(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 October 2015 (15.10.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/155253 A1

(51) International Patent Classification:
A61M 5/00 (2006.01)

(21) International Application Number:
PCT/EP2015/057638

(22) International Filing Date:
8 April 2015 (08.04.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14/248,004 8 April 2014 (08.04.2014) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *with amended claims and statement (Art. 19(1))*

WO 2015/155253 A1

(54) Title: HINGED CAP NEEDLE ASSEMBLIES AND RELATED METHODS

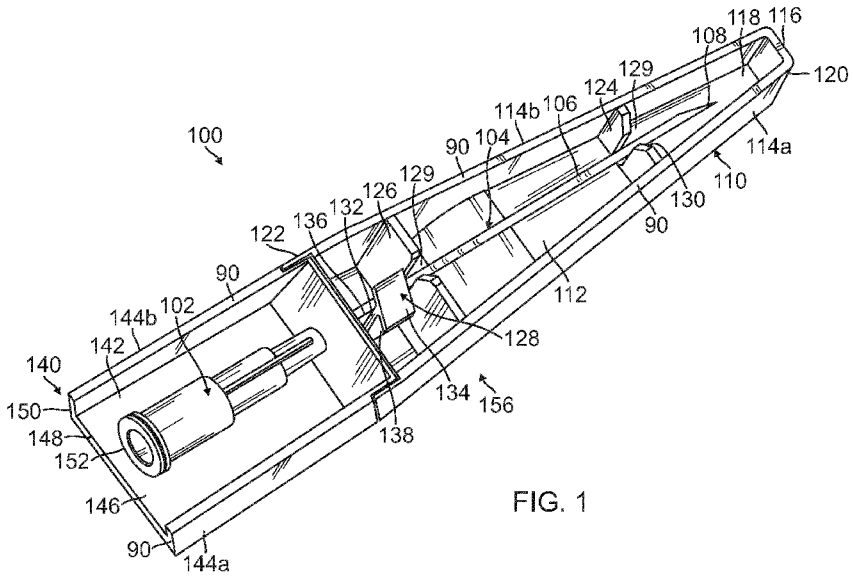


FIG. 1

(57) Abstract: A dual purpose needle assembly and related method are disclosed having a needle hub (102) and needle (104) sealed inside a packaging housing with a film cover or layer. The packaging housing has separately formed and subsequently joined cap (110) and base unit (140) with a living hinge optionally joining the two components. The needle assembly is usable without additional packaging and is usable as a hinged cap safety device upon removal of at least a section of the film cover.

HINGED CAP NEEDLE ASSEMBLIES AND RELATED METHODS

FIELD OF ART

The present invention generally relates to safety needle assemblies and more specifically to hinged cap needle assemblies with packaging and related methods.

BACKGROUND

Hinged cap needle assemblies are well known and are designed to cap a needle following use to prevent inadvertent needle sticks. The combination needle hub and needle is typically used with a syringe. The hinged cap may engage the needle hub via a collar to convert the standard needle hub into a hinged cap safety needle device. The needle hub and needle may instead be incorporated with the cap via a hinge in a unitary or integrated construction.

An embodiment of a prior art hinged cap device comes with a removable temporary cap mounted over the needle in a packaging unit, which differs from the hinged cap for capping needle following use. This has the disadvantage that the hinged cap must be set off at an angle from the removeable cap and thus increases the size of the package. This in turn has negative consequences for the whole distribution chain. After the hinged cap device is removed from the packaging unit, the hub of the hinged cap is placed onto a syringe tip and the temporary cap removed and discarded. The needle is then used, such as to draw a sample or deliver an injection, and then subsequently capped with the hinged cap, which has means for preventing re-opening of the cap to deter re-use.

Recapping is a common procedure for periods between drawing up fluids into a syringe and administering injections through the needle. The recapping procedure can occasionally cause needle sticks since users sometime misalign the needles with the openings on the caps. Injuries can also occur after an injection and prior to the discarding of the needles. Needle sticks can be painful, but can also cause great inconvenience because all needle sticks must be reported. Also, since needles related to needle sticks must be discarded, medications contained within the syringes are unnecessarily wasted. Furthermore, fluids linked to these “clean” type of needle sticks can cause injuries and adverse reactions.

SUMMARY

A combination safety needle assembly and a packaging system for the safety needle assembly is provided in accordance with aspects of the present disclosure. The combination device comprising: a base unit comprising a base wall located between two sidewalls and defining an interior cavity; a cap connected to the base unit at an interface, the cap comprising a base wall located between two sidewalls and defining an interior cavity having a latch; a needle hub and a needle combination, said needle hub attached to the base unit and said needle extending into the interior cavity of the cap; wherein the sidewalls of the cap and the sidewalls of the base unit define an open perimeter edge and the interior cavity of the cap and the interior cavity of the base unit define a package cavity; and wherein a thermoplastic film is attached to the open perimeter and extend across the interface between the cap and the base unit to enclose the combination needle hub and needle within the package cavity and forms a hinge at the interface.

The combination wherein the thermoplastic film can comprise a first film piece and a second film piece separated from one another by a perforation or a distinct separation.

The combination wherein the two sidewalls of the base unit and the two sidewalls of the cap can overlap along an axial direction.

The combination wherein the needle hub can be unitarily formed with the base unit.

The combination wherein the needle hub can be molded with a distal wall on the base unit.

The combination wherein the distal wall on the base unit can connect to the base wall and the two sidewalls of the base unit.

The combination can further comprise a latch comprising a post and a ramp mounted at an end of the post. The needle can be located on a first side of the latch in a holding state and on a second side of the latch in a locked state.

A further feature of the present disclosure is a combination safety needle assembly and a packaging system for the safety needle assembly comprising a unique hinge system. The combination device comprising a base unit comprising an enclosure having a base wall located between two sidewalls, said enclosure having an interior cavity and a perimeter edge with a proximal end edge; a cap hingedly connected to the base unit at an interface by a film layer, the cap comprising an enclosure having a base wall located between two sidewalls, said enclosure

defining an interior cavity having a latch and a perimeter edge; a needle hub and a needle combination, said needle hub attached to the base unit and said needle extending into the interior cavity of the cap; wherein the needle hub is recessed within the proximal end edge of the base unit and wherein a film cover is attached to the perimeter edge of the cap and the perimeter edge of the base unit to enclose the combination needle hub and needle within the interior cavity of the cap and the interior cavity of the base unit.

The combination wherein the film layer and the film cover can be spaced from one another.

The combination wherein a perforation can be provided between the film layer and the film cover.

The combination wherein the two sidewalls of the cap and the two sidewalls of the base unit can overlap along an axial direction.

The combination can further comprise a needle assembly connected to the base unit and cap via a tear line in an array.

The combination wherein the needle hub can be unitarily formed with the base unit.

The combination wherein the needle hub can snap fit into a C-clamp formed on the base unit.

A dual use needle assembly comprising a packaging housing having a needle hub and a needle located within an enclosure having a perimeter edge and a film cover attached to the perimeter edge to seal the needle hub and needle within the packaging housing, and wherein the packaging housing comprises a cap having two sidewalls and a base unit having two sidewalls and wherein the sidewalls of the cap and the base unit overlap along an axial direction.

The dual use needle assembly wherein the cap can attach to the base unit by a living hinge.

The dual use needle assembly wherein the cap can attach to the base unit by a second film cover that spans across a seam located between the cap and the base unit.

The dual use needle assembly can further comprise a second dual use needle assembly and a third dual use needle assembly connected in an array.

A further feature of the present disclosure is a method for manufacturing a dual use needle assembly. The method comprising forming a base unit comprising two sidewalls, a base wall, and a needle hub having a needle with a sharpened needle tip; forming a cap comprising

two sidewalls and a base wall; attaching a film cover to outer edges of the two sidewalls of the cap and of the base unit; and overlapping the two sidewalls of the cap with the two sidewalls of the base unit along an axial direction.

The method can further comprise attaching a second film cover across a seam located between the base wall of the cap and the base wall of the base unit.

The method wherein the base wall of the base unit can attach to the base wall of the cap by a living hinge.

The method can further comprise placing the needle on a first side of a latch comprising a post and a ramp.

A still yet further feature of the present disclosure is a dispenser system comprising a dispenser having a wall structure defining a storage space, an array of needle assemblies, a dispersed bundle of needle assemblies, or both an array of needle assemblies and a dispersed bundle of needle assemblies located in the storage space; and wherein each needle assembly comprises: a package housing comprising a base unit comprising sidewalls and a base wall hingedly connected to a cap comprising sidewalls and a base wall; a film cover affixed to a perimeter edge of the package housing; and a needle hub and needle sealed inside the package housing by the film cover; and sidewalls of the cap and the base unit overlapping along an axial direction.

The dispenser system wherein the dispenser has a frame for mounting on a wall or place on a flat surface.

A combination safety needle assembly and a packaging system for the safety needle assembly is provided in accordance with aspects of the present disclosure. The combination safety needle assembly and packaging system for the safety needle assembly can comprise a base unit defining an interior cavity, a cap hingedly connected to the base unit at an interface, the cap defining an interior cavity having a latch, a needle having a needle shaft and a sharp distal tip, the needle extending distally from the base unit and projecting into the interior cavity of the cap, and a film removably attached to perimeter edges of the cap and the base unit.

The combination wherein the cap can have a base wall and two sidewalls extending from the base wall.

The combination wherein the two sidewalls of the cap can be substantially parallel to each other.

The combination wherein the two sidewalls can be tapered inwardly from a proximal end to a distal end.

The combination wherein the two sidewalls can be tapered outwardly from a proximal end to a distal end.

The combination wherein the cap can further comprise a rib set attached to the base wall and the sidewalls to structurally support the base wall and sidewalls of the cap, with a passage defined through the rib set to receive the needle shaft.

The combination wherein the passage can have a tapered inlet end to facilitate guiding the needle shaft into the passage.

The combination wherein the latch can comprise a leg and a ramp attached to the leg.

The combination wherein the ramp can be positioned bisected by the leg.

The combination wherein the ramp can be slanted.

The combination wherein the ramp and the leg can form a hold side defined by an obtuse angle between the ramp and the leg.

The combination wherein the ramp and the leg can form a lock side defined by an acute angle between the ramp and the leg.

The combination wherein the cap can be formed by plastic molded injection.

The combination wherein a needle hub can be attached to the base unit, with the needle extending from the needle hub.

The combination wherein the needle hub can be integrally formed with the base unit.

The combination wherein the base unit can have a base wall and two sidewalls extending from the base wall.

The combination wherein the needle hub can be attached to a standardized Luer lock syringe.

The combination wherein the base unit can be formed by plastic molded injection.

The combination wherein proximal end edges of the base wall and the sidewalls of the base unit can extend proximally of a proximal end edge of the needle hub.

The combination wherein proximal end edges of the base wall and the sidewalls of the base unit can be substantially flush of a proximal end edge of the needle hub.

The combination wherein the film can cover the interior cavities of the base unit and the cap.

The combination wherein the needle hub can comprise a base hub section and a nose section.

The combination wherein the base hub section can have standardized exterior threads.

The combination wherein the nose section can have the needle attached thereto.

The combination wherein the needle hub can have a proximal end having an interior bore sized with a standardized female Luer taper threads to define a standardized threaded female Luer for receiving a standardized male Luer, with (Luer lock) or without (Luer slip) a threaded collar.

The combination wherein the nose section can comprise a first nose section and a second nose section

The combination wherein the first nose section can have a larger diameter than the second nose section but smaller than the base hub section.

The combination wherein the nose section can have a single constant diameter or a single tapering surface.

The combination wherein an optional rib can be connected to both the base hub section and the nose section.

The combination wherein the needle hub can be attached to the base wall of the base unit.

The combination wherein the needle hub can be unitarily formed with the base wall of the base unit.

The combination wherein a rib or connecting channel can be formed between the needle hub and the base wall.

The combination wherein two ribs can be provided to connect the needle hub to the two sidewalls of the base unit.

The combination wherein the rib can be located sufficiently distal of the proximal end of the needle hub so as not to interfere with a connector mating with the proximal end.

The combination wherein the needle hub can be sufficiently spaced from the base wall and the sidewalls so as not to interfere with a connector mating with the proximal end.

The combination wherein a C-clamp type structure can be molded with the base unit, wherein the needle hub 102 can engage with the C-clamp type structure.

The combination wherein the C-clamp type structure can be secured to the needle hub with adhesive or welding.

The combination wherein an isolation zone can be defined between the base unit and the cap.

The combination wherein the isolation zone can comprise matching contoured sidewall sections that mate to form a tight fitting section having a form fit with a gap therebetween.

The combination wherein the two contoured sidewall sections can physically contact each other.

The combination wherein the sidewalls of the base unit can be reduced or stepped to mate with corresponding stepped sections formed on the sidewalls of the cap.

The combination wherein the sidewalls of the base unit can form a tapered interface mating with the tapered interface of the cap at the isolation zone to provide a tight fitting contact.

The combination wherein mated corners between the base unit and the cap can be relieved or beveled to ensure the cap can close onto the base unit.

The combination wherein the film can seal the interior cavities of the base unit and the cap to seal the needle hub and needle.

The combination wherein the film can be bonded to the perimeter edge from an end wall to an end edge of the base unit, and over a rear exterior surface of the base unit.

The combination wherein the film can further be bonded to a rear exterior surface of the cap.

The combination wherein the film an extension can be provided beyond the end wall to facilitate gripping and removing the film.

The combination wherein the extension can be positioned on either side of the sidewalls of the cap to facilitate removing the film.

The combination wherein the film can be a single continuous piece extending from the end wall of the cap to a terminal end at the rear exterior surface of the cap.

The combination wherein the film can extend across the interface between the cap and the base unit.

The combination wherein the film can comprise two or more separate strips or pieces.

The combination wherein the film can comprise a first film piece extending from the end wall of the cap to a first base corner of the base unit and around the first base corner to the second base corner of the base unit.

The combination wherein the first film piece can extend past the second base corner.

The combination wherein the film can comprise a second film piece extending between the cap and the base unit and across the interface between the cap and the base unit.

The combination wherein the film can comprise a clear separation line or perforation between the first film piece and the second film piece.

The combination wherein the clear separation line or perforation can be provided between the first film piece and the second film piece at the base corner of the base unit.

The combination wherein the first film piece can be removably attached to the second film piece.

The combination wherein the second film piece can hingedly connect the cap to the base unit.

The combination wherein the film can have a first section extending across the length of the cap and the base unit, a second section extending across the width of the base unit near the needle hub opening, and a third section extending across the rear exterior surfaces of the cap and the base unit and across the seam or interface to function as a hinge.

The combination wherein the cap and the base unit can be hingedly connected by a living hinge.

The combination wherein the living hinge can be a unitarily formed plastic strip formed with the cap and the base unit.

The combination wherein the film can bond to polyethylene (PE), polypropylene (PE), polyethylene terephthalate (PET), polyvinyl chloride (PVC), or other equivalent plastic materials.

The combination wherein the film can be a single film type or a single film sheet.

The combination wherein the film can be HDPE (high density PE).

The combination wherein the film can be a multi-laminate comprising several different film layers.

The combination wherein the film can include a metallic foil layer to provide oxygen impermeability.

The combination wherein the film can comprise an outer layer of metalized PET, adhesive, and a poly film, such as PE.

The combination wherein the film can include a first outer most PET layer, a second or next layer of PE, a third or next layer of foil, and a fourth or most inner layer of PE.

The combination wherein adhesive can be provided between the different film layers.

The combination wherein the film can include polyvinylidene chloride (PVDC), adhesive, and a poly film which can include PE, HDPE, or PP.

The combination wherein the film can be spun bound polypropylene.

The combination wherein the first film piece can be different in material construction from the second film piece.

The combination wherein the second film piece can be thicker and more durable than the first film piece.

The combination wherein the second film piece can be a hinge, and the first film piece can seal the interior cavities of the base unit and the cap.

The combination wherein the second film piece can be fixed to the rear exterior surfaces of the cap and the base unit.

The combination wherein the first and second film pieces can be made from the same material.

The combination wherein the first and second film pieces can have different bond strengths.

The combination wherein a recess can be formed on the rear exterior surface of the base unit to define an anchor point.

The combination wherein the recess can be bounded by a perimeter and a bottom surface, and a first detent member can be provided in the recess.

The combination wherein the first detent member can be a boss or an engagement bore.

The combination wherein the perimeter can be generally round.

The combination wherein the perimeter can be oval.

The combination wherein the perimeter can be irregular in shape.

The combination wherein the perimeter can be polygonal.

The combination wherein the perimeter can be rectangular.

The combination wherein the film at the rear exterior surface of the base unit can include an opening formed around the perimeter.

The combination wherein the opening at film at the rear exterior surface of the base unit can be a perforation to facilitate access to the recess.

The combination wherein the recess can be configured to receive a tab located on the cap when the cap is rotated or retracted away from the needle to expose the needle during use.

The combination wherein the tab can project from an elongated rib formed on the cap.

The combination wherein a second detent member on the cap can engage the first detent member in the recess.

The combination wherein the second detent member can be an engagement bore or a boss to matingly engage with the first detent member.

The combination wherein the projection defining the tab can be sized and shaped to at least partially project into the recess on the base unit to allow the first and second detent members to engage one another to hold the cap in the retracted position.

The combination wherein the cap can be maintained in a retracted position by friction fit or an interference fit.

The combination wherein the rib on the cap can comprise a blunt edge that slides into a gap provided by two projections formed on the base unit having a gap therebetween, wherein the cap can be held in the retracted position by the friction or interference between the blunt edge sliding in between the gap and held by friction or interference fit.

The combination wherein the post can have a width that is less than the width of the ramp.

The combination wherein the post can have a width that is wider than the width of the ramp.

The combination wherein the needle assembly can be attached to an end of a syringe.

The combination wherein a syringe tip can be inserted into a bore of the needle hub.

The combination wherein the film can be opaque or semi-opaque.

The combination wherein the film can have printed information on the film.

The combination wherein the first film piece can extend past the recess.

A further feature of the present disclosure is a dispenser system which can comprise a dispenser having a plurality of the combination of the needle assembly and the packaging system in an array.

The combination can be joined to one or two combinations along a tear line of the film between two adjacent needle assemblies to form an array.

The combination can be generally rectangular in shape to provide for a uniform array.

The combination can have different shapes and the seam corresponding to the tear line does not need to extend the entire length of two adjacent needle assemblies.

The dispenser system wherein each needle assembly can be separated from the array one at a time along the tear line.

The dispenser system can comprise a dispenser and an array of combinations.

The dispenser system wherein the dispenser can comprise a frame for placing or mounting the dispenser system.

The dispenser system wherein a shell can be provided for holding the array of combinations within the dispenser.

The dispenser system wherein the dispenser can be hung on a wall using one or more screws passing through the wall surface of the frame or resting the lower frame section on a table top.

The dispenser system wherein the shell can comprise a storage area for holding the plurality of combinations.

The dispenser system wherein the storage area can be bounded by a panel system that can be operated to open or close access to the storage area.

The dispenser system wherein the panel system can comprise a door that can pivot about a hinge.

The dispenser system wherein a side wall can snap on and off to provide access for loading the array into the dispenser.

The dispenser system wherein the shell can further comprise a dispenser opening located adjacent a frame extension for dispensing the combinations, which can have a lip to prevent the combinations from spilling over the edge.

The dispenser system wherein the dispenser can be made from metal or from plastic.

The dispenser system wherein the array can be rolled into a rolled bundle of combinations and placed into the storage space of the dispenser system.

The dispenser system wherein the end-most combination can be placed through the dispenser opening and rested on the frame extension before the remaining rolled bundle of combinations are lowered into the storage space.

The dispenser system wherein the dispenser can comprise a frame for mounting the dispenser system on a wall, and a mounting bracket attached to the frame.

The dispenser system wherein the mounting bracket can be hung on a wall first and then the frame attached to the mounting bracket.

The dispenser system wherein the shell can comprise a storage area for holding the plurality of combinations.

The dispenser system wherein the storage area can be bounded by a panel system or a wall structure having a lid or door that can be operated to open or close access to the storage area.

The dispenser system wherein the door can be located along an upper region of the dispenser and is pivotably mounted to the shell via a hinge.

The dispenser system wherein the shell can further comprise a dispenser opening located adjacent a frame extension for dispensing the needle assemblies.

The dispenser system wherein the frame extension can have a lip to act as a stop to prevent the needle assemblies from spilling over the frame extension.

The dispenser system wherein a hopper style lower end section can be provided with a slanted bottom wall to increase the distance or gap between the end-most combination and the rolled section of the array.

The dispenser system wherein the plurality of combinations can be positioned inside the storage space of the dispenser system as a dispersed bundle without a tear line connecting two adjacent needle assemblies.

The dispenser system wherein the combinations can be positioned inside the storage space as a dispersed bundle and in an array.

A broad feature of the present disclosure includes a dual use needle assembly comprising a packaging housing having a needle hub and a needle located within an enclosure and wherein the enclosure is pivotable relative to the needle hub.

Yet an additional feature of the present disclosure includes methods for manufacturing needle assemblies or combinations of features of the needle assemblies noted herein.

Yet an additional feature of the present disclosure includes methods for using needle assemblies noted herein.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present device, system, and method will become appreciated as the same becomes better understood with reference to the specification, claims and appended drawings wherein:

FIG. 1 is a schematic perspective view of a needle assembly provided in accordance with aspects of the present device, system, and method.

FIG. 2 is an expanded perspective view of a section of the needle assembly of FIG. 1.

FIG. 2A is a partial top view of an alternative isolation zone.

FIG. 3 is a cross-sectional side view of the needle assembly of FIG. 1 with a film layer covering the housing cavities.

FIG. 4 is a cross-sectional side view of the needle assembly of FIG. 1 in a cap retracted and needle exposed position.

FIG. 4A shows the needle assembly of FIG. 4 coupled to a syringe.

FIG. 5 is an expanded perspective view of a section of the needle assembly of FIG. 1 in a capped position following use with the needle in a locked state.

FIG. 6 shows the needle assembly of FIG. 3 in perspective view.

FIG. 7 shows a top view of the cap and the base unit of the needle assembly of FIG. 1.

FIG. 8 shows the needle assembly of FIG. 3 with the film cover partially removed.

FIG. 9 shows an array of needle assemblies joined to one another with adjacent needle assemblies separated by a tear line.

FIG. 10 shows a dispenser system in accordance with aspects of the present disclosure for dispensing needle assemblies.

FIG. 11 shows an alternative dispenser system in accordance with aspects of the present disclosure for dispensing needle assemblies.

DETAILED DESCRIPTION

The detailed description set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of hinged cap needles provided in accordance with aspects of the present devices, systems, and methods and is not intended to represent the only forms in which the present devices, systems, and methods may be constructed or utilized. The description sets forth the features and the steps for constructing and using the embodiments of the present devices, systems, and methods in connection with the illustrated

embodiments. It is to be understood, however, that the same or equivalent functions and structures may be accomplished by different embodiments that are also intended to be encompassed within the spirit and scope of the present disclosure. As denoted elsewhere herein, like element numbers are intended to indicate like or similar elements or features.

With reference now to FIG. 1, a perspective view of needle assembly 100 provided in accordance with aspects of the present embodiment is shown. The needle assembly 100 may sometime be referred to as a hinged cap needle assembly or simply hinged cap device or assembly. As shown, the needle assembly 100 comprises a needle hub 102 having a needle 104 attached thereto. The needle 104 comprising a needle shaft 106 defining a lengthwise axis and a sharpened distal tip 108. Thus, as used herein, the term "axial" implies a spatial relationship along the axial length or axial direction of the needle axis. The needle assembly 100 is shown in a covered positioned in which the needle 104 is positioned inside a cap 110 and the needle tip 108 is covered by the wall enclosures of the cap to prevent inadvertent needle sticks.

As shown, the cap 110 has a base wall 112 disposed between two sidewalls 114a, 114b and an end wall 116, which together define an interior cavity 118, such as an interior space, for accommodating or receiving the needle 104. The cap 110 has a distal end 120 and a proximal end 122. The two sidewalls 114a, 114b may be generally parallel so that the width of the cap and the proximal and distal ends 120, 122 are about the same width. As shown, the sidewalls 114a, 114b tapered inwardly in the direction of the needle shaft 106 so that the distal end 120 of the cap 110 is narrower than the proximal end 122 of the cap. Conceivably the distal end 120 can be wider than the proximal end 122.

Internally of the interior cavity 118, a first rib set 124, a second rib set 126, and a latch 128 are provided. The first and second rib sets 124, 126 are attached to the base wall 112 and the sidewalls 114a, 114b to structurally support the walls and each comprises a passage 129 for receiving the needle shaft 106. The ribs preferably include a tapered inlet end 130 to facilitate centering the shaft in the event of a misalignment or contact into the two passages 129 when closing the cap over the needle.

The latch 128 is shown with a leg or post 132 and a ramp 134 connected to the post or leg. As shown, the ramp 134 is slanted and is bisected by the leg. The slanted configuration of the ramp defines a first side 136 in which the wall and leg define an obtuse angle therebetween and a second side 138 in which the wall and the leg define an acute angle therebetween. As

shown, the needle 104 is located on the first side 136 of the latch 128 when the cap is rotated to cover the needle in the packaged position or pre-use configuration. After using the needle, the cap 110 can be rotated and the needle 104 moved to the second side 138 of the latch 128 to lock the needle within the cap 110. Thus, the latch 128 is understood to have a hold side and a lock side, which can be the first side 136 and the second side 138, respectively.

Also shown is a base unit 140 surrounding the needle hub 102. In one exemplary embodiment, the base unit 140 has a base wall 142 located between two sidewalls 144a, 144b, which together define a cavity 146 for accommodating the needle hub 102. The cavity 118 of the cap and the cavity 146 of the base unit together define a package cavity. Sufficient clearance is provided around the needle hub 102 for attaching a standardized luer lock syringe. As further discussed below, the cap 110 and the base unit 140 are separately formed, such as by plastic molded injection, and subsequently attached together using a unique hinge system of the present device, system, and method. The base unit 140 and the cap 110 has a lengthwise axis, which is generally coincident with the lengthwise axis of the needle.

In one example, the proximal end edge 148 of the base wall 142, the proximal end edge 150 of the sidewalls 144a, 144b both extend further proximally of the proximal end edge 152 of the needle hub. In other words as shown, the base unit 140 has at least one or more walls having an end edge that extend further proximally, i.e., the needle hub is recessed from the end edge of one or more walls, of the needle hub so as to cover the needle hub. Alternatively, the proximal end edges of the base and side walls can be flush with the proximal end edge of the needle hub. As further discussed below, the base unit 140 with the extended walls and the cap 110 define a package or packaging housing 156 to house the needle hub 102 and needle 104 and also functions as a safety shield for capping the needle tip 108 following use. A separate package or blister pack shell for housing the needle assembly 100 during manufacturing, shipping, and storage is not required with the present needle assembly, which has a self-contained packaging system, as further discussed below. The open perimeter edge 90 of the base unit 140 and the cap 110 together define a perimeter for a film cover to seal in the two respective cavity sections 118, 146 with the needle and needle hub located inside, as further discussed below. The film cover allows the needle assembly 100 to be manufactured and shipped without separately providing a package or blister pack. Thus, an aspect of the present device, system, and method is a dual use needle assembly 100 that is configured to house a needle hub 102 and needle 104 for storing,

shipping, and distribution purposes and that also functions as a safety cap for capping the needle following use.

With reference now to FIG. 2, an expanded perspective view of the needle assembly 100 of FIG. 1. As shown, the needle hub 102 comprises a base hub section 160 having standardized exterior threads 166 and a nose section 168 having the needle 104 attached thereto. The hub 102 has an interior bore 172 that is sized with a standardized female Luer taper and together with the threads 166 define a standardized threaded female Luer for receiving a standardized male Luer, with (Luer lock) or without (Luer slip) a threaded collar. As shown, the nose section 168 comprises a first nose section 162 and a second nose section 164. The first nose section 162 can have a larger diameter than the second nose section 164 but smaller than the base hub section 160. In an alternative embodiment, the nose section 168 has a single constant diameter or a single tapering surface, such as a cone surface. An optional rib 170 is provided connecting to both the base hub section 160 and the nose section 168. In an example, the needle hub 102 is attached to the base wall 142 of the base unit 140. For example, the needle hub 102 may be unitarily formed, via plastic injection molding, to the base wall 142. A rib or connecting channel may be formed during plastic injection molding between the needle hub nose section and the base wall. Alternatively, two ribs may be provided to connect the needle hub to the two sidewalls of the base unit. The rib or ribs should be located sufficiently distal of the threads 166 so as not to interfere with a threaded collar of a male Luer during use of the needle assembly. Also, the needle hub 102 should be sufficiently spaced from the base wall 142 and the two sidewalls 144a, 144b to permit connection with a male threaded Luer, such as a syringe tip, without interfering with the collar of the male threaded Luer. In the present embodiment, the needle hub 102 is attached to a distal wall 174 of the base unit 140. For example, the nose section 168, such as the second nose section 164, is unitarily formed with the distal wall 174. The needle hub is therefore suspended within the base unit at its nose section. In another embodiment, at least one rib is provided between the needle hub and one of the walls, either the base wall or one of the two sidewalls, in addition to the connection with the distal wall 174. Thus, in one embodiment, the base unit 140 and the needle hub 102 are understood to be formed as a unitary construction, such as by injection molding the two as a single unit. In yet another embodiment, a C-clamp type structure is molded with the base unit 140 and the needle hub 102

engages, such as snaps into, the C-clamp type structure. Adhesive or welding may be used to provide a more secured arrangement when incorporating the C-clamp type structure.

As noted above, the dual use needle assembly 100 is configured for use as a packaging device with a needle and needle hub inside and as a needle safety device with a protective hinged cap, as further discussed below. To ensure appropriate isolation of the interior cavities for packaging purposes, the present package housing 156 is equipped with an isolation zone 180 between the base unit 140 and the cap 110. In one example, the isolation zone 180 comprises matching contoured sidewall sections 182, 184 that mate to form a tight fitting section having a form fit with a gap 186 therebetween, which is shown enlarged for discussion purposes only. The surfaces where the two cut sidewall sections 182, 184 mate can physically contact so as to eliminate any path for potential contamination and/or bio growth. As shown, the two sidewalls 144a, 144b of the base unit 140 have part of their wall layers reduced or stepped to mate with corresponding stepped sections formed on the two sidewalls 114a, 114b of the cap 110. To facilitate closing the cap 110 over the needle and the cut sidewall sections 182, 184 mesh when closed, the mated corners 188, 190 may be relieved or beveled. In an alternative embodiment, the isolation zone 180 may be provided with a different cut configuration. As shown in the alternative embodiment of FIG. 2A, the isolation zone 180 can utilize two single cuts, such as two matching tapered surfaces, on each of the two mating sidewalls 114a/144a and 114b/144b to provide the tight fitting contacts.

FIG. 3 is a cross-sectional side view of the needle assembly 100 of FIG. 1 in a sealed or packaged state. A film cover or layer 190 is shown applied to the open perimeter edge 90 of the package housing 156 to seal the interior cavity sections 118, 146 of the housing to thereby seal the needle hub 102 and needle. As shown, the film cover 190 is bonded to the perimeter edge 90 from the end wall 116, to end edge 192 of the base unit 140, and over the rear exterior surface 194 of the base unit and the rear exterior surface 196 of the cap 110. An extended piece or extension may be provided beyond the end wall 116 to serve as a gripping point or section to facilitate gripping and removing the film cover 190, which may be considered a film cover layer. If the film cover 190 is wider than the distal end of the cap 110, which in the present embodiment has a tapered distal end, then there will be a pull tab on either side of the two sidewalls 114a, 114b to facilitate opening of the package. In one example, the film cover 190 is a single continuous piece that extends from the end wall 116 of the cap to the terminal end 198,

at the rear exterior surface 196 of the cap 110. In another example, the film cover 190 is formed from two or more separate strips or pieces. For example, the first film piece 204 can extend from the end wall 116 to the first base corner 199 and around the first base corner to the second base corner 200 of the base unit 140. In another example, the first film piece can extend past the second base corner 200. A second film piece 206 can extend between the cap 110 and the base unit 140 and across the interface or seam 202 between the two components. Preferably, a clear separation line or a perforation 208 is provided between the first film piece 204 and the second film piece 206. For example, a clear separation or a perforation can be provided between the first film piece 204 and the second film piece 206 at the base corner 200 of the base unit. When the first film piece 204 is removed from the package housing 156, the second film piece 206 remains and holds the cap 110 to the base unit 140. The second film piece 206 therefore functions as a hinge 205 between the cap 110 and the base unit 140. The hinge 205 enables the cap 110 to rotate back against the base unit 140 and away from the needle 104, as further discussed below.

The film cover 190 is shown affixed to the open perimeter edge 90 along the lengthwise direction 92 of the package housing 156 and along the widthwise direction 94 around the first base corner 199 of the package housing. Preferably, the film cover 190 continues to the second base corner 200 of the base unit 140. Together with the wall surfaces 116, 114a, 114b, 144a, 144b of the package housing 156, the film cover 190 seals in the interior cavities 118, 146 of the package housing 156. The same film cover 190, either as a continuous piece or as a separate film piece, extends along the rear exterior surface 194 of the base unit and the rear exterior surface 196 of the cap and across the interface or seam 202 where the two components are joined. In one embodiment, the film cover 190 has at least three distinct film cover sections: the first extending across the length of the package housing, the second extending across the width of the package housing near the needle hub opening, and the third extending across the rear exterior surfaces of the cap and the base unit and across the seam or interface 202 to also function as a hinge 205. The sealed assembly further comprises at least two overlapping sidewalls. As disclosed, two sets of sidewalls are overlapped at two different isolation zones 180 (FIG. 2), one on each side of the package unit. In still another example, the film cover 190 extends across the length and the width of the package housing but wherein the cap and the base

unit are joined by a living hinge, which is a unitarily formed plastic strip that is formed with the cap 110 and the base unit 140.

In one example, the film cover 190 is configured to bond to a variety of rigid plastic package housing material, including polyethylene (PE), polypropylene (PE), polyethylene terephthalate (PET), polyvinyl chloride (PVC), and other equivalent plastic materials. The film cover 190 may be a single film type or a single film sheet, such as HDPE (high density PE). More preferred, the film 190 is a multi-laminate comprising several different film types or layers with an optional metallic foil layer to provide oxygen impermeability. For example, the film cover 190 can comprise an outer layer of metalized PET, adhesive, and a poly film, such as PE. Another example includes a first outer most PET layer, a second or next layer of PE, a third or next layer of foil, and a fourth or most inner layer of PE. Appropriate adhesive is understood to be provided between the layers. Another example includes polyvinylidene chloride (PVDC), adhesive, and poly film, such as PE or HDPE, or PP. Yet another film material could be spun bound polypropylene, such as the Tyvek® brand of films. In some examples, the first film piece 204 differs in material construction from the second film piece 206. For example, the second film piece 206 may be thicker and selected with more durable materials than the first film piece to function as a hinge whereas the first film piece 206 is configured to seal in the interior cavities only and be peelable. The second film piece 206 should resist and should not be easily peeled from the rear exterior surfaces of the cap and the base unit. The material for the second film piece 206 should be selected to have a stronger bond to the package housing 156 to better operate as a hinge and be resistant or impervious to peeling from the wall surfaces of the package housing. In yet other examples, the first and second film pieces are made from the same material but using different sealing applications to possess different bond strengths, such as using different welding temperature, different adhesive, and/or different pressure. It is understood that other film pieces known in the art may be usable with the package housing 156 of the present embodiment in the configuration disclosed.

Also shown in FIG. 3 is a recess 214 formed on the rear exterior surface 194 of the base unit 140, which defines an anchor point. The recess 214 is bounded by a perimeter 218 and a bottom surface 220 and comprises a first detent member 216, which can be a boss or an engagement bore. In one example, the perimeter 218 is generally round. In other examples, the perimeter 218 is oval, irregular in shape, or polygonal, such as square or rectangular. As shown

with reference to FIG. 7, the recess 214 is generally rectangular in shape. The film cover layer 190 at the rear exterior surface 194 of the base unit 140 may include an opening formed around the perimeter 218 or may cover the recess 214, such as opening 250 shown in FIG. 7. If the film layer 190 covers the recess 214, a perforation is preferably provided with the film cover or layer 190 at the recess to facilitate tearing or rupturing that section of the film cover or layer to permit accessing the recess 214.

The recess 214 is configured to receive the tab 222 located on the cap 110 when the cap is rotated or retracted away from the needle 104 to expose the needle during use. As shown, the tab 222 projects from an elongated rib 224 formed on the cap 110 and has a second detent member 226 for engaging the first detent member 216 in the recess 214. The second detent member 226 can be the other one of an engagement bore or a boss. The projection defining the tab 222 is sized and shaped to at least partially project into the recess 214 on the base unit 140 to allow the first and second detent members 216, 226 to engage one another to hold the cap 110 in the retracted position, as further discussed below with reference to FIG. 4. In an alternative embodiment, a cap to base unit securing system to maintain the cap in a retracted position may comprise a friction fit and/or an interference fit. For example, the rib 224 on the cap may comprise a blunt edge that slides into a gap provided by two projections formed on the base unit 140 having a gap therebetween. The cap can be held in the retracted position by the friction and/or interference between the blunt edge sliding in between the gap and held by friction and/or interference fit.

With reference again FIG. 3 in addition to FIG. 1, in the sealed state, the cap 110 is firmly secured to the base unit 140 although the two components are separately formed and subsequently joined. As shown and described, the cap 110 and the base unit 140 are secured to one another by the film cover or layer 190. Additionally, the two components are structurally supported laterally of the lengthwise axis of the needle by the shaped contacts 182, 184 at the isolation zone 180. Thus, an aspect of the present disclosure is understood to include a needle assembly 100 comprising a needle hub and needle sealed inside a package housing 156 with a film cover or layer 190, the packaging housing comprising separately formed and subsequently joined cap and base unit. In another example, the cap and the base unit are joined to one another by a living hinge. The needle assembly 100 is usable without additional packaging and is usable as a hinged cap safety device upon removal of at least a section of the film layer 190. In one

example, the needle assembly 100 comprises a thermoplastic film that functions as a hinge and wherein the film holds the protective cap to the base unit and wherein the cap is rotatable relative to the base unit about the thermoplastic film and wherein the base unit comprises a needle hub. In the example shown, the needle hub is unitarily formed to the base unit. In another example, the base unit comprises a C-type clamp and the needle hub snap-fit into the C-clamp. Adhesive or welding may be used with the snap-fit configuration to more permanently secure the needle hub to the base unit.

In FIG. 3, an alternative latch 128 comprising a post 132 having a width that is less than the width of the ramp 134 is shown, which differs from the latch of FIG. 1 in which the two widths are the same. In other examples, the post 132 has a width that is wider than the width of the slanted wall. The width and/or thickness at a localized area of the post may be selected to control resiliency or ability of the post to deflect when the slanted wall 134 comes in contact with the needle 104.

With reference now to FIG. 4, the cap 110 is shown pivoted or retracted away from the needle 104 and the tab 222 on the cap engaging the recess 214 on the base unit 140. With reference also to FIGs. 1 and 3 in addition to FIG. 4, the cap 110 may be pivoted by first removing the film cover 190, or at least part of the film cover to leave the remaining film cover bonded to the cap and the base unit to function as a hinge. In an embodiment with a living hinge, the entire film cover 190 may be removed. At this point, the needle 104 is located on the first or hold side 136 of the latch 128 located in the cap 110 (FIG. 1). The obtuse angle between the ramp 134 and the leg 132 allows the needle to slip past the latch 128. For example, the leg 132 and/or the needle 104 can deflect to clear one another to then allow the cap to retract away from the needle. The cap is then pivoted until the first and second detent members 216, 226 engage one another to hold the cap in the retracted position shown in FIG. 4. At this point, the needle hub 102 may be placed over a male Luer tip of a syringe or other medical instrument. Alternatively, the needle hub may be placed over the syringe tip or other medical instrument after removing the film cover layer and before retracting the cap away from the needle. Also shown in FIG. 4 is one of the cut sidewall sections 184 of the cap 110.

FIG. 4A shows the needle assembly 100 attached to an end of a syringe 230. More specifically, the syringe tip is shown inserted into the bore of the needle hub 102. The syringe 230 is shown with a barrel 232 and a plunger 234 and can embody any prior art syringes. The

combination needle assembly 100 and syringe 230 may now be used to draw a sample or provide an injection. Following use, the cap 110 may be pivoted over the needle to cover the needle tip, as further discussed below.

With reference now to FIG. 5, the needle assembly 100 is shown in a locked state with the needle 104 positioned on the second side 138 of the latch 128, such as by pivoting the cap 110 from the retracted position shown in FIG. 4A in the reverse direction to capture the needle 104 within the sidewalls 114a, 114b of the cap 110. The needle assembly 100 is shown without the syringe 230, which can be present while pivoting the cap 110 to the locked or capped position. During the rotation and prior to locking the needle 104 below the ramp 134 shown in FIG. 5, the needle 104 contacts or impacts the top 133 of the ramp 134 at a central section of the wall between the two ends 240a, 240b as the cap 110 is rotated over the needle. As the wall 134 is orientated in the direction of rotation of the cap, the needle slides down the ramp 134 and the needle 104, the leg 132, or both the needle and the leg deflect to clear one another. Once the needle 104 clears the lower edge 240a of the ramp 134, it snaps back under the ramp 134 and is trapped by the ramp and the leg, which define a lock space 242 having an acute angle. Once in the position shown on the second side 138 of the latch 128, the needle is secured by the acute angle defining the lock space 242.

Thus, the present needle assembly 100 is understood to comprise a cap hinged to a base unit by a flexible hinge, which together defines a packaged housing. The needle assembly further comprises a needle hub having a needle and wherein the needle hub is unitarily formed with the base unit. In an alternative embodiment, the needle hub is engaged to a C-type clamp located on the base unit and the flexible hinge is a thermoplastic film adhered to both the cap and the base unit. The thermoplastic film has a length that spans across a seam or interface between the cap and the base unit. The needle assembly 100 has a packaged state (FIG. 3) in which a film cover 190 is affixed to an open perimeter edge of the package housing 156, which seals the needle hub 102 and needle 104 within the interior cavities 118, 146 of the cap and the base unit. In the packaged state, the needle 104 is held in a temporary hold position on the first side 136 of a latch 128 located inside the cavity of the cap. The cap is retractable away from the needle to expose the needle for an injection or for taking a sample. The needle hub is usable with a standardized Luer tip, such as a syringe tip. After use, the needle may be capped by pivoting the cap over the needle and latching the needle against the latch by moving the needle past a ramp

over to a lock side of the latch, which has an acute angle formed between a leg and the slanted wall. In one example, the film cover is affixed to a length of the package housing and the width of the packaged housing. The film cover is removable from the length and the width of the package housing to allow access to the needle and needle hub located inside the walls of the cap and of the base unit, respectively.

FIG. 6 is a perspective view of the needle assembly 100 of FIG. 3 with a transparent film layer 190. In other examples, the film layer can be opaque or semi-opaque and can have printed information on the film, such as product information. The transparent film allows the cap 110, base unit 140, needle 104, needle hub 102, and latch 128 to be more clearly viewed even when the film layer 190 is attached to the open perimeter edge 90 of the packaged housing 156.

FIG. 7 is a top view of the rear or back side of the needle assembly 100 of FIG. 1, which shows the rear exterior surface 194 of the base unit 140 and the rear exterior surface 196 of the cap 110, along with the seam 202 located between the two. Also shown is the recess 214 for receiving the tab 222 on the cap 110 to hold the cap in the retracted position to expose the needle tip. Also shown is a cut-out 250 on the film cover 190 around the recess 214 to facilitate engagement between the first and second detent members 216, 226. As previously discussed, a perforation instead of a cut-out may be provided around the recess 214. Also shown is a perforation 252 on the rear exterior surface 194 of the base unit 140, which is an alternative embodiment to the film cover layer 190 having a separation line at the first base corner 199, the second base corner 200 or somewhere on the rear exterior surface 194 of the base unit. As shown, the first film piece 204 of the film cover layer 190 extends from the end wall 116 of the cap past the first base corner 199, and past the second base corner 200 and extends to the perforation 252. Said differently, this first film piece 204 may be removed from the end wall 116 of the cap all the way to the perforation 252. For this version of the first film piece 204, the cut-out 250 around the recess 214 may be omitted, i.e., providing a solid film section around the recess, since the entire recess will be exposed upon removable of the first film piece. The second film piece 206 shown will remain with the cap 110 and the base unit 140 and functions as a flexible hinge between the two components. In an alternative embodiment, a living hinge is provided between the cap 110 and the base unit 140.

FIG. 9 is a schematic top view of a plurality of needle assemblies 100 in an array 260. As shown, a needle assembly 100 is joined to one or two adjacent needle assemblies along a tear

line 262, which can be a perforation formed on the film cover layer 190 between two adjacent side walls 114a/114b, 144a/144b of the cap 110 and base unit 140 of two adjacent needle assemblies 100. The array 260 is preferred when the needle assemblies 100 are provided to end users in bulk. As shown, each needle assembly 100 is generally rectangular in shape. In an array embodiment, the cap 110 of each needle assembly 100 may be provided with a general rectangular shape to provide for a uniform array. In other embodiments, the package housing 156 of each needle assembly 100 can have different shapes and the seam corresponding to the tear line 262 does not have to extend the entire length of two adjacent needle assemblies.

In use, a needle assembly 100 may be separated from the array 260 one at a time along the tear line 262. Once a single needle assembly 100 is separated from the array 260, the film cover layer 190 of each needle assembly 100 may be removed and the needle assembly used in the manner described above.

FIG. 8 is a schematic cross-sectional side view of the needle assembly 100 of FIG. 3, which shows the film cover layer 190 partially opened near the end wall 116 of the cap 110. The film layer 190 may be provided with an extended pull tab 270, which extends beyond the end edge 272 of end wall 116. The pull tab 270 presents a convenient point or location to grab and pull on the film cover 190 to remove it from the package housing 156. As described above, the film cover 190 may be wider at the distal end area of the cap so that pull tabs are provided on either side of end wall 116.

FIG. 10 is a schematic cross-section end view of a dispensing system 280 comprising a dispenser 282 and an array 260 of needle assemblies 100, which may be one of the needle assemblies discussed elsewhere herein. As shown, the dispenser 282 comprises a frame 284 for placing the dispenser system on a counter top, table top, trolly, or for mounting the dispenser system on a wall. A shell 285 is provided for holding the array of needle assemblies within the dispenser 282. The dispenser 282 may be hung on a wall using one or more screws passing through the wall surface of the frame 284 or resting the lower frame section 283 on a table top. The shell 285 comprises a storage area 286 for holding the plurality of needle assemblies. The storage area 286 is bounded by a panel system 288 that can be operated to open or close access to the storage area 286. In one example, the panel system 288 comprises a door 290 that can pivot about a hinge 292. In another example, a side wall can snap on and off to provide access for loading a roll of needles into the dispenser. The shell 285 further comprises a dispenser

opening 294 locating adjacent a frame extension 296 for dispensing the needle assemblies 100, which has a lip 314 to prevent the needle assemblies from spilling over the edge. The dispenser may be made from metal or from plastic.

As shown, the needle assemblies 100 are provided as an interconnected array 260, similar to that shown in FIG. 9. The array 260 is rolled into a rolled bundle of needle assemblies and placed into the storage space 286 of the dispenser system. In practice, the end-most needle assembly 298 is placed through the dispenser opening 294 and rested on the frame extension 296 before the remaining rolled bundle of needle assemblies are lowered into the storage space 286. Each needle assembly 100 may be used by a user by grabbing the end-most needle assembly 298 and separating it at the tear line 262. Once separated, the needle assembly may be used as described above.

FIG. 11 is a schematic cross-section end view of an alternative dispensing system 310 comprising dispenser 282 and an array 260 of needle assemblies 100, which may be one of the needle assemblies discussed elsewhere herein. The dispenser comprises a frame 284 for mounting the dispenser system on a wall. A mounting bracket 312 is provided and attaches to the frame 284. The mounting bracket 312 may be hung on a wall first and then the frame 284 attached to the mounting bracket 312. A shell 285 for holding the array of needle assemblies is provided with the frame 284. The shell 285 comprises a storage area 286 for holding the plurality of needle assemblies 100. The storage area 286 is bounded by a panel system or wall structure 288 having a lid or door 290 that can be operated to open or close access to the storage area 286. In one example, the door 290 is located along an upper region of the dispenser and is pivotably mounted to the shell via a hinge 292. The shell 285 further comprises a dispenser opening 294 located adjacent a frame extension 296 for dispensing the needle assemblies 100. The frame extension 296 has a lip 314 to act as a stop to prevent the needle assemblies from spilling over the frame extension 296.

As shown, the needle assemblies 100 are provided as an interconnected array 260, similar to that shown in FIG. 9. The array 260 is rolled into a rolled bundle of needle assemblies and placed into the storage space 286 of the dispenser system. In practice, the end-most needle assembly 298 is placed through the dispenser opening 294 and rested on the frame extension 296 before the remaining rolled bundle of needle assemblies are lowered into the storage space 286. Each needle assembly 100 may be used by a user by simply grabbing the end-most needle

assembly 298 and separating it at the tear line 262. Once separated, the needle assembly may be used as described above.

To ensure adequate or proper loading of the needle assemblies 100 at the dispenser opening 294, the present dispenser 280 incorporates a hopper style lower end section 318. As shown, the lower end section 318 is provided with a slanted bottom wall 320 to increase the distance or gap between the end-most needle assembly 298 and the rolled section 322 of the array 260 of needle assemblies. This gap ensures a sufficient head pressure due to gravity on the end-most needle assembly 298 to ensure that it will slide down the sloped bottom wall 320 and be available at the opening 294 for use.

In an alternative embodiment, a plurality of needle assemblies 100 are positioned inside the storage space of the dispenser system of FIGs. 10 and/or 11 as a dispersed bundle, i.e., without a tear line connecting two adjacent needle assemblies. In still other embodiments, the needle assemblies are positioned inside the storage space as a dispersed bundle and in an array.

Although limited embodiments of needle assemblies and their components including dispensing system have been specifically described and illustrated herein, many modifications and variations will be apparent to those skilled in the art. Accordingly, it is to be understood that the needle assemblies and their components constructed according to principles of the disclosed device, system, and method may be embodied other than as specifically described herein. The disclosure is also defined in the following claims.

CLAIMS

What is claimed is:

1. A combination safety needle assembly (100) and a packaging system for the safety needle assembly (100) comprising:

a base unit (140) comprising a base wall (142) located between two sidewalls (144a, 144b) and defining an interior cavity (146);

a cap (110) connected to the base unit (140) at an interface, the cap (110) comprising a base wall (112) located between two sidewalls (114a, 114b) and defining an interior cavity (118) having a latch (128);

a needle hub (102) and a needle (104) combination, said needle hub (102) attached to the base unit (140) and said needle (104) extending into the interior cavity (118) of the cap (110);

wherein the sidewalls (114a, 114b) of the cap (110) and the sidewalls (144a, 144b) of the base unit (140) define an open perimeter edge (90) and the interior cavity (118) of the cap (110) and the interior cavity (146) of the base unit (140) define a package cavity ; and

wherein a thermoplastic film is attached to the open perimeter edge (90) and extends across the interface between the cap (110) and the base unit (140) to enclose the combination needle hub (102) and needle (104) within the package cavity and forms a hinge at the interface.

2. The combination of claim 1, wherein the thermoplastic film comprises a first film piece (204) and a second film piece (206) separated from one another by a perforation (208) or a distinct separation.

3. The combination of claims 1 or 2, wherein the two sidewalls (144a, 144b) of the base unit (140) and the two sidewalls (114a, 114b) of the cap (110) overlap along an axial direction.

4. The combination of claims 1, 2, or 3, wherein the needle hub (102) is unitarily formed with the base unit (140).

5. The combination of claim 4, wherein the needle hub (102) is molded with a distal wall (174) on the base unit (140).

6. The combination of claim 5, wherein the distal wall (174) on the base unit (140) connects to the base wall (142) and the two sidewalls (144a, 144b) of the base unit (140).

7. The combination of claims 1, 2, 3, 4, 5, or 6 further comprising a latch (128) comprising a post (132) and a ramp (134) mounted at an end of the post (132).

8. A combination safety needle assembly (100) and a packaging system for the safety needle assembly (100) comprising:

a base unit (140) comprising an enclosure having a base wall (142) located between two sidewalls (144a, 144b), said enclosure having an interior cavity (146) and a perimeter edge (90) with a proximal end edge;

a cap (110) hingedly connected to the base unit (140) at an interface by a film layer, the cap (110) comprising an enclosure having a base wall (112) located between two sidewalls (114a, 114b), said enclosure defining an interior cavity (118) having a latch (128) and a perimeter edge (90);

a needle hub (102) and a needle (104) combination, said needle hub (102) attached to the base unit (140) and said needle (104) extending into the interior cavity (118) of the cap (110);

wherein the needle hub (102) is recessed within the proximal end edge (148, 150) of the base unit (140) and wherein a film cover (190) is attached to the perimeter edge (90) of the cap (110) and the perimeter edge (90) of the base unit (140) to enclose the combination needle hub (102) and needle (104) within the interior cavity (118) of the cap (110) and the interior cavity (146) of the base unit (140).

9. The combination of claim 8, wherein the film layer and the film cover (190) are spaced from one another.

10. The combination of claims 8 or 9, wherein a perforation is located between the film layer and the film cover (190).

11. The combination of claims 8, 9, or 10, wherein the two sidewalls (114a, 114b) of the cap (110) and the two sidewalls (144a, 144b) of the base unit (140) overlap along an axial direction.

12. The combination of claims 8, 9, 10, or 11, further comprising a needle assembly connected to the base unit (140) and cap (110) via a tear line.

13. The combination of claims 8, 9, 10, 11, or 12, wherein the needle hub (102) is unitarily formed with the base unit (140).

14. The combination of claims 8, 9, 10, 11, 12, or 13, wherein the needle hub (102) snap fits into a C-clamp formed on the base unit (140).

15. A dual use needle assembly (100) comprising a packaging housing (156) having a needle hub (102) and a needle (104) located within an enclosure having a perimeter edge (90)

and a film cover (190) attached to the perimeter edge (90) to seal the needle hub (102) and needle (104) within the packaging housing (156), and wherein the packaging housing (156) comprises a cap (110) having two sidewalls (114a, 114b) and a base unit (140) having two sidewalls (144a, 144b) and wherein the sidewalls (114a, 114b, 144a, 144b) of the cap (110) and the base unit (140) overlap along an axial direction.

16. The dual use needle assembly (100) of claim 15, wherein the cap (110) is attached to the base unit (140) by a living hinge.

17. The dual use needle assembly (100) of claims 15 or 16, wherein the cap (110) is attached to the base unit (140) by a second film cover (206) that spans across a seam (202) located between the cap (110) and the base unit (140).

18. The dual use needle assembly (100) of claims 15, 16, or 17, further comprising a second dual use needle assembly (100) and a third dual use needle assembly (100) connected in an array.

19. A method for manufacturing a dual use needle assembly (100) comprising:

forming a base unit (140) comprising two sidewalls (144a, 144b) and a base wall (142) and a needle hub (102) having a needle (104) with a sharpened needle tip;

forming a cap (110) comprising two sidewalls (114a, 114b) and a base wall (112);

attaching a film cover (190) to outer edges of the two sidewalls (114a, 114b, 144a, 144b) of the cap (110) and of the base unit (140); and

overlapping the two sidewalls (114a, 114b) of the cap (110) with the two sidewalls (144a, 144b) of the base unit (140) along an axial direction.

20. The method of claim 19, further comprising attaching a second film cover (206) across a seam (202) located between the base wall (112) of the cap (110) and the base wall (142) of the base unit (140).

21. The method of claims 19 or 20, wherein the base wall (142) of the base unit (140) is attached to the base wall (112) of the cap (110) by a living hinge.

22. The method of claims 19, 20, or 21, further comprising placing the needle (104) on a first side of a latch (128) comprising a post (132) and a ramp (134).

23. A dispenser system comprising a dispenser having a wall structure (288) defining a storage space (286), an array of needle assemblies (100), a dispersed bundle of needle assemblies (100), or both an array of needle assemblies (100) and a dispersed bundle of needle

assemblies (100) located in the storage space (286); and wherein each needle assembly (100) comprises:

a package housing (156) comprising a base unit (140) comprising sidewalls (144a, 144b) and a base wall (142) hingedly connected to a cap (110) comprising sidewalls (114a, 114b) and a base wall (112);

a film cover (190) affixed to a perimeter edge (90) of the package housing (156);

a needle hub (102) and needle (104) sealed inside the package housing (156) by the film cover (190); and

sidewalls (114a, 114b, 144a, 144b) of the cap (110) and the base unit (140) overlapping along an axial direction.

AMENDED CLAIMS
received by the International Bureau on 07 August 2015 (07.08.2015)

1. A combination safety needle assembly (100) and a packaging system for the safety needle assembly (100) comprising:

a base unit (140) comprising a base wall (142) located between two sidewalls (144a, 144b) and defining an interior cavity (146);

a cap (110) connected to the base unit (140) at an interface, the cap (110) comprising a base wall (112) located between two sidewalls (114a, 114b) and defining an interior cavity (118) having a latch (128);

a needle hub (102) and a needle (104) combination, said needle hub (102) attached to the base unit (140) and said needle (104) extending into the interior cavity (118) of the cap (110);

wherein the sidewalls (114a, 114b) of the cap (110) and the sidewalls (144a, 144b) of the base unit (140) define an open perimeter edge (90) and the interior cavity (118) of the cap (110) and the interior cavity (146) of the base unit (140) define a package cavity;

characterized in that

a thermoplastic film (190) is attached to the open perimeter edge (90) and extends along a rear exterior surface (194) of the base unit and the rear exterior surface (196) of the cap and across the interface or seam (202) between the cap (110) and the base unit (140) to enclose the combination needle hub (102) and needle (104) within the package cavity and forms a hinge at the interface or seam (202).

2. The combination of claim 1, wherein the thermoplastic film (190) comprises a first film piece (204) and a second film piece (206) separated from one another by a perforation (208) or a distinct separation.

3. The combination of claim 2, wherein the second film piece (206) remains and holds the cap (110) to the base unit (140), when the first film piece (204) is removed from the package cavity (156).

4. The combination of claim 2 or 3, wherein the second film piece (206) functions as a hinge (205) between the cap (110) and the base unit (140).

5. The combination of any of the preceding claims, wherein the two sidewalls (144a, 144b) of the base unit (140) and the two sidewalls (114a, 114b) of the cap (110) overlap along an axial direction.

6. The combination of any of the preceding claims, wherein the needle hub (102) is unitarily formed with the base unit (140).

7. The combination of claim 6, wherein the needle hub (102) is molded with a distal wall (174) on the base unit (140).

8. The combination of claim 7, wherein the distal wall (174) on the base unit (140) connects to the base wall (142) and the two sidewalls (144a, 144b) of the base unit (140).

9. The combination of any of the preceding claims, further comprising a latch (128) comprising a post (132) and a ramp (134) mounted at an end of the post (132).

10. A combination safety needle assembly (100) and a packaging system for the safety needle assembly (100) comprising:

a base unit (140) comprising an enclosure having a base wall (142) located between two sidewalls (144a, 144b), said enclosure having an interior cavity (146) and a perimeter edge (90) with a proximal end edge;

a cap (110) hingedly connected to the base unit (140) at an interface or a seam (202) by a film layer, the cap (110) comprising an enclosure having a base wall (112) located between two sidewalls (114a, 114b), said enclosure defining an interior cavity (118) having a latch (128) and a perimeter edge (90);

a needle hub (102) and a needle (104) combination, said needle hub (102) attached to the base unit (140) and said needle (104) extending into the interior cavity (118) of the cap (110);

wherein the needle hub (102) is recessed within the proximal end edge (148, 150) of the base unit (140) and wherein a film cover (190) is attached to the perimeter edge (90) of the cap (110) and the perimeter edge (90) of the base unit (140) to enclose the combination needle hub (102) and needle (104) within the interior cavity (118) of the cap (110) and the interior cavity (146) of the base unit (140).

11. The combination of claim 10, wherein the film layer and the film cover (190) are spaced from one another.

12. The combination of claims 10 or 11, wherein a perforation is located between the film layer and the film cover (190).

13. The combination of any of claims 10 to 12, wherein the two sidewalls (114a, 114b) of the cap (110) and the two sidewalls (144a, 144b) of the base unit (140) overlap along an axial direction.

14. The combination of any of claims 10 to 13, further comprising a needle assembly connected to the base unit (140) and cap (110) via a tear line.

15. The combination of any of claims 10 to 14, wherein the needle hub (102) is unitarily formed with the base unit (140).

16. The combination of any of claims 10 to 15, wherein the needle hub (102) snap fits into a C-clamp formed on the base unit (140).

17. A dual use needle assembly (100) comprising a packaging housing (156) having a needle hub (102) and a needle (104) located within an enclosure having a perimeter edge (90) and a film cover (190) attached to the perimeter edge (90) to seal the needle hub (102) and needle (104) within the packaging housing (156), and wherein the packaging housing (156) comprises a cap (110) having two sidewalls (114a, 114b) and a base unit (140) having two sidewalls (144a, 144b) and wherein the sidewalls (114a, 114b, 144a, 144b) of the cap (110) and the base unit (140) overlap along an axial direction.

18. The dual use needle assembly (100) of claim 17, wherein the cap (110) is attached to the base unit (140) by a living hinge.

19. The dual use needle assembly (100) of claims 17 or 18, wherein the cap (110) is attached to the base unit (140) by a second film cover (206) that spans across a seam (202) located between the cap (110) and the base unit (140).

20. The dual use needle assembly (100) of claim 17 to 19, further comprising a second dual use needle assembly (100) and a third dual use needle assembly (100) connected in an array.

21. A method for manufacturing a dual use needle assembly (100) comprising:

forming a base unit (140) comprising two sidewalls (144a, 144b) and a base wall (142) and a needle hub (102) having a needle (104) with a sharpened needle tip;

forming a cap (110) comprising two sidewalls (114a, 114b) and a base wall (112);

attaching a film cover (190) to outer edges of the two sidewalls (114a, 114b, 144a, 144b) of the cap (110) and of the base unit (140); and

overlapping the two sidewalls (114a, 114b) of the cap (110) with the two sidewalls (144a, 144b) of the base unit (140) along an axial direction.

22. The method of claim 21, further comprising attaching a second film cover (206) across a seam (202) located between the base wall (112) of the cap (110) and the base wall (142) of the base unit (140).

23. The method of claim 22, wherein the base wall (142) of the base unit (140) is attached to the base wall (112) of the cap (110) by the second film cover (206) which functions as a living hinge.

24. The method of claim 21 to 23, further comprising placing the needle (104) on a first side of a latch (128) comprising a post (132) and a ramp (134).

25. A dispenser system comprising a dispenser having a wall structure (288) defining a storage space (286), an array of needle assemblies (100), a dispersed bundle of needle assemblies (100), or both an array of needle assemblies (100) and a dispersed bundle of needle assemblies (100) located in the storage space (286); and wherein each needle assembly (100) comprises:

a package housing (156) comprising a base unit (140) comprising sidewalls (144a, 144b) and a base wall (142) hingedly connected to a cap (110) comprising sidewalls (114a, 114b) and a base wall (112) by a film layer (206) that extends between the cap (110) and the base unit (140);

a film cover (190) affixed to a perimeter edge (90) of the package housing (156);

a needle hub (102) and needle (104) sealed inside the package housing (156) by the film cover (190); and

sidewalls (114a, 114b, 144a, 144b) of the cap (110) and the base unit (140) overlapping along an axial direction.

Statement under Art. 19 (1) PCT

In response to the objections under novelty and inventive step (*Re Item V*) and defects of the International application (*Re Item VII*) raised in the Written Opinion of the International Searching Authority (ISA) a set of amended claims 1 to 25 is submitted herewith under A. 19 PCT, which shall replace originally filed claims 1 to 23:

Independent claim 1 has been amended to the two-part form with the novel feature being placed in the characterizing portion as required under Rule 6.3(b) PCT. Claim 1 has been amended to further specify that "*the thermoplastic film (190) extends along a rear exterior surface (194) of the base unit and the rear exterior surface (196) of the cap and across the interface or seam (202)*". Further, the expression "*seam (202)*" has been introduced in addition to "*interface*", both of which are used interchangeably throughout the application. These amendments make it clear that the thermoplastic film extends over the interface or seam located between the rear exterior surfaces of the base unit and the cap.

It is assumed that the novelty objection concerning original claim 1 under *Re item V.2* in the Written Opinion has been overcome by way of this amendment and it is submitted that the subject-matter of claim 1 and claims 2 to 9 dependent thereon are novel and also inventive over cited prior art document D1.

Independent claim 10 (original claim 8) has been similarly amended by including the feature "*or seam (202)*". Also this amendment makes it clear that the interface or seam 202 is located between the rear exterior surfaces of the base unit and the cap. It is therefore submitted that also the subject matter of claims 10 and claims 11 to 16 is novel and inventive over the disclosure in D1.

Independent claim 25 (original claim 23) has been amended by specifying that "*the base wall is hingedly connected to a cap by a film layer (206) that extends between the cap (110) and the base unit*". This amendment makes it clear that the hinge is formed by means of a film layer. Consequently, it is submitted that also the subject matter of claim 25 is novel and inventive over the disclosure of D1.

It is assumed that independent claims 1, 10, 17, 21, and 25 presently on file fulfil the requirements of Art. 33(2) and (3) PCT.

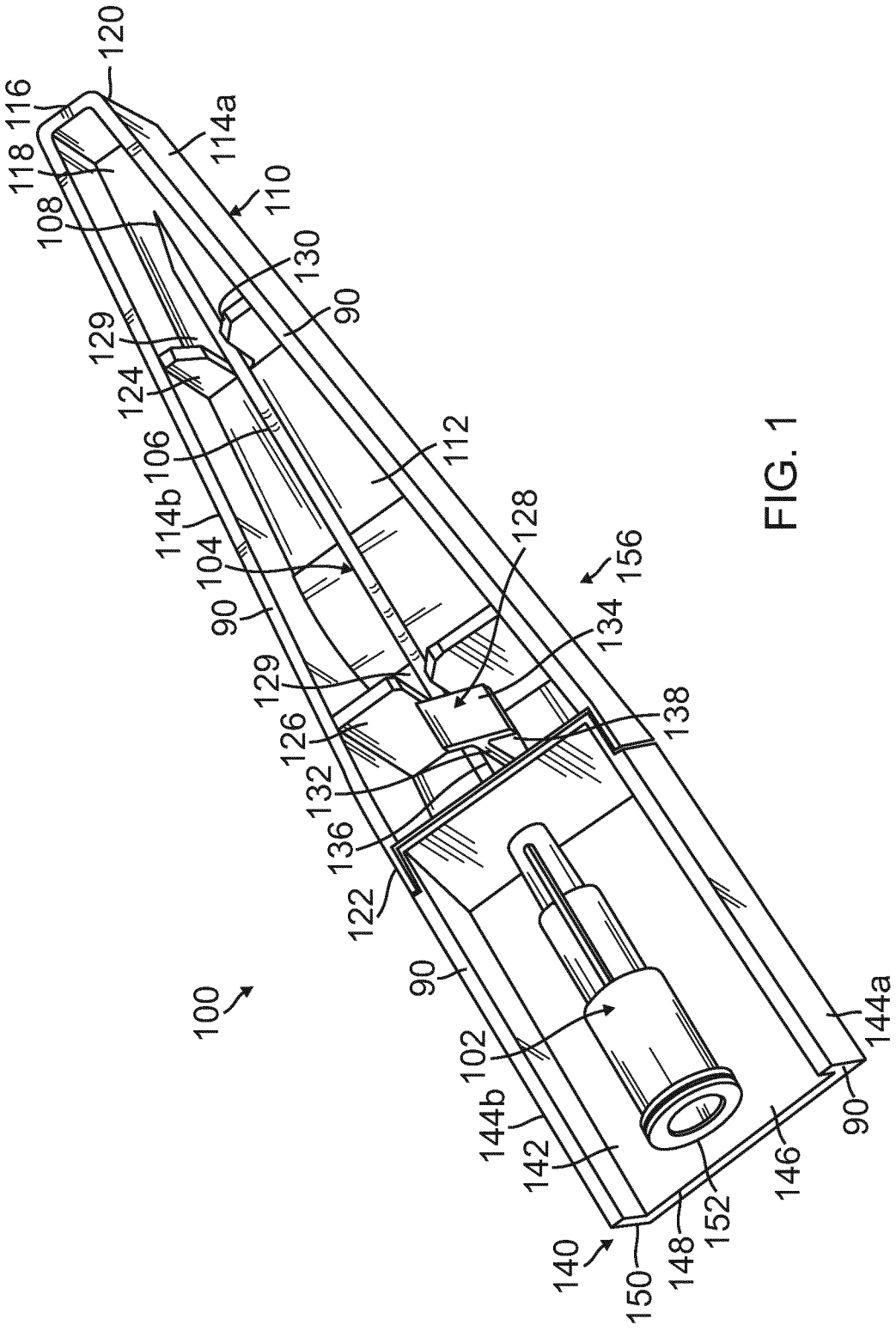

120
116
118
108
114a
110
130
90
129
124
106
114b
104
112
128
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144b
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144a

FIG. 1

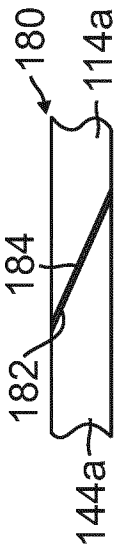

180
114a
184
182
144a

FIG. 2A

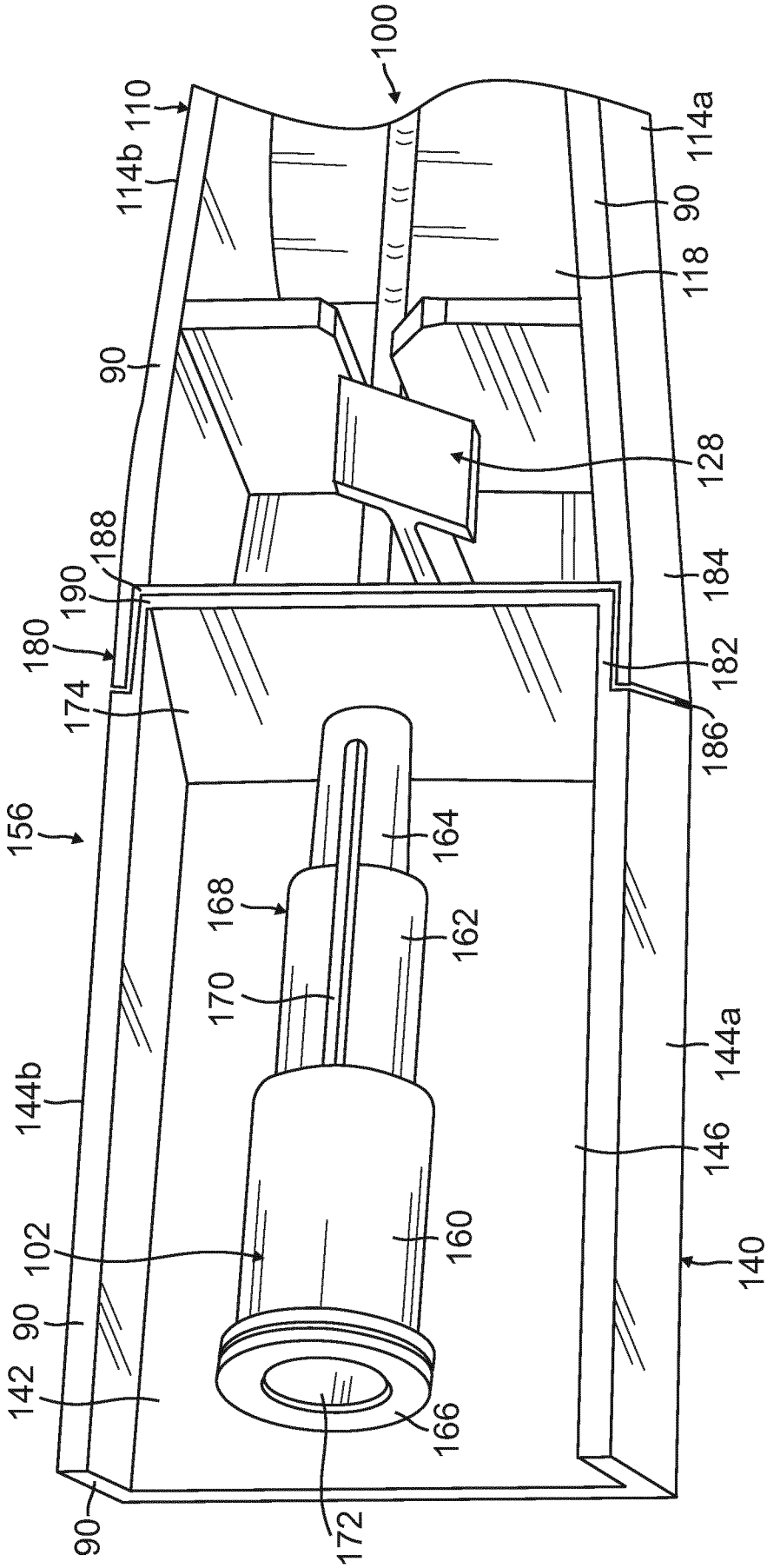

100
110
114b
114a
90
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128
188
190
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180
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174
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156
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168
162
170
144a
144b
146
102
160
140
90
142
166
172
90

FIG. 2

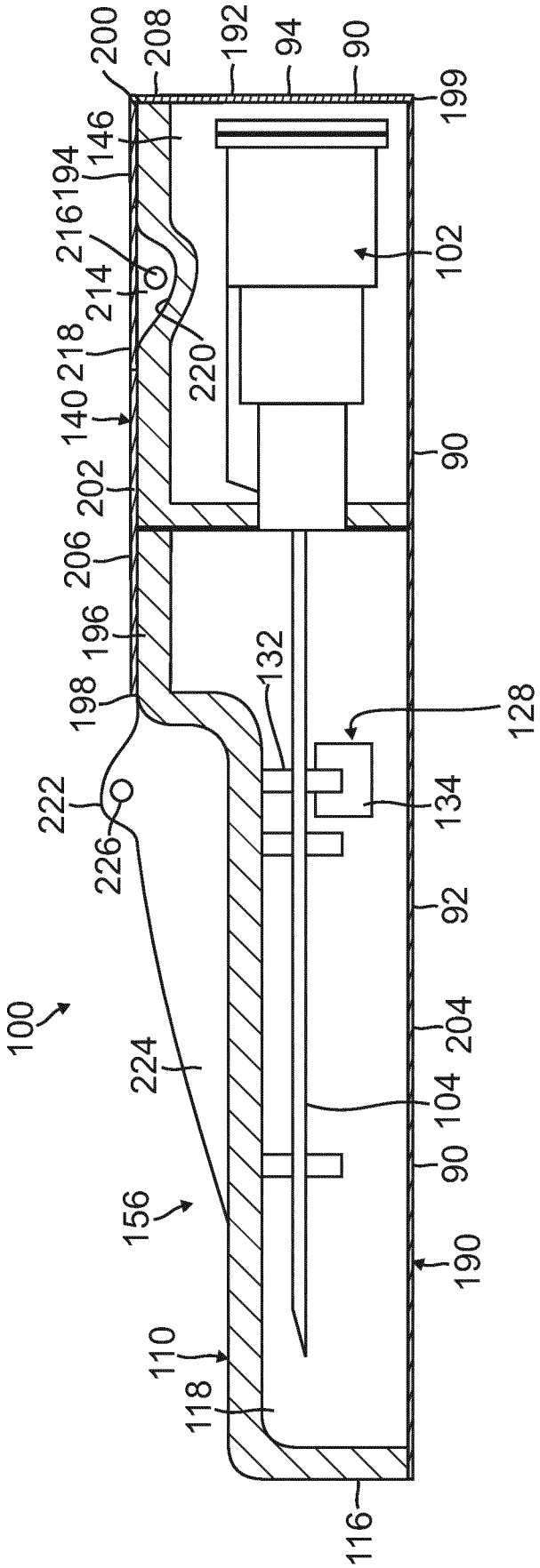

200
208
192
94
90
199
146
194
216
214
218
220
140
202
206
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198
102
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132
128
222
226
134
92
100
224
204
104
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156
190
110
118
116

FIG. 3

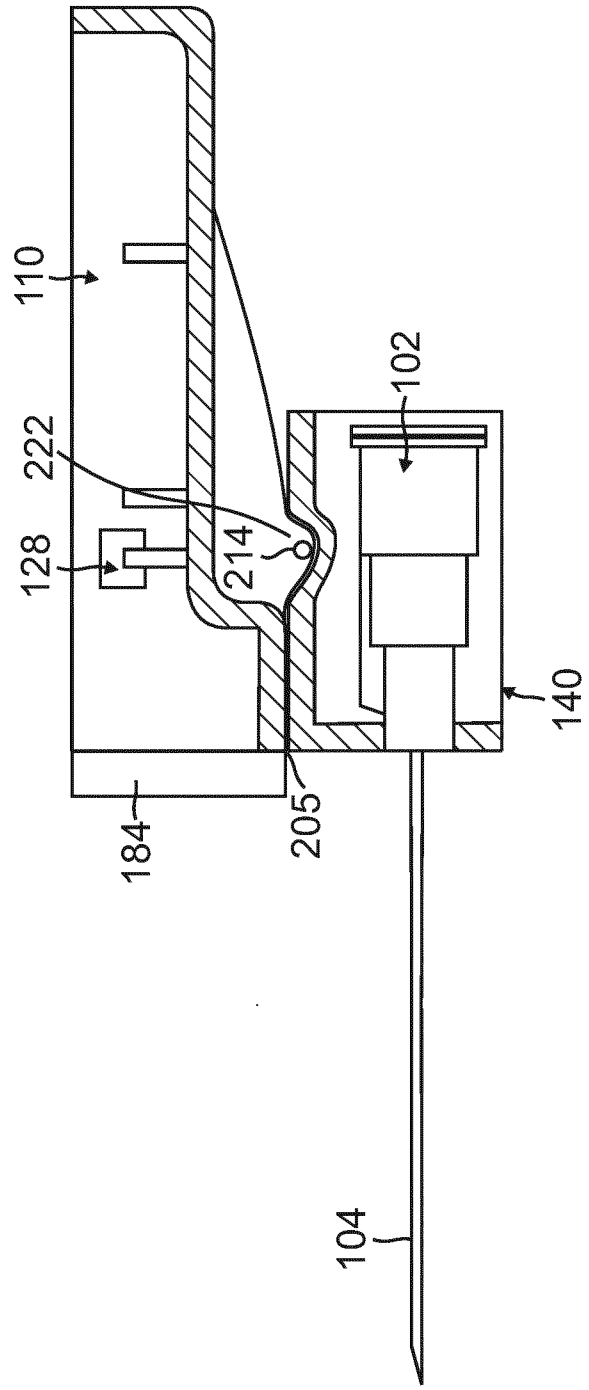


FIG. 4

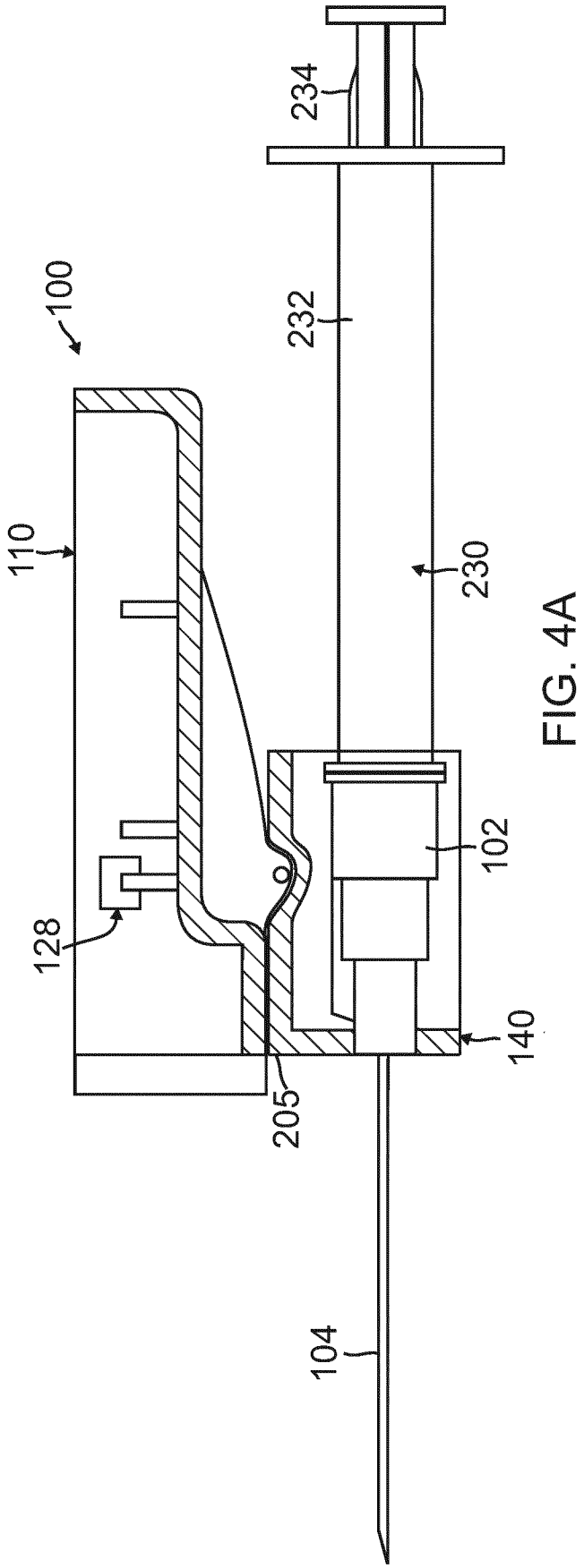


FIG. 4A

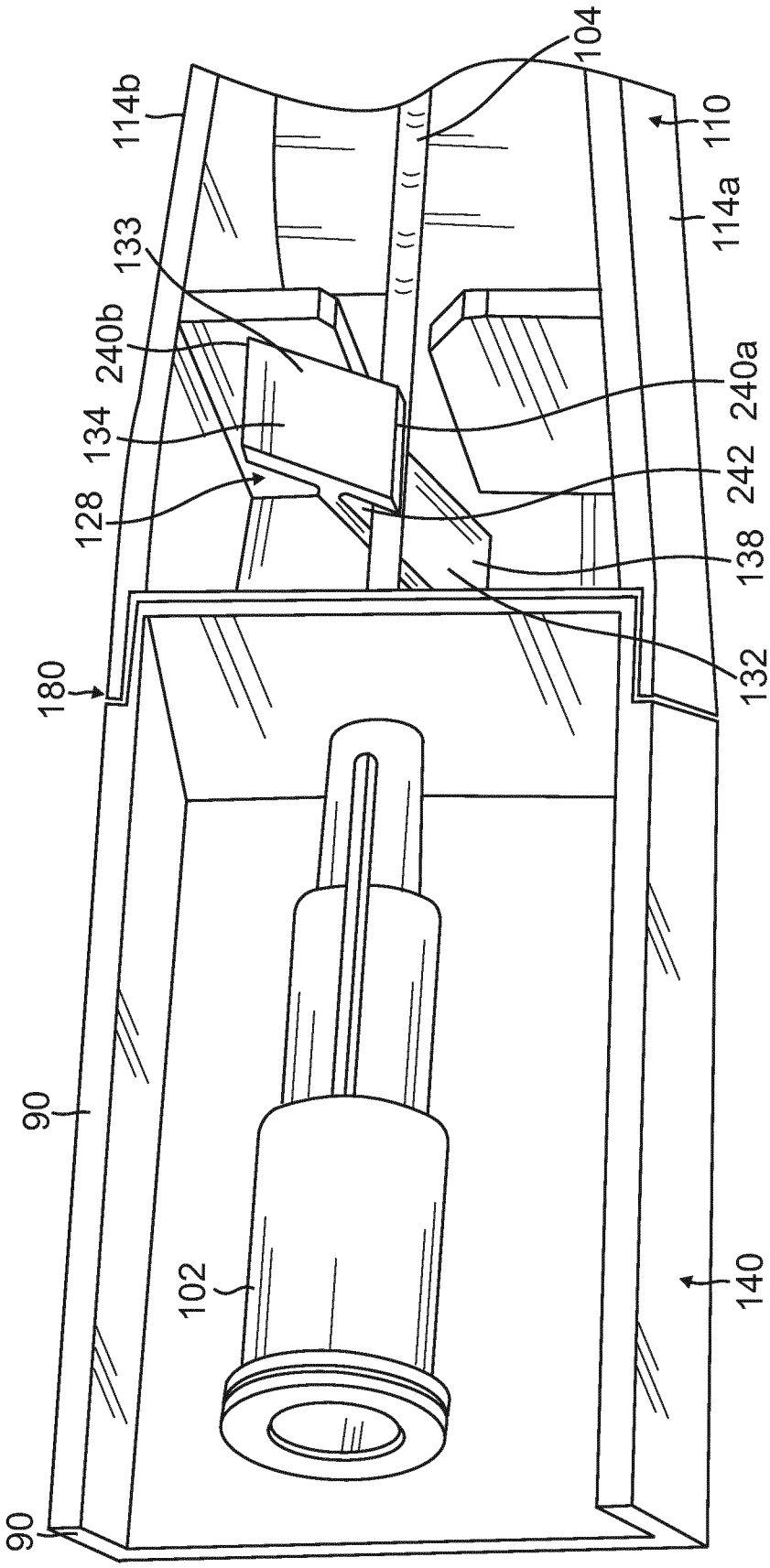

104
114b
110
133
114a
240b
240a
134
242
128
138
132
180
90
102
140
90

FIG. 5

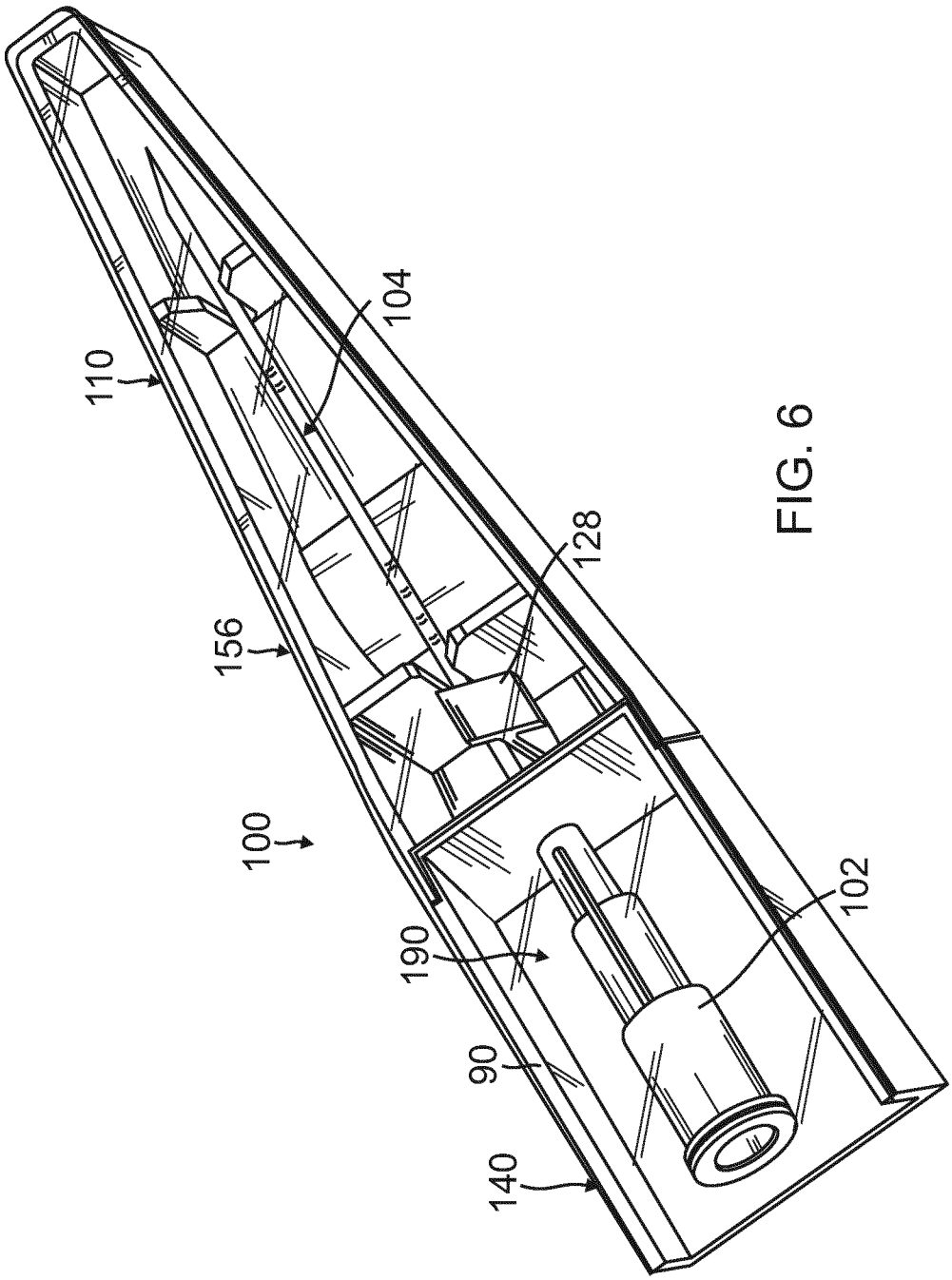


FIG. 6

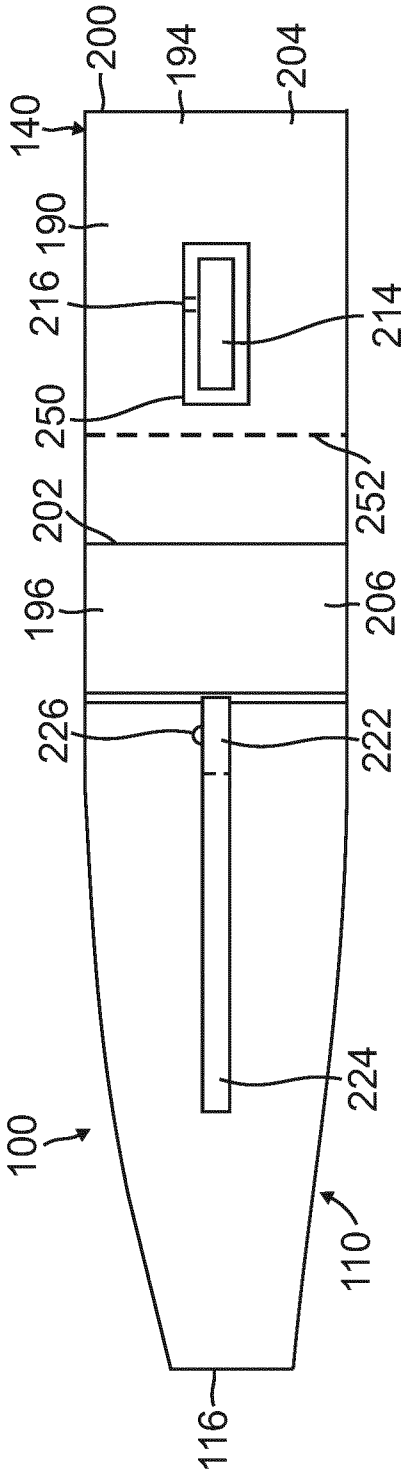

140
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194
204
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202
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116

FIG. 7

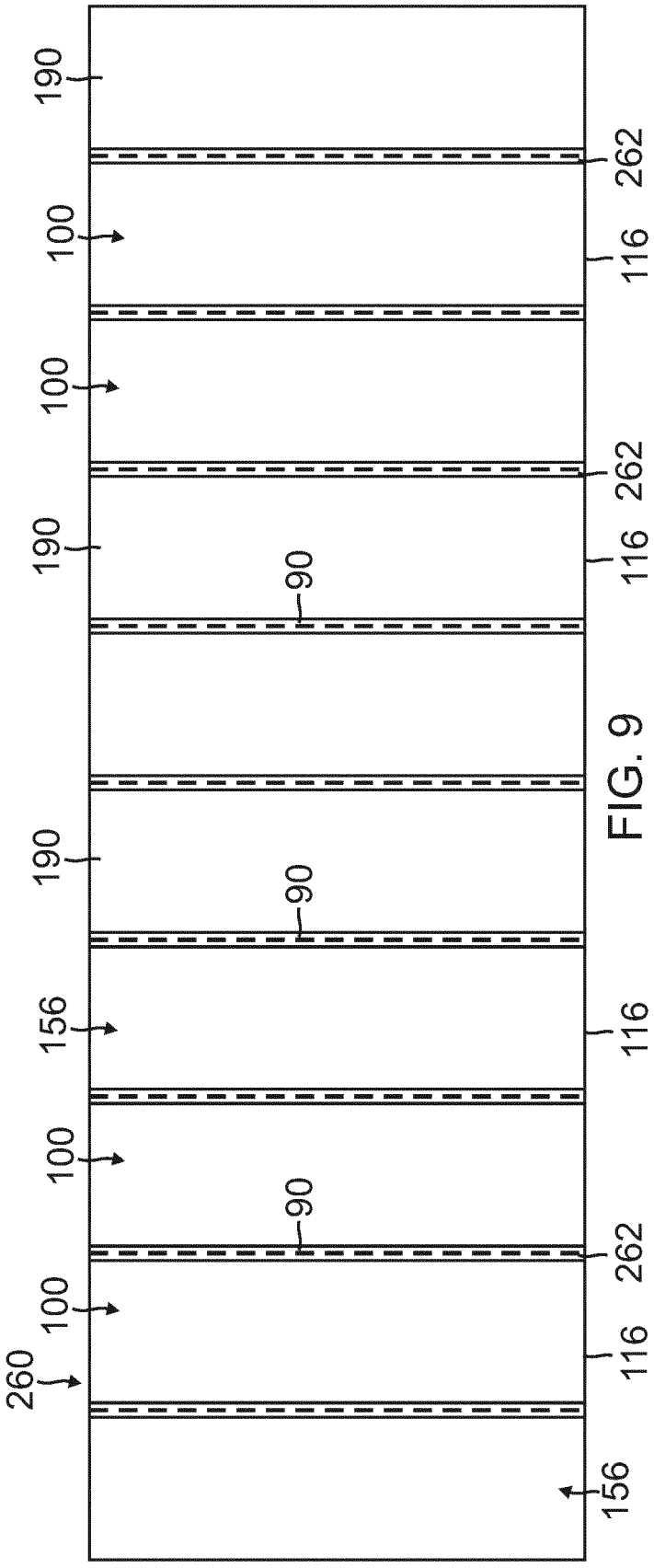

190
262
100
116
100
190
262
90
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190
90
156
116
100
90
262
100
116
260
156

FIG. 9

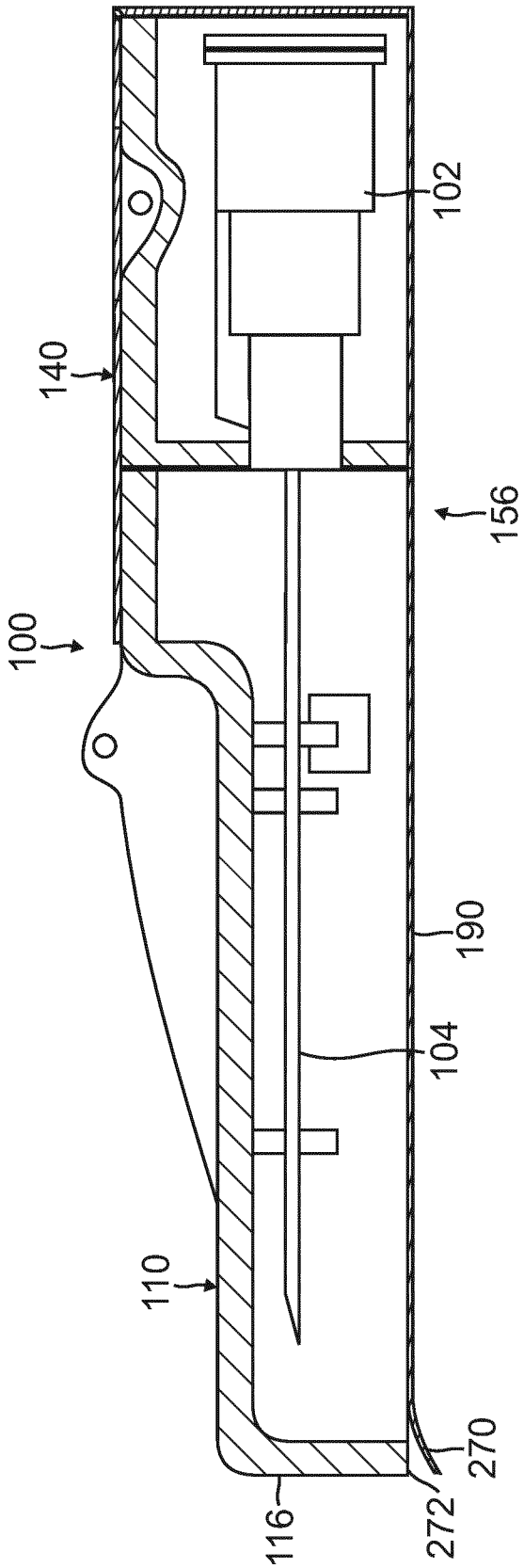
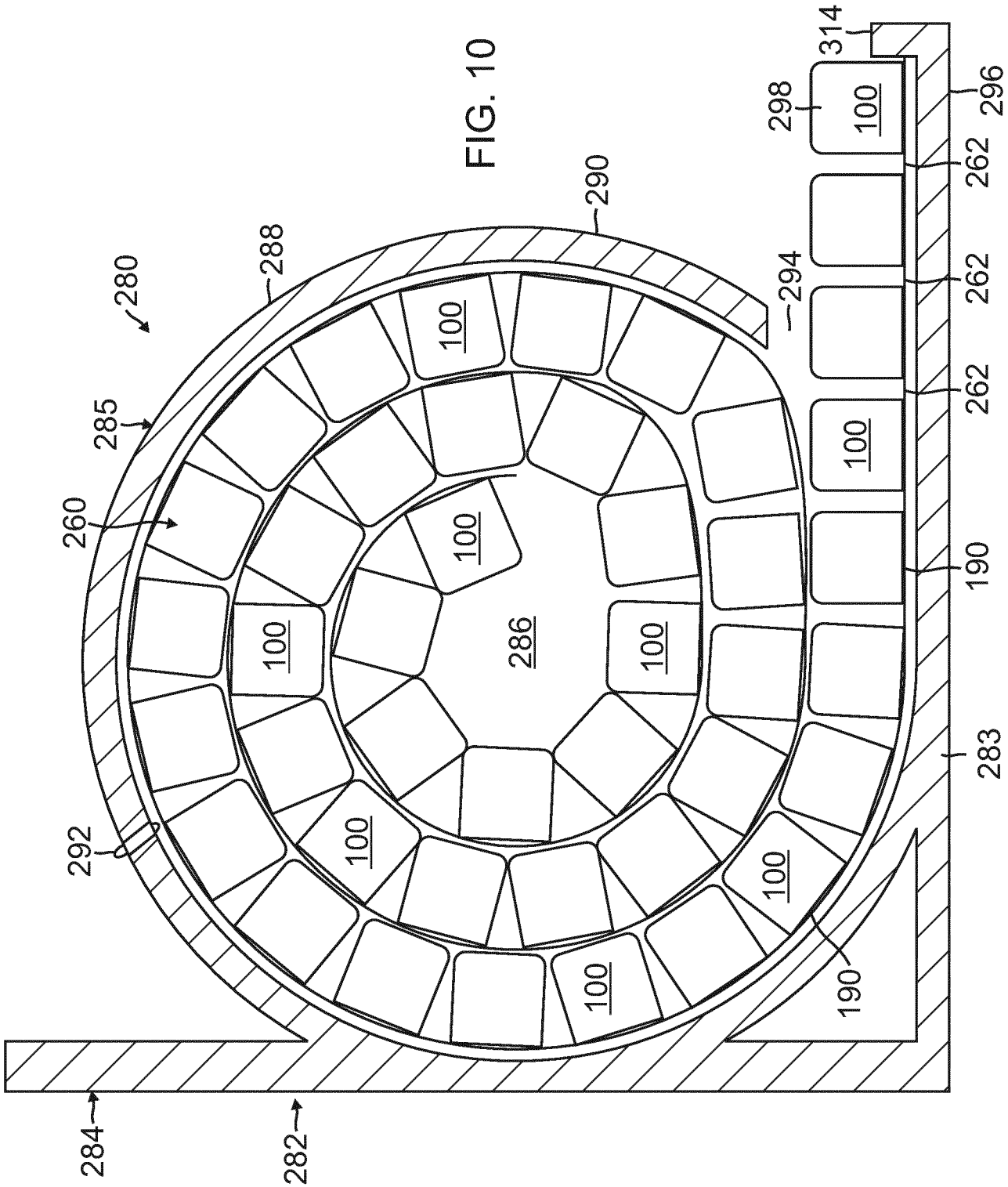


FIG. 8

FIG. 10


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190
283
100

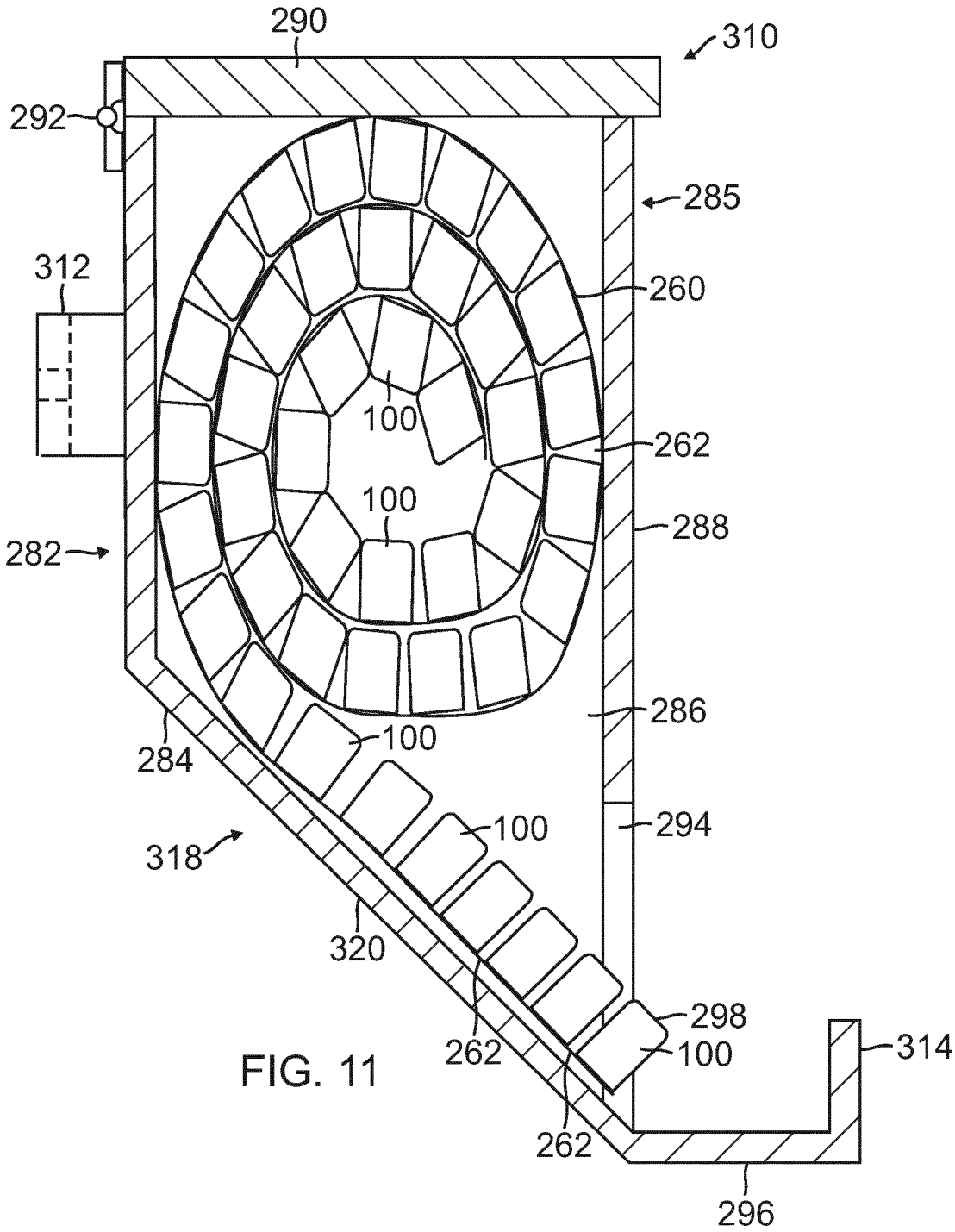

290
310
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285
312
260
100
262
100
282
288
286
284
100
294
318
100
320
298
262
100
314
262
296

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/057638

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/00
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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/036732 A1 (MARANO-FORD APRIL [US]) 20 February 2003 (2003-02-20)	1-3, 7-12, 14-17
Y	paragraph [0021] - paragraph [0031]; figures 1-6	4-6,13, 18,20,23
A		21,22

A	EP 0 916 355 A2 (TUERK RUDOLF DR MED [DE]) 19 May 1999 (1999-05-19) figure 1	1-23

X	WO 2009/007718 A1 (STAR SYRINGE LTD [GB]; MADIN GRAHAM JOHN [DE]; KOSKA MARC ANDREW [GB]) 15 January 2009 (2009-01-15)	19,21,22
Y	page 11, line 25 - page 12, line 2;	20
A	figures 16-18 page 6, line 8 - line 24 page 8, line 23 - page 10, line 29	1-18,23

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 June 2015	02/07/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Knychalla, Verena

2

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 664 259 A (LANDIS ROBERT [US]) 12 May 1987 (1987-05-12)	4-6,13
A	column 9, line 12 - line 19; figures 1-4	1-3, 7-12, 14-23
A	WO 2013/029529 A1 (SHANGHAI SOL MILLENNIUM MEDICAL PRODUCTS CO LTD [CN]; LIN ZUOQIAN [CN]) 7 March 2013 (2013-03-07) paragraph [0071]; figures 5,6	1-23
Y	US 3 074 540 A (BEICH FRANK R ET AL) 22 January 1963 (1963-01-22)	18
A	sentence 22, paragraph 4 - sentence 31; figure 8	1-17, 19-23
Y	US 2005/269227 A1 (ERICKSON THOMAS E [US] ET AL) 8 December 2005 (2005-12-08)	23
A	paragraph [0021]; figure 1	18
A	US 2006/124643 A1 (MARKERT BROOKS R [US] ET AL) 15 June 2006 (2006-06-15) paragraph [0037]; figures 1, 8A, 8B	1-23

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/057638

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003036732 A1	20-02-2003	AT 396762 T	15-06-2008
		AU 2002313744 A1	03-03-2003
		EP 1425056 A2	09-06-2004
		JP 2004538099 A	24-12-2004
		US 2003036732 A1	20-02-2003
		WO 03015842 A2	27-02-2003
EP 0916355 A2	19-05-1999	EP 0916355 A2	19-05-1999
		US 6159193 A	12-12-2000
WO 2009007718 A1	15-01-2009	AP 2952 A	31-08-2014
		AR 067515 A1	14-10-2009
		AU 2008273945 A1	15-01-2009
		BR PI0814547 A2	06-01-2015
		CA 2693719 A1	15-01-2009
		CL 2008002035 A1	24-10-2008
		CN 101790396 A	28-07-2010
		EP 2173415 A1	14-04-2010
		IL 203189 A	30-09-2014
		JP 2010533020 A	21-10-2010
		JP 2013135921 A	11-07-2013
		KR 20100051634 A	17-05-2010
		PE 08442009 A1	08-08-2009
		RU 2010104861 A	20-08-2011
		TW 200911314 A	16-03-2009
		US 2009018510 A1	15-01-2009
		US 2012029441 A1	02-02-2012
		UY 31218 A1	30-04-2009
		WO 2009007718 A1	15-01-2009
US 4664259 A	12-05-1987	NONE	
WO 2013029529 A1	07-03-2013	AU 2012303935 A1	20-03-2014
		CA 2847183 A1	07-03-2013
		CN 102363056 A	29-02-2012
		EP 2750743 A1	09-07-2014
		JP 2014527443 A	16-10-2014
		KR 20140077161 A	23-06-2014
		MA 35454 B1	01-09-2014
		US 2014221872 A1	07-08-2014
		WO 2013029529 A1	07-03-2013
US 3074540 A	22-01-1963	NONE	
US 2005269227 A1	08-12-2005	US 2005269227 A1	08-12-2005
		US 2009255839 A1	15-10-2009
US 2006124643 A1	15-06-2006	NONE	