、第2の空間5と第1の空間4とを区画する仕切部22を構成する。この仕切部22の一部には、前記と同様の弱シール部23が形成されている。この弱シール部23を剥離（破断）することにより、第1の空間4と第2の空間5とが連通し、流動性物質10を第1の空間4へ流入させることができる。

【0082】このような構成の包装体1は、次のような効果（利点）を有する。まず第1に、第1の空間4内に入れる小包材11の容量を選択することにより、小包材11の内容物（流動性物質10等）の量や重量を容易に設定することができる。第2に、小包材11が第1の空間4内で移動可能であるため、弱シール部23を剥離（破断）する操作や、その後小包材11内から流動性物質10等をしごき出す操作を容易に行うことができる。

第3に、2重包装であるため、流動性物質10の容器である小包材11には、要求される水蒸気バリアー性のレベルが前記第1～第3実施例に比べて低くてよく、よって、小包材11の構成材料の選択の自由度が広がり、また、シート厚をより薄くできる等、製造上有利となる。第4に、小包材11は単独で製造可能なので、製造・管理がしやすい。

【0083】なお、第4実施例の包装体1の場合、小包材11のみが、水蒸気バリアー性を有するものであってもよい。

【0084】次に、上述した各包装体1の使用方法（作用）について説明する。

【0085】例えば前述したような方法により弱シール部23を剥離（破断）すると、第1の空間4と第2の空間5とが連通し、第2の空間5内に収納されていた流動性物質10が第1の空間4内に流入し、カテーテル7の表面に接触する。これにより、カテーテル7の表面に潤滑性が発現し、摩擦抵抗が低減する。なお、弱シール部23を剥離（破断）後、必要に応じて、包材2の外部から手で押圧（圧迫）する等して、第2の空間5から流動性物質10等をしごき出す操作を行ってもよい。

【0086】第1の空間4および第2の空間5は、予め滅菌処理がなされており、しかも、このようなカテーテル7の表面に潤滑性を発現させる操作は、密閉された包材2の内部で外気と接触することなく行われるため、カテーテル7は、無菌性を保持することができる。

【0087】なお、第1の空間4に流入した流動性物質10は、容器81を透過することはできないので、容器81内の脱臭剤8は、流動性物質10で濡れることはなく、よって、脱臭機能（消臭機能）の低下を生じることが防止される。

【0088】従来では、細菌感染を防ぐために、カテーテルを生体内に挿入する前に、そのカテーテルを例えば1%ポピドンヨードグリセリン液のような消毒液に浸漬し、消毒する操作を行っていた。しかし、消毒液の調整が非常に煩雑なことや、消毒液の入手自体が困難な場合も多々あり、患者自身への負担が大きく、安全性の確保が十分ではなかった。また、同一のカテーテルに対し、消毒を繰り返して複数回使用すると、カテーテル表面へのバイオフィルムの形成等により細菌繁殖の温床になることもあった。これに対し、本発明では、前述したように、包材2を開封することなくカテーテル7を使用可能な状態（低摩擦状態）とすることができ、かつ、カテーテル7の無菌性を保持したままそのような状態とすることができるので、かかる従来の問題点が解消される。

【0089】カテーテル7の表面に潤滑性を発現させる操作が終了したら、弱シール部24を剥離（破断）し、ジッパー3を開いて、第1の空間4内のカテーテル7を取り出し、生体の目的部位に挿入または装着する。カテ

ーテル7が尿道カテーテル（導尿カテーテル）である場合には、そのカテーテル7を尿道および膀胱に挿入し、該カテーテル7を介して排尿する。このとき、カテーテル7の挿入は、カテーテル7の表面が潤滑性を有しているため、円滑かつ安全に行うことができる。排尿が終了したら、カテーテル7を尿道から抜き取る。

【0090】使用済みのカテーテル7は、廃棄されるが、カテーテル7を単独で廃棄するのではなく、カテーテル7を再び包材2の第1の空間4内に戻し、ジッパー3を閉じ、包材2ごと廃棄するのが好ましい。

【0091】特に、患者による自己導尿においては、外出時においてトイレの個室内でカテーテル7を使用した後、設置してあるゴミ箱にそれを捨てることは難しく、そのため、自宅に持ち帰り、廃棄することを希望する。また、帰宅途中（運搬移動中）において、使用したカテーテル7から発生せられた尿臭気が外部へ漏れることは好ましくない。さらに、カテーテル7に残存する尿により、尿中の細菌、ウイルス等が繁殖することが懸念され、衛生的に好ましくない。

【0092】本発明では、使用済みのカテーテル7を包材2の第1の空間4内に収納した際、脱臭剤8がカテーテル7から発生せられる尿臭気等の臭気を消滅または減少させる。また、抗菌剤（酸化チタン、抗菌シート9等）が細菌、ウイルス等の増殖を抑制する。これにより、上記のような問題が解消され、使用済みのカテーテル7を臭気の放散を生じることなく、衛生的に搬送することができる。

【0093】図4は、本発明の包装体の第5実施例を示す平面図（内部透視図）である。以下、第5実施例の包装体について、前記第1実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0094】図4に示すように、第5実施例の包装体1は、包材2内に、仕切部25により仕切られた第1の空間4、第2の空間5および第3の空間6を有するものである。

【0095】包材2の外周部等には、包材2を構成するシート材を融着（または接着）した帯状のシール部21が形成されている。

【0096】仕切部25は、シール部21と同様にシート材を帯状に融着（または接着）したものであり、T字状をなしている。この仕切部25により、包材2内は、それぞれ独立した（互いに隔離された）第1の空間4、第2の空間5および第3の空間6に区画されている。

【0097】この場合、第1の空間4、第2の空間5および第3の空間6は、互いに隣接して配置されている。従って、後述するような第2の空間5から第1の空間4への液体の移動、および第1の空間4から第3の空間6への移動等を迅速、確実に行うことができる。

【0098】仕切部22には、前記弱シール部23と同様の弱シール部26および27が形成されている。弱シ

ール部26を剥離（破断）することにより、第1の空間4と第2の空間5とが連通し、弱シール部27を剥離（破断）することにより、第1の空間4と第3の空間6とが連通する。

【0099】第1の空間4内には、前述したカテーテル7が収納されており、第2の空間5には、前述した流動性物質10が収納されている。

【0100】第3の空間6には、液体を吸収、保持し得る物質として、吸水性材料12が収納されている。この吸水性材料12としては、例えば、ポリアクリル酸塩系、ポリビニルアルコール系、ポリアクリルアミド系、ポリオキシエチレン系またはマレイン酸系材料などの合成ポリマーや、デンプン、セルロース、アルギン酸のような多糖類材料などの天然材料などのような高分子吸水性材料が好ましい。また、その他、例えば、スポンジ、綿、ガーゼ、不織布や、それらに上記高分子吸水性材料を担持したもの（例えば、おむつ、生理用品などに用いられているもの）が挙げられる。これらの吸水性材料12は、例えば、粉末状、フィルム状、シート状、繊維状（繊維の集合体）などの種々の形態をとることができる。

【0101】なお、第1の空間4または第3の空間6に、前述した脱臭剤および／または抗菌剤が収納されていてもよい。特に、第3の空間6にこれらを収納する場合、吸水性材料12に、前述したような脱臭剤（脱臭機能を有する成分）および／または抗菌剤（抗菌機能を有する成分）が担持された構成とすることが好ましい。

【0102】図5は、本発明の包装体の第6実施例を示す平面図（内部透視図）である。以下、第6実施例の包装体について、前記第5実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0103】図5に示すように、第6実施例の包装体1は、第1の空間4と第3の空間6とが弱シール部27を有する仕切部25により隔離され、第2の空間5が第1の空間4の内側に形成されているものである。すなわち、包材2の第1の空間4内には、前述したカテーテル7と、前記と同様の小包材（袋体）11とが収納されている。

【0104】小包材11の外周部は、弱シール部23を有する仕切部22で構成され、その内側には、第2の空間5が形成されている。この第2の空間5には、前述した流動性物質10が収納（充填）されている。弱シール部23を剥離（破断）することにより、第1の空間4と第2の空間5とが連通し、流動性物質10を第1の空間4へ流入させることができる。

【0105】また、第3の空間6内には、前記と同様の吸水性材料（液体を吸収、保持し得る物質）12が収納されている。

【0106】このような構成の包装体1は、前記第4実施例の包装体1と同様の効果（利点）を有する。

【0107】図6は、本発明の包装体の第7実施例を示す平面図（内部透視図）である。以下、第7実施例の包装体について、前記第5実施例、第6実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0108】図6に示すように、第7実施例の包装体1は、第2の空間5および第3の空間6がそれぞれ第1の空間4の内側に形成されているものである。すなわち、包材2の第1の空間4内には、前述したカテーテル7と、小包材（袋体）14とが収納されている。

【0109】小包材14は、前述した包材2を構成するシート材と同様のシート材を重ね、その外周部および途中を融着（または接着）によりシールして袋状としたものであり、その内部には、仕切部28を介して第2の空間5と第3の空間6とが形成されている。

【0110】第2の空間5には、前述した流動性物質10が収納（充填）され、第3の空間6には、前述した吸水性材料（液体を吸収、保持し得る物質）12が収納されている。

【0111】小包材14の外周部および途中を横断するシール部は、第1の空間4、第2の空間5および第3の空間6を隔離（区画）する仕切部28を構成する。この仕切部28の一部には、第2の空間5を開封するための弱シール部26と、第3の空間6を開封するための弱シール部27とが形成されている。なお、本実施例では、弱シール部27は、2箇所に設けられている。

【0112】このような構成の包装体1は、次のような効果（利点）を有する。まず第1に、第1の空間4内に入れる小包材14の容量（第2の空間5および第3の空間6のそれぞれの容量）を選択することにより、小包材14の内容物（流動性物質10および吸水性材料12）の量や重量を容易に設定することができる。第2に、小包材14が第1の空間4内で移動可能であるため、弱シール部26、27を剥離（破断）する操作や、第2の空間5から流動性物質10等をしごき出す操作、第3の空間6へ液体を回収する操作を容易に（適正な位置で）行うことができる。また、前述した小包材11の第3および第4の利点についても同様である。

【0113】なお、本実施例では、1つの小包材14に第2の空間5および第3の空間6が形成されているが、これに限らず、第1の空間4内に2つの分離された小包材が収納され、それらの小包材にそれぞれ第2の空間5および第3の空間6が形成された構成であってもよい。この構成の場合にも、前記と同様の効果が得られる。

【0114】図7は、本発明の包装体の第8実施例を示す平面図（内部透視図）である。以下、第8実施例の包装体について、前記第5実施例等との相違点を中心に説明し、同様の事項の説明は省略する。

【0115】図7に示すように、第8実施例の包装体1は、その下端部側にU字状の第2の空間5を有し、該第2の空間5内には、前述した流動性物質10が収納（充

填）されている。

【0116】また、第2の空間5の内側（包材2の中心側）には、U字状の仕切部29を介して第3の空間6が形成され、該第3の空間6内には、前述した吸水性材料（液体を吸収、保持し得る物質）12が収納されている。

【0117】仕切部25は、第1の空間4と第2の空間5、および第1の空間4と第3の空間6とをそれぞれ隔離している。この仕切部25には、第3の空間6を開封するための弱シール部27が形成されている。

【0118】仕切部25の一方の側部には、破断して開封可能な封止部材13が設置されている。この封止部材13は、仕切部25と交差するように仕切部25に挟まれて融着されている。以下、封止部材13の構成について説明する。

【0119】図8は、封止部材13の構成例を示す縦断面図である。同図に示すように、封止部材13は、例えば軟質ポリ塩化ビニルのような可撓性を有する樹脂により構成された短チューブ131と、この短チューブ131内に液密に嵌入され、中実柱状部133によりその一端が閉塞された筒体132とで構成されている。

【0120】短チューブ131の図8中上端部は、第1の空間4に連通し、筒体132の図8中下端部は、第2の空間5に連通している。

【0121】筒体132の途中の外周には、薄肉で脆弱な破断部134が形成されている。手指等により短チューブ131の外部から短チューブ131ごと中実柱状部133を折り曲げて破断部134を破断し、中実柱状部133を分離することにより、封止部材13の内部流路が開通する。これにより、第1の空間4と第2の空間5とが連通し、第2の空間5内の流動性物質10を第1の空間4へ流入させることができる。

【0122】筒体132の構成材料としては、例えば、硬質ポリ塩化ビニル、ポリカーボネート、ポリエステル等の硬質材料が挙げられる。

【0123】また、中実柱状部133の上端部135は、くさび形状（扁平形状）をなしている。これにより、中実柱状部133の破断分離後に中実柱状部133が短チューブ131を閉塞せず、十分な液流通を確保することができる。

【0124】また、短チューブ131の図8中上端部は、その内径が縮径しており、破断分離後の中実柱状部133がこの縮径部136を通過することができないようになっている。これにより、破断分離された中実柱状部133が第1の空間4内に入り、第1の空間4内で自由に移動することを防止することができる。

【0125】前記第5実施例、第6実施例、第7実施例および第8実施例においては、第2の空間5には流動性物質10が収納されていたが、これらの各実施例において、流動性物質10に代わり、第2の空間5内に血液抗

凝固剤（抗血栓剤）を含有する液体が収納されていてもよい。これにより、カテーテル7を使用するに際し、カテーテル7に血液抗凝固機能を付与することができる。血液抗凝固剤としては、例えば、下記表1に示すものが挙げられる。

【0126】
【表1】

表 1

ACD液	クエン酸ナトリウム	2.2%
	クエン酸	0.8%
	ブドウ糖	2.2%
CPD液	クエン酸ナトリウム	2.63%
	クエン酸	0.327%
	ブドウ糖	2.32%
	リン酸・1・ナトリウム	0.222%
CPDA - 1 液	クエン酸ナトリウム	2.63%
	クエン酸	0.327%
	ブドウ糖	2.9%
	リン酸・1・ナトリウム	0.222%
	アデニン	0.0275%
ヘパリン	塩化ナトリウム	0.9%
	ヘパリンナトリウム	1000単位/30ml

【0127】以上の各実施例では、包材2として、可撓性を有するシート材で構成されたものを挙げたが、これに限らず、例えば、一部が比較的硬質な材料で構成されたものでもよい。その具体例としては、いわゆるプリスター容器と呼ばれるものが挙げられる。このプリスター容器は、比較的硬質な材料で構成され、収納空間（例えば第1の空間）を形成する凹部を有する本体と、前記凹部の開口部を気密的に封止するフィルムとで構成され、該フィルムを剥がすことにより開封するものである。

【0128】次に、第5～第8実施例の各包装体1の使用法（作用）について説明する。弱シール部23または26を剥離（破断）すると（第8実施例の場合には、封止部材13の中実柱状部133を破断分離すると）、第1の空間4と第2の空間5とが連通し、第2の空間5内に収納されていた流動性物質10が第1の空間4内に流入し、カテーテル7の表面に接触する。これにより、カテーテル7の表面に潤滑性が発現し、摩擦抵抗が低減

する。なお、必要に応じ、包材2の外部から手で押圧（圧迫）する等して、第2の空間5から流動性物質10等をしごき出す操作を行ってもよい。

【0129】第1の空間4および第2の空間5は、予め滅菌処理がなされており、しかも、このようなカテーテル7の表面に潤滑性を発現させる操作は、密閉された包材2の内部で外気と接触することなく行われるため、カテーテル7は、無菌性を保持することができる。このように、包材2を開封することなくカテーテル7を使用可能な状態（低摩擦状態）とすることができ、かつ、カテーテル7の無菌性を保持したままそのような状態とすることができるので、前述した従来の問題点が解消される。

【0130】カテーテル7の表面に潤滑性を発現させる操作が終了したら、弱シール部24を剥離（破断）し、ジッパー3を開いて、第1の空間4内のカテーテル7を取り出し、生体の目的部位に挿入または装着する。カテ

ーテル7が尿道カテーテル（導尿カテーテル）である場合には、そのカテーテル7を尿道および膀胱に挿入し、該カテーテル7を介して排尿する。このとき、カテーテル7の挿入は、カテーテル7の表面が潤滑性を有しているため、円滑かつ安全に行うことができる。排尿が終了したら、カテーテル7を尿道から抜き取る。

【0131】使用済みのカテーテル7は、廃棄されるが、カテーテル7を単独で廃棄するのではなく、カテーテル7を再び包材2の第1の空間4内に戻し、ジッパー3を閉じ、包材2ごと廃棄するのが好ましい。

【0132】このとき、前述したような方法により、弱シール部27を剥離（破断）し、開封する。これにより、第1の空間4と第3の空間6とが連通し、カテーテル7の表面に付着し、またはカテーテル7内に残存している尿等の体液を、第3の空間6内に収納されている吸水性材料12で吸収し、保持することができる。その結果、尿等の体液の漏れ出しをより確実に防止することができる。使用済みのカテーテル7を包材2ごと衛生的に搬送し、廃棄することができる。

【0133】特に、吸水性材料12に、脱臭剤（脱臭機能を有する成分）および／または抗菌剤（抗菌機能を有する成分）が担持されている場合には、臭気の放散や細菌、ウイルス等の増殖を抑制し、より衛生的で安全に搬送、廃棄処理を行うことができる。

【0134】以上のように、本発明の包装体1によれば、簡便にかつ無菌的に潤滑剤、血液凝固剤等とカテーテルとの接触を可能にし、患者等による運搬、開封操作等も簡単であるばかりでなく、カテーテルの使用後も衛生的に安全に運搬し、廃棄することができる。

【0135】本発明において、第1の空間4に収納される器具としては、以下のようなものが挙げられる。

【0136】・ 胃管カテーテル、栄養カテーテル、経管栄養用チューブ、酸素カテーテル、酸素カヌー、気管内チューブのチューブやカフ、気管切開チューブのチューブやカフ、気管内吸引カテーテル等の経口または経鼻的に挿入、留置されるカテーテル類。

【0137】・ 吸引カテーテル、排液カテーテル、腹腔カテーテル、直腸カテーテル、トロッカー等の各種体腔、臓器、組織内に挿入、留置されるカテーテル類。

【0138】・ 血管造影用カテーテル、PTCA用バルーンカテーテル、IABP用バルーンカテーテル、静脈留置カテーテル、動注用カテーテル等の血管内に挿入、留置されるカテーテル類。

【0139】・ 単独で、または、前記各カテーテル類とともに使用される各種ガイドワイヤー。

・ 人工血管、ステント、人工肛門、人工骨、人工関節、補綴物、義眼。

・ 注射針、留置針、シース、カテーテルイントロデューサ。

【0140】・ 内視鏡、心拍出量測定器具、超音波測

定・診断器具、超音波破碎プローブ、ペースメーカー、体温計。

・ 縫合用または結さつ用の糸
・ 浣腸
・ コンタクトレンズ
・ コンドーム等の避妊具

【0141】また、本発明において、第1の空間4、第2の空間5、第3の空間6の配置は、図示の各実施例のものに限らず、例えば、第2の空間、第1の空間および第3の空間が、この順に一例に配置された構成であってもよい。また、包材は、さらに第4の空間を有していてもよい。

【0142】また、第1の空間4、第2の空間5および第3の空間6には、それぞれ、前述した以外の任意のものが収納されていてもよい。

【0143】

【実施例】以下、実施例を挙げて本発明を具体的に説明する。

【0144】（実施例1A）ポリプロピレン（XF1800、チッソ（株）製）60重両部とスチレン系エラストマー（ハイブラHVS-3、クラレ（株）製）40重量部を用いて、共押出成形によるインフレーションシート（厚さ300 μ m、水蒸気透過度15g/m²・24hrs・25 μ m厚・40℃・90%RH）を得た。このシートを熱融着によりシールして、図1に示す構成の包材を成形した。

【0145】包材の第1の空間には、尿道に挿入して使用されるカテーテルとしてのネラトンカテーテル（サフィード、14Fr、テルモ（株）製）と、水不透過性多孔質体であるポリエチレン製不織布（商標名：タイベック、旭・デュボンフラッシュスパンプロダクツ（株）製）により包装された消臭・芳香剤（商標名：エアニップ、有限会社タクト製）とを入れた。なお、このネラトンカテーテルとしては、表面が、0.2wt%ポリビニルピロリドン-クロロホルム溶液（商標名：コリドンK30、BASFジャパン（株）製）でコーティングされ、親水性高分子材料の層が形成されているものを用いた。また、包材の第2の空間には、水10mlを入れ、密封した。

【0146】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0147】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、水とカテーテルとの接触はなかった。

【0148】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテ

ーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。

【0149】また、水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。

【0150】その後、カテーテルを下記表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定

時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。

【0151】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩しないため、衛生上も好ましいことが示唆された。

【0152】

【表2】

表 2 人工尿の成分

化合物	含有量 (g/L)	化合物	含有量 (g/L)	化合物	含有量 (g/L)
$\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$	0.65	$\text{Na}_2\text{H}_2\text{C}_6\text{H}_5\text{O}_7$	0.65	NH_4Cl	2.00
$\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$	0.65	$(\text{COONa})_2$	0.02	NH_4CONH_2	12.00
NaCl	4.60	KH_2PO_4	2.80	$\text{C}_4\text{H}_7\text{N}_3\text{O}$	1.10
Na_2SO_4	2.30	KCl	1.60	pH	5.7~5.8

【0153】(実施例2A、3A、4A) 実施例1Aと同様のインフレーションシートを熱融着によりシールして、図1に示す構造の包材を成形した。

【0154】包材の第1の空間には、前記と同様のネラトンカテーテル（表面のコーティングなし）を入れ、第2の空間には、下記表3に示す組成の潤滑剤を入れ、そ

れぞれを密封した。また、第1の空間には、下記表3に示す水不透過性多孔質体で包装された消臭剤、芳香剤等を入れた。

【0155】

【表3】

表 3 第1、第2の空間の収納物

実施例	潤滑剤等	水不透過性多孔質体（包装体）	消臭剤、芳香剤等
2A	グリセリン水溶液 （健栄製薬（株）製）	タイベック （旭・デュポンフラッシュスバンプロダクツ（株）製）	エアニップ （有限会社タクト製）
3A	生理食塩水 （テルモ（株）製）	プレスロン （日東電工（株）製）	微香空間 （小林製薬（株）製）
4A	ミルトン液 （マックスファクター（株）製）	ジュラガード （ポリプラスチックス（株）製）	ピーターラビット消臭剤 （積水化学工業（株）製）

【0156】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0157】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0158】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥

離し、第2の空間内の液体が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に液体とカテーテルとの接触が可能であることが確認された。

【0159】また、第2の空間内の液体とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が低減しており、体腔への挿入操作の操作性向上が示唆された。

【0160】その後、カテーテルを表2に示す成分の人

工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。

【0161】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩しないため、衛生上も好ましいことが示唆された。

【0162】(実施例5A、6A) 実施例1Aと同様の

表 4 第1、第2空間の収納物

実施例	潤滑剤等	抗菌シート
5 A	グリセリン水溶液 (健栄製薬(株)製)	アバタッチ (旭光工業(株)製)
6 A	ミルトン液 (マックスファクター(株)製)	お弁当用抗菌シート (リンテック(株)製)

【0165】包材のシール部(弱シール部以外の部位)は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0166】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0167】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の液体が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に液体とカテーテルとの接触が可能であることが確認された。

【0168】また、第2の空間内の液体とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が低減しており、体腔への挿入操作の操作性向上が示唆された。

【0169】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。さらに、抗菌シートの抗菌作用により、カテーテルに付着、残存している尿中の細菌、ウイルス等の増殖が抑制された。

【0170】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩せず、細菌感染のおそれもないため、衛生上も好ましいことが示唆された。

【0171】(実施例7A) 実施例1Aと同様のインフ

レーションシートを熱融着によりシールして、図2に示す構造の包材を成形した。

【0163】包材の第1の空間には、前記と同様のネラトンカテーテル(表面のコーティングなし)を入れ、第2の空間には、下記表4に示す組成の潤滑剤を入れ、それぞれを密封した。また、第1の空間には、下記表4に示す抗菌シートを入れた。

【0164】

【表4】

レーションシートを熱融着によりシールして、図2に示す構造の包材を成形した。

【0172】包材の第1の空間には、前記と同様のネラトンカテーテル(表面に実施例1Aと同様のコーティングを施したもの)を入れ、第2の空間には、水10mlを入れ、それぞれを密封した。また、第1の空間には、酸化チタンを含む脱臭・抗菌シート(商標名:PM-IN-CD、三菱製紙(株)製)を入れた。

【0173】包材のシール部(弱シール部以外の部位)は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0174】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0175】次に、包材を手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。

【0176】また、第2の空間内の水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が大幅に低減しており、体腔への挿入操作の操作性向上が示唆された。

【0177】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。さらに、脱臭・抗菌シートの抗菌作用により、カテーテルに付着、残存している尿中の細菌、ウイルス等の増殖が抑制された。

【0178】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩せず、細菌感染のおそれもないため、衛生上も好ましいことが示唆された。

【0179】(実施例8A) 実施例1Aと同様のインフレーションシートを熱融着によりシールして、図3に示す構造の小包材を内蔵する包材を成形した。

【0180】包材の第1の空間には、実施例1Aと同様のネラトンカテーテルと小包材とを入れ、密封した。小包材の第2の空間には、水20mlを入れ、密封した。また、第1の空間には、水不透過性多孔質体であるポリエチレン製不織布(商標名:タイベック、旭・デュポンフラッシュスパンプロダクツ(株)製)により包装された消臭・芳香剤(商標名:エアニップ、有限会社タクト製)を入れた。

【0181】包材および小包材のシール部(弱シール部以外の部位)は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、110℃、60分間高圧蒸気滅菌を行った。

【0182】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、第2の空間内の液体とカテーテルとの接触はなかった。

【0183】次に、小包材を包材の上から手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、小包材の開封操作をより簡便、確実に行うことができた。

【0184】また、第2の空間内の水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、カテーテルが乾燥状態のときと比較して、表面の摺動抵抗値が大幅に低減しており、体腔への挿入操作の操作性向上が示唆された。

【0185】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封し、所定時間放置した。包材に顔を近づけたが、尿臭気を感じる等、不快な感じは確認されなかった。さらに、脱臭・抗菌剤の抗菌作用により、カテーテルに付着、残存している尿中の細菌、ウイルス等の増殖が抑制された。

【0186】よって、患者は、カテーテル使用后、そのカテーテルを簡便に、また、周辺に気兼ねすることなく自宅へ持ち帰ることが可能であり、精神的負担から開放されるばかりでなく、外気へ尿臭気が漏洩せず、細菌感染のおそれもないため、衛生上も好ましいことが示唆さ

れた。

【0187】(実施例1B) ポリプロピレン(XF1800、チッソ(株)製)60重両部とスチレン系エラストマー(ハイブラHVS-3、クラレ(株)製)40重量部を用いて、共押出成形によるインフレーションシート(厚さ300μm、水蒸気透過度15g/m²・24hrs・25μm厚・40℃・90%RH)を得た。このシートを熱融着によりシールして、図4に示す構造の包材を成形した。

【0188】包材の第1の空間には、前記実施例1Aと同様のネラトンカテーテルを入れ、第2の空間には、水10mlを入れ、第3の空間には、吸水性材料である架橋ポリアクリル酸ナトリウム(商標名:アクアリック、日本触媒化学工業(株)製)1gを入れ、それぞれを密封した。

【0189】包材のシール部(弱シール部以外の部位)は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0190】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、水とカテーテルとの接触および水と吸水性材料との接触はなかった。

【0191】次に、包材を手で押圧、圧迫し、弱シール部26に負荷をかけたところ、弱シール部26のみが剥離し、第2の空間内の水が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に水とカテーテルとの接触が可能であることが確認された。

【0192】また、水とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。

【0193】その後、カテーテルを牛血に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0194】次に、弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた血液が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても血液の漏洩は生じなかった。

【0195】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に血液の漏洩がなく、血液による汚染、感染が防止され、安全性が高いことが示唆された。

【0196】(実施例2B) 実施例1Bと同様のインフレーションシートを熱融着によりシールして、図5に示す構造の小包材を内蔵する包材を成形した。

【0197】包材の第1の空間には、前記実施例1Aと

同様のネラトンカテーテルおよびガイドワイヤー（カテーテルの内腔に挿入された状態）と、小包材とを入れ、密封した。小包材の第2の空間には、血液抗凝固剤液として前記表1に示すCPDA-1液18mlを入れ、密封した。包材の第3の空間には、吸水性材料である架橋ポリアクリル酸ナトリウム（商標名：アクアリック、日本触媒化学工業（株）製）2gを入れ、密封した。

【0198】包材および小包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0199】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、抗凝固剤液とカテーテルとの接触および抗凝固剤液と吸水性材料との接触はなかった。

【0200】次に、小包材を包材の上から手で押圧、圧迫し、弱シール部23に負荷をかけたところ、弱シール部23のみが剥離し、第2の空間内の抗凝固剤液が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に抗凝固剤液とカテーテルとの接触が可能であることが確認された。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、小包材の開封操作をより簡便、確実に行うことができた。

【0201】また、抗凝固剤液とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、抗凝固剤液の水分によりカテーテル表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。また、カテーテルの表面には、抗凝固剤が付着しているため、血管内へ挿入した際に、優れた抗凝固作用を発揮するものと考えられる。

【0202】その後、カテーテルを牛血に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0203】次に、弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた血液が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても血液の漏洩は生じなかった。

【0204】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に血液の漏洩がなく、血液による汚染、感染が防止され、安全性が高いことが示唆された。

【0205】（実施例3B）実施例1Bと同様のインフレーションシートを熱融着によりシールして、図6に示す構造の小包材を内蔵する包材を成形した。

【0206】包材の第1の空間には、前記実施例1Aと同様のネラトンカテーテルおよびガイドワイヤー（カテ

ーテルの内腔に挿入された状態）と、小包材とを入れ、密封した。小包材の第2の空間には、血液抗凝固剤液として前記表1に示すヘパリン液18mlを入れ、第3の空間には、吸水性材料である架橋ポリアクリル酸ナトリウム（商標名：アクアリック、日本触媒化学工業（株）製）2gを入れ、それぞれを密封した。

【0207】包材および小包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0208】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離は観察されず、抗凝固剤液とカテーテルとの接触および抗凝固剤液と吸水性材料との接触はなかった。

【0209】次に、小包材の図6中上半分を包材の上から手で押圧、圧迫し、弱シール部26に負荷をかけたところ、弱シール部26のみが剥離し、第2の空間内の抗凝固剤液が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に抗凝固剤液とカテーテルとの接触が可能であることが確認された。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、弱シール部26の開封操作をより簡便、確実に行うことができた。

【0210】また、抗凝固剤液とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、抗凝固剤液の水分によりカテーテル表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。また、カテーテルの表面には、抗凝固剤が付着しているため、血管内へ挿入した際に、優れた抗凝固作用を発揮するものと考えられる。

【0211】その後、カテーテルを牛血に30秒間浸し、次いで、このカテーテルとガイドワイヤーとを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0212】次に、小包材の弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた血液が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても血液の漏洩は生じなかった。なお、包材内で小包材を好適な位置へ移動してこの操作を行ったため、弱シール部27の開封操作および残存血液の吸収をより簡便、確実に行うことができた。

【0213】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に血液の漏洩がなく、それによる汚染、感染が防止され、安全性が高いことが示唆された。

【0214】（実施例4B、5B、6B）実施例1Bと同様のインフレーションシートを熱融着によりシールし

て、図7に示す構造の包材を成形した。

【0215】包材の第1の空間には、前記実施例1Bと同様のネラトンカテーテル（表面のコーティングなし）を入れ、第2の空間には、下記表5に示す組成の潤滑剤

等を入れ、それぞれを密封した。また、第3の空間には、下記表5に示す吸水性材料を入れ、密封した。

【0216】

【表5】

表 5 第2、第3の空間の収納物

実施例	潤滑剤等	吸水性材料
4B	グリセリン水溶液 (健栄製薬(株)製)	サンウエット (三洋化成(株)製)
5B	生理食塩水 (テルモ(株)製)	スミカゲル (住友化学(株)製)
6B	ミルトン液 (マックスファクター(株)製)	アクアリザーブGP (日本合成化学(株)製)

【0217】包材のシール部（弱シール部以外の部位）は、200℃、4秒、0.25kgf/cm²で、弱シール部は、105℃、4秒、0.25kgf/cm²でそれぞれヒートシールし、2Mradでγ線滅菌を行った。

【0218】滅菌後、この包装体を激しく振動させたが、弱シール部の剥離や封止部材の破断は観察されず、潤滑剤とカテーテルとの接触および潤滑剤と吸水性材料との接触はなかった。

【0219】次に、包材の外側から封止部材（図8に示す構造）を手で折り曲げ、中実柱状部を破断部にて破断分離し、包材の第2の空間の部分を押迫したところ、第2の空間内の潤滑剤が第1の空間内へ流出し、カテーテルと接触した。これにより、簡便にかつ無菌的に潤滑剤とカテーテルとの接触が可能であることが確認された。

【0220】また、潤滑剤とカテーテルとの接触後、弱シール部24を開封し、カテーテルを取り出して表面を擦って見たところ、表面が潤滑性を示し、摩擦抵抗が低減しており、体腔への挿入操作の操作性の向上が示唆された。

【0221】その後、カテーテルを表2に示す成分の人工尿に30秒間浸し、次いで、このカテーテルを包材の第1の空間に戻し、ジッパーを閉じて密封した。

【0222】次に、弱シール部27を開封して第1の空間と第3の空間とを連通させ、包材を振動させたところ、カテーテルの表面および内部に付着、残存していた人工尿が第3の空間内の吸水性材料に吸収され、保持された。そのため、ジッパーを開封しても人工尿の漏洩は生じなかった。

【0223】よって、使用済みのカテーテルを包材に入れて搬送し、包材ごと廃棄しても、その間に尿等の体液の漏洩がなく、それによる汚染、感染が防止され、安全性が高いことが示唆された。

【0224】（実施例1C）包材を構成するシートとして、ポリプロピレン（三菱化学（株）製、SPX9600）の単層フィルム（フィルム厚300μm、水蒸気透過度21g/m²・24hrs・25μm厚・40℃・

90%RH）を用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0225】（実施例2C）包材を構成するシートとして、直鎖状低密度ポリエチレン（日本ポリケム（株）製、ノバテックLL UF340）とポリプロピレン（チッソ（株）製、チッソポリプロ K7714）とのポリマーブレンドによる単層フィルム（フィルム厚300μm、水蒸気透過度18g/m²・24hrs・25μm厚・40℃・90%RH）を用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0226】（実施例3C）包材を構成するシートとして、直鎖状低密度ポリエチレンとポリプロピレンとのポリマーブレンドフィルムによる第1層、およびシリカ蒸着ポリエチレンテレフタレートフィルムによる第2層から構成される2層積層フィルム（大日本印刷（株）製、フィルム厚300μm、水蒸気透過度0.6g/m²・24hrs・25μm厚・40℃・90%RH）を、第1層同士が接合されるように用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0227】（実施例4C）包材を構成するシートとして、直鎖状低密度ポリエチレンとポリプロピレンとのポリマーブレンドフィルムによる第1層、アルミニウムフイルムによる第2層、およびポリエチレンテレフタレートフィルムによる第3層から構成される3層積層フィルム（東洋アルミニウム（株）製、フィルム厚300μm、水蒸気透過度0.3g/m²・24hrs・25μm厚・40℃・90%RH）を、第1層同士が接合されるように用いた以外は、実施例1Aと同様にし、図1に示す構成の包装体を製造した。包材の第1の空間および第2の空間内の収納物も、実施例1Aと同様である。

【0228】（実施例5C）第2の空間に収納した液体

をグリセリン水溶液（健栄製薬（株）製、グリセリン濃度：84～87％）10mlとした以外は、実施例4Cと同様の包装体を製造した。

【0229】＜試験1＞実施例1C～5Cの各包装体を温度40℃、湿度75％RHの環境下で4週間放置し、1週間後、2週間後および4週間後に、それぞれ、第2の空間内に収納された液体の減少率の経時変化を調べ

た。その結果を下記表6に示す。ここで、液体の減少率は、次式により算出した。

$$【0230】減少率（\%）=（W_0 - W）/ W_0 \times 100$$

ここで、 W_0 ：試験開始時の液体の総重量（10g）

W ：1、2、4週間後のそれぞれの液体の重量

【0231】

【表6】

表 6 液体の減少率

実施例	1週間後	2週間後	4週間後
1C	0.5%	1.1%	2.0%
2C	0.4%	0.9%	1.7%
3C	0.2%	0.3%	0.7%
4C	0.1%	0.1%	0.3%
5C	0.0%	0.0%	0.1%

【0232】表6に示すように、実施例1C～5Cの包装体は、いずれも、包材が水蒸気バリア性を有するため、液体の減少率が低く、従って、第2の空間内の液体の減少、濃縮を防止することができるとともに、第1の空間内への水蒸気の侵入も防止することができることが確認された。

【0233】特に、水蒸気透過度が $1\text{g}/\text{m}^2 \cdot 24\text{hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下の実施例3C～5Cの包装体は、液体の減少率が極めて少なく、このような効果がより顕著に発現する。なお、実施例5Cにおいては、第2の空間内に収納される液体が、水よりも揮発性の低いグリセリン水溶液であったため、液体の減少は、ほとんど生じなかった。

【0234】＜試験2＞実施例1C～5Cの各包装体について、前記環境下でさらに4週間放置したが、弱シール部23、24の剥離は認められず、第2の空間からの水の漏れ出しは生じなかった。

【0235】また、その後、包材の第2の空間を形成する部分を手で押圧、圧迫したところ、いずれの包装体についても、弱シール部23を容易かつ確実に剥離することができ、イージーピールシール性が確保されていることが確認された。

【0236】＜包装体の有効保存期間の検討＞本実施例の包装体において、第2の空間内に収納されている液体が蒸散により減少し、その重量が約半以下になると、加圧による弱シール部の開封（剥離）がし難くなってくる。従って、本試験条件下において、第2の空間内に収納されている液体の量が半分まで減少する時間を次式により算出した。

【0237】

$$\text{時間（年）} = (5\text{g} / \Delta W) \times (28\text{日} / 365\text{日})$$

ここで、 ΔW ：4週間後の液体の減少量

$$\Delta W = 10\text{g} \times (4\text{週間後の液体の減少率} / 100)$$

【0238】その結果、実施例1Cで1.9年、実施例2Cで2.2年、実施例3Cで5.4年、実施例4で12.7年、実施例5Cで38.0年となる。

【0239】以上の結果より、実施例1C～5Cのような水蒸気バリア性を有する包材を用いることにより、収納される液体の減少を抑制し、長期間保持することが可能であることが分かった。

【0240】

【発明の効果】以上述べたように、本発明によれば、簡便にかつ無菌的にカテーテル等の器具と液体とを接触させることができる。特に、包材内の隔離された空間同士の連通操作や、包材の開封操作を容易かつ確実に行うことができる。

【0241】また、第2の空間に収納する液体の種類、組成、量等の選択により、器具に対し種々の機能、特に、表面の潤滑性、抗凝固性（抗血栓性）等の、器具を生体に挿入または装着するに際しての有利な機能を付与することができる。

【0242】また、使用済みの器具を包材内に収納することにより、外部への臭気の放散、微生物の増殖、または器具に付着または残存した液体の漏れ出しによる汚染、感染等を防止することができ、安全性の向上にも寄与する。また、包装体の小型化にも有利である。そのため、使用済みの器具の廃棄処理、または廃棄処理までの間の運搬、保管に有利となる。

【0243】特に、患者自身がカテーテルを使って排尿する自己導尿においては、外出時の使用済みカテーテルの搬送、廃棄において、労力や精神的負担が軽減されるため、患者の快適な生活（クオリティー・オブ・ライフ）に大きく貢献する。

【図面の簡単な説明】

【図1】本発明の包装体の第1実施例を示す平面図（内部透視図）である。

【図2】本発明の包装体の第3実施例を示す平面図（内部透視図）である。

【図3】本発明の包装体の第4実施例を示す平面図（内部透視図）である。

【図4】本発明の包装体の第5実施例を示す平面図（内部透視図）である。

【図5】本発明の包装体の第6実施例を示す平面図（内部透視図）である。

【図6】本発明の包装体の第7実施例を示す平面図（内部透視図）である。

【図7】本発明の包装体の第8実施例を示す平面図（内部透視図）である。

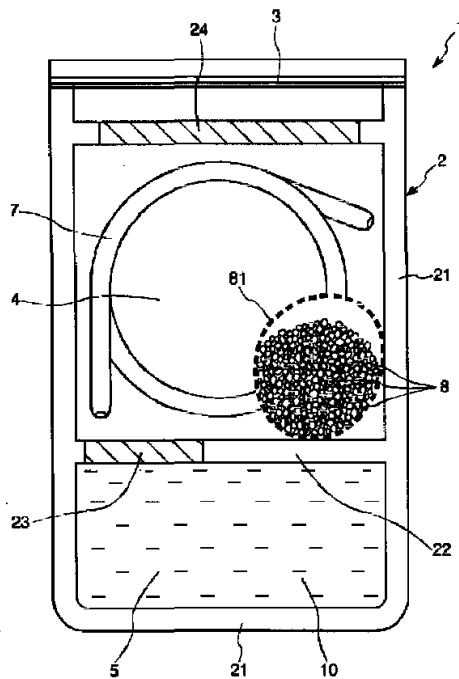
【図8】封止部材の構成例を示す縦断面図である。

【符号の説明】

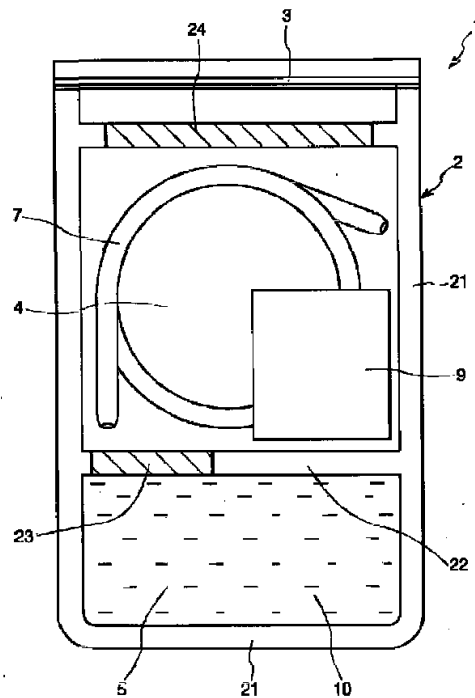
1 包装体
2 包材
21 シール部
22 仕切部
23、24 弱シール部
25 仕切部

26、27 弱シール部
28、29 仕切部
3 ジッパー
4 第1の空間
5 第2の空間
6 第3の空間
7 カテーテル
8 脱臭剤
81 容器
9 抗菌シート
10 流動性物質
11 小包材
12 吸水性材料
13 封止部材
131 短チューブ
132 筒体
133 中実柱状部
134 破断部
135 上端部
136 縮径部
14 小包材

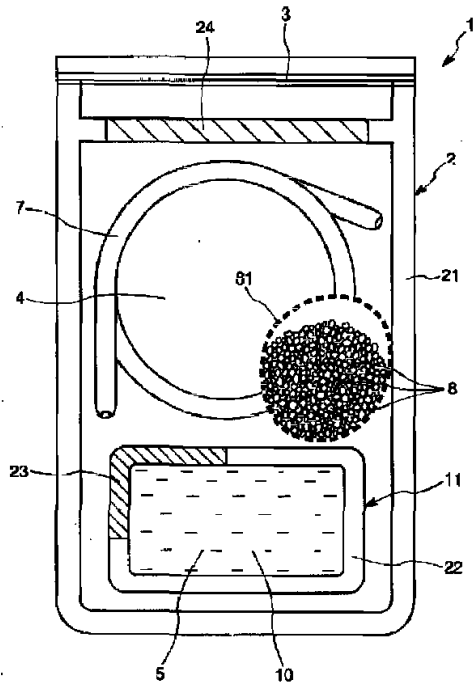
【図1】



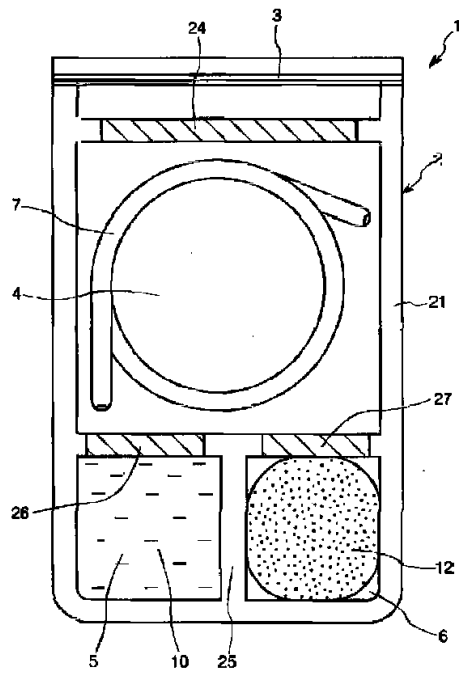
【図2】



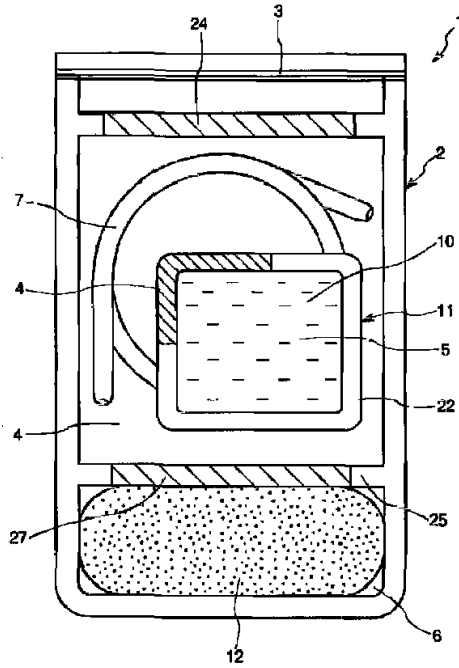
【図3】



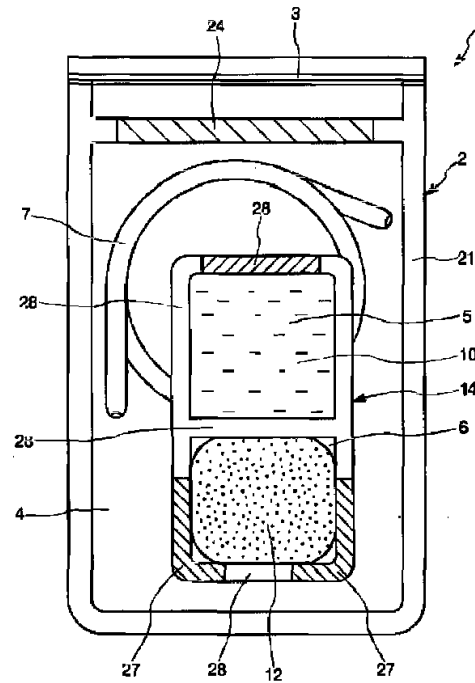
【図4】



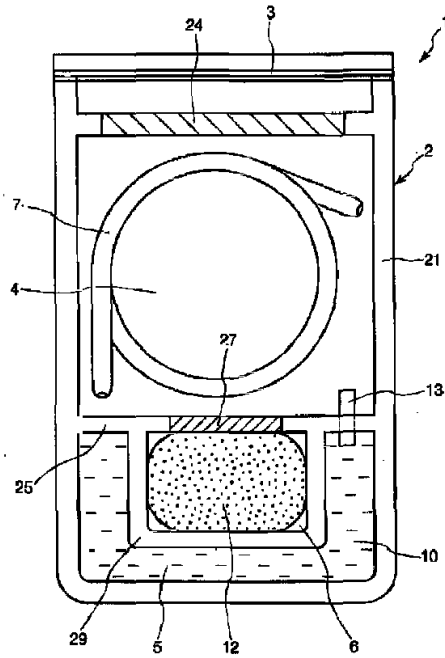
【図5】



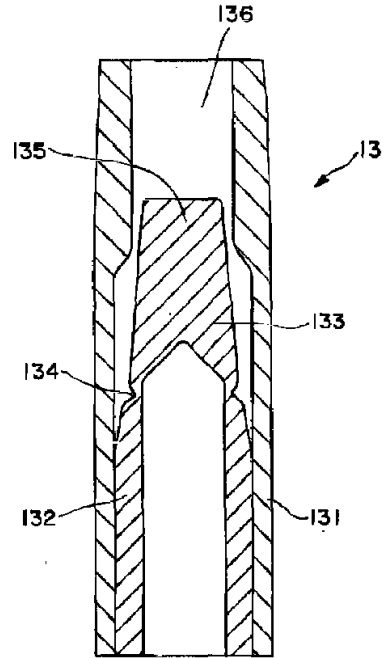
【図6】



【図7】



【図8】



フロントページの続き

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Abstract

PROBLEM TO BE SOLVED: To provide a package wherein an internal container is hardly broken accidentally. **SOLUTION:** The package 1A comprises a catheter 7 and a container 8 with a liquid 89 sealed therein, which are received in a wrapping material 2A comprising a first sheet 28 and a second sheet 29. A first recess 231 is formed in the vicinity of the center of the first sheet 28, and a wall-like protrusion 25 is formed around the recess 231. A second recess 241 is formed outside the protrusion 25. The container 8 is received in the first recess 231, while the catheter 7 is received in the second recess 241. In such a package 1A, the wrapping material 2A in a part where the container 8 is received is thicker than the material 2A in a part where the catheter 7 is received. In addition, the protrusion 25 regulates a position of the container 8 to prevent a region where the liquid 89 is sealed from overlapping with the catheter 7.

Description

DETAILED DESCRIPTION OF THE INVENTION

[0001]

BACKGROUND OF THE INVENTION 1. Field of the Invention The present invention relates to a package.

[0002]

2. Description of the Related Art As a treatment method for various dysuria including neuropathic bladder, an intermittent self-urinating method (Clea

n Intermittent Catheterization (hereinafter abbreviated as "CIC"). CIC means that a person other than medical personnel, mainly the patient himself, inserts a catheter into the bladder,

This is a therapy that drains urine accumulated in the bladder. This CIC

Thus, the risk of urinary tract infection and kidney damage caused by urine accumulated in the bladder is reduced. This CIC

Can be performed when needed by the patient himself, and can be performed on the go, so the patient's

QOL (Qualit

It is extremely effective in improving y Of Life (quality of life).

In such a CIC, the catheter needs to have lubricity on its surface in order to prevent mucosal inflammation and mucosal damage when the catheter is inserted into the bladder. At present, catheters that exhibit lubricity when the surface is wetted have been used for CIC. Because such catheters are kept dry until just before use, during a long period of time until the catheter is used, the lubricant deteriorates or deteriorates, Peeling from the surface of the catheter is suitably prevented.

[0004]

In order to enable such a catheter to be wetted smoothly and aseptically, the assignee of the present application has disclosed that a catheter and a container containing a flowable substance are provided in one packing material. (Japanese Patent Application No. 11-088544). In this package, the catheter can be moistened by breaking the container housed in the package inside the package. By using this package, lubricating properties can be imparted to the surface of the catheter aseptically in the package immediately before use of the catheter. This reduces the risk of bacterial infection and makes CIC safer.

Can be performed.

In such a package, it is necessary to prevent the container from being unintentionally ruptured when not in use. For example, during storage or transportation, it is difficult for the container in the package to burst. In particular, CIC may be performed on the go by the patient. For this reason, it is desirable that the container in the package is not ruptured even when the patient forcibly pushes the package into a bag or a bag. Accordingly, an object of the present invention is to provide a package in which an internal container is less likely to break unintentionally.

[0007]

This and other objects are achieved by the present invention described below.

(1) A package comprising an instrument used by being inserted or inserted into a living body, a container sealed with a fluid substance, and a packaging material for accommodating the instrument and the container. A package body having a position regulating means for regulating a position of the container so that part or all of the container does not overlap with the device.

(2) A package comprising a device to be inserted or inserted into a living body, a container in which a fluid substance is sealed, and a packaging material for storing the device and the container. The portion of the container in which the fluid substance is sealed,

A package body having a position regulating means for regulating the position of the container so as not to completely overlap with the device.

(3) The position restricting means is constituted by a protruding portion protruding inside the packaging material.

Or the package according to (2).

(4) The package according to (3), wherein the protruding portion has a wall shape.

(5) The package according to (3) or (4), wherein the projecting portion is formed by molding the packaging material.

(6) The package according to any one of (3) to (5), wherein the protruding portion is adjacent to or in contact with the packaging material on the side opposite to the protruding portion.

(7) A package comprising a device to be inserted or inserted into a living body, a container in which a fluid substance is sealed, and a packaging material for storing the device and the container. A package body in which a thickness of the packaging material in a portion where the container is stored is smaller than a thickness of the packaging material in a portion where the device is stored.

(8) The thickness of the packaging material in the portion where the container is stored is not more than 4/5 of the thickness of the packaging material in the portion where the device is stored. Packaging.

(9) The wrapping material is obtained by stacking a flat sheet material with a bulged sheet material capable of storing the device and the container, and sealing the edges thereof. 8) The package according to any one of the above.

(10) The package according to any one of (1) to (9), wherein the container can be opened inside the packaging material without opening the packaging material.

(11) The container is formed by sealing a sheet material with a seal portion, and the container can be opened by providing a weak seal portion having a smaller bonding strength than the seal portion. The

package according to (10) above.

(12) The package according to the above (10) or (11), further comprising a guide surface for guiding the fluid substance flowing out of the container to the device.

(13) The package according to any one of (1) to (12), further including a concave portion for storing the container, wherein the shape of the concave portion corresponds to the shape of the container.

(14) The package according to any one of (1) to (13), wherein the device is a long device, and is installed in the packaging material so as to surround the container. .

(15) The package according to any one of (1) to (14), wherein the device is a catheter.

[0023]

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS Hereinafter, the present invention will be described in detail based on preferred embodiments shown in the accompanying drawings. FIG. 1 is an exploded perspective view showing a first embodiment of the package of the present invention. FIG.

FIG. 2 is an end view taken along line II of the package shown in FIG. 1.

As shown in FIG. 1, the package 1A is

A has a configuration in which a catheter 7 and a container 8 in which a liquid 89 is sealed are housed in A. The package 1A is used, for example, for an intermittent self-urinary method. For example, before opening the package 1A, the user strongly presses the container 8 to break it, and wets the catheter 7 with the liquid 89. afterwards,

The package 1A is opened, the catheter 7 is taken out, and the catheter 7 is inserted into the patient's body (for example, the urethra). First, the packaging material 2A will be described.

The packaging material 2A includes a pair of sheet materials, a first sheet material 28 and a second sheet material 29. As shown in FIG. 1, the first sheet material 28 and the second sheet material 29 have substantially the same planar shape (plan view shape), and both have a substantially square shape.

Correspondingly, the planar shape of the packaging material 2A is also substantially square.

In the packaging material 2A, the first sheet material 28 and the second sheet material 29 are overlapped, and their edges are fused (heat fusion, high frequency fusion, ultrasonic fusion, or the like) or bonded (adhesive). Or adhesion with a solvent) to form a bag. In FIG. 1, the sealed portion is shown as hatching as a seal portion 21. As shown in FIG.

It is formed in a belt shape along the outer peripheral portion of the packaging material 2A.

As shown in FIGS. 1 and 2, the second sheet material 29 is formed (formed) into a flat shape. On the other hand, the first sheet material 28 is formed (formed) in a protruding shape (blister shape) capable of storing the catheter 7 and the container 8. In other words, the first sheet material 28

Has a bulge so that the catheter 7 and the container 8 can be stored therein. And inside this bulge (hereinafter,

The catheter 7 and the container 8 are stored in the "storage space 22".

The storage space 22 is surrounded by a first sheet material 28, a second sheet material 29, and a seal portion 21 and is isolated from the outside. Therefore, the catheter 7 and the container 8 stored in the storage space 22 are preferably kept in a sterile state until use.

At least one corner of the packaging material 2A is provided with a peel tab (opening portion) 211 formed by not sealing the sheet material. For example, the second sheet material 29 is changed to the first sheet material 28 by the peel tab 211.

By pulling in the direction away from the

Is peeled off, and the packaging material 2A can be opened.

Hereinafter, the side where the storage space 22 is open (the upper side in FIGS. 1 and 2, that is, the side where the second sheet material 29 is located) is referred to as "upper", and the side opposite to the upper side (FIG. In the lower part of FIG.

That is, the side on which the first sheet material 28 is located) is referred to as "down".

In the vicinity of the center of the first sheet material 28, a first concave portion 231 having a substantially square planar shape is formed. The packaging material 2A stores the container 8 in the first recess 231.

The first recess 231 is formed by molding the first sheet material 28. In the present embodiment, the first recess 231 forms a container storage section 23 that stores the container 8. The shape and size of the container storage portion 23, that is, the shape and size of the first concave portion 231 correspond to the shape and size of the container 8.

Around the first recess 231, the packaging material 2 A

Wall-shaped protruding portion 25 protruding into the interior (in the storage space 22)

Are formed. As shown in FIG.

Has a shape (an angular C-shape) in which one side of a square is open, and surrounds the container storage portion 23. The protrusion 25 has a function of regulating the position of the container 8 stored in the container storage 23. In particular,

The projecting portion 25 defines the position of the container 8 so that the portion (the internal space 81) in which the liquid 89 is sealed does not overlap with the catheter 8. As described above, in the package 1A, a position regulating unit that regulates the position of the container 8 by the protrusion 25 so that the portion where the liquid 89 is sealed does not overlap the catheter 8 is configured. In addition, the protrusion part 25 does not need to be made into a wall shape.

As shown in FIG. 2, the protruding portion 25 is adjacent to or in contact with the packaging material 2A on the opposite side of the protruding portion 25, that is, the second sheet material 29. Thereby, for example, the package 1

Even if the container 8 is violently shaken in the packaging material 2A by violently rocking the container A, the container 8 can be prevented from jumping out of the container storage portion 23 over the projecting portion 25 in a very suitable manner. Become. That is, when the protruding portion 25 is adjacent to or in contact with the second sheet material 29, the internal space 81 of the container 8 is less likely to overlap the catheter 7. Such an effect can be obtained more effectively when the gap between the protruding portion 25 and the second sheet material 29 (the distance between the protruding portion 25 and the second sheet material 29) is less than half the thickness of the container 8. Can be

In the packaging material 2A of the present embodiment, the protruding portion 25 is adjacent to or in contact with the second sheet material 29 over substantially the entire circumference, but the protruding portion 25 is partially adjacent to or in contact with the second sheet material 29. It only needs to be in contact. Further, the protrusion 25 may not be adjacent to or in contact with the second sheet material 29. The projecting portion 25 is provided on the first sheet material 2.

8 is formed by molding. In this manner, when the protrusion 25 is formed integrally with the first sheet material 28, the number of components of the packaging material 2A can be reduced,

The manufacturing of the packaging material 2A can be performed more easily. Note that the protrusion 25 may not be provided.

Outside the protruding portion 25, a second concave portion 241 having a rectangular shape in plan view is formed. The packaging material 2A stores the catheter 7 in the second concave portion 241. The second recess 241 is formed by molding the first sheet material 28. In the present embodiment, the second The concave portion 241 forms a catheter storage portion 24 that stores the catheter 7.

As shown in FIG. 1, a rib (engaging portion) 2 is provided along the long side of the packaging material 2A. 7 are provided. As shown in FIG.

Is formed so as to protrude from the inner wall 245 on the outer peripheral side of the second recess 241, and is located near the second sheet material 29, that is, above the catheter 7. The rib 27 is used for the first sheet material 2.

8 is formed by molding.

The rib 27 can engage (contact) the catheter 7 when the catheter 7 moves relatively upward. For this reason, for example, even when the second sheet material 29 is pulled vigorously to open the package 1 </ b> A and the catheter 7 flies upward, the catheter 7 is

7 is prevented (engaged) from jumping out of the packaging material 2A. Thus, in the package 1A, the rib 27

Thus, a pop-out preventing means for preventing the catheter 7 from popping out of the packaging material 2A when the packaging material 2A is opened is configured.

In the packaging material 2A, the bottom surface 23 of the first concave portion 231

2 is substantially parallel to the bottom surface 242 of the second recess 241. Therefore, when the package 1A is placed so that the bottom surface 242 of the second recess 241 is grounded, the bottom surface 232 of the first recess 231 is substantially horizontal.

As shown in FIG. 1, the catheter housing 24

A guide surface 26 is formed in a portion where the projecting portion 25 is not formed between the

container and the container storage portion 23. The guide surface 26 guides the liquid 89 flowing out of the container 8 to the catheter storage section 24, that is, the catheter 7. As shown in FIG. 1, the guide surface 26 has a substantially square shape, and one edge is adjacent to the container storage section 23, and the opposite edge is adjacent to the catheter storage section 24. FIG.

As shown in (2), the guide surface 26 is inclined at a predetermined angle from the bottom surface 242 of the second concave portion 241 and has a tapered shape.

As shown in FIG. 1, the guide surface 26

The protrusion 25 is located on one side of the square. In other words, when the packaging material 2 > A is viewed in a plan view, the periphery of the container housing portion 23 is completely surrounded by the guide surface 26 and the protruding portion 25.

In such a package 1A, the thickness T1 of the packaging material 2A in the portion where the container 8 is stored is smaller than the thickness T2 of the packaging material 2A in the portion where the catheter 7 is stored.

As a result, the container 8 breaks before use of the package 1A, such as during storage or transportation of the package 1A, and the liquid 89

Is suitably prevented from leaking. As will be described later, the container 8 is strongly pressed or the like to

When the internal pressure increases, the liquid 89 breaks and the liquid 89 flows out of the container 8. In the package 1A of the present invention, since the thickness T1 is smaller than the thickness T2, an object hits the first sheet material 29 or the second sheet material 28 and a force is applied in a direction in which the package 2A is compressed. However, such a force is mainly applied to the catheter storage section 24 and not much to the container storage section 23. Therefore, even when a large number of packages 1A are pushed into a box or the like for storage or transportation, the pressing force against the packages 1A is mainly applied to the catheter storage section 24 in each package 1A. For this reason, the pressing force applied to the container 8 is reduced, and the internal pressure of the internal space 89 of the container 8 is prevented from being extremely increased.

Thereby, careless breakage of the container 8 is prevented.

In particular, in the package 1A, the thickness T1 is preferably set to 4/5 or less of the thickness T2, more preferably 2/3.

By setting the following, such an effect can be obtained more effectively.

In the package 1A of the present invention, the container 8 is also prevented from being inadvertently broken by the position restricting means (projection 25) described above. As described above, the catheter housing portion 24 is a portion where a pressing force from the outside is easily applied. For this reason, when the catheter housing portion 24 is deformed or the like, there is a possibility that an external pressing force is applied to the catheter 7 as well. In this case, if the internal space 81 of the container 8 overlaps the catheter 7, a pressing force from the outside to the package 1 > A is applied to the portion of the container 8 where the liquid 89 is sealed via the catheter 7. there is a possibility.

In the package 1A of the present invention, such a situation is prevented by the position regulating means.

Package 1 of the present invention

In A, the position regulating means is such that the internal space 81 is the catheter 7

Therefore, the catheter 7 is prevented from pressing the portion of the container 8 where the liquid 89 is sealed. In the package 1A of the present invention, this also prevents the internal pressure of the internal space 81 from increasing, thereby preventing the container 8 from breaking. Therefore, for example, even when the edge of the package 1A is locally strongly pressed in a bag, a bag, or the like, the container 8 is preferably prevented from breaking.

Further, in the package 1A of the present embodiment,

The fact that the protruding portion 25 is adjacent to or in contact with the second sheet material 29 also contributes to the container 8 being hardly pressed. In the package 1A, when the vicinity of the center portion, that is, the container housing portion 23 is pressed, the protruding portion 25 can withstand this pressing force to some extent. Therefore, the pressing force applied to the container 8 is reduced. In particular, the package 1 of the present embodiment

When the protruding portion 25 has a wall shape as in A, such an effect can be obtained more effectively.

Furthermore, like the package 1A of the present embodiment, the first recess 231

When the shape and the size correspond to the shape and the size of the container 8, the protruding portion 25 comes to be located near the container 8.

This point also contributes to the improvement of such an effect. Further, such an effect can be more effectively obtained when the projecting portion 25 is formed so as to surround the container storage portion 23.

From the viewpoint of suitably obtaining such effects,

It is desirable that the packaging material 2A, particularly the first sheet material 28, have shape retention properties. Thereby, the above-described effects are more effectively obtained, and the container 8 is less likely to be unintentionally broken.

Further, it is preferable that the packaging material 2A, particularly the first sheet material 28, has a certain degree of flexibility. Thereby, at the time of use, the container 8 can be suitably broken. The packaging material 2A preferably includes ethylene oxide,

A material having gas permeability and heat resistance that can cope with sterilization of an autoclave, radiation, electron beam, or the like, or a material that can maintain sterility after sterilization is used. In addition, packaging material 2A

In order to prevent deterioration of the catheter, a material having a UV shielding effect can be used. In order to ensure the visibility of the contents, the first sheet material 28 and the second sheet material 2

It is preferable that at least one of 9 is transparent.

From such a viewpoint, the first sheet material 2

8. For the second sheet material 29, for example, polyolefin resins such as polyethylene and polypropylene, blend resins of these polyolefin resins, polyester resins such as polyethylene terephthalate, polystyrene, polyvinylidene chloride, vinyl chloride-vinylidene chloride copolymer, etc. A single-layer film, a film obtained by depositing aluminum, silica, or the like on these films, a metal foil such as an aluminum film or an aluminum laminate film, or a film containing a metal foil is preferably used. Further, a film obtained by laminating two or more of these films can also be used.

Further, a plastic nonwoven fabric or paper may be used as the sheet material. Needless to say, the first sheet material 28 and the second sheet material 29 may be made of other materials.

The thickness of the first sheet material 28 and the second sheet material 29 (single-layer or multi-layer laminate) depends on the layer structure and the characteristics of the material used (flexibility, strength, water vapor permeability, heat resistance, etc.). Is appropriately determined in accordance with, and is not particularly limited, but usually,

It is preferably about 60 to 700 μm , and 100 to 5 μm .

More preferably, it is about 00 μm . The thicknesses of the first sheet material 28 and the second sheet material 29 may be different or may be substantially the same.

The first sheet material 28 and the second sheet material 29 are formed by, for example, an inflation method, a T-die method, a blow molding method, a dry lamination method, a hot melt lamination method, a co-extrusion inflation method, a co-extrusion T-die. Law,

It can be manufactured by various methods such as a hot press method.

Hereinafter, the catheter 7 and the container 8 housed in the packaging material 2A will be described.

The catheter 7 housed in the packaging material 2A

It is a long instrument that is used by being inserted or attached to a living body. The catheter 7 is a strong device (especially more than the container 8) that is not easily broken by an external pressing force.

Therefore, even when a certain amount of external force is applied to the catheter 7, the catheter 7 can withstand this external force.

As shown in FIG. 1, the catheter 7 is bent (curved) in an annular shape so as to surround the container 8, and is housed in the catheter housing 24. As described above, if the catheter 7 is curved in an annular shape and accommodated in the packaging material 2A, the length of the packaging material 2A can be shortened. For this reason, the package 1A becomes compact, and storage in a bag or bag becomes convenient. When the catheter 7 is installed so as to surround the container 8, for example, the package 1A Even when force is applied from various directions, the container 8 is suitably guarded by the catheter 7, so that the container 8 is not subjected to much force.

The catheter 7 has an insertion portion 71 to be inserted into a living body. The insertion portion 71 is

preferably formed of a flexible tube. The insertion portion 71 is required to smoothly insert into the living body, and for that purpose, a substance that expresses lubricity by wetting is applied to the whole or a part of the surface of the insertion portion 71. Is preferred.

Examples of such a substance include hydrophilic polymers as described in JP-A-60-259269 and JP-A-1-95863.

Also, for example, Japanese Patent Publication No. 6-32652,

No. 426, International Application WO8802623, International Application WO

8907521, International Application WO8909246, International Application WO900144, International

Application WO9219289,

International application WO9311751, international application WO95297

22, Tokiohei 10-502854, Tokiohei 10-50

The materials and methods disclosed in Japanese Patent No. 2855 and Japanese Translation of PCT International Publication No. 10-502856 may be used. Such a substance usually exists on the surface of the insertion section 71 in a non-wetting state (dry state).

Such a substance is a polymer chemically bonded to the surface of the base material of the insertion portion 71, and is not peeled off from the surface of the base material or eluted into water, a physiological isotonic solution, other lubricants, or the like. Those which are unlikely to occur are preferred from the viewpoints of lubricity continuity and safety. For this reason, prior to use of the catheter 7, the liquid 89 ejected from the container 8 is brought into contact with the insertion portion 71, and the lubricity is developed by wetting.

The type, use, and the like of the catheter 7 stored in the packaging material 2A are not particularly limited, and include, for example, trachea, digestive tract, urethra, vagina, blood vessels, lymph vessels, bile ducts, and other body cavities. Examples include various catheters and balloon catheters inserted into various organs such as lungs, heart, and kidney, and other living tissues. Among these, a catheter (urethral catheter, urinary catheter) used by inserting into the urethra is particularly preferable.

The urinary drainage method for urinary disturbance is preferably an aseptic intermittent urinary drainage method instead of an indwelling catheter. In recent years, self-urinary drainage, in which patients themselves discharge urine using a catheter, has become widespread as an effective treatment method. . Dysuria is caused by obstruction of the urethra due to benign prostatic hyperplasia, stones, and tumors, and neuropathic bladder caused by disorders of the brain, spinal cord, and pelvic nerves. It is necessary to drain urine regularly because the internal pressure increases and places a burden on the kidneys. The self-guided urinary method performed at this time has the advantages of completely excreting urine at low pressure, reducing existing urinary infections, relieving urinary frequency, urinary incontinence, and not burdening the bladder and kidneys. The patient inserts a catheter into the bladder through the urethra about 4 to 6 times a day, and removes the urine when the urine has been discharged. The frequency is, for example, 4 Every 5 hours, the night is before bedtime.

The container 8 has an internal space 81 inside, and a liquid 89 is sealed and stored in the internal space 81.

In the present embodiment, the container 8 is in contact with or adjacent to the second sheet material 29 as well as the first sheet material 28.

The container 8 is formed, for example, by folding a central portion of a flat sheet material (inflation sheet material) and sealing the three sides by fusing (or bonding) to form a bag. An internal space 81 is formed inside the bag, and a liquid 89 is stored (filled) therein. Hereinafter, the portion of the container 8 where the sheet material is sealed is referred to as a seal portion 82. The container 8 is not limited to the one formed as shown in the figure. For example, both ends of a sheet material formed into a cylindrical shape are fused (or bonded) to form a bag, or two containers are formed. Sheets are laminated and the entire periphery is fused (or bonded).

Alternatively, it may be a bag.

As shown in FIG. 1 with a lattice, a part of the seal part 82 is a weak seal part (easy peel seal part) 83 having a lower joining strength (peeling strength) than the other part (seal part 821). It is configured. The sealing portion 821 is in a state where the opposing sheet materials are completely fused and firmly joined, while the weak sealing portion 83 is fused at a lower temperature and the like. The state is such that the clothes are somewhat incomplete. However, the liquid tightness (airtightness) is ensured also in the weak seal portion 83. And the effect lasts over time.

Therefore, for example, when the portion of the container 8 in which the liquid 89 is stored is pressed (pressed) to increase the internal pressure of the internal space 81, the weak seal portion 83 is peeled off (ruptured) preferentially. Thus, the internal space 81 communicates with the outside of the container 8, and the liquid 89 flows out of the container 8. As described above, in the container 8, the weak seal portion 83 forms an opening for opening the container 8.

In the package 1A of the present embodiment, the container 8 is

It can be pressed over the first sheet material 28 and the second sheet material 29. In particular, like the package 1A of the present embodiment, the container 8

Is more adjacent or in contact with the first sheet material 28 and the second sheet material 29, such an operation is further facilitated. Therefore, in the package 1A, the container 8 can be opened by an extremely simple operation in a state where the package 1A is not opened. In the present embodiment, the bottom surface 232 of the first recess 23 is formed.

Is substantially parallel to the second sheet material 29, which also contributes to easier pressing of the container 8. In addition, the method of peeling the weak seal portion 83 is not limited to the above-described method. For example, the weak seal portion 83 may be manually rubbed over a sheet material. The opening may be configured so that, for example, the seal width of the seal portion 82 is locally narrower than the seal width of other portions.

The thickness of such a container 8 depends on the catheter 7

Is preferably smaller than the thickness (outer diameter). Thereby, even if a strong force is applied to the package 1A and the first sheet material 28 is compressed and deformed, the force applied to the package 1A is mainly applied to the catheter 7. Therefore, the force applied to the container 8 is more suitably reduced, and the damage to the container 8 is more suitably prevented.

It is preferable that the container 8 has a vapor barrier property of the fluid substance stored in the internal space 81.

For example, when the fluid substance is water, the vapor barrier property means that the water vapor permeability is preferably $30 \text{ g} / \text{m} \cdot \text{sup.2} \cdot 24\text{hrs}$.

$25\mu\text{m}$ thickness 40°C 90% RH or less,

More preferably $10 \text{ g} / \text{m} \cdot \text{sup.2} \cdot 24 \text{ hrs}$. Math. $25 \mu\text{m}$ thickness. Math. 40°C . Math. 90% RH or less, still more preferably $1 \text{ g} / \text{m}$

It refers to $\text{sup.2} \cdot 24\text{hrs}$. Math. $\text{sup.25}\mu\text{m}$ or less thick. Math. 40°C . Math. 90% RH. This water vapor permeability is measured according to JIS K7

129 (method A). Container 8

By having a water vapor barrier property, evaporation of water from the inside of the container 8 can be prevented. As a result, the internal space 8

The reduction and concentration of the liquid 89 in the container 1 can be prevented, and the amount of the liquid 89 can be reduced to a minimum necessary amount, so that the volume and weight of the entire package 1A can be reduced.

Sheet material (film) constituting the container 8;

In particular, examples of the sheet material having the steam barrier property include the following. [1] a single-layer film composed of one kind of polyolefin resin, [2] a single-layer film composed of a blend resin of two or more incompatible polyolefin resins,

[3] A multilayer film of a polyolefin resin or a polyester resin using a polyolefin resin (a blended resin of a polyolefin resin can be used) for the sealant layer (a layer involved in fusion), [4] a sealant layer of the polyolefin resin (polyolefin resin). A film composed of a blended resin, a multi-layer film composed of a polyvinylidene chloride-coated polyolefin or polyester film, etc., [5] a sealant layer of a polyolefin resin (a blended resin of polyolefin resin can also be used) [6] The sealant layer is made of a polyolefin resin (polyolefin resin). Film composed of a blend resin can be used) of the fat, the intermediate layer is aluminum film,

A multilayer film composed of a polyester film or the like as the outermost layer, [7] a polyolefin resin as the sealant layer (a blended resin of the polyolefin resin can also be used), a nylon film as the intermediate layer, a polyolefin having the outermost layer deposited with aluminum or silica, or A multilayer film composed of a polyester film or the like. In this case, if one of a pair of sheet materials facing each other is

an opaque aluminum film and the other is a transparent water vapor barrier film such as a silica vapor-deposited film, the content of the container 8 is This is more preferable because it can be confirmed by visual recognition of an object. The aluminum film may be partly or wholly removable if necessary.

In the weak seal portion 83, a layer (sealant layer) directly involved in fusion is made of a blend resin of two or more incompatible polyolefin resins or a segment of two or more incompatible polyolefin resins. It is preferable to be composed of a random or block copolymer having the above.

The thickness of the sheet material (single-layer or multi-layer laminate) constituting the container 8 is appropriately determined according to the layer structure and the characteristics (flexibility, strength, water vapor permeability, heat resistance, etc.) of the material used. Although it is determined and not particularly limited, it is usually preferably about 20 to 700 μm ,

More preferably, it is about 500 μm .

The sheet material constituting such a container 8 is as follows.

For example, inflation method, T-die method, blow molding method, dry lamination method, hot melt lamination method,

It can be manufactured by various methods such as a coextrusion inflation method, a coextrusion T-die method, and a hot press method.

The container 8 having the above-described characteristics is

For example, it can be suitably manufactured by referring to Japanese Patent Application No. Hei 11-088544.

The package 1A provided with such a container 8 is

It has the following effects (advantages). First, by selecting the capacity of the container 8 to be put in the packaging material 2A, the amount and weight of the contents (such as the liquid 89) of the container 8 can be easily set. Secondly, since the container 8 can be manufactured independently from the packaging material 2A, manufacturing and management are easy.

The liquid 89 stored in such a container 8

Is preferably a substance (liquid or semi-liquid) that can come into contact with the surface of the insertion section 71 of the catheter 7 and reduce its frictional resistance.

Examples of the liquid 89 include, but are not particularly limited to, water, physiologically isotonic liquids (physiological saline), oils such as glycerin, silicone oil and olive oil, and xylocaine jelly.

Hereinafter, an example of the method of use (action) of the package 1A will be described. As described above, in the package 1A of the present invention, the container 8 is hardly damaged during storage. After storage, when the medical device in the package 1A is used, the following operation is performed.

First, the container 8 is pressed and pressed from outside the packaging material 2A with a finger or the like. Thereby, the weak seal portion 83 is peeled (ruptured), and the liquid 89 flows out from the peeled portion. The liquid 89 flowing out of the container 8 travels on the guide surface 26 and flows into the catheter housing 24.

Then, the liquid 89 flowing into the catheter storage section 24

Spreads on the bottom surface 242 of the second recess 241. Thereby, the insertion portion 71 of the catheter 7 is wet (wet), and the surface of the insertion portion 71 exhibits lubricity. That is, the insertion portion 7

The frictional resistance of one surface is reduced. At this time, if necessary, an operation of alternately raising and lowering both ends (an end forming a short side or an end forming a long side) of the package 1A may be performed. As a result, the liquid 89 spreads more suitably in the catheter housing portion 24, and the insertion portion 71 becomes more evenly and more uniformly wet. After the container 8 is opened, if necessary, an operation of pressing (pressing) the container 8 with a finger or the like from the outside of the package 1A to discharge all the liquid 89 in the container 8 is performed. Good.

When the shape and size of the container storage section 23 substantially correspond to the shape and size of the container 8 as in the package 1A of the present embodiment, the inside of the container storage section 23 (the first recess 231). The amount of the liquid 89 remaining on the bottom surface 232) and not flowing into the catheter housing portion 24 is reduced. Therefore, the insertion portion 71 of the catheter 7 can be more efficiently wetted with a relatively small amount of the liquid 89.

As described above, when lubricity develops on the surface of the insertion portion 71 of the catheter 7, the

peel tab 211 is pulled, and the packaging material 2A is opened. Then, the catheter 7 is taken out of the packaging material 2A.

The catheter 7 removed from the packaging material 2A

Is inserted or attached to a target site of a living body. When the catheter 7 is a urethral catheter (urinary catheter), the insertion section 71 is inserted into the urethra and the bladder from the distal end side. At this time, since the surface of the insertion portion 71 has lubricity, the operation of inserting the catheter 7 can be performed smoothly and safely. Thereafter, the patient performs urination via the catheter 7.

As described above, if the package 1A is used, the operation of developing the lubricity on the surface of the insertion portion 71 of the catheter 7 can be performed in the sealed packaging material 2A without contact with the outside air. Therefore, in the package 1A of the present invention, the sterility of the catheter 7 is favorably maintained until immediately before use.

Hereinafter, a second embodiment of the package of the present invention will be described. In the following description, description of items common to the package of the first embodiment will be omitted, and different items will be mainly described. FIG. 3 is an end view showing a second embodiment of the package of the present invention. The upper and lower concepts of this embodiment are the same as those of the first embodiment.

As shown in the figure, in the package 1B, the first

The bottom surface 232 ' of the concave portion 231 is

It is inclined at a predetermined angle with respect to 42 and has a tapered shape.

Specifically, the bottom surface 232 ' is separated from the second sheet material 29 so as to be lowered in the direction of the guide surface 26 (the second concave portion 241).

(To get closer to the bottom surface 242). Correspondingly, the container 8 is moved away from the second sheet material 29 so that the weak seal portion 83 is lowered.

(Close to the bottom surface 242 of the container). Further, the guide surface 26 ' is

Is almost perpendicular to the bottom surface 242 of the second.

When the packaging material 2A has such a structure, the liquid 89 can be formed without much operation such as tilting the package 1B.

Flows smoothly into the catheter storage section 24.

When the thickness T1 of the packaging material 2B at the portion where the container 8 is stored is not uniform as in the present embodiment, for example, the thickness near the center of the portion at which the container 8 is stored is reduced by the thickness It can be used as an index of the length T1.

Hereinafter, a third embodiment of the package of the present invention will be described. In the following description, description of items common to the package of the first embodiment will be omitted, and different items will be mainly described. FIG. 4 is an end view showing a third embodiment of the package of the present invention. The upper and lower concepts of this embodiment are the same as those of the first embodiment.

[0086] As shown in FIG.

The inner wall 245 on the outer peripheral side of the concave portion 241 has a tapered shape. More specifically, the inner wall 245 is inclined at a predetermined angle with respect to the normal line of the bottom surface 242 of the second recess 241, and the upper portion (the portion opposite to the bottom surface 242) protrudes toward the inside of the storage space 22. (Protruding).

The protruding portion (hereinafter referred to as protruding portion 27 ') of the upper portion of the inner wall 245 is formed along the long side of the packaging material 2C. This protruding portion (engaging portion) 27 ' is located above the catheter 7. The protruding portion (projection) 27 ' can engage (contact) with the catheter 7 when the catheter 7 relatively moves upward.

Further, in the package 1C of the present embodiment, when the catheter 7 is flipped upward, the catheter 7 The contact with the inner wall 245 on the outer peripheral side of the concave portion 241 is restricted from moving upward.

For this reason, in the package 1C of the present embodiment,

At the time of opening the packaging material 2C, it is possible to extremely suitably prevent the catheter 7 from jumping out of the packaging material 2C. In this embodiment, the pop-out prevention means includes a tapered inner wall 245.

And a protruding portion 27 '.

Hereinafter, a fourth embodiment of the package of the present invention will be described. In the following description, description of items common to the package of the first embodiment will be omitted, and different items will be mainly described. FIG. 5 is an exploded perspective view showing the first embodiment of the package of the present invention. FIG. 6 is an end view taken along line II-II of the package shown in FIG.

As shown in the figure, in the package 1D, the first

The concave portion 231 ' and the container storage portion 23 ' are located close to one long side.

Further, as shown in FIG. 5, the planar shape of the protruding portion 25 'has a U-shape forming three sides of a square, and surrounds the container housing portion 23'. And the protruding part 25 'is open toward the long side.

In the package 1D of the present embodiment, since the container housing portion 23 'is installed close to the inner wall 245 on the outer peripheral side of the second concave portion 241', as shown in FIG.

The unsealed portion (weak seal portion 83) is in contact with or adjacent to the inner wall 245. Therefore, the liquid 8 flowing out of the container 8

9 comes into contact with the inner wall 245 and travels along the inner wall 245,

It will be guided to the catheter storage part 24 '. As described above, in the package 1D of the present embodiment, the inner wall 245 on the outer peripheral side of the second concave portion 241 ' facing the unsealing portion of the container 8 causes

A guide surface 26 " for guiding the liquid 89 to the catheter 7 is formed.

As described above, the container storage portion 23 'is located at a position slightly shifted from the center of the packaging material 2D to one long side. For this reason, on the side where the container storage portion 23 ' approaches the inner wall 245 on the outer peripheral side of the second concave portion 241 ', the second

The area of the bottom surface (hereinafter, referred to as the bottom surface 242a) of the concave portion 241 'is small. On the other hand, the container storage section 23 '

Is on the side away from the inner wall 245,

42b).

In the package 1D of the present embodiment, the absorber 9 capable of absorbing and holding the liquid 89 and the like is provided on the bottom surface 242b, that is, in the catheter housing portion 24 'on the bottom surface 242b side. You. By putting the absorber 9 in the packaging material 2D, it becomes possible for the absorber 9 to absorb the excess liquid 89 after wetting the catheter 7.

The absorber 9 is not particularly limited, but

For example, polyacrylates, polyvinyl alcohols, polyacrylamides, synthetic polymers such as polyoxyethylene or maleic acid materials, and starch, cellulose, natural materials such as polysaccharide materials such as alginic acid, etc. Those composed of a polymer absorbing material are preferred. In addition, for example, sponge, cotton, gauze, non-woven fabric, and those in which the above-mentioned polymer water-absorbing material is carried (for example, those used in diapers, sanitary products, etc.)

Is also possible. Such an absorber 9 can take a form (shape) such as a block shape, a powder shape, a film shape, a sheet shape (plate shape), and a fibrous shape. 5 and 6, a block-shaped absorber 9 is shown as an example.

As described above, in the packaging material 2D of the present embodiment,

It is easy to secure a space for installing members other than the catheter 7 and the container 8 inside, and it is easy to install a new member such as the absorber 9 in such a space.

The new member such as the absorber 9 other than the catheter 7 and the container 8 is not particularly limited. In addition to the absorber 9, for example, a sheet capable of disinfecting the vicinity of the urethral opening before and after insertion of the catheter. And a deodorant that suppresses the odor generated before the used catheter is discarded, and an antibacterial agent that suppresses the growth of microorganisms such as bacteria and viruses.

Although the present invention has been described based on the preferred embodiments shown in the drawings, the present invention is not limited to these embodiments.

In the present invention, examples of the long catheter 7 used by being inserted or attached to a living body include the following. -Oral or nasal insertion of gastric tube catheter, feeding catheter, tube for tube feeding, oxygen catheter, oxygen cannula, tube or cuff for endotracheal tube, tube or cuff for tracheostomy tube, endotracheal suction catheter, etc. Indwelling catheters. Suction catheter, drainage catheter, peritoneal catheter,

Catheters to be inserted and placed in various body cavities, organs and tissues such as rectal catheters and trocars. Catheters to be inserted and placed in blood vessels such as angiography catheters, PTCA balloon catheters, IABP balloon catheters, indwelling catheters, and arterial infusion catheters.

Further, examples of long instruments used by being inserted or inserted into a living body include the following in addition to a catheter. -Various guide wires used alone or with each of the catheters. -Artificial blood vessels and stents. Injection needle, indwelling needle, catheter introducer. Endoscope, ultrasonic crushing probe. • sutures or ligatures.

Further, the instrument used by being inserted or inserted into the living body does not need to be long. Examples of the instrument used by being inserted or inserted into the living body accommodated in the package include the following, in addition to those described above. Cardiac output measuring instrument, ultrasonic measuring / diagnostic instrument, pacemaker, thermometer. -Artificial anus, artificial bone, artificial joint, prosthesis, artificial eye. .Math.sheath. .Math.enema. Contraceptive devices such as condoms. In the embodiment described above, the liquid 89 is described as the fluid substance contained in the container 8.

May contain a substance having fluidity other than the liquid 89, for example, a gel-like or jelly-like substance, powder, granules, or the like. Note that the package may contain any other items than those described above.

[0103]

As described above, according to the present invention, it is possible to provide a package in which the internal container is less likely to break unintentionally. Therefore, for example, when the present invention is applied to the intermittent self-guiding method, the patient can carry the package of the present invention with ease, and even when away from home, easily and reliably perform self-guiding. be able to. Therefore, the present invention can greatly contribute to improving the quality of life of patients.

[Brief description of the drawings]

FIG. 1 is an exploded perspective view showing a first embodiment of a package of the present invention.

FIG. 2 is an end view taken along line II of the package shown in FIG. 1;

FIG. 3 is a vertical end view showing a second embodiment of the package of the present invention.

FIG. 4 is a vertical end view showing a third embodiment of the package of the present invention.

FIG. 5 is an exploded perspective view showing a fourth embodiment of the package of the present invention.

FIG. 6 is an end view taken along line II-II of the package shown in FIG. 5;

[Explanation of symbols]

1A, 1B, 1C, 1D Package 2A, 2B, 2C, 2D Packaging material 21 Seal part 211 Peel tab 22 Storage space 23, 23 'Container storage part 231, 231' First concave part 232, 232 'Bottom surface 24, 24' Catheter Storage portions 241, 241 'Second concave portion 242, 242a, 242b Bottom surface 245 Outer inner wall 25, 25' Projection portion 26, 26 ', 26 "Guide surface 27 Rib 27' Projecting portion 28 First sheet material 29 Second sheet Material 7 Catheter 71 Insertion part 8 Container 81 Inner space 82 Seal part 821 Seal part other than weak seal part 83 Weak seal part 89 Liquid 9 Absorber T1 Thickness of packaging material in which container was stored T2 Catheter was stored Part packaging material thickness

Continuing from the front page (72) Inventor Kenichi Shimura 1500 Inoguchi, Nakai-machi, Ashigara-gun, Kanagawa Prefecture Terumo Corporation F-term (reference) 3E067 AA11 AB83 AC06 BA02A BB14A BC07A CA24 EE44 GD08

Claims

- Claims 1. A package comprising an instrument used by being inserted or inserted into a living body, a container in which a fluid substance is sealed, and a packaging material for accommodating the instrument and the container, A package, wherein a part or the whole of the container has a position regulating means for regulating a position of the container so as not to overlap the device.
2. A package comprising: an instrument used by being inserted or inserted into a living body; a container in which a fluid substance is sealed; and a packaging material for accommodating the instrument and the container. A package body having a position regulating means for regulating a position of the container so that a portion of the container in which the fluid substance is sealed does not completely overlap the device.
3. The positioning device according to claim 1, wherein the position restricting means comprises a projecting portion projecting into the packaging material.
- A package according to item 1.
4. The package according to claim 3, wherein the protrusion has a wall shape.
5. The package according to claim 3, wherein the projecting portion is formed by molding the packaging material.
6. The package according to claim 3, wherein the protruding portion is adjacent to or in contact with the packaging material on the side opposite to the protruding portion.
7. A package comprising: a device used by being inserted or inserted into a living body; a container in which a fluid substance is sealed; and a packaging material for storing the device and the container, A package, wherein a thickness of the packaging material in a portion where the container is stored is smaller than a thickness of the packaging material in a portion where the device is stored.
8. The package according to claim 7, wherein the thickness of the packaging material in the portion where the container is stored is $\frac{4}{5}$ or less of the thickness of the packaging material in the portion where the device is stored. .
9. The packaging material according to claim 1, wherein a flat sheet material is overlapped with a bulged sheet material capable of storing the device and the container, and their edges are sealed.
9. The package according to any one of items 1 to 8.
10. The package according to claim 1, wherein the container can be opened in the packaging material without opening the packaging material.
11. The container is formed by sealing a sheet material with a seal portion. By providing the container with a weak seal portion having a smaller bonding strength than the seal portion, the container can be opened. The package according to claim 10, wherein the package comprises:
12. The package according to claim 10, further comprising a guide surface for guiding the flowable substance flowing out of the container to the device.
13. The package according to claim 1, further comprising a recess for accommodating the container, wherein the shape of the recess corresponds to the shape of the container.
14. The package according to claim 1, wherein the device is a long device, and is installed in the packaging material so as to surround the container.
15. The package according to claim 1, wherein the device is a catheter.

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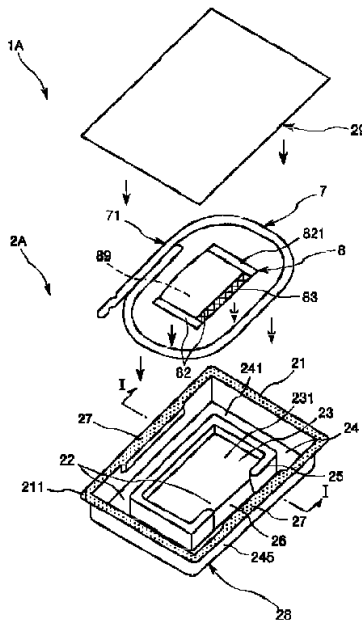
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(54) 【発明の名称】 包装体

(57) 【要約】

【課題】内部の容器が不本意に破断しにくい包装体を提供すること。

【解決手段】包装体1Aは、第1シート材28と第2シート材29とで構成された包材2A内に、カテーテル7と、液体89を密封した容器8とが収納された構成となっている。第1シート材28の中央部付近には、第1凹部231が形成され、この第1凹部231の周囲には、壁状の突出部25が形成されている。突出部25の外側には、第2凹部241が形成されている。第1凹部231には、容器8が収納され、第2凹部241には、カテーテル7が収納される。このような包装体1Aでは、容器8が収納された部分の包材2Aの厚さは、カテーテル7が収納された部分の包材2Aの厚さよりも薄くなっている。また、突出部25は、液体89が密封された部位がカテーテル7と重ならないように、容器8の位置を規定している。



【特許請求の範囲】

【請求項1】 生体に挿入または挿着して使用される器具と、

流動性の物質が密封された容器と、
前記器具と前記容器とを収納する包材とを有する包装体であって、
前記容器の一部または全部が、前記器具に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【請求項2】 生体に挿入または挿着して使用される器具と、
流動性の物質が密封された容器と、
前記器具と前記容器とを収納する包材とを有する包装体であって、
前記容器の前記流動性の物質が密封された部位が、前記器具に完全に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【請求項3】 前記位置規制手段は、前記包材の内部に突出した突出部により構成されている請求項1または2に記載の包装体。

【請求項4】 前記突出部は、壁状をなしている請求項3に記載の包装体。

【請求項5】 前記突出部は、前記包材を成型して形成されたものである請求項3または4に記載の包装体。

【請求項6】 前記突出部は、前記突出部と反対側の包材に隣接または接触している請求項3ないし5のいずれかに記載の包装体。

【請求項7】 生体に挿入または挿着して使用される器具と、
流動性の物質が密封された容器と、
前記器具と前記容器とを収納する包材とを有する包装体であって、
前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さよりも薄いことを特徴とする包装体。

【請求項8】 前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さの4/5以下である請求項7に記載の包装体。

【請求項9】 前記包材は、前記器具および前記容器を収納可能な膨らみを有するシート材と平坦なシート材とを重ね、これらの縁部をシールしたものである請求項1ないし8のいずれかに記載の包装体。

【請求項10】 前記容器は、前記包材を開封しないで前記包材内で開封可能である請求項1ないし9のいずれかに記載の包装体。

【請求項11】 前記容器は、シート材をシール部によりシールしてなるものであり、
前記容器に前記シール部よりも接合強度が小さい弱シール部を設けたことにより、前記容器を開封可能とした請求項10に記載の包装体。

【請求項12】 前記容器から流出した前記流動性の物質を前記器具に案内するガイド面を有する請求項10または11に記載の包装体。

【請求項13】 前記容器を収納する凹部を有し、この凹部の形状は、前記容器の形状に対応している請求項1ないし12のいずれかに記載の包装体。

【請求項14】 前記器具は、長尺の器具であり、前記容器の周りを囲むように、前記包材内に設置される請求項1ないし13のいずれかに記載の包装体。

【請求項15】 前記器具は、カテーテルである請求項1ないし14のいずれかに記載の包装体。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、包装体に関するものである。

【0002】

【従来の技術】神経因性膀胱をはじめとして様々な排尿障害に対する治療方法として、間歇式自己導尿法（Clean Intermittent Catheterization；以下「CIC」と略す）が、普及してきている。CICとは、医療関係者以外の、主に患者自身がカテーテルを膀胱内に挿入し、膀胱内に溜まった尿を排出する療法である。このCICにより、膀胱内に溜まった尿によって引き起こされる尿路感染や腎臓障害の危険性が、低減される。このCICは、患者自身が必要な時に行うことができ、しかも、外出先でも行うことができるため、患者のQOL（Quality Of Life＝生活の質）を向上する上で、極めて有効である。

【0003】このようなCICでは、カテーテルを膀胱内へ挿入する際に粘膜炎症や粘膜損傷が起きるのを防止するため、カテーテルは、表面に潤滑性を有することが必要とされる。現在、CICには、表面を湿潤させると潤滑性が発現するようなカテーテルが用いられるようになってきている。このようなカテーテルは、使用直前まで乾燥状態が保たれるため、カテーテルが使用されるまでの長期間の間に、潤滑剤が変質したり、劣化したり、カテーテルの表面から剥離したりすることが好適に防止される。

【0004】

【発明が解決しようとする課題】このようなカテーテルの湿潤を円滑かつ無菌的に行えるようにするため、本願特許出願人は、カテーテルと流動性の物質を入れた容器とを1個の包材内に収納した包装体を提案した（特願平11-084854）。この包装体では、包装体内に収納した容器を包装体内で破断させることにより、カテーテルを湿潤させることができる。この包装体を用いれば、カテーテルの使用直前に、包装体内で無菌的に、カテーテルの表面に潤滑性を付与することができる。これにより、細菌感染の危険性が低減し、より安全にCICを行える。

【0005】このような包装体では、非使用時に、不本意に容器が破裂しないようにする必要がある。例えば保管中や運搬中に、包装体中の容器が破裂しては困る訳である。特に、CICは、患者が外出先で行う場合がある。このため、患者が鞆やバッグ等に包装体を強引に押し込んだ場合でも、包装体中の容器が破裂しないようにすることが望ましい。

【0006】そこで、本発明の目的は、内部の容器が不本意に破断しにくい包装体を提供することにある。

【0007】

【課題を解決するための手段】このような目的は、下記の本発明により達成される。

【0008】(1) 生体に挿入または挿着して使用される器具と、流動性の物質が密封された容器と、前記器具と前記容器とを収納する包材とを有する包装体であって、前記容器の一部または全部が、前記器具に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【0009】(2) 生体に挿入または挿着して使用される器具と、流動性の物質が密封された容器と、前記器具と前記容器とを収納する包材とを有する包装体であって、前記容器の前記流動性の物質が密封された部位が、前記器具に完全に重ならないよう前記容器の位置を規制する位置規制手段を有することを特徴とする包装体。

【0010】(3) 前記位置規制手段は、前記包材の内部に突出した突出部により構成されている上記(1)または(2)に記載の包装体。

【0011】(4) 前記突出部は、壁状をなしている上記(3)に記載の包装体。

【0012】(5) 前記突出部は、前記包材を成型して形成されたものである上記(3)または(4)に記載の包装体。

【0013】(6) 前記突出部は、前記突出部と反対側の包材に隣接または接触している上記(3)ないし(5)のいずれかに記載の包装体。

【0014】(7) 生体に挿入または挿着して使用される器具と、流動性の物質が密封された容器と、前記器具と前記容器とを収納する包材とを有する包装体であって、前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さよりも薄いことを特徴とする包装体。

【0015】(8) 前記容器が収納された部分の前記包材の厚さが、前記器具が収納された部分の前記包材の厚さの4/5以下である上記(7)に記載の包装体。

【0016】(9) 前記包材は、前記器具および前記容器を収納可能な膨らみを有するシート材と平坦なシート材とを重ね、これらの縁部をシールしたものである上記(1)ないし(8)のいずれかに記載の包装体。

【0017】(10) 前記容器は、前記包材を開封しないで前記包材内で開封可能である上記(1)ないし

(9)のいずれかに記載の包装体。

【0018】(11) 前記容器は、シート材をシール部によりシールしてなるものであり、前記容器に前記シール部よりも接合強度が小さい弱シール部を設けたことにより、前記容器を開封可能とした上記(10)に記載の包装体。

【0019】(12) 前記容器から流出した前記流動性の物質を前記器具に案内するガイド面を有する上記(10)または(11)に記載の包装体。

【0020】(13) 前記容器を収納する凹部を有し、この凹部の形状は、前記容器の形状に対応している上記(1)ないし(12)のいずれかに記載の包装体。

【0021】(14) 前記器具は、長尺の器具であり、前記容器の周りを囲むように、前記包材内に設置される上記(1)ないし(13)のいずれかに記載の包装体。

【0022】(15) 前記器具は、カテーテルである上記(1)ないし(14)のいずれかに記載の包装体。

【0023】

【発明の実施の形態】以下、本発明を添付図面に示す好適実施形態に基づいて詳細に説明する。図1は、本発明の包装体の第1実施形態を示す分解透視図である。図2は、図1に示す包装体のI-I線端面図である。

【0024】同図に示すように、包装体1Aは、包材2A内に、カテーテル7と、液体89を密封した容器8とが収納された構成となっている。この包装体1Aは、例えば、間歇式自己導尿法などに用いられる。例えば、使用者は、包装体1Aの開封前に、容器8を強く押圧して破断し、液体89でカテーテル7を湿らせる。その後、包装体1Aを開封してカテーテル7を取り出し、このカテーテル7を、患者の体内(例えば尿道等)に挿入する。まず始めに、包材2Aについて説明する。

【0025】包材2Aは、一対のシート材、第1シート材28と第2シート材29とで構成されている。図1に示すように、これら第1シート材28および第2シート材29の平面形状(平面視形状)は、ほぼ同形状をなし、いずれも略四角形状をなしている。これに対応して、包材2Aの平面形状も、略四角形状をなしている。

【0026】包材2Aは、第1シート材28と第2シート材29とを重ね、これらの縁部を融着(熱融着、高周波融着、超音波融着等)または接着(接着剤や溶剤による接着)によりシールして、袋状としたものである。図1では、シールされた部分をシール部21として、網掛けを付して示す。同図に示すように、シール部21は、包材2Aの外周部に沿って、帯状に形成されている。

【0027】図1および図2に示すように、第2シート材29は、平坦な形状に成形(形成)されている。これに対し、第1シート材28は、カテーテル7および容器8を収納可能な突出形状(プリスター形状)に、成形(形成)されている。換言すれば、第1シート材28

は、カテーテル7および容器8を収納できるように、膨らみを有している。そして、この膨らみの内部（以下、「収納空間22」という）に、カテーテル7と容器8とが収納される。

【0028】この収納空間22は、第1シート材28と第2シート材29とシール部21とで囲まれており、外部から隔離されている。したがって、収納空間22内に収納されたカテーテル7および容器8は、使用時まで好適に無菌状態が保たれる。

【0029】この包材2Aの少なくとも一つの角部には、シート材をシールしないことにより形成したピールタブ（開封部）211が設けられている。このピールタブ211で例えば第2シート材29を第1シート材28から離間する方向に引っ張ることにより、シール部21を剥離し、包材2Aを開封することができる。

【0030】以下、収納空間22が開放している側（図1、図2の上、すなわち第2シート材29が位置する側）を「上」といい、上と反対側（図1、図2の下、すなわち第1シート材28が位置する側）を「下」という。

【0031】第1シート材28の中央部付近には、平面形状が略四角形の第1凹部231が形成されている。包材2Aは、この第1凹部231内に容器8を収納する。この第1凹部231は、第1シート材28を成型することにより形成されたものである。本実施形態では、この第1凹部231により、容器8を収納する部分である容器収納部23が構成されている。この容器収納部23の形状、大きさ、すなわち第1凹部231の形状、大きさは、容器8の形状、大きさに対応している。

【0032】この第1凹部231の周囲には、包材2Aの内部（収納空間22内）に突出した壁状の突出部25が形成されている。図1に示すように、この突出部25の平面形状は、四角形の一辺が開放したような形状（角ばったCの字状）をなし、容器収納部23を囲んでいる。この突出部25は、容器収納部23に収納された容器8の位置を規制する機能を有している。具体的には、この突出部25は、液体89が密封された部位（内部空間81）がカテーテル8と重ならないように、容器8の位置を規定している。このように、包装体1Aでは、突出部25により、液体89が密封された部位がカテーテル8と重ならないように容器8の位置を規制する位置規制手段が、構成されている。なお、突出部25は、壁状としなくてもよい。

【0033】図2に示すように、突出部25は、突出部25と反対側の包材2A、すなわち第2シート材29に隣接または接触している。これにより、例えば包装体1Aを激しく揺動かしたりして、容器8が包材2A内で激しく動いた場合でも、容器8が突出部25を乗り越えて容器収納部23の外に飛び出すことが、極めて好適に防止されるようになる。つまり、突出部25が第2シ

ト材29に隣接または接触していると、容器8の内部空間81が、カテーテル7に、より重なりにくくなる。このような効果は、突出部25と第2シート材29との間隙（突出部25と第2シート材29との距離）を、容器8の厚さの半分以下とすると、より効果的に得られる。なお、本実施形態の包材2Aでは、突出部25は、ほぼ全周にわたって第2シート材29に隣接または接触しているが、突出部25は、部分的に第2シート材29に隣接または接触していればよい。また、突出部25は、第2シート材29に隣接または接触していなくてもよい。

【0034】このような突出部25は、第1シート材28を成型することにより形成されたものである。このように、突出部25を第1シート材28と一体的に形成すると、包材2Aの構成部材の数を削減することができ、包材2Aの製造をより簡易に行うことができるようになる。なお、突出部25は、設けなくてもよい。

【0035】突出部25の外側には、平面形状が口の字状の第2凹部241が形成されている。包材2Aは、この第2凹部241内に、カテーテル7を収納する。この第2凹部241は、第1シート材28を成型することにより形成されたものである。本実施形態では、この第2凹部241により、カテーテル7を収納する部分であるカテーテル収納部24が構成されている。

【0036】このカテーテル収納部24には、図1に示すように、包材2Aの長辺に沿って、リブ（係合部）27が設けられている。図2に示すように、このリブ27は、第2凹部241の外周側の内壁245に突出形成され、第2シート材29の近傍、すなわちカテーテル7の上方に位置している。このリブ27は、第1シート材28を成型することにより形成されたものである。

【0037】このリブ27は、カテーテル7が相対的に上方に移動した場合、カテーテル7に係合（接触）することができる。このため、例えば第2シート材29を勢いよく引っ張って包装体1Aを開封し、カテーテル7が上方に弾んだ場合でも、かかるカテーテル7が、リブ27に引っかかり（係合し）、包材2Aから飛び出すことが防止される。このように、包装体1Aでは、リブ27により、包材2Aの開封時にカテーテル7が包材2Aから飛び出すのを防止する飛び出し防止手段が構成されている。

【0038】包材2Aでは、第1凹部231の底面232は、第2凹部241の底面242とほぼ平行になっている。したがって、第2凹部241の底面242が接地するように包装体1Aを置くと、第1凹部231の底面232は、ほぼ水平になる。

【0039】図1に示すように、カテーテル収納部24と容器収納部23との間の突出部25が形成されていない部分には、ガイド面26が、形成されている。このガイド面26は、容器8から流出した液体89を、カテーテル収納部24、すなわちカテーテル7に案内する。図

1に示すように、ガイド面26は略四角形状をなしており、一辺の縁部は容器収納部23に隣接し、その反対側の縁部は、カテーテル収納部24に隣接している。図2に示すように、ガイド面26は、第2凹部241の底面242から所定角度傾斜して、テーパ状をなしている。

【0040】図1に示すように、このガイド面26は、突出部25が構成する四角形の一辺上に、位置している。換言すれば、包材2Aを平面視した場合、ガイド面26と突出部25とで、容器収納部23の周囲は、完全に囲まれている。

【0041】このような包装体1Aでは、容器8が収納された部分の包材2Aの厚さT1は、カテーテル7が収納された部分の包材2Aの厚さT2よりも薄くなっている。

【0042】これにより、包装体1Aの保管時、運搬時等、包装体1Aの使用前に、容器8が破断し、液体89が漏れることが好適に防止されるようになる。後述するように、容器8は、強く押圧される等して内部空間81の内圧が高まると、破断し、液体89が容器8の外に流出するようになっている。本発明の包装体1Aでは、厚さT1が厚さT2よりも薄いため、第1シート材29や第2シート材28に物が当たり、包装体2Aが圧縮される方向に力が加わった場合でも、かかる力は、主にカテーテル収納部24にかかり、容器収納部23には、あまりかからない。したがって、保管や運搬のため、多数の包装体1Aを箱等の中に押し込んだ場合でも、各包装体1Aでは、包装体1Aに対する押圧力は、主としてカテーテル収納部24にかかるようになる。このため、容器8に加わる押圧力は低減され、容器8の内部空間89の内圧が極度に増大することが、防止されるようになる。これにより、容器8の不用意な破断が防止される。

【0043】特に、包装体1Aでは、厚さT1を、好ましくは厚さT2の4/5以下に、より好ましくは2/3以下に設定すると、このような効果を、さらに効果的に得られるようになる。

【0044】また、本発明の包装体1Aでは、前述した位置規制手段(突出部25)によっても、容器8の不用意な破断が防止される。前述したように、カテーテル収納部24は、外からの押圧力がかかりやすい部分である。このため、カテーテル収納部24が変形した場合等には、カテーテル7にも、外からの押圧力がかかる可能性がある。この場合、容器8の内部空間81がカテーテル7に重なってしまうと、外からの包装体1Aへの押圧力が、カテーテル7を介して、容器8の液体89が密封された部位にかかってしまう可能性がある。

【0045】本発明の包装体1Aでは、位置規制手段により、このような事態が防止される。本発明の包装体1Aでは、位置規制手段が、内部空間81がカテーテル7と重なることを防止するので、カテーテル7が容器8の液体89が密封された部位を押圧することが、防止され

る。本発明の包装体1Aでは、これによっても、内部空間81の内圧が高まることが防止され、容器8の破断が防止される。したがって、例えば、靴やバッグ等の中で、包装体1Aの縁部が局所的に強く押圧された場合でも、容器8が破断することが、好適に防止されるようになる。

【0046】さらには、本実施形態の包装体1Aでは、突出部25が第2シート材29に隣接または接触していることも、容器8が強く押圧されにくくなることに貢献している。包装体1Aでは、中央部付近、すなわち容器収納部23が押圧された場合、突出部25がこの押圧力にある程度抗することができる。このため、容器8に加わる押圧力が緩和される。特に、本実施形態の包装体1Aのように、突出部25が壁状をなしていると、このような効果がより効果的に得られるようになる。さらには、本実施形態の包装体1Aのように、第1凹部231の形状、大きさが容器8の形状、大きさに対応していると、突出部25が容器8の近傍に位置するようになる。かかる点も、このような効果の向上に貢献している。また、このような効果は、突出部25が容器収納部23を囲むように形成されていると、さらに効果的に得られる。

【0047】このような効果を好適に得る観点からは、包材2A、特に第1シート材28は、保形性を有することが望ましい。これにより、前述した効果がより効果的に得られ、容器8が、より不本意に破断しにくくなる。また、包材2A、特に第1シート材28は、ある程度の柔軟性を有することが好ましい。これにより、使用時には、容器8を好適に破断させることができるようになる。包材2Aには、好ましくは、エチレンオキサイド、オートクレーブ、放射線、電子線等の滅菌に対応可能なガス透過性や耐熱性を有する材料、あるいは、滅菌後に無菌性を維持できる材料が用いられる。また、包材2Aには、カテーテルの劣化を防ぐために、UV遮蔽効果のある材料を用いることもできる。なお、内容物の視認性を確保するために、第1シート材28、第2シート材29のうち少なくとも一方は、透明であることが好ましい。

【0048】このような観点からは、第1シート材28、第2シート材29には、例えば、ポリエチレン、ポリプロピレン等のポリオレフィン樹脂、これらポリオレフィン樹脂のブレンド樹脂、ポリエチレンテレフタレート等のポリエステル樹脂、ポリスチレン、ポリ塩化ビニリデン、塩化ビニル-塩化ビニリデン共重合体等の単層フィルム、これらのフィルムにアルミニウム、シリカ等を蒸着したもの、アルミニウムフィルム、アルミニウムラミネートフィルム等の金属箔または金属箔を含むフィルムなどが、好適に用いられる。さらには、これら各フィルムを2層以上積層したものをを用いることもできる。また、前記シート材としてプラスチック製不織布や紙を

用いてもよい。なお、第1シート材28および第2シート材29を、これ以外の材料で構成してもよいことは言うまでもない。

【0049】第1シート材28、第2シート材29（単層または多層積層体）の厚さは、その層構成や用いる素材の特性（柔軟性、強度、水蒸気透過性、耐熱性等）等に応じて適宜決定され、特に限定されないが、通常は、60～700 μ m程度であるのが好ましく、100～500 μ m程度であるのがより好ましい。なお、第1シート材28、第2シート材29の厚さは、異なるものとしてもよいし、ほぼ同じものとしてもよい。

【0050】このような第1シート材28、第2シート材29は、例えば、インフレーション法、Tダイ法、ブロー成型法、ドライラミネート法、ホットメルトラミネート法、共押出インフレーション法、共押出Tダイ法、ホットプレス法等の種々の方法により製造することができる。

【0051】以下、このような包材2Aに収納されるカテーテル7および容器8について説明する。

【0052】包材2A内に収納されるカテーテル7は、生体に挿入または装着して使用される長尺の器具である。このカテーテル7は、外部からの押圧力に対して容易に破壊されにくい（特に容器8よりも）強い器具である。このため、カテーテル7にある程度の外力が加わった場合でも、カテーテル7は、この外力に抗することができる。

【0053】図1に示すように、カテーテル7は、容器8の周りを囲むように環状に曲げられ（湾曲され）、カテーテル収納部24内に収納される。このように、カテーテル7を環状に湾曲させて包材2A内に収納すると、包材2Aの長さを短くすることができる。このため、包装体1Aがコンパクトになり、鞆やバッグへの収納が便利になる。また、容器8の周りを囲むようにカテーテル7が設置されると、例えば、包装体1Aに、様々な方向から力が加わった場合でも、容器8は、カテーテル7で好適にガードされ、容器8には、あまり力が加わらないようになる。

【0054】カテーテル7は、生体内に挿入される挿入部71を有している。挿入部71は、好ましくは可撓性を有する管体で構成されている。この挿入部71は、生体内への挿入を円滑に行うことが必要とされ、そのために、挿入部71の表面の全体または一部には、湿潤により潤滑性を発現する物質が付与されているのが好ましい。

【0055】このような物質としては、例えば、特開昭60-259269号、特開平1-195863号公報に記載されているような親水性ポリマーが挙げられる。また、例えば、特公平6-32652号、特開平6-7426号、国際出願WO8802623、国際出願WO8907521、国際出願WO8909246、国際出

願WO9001344、国際出願WO9219289、国際出願WO9311751、国際出願WO9529722、特表平10-502854号、特表平10-502855号、特表平10-502856号に開示されている物質や方法を用いてもよい。このような物質は、通常、挿入部71の表面に、湿潤していない状態（乾燥状態）で存在している。

【0056】このような物質は、挿入部71の基材表面に化学結合されたポリマーであって、該基材表面からの剥離や、水、生理等張液、その他潤滑剤等への溶出が生じ難いものが、潤滑性の持続性、安全性の点から好ましい。このようなことから、カテーテル7の使用に先立ち、容器8から噴出した液体89を挿入部71に接触させ、湿潤により潤滑性を発現させる。

【0057】包材2A内に収納されるカテーテル7の種類、用途等は、特に限定されず、例えば、気管、消化管、尿道、膣、血管、リンパ管、胆管、その他の体腔や、例えば、肺、心臓、腎臓等の各種臓器、その他の生体組織等へ挿入される種々のカテーテル、バルーンカテーテル等が挙げられる。この中でも、特に、尿道に挿入して使用されるカテーテル（尿道カテーテル、導尿カテーテル）が好ましい。

【0058】排尿障害における導尿法は、留置カテーテルではなく無菌間歇導尿法が好ましいが、近年、患者自身がカテーテルを使って尿を排出する自己導尿が有効な治療方法として普及してきている。排尿障害は、前立腺肥大症、結石、腫瘍などによる尿道閉塞や、脳・脊髄および骨盤神経などの障害により見られる神経因性膀胱によって起こるが、尿を完全に出しきれない状態になると、尿路内圧が上がって腎臓に負担をかけるので、定期的に尿を排出する必要がある。この際に行われる自己導尿法は、低圧で完全に尿を排出できるので、既にある尿感染が低減する、頻尿、尿失禁が治る、膀胱と腎臓に負担をかけない等の利点があり、患者自身が1日4～6回程度、尿道から膀胱内にカテーテルを挿入し、尿の排出が終了したら抜去する。その頻度は、例えば、昼間は4～5時間毎、夜間は就寝前とされる。

【0059】容器8は、内部に内部空間81を有し、この内部空間81内に、液体89を密封・貯留している。本実施形態では、この容器8は、第1シート材28のみならず、第2シート材29にも接触または隣接している。

【0060】この容器8は、例えば、平坦なシート材（インフレーションシート材）の中央部を折り曲げ三方を融着（または接着）によりシールし、袋状としたものである。この袋の内部に内部空間81が形成され、ここに、液体89が貯留（充填）される。以下、容器8のシート材がシールされた部分を、シール部82という。なお、容器8は、図示のように形成したものに限定されず、例えば、筒状に成形されたシート材の両端部を融着

(または接着)し、袋状としたもの、あるいは、2枚のシート材を重ね、その外周部全周を融着(または接着)し、袋状としたものでもよい。

【0061】図1で格子を施して示すように、シール部82の一部は、他の部分(シール部821)より接合強度(剥離強度)が弱い弱シール部(イーザービールシール部)83で構成されている。シール部821は、対向するシート材同士が完全に融着され、強固な接合状態であるのに対し、弱シール部83は、それより低温で融着する等により、対向するシート材同士の融着がある程度不完全であるような状態とされる。ただし、弱シール部83においても、液密性(気密性)は、確保されている。そして、その効果は、経時的に持続する。

【0062】したがって、例えば、容器8の液体89が貯留された部分を押圧(圧迫)し、内部空間81の内圧を高めると、弱シール部83が優先的に剥離(破断)する。これにより、内部空間81と容器8の外部とが連通し、液体89が容器8の外に流出する。このように、容器8では、弱シール部83により、容器8を開封する部分である開封口が構成されている。

【0063】本実施形態の包装体1Aでは、容器8を、第1シート材28および第2シート材29越しに押圧できる。特に、本実施形態の包装体1Aのように、容器8が第1シート材28および第2シート材29に隣接または接触していると、かかる操作がさらに容易となる。したがって、包装体1Aでは、包装体1Aが未開封の状態、極めて簡単な操作で、容器8を開封することができる。また、本実施形態では、第1凹部23の底面232が第2シート材29と略平行であることも、容器8の押圧がさらに容易となることに、寄与している。なお、弱シール部83を剥離する方法は、上記方法に限定されず、例えば、弱シール部83を、シート材越しに手で揉みほぐしてもよい。なお、開封口は、例えば、シール部82のシール幅を、局所的に他の部分のシール幅よりも狭くするような構成としてもよい。

【0064】このような容器8の厚さは、カテーテル7の厚さ(外径)よりも薄いことが好ましい。これにより、包装体1Aに強い力が加わり、第1シート材28が圧縮され、変形しても、包装体1Aに加わる力は、主としてカテーテル7に加わることになる。このため、容器8に加わる力はより好適に低減され、容器8の破損がより好適に防止される。

【0065】また、容器8は、内部空間81に貯留される流動性物質の蒸気バリア性を有するのが好ましい。例えば、前記流動性物質が水である場合、この蒸気バリア性とは、水蒸気透過度が、好ましくは $30\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、より好ましくは $10\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下、さらに好ましくは $1\text{ g/m}^2 \cdot 24\text{ hrs} \cdot 25\mu\text{m厚} \cdot 40^\circ\text{C} \cdot 90\%\text{RH}$ 以下

であることを言う。この水蒸気透過度は、JIS K7129(A法)に記載の方法により測定される。容器8が水蒸気バリア性を有することにより、容器8の内部からの水分の蒸散が防止できる。その結果、内部空間81内の液体89の減少、濃縮を防止することができるとともに、液体89の量が必要最少限の量で済み、包装体1A全体の容積や重量を小さくすることができる。

【0066】容器8を構成するシート材(フィルム)、特に水蒸気バリア性を有するシート材としては、例えば、下記のものなどが挙げられる。

[1] 1種のポリオレフィン樹脂で構成される単層フィルム、[2] 2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂より構成される単層フィルム、

[3] シーラント層(融着に関与する層)にポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)を用いたポリオレフィン樹脂もしくはポリエステル樹脂の多層フィルム、[4] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)より構成されるフィルム、外層がポリ塩化ビニリデンをコーティングしたポリオレフィンまたはポリエステルフィルム等で構成される多層フィルム、[5] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)より構成されるフィルム、外層がアルミ蒸着もしくはシリカ蒸着されたポリオレフィンフィルムまたはポリエステルフィルム等で構成される多層フィルム、[6] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)より構成されるフィルム、中間層がアルミニウムフィルム、最外層がポリエステルフィルム等で構成される多層フィルム、[7] シーラント層がポリオレフィン樹脂(ポリオレフィン樹脂のブレンド樹脂も使用可能)、中間層がナイロンフィルム、最外層がアルミ蒸着もしくはシリカ蒸着されたポリオレフィンまたはポリエステルフィルム等で構成される多層フィルム、この場合、対向する一対のシート材のうち的一方を不透明なアルミニウムフィルム、他方をシリカ蒸着フィルム等の透明な水蒸気バリア性フィルムとすれば、容器8の内容物の視認による確認が行えるので、さらに好ましい。なお、アルミニウムフィルムは、必要に応じその一部もしくは全部が剥離除去可能であってもよい。

【0067】なお、弱シール部83においては、直接融着に関与する層(シーラント層)が2種以上の互いに相溶しないポリオレフィン樹脂のブレンド樹脂、もしくは2種以上の互いに相溶しないポリオレフィンをセグメントに有するランダムもしくはブロック共重合体で構成されていることが好ましい。

【0068】容器8を構成するシート材(単層または多層積層体)の厚さは、その層構成や用いる素材の特性(柔軟性、強度、水蒸気透過性、耐熱性等)等に応じて適宜決定され、特に限定されるものではないが、通常

は、20〜700 μ m程度であるのが好ましく、40〜500 μ m程度であるのがより好ましい。

【0069】このような容器8を構成するシート材は、例えば、インフレーション法、Tダイ法、ブロー成型法、ドライラミネート法、ホットメルトラミネート法、共押出インフレーション法、共押出Tダイ法、ホットプレス法等の種々の方法により製造することができる。

【0070】なお、以上述べた特性を有する容器8は、例えば特願平11-084854を参照することにより、好適に製造することができる。

【0071】このような容器8を備えた包装体1Aは、次のような効果（利点）を有する。第1に、包材2A内に入れる容器8の容量を選択することにより、容器8の内容物（液体89等）の量や重量を容易に設定することができる。第2に、容器8は、包材2Aとは別個に単独で製造可能なので、製造・管理がしやすい。

【0072】このような容器8内に収納される液体89は、カテーテル7の挿入部71の表面と接触して、その摩擦抵抗を低減させることができる物質（液状または半液状物）であるのが好ましい。

【0073】このような液体89としては、特に限定されないが、例えば、水、生理等張液（生理食塩水）、グリセリン、シリコンオイル、オリーブオイル等のオイル類、キシロカインゼリー等が挙げられる。

【0074】以下、包装体1Aの使用法（作用）の一例について説明する。前述したように、本発明の包装体1Aは、保管中に、容器8が破損しにくい。保管後、包装体1A内の医療器具を使用する際には、下記のような操作を行う。

【0075】まず、包材2Aの外部から容器8を指等で押圧・圧迫する。これにより、弱シール部83が剥離（破断）して、かかる剥離した部分から、液体89が流出する。

【0076】容器8から流出した液体89は、ガイド面26上を伝わり、カテーテル収納部24内へ流入する。そして、このカテーテル収納部24へ流入した液体89は、第2凹部241の底面242で広がる。これにより、カテーテル7の挿入部71が濡れ（湿潤し）、挿入部71の表面に、潤滑性が発現する。つまり、挿入部71表面の摩擦抵抗が低減する。このとき、必要に応じて、包装体1Aの両端（短辺を構成する端部、あるいは長辺を構成する端部）を交互に上下させる等の操作を行ってもよい。これにより、液体89がより好適にカテーテル収納部24内に広がり、挿入部71が、より満遍なく、より均一に濡れるようになる。なお、容器8を開封後、必要に応じて、包装体1Aの外部から容器8を指等で押圧（圧迫）する等して、容器8内の液体89を残らず排出する操作を行ってもよい。

【0077】本実施形態の包装体1Aのように、容器収納部23の形状、大きさが容器8の形状、大きさにほぼ

対応していると、容器収納部23内（第1凹部231の底面232）に残存しカテーテル収納部24に流れない液体89の量が減少する。このため、比較的少ない液体89の量で、より効率よくカテーテル7の挿入部71を濡らすことができる。

【0078】以上のようにして、カテーテル7の挿入部71の表面に潤滑性が発現したら、ピールタブ211を引っ張って、包材2Aを開封する。そして、カテーテル7を包材2A内から取り出す。

【0079】包材2Aから取り出されたカテーテル7は、生体の目的部位に挿入または装着される。カテーテル7が尿道カテーテル（導尿カテーテル）である場合には、挿入部71を先端側から尿道および膀胱に挿入する。このとき、挿入部71の表面が潤滑性を有しているため、カテーテル7の挿入操作を、円滑かつ安全に行うことができる。その後、患者は、カテーテル7を介して排尿を行う。

【0080】このように、包装体1Aを用いれば、カテーテル7の挿入部71の表面に潤滑性を発現させる操作を、密閉された包材2A内で外気と接触することなく行うことができる。したがって、本発明の包装体1Aでは、カテーテル7は、使用直前まで、無菌性が良好に保たれる。

【0081】以下、本発明の包装体の第2実施形態について説明する。なお、以下の説明では、第1実施形態の包装体と共通する事項については説明を省略し、相違する事項を中心に説明する。図3は、本発明の包装体の第2実施形態を示す端面図である。なお、本実施形態の上下の概念は、第1実施形態と同様である。

【0082】同図に示すように、包装体1Bでは、第1凹部231の底面232'が、第2凹部241の底面242に対して所定角度傾斜し、テーパ状をなしている。詳しくは、底面232'は、ガイド面26'の方向に下がるように（第2シート材29から離間し第2凹部241の底面242に近づくように）、テーパ状をなしている。これに対応して、容器8は、弱シール部83が下がるように（第2シート材29から離間し第2凹部241の底面242に近づくように）、容器収納部23に設置されている。また、ガイド面26'は、第2凹部241の底面242とはほぼ直行している。

【0083】包材2Aをこのような構成にすると、包装体1Bを傾ける等の操作をあまりしなくても、液体89が、カテーテル収納部24内に、円滑に流れて行くようになる。

【0084】本実施形態のように、容器8が収納された部分の包材2Bの厚さT1が均一でない場合は、例えば、容器8が収納された部分の中央部付近の厚さを、厚さT1の指標とすることができる。

【0085】以下、本発明の包装体の第3実施形態について説明する。なお、以下の説明では、第1実施形態の

包装体と共通する事項については説明を省略し、相違する事項を中心に説明する。図4は、本発明の包装体の第3実施形態を示す端面図である。なお、本実施形態の上下の概念は、第1実施形態と同様である。

【0086】同図に示すように、包装体1Cでは、第2凹部241の外周側の内壁245が、テーパ状をなしている。詳しくは、内壁245は、第2凹部241の底面242の法線に対して所定角度傾斜しており、その上部（底面242と反対側の部分）が、収納空間22の内部に向かってせり出している（突出している）。

【0087】この内壁245上部のせり出した部分（以下、せり出し部27'という）は、包材2Cの長辺に沿って、形成されている。このせり出し部（係合部）27'は、カテーテル7の上方に位置している。このせり出し部（凸部）27'は、カテーテル7が上方に相対的に移動した場合、カテーテル7に係合（接触）することができる。

【0088】しかも、本実施形態の包装体1Cでは、カテーテル7が上方に弾んだ場合、カテーテル7は、第2凹部241の外周側の内壁245に当接して、上方への移動が規制されることとなる。

【0089】このため、本実施形態の包装体1Cでは、包材2Cの開封時にカテーテル7が包材2Cから飛び出すことが、極めて好適に防止されるようになる。本実施形態では、飛び出し防止手段は、テーパ状の内壁245と、せり出し部27'とにより、構成されている。

【0090】以下、本発明の包装体の第4実施形態について説明する。なお、以下の説明では、第1実施形態の包装体と共通する事項については説明を省略し、相違する事項を中心に説明する。図5は、本発明の包装体の第1実施形態を示す分解透視図である。図6は、図5に示す包装体のII-II線端面図である。

【0091】同図に示すように、包装体1Dでは、第1凹部231'および容器収納部23'は、一方の長辺に接近して位置している。また、突出部25'の平面形状は、図5に示すように、四角形の三辺を構成するコの字状をなし、容器収納部23'を囲んでいる。そして、突出部25'は、長辺に向かって、開放している。

【0092】本実施形態の包装体1Dでは、容器収納部23'が、第2凹部241'の外周側の内壁245に接近して設置されているため、図6に示すように、容器8の開封部（弱シール部83）は、内壁245に当接または隣接している。このため、容器8から流出した液体89は、内壁245に接触し、この内壁245を伝って、カテーテル収納部24'に案内されることとなる。このように、本実施形態の包装体1Dでは、容器8の開封部に臨む第2凹部241'の外周側の内壁245により、液体89をカテーテル7に案内するガイド面26"が構成されている。

【0093】前述したように、容器収納部23'は、包

材2Dの中央部から一方の長辺側に若干ずれたところに位置している。このため、容器収納部23'が第2凹部241'の外周側の内壁245に接近した側では、第2凹部241'の底面（以下、底面242aという）の面積が小さくなっている。これに対し、容器収納部23'が内壁245から離間した側では、底面（以下、底面242bという）の面積が大きくなっている。

【0094】そして、本実施形態の包装体1Dでは、底面242b上に、すなわち底面242b側のカテーテル収納部24'内に、液体89等を吸収し、保持することができる吸収体9が設置される。吸収体9を包材2D内に入れることにより、吸収体9に、カテーテル7を濡らした後の余剰の液体89を吸収させることが可能となる。

【0095】吸収体9としては、特に限定されないが、例えば、ポリアクリル酸塩系、ポリビニルアルコール系、ポリアクリルアミド系、ポリオキシエチレン系またはマレイン酸系材料等の合成ポリマーや、デンプン、セルロース、アルギン酸のような多糖類材料等の天然材料等のような高分子吸収材料で構成されたものが好ましい。また、その他、例えば、スポンジ、綿、ガーゼ、不織布やそれらに前記高分子吸水性材料を担持したもの（例えば、おむつ、生理用品等に用いられているもの）も可能である。このような吸収体9は、ブロック状、粉末状、フィルム状、シート状（板状）、繊維状などの形態（形状）をとることができる。図5、6では、一例として、ブロック状の吸収体9を示した。

【0096】このように、本実施形態の包材2Dでは、内部にカテーテル7および容器8以外の部材を設置するスペースを確保することが容易となり、かかるスペースに、吸収体9等の新たな部材を設置することが容易となる。

【0097】吸収体9のようなカテーテル7および容器8以外の新たな部材としては、特に限定されないが、吸収体9の他に、例えば、カテーテル挿入前後に尿道口付近を消毒することができるシート、使用済みカテーテルを廃棄するまでに発生する臭気を抑制する脱臭剤、細菌、ウイルス等の微生物の繁殖を抑制する抗菌剤などが挙げられる。

【0098】以上、本発明を図示の好適実施形態に基づいて説明してきたが、本発明はこれに限定されるものではない。

【0099】本発明において、生体に挿入または装着して使用される長尺のカテーテル7としては、例えば、以下のようなものが挙げられる。

・胃管カテーテル、栄養カテーテル、経管栄養用チューブ、酸素カテーテル、酸素カヌラ、気管内チューブのチューブやカフ、気管切開チューブのチューブやカフ、気管内吸引カテーテル等の経口または経鼻的に挿入、留置されるカテーテル類。

・吸引カテーテル、排液カテーテル、腹腔カテーテル、直腸カテーテル、トロッカー等の各種体腔、臓器、組織内に挿入、留置されるカテーテル類。

・血管造影用カテーテル、PTCA用バルーンカテーテル、IABP用バルーンカテーテル、静脈留置カテーテル、動注用カテーテル等の血管内に挿入、留置されるカテーテル類。

【0100】さらには、生体に挿入または挿着して使用される長尺の器具としては、カテーテルの他に、例えば、以下のようなものが挙げられる。

・単独で、または、前記各カテーテル類とともに使用される各種ガイドワイヤー。

・人工血管、ステント。

・注射針、留置針、カテーテルイントロデューサ。

・内視鏡、超音波破碎プローブ。

・縫合用または結紮用の糸。

【0101】さらには、生体に挿入または挿着して使用される器具は、長尺状のものでなくてもよい。包装体に収納される生体に挿入または挿着して使用される器具としては、上述したもの以外に、例えば、以下のようなものが挙げられる。

・心拍出量測定器具、超音波測定・診断器具、ペースメーカー、体温計。

・人工肛門、人工骨、人工関節、補綴物、義眼。

・シース。

・浣腸。

・コンドーム等の避妊具。

【0102】以上述べた実施形態では、容器8に収納される流動性の物質として、液体89を挙げたが、容器8には、液体89以外の流動性を有する物質、例えば、ゲル状、ゼリー状の物、粉体、粒体などを収納してもよい。なお、包装体内には、前述した以外の任意のものが収納されていてもよい。

【0103】

【発明の効果】以上述べたように、本発明によれば、内部の容器が不本意に破断しにくい包装体を提供することができる。したがって、例えば本発明を間歇式自己導尿法に適用した場合、患者は、本発明の包装体を安心して携帯することができ、しかも、外出先においても、簡便かつ確実に自己導尿を行うことができる。よって、本発明は、患者の生活の質の向上に、大きく貢献できる。

【図面の簡単な説明】

【図1】本発明の包装体の第1実施形態を示す分解透視図である。

【図2】図1に示す包装体のI-I線端面図である。

【図3】本発明の包装体の第2実施形態を示す縦端面図である。

【図4】本発明の包装体の第3実施形態を示す縦端面図である。

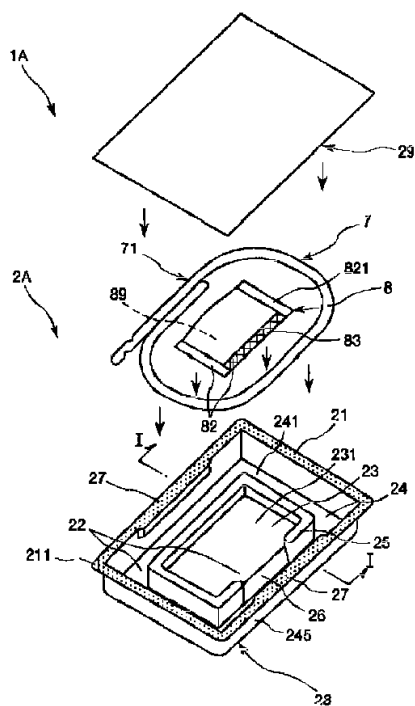
【図5】本発明の包装体の第4実施形態を示す分解透視図である。

【図6】図5に示す包装体のII-II線端面図である。

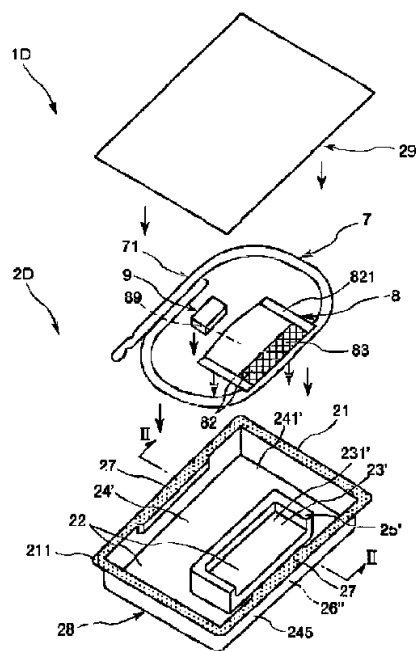
【符号の説明】

1A、1B、1C、1D	包装体
2A、2B、2C、2D	包材
21	シール部
211	ピールタブ
22	収納空間
23、23'	容器収納部
231、231'	第1凹部
232、232'	底面
24、24'	カテーテル収納部
241、241'	第2凹部
242、242a、242b	底面
245	外周側の内壁
25、25'	突出部
26、26'、26''	ガイド面
27	リブ
27'	せり出し部
28	第1シート材
29	第2シート材
7	カテーテル
71	挿入部
8	容器
81	内部空間
82	シール部
821	弱シール部以外のシール部
83	弱シール部
89	液体
9	吸収体
T1	容器が収納された部分の包材の厚さ
T2	カテーテルが収納された部分の包材の厚さ

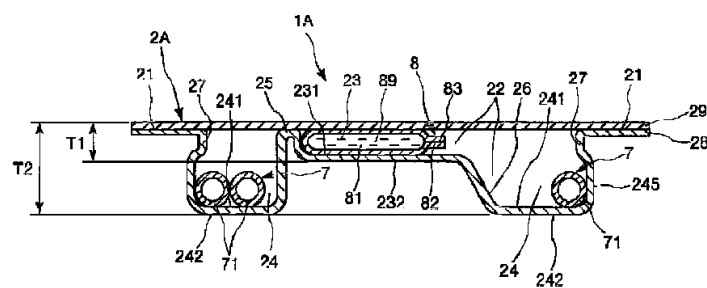
【例 1】



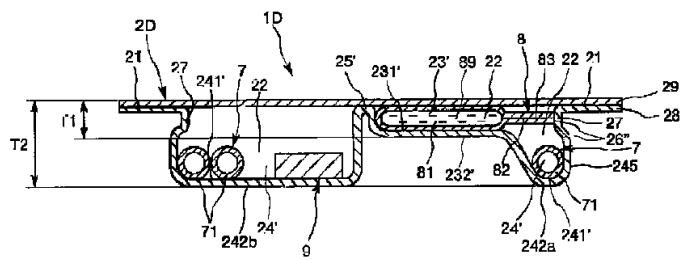
【図5】



【图2】

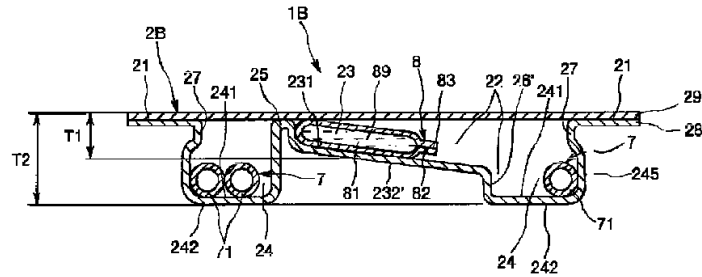


【图6】

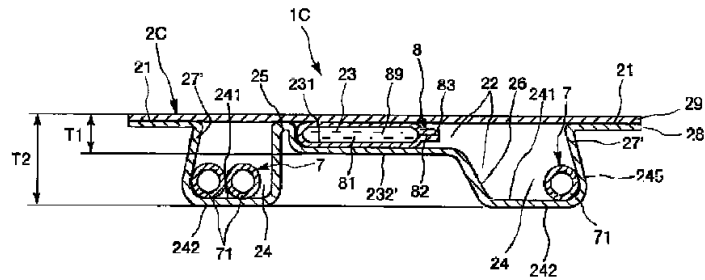


(12) 2002-68309 (P2002-68309A)

【図3】



【図4】



フロントページの続き

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テルモ株式会社内

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BB14A BC07A CA24 EE44
GD08

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	10055UCIP2D1C1C1C1C1	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ₁	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4411656		1983-10-25	Cornett, Walter	
		4439184		1984-03-27	Wheeler, Robert P.	
		9693756		2017-07-04	Tomes, Jennifer	
		9745088		2017-08-29	Tomes, Jennifer	
		9808596		2017-11-07	Tomes, Jennifer	
		10512752		2019-12-24	Tomes, Jennifer	
		10946169		2021-03-16	Lockwood, Robert	
		10946992		2021-03-16	Tomes, Jennifer	
U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ₁	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
FOREIGN PATENT DOCUMENTS						

Doc code: IDS

PTO/SB/08a (01-10)

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
		2000281144	JP		2000-10-10	Shimura, Kenichi		
		2002068309	JP		2002-03-08	Nishizawa, Yasushi et al.		
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		JP2000281144-A Machine translation 17 Oct 2022; Cited in USSN 16/721,718 on October 26, 2022,						
		JP2002068309-A Machine translation 17 Oct 2022; Cited in USSN 16/721,718 on October 26, 2022,						
		KLEIN, BENJAMIN , "Non-Final Office Action", USSN 16/688,185; Filed November 19, 2019; Attorney Docket No. BPMDL10055U P1C2D1; Mailed January 31, 2023,						
		MARCETICH, ADAM M. , "Notice of Allowance", USSN 16/721,718; Filed December 19, 2019; Attorney Docket No. 10055U CIP3 C1 C1 C1; Mailed October 26, 2022,						
		MARCETICH, ADAM M. , "Non-Final Office Action", USSN 16/944,667; Filed July 31, 2020; Attorney Docket No. 10055U CIP2 D1 C1C1C1C1C1; Mailed October 7, 2022,						

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	10055UCIP2D1C1C1C1C1	

		POON, ROBERT , "NonFinal Office Action", USSN 17/835,747; Filed June 8, 2022; Attorney Docket NO. 10055U D1 C2 C1 C1; Mailed October 12, 2022,	
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		REIP, DAVID O. , "Re-Exam Non-Final Office Action", USSN 90/015,051; Filed June 8, 2022; Reference No. 10055U CIP2 D1; Mailed December 14, 2022,	
EXAMINER SIGNATURE			
Examiner Signature		Date Considered	
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CERTIFICATION STATEMENT	
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☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).	

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Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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OR

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

☐ See attached certification statement.

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

☐ None

SIGNATURE

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

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-02-09
Name/Print	Philip H. Burrus	Registration Number	45,432

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Electronic Patent Application Fee Transmittal				
Application Number:		16833575		
Filing Date:		28-Mar-2020		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		10055UCIP2D1C1C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 2 months with \$0 paid	1252	1	640	640
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	1806	1	260	260
Total in USD (\$)				900

Electronic Acknowledgement Receipt	
EFS ID:	47517065
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	13-FEB-2023
Filing Date:	28-MAR-2020
Time Stamp:	15:57:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$900
RAM confirmation Number	E20232CF57498593
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10055U_CIP2_D1C1C1C1C1_U SA_2022-12-4_Amend.pdf	262822	yes	12
			a09349ea14eb416c72602f5c26175e58d7581829		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Request for Reconsideration-After Non-Final Rejection		1	1	
	Claims		2	6	
	Applicant Arguments/Remarks Made in an Amendment		7	11	
	Extension of Time		12	12	
Warnings:					
Information:					
2	Non Patent Literature	10055U_CIP_C2_D1_USA_2023-1-31_NonFinalOA.pdf	748254	no	11
			7230c6ecd248bc633128bb097ce1013af507e638		
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3	Non Patent Literature	10055U_CIP2_D1C1C1C1C1C1_USA_2022-10-7_NonFinalOA.pdf	1713361	no	25
			38d3f8d1e63cb8084f8e7966a15794b0aba70211		
Warnings:					
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4	Non Patent Literature	10055U_CIP2D1_USA_2022-12-14_ReexamOA.pdf	815869	no	12
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Warnings:					
Information:					

5	Non Patent Literature	10055U_CIP3_C1C1C1_USA_2022-10-26_NoticeOfAllowance.pdf	1409288	no	16
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Warnings:					
Information:					
6	Non Patent Literature	10055U_CIP3_C1C1C1_USA_2023-2-9_NoticeOfAllowance.pdf	1500492	no	18
			6a551fbcb28207f34cb2df733117e2b45e4f3e1a		
Warnings:					
Information:					
7	Non Patent Literature	10055U_D1_C2_C1_C1_USA_2022-10-12_NonFinalOA.pdf	676814	no	10
			49c76c3738d9c349cb332ddb6421a326499861d		
Warnings:					
Information:					
8	Foreign Reference	JP2000281144A_English.pdf	3673366	no	22
			265d6d2f1f4db6fc10b56db202034ba9a410ee51		
Warnings:					
Information:					
9	Foreign Reference	JP2000281144A.pdf	3626337	no	20
			05b08a63620f12448d43d754bfd794c012dc80df		
Warnings:					
Information:					
10	Foreign Reference	JP2002068309A_English.pdf	2166063	no	13
			b8d5b390eaa95b7f41a02dd088022f16bcb049a		
Warnings:					
Information:					
11	Foreign Reference	JP2002068309A.pdf	2168950	no	12
			ef3962716d23176e8739ba473a1977aa712aa02b		
Warnings:					
Information:					

12	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2_D1C1C1C1C1_U SA_2023-2-9_IDS.pdf	148369	no	4
			e17a9d89301726fe05eb64051b67a645172 48894		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
13	Fee Worksheet (SB06)	fee-info.pdf	40694	no	2
			5f2f278f449d566270c1a974be65515152b0 90c2		
Warnings:					
Information:					
Total Files Size (in bytes):			18950679		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

189038 7590 02/24/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3781

DATE MAILED: 02/24/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1	5069

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/24/2023

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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

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

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

189038 7590 02/24/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1	5069

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/24/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3781	604-540000

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

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

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

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1	5069
189038	7590	02/24/2023	EXAMINER	
Philip H. Burrus, IV Burrus Intellectual Property Law Group LLC (MDL) 222 12th Street NE Suite 1803 Atlanta, GA 30309			MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER
			3781	
DATE MAILED: 02/24/2023				

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

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

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

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

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

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

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.** Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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

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

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

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

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

3. ☒ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

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

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

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

Attachment(s)

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

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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EXAMINER'S COMMENT / AMENDMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

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

Examiner's Comment

The rejection of claim 14 under 35 USC § 112 is withdrawn in view of the amendments filed 13 February 2023.

Terminal Disclaimer

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

- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 9522753 B2)
- Tomes; Jennifer E. et al. (US 10251812 B2)
- Tomes; Jennifer E. et al. (US 9808400 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 9283352 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)

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

Examiner's Amendment

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

Claims 5, 6 and 9 are amended as follows. **[[Deletions are in double brackets]]** and **additions are underlined.** Ellipsis ... designates unchanged portions of claims which have been omitted for brevity.

Claim 5 (amended in part) "The medical procedure kit of claim 4, wherein **the** left-to-right configuration comprises ..."

Claim 6 (amended in part) "... in accordance with an order with which **[[they]]** **the** syringe containing the lubricating jelly ..."

Claim 9 (amended in part) "The medical procedure kit of claim 7, the second syringe **[[containing water]]** is for attachment to the Foley Catheter."

Allowable Claims

Claims 1-20 are allowed.

Reasons for Allowance

Applicant's arguments filed 13 February 2023 regarding **Solazzo; Anthony (US 20060009742 A1), Serany; Frank J. Jr. et al. (US 3329261 A) and Fischer; Herbert et al. (US 4554156 A)** have been considered and are persuasive. Examiner advances additional reasons for allowance.

Solazzo, the closest art of record, lacks a syringe containing lubricating jelly wherein the syringe is situated within the lubricating jelly application chamber. Instead, Solazzo describes a pair of lubricating jelly application chambers which are too shallow to accommodate a container or a syringe of lubricating jelly. Figs. 4 and 5 show side views of lubricating wells 31 and 33 which lack sufficient depth to hold a container or syringe (¶ [0040] Optional Foley catheter lubricating wells 31 and 33). To properly accommodate the size of a lubricating jelly container and a water-filled syringe, Solazzo places these two items in larger compartments separate from the two lubricating jelly application chambers. The lubricant fluid 140 is placed in back 13 of recessed area 3, and the inflation syringe 10 is placed in compartment 27 (Figs. 1 and 8).

Also of record, **Serany** lacks a single layer tray having a syringe containing lubricating jelly situated in a lubricating jelly application chamber. Instead, Serany discloses a multi-level tray having separate parts (col. 1, lines 60-65, a box 10 having an open top with a tray 12 mounted thereon); and

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

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

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

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

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

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8am-4pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Weiss can be reached at 571-270-1775. The fax phone number for the organization where this application is assigned is 571-273-8300.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>.

Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

<i>Notice of References Cited</i>	Application/Control No. 16/833,575		Applicant(s)/Patent Under Reexamination Tomes et al.	
	Examiner Adam M Marcetich		Art Unit 3781	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20110218520-A1	09-2011	Andrich; Daniela	A61M25/0017	604/544
*	B	US-4460360-A	07-1984	Finegold; Aaron N.	A61M25/00	604/288
	C					
	D					
	E					
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	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

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

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Issue Classification 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

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

CPC Combination Sets					
Symbol	Type	Set	Ranking	Version	
/					

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 21 February 2023		O.G. Print Claim(s) 1	O.G. Print Figure 7

Issue Classification 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

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

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) _____		21 February 2023 O.G. Print Claim(s) 1	O.G. Print Figure 7

Issue Classification 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 21 February 2023		O.G. Print Claim(s) 1	O.G. Print Figure 7

<i>Search Notes</i> 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B50/30, A61B50/33, A61M25/00, A61M25/002, A61B2050/3008, A61J2205/50, A61M5/002, A61M25/0017, A61M2209/06	09/06/2022	AMM
B65B11/00, A61L2202/18, A61L2202/182	09/06/2022	AMM
update search	02/21/2023	AMM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search in US-PGPUB, USPAT	09/06/2022	AMM
Review cited art for related cases 12495148, 12647515, 13153265, 13153300, 13155026, 13860902, 14793455, 15684787	09/06/2022	AMM
Review Inter Partes Review cases IPR2015-00509, IPR2015-00511, IPR2015-00513, IPR2019-00035, IPR2019-00036, IPR2019-00109	09/06/2022	AMM
update search	02/21/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	claim keyword search	02/21/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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Receipt date: 02/13/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	10055UCIP2D1C1C1C1C1	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ₁	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4411656		1983-10-25	Cornett, Walter	
		4439184		1984-03-27	Wheeler, Robert P.	
		9693756		2017-07-04	Tomes, Jennifer	
		9745088		2017-08-29	Tomes, Jennifer	
		9808596		2017-11-07	Tomes, Jennifer	
		10512752		2019-12-24	Tomes, Jennifer	
		10946169		2021-03-16	Lockwood, Robert	
		10946992		2021-03-16	Tomes, Jennifer	
U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ₁	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
FOREIGN PATENT DOCUMENTS						

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0698

Receipt date: 02/13/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	10055UCIP2D1C1C1C1C1	

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
		2000281144	JP		2000-10-10	Shimura, Kenichi		
		2002068309	JP		2002-03-08	Nishizawa, Yasushi et al.		

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
		JP2000281144-A Machine translation 17 Oct 2022; Cited in USSN 16/721,718 on October 26, 2022,	
		JP2002068309-A Machine translation 17 Oct 2022; Cited in USSN 16/721,718 on October 26, 2022,	
		KLEIN, BENJAMIN , "Non-Final Office Action", USSN 16/688,185; Filed November 19, 2019; Attorney Docket No. BPMDL10055U P1C2D1; Mailed January 31, 2023,	
		MARCETICH, ADAM M. , "Notice of Allowance", USSN 16/721,718; Filed December 19, 2019; Attorney Docket No. 10055U CIP3 C1 C1 C1; Mailed October 26, 2022,	
		MARCETICH, ADAM M. , "Non-Final Office Action", USSN 16/944,667; Filed July 31, 2020; Attorney Docket No. 10055U CIP2 D1 C1C1C1C1C1; Mailed October 7, 2022,	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0699

Receipt date: 02/13/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Art Unit	3781	
	Examiner Name	Adam M Marcetich	
	Attorney Docket Number	10055UCIP2D1C1C1C1C1	

		POON, ROBERT , "NonFinal Office Action", USSN 17/835,747; Filed June 8, 2022; Attorney Docket NO. 10055U D1 C2 C1 C1; Mailed October 12, 2022,	
		MARCETICH, ADAM M. , "Notice of Allowance", USSN 16/721,718; Filed December 19, 2019; Attorney Docket No. 10055U CIP3 C1 C1 C1; Mailed February 9, 2023,	
		REIP, DAVID O. , "Re-Exam Non-Final Office Action", USSN 90/015,051; Filed June 8, 2022; Reference No. 10055U CIP2 D1; Mailed December 14, 2022,	
EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	02/21/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0700

Receipt date: 02/13/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marcetich
	Attorney Docket Number	10055UCIP2D1C1C1C1C1

OR

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

☐ See attached certification statement.

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

☐ None

SIGNATURE

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

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-02-09
Name/Print	Philip H. Burrus	Registration Number	45,432

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0701

Receipt date: 10/20/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit		3781
	Examiner Name	Adam M Marceitch	
Attorney Docket Number		BPMDL0005JT.P2.D1.C1.C1.C1.C1	

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		3650393		1972-03-21	Reiss, Robert E.	
		4085845		1978-04-25	Perfect, Alan	
U.S.PATENT APPLICATION PUBLICATIONS						
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		20060011506		2006-01-19	Riley, Kimberly	
		20070197998		2007-08-23	Itou, Yasushi	
		20080125722		2008-05-29	Hess, Brian	
		20110284410		2011-11-24	Lockwood, Robert	
		20120267272		2012-10-25	Agrawal, Sony	
FOREIGN PATENT DOCUMENTS						

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0702

Receipt date: 10/20/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

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Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		C. R. Bard, Inc. v. Medline Industries, Inc., 2020-1900, 2020-1905, 2020-1908, 2020-1910 Slip Opinion (Fed. Cir. 2021). Dated August 13, 2021,						
		"Ex Parte Reexamination Request", Reexamination Control No 90/015,051 for Patent No. 9522753; Mailed June 28, 2022; Request and Exhibits 1-28,						
		"Request for Ex Parte Reexamination", Reexam Control No. 90/014,964 for Patent No. 8,448,786; Mailed March 8, 2022; Request and Exhibits 1-35,						
		POON, ROBERT , "Final Office Action", USSN 16/258,231; Filed January 25, 2019; Attorney Docket No. 10055U D1 C2 C1; Mailed October 7, 2021,						
		POON, ROBERT , "Final Office Action", USSN 16/986,803; Filed August 6, 2020; Attorney Docket 1037-001-03US; Mailed July 5, 2022,						

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0703

Receipt date: 10/20/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M Marceitch	
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1	

		POON, ROBERT , "Final Office Action", USSN 17/180,680; Filed February 19, 2021; Attorney Docket No. 1037-002-10US; Mailed September 16, 2022,	
		POON, ROBERT , "Non-Final Office Action", USSN 17/180,680; Attorney Docket No. 1037-002-10US; Mailed December 22, 2021,	
		REIP, DAVID OWEN , "Ex Parte Reexamination Order - Request Granted", Reexam Control No. 90/014,964 for Patent No. 8,448,786; Mailed April 19, 2022,	
		REIP, DAVID OWEN , "Ex Parte Reexamination Order - Request Granted", Reexamination Control No 90/015,051 for Patent No. 9522753; Mailed July 7, 2022,	
		REIP, DAVID OWEN , "Reexam NonFinal Office Action", USSN 90/014,964; Filed February 24, 2022; Attorney Docket 10055U CIP2 48010-28031.00; Mailed September 29, 2022,	
EXAMINER SIGNATURE			
Examiner Signature	/Adam Marcetich/	Date Considered	02/21/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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Bard Exhibit 1004.0704

Receipt date: 10/20/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M Marceitch
	Attorney Docket Number	BPMDL0005JT.P2.D1.C1.C1.C1.C1

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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

CERTIFICATION STATEMENT

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OR

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☐ See attached certification statement.

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

☐ None

SIGNATURE

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

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2022-10-20
Name/Print	Philip H. Burrus	Registration Number	45,432

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0705

Receipt date: 10/20/2022

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Art Unit		3781
	Examiner Name	Adam M Marceitch	
	Attorney Docket Number		BPMDL0005JT.P2.D1.C1.C1.C1.C1

FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0706

PE2E SEARCH - Search History (Prior Art)

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

L214	68	((US-3485352-A OR US-3830035-A OR US- 3780857-A OR US- 3750663-A OR US- 3851649-A OR US- 5447237-A OR US- 4282972-A OR US- 4226328-A OR US- 6691946-B2 OR US- 4170300-A OR US- 4366901-A OR US- 6012586-A OR US- 4811847-A OR US- 4925448-A OR US- 4928830-A OR US- 3978983-A OR US- 6540078-B1 OR US- 4085845-A OR US- 3107786-A OR US- 4523679-A OR US- 5635134-A OR US- 3750664-A OR US- 3998221-A OR US- 3225920-A OR US- 5174306-A OR US- 6142152-A OR US- 3650393-A OR US- 4051845-A OR US- 5072832-A OR US- 9745088-B2 OR US- 11116937-B2).did. AND USPT.dbnm.) OR ((US- 3542019-A OR US- 2734543-A OR US- 3166189-A).did. AND USOC.dbnm.) OR ((US- 20080272023-A1 OR US-20070161971-A1 OR US-20040004019- A1 OR US- 20170216558-A1 OR US-20030038475-A1 OR US-20060009742- A1 OR US- 20060025753-A1 OR US-20030159968-A1 OR US-20060011501- A1 OR US- 20110284410-A1 OR US-20090099531-A1 OR US-20090236259- A1 OR US- 20040055925-A1 OR US-20070026472-A1 OR US-20040076564- A1 OR US-	VN, UA, VN, WO); JPO) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/09/06 12:53 PM
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		20040074593-A1 OR US-20110192115-A1 OR US-20110033137- A1 OR US- 20020185406-A1 OR US-20050022822-A1 OR US-20100186754- A1 OR US- 20060104856-A1 OR US-20020064478-A1 OR US-20100252473- A1 OR US- 20150034521-A1 OR US-20070095699-A1 OR US-20060185326- A1 OR US- 20110214679-A1 OR US-20070225687-A1 OR US-20090152160- A1 OR US- 20060067855-A1 OR US-20050079093-A1 OR US-20200223571- A1).did. AND PGPB.dbnm.) OR ((JP- 2007229520-A).did. AND FTDB.dbnm.)					
L215	14	L214 AND (swab swabstick)	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 12:53 PM
L216	55	L209 AND (tray kit package compartment chamber zone box divider divided division subdivided subdivision) near3 (lubricat\$3 lubricant jelly gel)	(USPAT)	OR	ON	ON	2022/09/06 03:37 PM
L217	278	("10640243" "20040031 721" "20170202699" "2 0170216558" "2017036 8302" "20190344044" " 5289919" "10251812" " 20020000018" "200300 00003" "20030000007" " "200300000015" "20030 038475" "2004000" "20 040000005" "20040000 016" "20040000018" "2 0040000019" "2004000 0023" "20050000002" " 20050000010" "200500 00022" "20050000025" " "20050000028" "20050 241986" "2006000" "20 060000001" "20060000 002" "20060000008" "2 00600000009" "2006000 0018" "20060000026" "	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 03:38 PM

		20060000027 "200600 00264 "20070000002 " "20070000006 "20070 000008 "20070000009 "20070000014 "2007 0000016 "2007000002 0 "20070000022 "200 70000029 "200800000 11 "20080000022 "20 080000024 "20080000 028 "20080000121 "2 0080281254 "2008028 3433 "20090000007 " 20090000015 "200900 00018 "20090000019 " "20090000023 "20090 000031 "20090004055 "20090099531 "2010 0000027 "2010000003 0 "20100000031 "201 00307941 "201003110 26 "20110000010 "20 110000015 "20110000 023 "20110000028 "2 0110000029 "2011023 3079 "20110290260 " 20110290262 "201200 00014 "20120145589 " "20140000011 "26594 85 "2715296 "278161 1 "2886316 "2947415" "2954642 "2959891 " 3013656 "3133635 "3 166189 "3315802 "33 29261 "3379339 "348 5352 "3542019 "3726 281 "3770119 "38516 49 "3901235 "396590 0 "3967728 "3976195" "3978983 "3998221 " 4011944 "4053280 "4 075782 "4140127 "41 60505 "4170300 "422 6328 "4266669 "4269 310 "4282678 "43075 39 "4334537 "445870 5 "4501363 "4523679" "4530349 "4761008 " 4767008 "4795441 "4 811847 "4828113 "48 44259 "4858821 "492 5448 "4928830 "4991 877 "5007535 "50243 26 "5031768 "509462 1 "5163557 "5170804" "5197885 "5232369 " 5242398 "5244394 "5 312287 "5314339 "53					
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		18543 "5324201 "533 9955 "5392918 "5411 437 "5487566 "56659 45 "5713778 "572050 2 "5778574 "5779053" "5795213 "5810738 "5 5820441 "5827262 "5 829790 "5872262 "59 31303 "5941241 "594 7284 "5954369 "5975 295 "6004136 "60125 86 "6068121 "608994 3 "6142152 "6158437" "6159017 "6330427 "6 6361396 "6382212 "6 405863 "6454097 "65 79271 "6659506 "668 1933 "6769546 "6793 078 "6840379 "68961 41 "6915901 "692670 8 "6948742 "7048120" "7066328 "7264869 "7 7278987 "7401703 "7 434687 "7624869 "77 85312 "7789873 "844 8786 "8628549 "8631 935 "8678190 "87089 99 "9084593 "928335 2 "9522753 "9795761" "9808400 "D209641 "D D218077 "D234404 "D D237315 "D237317 "D D242654 "D243798 "D D248871 "D249362 "D D262995 "D268130 "D D275886 "D276462 "D D277508 "D280663 "D D280933 "D280993 "D D283051 "D287760 "D D310896 "D334973 "D D337830 "D343687 "D D351661 "D380272 "D D387177 "D387559 "D D442697 "D450130 "D D450391 "D495491 "D D530920 "D547064 "D D549454 "D557047 "D D561473 "D563673 "D D579662 "D590596 "D D596311 "D609819 "D D612153 "D623765 "D D636894 "D638137 "D D650912 "D662218 "D D688461 "D704856 "D D708347 "D708759 "D D720470 "D720471 "D D742028 "D779082 "D D800337 "D832456").P				
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L218	39	N. L217 AND (lubricat\$3 lubricant jelly gel)	(USPAT)	OR	ON	ON	2022/09/06 03:38 PM
L219	2	(10/888659).APP.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 03:47 PM
L220	79	("20060009742" "20060009742" "7278987" "20090050516" "7657953" "20110225726" "20120103840" "9283352" "9522753" "9693756" "9795761" "9808400" "10106295" "10758705" "10960260" "11116937" "8042689" "8382730" "9011563" "7866471" "8608719" "10029075" "2032593" "2563060" "2783109" "3166189" "3329261" "3532336" "3795015" "3851649" "4160505" "4226328" "4503864" "4595102" "4635913" "4752293" "4811847" "4925448" "5242398" "5339955" "5383411" "5438938" "5586163" "5697921" "5792125" "6012586" "6090075" "6485438" "20030056285" "20050205450" "2032593" "2563060" "2783109" "3166189" "3329261" "3532336" "3795015" "3851649" "4160505" "4226328" "4503864" "4752293" "4595102" "4635913" "4811847" "4925448" "5242398" "5339955" "5383411" "5438938" "5586163" "5697921" "5792125" "6012586" "6090075" "6485438" "20030056285" "20050205450" "8327480" "7657953" "7757317" "7798331" "20090050516" "9522753" "9693756" "9745088" "10512752" "9808596" "10251812" "9808400" "9283352")	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/06 03:49 PM

L221	81	"10624614" "10946992" "9795761" "20180001052" "20180057196" "10946169" "10640243" "20110225726" "10106295" "20120103840" "8584849" "10758705" "10905848" "11116937" "10960260" "20060009742" "7278987" "10449328" "6007521" "8414562" "8317775" "6004305" "20090054876" "20090024111" "8491621" "20210162169").pn. ("5339955" "5441152" "5706991" "5772031" "5791472" "5848693" "6012586" "6089370" "6426041" "20030073155" "20030072686" "6634513" "20040144667" "6783976" "6929926" "20050247585" "20060009742" "6998250" "20060042977" "7008777" "20060096877" "20060118444" "7119689" "20060272979" "20080237084" "7441655" "20090050516" "7660724" "20100270442" "20100311026" "20100307941" "20110017621" "7970722" "20110203957" "8195328" "8448786" "8560460" "8628155" "20140069841" "8678190" "20150021221" "9168107" "9721064" "9795761" "10106295" "20190038829" "20190167375" "10350020" "10466143"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/06 03:54 PM
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		"20200138536" "10758705" "11116937" "435108" "2659485" "2766919" "3133635" "3380573" "3437423" "3489268" "3601277" "3907111" "4153160" "4195734" "4655360" "5005590" "5024326" "5173273" "435108" "2659485" "2766919" "3133635" "3437423" "3380573" "3489268" "3601277" "3907111" "4655360" "4153160" "4195734" "5005590" "5024326" "5173273" "5441152" "5791472" "5772031" "5706991" "5848693" "6012586" "6634513" "6089370" "8005777" "8160988" "7970722" "6426041" "6998250" "6929926" "20030073155" "20030072686" "7008777" "6783976" "20040144667" "6902057" "7123150" "8868434" "8204620" "7126480" "7138918" "8296243" "8195328" "7119689" "7664656" "8355994" "8595021" "8560460" "7660724" "20050247585" "7278987" "20060009742" "20060042977" "8616215" "9168107" "9721064" "20060096877" "8556115" "20060118444" "7441655" "20060272979" "20080237084" "7798331" "20090050516" "9745088" "9693756" "9522753" "7980517" "20110017621" "8453977" "20100270442" "20110203957" "20100307942" "9808400" "9808596" "8631935" "9283352"				
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L222	49	"10512752" "10251812" "8746452" "20140231288" "20140231287" "20100307941" "20100311026" "10640243" "8678190" "8448786" "10624614" "9795761" "10946992" "10946169" "8628155" "10106295" "20140014544" "9179975" "20140069841" "9198811" "10905515" "10111710" "9532847" "20150021221" "10905848" "10758705" "10350020" "10952805" "11284961" "10466143" "20190038829" "10478262" "20190167375" "11116937" "20200138536" "11219499" "5339955" "5353929" "4793483" "7036661" "5511674" "6827212" "7441655" "6896141" "4142632" "5201430" "5617952" "5971920" "5005590" "20060042977" "5848693" "5386908" "5097963" "5271500" "20070039845" "10835339" "5791472" "4321999" "20100270442" "20050205450").pn. AND @Ad<"20110131" ("3601277" "3894649" "3897885" "4013798" "4090275" "4160505" "4304330" "4718555" "5019124" "5335787" "5339955" "5368183" "5511653" "20060113204" "20060157377" "20060172043" "20070062965" "7225927" "20090092738" "20090090648" "20090089993" "20090092719" "20090091059"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/06 04:09 PM
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L223	47	"20090090649" "20090200194" "20090200316" "20090200701" "20090200195" "20090200197" "20100181226" "1595356" "2738915" "3051346" "3197058" "3203573" "3353886" "1595356" "2738915" "3051346" "3203573" "3197058" "3353886" "3897885" "3894649" "4013798" "4090275" "4160505" "4304330" "4718555" "5019124" "5335787" "5339955" "5368183" "5511653" "5887749" "20060113204" "7225927" "20060157377" "20060172043" "20070062965" "7934449" "7736580" "7735651" "20090092719" "20090091059" "20090090649" "20090089993" "8006369" "20090092738" "7802684" "20090090648" "20090200194" "20090200197" "20100181226" "20090200195" "20090200701" "20090200316" "3601277" "3675811" "3366290" "3704779" "3401863" "3807622" "3955672" "3349943" "4787527" "3506154" "3261494" "3720365" "4381847" "4736977" "3146885" "3786932" "4006818" "4278197" "2946621" "3765592" "2509447" "3931888").pn. AND @Ad<"20110131" ("4160505" "4266669" "4479762" "4573576" "4811847" "4936448" "4989733" "5098391"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/06 04:12 PM
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		"5099839" "5454797" "5931303" "6405863" "20030072686" "20030073155" "20030082664" "6783976" "6929926" "20060009742" "6998250" "20060271017" "20070062965" "20080119803" "20090200196" "20090200197" "20090236259" "20120103840" "20130105344" "9283352" "9522753" "9693756" "9795761" "9808400" "10106295" "10758705" "11116937" "11399911" "2319556" "3329261" "3485352" "3601277" "3851649" "2319556" "3329261" "3485352" "3601277" "3851649" "4266669" "4479762" "4573576" "4811847" "5099839" "5356427" "4936448" "5098391" "4989733" "5454797" "5931303" "6405863" "20030082664" "20030073155" "20030072686" "6929926" "6998250" "7008777" "6783976" "20060009742" "7278987" "20080119803" "8852171" "20060271017" "7736348" "7934449" "20070062965" "9745088" "9693756" "9522753" "20090200196" "20090200197" "20090236259" "9283352" "10512752" "9808400" "9808596" "10251812" "10640243" "10624614" "10946992" "10946169" "9795761" "10106295" "20120103840" "8584849" "20130105344"				
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		"10758705" "10905848" "10405938" "11399911" "11116937" "4160505" "4190153" "4976726" "6012586" "5000741" "7665491" "3774609" "3851649" "4917112" "3650267" "3166189" "4988296" "5454797" "5683655" "8753355" "5361781").pn. AND @Ad<"20110131"					
L224	7	L209 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe	(USPAT)	OR	ON	ON	2022/09/06 04:22 PM
L225	2	L207 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe.clm.	(USPAT)	OR	ON	ON	2022/09/07 07:30 AM
L227	2	("3329261").pn.	(USPAT; USOCR)	OR	ON	ON	2022/09/07 07:43 AM
L228	461572	(B65B A61B A61J A61L A61M A61F) .cpcl. AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/09/07 07:45 AM
L229	304	L228 AND (lubricant lubricating gel gell jel jell jelly) near3 syringe	(USPAT)	OR	ON	ON	2022/09/07 07:45 AM
L230	2	(12/763687).APP.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 07:46 AM
L231	5	"9703710".pn.	(FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN, UA, VN, WO); FPRS)	OR	ON	ON	2022/09/07 07:47 AM
L232	5	L207 AND (tubing coil coiled catheter) near3 (opening through hole).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 11:14 AM
L233	0	L207 AND (third further extra) near3 (swab swabstick swabsticks).clm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/09/07 11:16 AM
L234	86	((US-3485352-A OR US-3830035-A OR US- 3780857-A OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2022/09/29 12:39 PM

		3750663-A OR US- 3851649-A OR US- 5447237-A OR US- 4282972-A OR US- 4226328-A OR US- 6691946-B2 OR US- 4170300-A OR US- 4366901-A OR US- 6012586-A OR US- 4811847-A OR US- 4925448-A OR US- 4928830-A OR US- 3978983-A OR US- 6540078-B1 OR US- 4085845-A OR US- 3107786-A OR US- 4523679-A OR US- 5635134-A OR US- 3750664-A OR US- 5072832-A OR US- 3225920-A OR US- 5174306-A OR US- 6142152-A OR US- 3650393-A OR US- 4051845-A OR US- 3998221-A OR US- 9745088-B2 OR US- 9795761-B2 OR US- 7278987-B2 OR US- 5339955-A OR US- 5706991-A OR US- 3601277-A OR US- 5887749-A OR US- 4160505-A OR US- 4503864-A OR US- 5853749-A OR US- 4554156-A OR US- 11116937-B2).did. AND USPT.dbnm.) OR ((US- 3542019-A OR US- 2734543-A OR US- 3166189-A OR US- 3329261-A).did. AND USOC.dbnm.) OR ((US- 20080272023-A1 OR US-20070161971-A1 OR US-20040004019- A1 OR US- 20170216558-A1 OR US-20030038475-A1 OR US-20060009742- A1 OR US- 20060025753-A1 OR US-20030159968-A1 OR US-20060011501- A1 OR US- 20110284410-A1 OR US-20090099531-A1	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
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		OR US-20090236259-A1 OR US-20040055925-A1 OR US-20070026472-A1 OR US-20040076564-A1 OR US-20040074593-A1 OR US-20110192115-A1 OR US-20110033137-A1 OR US-20020185406-A1 OR US-20050022822-A1 OR US-20100186754-A1 OR US-20060104856-A1 OR US-20020064478-A1 OR US-20070225687-A1 OR US-20100252473-A1 OR US-20150034521-A1 OR US-20070095699-A1 OR US-20060185326-A1 OR US-20110214679-A1 OR US-20090152160-A1 OR US-20060067855-A1 OR US-20050079093-A1 OR US-20200223571-A1 OR US-20120103840-A1 OR US-20110225726-A1 OR US-20050205450-A1 OR US-20110017621-A1 OR US-20060096877-A1 OR US-20060042977-A1 OR US-20100272669-A1).did. AND PGPB.dbnm.) OR ((JP-2007229520-A).did. AND FTDB.dbnm.)					
L236	15	(12/495148 12/647515 13/153265 13/153300 13/155026 13/860902 14/793455 15/684787 16/833575).app.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/21 08:19 AM
L239	15	("10512752" "10946169" "10946992" "4411656" "4439184" "9693756" "9745088" "9808596").P N. ("20060011506" "20070197998" "20080125722" "20110284410" "20120267272" "3650393" "4	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/21 10:24 AM

L240	14	085845").PN. L239 AND syringe	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/21 11:39 AM
L242	227	("2699167" "2717598" "2731053" "2935067" "4007740" "2591046" "3881484" "3985122" "4067333" "4188949" "4235235").pn. OR ("4411656" "4439184").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/02/21 04:30 PM
L243	88	L242 AND (lubricant lubricating gel jel jelly friction syringe) AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/02/21 04:30 PM
L244	35	L242 AND (lubricant lubricating gel jel jelly friction) AND syringe AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/02/21 04:30 PM
L245	21525	(lubricant lubricating gel jel jelly friction) SAME syringe AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/02/22 07:39 AM
L246	18927	(lubricant lubricating gel jel jelly) SAME syringe AND @Ad<"20110131"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/02/22 07:39 AM
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PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N213	1097	((lubricant lubricating gel jel jelly friction) SAME syringe).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/02/22 07:41 AM
N214	307	N213 AND (package kit tray assembly assemblage box pan) WITH syringe.clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/02/22 07:41 AM

Bibliographic Data

Application No: 16/833,575

Foreign Priority claimed: ☐ Yes ☒ No

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

Verified and Acknowledged:

/Adam Marcetich/

Examiner's Signature

Initials

Title:

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

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
03/28/2020	604	3781	10055UCIP2D1C1C1C1C1
RULE			

APPLICANTS

Medline Industries, LP, Northfield, IL, UNITED STATES

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Earl Wilson, Ingleside, IL, UNITED STATES

John Kutsch, Harvard, IL, UNITED STATES

CONTINUING DATA

This application is a CON of 15684787 08/23/2017 PAT 10640243

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

14793455 is a CON of 13860902 04/11/2013 PAT 9522753

13860902 is a DIV of 13155026 06/07/2011 PAT 8448786

13155026 is a CIP of 13153265 06/03/2011 PAT 9795761

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

13155026 has PRO of 61437796 01/31/2011

13155026 has PRO of 61428944 12/31/2010

13155026 has PRO of 61352155 06/07/2010

13155026 has PRO of 61352140 06/07/2010

13155026 is a CIP of 12647515 12/27/2009ABN

13155026 is a CIP of 12495148 06/30/2009 PAT 8631935

12495148 has PRO of 61183629 06/03/2009

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

04/07/2020

STATE OR COUNTRY

UNITED STATES

ADDRESS

Philip H. Burrus, IV

Burrus Intellectual Property Law Group LLC (MDL)

222 12th Street NE

Suite 1803

Atlanta, GA 30309

UNITED STATES

FILING FEE RECEIVED

\$1,720

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

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
16833575	28-Mar-2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1C1	5069

TITLE OF INVENTION :

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

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	3781	540000	ADAM MARCETICH
Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
\$1200	\$0	\$1200	24-May-2023	\$0

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

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

2.Entity Status**Change in Entity Status**

Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.

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



Applicant asserting small entity status. See 37 CFR 1.27.

Note: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.



Applicant changing to regular undiscounted fee status.

Note: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.



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

3.The Following Fee(s) Are Submitted:☒ Issue Fee☐ I authorize USPTO to apply my previously paid issue fee to the current fees due☐ Publication Fee☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____☐ Advance Order - # of copies _____

☐ If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number _____.

☐ The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed**NOTE: If no name is listed, no name will be printed**

For printing on the patent front page, list to be displayed as entered

1. Philip H. Burrus, IV

2.

3.

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

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

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

6.Signature

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

Signature	/Philip H. Burrus, IV/	Date	02-28-2023
Name	Philip Henry Burrus	Registration Number	45432

Electronic Patent Application Fee Transmittal				
Application Number:		16833575		
Filing Date:		28-Mar-2020		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		10055UCIP2D1C1C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

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

Electronic Acknowledgement Receipt	
EFS ID:	47607755
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	28-FEB-2023
Filing Date:	28-MAR-2020
Time Stamp:	17:34:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$1200
RAM confirmation Number	E20232RH34445103
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	62304	no	2
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Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	40376	no	2
			ca9f47a37d503d106d6ce3e7b1a1f45793ca688c		
Warnings:					
Information:					
Total Files Size (in bytes):			102680		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
Examiner: Marcetich, Adam M.
Art Group: 3781
Reference No.: BPMDL0005JT CIP2 D1 C1 C1 C1 C1
(10055U CIP2 D1 C1 C1 C1 C1)
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

February 28, 2023

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

AMENDMENT AFTER ALLOWANCE UNDER 37 CFR 1.312

Applicant files this amendment under 37 CFR 1.312 to correct a minor and inadvertent scrivener's error occurring in claim 3 and an antecedent issue arising in claim 10 in view of the Examiner's Amendment made in the Notice of Allowance mailed February 24, 2023. Applicant respectfully submits that the claims remain patentable and require no further search after amendment because these changes are only made to dependent claims, which are allowable as a matter of law for at least the reason that they depend from an allowable claim as noted in the Notice of Allowance mailed February 24, 2023. Applicant respectfully requests entry of the amendment into the file, and further submits the case remains in condition for issuance.

CLAIMS:

Listing of the Claims:

1. (Previously Presented) A medical procedure kit, comprising:
 - a single layer tray comprising a compartment separated by a wall from a lubricating jelly application chamber;
 - a container of lubricating jelly disposed within the single layer tray; and
 - a coiled tubing coupled between a Foley catheter and a drain bag, wherein the coiled tubing, the drain bag, and the Foley catheter are disposed within the medical procedure kit;wherein the lubricating jelly application chamber is configured to receive lubricating jelly from the container of lubricating jelly for lubricating at least a portion of the Foley catheter with the lubricating jelly;
 - the container of lubricating jelly comprising a syringe containing the lubricating jelly; and
 - the syringe situated within the lubricating jelly application chamber.
2. (Previously Presented) The medical procedure kit of claim 1, further comprising one or more swabsticks disposed within the single layer tray.
3. (Currently Amended) The medical procedure kit of claim 1, further comprising a syringe containing water disposed within the single layer tray; ~~wherein the syringe is at least partially disposed in the compartment with the Foley catheter.~~

4. (Previously Presented) The medical procedure kit of claim 3, wherein the syringe containing the lubricating jelly and the syringe containing the water are arranged within the single layer tray in a left-to-right configuration.
5. (Previously Presented) The medical procedure kit of claim 4, wherein the left-to-right configuration comprises a left-to-right usage configuration.
6. (Previously Presented) The medical procedure kit of claim 3, wherein the syringe containing the lubricating jelly and the syringe containing the water are arranged within the single layer tray in accordance with an order with which the syringe containing the lubricating jelly and the syringe containing the water are removed from the single layer tray.
7. (Previously Presented) The medical procedure kit of claim 1, further comprising a second syringe disposed within the single layer tray, wherein the syringe containing the lubricating jelly and the second syringe are arranged within the single layer tray in accordance with an order with which the syringe containing the lubricating jelly and the second syringe are drawn out of the single layer tray.
8. (Original) The medical procedure kit of claim 7, the second syringe at least partially situated in the compartment.
9. (Previously Presented) The medical procedure kit of claim 7, the second syringe is for attachment to the Foley Catheter.
10. (Currently Amended) The medical procedure kit of claim 9, wherein the second syringe contains water ~~comprises sterile water~~.

11. (Previously Presented) The medical procedure kit of claim 7, wherein the syringe and the second syringe are arranged in the single layer tray in accordance with an order of use during a Foley catheterization procedure.
12. (Original) The medical procedure kit of claim 11, the lubricating jelly application chamber comprising one or more contours for accommodating flanges of one or more of the syringe or the second syringe.
13. (Previously Presented) A medical procedure kit, comprising:
 - a first syringe and a second syringe;
 - a medical assembly comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter;
 - a single layer tray comprising a first compartment for receiving the first syringe and the second syringe and a second compartment for receiving at least a portion of the medical assembly, the medical procedure kit allowing passage of at least some of the Foley catheter into a lubricating jelly application chamber; and
 - an outer packaging disposed about the single layer tray;wherein:
 - one of the first syringe or the second syringe contains lubricating jelly;
 - another of the first syringe or the second syringe contains water;
 - the first syringe and the second syringe are ordered within the single layer tray in accordance an order with which they are drawn out of the single layer tray during a Foley catheterization procedure; and

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

14. (Previously Presented) The medical procedure kit of claim 13, wherein the second syringe is attachable to the Foley catheter.

15. (Previously Presented) The medical procedure kit of claim 14, wherein the single layer tray comprises a third compartment containing one or more swabsticks.

16. (Previously Presented) The medical procedure kit of claim 15, wherein a boundary surface defines the lubricating jelly application chamber.

17. (Previously Presented) The medical procedure kit of claim 16, wherein the medical procedure kit allows passage of at least some of the coiled tubing into the lubricating jelly application chamber.

18. (Previously Presented) A medical procedure kit, comprising:

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

wherein:

the lubricating jelly application chamber is configured to receive at least some lubricating jelly from the first syringe for lubricating at least a portion of the Foley catheter with the at least some lubricating jelly

when the at least some lubricating jelly is in the lubricating jelly application chamber; and

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

19. (Previously Presented) The medical procedure kit of claim 18, wherein the one or more swabsticks are disposed within the single layer tray.

20. (Previously Presented) The medical procedure kit of claim 19, further comprising a wall situated between the single compartment and the lubricating jelly application chamber.

REMARKS – General

Claim Amendments:

Claim 3 has been amended to obviate a potential ambiguity. Specifically, the initially overlooked recitation of “the syringe” in the second clause of claim 3 following the comma has been deleted to remove any potential ambiguity in view of the amendment of the limitations of claim 6 into claim 1 made February 13, 2023.

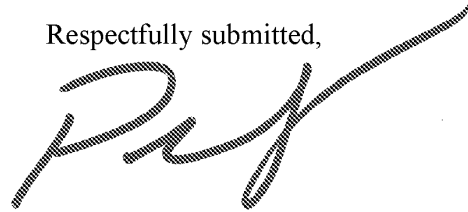
Claim 10 has been amended with support found in claim 9 as previously pending. In the Notice of Allowance mailed February 24, 2023, an Examiner’s Amendment deleted “water” from claim 9, which gave rise to an antecedent issue in claim 10. Accordingly, to obviate this issue, claim 10 has been amended with support found in claim 9 as previously pending.

Since these amendments correct only overlooked scrivener’s errors occurring in the dependent claims, it is respectfully submitted that no additional search or examination is required. This is true because these claims depend from claim 1. As noted in the Notice of Allowance mailed February 24, 2023, claim 1 is allowable. Accordingly, these claims are allowable as well as a matter of law for at least the reason that they depend from at least one allowable claim. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Entry of this paper pursuant to MPEP §714.17 and 37 CFR. 1.312 is respectfully requested as it presents the claims in better form for allowance.

CONCLUSION

For the above reasons, Applicant believes the specification and claims are now in proper form, and that the claims all define patentably over the prior art. Applicant believes this application is now in condition for allowance, for which it respectfully submits.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Burrus, IV', with a long, sweeping horizontal stroke extending to the right.

Philip H. Burrus, IV

Attorney for Applicant

Registration No.: 45,432

404-797-8111

404-880-9912 (fax)

pburrus@burrusiplaw.com

Electronic Acknowledgement Receipt	
EFS ID:	47607608
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	28-FEB-2023
Filing Date:	28-MAR-2020
Time Stamp:	17:29:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10055U_CIP2_D1_C1_C1_C1_C1_C1_C1_USA_2023-2-28_AmendAfter Allowance_R2.pdf	224272	yes	8
			ad1548c775f8c65cb4243df938b6bad683f4a69		

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Amendment after Notice of Allowance (Rule 312)	1	1	
Claims	2	6	
Applicant Arguments/Remarks Made in an Amendment	7	8	

Warnings:

Information:

Total Files Size (in bytes):	224272
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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

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



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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1	5069
189038	7590	03/14/2023	EXAMINER	
Philip H. Burrus, IV			MARCETICH, ADAM M	
Burrus Intellectual Property Law Group LLC (MDL)				
222 12th Street NE			ART UNIT	PAPER NUMBER
Suite 1803			3781	
Atlanta, GA 30309			NOTIFICATION DATE	DELIVERY MODE
			03/14/2023	ELECTRONIC

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

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

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

BIPLaw_docketing@burrusiplaw.com
pburrus@burrusiplaw.com

Receipt date: 03/28/2020

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Change(s) applied
to document,
/P.H./
3/3/2023

		D310896		~~2016-09-25~~ 09/1990	Winjum, Jack	
		9522753		2016-12-20	Tomes et al.	
		D779082		2017-02-14	Andre et al.	
		D800337		2017-10-17	Daines, Eric	
		9795761		2017-10-24	Lockwood et al.	
		9808400		2017-11-07	Tomes et al.	
		10251812		2019-04-09	Tomes et al.	

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2002/018 5406		2002-12-12	Massengale, Roger	
		2003/003 1995		2003-02-13	Laura, Abbey	
		2003/003 8475		2003-02-27	Stancil, Michelle	
		2003/007 5474		2003-04-24	Moyer et al.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0745

Receipt date: 03/28/2020

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Change(s) applied
to document,
/P.H./
3/3/2023

		7066328		2006-06-27	Janice Pulsifer	
		D530920		2006-10-31	Snell, Russell	
		D547064		2007-07-24	Snell, Russell	
		D549454		2007-08-28	~~Ahman~~ ~~ANG-hman, Daniel~~	
		7264869		2007-09-04	Tobita	
		7278987		2007-10-09	Solazzo, Anthony	
		D557047		2007-12-11	Dretzka, Philip	
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		D563673		2008-03-11	Dretzka, Philip	
		7401703		2008-07-22	McMichael, Donald J.	
		7434687		2008-10-14	Itou et al.	
		D579662		2008-11-04	Dretzka, Philip	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0746

Receipt date: 03/28/2020

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

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

Change(s) applied
to document.
/P.H./
3/3/2023

		5487566		1996-01-30	Hedge, Jr., J. R.	
		5779053		~~1997-06-24~~ 07/1998	Partika	
		D380272		1997-06-24	Partika et al.	
		5665945		1997-09-09	Oshima, Mikio	
		D387177		1997-12-02	Davis, Mark S.	
		D387559		1997-12-16	Williamson, Edward	
		5713778		1998-02-03	Rodeosevich et al.	
		5720502		1998-02-24	Cain, John R.	
		5778574		1998-07-14	Reuben, Ronnie	
		5795213		1998-08-18	Goodwin, Richard P.	
		5810738		1998-09-22	Thomas II, Donald D.	
		5820441		1998-10-13	Pracas, Victor	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0747

Receipt date: 03/28/2020

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
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	Art Unit		
	Examiner Name		
	Attorney Docket Number		10055U CIP2 D1 C1 C1 C1 C1

Change(s) applied
to document,
/P.H./
3/3/2023

		D249362		1978-09-12	Forsman et al.	
		4140127		1979-02-20	Ciani et al.	
		4160505		1979-07-10	Rauschenberger, Richard	
		4170300		1979-10-09	Pick, Ernest	
		4053280		~~1979-10-11~~ 10/1977	Salisbury, Thomas	
		4226328		1980-10-07	Beddow	
		4266669		1981- 05-12	Watson	
		4269310		1981- 05-26	Uson, Aurelio	
		4282678		1981-08-11	Tsui, Kwok	
		4307539		1981-12-29	Klein, Claus-Dieter	
		D262995		1982-02-09	Gaba et al.	
		4334537		1982-06-15	Peterson, James	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0748



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	04/11/2023	11623774	10055UCIP2D1C1C1C1	5069

189038 7590 03/22/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 421 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

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

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

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

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

Medline Industries, LP, Northfield, IL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Electronic Patent Application Fee Transmittal				
Application Number:		16833575		
Filing Date:		28-Mar-2020		
Title of Invention:		Catheter Tray, Packaging System, Instruction Insert, and Associated Methods		
First Named Inventor/Applicant Name:		Jennifer E. Tomes		
Filer:		Philip Henry Burrus/Kayla Burrus		
Attorney Docket Number:		10055UCIP2D1C1C1C1C1		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
PETITION FEE- 37 CFR 1.17(H) (GROUP III)	1464	1	140	140
RCE- 1ST REQUEST	1801	1	1360	1360
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

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



UNITED STATES PATENT AND TRADEMARK OFFICE

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

Decision Date : April 6, 2023

In re Application of :

Jennifer E. Tomes

DECISION ON PETITION

UNDER CFR 1.313(c)(2)

Application No : 16833575

Filed : 28-Mar-2020

Attorney Docket No : 10055UCIP2D1C1C1C1C1

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

The petition is **GRANTED**.

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

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

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

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

Office of Petitions

Electronic Acknowledgement Receipt	
EFS ID:	47803398
Application Number:	16833575
International Application Number:	
Confirmation Number:	5069
Title of Invention:	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
First Named Inventor/Applicant Name:	Jennifer E. Tomes
Customer Number:	189038
Filer:	Philip Henry Burrus/Kayla Burrus
Filer Authorized By:	Philip Henry Burrus
Attorney Docket Number:	10055UCIP2D1C1C1C1C1
Receipt Date:	06-APR-2023
Filing Date:	28-MAR-2020
Time Stamp:	14:45:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$1500
RAM confirmation Number	E202346E45269331
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	ePetition Request Form	petition-request.pdf	39818	no	2
			3911a74db1e07c4196934f7b92658eb4122ee430		
Warnings:					
Information:					
2	Quick Path Information Disclosure Statement	10055U_CIP2D1C1C1C1C1_USA_2023-4-6_QPIDSReq.pdf	173834	no	2
			39b7ede7c590fa7a176d5b7b320baedcbac91dea		
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	10055U_CIP2D1C1C1C1C1_USA_2023-4-6_IDS.pdf	192585	no	3
			3b42c77f2e99fde01acb95e609e374e34c54d91		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Non Patent Literature	10055U_CIP2_D1_USA_2023-4-4_ReExamFinalOA.pdf	1009043	no	14
			6b217249c6fd0167dcc30808b5dbed09cfd70a19		
Warnings:					
Information:					
5	Non Patent Literature	10055U_CIP2_USA_2023-3-21_NoticeIntent_IssueReexamCertificate.pdf	382839	no	6
			07a5f6bf3e161b973ca6289bac64961932f0518e		
Warnings:					
Information:					
6	Request for Continued Examination (RCE)	10055U_CIP2_D1_C1C1C1C1_USA_2023-4-6_RCE.pdf	1349909	no	3
			7441eac70e7e2a74a400362d1547b220efd6f454		
Warnings:					

Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	40484	no	2
			6c544613327eac4b3e33288ed5c82ff40818dc3		
Warnings:					
Information:					
Total Files Size (in bytes):			3188512		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Doc Code: PET.AUTO Document Description: Petition automatically granted by EFS-Web		PTO/SB/140 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	PETITION TO WITHDRAW AN APPLICATION FROM ISSUE AFTER PAYMENT OF THE ISSUE FEE UNDER 37 CFR 1.313(c)	
Application Number	16833575	
Filing Date	28-Mar-2020	
First Named Inventor	Jennifer Tomes	
Art Unit	3781	
Examiner Name	ADAM MARCETICH	
Attorney Docket Number	10055UCIP2D1C1C1C1	
Title	Catheter Tray, Packaging System, Instruction Insert, and Associated Methods	
An application may be withdrawn from issue for further action upon petition by the applicant. To request that the Office withdraw an application from issue, applicant must file a petition under this section including the fee set forth in § 1.17(h) and a showing of good and sufficient reasons why withdrawal of the application from issue is necessary. APPLICANT HEREBY PETITIONS TO WITHDRAW THIS APPLICATION FROM ISSUE UNDER 37 CFR 1.313(c). A grantable petition requires the following items: (1) Petition fee; and (2) One of the following reasons: (a) Unpatentability of one or more claims, which must be accompanied by an unequivocal statement that one or more claims are unpatentable, an amendment to such claim or claims, and an explanation as to how the amendment causes such claim or claims to be patentable; (b) Consideration of a request for continued examination in compliance with § 1.114 (for a utility or plant application only); or (c) Express abandonment of the application. Such express abandonment may be in favor of a continuing application, but not a CPA under 37 CFR 1.53(d).		
Petition Fee		
☐ Small Entity		
☐ Micro Entity		
☒ Regular Undiscounted		
Reason for withdrawal from issue		

CERTIFICATION AND REQUEST FOR CONSIDERATION OF AN INFORMATION DISCLOSURE STATEMENT FILED AFTER PAYMENT OF THE ISSUE FEE UNDER THE QPIDS PROGRAM	
Non-Provisional Application Number: 16833575	Filing Date: 2020-03-28
First Named Inventor: Jennifer E. Tomes	Title of Invention: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods
THE UNDERSIGNED HEREBY CERTIFIES AND REQUESTS THE FOLLOWING FOR THE ABOVE-IDENTIFIED APPLICATION. 1. Consideration is requested of the information disclosure statement (IDS) submitted herewith, which is being filed after payment of the issue fee. 2. Check the box next to the appropriate selection: ☐ Each item of information contained in the IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(1). OR ☒ No item of information contained in the IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the IDS. See 37 CFR 1.97(e)(2). OR ☐ See attached certification statement in compliance with 37 CFR 1.97(e). 3. Please charge the IDS fee set forth in 37 CFR 1.17(p) to Deposit Account No. <u>503608</u>. 4. A Petition to Withdraw from Issue After Payment of the Issue Fee (37 CFR 1.313(c)(2)), including the petition fee set forth in 37 CFR 1.17(h), is submitted herewith as a Web-based ePetition. WARNING: Do <u>not</u> submit the petition as a follow-on paper via EFS-Web. Submit the petition as a Web-based ePetition by signing on to EFS-Web as a registered user, selecting the radio button next to "Existing application/patent," and then selecting the radio button next to "ePetition (for automatic processing and immediate grant, if all petitions requirements are met)." Failure to use the Web-based ePetition interface will result in automatic entry of the RCE. 5. A request for continued examination (RCE) under 37 CFR 1.114 and the RCE fee under 37 CFR 1.17(e) are submitted herewith. 6. The RCE will be treated as a "conditional" RCE. In the event the examiner determines that any item of information contained in the IDS necessitates the reopening of prosecution in the application, the undersigned understands that (i) the RCE will be processed and treated as an RCE under 37 CFR 1.114 and therefore (ii) the IDS fee under 37 CFR 1.17(p) will be returned in accordance with 37 CFR 1.97(b)(4). In the event that no item of information in the IDS necessitates reopening prosecution, the undersigned understands that the RCE will not be processed and the RCE fee under 37 CFR 1.17(e) will be returned. 7. This certification and request is being filed as a Web-based ePetition and is not accompanied by an amendment to the application. Inclusion of an amendment will result in automatic entry of the RCE.	
Signature /Philip H. Burrus, IV/	Date 2023-04-06
Name (Print/Typed) Philip H. Burrus, IV	Practitioner Registration Number (if applicable) 45432
Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.*	
☐ *Total of _____ forms are submitted.	

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M. Marcetich	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023						
		REIP, DAVID O. , "ReExamination Final Office Action", USSN 90/015,051; Filed June 8, 2022; Patent Under Reexam 9522753; Mailed April 4, 2023						
EXAMINER SIGNATURE								

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M. Marcetich	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1	

Examiner Signature		Date Considered	
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT			
Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):			
☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (1).			
OR			
☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e) (2).			
☐ See attached certification statement.			
☒ The Director is hereby authorized to charge the fee set forth in 37 CFR 1.17 (p) to Deposit Account No. 50-3608. Additionally, the Director is hereby authorized to charge any underpayment of fees to Deposit Account No. 50-3608.			
☐ None			
SIGNATURE			
A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.			
Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-04-06
Name/Print	Philip H. Burrus	Registration Number	45,432

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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



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I20234B810235711	1806	SUBMISSION- INFORMATION DISCLOSURE STMT	\$260.00	Deposit Account



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	03/28/2020	Jennifer E. Tomes	10055UCIP2D1C1C1C1	5069
189038	7590	04/14/2023	EXAMINER	
Philip H. Burrus, IV			MARCETICH, ADAM M	
Burrus Intellectual Property Law Group LLC (MDL)				
222 12th Street NE			ART UNIT	PAPER NUMBER
Suite 1803			3781	
Atlanta, GA 30309			NOTIFICATION DATE	DELIVERY MODE
			04/14/2023	ELECTRONIC

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

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

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

BIPLaw_docketing@burrusiplaw.com
pburrus@burrusiplaw.com

Corrected Notice of Allowability	Application No. 16/833,575	Applicant(s) Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	AIA (FITF) Status No

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

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

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

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

3. ☒ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
 a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 * Certified copies not received: _____.

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

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

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

Attachment(s)

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

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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EXAMINER'S COMMENT / AMENDMENT / REASONS FOR ALLOWANCE

Notice of Pre-AIA or AIA Status

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

Continued Examination Under 37 CFR 1.114

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

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

Examiner's Comment

The rejection of claim 14 under 35 USC § 112 is withdrawn in view of the amendments filed 13 February 2023.

Terminal Disclaimer

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

- Tomes; Jennifer E. et al. (US 9745088 B2)
- Tomes; Jennifer E. et al. (US 9522753 B2)
- Tomes; Jennifer E. et al. (US 10251812 B2)

- Tomes; Jennifer E. et al. (US 9808400 B2)
- Tomes; Jennifer E. et al. (US 9808596 B2)
- Tomes; Jennifer E. et al. (US 9283352 B2)
- Tomes; Jennifer E. et al. (US 10946992 B2)
- Tomes; Jennifer E. et al. (US 10640243 B2)

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

Examiner's Amendment

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

Claims 5, 6 and 9 are amended as follows. **[[Deletions are in double brackets]]** and **additions are underlined**. Ellipsis ... designates unchanged portions of claims which have been omitted for brevity.

Claim 5 (amended in part) "The medical procedure kit of claim 4, wherein **the** left-to-right configuration comprises ..."

Claim 6 (amended in part) "... in accordance with an order with which **[[they]]** **the** syringe containing the lubricating jelly ..."

Claim 9 (amended in part) "The medical procedure kit of claim 7, the second syringe **[[containing water]]** is for attachment to the Foley Catheter."

Allowable Claims

Claims 1-20 are allowed.

Reasons for Allowance

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

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

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

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

However, none of these references teaches or suggests a medical procedure kit comprising a single layer tray having first and second compartments containing first and second syringes and a Foley catheter. **Wheeler and Serany** were discussed in the Notice of Allowance mailed 24 February 2023.

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

However, Pilger lacks multiple compartments and at most discloses posts, supports or grooves that accommodate various accessories (col. 2, lines 40-45,

Extending upwardly from bottom 2 are a series of posts 5, 6 and 7 which are near but spaced from the side wall 3; col. 2, lines 50-55, a series of posts 5, 11 and 12; col. 2, lines 60-70, the syringe which is filled with sterile liquid is confined between posts 6, 11, 12 and 16 in the dish portion. A ledge section 17 abuts a plunger 18 of the hypodermic syringe).

The posts do not divide the tray into compartments but instead extend as islands or pegs within a single compartment of the tray (Figs. 1-5). Since Pilger's tray lacks separate compartments, it also lacks a lubricating jelly application chamber.

Pilger also fails to disclose a syringe containing lubricating jelly and instead stores lubricant in a packet (col. 2, lines 50-55, lubricant packet 9).

McMichael discloses a tray having a plurality of compartments (§ [0024] The PEG kit 20 may include a tray 22 having a plurality of planar surfaces and a plurality of recesses; § [0033], the tray 22 may include a first planar surface 64. Several recesses are disposed in surface 64, including two recesses 76 that may be used to hold or support coiled articles and a needle recess 81; § [0034] The first surface 64 may also include a recess 103 that may be configured to have elongated portions 104 and 105; § [0038] A recess 110 may also be provided in the second planar surface 66, the recess 110 being adapted to hold an exterior tube retention device 110A).

However, the tray is not configured to hold a coiled tubing coupled between a fluid drain bag and a Foley catheter, and instead holds supplies for a percutaneous endoscopic gastrostomy (§ [0005], [0023]). McMichael suggests that the tray may be used for other procedures (§ [0023], the invention is not limited to a PEG kit or any other

particular type of kit). However, McMichael does not disclose any elements from another type of kit, and does not list any examples of alternate applications. McMichael does not configure any of the compartments as a lubricating jelly application chamber.

Applicant's arguments filed 13 February 2023 regarding **Solazzo; Anthony (US 20060009742 A1)**, **Serany; Frank J. Jr. et al. (US 3329261 A)** and **Fischer; Herbert et al. (US 4554156 A)** have been considered and are persuasive. Examiner advances additional reasons for allowance.

Solazzo, the closest art of record, lacks a syringe containing lubricating jelly wherein the syringe is situated within the lubricating jelly application chamber. Instead, Solazzo describes a pair of lubricating jelly application chambers which are too shallow to accommodate a container or a syringe of lubricating jelly. Figs. 4 and 5 show side views of lubricating wells 31 and 33 which lack sufficient depth to hold a container or syringe (¶ [0040] Optional Foley catheter lubricating wells 31 and 33). To properly accommodate the size of a lubricating jelly container and a water-filled syringe, Solazzo places these two items in larger compartments separate from the two lubricating jelly application chambers. The lubricant fluid 140 is placed in back 13 of recessed area 3, and the inflation syringe 10 is placed in compartment 27 (Figs. 1 and 8).

Also of record, **Serany** lacks a single layer tray having a syringe containing lubricating jelly situated in a lubricating jelly application chamber. Instead, Serany discloses a multi-level tray having separate parts (col. 1, lines 60-65, a box 10 having an open top with a tray 12 mounted thereon); and

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

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

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

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

Finegold; Aaron N. (US 4460360 A) discloses an instrument and method of applying a local anesthetic to the urethra including a syringe containing a lubricant (col. 3, lines 20-25, The syringe body 12 contains a suitable anesthetic, such as a lidocaine hydrochloride solution or jelly). However, Finegold does not package the syringe in a tray and at most describes a freestanding syringe configured to deliver the lubricant

through a lumen of a catheter (col. 3, lines 20-40, The barrel 28 is inserted into the anterior urethra 48 ... the anesthetic is applied to the interior walls of first the posterior urethra 46 and then the anterior urethra 48).

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Tel 571-272-2590
Fax 571-273-2590
Email Adam.Marcetich@uspto.gov

The Examiner can be reached 8am-4pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sarah Al-Hashimi can be reached at 571-272-7159. The fax phone number for the organization where this application is assigned is 571-273-8300.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>.

Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Primary Examiner, Art Unit 3781

Issue Classification 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	

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

CPC Combination Sets					
Symbol	Type	Set	Ranking	Version	
/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	11 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

Issue Classification 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.	
	Examiner Adam M Marcetich	Art Unit 3781	

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

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781	11 April 2023	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	7

Issue Classification 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

☒ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 20	
/Adam Marcetich/ Primary Examiner, Art Unit 3781 (Primary Examiner) _____ (Date) 11 April 2023		O.G. Print Claim(s) 1	O.G. Print Figure 7

<i>Search Notes</i> 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61B50/30, A61B50/33, A61M25/00, A61M25/002, A61B2050/3008, A61J2205/50, A61M5/002, A61M25/0017, A61M2209/06	09/06/2022	AMM
B65B11/00, A61L2202/18, A61L2202/182	09/06/2022	AMM
update search	02/21/2023	AMM

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Inventor search in US-PGPUB, USPAT	09/06/2022	AMM
Review cited art for related cases 12495148, 12647515, 13153265, 13153300, 13155026, 13860902, 14793455, 15684787	09/06/2022	AMM
Review Inter Partes Review cases IPR2015-00509, IPR2015-00511, IPR2015-00513, IPR2019-00035, IPR2019-00036, IPR2019-00109	09/06/2022	AMM
update search	02/21/2023	AMM
update search	04/11/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 16/833,575	Applicant(s)/Patent Under Reexamination Tomes et al.
	Examiner Adam M Marcetich	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	claim keyword search	02/21/2023	AMM

/Adam Marcetich/ Primary Examiner, Art Unit 3781	
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Receipt date: 04/06/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16/833,575
	Filing Date		Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes	
	Art Unit	3781	
	Examiner Name	Adam M. Marcetich	
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1	

U.S.PATENTS								
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
U.S.PATENT APPLICATION PUBLICATIONS								
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
FOREIGN PATENT DOCUMENTS								
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
NON-PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						T ⁵
		REIP, DAVID O. , "Notice of Intent to Issue Ex Parte Reexam Certificate", USSN 90/014,964; Patent Under Reexam 8448786; Mailed March 21, 2023						
		REIP, DAVID O. , "ReExamination Final Office Action", USSN 90/015,051; Filed June 8, 2022; Patent Under Reexam 9522753; Mailed April 4, 2023						
EXAMINER SIGNATURE								

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0779

Receipt date: 04/06/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

Examiner Signature	/Adam Marcetich/	Date Considered	04/10/2023
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.			

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ None

SIGNATURE

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

Signature	/Philip H. Burrus, IV/	Date (YYYY-MM-DD)	2023-04-06
Name/Print	Philip H. Burrus	Registration Number	45,432

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0780

Receipt date: 04/06/2023

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Field

PTO/SB/08a (01-10)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16/833,575
	Filing Date	Mar 28, 2020
	First Named Inventor	Jennifer E. Tomes
	Art Unit	3781
	Examiner Name	Adam M. Marcetich
	Attorney Docket Number	10055U CIP2 D1 C1 C1 C1 C1

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMM/

Bard Exhibit 1004.0781



United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :Simret Direta

Refund Accounting Date:04/18/2023

Effective Date	Sale Item Reference Number	Refund Total
04/06/2023	16833575	\$1,360.00

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method	Account Number
I20234H026258012	1801	RCE- 1ST REQUEST	\$1,360.00		*****3000



United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :Simret Direta

Sale Adjustment Accounting Date:04/18/2023

Effective Date	Sale Accounting Date	Sale Item Reference Number
04/06/2023	04/18/2023	16833575

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I20234H026258012	1801	RCE- 1ST REQUEST	\$1,360.00	



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/833,575	05/30/2023	11661219	10055UCIP2D1C1C1C1	5069

189038 7590 05/10/2023
Philip H. Burrus, IV
Burrus Intellectual Property Law Group LLC (MDL)
222 12th Street NE
Suite 1803
Atlanta, GA 30309

ISSUE NOTIFICATION

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

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

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment is 433 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

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

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

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

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

Medline Industries, LP, Northfield, IL;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	ISSUE DATE	PATENT NO.
16/833,575	30-MAY-23	11661219

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

EGRANT NOTIFICATION

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

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



UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC PAYMENT RECEIPT

APPLICATION #
16/833,575

RECEIPT DATE / TIME
12/01/2023 05:02:09 PM Z ET

ATTORNEY DOCKET #
10055UCIP2D1C1C1C1C1

Title of Invention

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

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # 11661219

CONFIRMATION # 5069

FILED BY Kayla Burrus

PATENT CENTER # 63448084

AUTHORIZED BY Phillip Burrus

CUSTOMER # 189038

FILING DATE 03/28/2020

CORRESPONDENCE
ADDRESS -

FIRST NAMED
INVENTOR Jennifer E. Tomes

Payment Information

PAYMENT METHOD
CARD / 3000

PAYMENT TRANSACTION ID
E2023B1H03255114

PAYMENT AUTHORIZED BY
Kayla Burrus

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

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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



UNITED STATES
PATENT AND TRADEMARK OFFICE

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

ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #
16/833,575

RECEIPT DATE / TIME
12/01/2023 05:02:09 PM Z ET

ATTORNEY DOCKET #
10055UCIP2D1C1C1C1C1

Title of Invention

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

Application Information

APPLICATION TYPE Utility - Nonprovisional Application
under 35 USC 111(a)

PATENT # 11661219

CONFIRMATION # 5069

FILED BY Kayla Burrus

PATENT CENTER # 63448084

FILING DATE 03/28/2020

CUSTOMER # 189038

FIRST NAMED INVENTOR Jennifer E. Tomes

CORRESPONDENCE ADDRESS -

AUTHORIZED BY Philip Burrus

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
10055U_CIP2_D1C1C1C1C1__USA_2023-11-30_Petition.pdf	17	Petition for review by the Technology Center Special Program Examiner(SPRE)	1560 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
10055U_CIP2_D1C1C1C1C1__USA_2023-11-30_Petition.pdf	DD514F3D6C37026EF4C42FB77A6F731269D248B69AAC225F78EE70AF0C3FD4F86ABCF5FE945D5618E478084A7515772D20FA89A103AEE1374D27E682BEF591CA

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

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

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U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

August 30, 2023

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

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

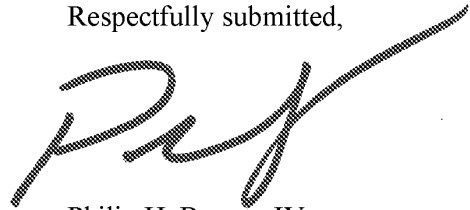
This Petition is filed under 37 CFR §1.324 to correct inventorship of US Patent No. 11,661,219. The Petition is being submitted concurrently with affidavits of the named inventors, and inventors petitioning to be named, and the assignee of record. The Petition Fee is enclosed herewith. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-3608.

Statement of Facts and Request for Relief:

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

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

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Burrus, IV', with a long, sweeping horizontal stroke extending to the right.

Philip H. Burrus, IV

Attorney for Applicant

Registration No.: 45,432

404-797-8111

404-880-9912 (fax)

pburrus@burrusiplaw.com

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16,833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

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

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

I, David S. Noskowicz, declare as follows:

1. I am Patent Counsel for Medline Industries, LP, assignee of one hundred percent (100%) interest in the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I am authorized to sign declarations on behalf of Medline Industries, LP.
3. Medline Industries, LP, is the assignee of the patent by way of an assignment from inventors Jennifer E. Tomes and Sarah Dickinson (formally Sarah Zybert), which was recorded in the Patent Office at Reel 026750, beginning at Frame 0103 on August 15, 2011, and further by way of another assignment from Deborah Adler, Jack Maze, Alberto Savage, Earl Wilson, John Kutsch, and Kenneth S. Chua to Medline Industries, Inc., which was recorded in the

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

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

David Noskowitz

David S. Noskowitz

DATE: 09/20/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

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

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

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

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Jennifer E. Tomes

DATE: 09/27/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

AFFIDAVIT OF SARAH DICKINSON, PURSUANT TO 37 CFR §1.324

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

I, Sarah Dickinson, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Sarah Dickinson

Sarah Dickinson

DATE: 09/19/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

AFFIDAVIT OF DEBORAH ADLER, PURSUANT TO 37 CFR §1.324

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

I, Deborah Adler, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Deborah Adler

DATE: 11/29/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

AFFIDAVIT OF JACK MAZE, PURSUANT TO 37 CFR §1.324

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

I, Jack Maze, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.

Jack E Maze

Jack Maze

DATE: 09/26/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

AFFIDAVIT OF ALBERTO SAVAGE, PURSUANT TO 37 CFR §1.324

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

I, Alberto Savage, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Alberto Savage

DATE: 09/19/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

AFFIDAVIT OF KENNETH CHUA, PURSUANT TO 37 CFR §1.324

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

I, Kenneth Chua, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Kenneth Chua

DATE: 09/29/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

AFFIDAVIT OF EARL WILSON, PURSUANT TO 37 CFR §1.324

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

I, Earl Wilson, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



Earl Wilson

DATE: November 17, 2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

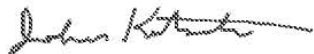
Title: Catheter Tray, Packaging System, Instruction Insert, and Associated Methods

AFFIDAVIT OF JOHN KUTSCH, PURSUANT TO 37 CFR §1.324

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

I, John Kutsch, hereby declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I understand that Susan E. Macinnes is filing a Petition to be added as an inventor to this patent.
3. I have no disagreement with, and do not object to, these requested changes.
4. The undersigned, being warned that willful false statements are punishable under 18 USC §1001, and that willful false statements may jeopardize the validity of the application or any registration stemming therefrom, declares that all statements made herein are true, and all statements made on information and belief are believed to be true.



John Kutsch

DATE: 09/21/2023

U.S.S.N. 16/833,575

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 16/833,575
US Pat. No.: 11,661,219
Examiner: Marcetich, Adam M
Art Group: 3781
Reference No.: 10055U CIP2 D1 C1 C1 C1 C1
Appn. Filed: March 28, 2020
First Inventor: Tomes, Jennifer E.

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

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

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

I, Susan E. Macinnes, declare as follows:

1. I am an inventor on the above-identified US Patent Application, which has now issued as US Patent No. 11,661,219.
2. I was not listed as an inventor with the application was filed.
3. I am now hereby petitioning to be added as a named inventor to the issued patent.
4. The inventorship error of failing to include me as an inventor of the patent occurred without any deceptive intention on the part of me, Susan E. Macinnes.

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

Susan E. Macinnes

Susan E. Macinnes

DATE: 09/18/2023

**COMBINATION DECLARATION AND ASSIGNMENT
FOR UTILITY AND DESIGN APPLICATIONS**

United States Patent Rights Plus
All Foreign Rights

INVENTION TITLE:

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

DECLARATION UNDER 37 CFR §1.63:

As a below named inventor, I hereby declare that:

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

United States Application Number 16/833,575, now US Pat. No. 11,661,219;

Which was filed on March 28, 2020.

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

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

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

ASSIGNMENT OF RIGHTS AND AGREEMENT:

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

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

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

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

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

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

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

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

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

Customer No.: 189038

PATENT
Atty. Docket No.: 10055U CIP2 D1 C1 C1 C1 C1

IN WITNESS WHEREOF, I have hereunto set my hand and seal on
09/18/2023.

Susan E. MacInnes

Name: Susan E. Macinnes