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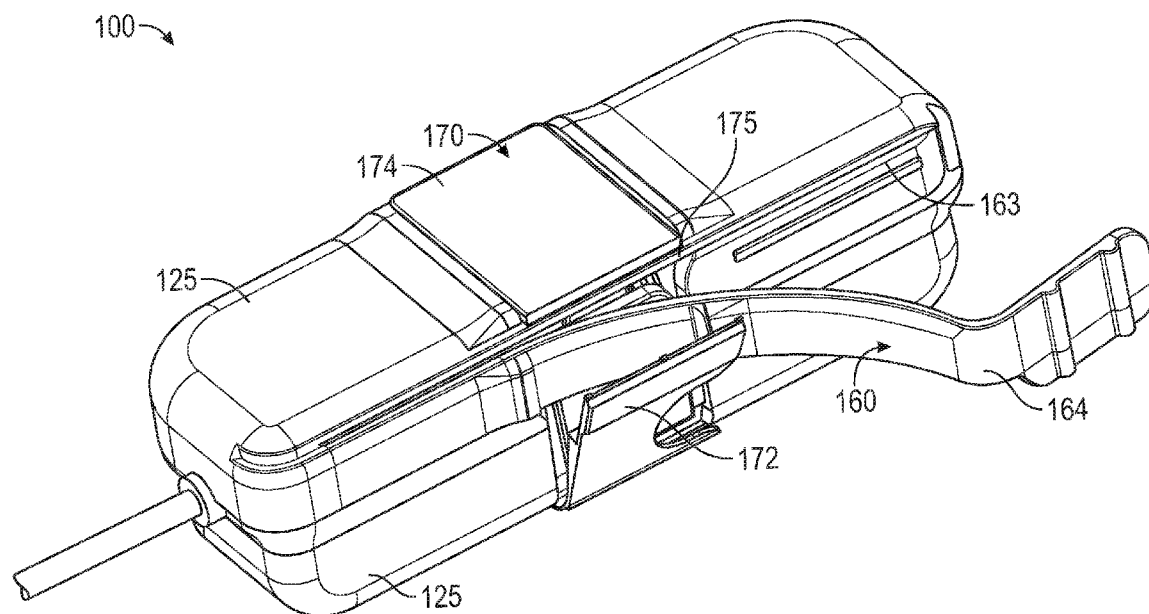


FIG. 8

(57) Abstract: The disclosed tamper-evident closure encloses a medical access device, such as a vascular access device. The tamper-evident closure has a holding cavity formed from a first part and a second part, a closure mechanism holding together the first part and second part around a perimeter of the first part and second part. A wall guard extends from one of the first part or second part into the holding cavity adjacent the tab to block attempted entry into the holding cavity.



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TAMPER-EVIDENT CLOSURE WITH AN INTERNAL WALL GUARD

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Technical Field

The present disclosure relates to a tamper-evident closure. In particular, the present disclosure relates to a tamper-evident closure for medical access devices, such as intravenous access points, with an internal wall guard.

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Background

Patients receiving medical care will commonly have a medical access device, such as a vascular access device, inserted to assist the healthcare provider in delivering medications to the patient. Some medical access devices are for allowing fluids to be removed from a patient, like a urinary catheter or a surgical drain line. When a person is under the care of a healthcare provider it is important to control the medications that are delivered to the patient. Patients with psychiatric conditions, intellectually delayed patients, pediatric patients, or intravenous drug users may tamper with intravenous access points or intentionally deliver drugs or medications to the vascular access device. Unprescribed drugs entering the vascular access device can cause medical problems, drug interactions, blood stream infections.

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Summary

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The disclosed tamper-evident closure encloses a medical access device, such as a vascular access device. The tamper-evident closure has a holding cavity formed from a first part and a second part, a closure mechanism holding together the first part and second part around a perimeter of the first part and second part. The closure mechanism comprises a tear strip and a tab. A wall guard extends from one of the first part or second part into the holding cavity adjacent the tab to block attempted entry into the holding cavity.

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In one embodiment, at the closure mechanism there is a gap in the tear strip between the first part and second part into the holding cavity, and wherein the wall guard extends into the holding body cavity to coincide with the gap. In one embodiment, the wall guard has a depth which is the distance the wall guard extending from the second part in to holding cavity, wherein the depth of the wall guard is the same as or greater than the gap. In one embodiment, the closure mechanism extends around substantially the entire perimeter of the first part and second part and where in the tab covers the gap. In one embodiment, the tab is spaced a distance from the first or second part. In one embodiment, the wall guard linearly extends along a portion tear strip.

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In one embodiment, the tamper-evident closure further comprising a securing strap secured to the holding cavity, wherein the securing strap comprises a first securing strap portion secured to the first part, a second securing strap portion with a free end for removably securing to the second part, and an area of weakness separating the first securing strap portion from the second securing strap portion, wherein the force to break the area of weakness is less than the force to separate the securing strap from the first part

or second part. In one embodiment, the wall guard linearly extends along a portion of the tear strip from the gap to the securing strap.

A method of enclosing a medical access device in the tamper-evident closures comprises inserting the medical access device into the holding cavity and closing the first part and second part to align the wall guard within the holding cavity adjacent to the tab of the closure mechanism. In one embodiment, the method comprises removing a portion of the tear strip, wherein the wall guard within the holding cavity is adjacent the portion of the removed tear strip.

Brief Description of Drawings

FIG. 1 is a perspective view of one embodiment of a tamper-evident closure in an open position to expose the holding cavity and to receive a medical access device with the tamper-evident closure having an actuatable door covering an access point;

FIG. 2 is a top view of FIG. 1;

FIG. 3 is a perspective view of the tamper-evident closure of FIG. 1 in a closed position, with a securing strap retained and with a medical access device contained in the holding cavity and the actuatable door covering an access point;

FIG. 4 is a perspective view of the tamper-evident closure of FIG. 1 with the actuatable door hinged to provide the access point into the holding cavity;

FIG. 5 is a top view of the tamper-evident closure of FIG. 4;

FIG. 6 is a sectional view of the tamper-evident closure of FIG. 3 through the securing strap surrounding the holding cavity, with the medical access device removed;

FIG. 7 is a perspective view of the tamper-evident closure of FIG. 3 with the securing strap broke at the area of weakness to indicate tampering;

FIG. 8 is a perspective view of the tamper-evident closure of FIG. 3 where the tear strip has been released to open the tamper-evident closure and break the securing strap.

While the above-identified drawings and figures set forth embodiments of the invention, other embodiments are also contemplated, as noted in the discussion. In all cases, this disclosure presents the invention by way of representation and not limitation. Numerous other modifications and embodiments can be devised by those skilled in the art, which fall within the scope and spirit of this invention. The figures may not be drawn to scale.

Detailed Description

Various designs for tamper-evident closures are disclosed. The disclosed tamper-evident closure 100 has a holding cavity 110 formed from a first part 125 and second part 126 connected together by a closure mechanism 160. The closure mechanism comprising a releasable tab 168 on a tear strip 164. Within the holding cavity 110 extending from one of the first part 125 or second part 126, or both, is a wall guard 130 adjacent the releasable tab 168 to limit access into the holding cavity.

To enable tamper evidence the tamper-evident closure further comprises a securing strap 170, and optional closure mechanism 160 such that upon tampering or removal of the securing strap 170 there is a visually apparent indication that securing strap 170 had broken and has been released. The disclosed tamper-evident closures are well suited for securing a medical access device 200 for delivering fluid to a patient, removing fluid from a patient or connecting to other devices through a tube 220. In some embodiment, caps 230, such as a 3M™ Curo™ Disinfecting Cap that contain disinfectant are secured over the medical access device 200.

The holding cavity 110 has a length in the y direction, a width in the x direction, and a height in the z direction. The holding cavity has a perimeter 111 surrounding at least a portion of the holding cavity 110. At least one access point 113 is in the holding cavity 110, when the holding cavity is closed (FIG. 2, 5, 6) to allow for the tube 220 of the medical device to exit the holding cavity 110. Typically, the tamper evident closure 100 can be open so the access device 200 to be placed in the holding cavity 110 and closed to secure the access device 200 within the holding cavity 110.

An actuatable door 127 is in the holding cavity 110 and optionally provides for the access point 113. Some or all of the access points 113 could include actuatable doors 127. However, as shown in the embodiment, one access point 113 does not have an actuatable door, while an optional access point 113 in the side along the length of the tamper-evident closure 100 includes the actuatable door.

In one embodiment the securing strap 170 retains the tamper-evident closure 100 closed. In one embodiment, an optional closure mechanism 160 retains the tamper-evident closure 100 closed. Various design of the holding cavity 110, securing straps 170, and optional closure mechanism 160 are contemplated and disclosed herein.

The holding cavity 110 of the tamper-evident closure 100 contains the medical access device 200. The medical access device 200 can be any site on a catheter or intravenous tubing where medications can be administered and/or where fluid can be removed. The medical access device 200 can be a vascular access device that is a connection to the patient's vascular system for either administering medication or removing blood. The medical access device 200 can be any portion of the infusion tubing, catheter, tube, or other medical device. This can be any site on a catheter, intravenous tubing, or other topical or percutaneous medical device. This may be a luer active device ("LAD") on a y-site, a LAD on the end of a line, or a male/female connection in the middle of the line or any other connection used on a topical or percutaneous medical device. A luer activated device can be either capped or un-capped.

In some embodiments like shown in the figures, the fluid access point of the medical access device 200 is covered with a cap 230 (FIG. 3) for covering the fluid access point prior to use. Caps 230 can contain a disinfecting agent to keep the fluid access point 210 clean until use. Exemplary caps 230 are described in US Patents 7,282,186; 7,780,794; 9,907,617; 9,259,284, the disclosures of which are herein incorporated by reference. Exemplary caps 230 are sold as 3M™ CUROS™ Disinfecting Caps for Needleless Connectors, available from 3M Company.

When the holding cavity 110 is closed, the fluid access into the medical access device 200 is inaccessible to prevent access to the medical access device. The tab 168 can be pulled from the tamper-

evident closure 100 to begin removing the tear strip 164. This can create a tear strip gap 163 that allows for an access point into the holding cavity 110. Included in the tamper-evident closure 100 is a wall guard 130 that extends into the holding cavity 110 between the exterior and the medical access device to block external access to the medical access device.

5 If the securing strap 170 is included, if a user attempts to remove the securing strap 170 to open the tamper-evident closure, it will partially or completely separate and it will be visually apparent it has been tampered. If the tamper-evident closure 100 has been opened – either legitimately or through tampering – the securing strap 170 will completely separate and it will be visually apparent the tamper-evident closure 100 have been open. Further, it will not be possible to reclose the tamper-evident closure
10 100.

In the disclosed tamper-evident closure 100, the securing strap 170 comprises an area of weakness 175. The force to break the area of weakness 175 is less than the force to separate the securing strap 170 from the tamper-evident closure 100. Therefore, even without opening the holding cavity 110, tampering will be evident from the broken area of weakness 170.

15 In some embodiment, materials that are highly resistant to breaking by cutting or impact, such as plastics, films, metals or ceramics, could be used to make the tamper-evident closure a tamper-resistant or even tamper-proof closure.

FIG. 1 is a perspective view of one embodiment of a tamper-evident closure 100 in an open position to expose the holding cavity 110 and to receive a medical access device within the tamper-evident closure 100, where there is an actuatable door 127 covering a potential access point. FIG. 2 is a
20 top view of FIG. 1. FIG. 3 is a perspective view of the tamper-evident closure 100 of FIG. 1 in a closed position, with a securing strap 170 retained and with a medical access device 200 contained in the holding cavity 110 and the actuatable door 127 covering a potential access point. FIG. 4 is a perspective view of the tamper-evident closure 100 of FIG. 1 with the actuatable door 127 hinged to provide the access point
25 113 into the holding cavity 110. FIG. 5 is a top view of the tamper-evident closure of FIG. 4. FIG. 6 is a sectional view of the tamper-evident closure 100 of FIG. 3 through the securing strap 170 surrounding the holding cavity 110, with the medical access device removed. FIG. 7 is a perspective view of the tamper-evident closure 100 of FIG. 3 with the securing strap 170 broke at the area of weakness 175 to indicate tampering. FIG. 8 is a perspective view of the tamper-evident closure 100 of FIG. 3 where the tear strip
30 164 has been released to open the tamper-evident closure 100 and break the securing strap 170.

In this embodiment, the tamper-evident closure 100 comprises a first part 125 and a second part 126 that connect together to form the holding cavity 110. The medical access device 200 (FIGS. 2, 3, 5) can be placed in the first part 125, and then the second part 126 overlies the first part 125, like shown in FIG. 2. The first part 125 and second part 126 can be two separate parts or could be connected to one
35 another by a hinge 123 (as best seen in FIG. 4). There are access points 113 in the tamper-evident closure 100 to allow the medical access devices tubing 220 to exit from the holding cavity 110 while the medical access device 200 is contained within the holding cavity 110. Other suitable designs of a tamper-evident

closure 100 are shown and described in PCT Publication WO 2021/024139, the disclosure of which is here in incorporated by reference.

The first part 125 and the second part 126 are held in a close position by a closure mechanism 160. In this embodiment, a closure mechanism 160 for holding the holding cavity 110 closed comprises a tear strip 164 extends around at least a portion of the perimeter 111 of the tamper-evident closure 100 connecting the first part 125 and second part 126. The tear strip 164 comprises a mechanical interlocking system linking between the first part 125 and the second part 126. In the embodiment shown, the tear strip 164 comprises a longitudinally extending protruding portion 165 that interlocks with a longitudinally extending receiving portion 166 on the first part 125 for securing the tamper-evident closure 100 in a closed position. It is understood that the extending or receiving portions could be alternatively be included on the other first part 126 or second part 126. The tear strip 164 has a line of weakness 167 adjacent to the tear strip 164 that connects the tear strip 164 to the second part 126 in this embodiment, but it is understood is could alternatively connect the tear strip 164 to the first part 125.

The tear strip 164 can have a tab 168 for a user to be able to easily grab the tear strip 164 to begin removal of the tear strip 164. Removal of the tear strip 164 separates the tear strip 164 from the second part 126 along the line of weakness 167. The tab 168 could be anywhere along the tear strip 164. Typically, it is on an end of the tamper-evident closure 100 without an access point 113 so as not to interfere with the tube 220 that leaves the access point 113. However, if the tab 168 is on an end also containing an access point 113, the tab 168 is dimensioned and positioned to not interfere with the exiting tube 220. The tab 168 is therefore ideally positioned slightly removed from the tamper-evident closure 100, like shown in the top view of FIG. 5. However, to ensure the tab 168 is not so disconnected and to help strengthen the connection of the tear strip 164 to the closed holding cavity 110, optional tab ties 169 are included to secure a portion of the tab 168 to the tamper-evident closure 100. These tab ties 169 add strength to the tab 168 connection to prevent the tab from snagging and inadvertently separating from the tamper-evident closure 100. Also, the tab 168 being separated from the tamper-evident closure 100 creates a slight area of weakness and the tab ties 169 secure the tab 168 adding strength to the closure.

Pulling the tab 168 begins to create access into the holding cavity 110. In some embodiment, as can be seen in FIGS. 2 and 5, the tab 168 being spaced away from the tamper-evident closure 100 creates a tear strip gap 163 in a portion of the perimeter 111 which also could be an access into the holding cavity 110. To block this access, a wall guard 130 is positioned within the holding cavity 110 adjacent the tab 168. In an embodiment like shown in FIG. 2 and 5, where there is a tear strip gap 163, the wall guard 130 is adjacent the tear strip gap 163. The wall guard 130 is positioned in the holding cavity 100 between the inserted medical access device 200 and the first part 125/second part 126. The wall guard 130 extends in a depth (FIG. 1) from the second part 126 into the holding cavity to create a block from external access into the inserted medical access device 200.

The wall guard 130 at least blocks the tear strip gap 163. In some embodiments, like shown in FIG. 1 and 2, the wall guard extends laterally from the tear strip gap 163 towards the center of the tamper evident box along the direction of the propagation of the tearing of the tear strip 164. For example, in

FIG. 6 as the tear strip 164 is pulled there becomes a longer tear strip gap 163 between the first part 125 and second part 126. The wall guard 130, which extend from the second part into the holding cavity blocks access into the medical access device 200. In this embodiment, which includes the securing strap 170 (which will be described in more detail below), once the tear strip 164 breaks the securing strap 170, tampering would be evident and then blocking access to the medical access device 200 is irrelevant. Therefore, in this embodiment, the wall guard 130 extends longitudinally along the direction of the tear strip 164 and toe to the securing strap 170.

The securing strap 170 indicates tampering if a user was to attempt to remove the securing strap 170 from the tamper-evident closure 100 or to open the tamper-evident closure 100. In some embodiments, the securing strap 170 also functions to hold the tamper-evident closure 100 in a closed position. The securing strap 170 comprises a first securing strap portion 172 secured to the first part 125 and a second securing strap portion 174 that includes a free end 173 that is disconnected from the tamper-evident closure 100 before the tamper-evident closure 100 has been closed, like shown in FIG. 1 and 3. In one embodiment, the first securing strap portion 172 is rigidly, integrally, or substantially permanently connected with the first part 125. Between the first securing strap portion 172 and the second securing strap portion 172 is an area of weakness 175 of the securing strap 170.

As shown in FIG. 3, once the first part 125 closes over the second part 126, the securing strap 170 extends from the first part 125 to the second part 126. In this embodiment, the securing strap 170 extends around a substantial portion of the tamper-evident closure 100. In this embodiment, the securing strap 170 extend from one side of the tamper-evident closure 100 to the opposing side of the tamper evident closure 100, across the entire height (z-direction) of the tamper-evident closure 100.

Various mechanism could be included for attachment of the second securing strap portion 174 to the tamper-evident closure 100. For example, mechanical of interlocking mechanism, adhesive attachments of one or both ends, etc. As shown in the embodiment, the second securing strap portion 174 to the second part 126. Typically, the attachments is a one-way, irreversible connection of the second securing strap portion 174. For example, in one embodiment, the mechanical attachment to allow for the free end 173 to secure to the second part 126 and then for the free end 173 to release from the second part 126 can be included. In the embodiment shown, the second securing strap portion 174 includes a latch extension 171 for mechanical engagement within a receiving latch 128a which is contained within a slot 128 (see FIG. 3 and 4). The slot 128 passes through the second part 126 and within the slot 128 is the receiving latch 128a. In the embodiment shown, the latch extension 171 and receiving latch 128a interlock in a one-way, irreversible manner and therefore the interlock does not release. Here, the latch extension 171 will break if removal of the connection is attempted. This keeps the securing strap 170 securely connected to the first part 125 and second part 126. Also, in this embodiment, the securing strap 170 functions to hold the tamper-evident closure 100 in a closed position.

Optionally, within the holding cavity 110, the slot 128 for receiving the latch extension 171 is surrounded by a slot wall 129 that extends to prevent possible actuation of the latch extension 171 for release from the receiving latch 128a if tampering includes access from within the cavity pressing against

the latch extension 171 (see FIG. 4). In other words, with an elongated tool, a user could press against the latch extension 171 and release it from the receiving latch 128a. The slot wall 129 is within the holding cavity 110. In the embodiment shown, the slot wall 129 extends from the first part 125 to the second part 126 and substantially surround the latch extension 171.

5 The latch extension 171 in this embodiment is a barb, but any number of other one-way mechanical interlocks are suitable. For example, the latch extension could be a protruding portion like a ball that inserts into a receiver.

10 The securing strap 170 includes an area of weakness 175 that enables controlled breaking when attempting to release the securing strap 170 or attempting to open the holding cavity 110. The area of weakness 175 could be any number of designs where the force to break the area of weakness 175 is less than the force to separate the securing strap 170 from the first part 125 or second part 126. In other words, attempted removal, opening, destruction of the securing strap 170 will break at the area of weakness 175 before the securing strap 170 connection of the latch extension 171 and slot 128 will break or release. For example, the area of weakness 175 can be a substantially thinner material than the other portions of the
15 securing strap 170 or can be one or more perforations through the securing strap 170.

 The slot 128 is shaped to be a container so that if the latch extension 171 broke from tampering, the latch extension 171 will separate from the free end 173 of the securing strap 170 and fall into the slot 128 and advantageously collects and contains the loose part of the broken latch extension 171.

20 FIG. 7 depicts the tamper-evident closure 100 in a closed position but where a user has attempted to lift, remove, or release the second securing strap portion 172 from attachment with the second part 126. Here, the area of weakness 175 has separated the first securing strap portion 172 from the second securing strap portion 174 to indicate tampering. The area of weakness 175 broke before the latch extension 171 broke or released from the slot 128.

25 In this embodiment, with the tear strip 164, the securing strap 170 overlies the tear strip 164. To remove the tear strip 164, the tab 168 is pulled to break the line of weakness 167 that connects the tear strip 164 to the second part 126, and then further, the tear strip 164 breaks the area of weakness 175 in the securing strap 170, as best shown in FIG. 8. Removal of the tear strip 164 removes the longitudinally extending protruding portion 165 to disengage the longitudinally extending protruding portion 165 from the longitudinally extending receiving portion 166. Therefore, when the tear strip 164 is used to open the
30 tamper-evident closure 100, it disengages the locking connection between the first part 125 and the second part 126. Further, the tear strip 164 breaks the area of weakness 175 of the securing strap 170 irrevocably breaks the securing strap 170 so tampering is evident without the need for a secondary tool.

35 It is understood the closure mechanism 160 could accomplish the same function in other ways, such as, for example, the second part 126 could include the longitudinally extending protruding portion 165 and the first part 125 could include the longitudinally extending receiving portion 166 that interlocks with the longitudinally extending protruding portion 165. Further alternative closure mechanism 160 could be used to secure the holding cavity closed, such as those described in PCT Publication WO 2021/024139, the disclosure of which is here incorporated by reference.

In this embodiment with the securing strap 170 overlying a tear strip 164, the securing strap 170 can include a ramp edge 176, which align with the tear strip 164 (see FIG. 6). As the tear strip 164 is removed, the ramp edge 176 maintains alignment of the tear strip 164 with the area of weakness 175 so that the force applied by the tear strip 164 to the area of weakness 175 easily breaks the area of weakness 175. Without the ramp edge 176, the tear strip 164 might slide along the securing strap 170 and be misaligned with the area of weakness 175.

The tamper-evident closure 100 can include various access points 113. However, access points 113 can introduce points of egress into the holding cavity 110. For example, the tamper-evident closure 100 could include access points 113 on both opposing ends of the tamper-evident closure. But if an access point 113 is provided on both ends, then the medical access device 200 will include a cap 230 to prevent access into the medical access device 200. For accommodating various medical access devices 200, the tamper-evident closure 100 can include an actuatable door 127 in the holding cavity 110 for creating an access point 113. As shown in FIG. 3, the medical access device 200 only has a single tube 220, and in this embodiment the actuatable door 127 remains closed. As shown in FIG. 5, the medical access device 200 is a Y-site device with a side tube 220 and therefore the actuatable door 127 is pressed inward into the holding cavity 110.

The actuatable door 127 covering the potential access point, like shown in FIG. 1. The actuatable door 127 has a hinge 127c that connects the actuatable door 127 to the holding cavity 110. In this embodiment, the hinge 127c is a living hinge of the same material as the surrounding holding cavity 110, and best seen in FIG. 6. This is desirable because even upon actuation, the actuatable door 127 does not separate from the tamper-evident closure 100. Instead, the actuatable door 127 remains connected. Loose pieces and fragments of the tamper-evident closure 100 would be undesirable in a health care setting for possible choking hazard, for clean-up, and for inadvertent introduction into a surgical field.

To fully secure the actuatable door 127 into the holding cavity, the holding cavity 110 has a door stop 124. The door stop 124 pressure fits with the actuatable door 127 when the actuatable door 127 hingedly actuated into the holding cavity 110. In the embodiment shown best in FIG. 2, the door stop 124 is a protrusion within the holding cavity opposite from the actuatable door 127 and pressure fits with only a portion of the actuatable door when the actuatable door is hingedly actuated into the holding cavity.

The portions of the actuatable door 127 without the hinge 127c can be held to the holding cavity 110 such as shown on a first side 127a and second side 127b. First side 127a and second side 127b are typically structurally weak areas, such as a thin wall as shown in FIG. 2 or with perforations, to allow for easy disconnection of the actuatable door 127 at these areas.

The second part 127 can include a door support wall 122. When the actuatable door 127 is not actuated, but left closing the potential access point (like FIG. 3 and 6), then the actuatable door 127 abuts the door support wall 122 preventing the actuatable door 127 for pressing inward and allowing egress into the holding cavity 110.

The tamper-evident closure 100 can include reinforcing ribs 121 to add structural strength to the holding cavity. As described, typically the tamper-evident closure 100 is length is greater than the width,

this could cause weakness along the mid-section of the length. That weakness could allow a user to slightly squeeze and deform the tamper-evident closure 100. The deformation could disconnect the closure mechanism 160. The pressure to actuate the door 127 might cause the tamper-evident closure 100 to deform or flex too much making it difficult to actuate the door 127. Or if an actuatable door 127 is included, slight deformation might increase the space in and around the door 127 to allow a user to insert elongated objects into the holding cavity 110.

As shown in this embodiment, the securing strap 170 can overlay this removable door 127 and if it overlies the removable door 127, then the securing strap 170 includes a partial opening to allow for the medical access device 200 to exit the tamper-evident closure 100 and therefore accommodate Y-site medical access devices 200.

The securing strap 170 in this embodiment overlies the optional actuatable door 127. To allow for a potential tube 220 to exit from the access point 113 created when the actuatable door 127 is lowered, the securing strap 170 has a notch 177 through a portion aligned with the actuatable door 127.

In some embodiments, the securing strap 170 itself could include at the notch 177 the actuatable door 127 that is filled in and covers the access point 113, or if removed provides an access point 113 for a tube 220 into the holding cavity.

In alternative designs of the tamper-evident closure containing a securing strap 170, the securing strap 170 itself serves as the primary closure holding the first part 125 together with the second part 126. In such an embodiment, the area of weakness 175 separates and then allow for the first part 125 and second part 126 to open and allow access into the holding cavity 110. In this type of construction the securing strap 170 could include a tab 168 to allow for easy, intentional separation of the first securing strap portion 172 from the second securing strap portion 175.

It is understood that both the first securing strap portion 172 and the second securing strap portion 174 could include one-way engaging fasteners such as described herein with the latch extension 171 and slot 128. It is understood that although the description of the securing strap 170 is with the second securing strap portion 174 securing to the second part 126, instead the securing strap 170 might instead have the first securing strap portion 172 securing to the first part 125 as described herein.

The securing strap 170 is shown aligned over the actuatable door 127. In other embodiments, the securing strap 170 can be along any portion of the tamper-evident closure 100, where the first securing strap portion 172 secures with the first part 125 and the second securing strap portion 174 secures to the second part. Typically, the securing strap 170 will span the entire height (z-direction) of the tamper evident closure 100.

In use, when desiring to use the access point, the actuatable door 127 is pressed inward to the holding cavity 110. When there is a door stop 124, the actuatable door 127 is friction fit and pressed against the door stop 124 to secure the actuatable door 127 in place, such as shown in FIG. 5. Then, the medical access device 200 is placed in the open tamper-evident closure 100 such as shown in FIG. 5. The first part 125 and second part 126 close to form the holding cavity 110 around the medical access device 200. The free end 173 of the securing strap 170 is engaged with the second part 126 to hold the first part

125 and second part 126 closed. Specifically, the latch 171 locks in the slot 128. If included, the underlying closure mechanism 160, a tear strip 164 as shown, secures the first part 125 and second part 126 closed. In this embodiment the tear strip 164 aligns generally with the area of weakness 175 of the securing strip 170. The medical access device 200 is contained in the holding cavity 110 and access to the medical access device 200 is very limited.

To open the tamper-evident closure 100, the securing strap 170 is broken, which may separate the first part 125 from the second part 126. When there is a closure mechanism 160, such as the tear strip 164 shown, the tab 168 on the tear strip 164 is pulled to release the first part 125 from the second part 126, and the tear strip 164 also breaks the area of weakness 175 to separate the first securing strap portion 172 from the second securing strap portion 174.

To further aid in seeing any visual tampering, it could be that the securing strap 170 is one color and the tamper-evident closure 100 is a different color. Tamper-evident closures, such as those disclosed in this application, are designed to be closed and opened without the need for additional removal tools. For example, perforation lines, breakable securement straps, twistable or tearable structures or film can be used so that when a health care provider intentionally wants to access the vascular access device, it is easy to remove the tamper-evident closure. Also, it is desirable that when the tamper-evident closure is intentionally removed that the holding cavity opens cleanly with few separating parts.

The tamper-evident closure achieves the benefit of providing a strong holding cavity with limited ingress access into the holding cavity, that is easy to open without extra tools, and easy to break the securing strap while also including addition protections walls to limit ingress into the holding cavity.

Although specific embodiments have been shown and described herein, it is understood that these embodiments are merely illustrative of the many possible specific arrangements that can be devised in application of the principles of the invention. Numerous and varied other arrangements can be devised in accordance with these principles by those of skill in the art without departing from the spirit and scope of the invention. The scope of the present invention should not be limited to the structures described in this application, but only by the structures described by the language of the claims and the equivalents of those structures.

What is claimed is:

1. A tamper-evident closure for a medical access device comprising:

a holding cavity formed from a first part and a second part;

a closure mechanism holding together the first part and second part around a perimeter of the first part and second part; and

a wall guard extending from one of the first part or second part into the holding cavity adjacent the tab.

2. The tamper-evident closure of claim 1, wherein the closure mechanism comprises a tear strip and a tab.

3. The tamper-evident closure of any one of the preceding claims, comprising a gap at the connection of the tear strip between the first part and second part into the holding cavity, and wherein the wall guard extends into the holding body cavity to coincide with the gap.

4. The tamper-evident closure of claim 3, wherein the wall guard has a depth which is the distance the wall guard extending from the second part in to holding cavity, wherein the depth of the wall guard is the same as or greater than the gap.

5. The tamper-evident closure of claim 3, wherein the closure mechanism extends around substantially the entire perimeter of the first part and second part and where in the tab covers the gap.

6. The tamper-evident closure of any one of the preceding claims, wherein the tab is spaced a distance from the first or second part.

7. The tamper-evident closure of any one of the preceding claims, wherein the wall guard extends along a portion tear strip.

8. The tamper-evident closure of any one of the preceding claims, further comprising a securing strap secured to the holding cavity, wherein the securing strap comprises a first securing strap portion secured to the first part, a second securing strap portion with a free end for removably securing to the second part, and an area of weakness separating the first securing strap portion from the second securing strap portion, wherein the force to break the area of weakness is less than the force to separate the securing strap from the first part or second part.

9. The tamper-evident closure of any one of the preceding claims, wherein the wall guard linearly extends along a portion of the tear strip from the gap to the securing strap.

10. A method of enclosing a medical access device in any one of the tamper-evident closures of the preceding claims, comprising:

inserting the medical access device into the holding cavity;

5 closing the first part and second part to align the wall guard within the holding cavity adjacent to the tab of the closure mechanism.

11. The method of claim 10, further comprising:

removing a portion of the tear strip, wherein the wall guard within the holding cavity is adjacent the portion of the removed tear strip.

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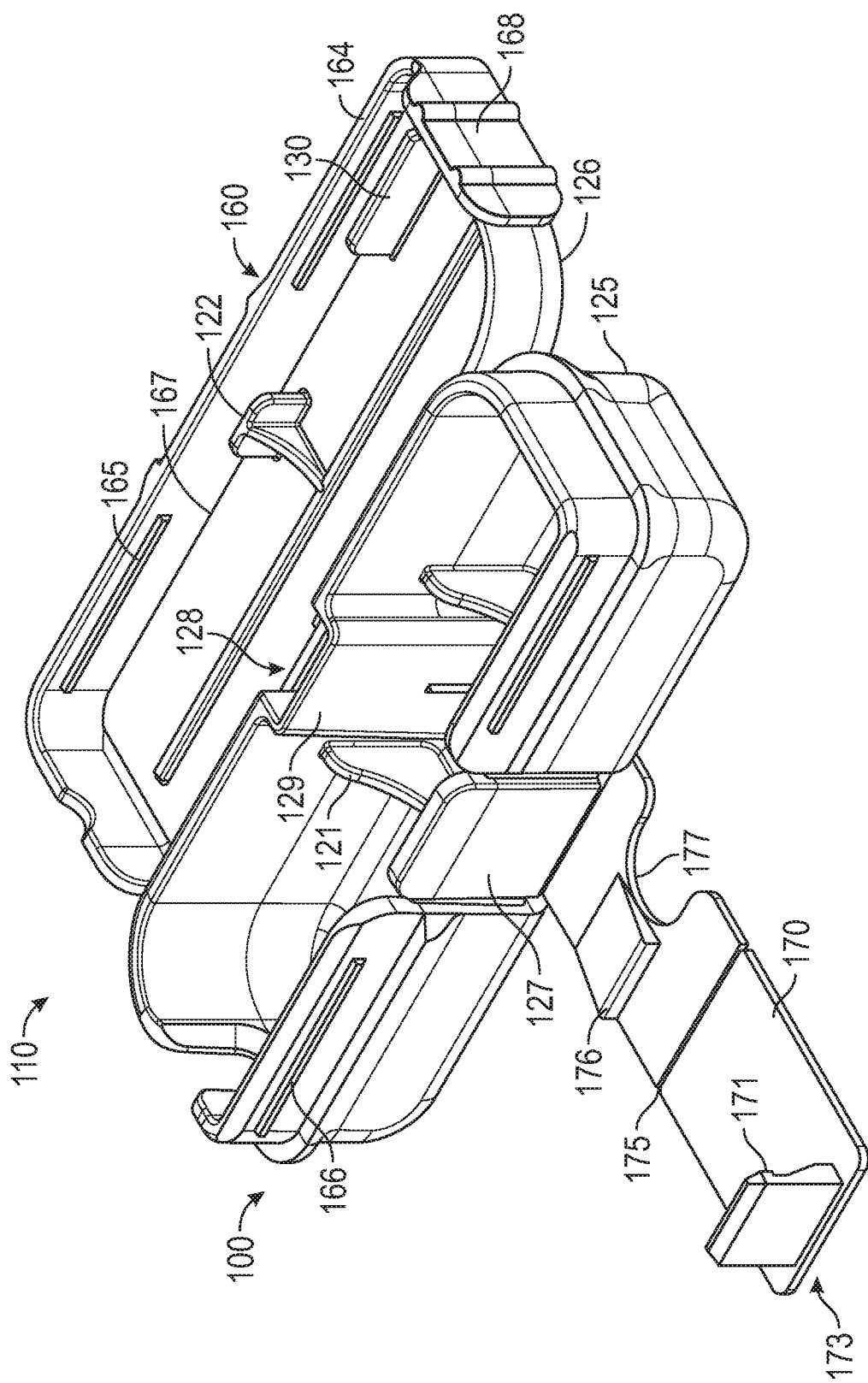


FIG. 1

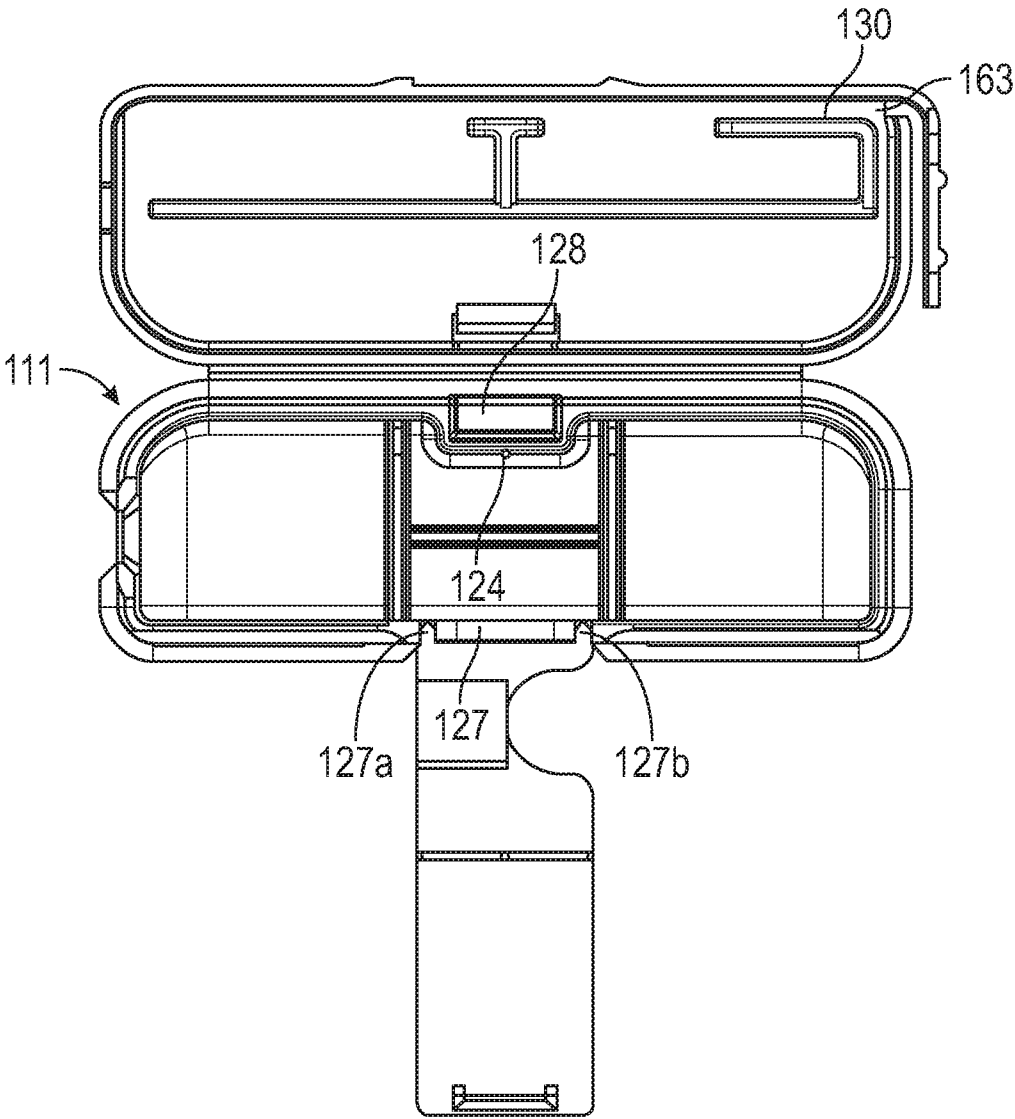


FIG. 2

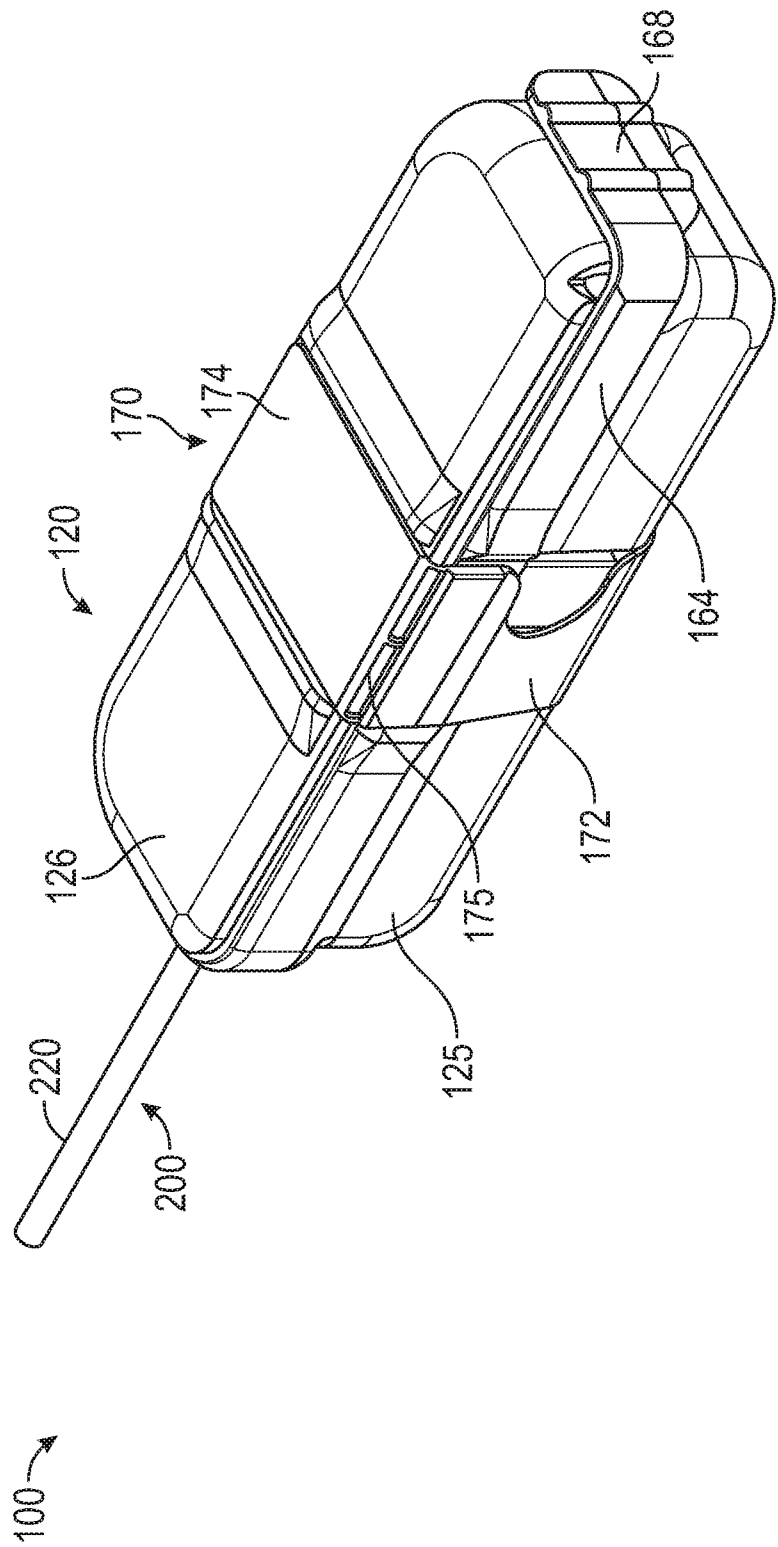


FIG. 3

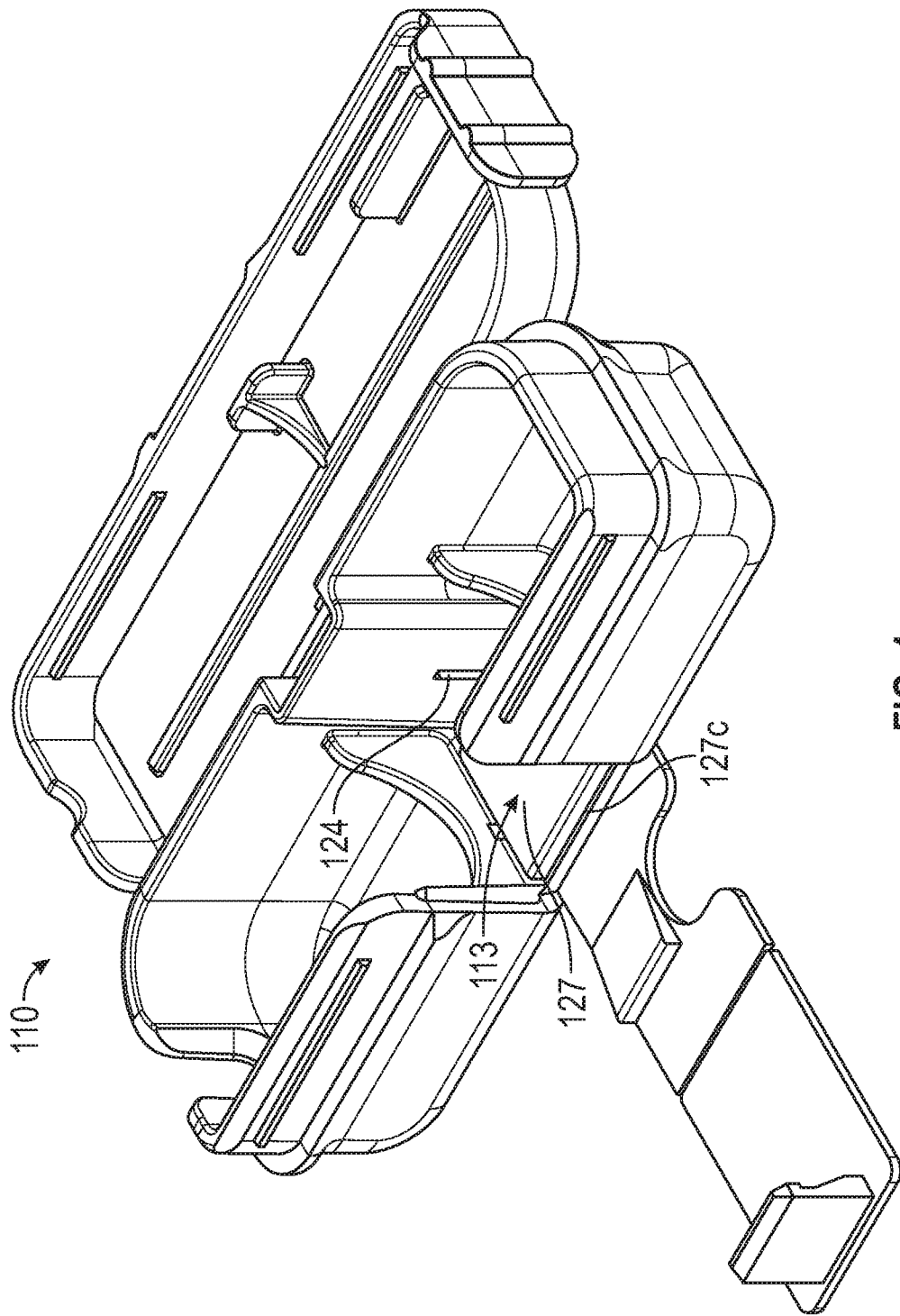


FIG. 4

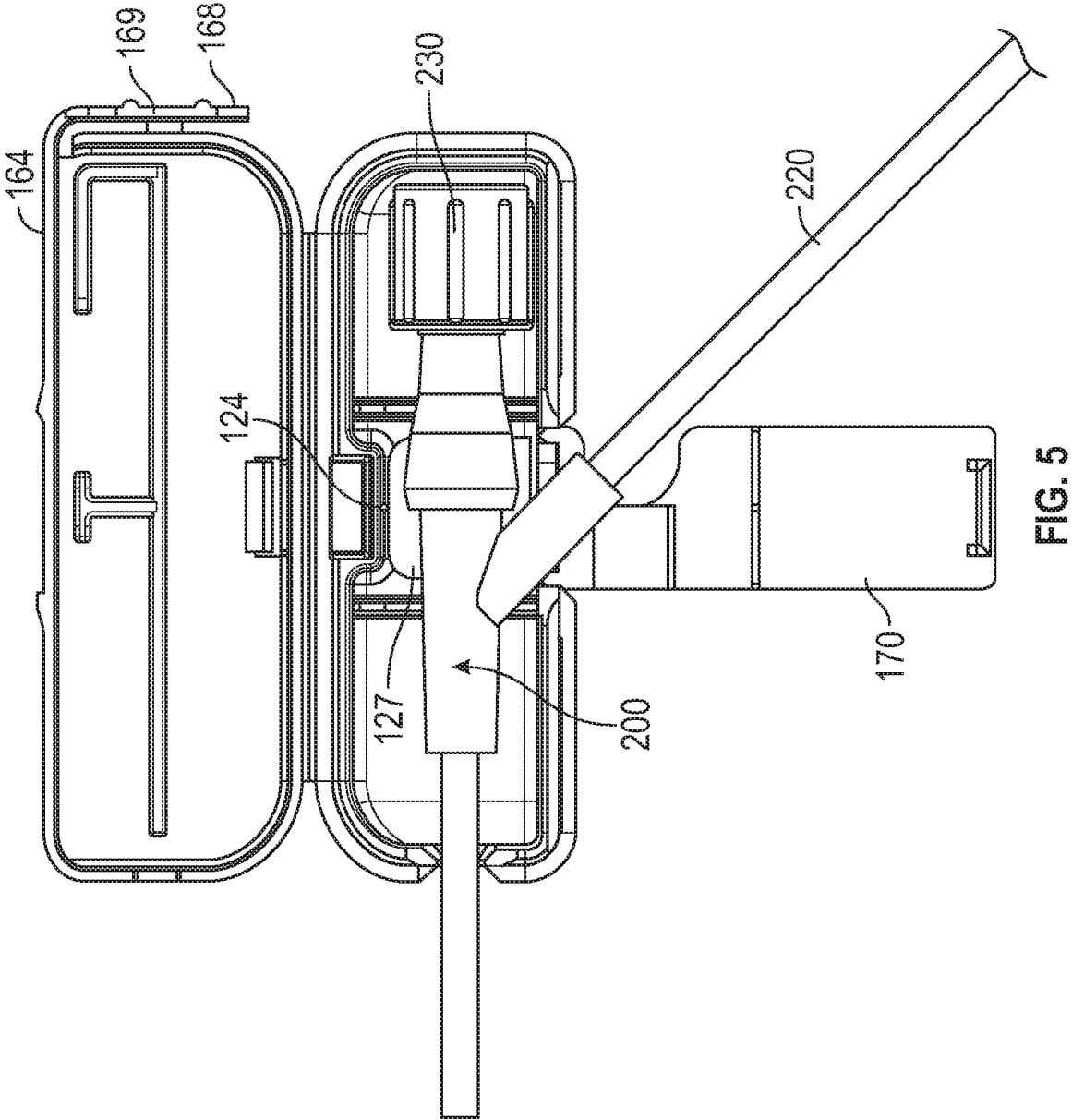


FIG. 5

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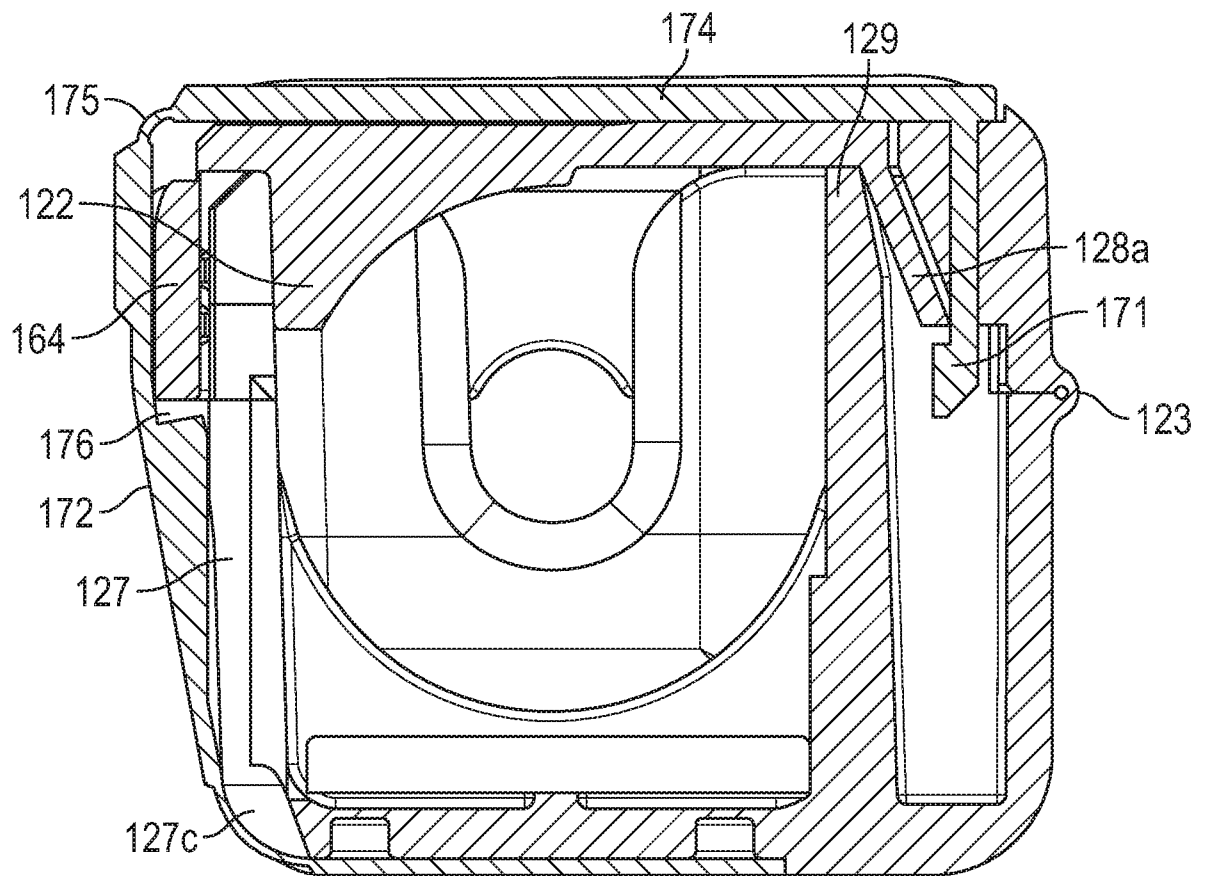


FIG. 6

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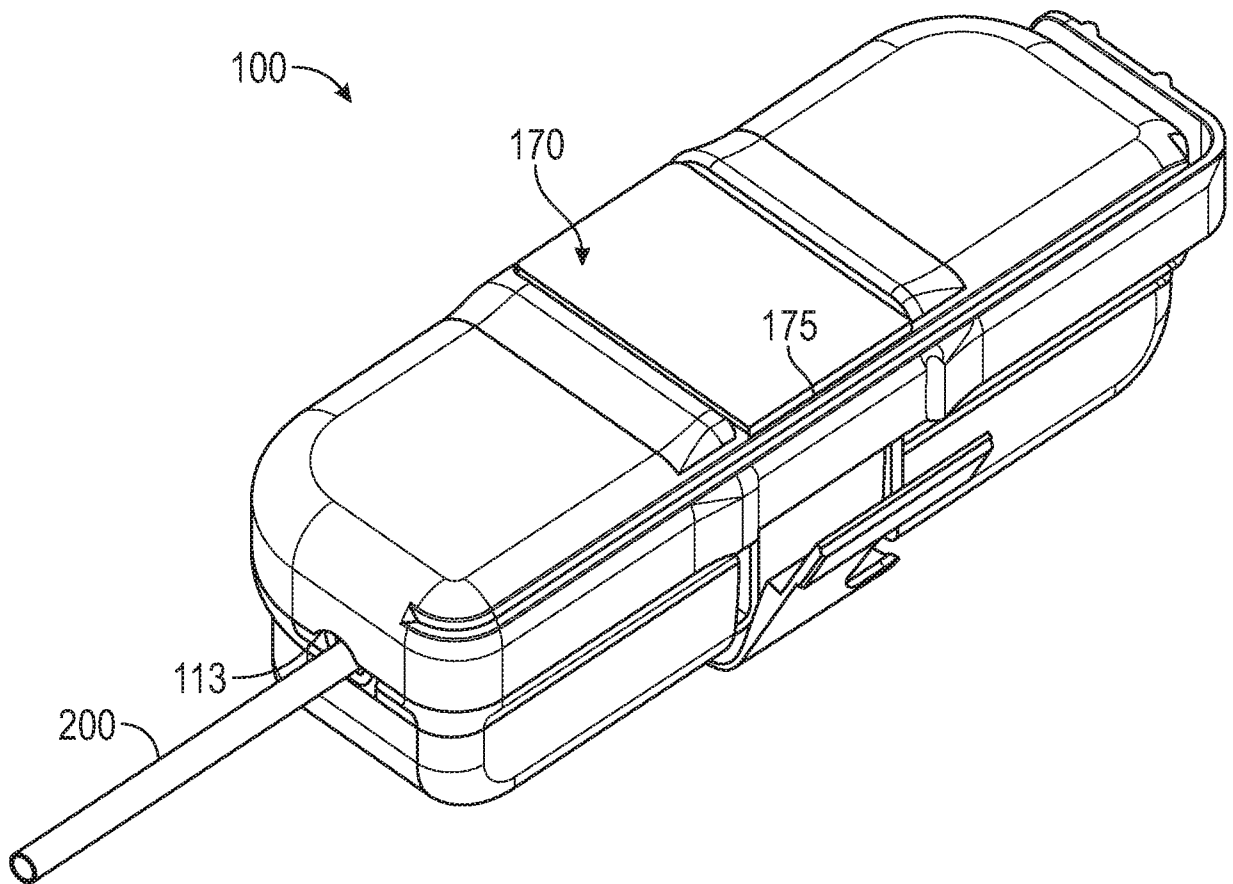


FIG. 7

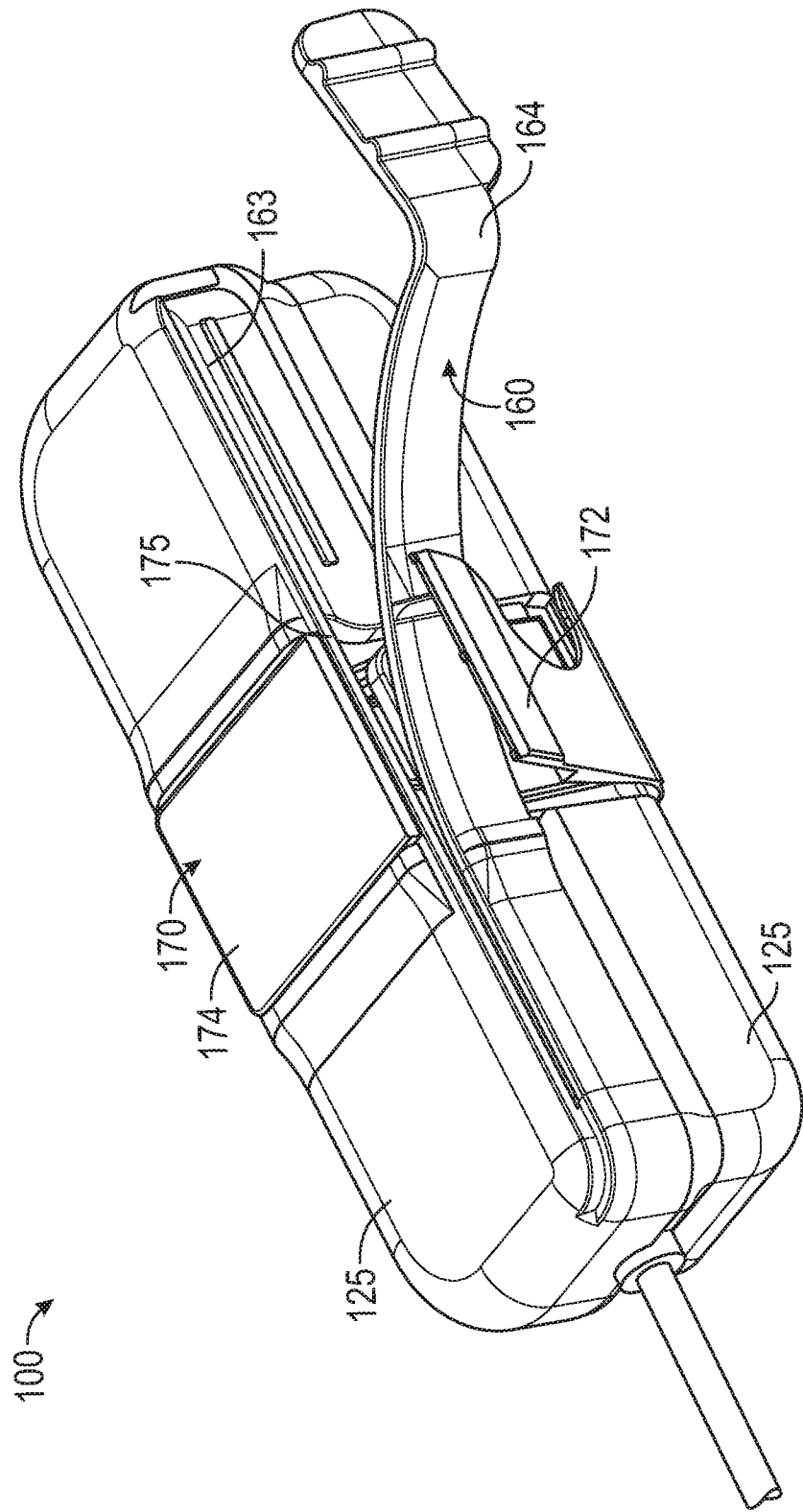


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2022/057091

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/50 A61M39/10 B65D55/02 A61M39/16 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61M B65D		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2021/024139 A1 (3M INNOVATIVE PROPERTIES CO [US]) 11 February 2021 (2021-02-11) paragraph [0049] - paragraph [0065]; figures 3A-D -----	1-11
X	US 5 830 195 A (PETERS JOSEPH L [GB] ET AL) 3 November 1998 (1998-11-03) column 6 - column 7; figures 25-27 -----	1-3, 6, 10, 11
X	US 10 722 680 B1 (MENCH MATTHEW M [US] ET AL) 28 July 2020 (2020-07-28) column 17 - column 24; figures 4A/B, 6A, 9A-D -----	1, 2, 8, 10, 11
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
13 October 2022		26/10/2022
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Filippi, Markus

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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