



(51) International Patent Classification:

A61M 35/00 (2006.01) A61F 13/40 (2006.01)

A61B 17/00 (2006.01) A61M 35/006 (2006.01)

(21) International Application Number:

PCT/US2021/026714

(22) International Filing Date:

09 April 2021 (09.04.2021)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/007,543 09 April 2020 (09.04.2020) 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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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).

(54) Title: DEVICES FOR BLEEDING REDUCTION AND METHODS OF MAKING AND USING THE SAME

(57) Abstract: A device that includes a reservoir, an ampule within the reservoir containing a medication, a release mechanism mechanically coupled to the ampule, and a topical applicator attached to the reservoir. The release mechanism is configured to, upon activation, apply a mechanical force that causes the ampule to break and the medication to be released. The released medication can be retained by the topical applicator and delivered to a wound. The medication may comprise tranexamic acid. The device can be used to treat wound and reduce bleeding of a wound.

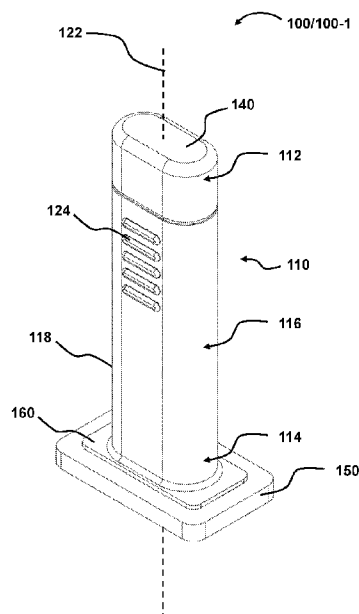


FIG. 1

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:

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

TITLE

DEVICES FOR BLEEDING REDUCTION AND METHODS OF MAKING AND USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of priority to U.S. Provisional Application No. 63/007,543, filed on April 9, 2020, which is herein incorporated by reference in its entirety for all purposes.

FIELD OF INVENTION

[0002] The present invention relates generally to devices having topical applicators, and more specifically to devices having topical applicators for reducing bleeding of a wound and/or achieving hemostasis at a wound.

BACKGROUND OF THE INVENTION

[0003] Health professionals continue to encourage patients with minor injuries to seek medical attention at primary care clinics, urgent care centers, and hospital emergency rooms. Many urgent care centers are not open twenty-four hours per day and seven days per week (24/7). Additionally, rural areas may have limited availability of these urgent care centers. A common type of visit to a hospital emergency room or urgent care center is a wound requiring cessation of bleeding, especially patients on a variety of anticoagulant or antiplatelet medications. As the population ages, more patients require these medications for a variety of conditions.

[0004] Better methods and devices are needed to allow patients, family members, and/or caretakers to safely treat at home, or at the place of the injury, minor wounds requiring the cessation of bleeding.

SUMMARY OF INVENTION

[0005] Some of the main aspects of the present invention are summarized below. Additional aspects are described in the Detailed Description of the Invention, Drawings, and Claims

sections of this disclosure. The description in each section of this disclosure is intended to be read in conjunction with the other sections. Furthermore, the various embodiments described in each section of this disclosure can be combined in various different ways, and all such combinations are intended to fall within the scope of the present invention.

[0006] The invention provides a device and methods for treating wounds and reducing bleeding of a wound.

[0007] In one aspect, the invention provides devices for delivering a medication to a wound. In embodiments of the invention, the devices comprise: (a) a reservoir comprising a closed end, an open end, walls between the closed end and open end that have an outer surface and an inner surface, and a longitudinal axis extending from the closed end to the open end; (b) an ampule contained within the reservoir, wherein the ampule comprises the medication and is comprised of a material that can be punctured or broken; (c) a release mechanism comprised in the reservoir, the release mechanism being configured to apply a mechanical force to the ampule upon activation of the release mechanism, wherein application of the mechanical force to the ampule directly or indirectly causes the ampule to break or puncture, and the medication to be released; and (d) a topical applicator attached to the open end of the reservoir, wherein the topical applicator comprises a material capable of retaining the medication released from the ampule.

[0008] In some embodiments, the ampule comprises a body portion and a neck portion, in which the neck portion is thinner than the body portion. In certain embodiments, the ampule is oriented in the reservoir such that the neck portion is positioned closer to the open end of the reservoir and the body portion is positioned closer to the closed end of the reservoir. In preferred embodiments, the ampule comprises a glass ampule.

[0009] In some embodiments, the inner surface of the wall of the reservoir comprises an abutment located adjacent to the ampule. In some embodiments, the abutment is located adjacent to the neck portion of the ampule. In certain embodiments, the abutment comprises an incline plane. In further embodiments, the release mechanism is positioned at the closed end of the reservoir, and the application of the mechanical force to the ampule upon activation of the release mechanism causes the ampule, preferably the neck portion of the ampule, to contact the abutment and results in the ampule breaking, preferably breaking at the neck portion.

[0010] In some embodiments, the release mechanism is positioned at the wall of the reservoir, and the application of the mechanical force to the ampule upon activation of the release mechanism causes the ampule to break, preferably break at the neck portion.

[0011] In embodiments of the invention, the devices comprise: (a) a reservoir comprising a closed end, an open end, walls between the closed end and open end that have an outer surface and an inner surface, and a longitudinal axis extending from the closed end to the open end; in which the reservoir is configured to contain an ampule comprising a medication; (b) a release mechanism comprised in the reservoir, the release mechanism being configured to apply a mechanical force to the ampule upon activation of the release mechanism, wherein application of the mechanical force to the ampule directly or indirectly causes the ampule to break or puncture, and the medication to be released; and (c) a topical applicator attached to the open end of the reservoir, wherein the topical applicator comprises a material capable of retaining the medication released from the ampule.

[0012] In some embodiments, the reservoir is configured to contain an ampule that comprises a body portion and a neck portion, in which the neck portion is thinner than the body portion. In certain embodiments, the reservoir is configured to contain an ampule that is oriented in the reservoir such that the neck portion is positioned closer to the open end of the reservoir and the body portion is positioned closer to the closed end of the reservoir. In preferred embodiments, the reservoir is configured to contain an ampule comprising a glass ampule.

[0013] In some embodiments, the inner surface of the wall of the reservoir comprises an abutment that is configured to be located adjacent to the ampule when the ampule is contained in the reservoir. In some embodiments, the abutment is configured to be located adjacent to the neck portion of the ampule. In certain embodiments, the abutment comprises an incline plane. In further embodiments, the release mechanism is positioned at the closed end of the reservoir and, when an ampule is installed and contained in the reservoir, the application of the mechanical force to the ampule upon activation of the release mechanism causes the ampule, preferably the neck portion of the ampule, to contact the abutment and results in the ampule breaking, preferably breaking at the neck portion.

[0014] In some embodiments, the release mechanism is positioned at the wall of the reservoir and, when an ampule is installed and contained in the reservoir, the application of the mechanical force to the ampule upon activation of the release mechanism causes the ampule to break, preferably break at the neck portion.

[0015] In embodiments of the invention, the release mechanism is activated by applying a force to the release mechanism, such as the force that can be generated by a thumb or finger of one hand.

[0016] In some embodiments, one or more portions of the outer surface of the reservoir of the devices comprise a surface feature that aids in gripping or holding the device. In certain embodiments, the surface feature comprises one or more ridges. In certain embodiments, the surface feature comprises a textured surface.

[0017] In some embodiments, the reservoir comprises one or more tabs on the inner surface of the walls of the reservoir that maintain, or are configured to maintain, the position of the ampule within the reservoir.

[0018] In some embodiments, the medication comprises an antifibrinolytic. In certain embodiments, the antifibrinolytic is selected from tranexamic acid, aminocaproic acid, and the medication protamine sulfate. In preferred embodiments, the antifibrinolytic is tranexamic acid.

[0019] In some embodiments, the topical applicator is attached to the reservoir via a fixation plate. In certain embodiments, the fixation plate is attached to the reservoir by an adhesive or welding.

[0020] In some embodiments, the topical applicator comprises a foam or sponge. In preferred embodiments, the topical applicator comprises a foam.

[0021] In some embodiments, the topical applicator is removably attached to the reservoir.

[0022] In some embodiments, the topical applicator comprises a medication pad and a blood absorption pad, and a divider therebetween. In certain embodiments, the topical applicator is configured such that only the medication pad is positioned to receive the medication from the ampule.

[0023] In some embodiments, a filter is positioned above the topical applicator.

[0024] In some embodiments, the devices further comprise an applicator cap that is configured to fit over the topical applicator.

[0025] In another aspect, the invention provides methods involving the devices of the invention. In embodiments of the invention, the method is of treating a wound in a subject in need thereof, reducing bleeding of a wound in a subject in need thereof, controlling bleeding

of a wound in a subject in need thereof, treating a wound having excess bleeding of a wound in a subject in need thereof, delivering a medication to a wound in a subject in need thereof, treating post-surgical or post-procedural external bleeding in a subject in need thereof, or treating a post-surgical or post-procedural wound in a subject in need thereof.

[0026] In some embodiments, the method comprises obtaining the device of the invention comprising a reservoir, ampule, release mechanism, and topical applicator; activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication; and applying the topical applicator of the device to the wound.

[0027] In some embodiments, the method comprises obtaining the device of the invention comprising a reservoir, ampule, release mechanism, and topical applicator; applying the topical applicator of the device to the wound; and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

[0028] In some embodiments, the method comprises obtaining the device of the invention comprising a reservoir, release mechanism, and topical applicator, and obtaining an ampule; installing the ampule into the device; activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication; and applying the topical applicator of the device to the wound.

[0029] In some embodiments, the method comprises obtaining the device of the invention comprising a reservoir, release mechanism, and topical applicator, and obtaining an ampule; installing the ampule into the device; applying the topical applicator of the device to the wound; and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

[0030] In some embodiments, the method further comprises removing the topical applicator from the device and fixating the topical applicator to the wound. In certain embodiments, the topical applicator is fixated to the wound using a bandage, patch, film, or surgical dressing.

[0031] In some embodiments, the method is performed by the subject in need of the treatment, the reduction in bleeding, the controlling of bleeding, or the delivery of the medication. In certain embodiments, the subject was taking, was prescribed, is taking, or is

prescribed, an anticoagulant therapy. In certain embodiments, the subject was administered, is administered, or is to be administered, one or more antiplatelet therapies.

[0032] In yet another aspect, the invention provides a kit. In embodiments of the invention, the kit comprises (a) a device of the invention comprising a reservoir, ampule, release mechanism, and topical applicator; and (b) instructions on how to use the device according to the methods of the invention.

[0033] In other embodiments, the kit comprises (a) a device of the invention comprising a reservoir, release mechanism, and topical applicator; (b) an ampule of the invention; and (c) instructions on how to use the device and ampule according to the methods of the invention.

[0034] In some embodiments, the kit further comprises a container for disposal of the device.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0035] The present disclosure will be further explained with reference to the attached drawing figures, wherein like structures are referred to by like numerals throughout the several views. The drawing figures shown are not necessarily to scale, with emphasis instead generally being placed upon illustrating the principles of the present disclosure, and some features may be exaggerated to show details of particular components. In addition, any measurements, specifications, and the like shown in the drawing figures, or described below, are intended to be illustrative, and not restrictive. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a representative basis for teaching one skilled in the art to variously employ the devices of the present invention and methods of their use.

[0036] **FIG. 1** is a perspective view of a device according to embodiments of the present invention, in which the release mechanism is at the closed end of the reservoir and is activated by applying a mechanical force to the release mechanism.

[0037] **FIG. 2** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, ampule, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir.

[0038] **FIG. 3** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, ampule, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir and comprises an outer portion and an inner portion.

[0039] **FIG. 4** is a perspective view of a device according to embodiments of the present invention, in which the release mechanism is at the wall of the reservoir.

[0040] **FIG. 5** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, ampule, release mechanism, and topical applicator; and in which the release mechanism is at the wall of the reservoir.

[0041] **FIG. 6** is a perspective view of a device according to embodiments of the present invention, in which the release mechanism is at the closed end of the reservoir and is activated by rotating the release mechanism.

[0042] **FIG. 7** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, ampule, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir and is activated by rotating the release mechanism.

[0043] **FIG. 8** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, ampule, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir and is activated by rotating the release mechanism, which activates a spring.

[0044] **FIG. 9** is a perspective view of a topical applicator according to embodiments of the present invention, in which the topical applicator comprises a medication pad and a blood absorption pad.

[0045] **FIG. 10** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir.

[0046] **FIG. 11** is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, release mechanism, and topical applicator; and in which the release mechanism is at the wall of the reservoir.

[0047] FIG. 12 is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir and is activated by rotating the release mechanism.

[0048] FIG. 13 is a cut-away view of a device according to embodiments of the present invention, in which the device comprises a reservoir, release mechanism, and topical applicator; and in which the release mechanism is at the closed end of the reservoir and is activated by rotating the release mechanism, which activates a spring.

DETAILED DESCRIPTION OF THE INVENTION

[0049] The present invention relates to devices and their use to treat and/or reduce bleeding of a wound.

[0050] The devices are used to deliver medication to the wound in order to treat or reduce bleeding of the wound. The devices are advantageously easy to use, and can be operated by persons with or without medical training, including at home or any other non-hospital/medical facility setting.

Definitions

[0051] The phraseology or terminology in this disclosure is for the purpose of description and not of limitation, such that the terminology or phraseology of the present specification is to be interpreted by the skilled artisan in light of the teachings and guidance.

[0052] As used in this specification and the appended claims, the singular forms “a,” “an,” and “the” include plural referents, unless the context clearly dictates otherwise. The terms “a” (or “an”) as well as the terms “one or more” and “at least one” can be used interchangeably.

[0053] Furthermore, “and/or” is to be taken as specific disclosure of each of the two specified features or components with or without the other. Thus, the term “and/or” as used in a phrase such as “A and/or B” is intended to include A and B, A or B, A (alone), and B (alone). Likewise, the term “and/or” as used in a phrase such as “A, B, and/or C” is intended to

include A, B, and C; A, B, or C; A or B; A or C; B or C; A and B; A and C; B and C; A (alone); B (alone); and C (alone).

[0054] Wherever embodiments are described with the language “comprising,” otherwise analogous embodiments described in terms of “consisting of” and/or “consisting essentially of” are included.

[0055] Units, prefixes, and symbols are denoted in their Système International de Unites (SI) accepted form. Numeric ranges are inclusive of the numbers defining the range, and any individual value provided herein can serve as an endpoint for a range that includes other individual values provided herein. For example, a set of values such as 1, 2, 3, 8, 9, and 10 is also a disclosure of a range of numbers from 1-10, from 1-8, from 3-9, and so forth. Likewise, a disclosed range is a disclosure of each individual value encompassed by the range. For example, a stated range of 5-10 is also a disclosure of 5, 6, 7, 8, 9, and 10.

[0056] A “subject” or “individual” or “patient” is any subject, particularly a mammalian subject, for whom diagnosis, prognosis, or therapy is desired. Mammalian subjects include humans, domestic animals, farm animals, sports animals, and laboratory animals including, e.g., humans, non-human primates, canines, felines, porcines, bovines, equines, rodents, including rats and mice, rabbits, etc.

[0057] As used herein, the term “bleeding” refers to conditions where blood flows through a break in the skin or mucosa of a subject. Non-limiting examples of bleeding include cuts and abrasions from trauma including from surgery.

[0058] As used herein, the term “minor cuts and abrasions” is intended to include any and all cuts and abrasions that do not require hospitalization. Cuts and abrasions that do not require hospitalization may include those that do not require stitches, liquid stitches, or butterfly stitches to close and heal.

[0059] As used herein, the terms “treating” and “treatment” refer to reduction in severity and/or frequency of symptoms, elimination of symptoms and/or underlying cause, prevention of the occurrence of symptoms and/or their underlying cause, and improvement or remediation of damage.

[0060] As used herein, the term “reduce” is used to refer to any decrease in occurrence or activity, including full blocking of the occurrence or activity.

Devices

[0061] An aspect of the invention relates to devices that can deliver to a wound a medication that treats wounds or reduces wound bleeding. Embodiments of the devices of the present invention are shown in **FIGS. 1-13**.

[0062] Devices **100** may comprise a reservoir **110**, an ampule **130**, a release mechanism **140**, and a topical applicator **150**.

[0063] The reservoir **110** comprises a closed end **112**, an open end **114**, walls **116** between the closed end **112** and open end **114** wherein the walls **116** have an outer surface **118** and an inner surface **120**, and a longitudinal axis **122** extending from the closed end **112** to the open end **114**. One or more portions of the outer surface **118** of the wall **116** of the reservoir **110** may comprise surface features **124** that aid in holding or gripping the device **100**. Surface features **124** may include, but are not limited to, one or more ridges (as shown in, for example, **FIGS. 1, 2, 4, and 5**), concave and/or convex curvatures (not shown), and a textured or course surface (not shown).

[0064] The reservoir **110** may comprise a shape that is ergonomic and easy to hold within one hand. Examples of such shape include, but are not limited to, cylinder, including a circular cylinder, oval cylinder, or elliptical cylinder; and a prism, including a cube, rounded square prism, rectangular prism, rounded rectangular prism, triangular prism, pentagonal prism, hexagonal prism, etc. In some embodiments, the reservoir comprises one or more rounded or beveled edges. In certain embodiments, the reservoir comprises a rounded rectangular prism shape with one or more rounded edges, as shown in **FIGS. 1 and 4**. In certain embodiments, the reservoir comprises a cylindrical shape, as shown in **FIG. 6**.

[0065] The reservoir **110** may be comprised of a rigid polymer material. Examples of rigid polymer materials include, but are not limited to, polyethylene, polypropylene, polyamide, polycarbonate, and the like.

[0066] The reservoir **110** is configured to contain the ampule **130** (see **FIGS. 2, 3, 5, 7, 8, and 10-13**). In some embodiments, the inner surface **120** of the reservoir **110** may comprise one or more tabs or other features that maintain the general position of the ampule **130** within the reservoir **110**.

[0067] The ampule **130** contains the medication **132**. The ampule **130** is comprised of a material that can be broken or punctured in order to release the medication **132**. In some

embodiments, the ampule **130** is comprised of a plastic or glass. In preferred embodiments, the ampule is a glass ampule.

[0068] The ampule **130** may comprise a neck portion **134** and a body portion **136**, and a longitudinal axis **138** extending between the neck portion **134** and the body portion **136**. The neck portion **134** may be narrower than the body portion **136**. In some embodiments, the ampule **130** is oriented in the reservoir **110** such that the neck portion **134** is positioned closer to the open end **114** of the reservoir **110** and the body portion **136** is positioned closer to the closed end **112** of the reservoir **110**. (see, e.g., FIGS. 2, 5, 7, and 8).

[0069] In preferred embodiments, the ampule comprises a glass ampule.

[0070] The ampule **130** may comprise a metered dose of the medication **132** ranging from about 1 mL to about 20 mL, or about 1 mL to about 1.5 mL, or about 2.5 mL to about 5 mL, or about 5 mL to about 10 mL, or about 10 mL to about 15 mL, or about 15 mL to about 20 mL. For example, the ampule **130** may comprise a metered dose of the medication **132** of about 1 mL, or about 2 mL, or about 3 mL, or about 4 mL, or about 5 mL, or about 6 mL, or about 7 mL, or about 8 mL, or about 9 mL, or about 10 mL, or about 11 mL, or about 12 mL, or about 13 mL, or about 14 mL, or about 15 mL, or about 16 mL, or about 17 mL, or about 18 mL, or about 19 mL, or about 20 mL.

[0071] The medication **132** may comprise an antifibrinolytic. Examples of antifibrinolytics include, but are not limited to, tranexamic acid, aminocaproic, and a medication equal or similar to protamine sulfate. In preferred embodiments, the medication **132** comprises tranexamic acid.

[0072] In some embodiments, the medication **132** also comprises a carrier, wherein the carrier comprises sterile water and/or a saline solution. In certain embodiments, the medication **132** may comprise between about 50% and about 100% tranexamic acid, and between about 50% and about 0% of the carrier. In certain embodiments, the medication **132** may comprise between about 10% and about 50% tranexamic acid, and between about 90% and about 50% of the carrier.

[0073] In some embodiments, the medication **132** may comprise an antifibrinolytic in an amount of about 50 mg/mL to about 300 mg/mL, including about 50 mg/mL, about 100 mg/mL, about 150 mg/mL, about 200 mg/mL, about 250 mg/mL, or about 300 mg/mL.

[0074] In some embodiments, the medication 132 may be comprised of a liquid or gel. For example, the medication 132 may have a viscosity of between about 0.75 mPa·s and about 0.98 mPa·s at approximately 25° C.

[0075] In some embodiments, the medication 132 may also include a colored dye to indicate that the medication 132 has been dispensed to the wound and is of a composition to be human viewable based on skin color and blood color (before and after clotting). In other embodiments, the medication 132 may not contain a colored dye.

[0076] The release mechanism 140 is comprised in the reservoir 110 and is configured to, upon activation, apply a mechanical force that directly or indirectly causes the ampule 130 to break and the medication 132 to be released. In some embodiments, as shown in FIGS. 1 and 2, the release mechanism 140 is at the closed end 112 of the reservoir 110 and is mechanically coupled to the ampule 130. In such embodiments, the reservoir 110 may further comprise an abutment 126, such as an inclined plane, on the inner surface 120 of the reservoir 110, in which the abutment 126 is adjacent to ampule 130, preferably to the neck portion 134 of the ampule 130, in the reservoir 110. Activation of the release mechanism 140 by application of a force on the release mechanism 140 in the direction along the longitudinal axis 122 towards the open end 114 of the reservoir 110 in turn applies a force on the ampule 130 in the direction along its longitudinal axis 138. Such a force can move the ampule 130 towards the open end of the reservoir 110, causing the ampule 130, preferably the neck portion 134 of the ampule 130, to contact against the abutment 126, and the ampule 130 to therefore break, preferably to break at the neck portion 134, and release the medication 132.

[0077] In some embodiments, as shown in FIG. 3, the release mechanism 140 is at the closed end 112 of the reservoir 110 and comprises an outer portion 140a and an inner portion 140b. The release mechanism 140 may comprise a plunger, a lever, or a twisting, or the like, and is configured such that activation of outer portion 140a causes the inner portion 140b to apply a force that directly or indirectly breaks the ampule 130 and release the medication 132.

[0078] In certain embodiments, the release mechanism 140 may be completely internal within the reservoir 110, such that squeezing the reservoir 110 causes the ampule 130 to compress and break, thereby releasing the medication 132 (not shown).

[0079] In some embodiments, as shown in FIGS. 4 and 5, the release mechanism 140 is on the wall 116 of the reservoir 110. Activation of the release mechanism 140 by application of

a force on the release mechanism **140** in the direction perpendicular, or generally perpendicular, to the longitudinal axis **122** of the reservoir **110** in turn applies a force on the ampule **130**, preferably on the neck portion **134** of the ampule **130**, in the direction perpendicular, or generally perpendicular, of its longitudinal axis **138**. Such a force can break the ampule **130**, preferably the neck portion **134** of the ampule **130**, causing the ampule **130** to break, preferably at the neck portion **134**, and release the medication **132**.

[0080] In some embodiments, as shown in **FIGS. 6-8**, the release mechanism **140** is at the closed end **112** of the reservoir **110** and is activated by rotating or otherwise activating the release mechanism **140**. The release mechanism **140** is mechanically coupled to the ampule **130**. In such embodiments, the reservoir **110** may further comprise an abutment **126**, such as an inclined plane, on the inner surface **120** of the reservoir **110**, in which the abutment **126** is adjacent to the ampule **130**, preferably to the neck portion **134** of the ampule **130**, in the reservoir **110**. In certain embodiments, turning the release mechanism **140** applies a force on the ampule **130** in the direction along its longitudinal axis **138**, and such a force moves the ampule **130** towards the open end of the reservoir **110**, causing the ampule **130**, preferably the neck portion **134** of the ampule **130**, to contact against the abutment **126**, and the ampule **130** to therefore break, preferably break at the neck portion **134**, and release the medication **132** (see **FIG. 7**). Alternatively, rotating or otherwise activating the release mechanism **140** activates a spring **142**, which applies a force on the abutment **126** in the direction along the longitudinal axis **138** of the ampule **130** and towards the body portion **136** of the ampule **130**, and such a force contacts the abutment **126** against the ampule **130**, preferably against the neck portion **134** of the ampule **130**, causing the ampule **130** to break, preferably break at the neck portion **134**, and release the medication **132**. (see **FIG. 8**).

[0081] In some embodiments, the device **100** may comprise a means of preventing the releasing mechanism **140** from being inadvertently activated. Such means include, but are not limited to, one or more tabs within the device **100** that prevent the release mechanism **140** from being able to apply a force to the ampule **130** unless a particular level of force is applied to the release mechanism **140**; or a locking mechanism that requires the release mechanism **140** to be unlocked before it is activated (not shown).

[0082] In some embodiments, the device **100** may comprise a means of preventing the neck portion **134** of the ampule **130** from inadvertently contacting the abutment **126**. Such means include, but are not limited to, one or more tabs **128** within the device **100**, for example on

the inner surface **120** of the reservoir **110** that prevents ampule **130** from moving to contact the abutment **126** unless a sufficient force is applied to the release mechanism **140**.

[0083] The topical applicator **150** is attached to the open end **114** of the reservoir **110**, and comprises a porous material. In some embodiments, the topical applicator **150** comprises a sponge or foam pad, preferably a foam pad, capable of retaining the medication **132**, to which the topical applicator **150** is exposed when the ampule **130** inside the reservoir **110** is broken. In certain embodiments, the foam pad is capable of releasing the retained medication **132** by physical contact.

[0084] In some embodiments, the topical applicator **150** is attached to the reservoir via a fixation plate **160**, as shown in **FIGS. 1, 4, and 6**. The fixation plate **160** is attached to the closed end of the reservoir via an adhesive or welding, and creates a seal to ensure that the medication **132** is directed to the topical applicator **150**. Thus, the fixation plate **160** comprises an opening (not shown) through which the medication **132** can contact the topical applicator **150**.

[0085] In some embodiments, the topical applicator **150** may comprise a surface area of between about 2 cm² and about 25 cm². In certain embodiments, the surface area may be between about 3 cm² and about 10 cm², or between about 10 cm² and about 20 cm². For example, the surface area may be about 2 cm², or about 3 cm², or about 4 cm², or about 5 cm², or about 6 cm², or about 7 cm², or about 8 cm², or about 9 cm², or about 10 cm², or about 11 cm², or about 12 cm², or about 13 cm², or about 14 cm², or about 15 cm², or about 16 cm², or about 17 cm², or about 18 cm², or about 19 cm², or about 20 cm², or about 21 cm², or about 22 cm², or about 23 cm², or about 24 cm², or about 25 cm².

[0086] The topical applicator **150** may comprise a shape appropriate for contacting and covering a wound. Examples of shapes include, but are not limited to, a circle, oval, ellipse, square, rounded square, rectangle, rounded rectangle, triangle, pentagon, hexagon, etc.

[0087] In some embodiments, the topical applicator **150** is removable from the reservoir **110** or the fixation plate **160**. For example, the topical applicator **150** may be attached to the reservoir **110** or the fixation plate **160** via an adhesive, and may be removed by peeling or by otherwise applying a force.

[0088] In some embodiments, the topical applicator **150** comprise a medication pad **150a** and a blood absorption pad **150b**. The medication pad **150a** and the blood absorption pad **150b**

may comprise the same material or may be different materials. The medication pad **150a** and the blood absorption pad **150b** may be configured such that only the medication pad **150a** can be accessed by the medication. In such embodiments, the medication pad **150a** may be adjacent, or may be concentric, with the blood absorption pad, as shown in **FIG. 9**. A divider **152** may be positioned between the medication pad **150a** and the blood absorption pad **150b**.

[0089] In some embodiments, the topical applicator **150** may contain a colored dye to indicate that the medication **132** has been dispensed to the wound and is of a composition to be human viewable based on skin color and blood color (before and after clotting).

[0090] In some embodiments, the device may further comprise a filter (not shown). The filter can be positioned within the reservoir, between the ampul and the topical applicator. Preferably, the filter is positioned adjacent to the topical applicator. The filter may be configured to capture particles or pieces (e.g., glass particles or pieces) generated from the breaking of the ampul, and prevent such particles or pieces from entering or contacting the topical applicator.

[0091] In some embodiments, the device **100** may further comprise an applicator cap **170** (see, e.g., **FIG. 3**). The applicator cap **170** comprises the same general shape as the topical applicator **150**, and is configured to fit over the topical applicator **150**. The applicator cap **170**, when positioned on the topical applicator **150**, protect the topical applicator **150** from the external environment until the device **100** is used as intended.

[0092] In some embodiments, the device **100** may further comprise an information label (not shown). The information label may be adhered to the outside of the reservoir **110** and/or to the applicator cap **170**. The information label may contain user instructions similar to the following:

Only apply only to superficial bleeding wounds 3 inches or less in length. Push the release mechanism to break the medication. Allow the medication to fully cover the topical applicator. Press down with the device over the wound for 10 minutes. Place an adhesive bandage over the wound. If bleeding does not stop, you may repeat up to 1 time as long as bleeding is not pulsatile or vascular in nature. If bleeding does not stop after 2 applications or if you feel dizzy, weak, or fatigued, seek professional medical treatment. Not to be used in the mouth. Not to be used on arteriovenous fistulas or deep wounds. Do not use if you have a history of seizures. Do not use for

penetrating wounds or puncture wounds (gunshot, knife, etc.). Do not drink this medication. Keep away from children or infants.

In some embodiments, the information label may further comprise one or more statements indicating one or more of the following: (i) remove the applicator cap before pressing down with the device over the wound; and (ii) peel the topical applicator from the rest of the device and use an adhesive bandage to keep the topical applicator on the wound.

[0093] In some embodiments, the device **100** may be labeled or stamped with an expiration date. For example, the device **100** may have a shelf life from a date of manufacture of three years. In other embodiments, the shelf life may be greater or less than three years. The device may also be labeled or stamped with a lot number and/or a date of manufacture. Additionally, the device **100** may be labeled with a bar code and/or Quick Response (QR) code.

[0094] In other embodiments, the device **100** may be implemented as a pipette. The pipette may be configured in a manner most suitable for the accuracy and precision needed for the size and location of the wound. For example, the pipette may be configured to be positioned within a patient's nostril.

[0095] Alternative embodiments relate to devices **100-1** comprising a reservoir **110** as described above, a release mechanism **140** as described above, and a topical applicator **150** as described above. In such embodiments, the ampule **130** is not in the reservoir **110**, but the reservoir **110** is configured to receive and contain the ampule **130**, which may be installed into the reservoir **110** when the device **100-1** is ready for use. In some embodiments, the closed end **112** of the device **100-1** may be removable and allow the ampule **130** to be installed within the reservoir **110**. Examples of devices **100-1** are provided in **FIGS. 10-13**, which depict the same reservoir, release mechanism, and topical applicator as shown in **FIGS. 2, 5, 7, and 8**, respectively.

Uses of the Device

[0096] An aspect of the invention relates to use of the device of the invention to deliver to a wound a medication that treats wounds or reduces wound bleeding.

[0097] Therefore, the present invention is directed to (i) a method of treating a wound; (ii) a method of reducing bleeding of a wound; (iii) a method of controlling bleeding of a wound;

(iv) a method of treating a wound having excess bleeding of a wound; (v) a method of delivering medication to a wound; (vi) a method of treating post-surgical or post-procedural external bleeding; or (vii) a method of treating post-surgical or post-procedural wound. The invention is also directed to the use of the device of the present invention to (i) treat a wound; (ii) reduce bleeding of a wound; (iii) control bleeding of a wound; (iv) treat a wound having excess bleeding of a wound; (v) deliver medication to a wound; (vi) treat post-surgical or post-procedural external bleeding; or (vii) treat post-surgical or post-procedural wound. Further the present invention is directed to a device of the present invention for use in (i) treating a wound; (ii) reducing bleeding of a wound; (iii) controlling bleeding of a wound; (iv) treating a wound having excess bleeding of a wound; (v) delivering medication to a wound; (vi) treating post-surgical or post-procedural external bleeding; or (vii) treating post-surgical or post-procedural wound. The methods and uses are performed with a device according to the present invention.

[0098] In embodiments of the invention, these methods and uses may comprise activating the release mechanism of the device, and applying the topical applicator of the device to the wound. In other embodiments of the invention, these methods and uses may comprise applying the topical applicator of the device to the wound, and activating the release mechanism of the device.

[0099] In embodiments of the invention, the methods and uses may also comprise obtaining the device of the invention.

[0100] In embodiments of the invention in which the device comprises a topical applicator cap, the methods and uses of the invention may further comprise removing the applicator cap before activating the release mechanism of the device, or before applying the topical applicator to the wound.

[0101] In embodiments of the invention in which the device comprises a locking mechanism that prevents activation of the release mechanism, the methods and uses of the invention may further comprise unlocking the locking mechanism before activating the release mechanism.

[0102] In embodiments of the invention in which the topical applicator is removable from the device, the methods and uses of the invention may further comprise removing the topical applicator from the device and fixating the topical applicator to the wound. For instance, the topical applicator may be fixated to the wound using a bandage, patch, film, or surgical dressing.

[0103] In embodiments of the invention in which the device is not prepared with an ampule in the reservoir, the methods and uses of the invention may further comprise installing an ampule into the reservoir, for example, before activating the release mechanism of the device, and/or before applying the topical applicator of the device to the wound.

[0104] In some embodiments, the wound is a superficial wound. Examples of a superficial wound includes, but is not limited to, a minor cut, abrasion, laceration, or break in the skin no greater than about 3 inches (e.g., about 1 to about 3 inches, about 1 inch, about 2 inches, about three inches, less than 1 inch) in any direction. In some embodiments, the device may be used for post-vascular access or post-procedural bleeding (e.g., central venous catheter insertion, arterial cannulation, chest thoracostomy tube, paracentesis, tracheostomy site, or other types of vascular access), hemostasis, or wound care.

[0105] In some embodiments, the wound is not one or more of: a penetrating wound, a puncture wound, a deep wound, and an arteriovenous fistula. In some embodiments, the wound is not on the mouth or on any mucosal surface.

[0106] In embodiments of the invention, the methods and uses are performed on a subject in need thereof. In some embodiments, the methods and uses are performed by the subject who is in need thereof. In some embodiments, the subject is a mammalian subject. In certain embodiments, the subject is a domestic animal. In preferred embodiments, the subject is human.

[0107] In some embodiments, the subject was taking or was prescribed, or is taking or is prescribed, an anticoagulant therapy. Examples of an anticoagulant therapies include, but are not limited to, heparin, warfarin, factor Xa inhibitor, and thrombin inhibitors.

[0108] In some embodiments, the subject may be administered or is to be administered one or more antiplatelet therapies. Examples of antiplatelet therapies include, but are not limited to, glycoprotein platelet inhibitors such as abciximab, eptifibatide, and tirofiban; platelet aggregation inhibitors such as aspirin, cangrelor, cilostazol, clopidogrel, dipyridamole, prasugrel, ticlopidine, and ticagrelor; and protease-activated receptor-1 antagonists such as vorapaxar.

[0109] In embodiments of the invention, the methods and uses can be performed by the subject with the wound. In some embodiments, the methods and uses can be performed outside of a hospital or medical facility, for example, at home or outside.

[0110] In some embodiments, the device is intended for a single user and one wound application. Therefore, the method and uses may further comprise discarding the device after a single use. The device may be discarded in a container such as a re-sealable bag, or the like.

Manufacturing the Device

[0111] Another aspect of the invention relates to methods of manufacturing the device of the invention.

[0112] In some embodiments, the method of manufacturing the device comprises installing the release mechanism to the reservoir, introducing the ampule to the reservoir, and coupling the topical applicator to the reservoir. In certain embodiments, the method may further comprise installing the applicator cap onto the topical applicator. These steps may be reordered as needed by the manufacturer.

[0113] Additional steps may include, but are not limited to, affixing user instruction labels to the reservoir and/or topical applicator cap; applying barcodes and/or QR codes to the reservoir and/or topical applicator cap; and labeling the reservoir and/or applicator cap with an expiration date.

Kits

[0114] An aspect of the invention relates to kits that comprise the device of the invention, and instructions on how to use the device according to the invention.

[0115] In embodiments in which the device is not manufactured with the ampule in the reservoir, the kit may comprise the device, one or more ampules, and instructions on how to use the device.

[0116] In some embodiments, the kit may also comprise a container for disposal of the device after use. The container may be a resealable bag or the like. In certain embodiments, the kit may further comprise a biohazard label and/or instructions for disposal.

* * * * *

The foregoing description is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications within the scope of the invention may be apparent to those having ordinary skill in the art.

Detailed embodiments of the present methods and devices are disclosed herein; however, it is to be understood that the disclosed embodiments are merely illustrative and that the methods and devices may be embodied in various forms. In addition, each of the examples given in connection with the various embodiments of the systems and methods are intended to be illustrative, and not restrictive.

The practice of a method disclosed herein, and individual steps thereof, can be performed manually and/or with the aid of or automation provided by electronic equipment. Although processes have been described with reference to particular embodiments, a person of ordinary skill in the art will readily appreciate that other ways of performing the acts associated with the methods may be used. For example, the order of various steps may be changed without departing from the scope or spirit of the method, unless described otherwise. In addition, some of the individual steps can be combined, omitted, or further subdivided into additional steps.

WHAT IS CLAIMED IS

1. A device for delivering a medication to a wound, the device comprising:
 - (a) a reservoir comprising a closed end, an open end, walls between the closed end and open end that have an outer surface and an inner surface, and a longitudinal axis extending from the closed end to the open end;
 - (b) an ampule contained within the reservoir, wherein the inner surface of the wall of the reservoir comprises an abutment located adjacent to the ampule, wherein the ampule comprises the medication and is comprised of a material that can be punctured or broken, and wherein the medication is an antifibrinolytic;
 - (c) a release mechanism comprised in the reservoir and positioned at the closed end of the reservoir, the release mechanism configured to apply a mechanical force to the ampule upon activation of the release mechanism, wherein application of the mechanical force to the ampule causes the ampule to contact the abutment and result in the ampule breaking, and the medication released; and
 - (d) a topical applicator attached to the open end of the reservoir, wherein the topical applicator comprises a foam material capable of retaining the medication released from the ampule.
2. The device of claim 1, wherein the ampule comprises a body portion and a neck portion, wherein the neck portion is thinner than the body portion.
3. The device of claim 2, wherein the ampule is oriented in the reservoir such that the neck portion is positioned closer to the open end of the reservoir and the body portion is positioned closer to the closed end of the reservoir.
4. The device of any one of claims 1-3, wherein the ampule comprises a glass ampule.
5. The device of any one of claims 2-4, wherein the abutment is located adjacent to the neck portion of the ampule.
6. The device of claim 5, wherein the abutment comprises an incline plane.

7. The device of claim 5 or 6, wherein the application of a mechanical force to the ampule causes the neck portion to contact the abutment and result in the ampule breaking at the neck portion.

8. A device for delivering a medication to a wound, the device comprising:

(a) a reservoir comprising a closed end, an open end, walls between the closed end and open end that have an outer surface and an inner surface, and a longitudinal axis extending from the closed end to the open end;

(b) an ampule contained within the reservoir, wherein the ampule comprises the medication and is comprised of a material that can be punctured or broken, and wherein the medication is an antifibrinolytic;

(c) a release mechanism comprised in the reservoir and positioned at the wall of the reservoir, the release mechanism configured to apply a mechanical force to the ampule upon activation of the release mechanism, wherein application of the mechanical force to the ampule causes the ampule to break, and the medication to be released; and

(d) a topical applicator attached to the open end of the reservoir, wherein the topical applicator comprises a foam material capable of retaining the medication released from the ampule.

9. The device of claim 8, wherein the ampule comprises a body portion and a neck portion, wherein the neck portion is thinner than the body portion.

10. The device of claim 9, wherein the ampule is oriented in the reservoir such that the neck portion is positioned closer to the open end of the reservoir and the body portion is positioned closer to the closed end of the reservoir.

11. The device of any one of claims 8-10, wherein the ampule comprises a glass ampule.

12. The device of any one of claims 9-11, wherein the release mechanism is adjacent to the neck portion of the ampule.

13. The device of claim 12, wherein the application of a mechanical force to the ampule causes the neck portion break.

14. A device for delivering a medication to a wound, the device comprising:

(a) a reservoir comprising a closed end, an open end, walls between the closed end and open end that have an outer surface and an inner surface, and a longitudinal axis extending from the closed end to the open end; wherein the reservoir is configured to contain an ampule comprising a medication, wherein the medication is an antifibrinolytic; and wherein the inner surface of the wall of the reservoir comprises an abutment configured to be located adjacent to the ampule;

(b) a release mechanism comprised in the reservoir and positioned at the closed end of the reservoir, the release mechanism configured to apply a mechanical force to the ampule that the reservoir is configured to contain upon activation of the release mechanism, wherein application of the mechanical force to the ampule causes the ampule to contact the abutment and result in the ampule breaking, and the medication to be released; and

(c) a topical applicator attached to the open end of the reservoir, wherein the topical applicator comprises a foam material capable of retaining the medication released from the ampule.

15. The device of claim 14, wherein the reservoir is configured to contain an ampule that comprises a body portion and a neck portion, wherein the neck portion is thinner than the body portion.

16. The device of claim 15, wherein the reservoir is configured to contain an ampule that is oriented such that the neck portion is positioned closer to the open end of the reservoir and the body portion is positioned closer to the closed end of the reservoir.

17. The device of any one of claims 14-16, wherein the reservoir is configured to contain an ampule comprising a glass ampule.

18. The device of any one of claims 15-17, wherein the abutment is configured to be located adjacent to the neck portion of the ampule upon installation of the ampule.

19. The device of claim 18 wherein the abutment comprises an incline plane.

20. The device of claim 18 or 19, wherein the application of a mechanical force to the ampule causes the neck portion to contact the abutment and result in the ampule breaking at the neck portion.

21. A device for delivering a medication to a wound, the device comprising:

(a) a reservoir comprising a closed end, an open end, walls between the closed end and open end that have an outer surface and an inner surface, and a longitudinal axis extending from the closed end to the open end; and wherein the reservoir is configured to contain an ampule comprising a medication, wherein the medication is an antifibrinolytic;

(b) a release mechanism comprised in the reservoir and positioned at the wall of the reservoir, the release mechanism is configured to apply a mechanical force to the ampule that the reservoir is configured to contain upon activation of the release mechanism, wherein application of the mechanical force to the ampule causes the ampule to break, and the medication to be released; and

(c) a topical applicator attached to the open end of the reservoir, wherein the topical applicator comprises a foam material capable of retaining the medication released from the ampule.

22. The device of claim 21, wherein the reservoir is configured to contain an ampule that comprises a body portion and a neck portion, wherein the neck portion is thinner than the body portion.

23. The device of claim 22, wherein the reservoir is configured to contain an ampule that is oriented such that the neck portion is positioned closer to the open end of the reservoir and the body portion is positioned closer to the closed end of the reservoir.

24. The device of any one of claims 21-23, wherein the reservoir is configured to contain an ampule comprising a glass ampule.

25. The device of any one of claims 22-24, wherein the release mechanism is configured to be adjacent to the neck portion of the ampule that the reservoir is configured to contain.

26. The device of claim 25, wherein the release mechanism is configured such that application of a mechanical force to the ampule that the reservoir is configured to contain causes the neck portion break.

27. The device of any one of claims 1-26, wherein the release mechanism is activated by applying a force to the release mechanism.

28. The device of any one of claims 1-27, wherein one or more portions of the outer surface of the reservoir comprise a surface feature that aid in gripping or holding the device.

29. The device of claim 28, wherein the surface feature comprises one or more ridges.

30. The device of claim 28, wherein the surface feature comprises a textured surface.

31. The device of any one of claims 1-30, wherein the reservoir comprises one or more tabs on the inner surface of the walls of the reservoir that maintain the position of the ampule within the reservoir.

32. The device of any one of claims 1-31, wherein the antifibrinolytic is selected from tranexamic acid, aminocaproic acid, and the medication protamine sulfate.

33. The device of any one of claims 1-32, wherein the antifibrinolytic is tranexamic acid.

34. The device of any one of claims 1-33, wherein the topical applicator is attached to the reservoir via a fixation plate.

35. The device of claim 34, wherein the fixation plate is attached to the reservoir by an adhesive or welding.

36. The device of any one of claims 1-35, wherein the topical applicator is removably attached to the reservoir.

37. The device of any one of claims 1-36, wherein the topical applicator comprises a medication foam pad and a blood absorption foam pad, and a divider therebetween.

38. The device of claim 37, wherein the topical applicator is configured such that only the medication foam pad is positioned to receive the medication from the ampule.

39. The device of any one of claims 1-38, further comprising an applicator cap that is configured to fit over the topical applicator.

40. A method of treating a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

41. A method of treating a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

42. A method of reducing bleeding of a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

43. A method of reducing bleeding of a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

44. A method of controlling bleeding of a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

45. A method of controlling bleeding of a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

46. A method of treating a wound having excess bleeding of a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

47. A method of treating a wound having excess bleeding of a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

48. A method of delivering an antifibrinolytic to a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the antifibrinolytic in the ampule of the device and expose the topical applicator to the antifibrinolytic, and applying the topical applicator of the device to the wound.

49. A method of delivering an antifibrinolytic to a wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the antifibrinolytic in the ampule of the device and expose the topical applicator to the antifibrinolytic.

50. A method of treating post-surgical or post-procedural external bleeding in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the site of the external bleeding.

51. A method of treating post-surgical or post-procedural external bleeding in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the site of the external bleeding, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

52. A method of treating post-surgical or post-procedural wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

53. A method of treating post-surgical or post-procedural wound in a subject in need thereof, the method comprising obtaining the device of any one of claims 1-13 and 27-39, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

54. A method of treating a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

55. A method of treating a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

56. A method of reducing bleeding of a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

57. A method of reducing bleeding of a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

58. A method of controlling bleeding of a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

59. A method of controlling bleeding of a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

60. A method of treating a wound having excess bleeding of a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

61. A method of treating a wound having excess bleeding of a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

62. A method of delivering an antifibrinolytic to a wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the antifibrinolytic in the ampule of the device and expose the topical applicator to the antifibrinolytic, and applying the topical applicator of the device to the wound.

63. A method of delivering an antifibrinolytic to a wound in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the antifibrinolytic in the ampule of the device and expose the topical applicator to the antifibrinolytic.

64. A method of treating post-surgical or post-procedural external bleeding in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the site of the external bleeding.

65. A method of treating post-surgical or post-procedural external bleeding in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the site of the external bleeding, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

66. A method of treating post-surgical or post-procedural wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication, and applying the topical applicator of the device to the wound.

67. A method of treating post-surgical or post-procedural wound in a subject in need thereof, the method comprising obtaining the device and an ampule of any one of claims 14-39, installing the ampule into the device, applying the topical applicator of the device to the wound, and activating the release mechanism of the device to release the medication in the ampule of the device and expose the topical applicator to the medication.

68. The method of any one of claims 40-67, further comprising removing the topical applicator from the device and fixating the topical applicator to the wound.

69. The method of claim 68, wherein the topical applicator is fixated to the wound using a bandage, patch, film, or surgical dressing.

70. The method of any one of claims 40-69, wherein the method is performed by the subject.

71. The method of any one of claims 40-70, wherein the subject was taking, is taking, was prescribed, or is prescribed an anticoagulant therapy.

72. The method of any one of claims 40-71, wherein the subject was administered, is administered, or is to be administered one or more antiplatelet therapies.

73. A kit comprising: (a) a device of any one of claims 1-13 or 27-39, and (b) instructions on how to use the device according to the methods of any one of claims 40-53 and 68-72.

74. A kit comprising: (a) a device and an ampule of any one of claims 14-39, and (b) instructions on how to use the device according to the methods of any one of claims 54-72.

75. The kit of claim 73 or 74, further comprising a container for disposal of the device.

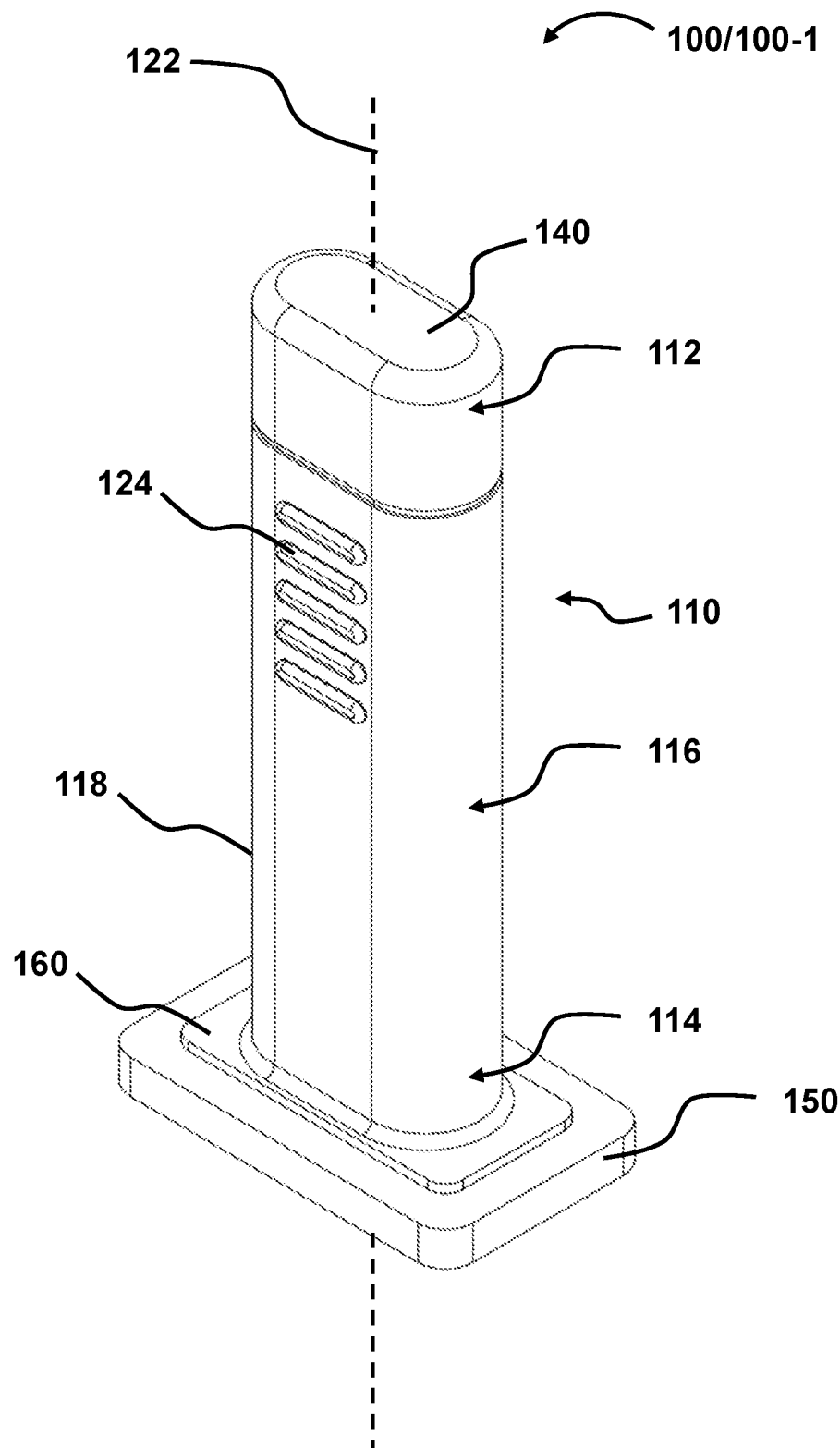


FIG. 1

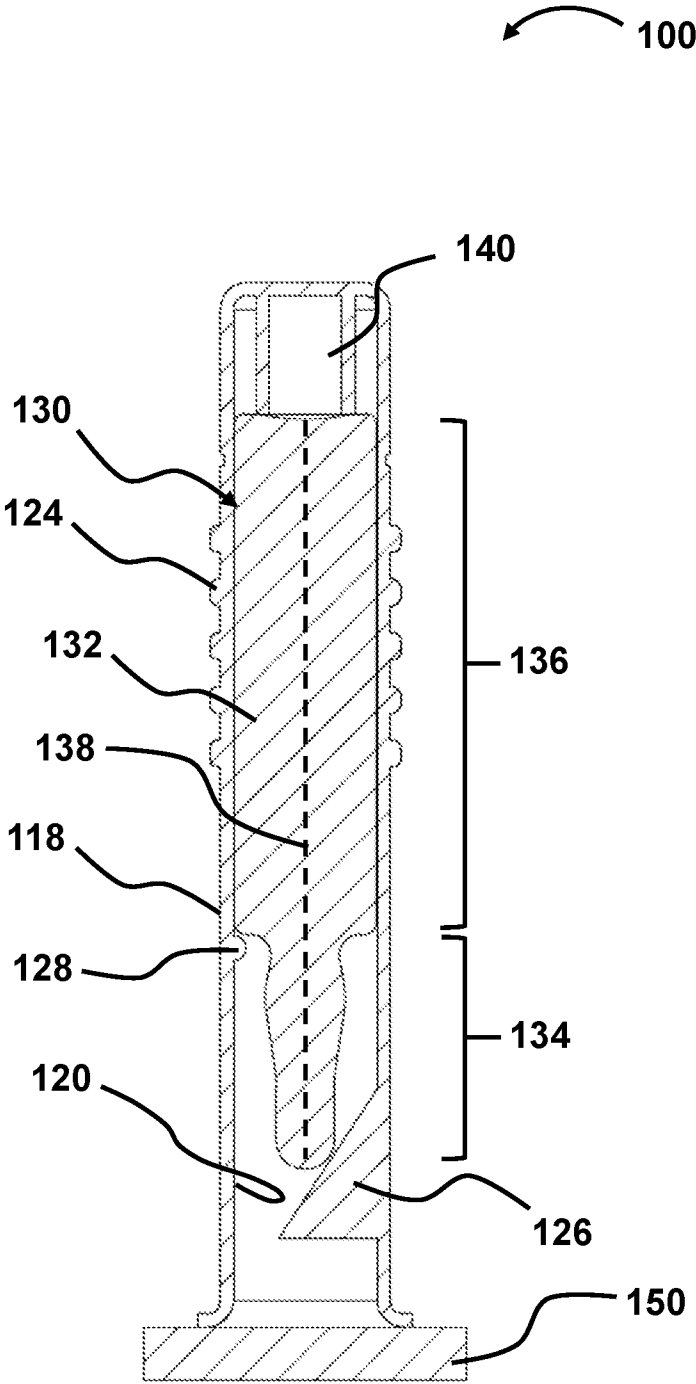


FIG. 2

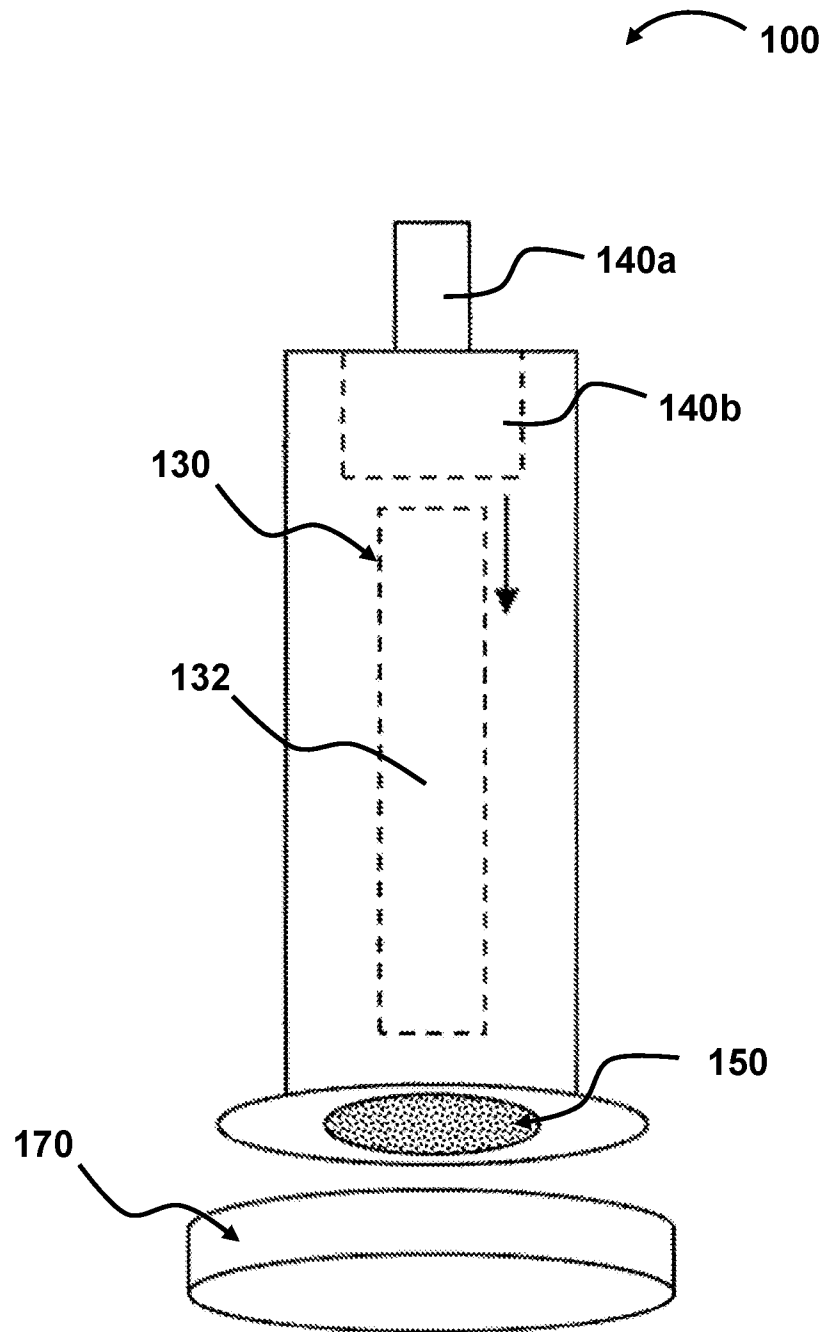


FIG. 3

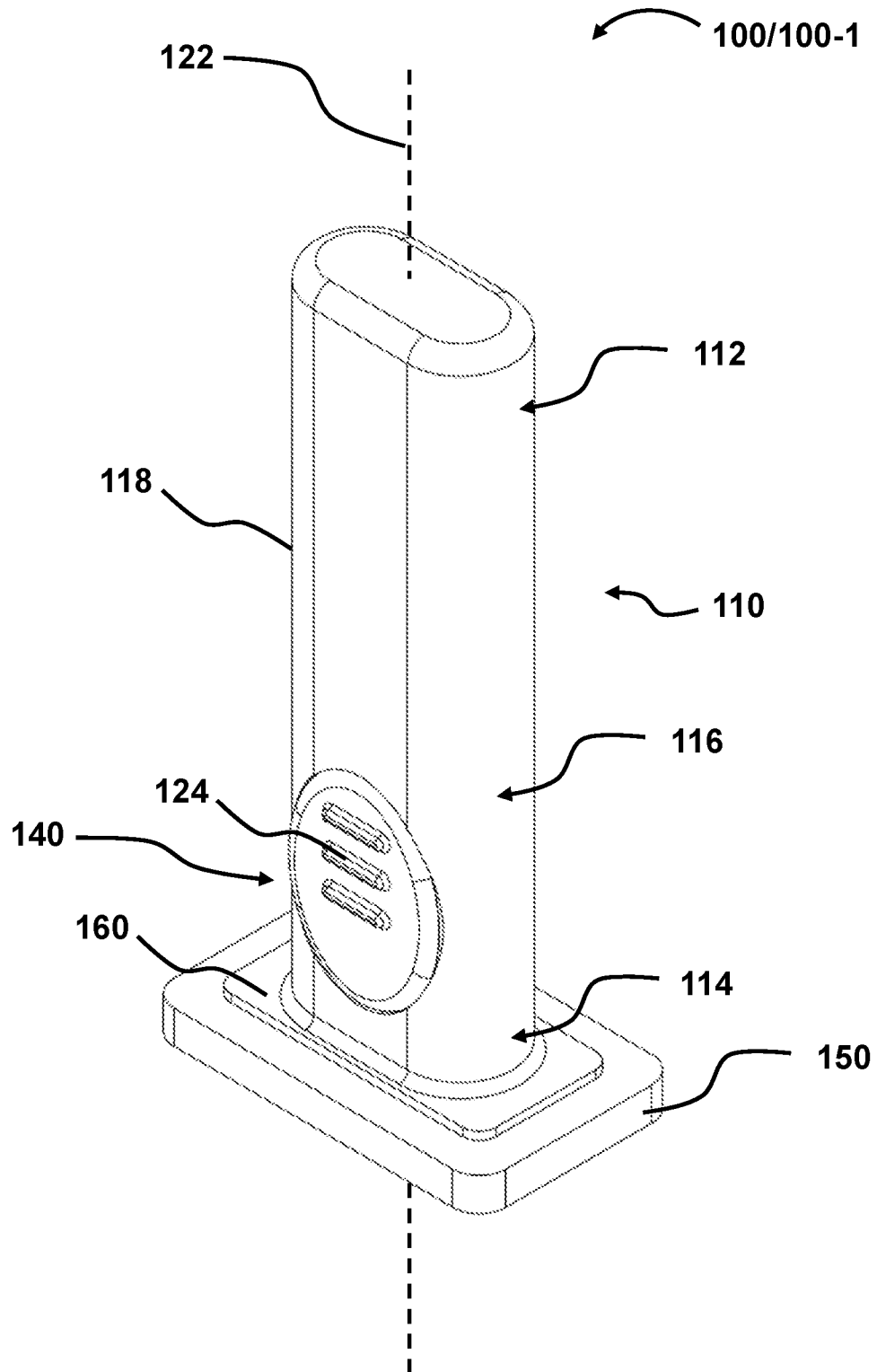


FIG. 4

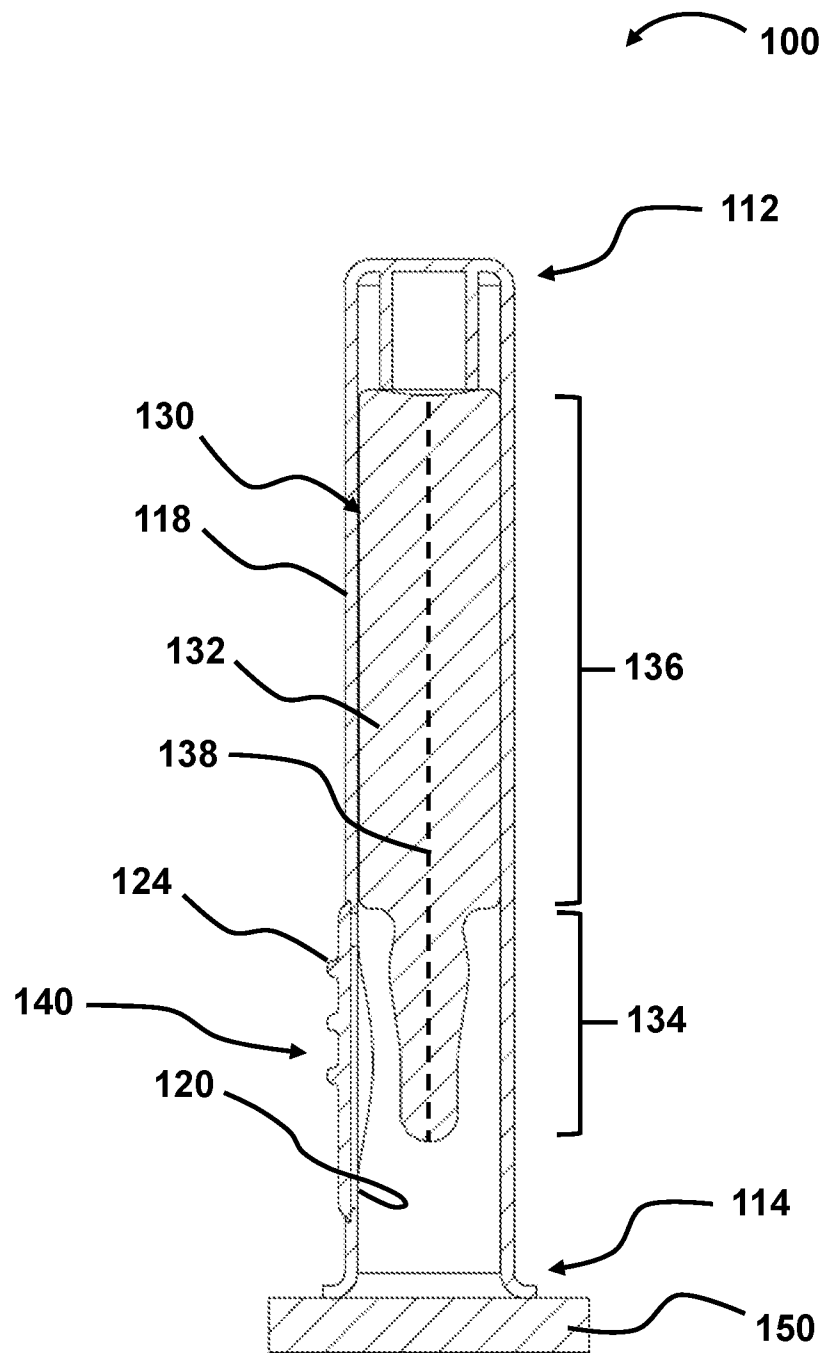


FIG. 5

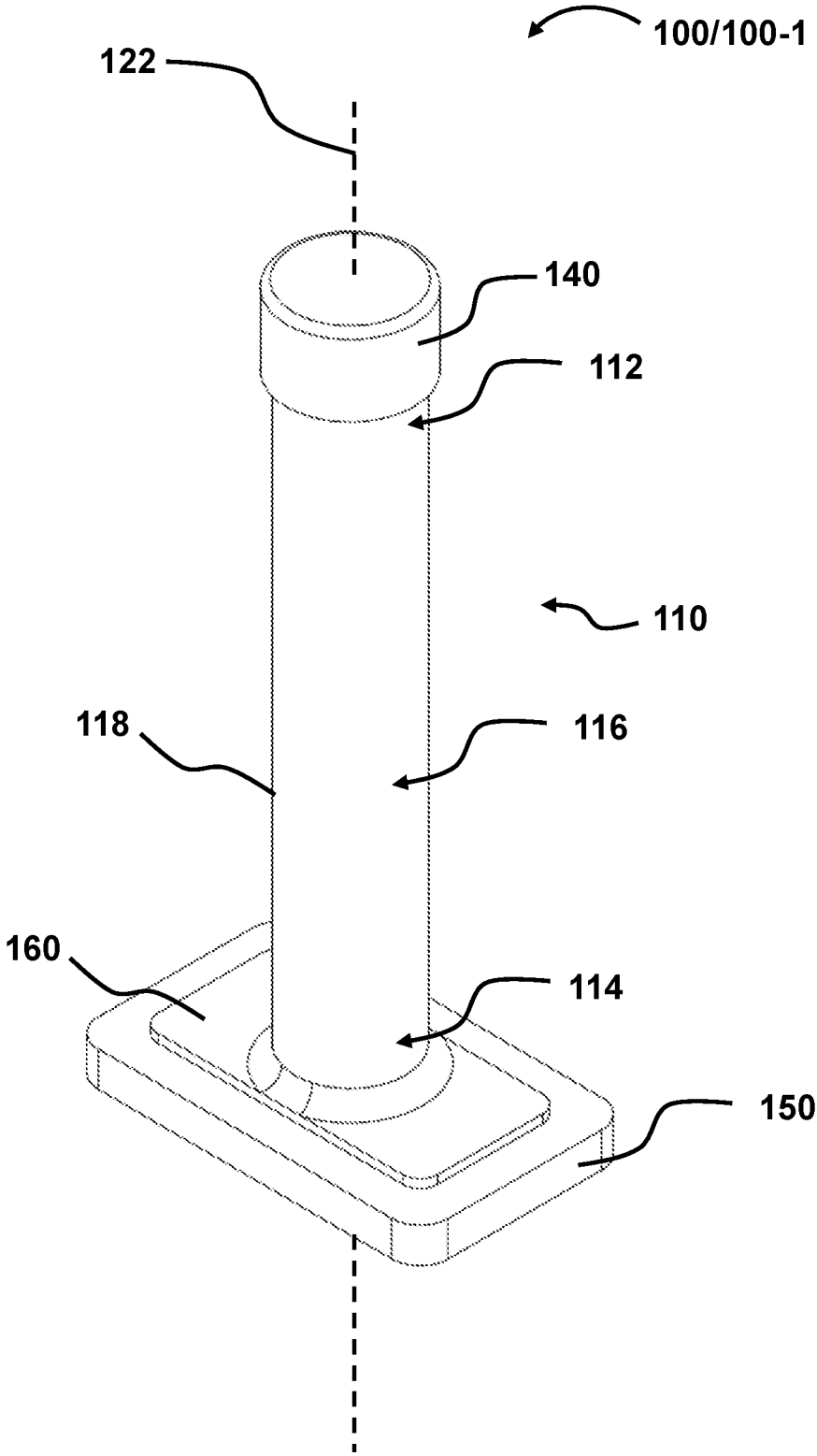


FIG. 6

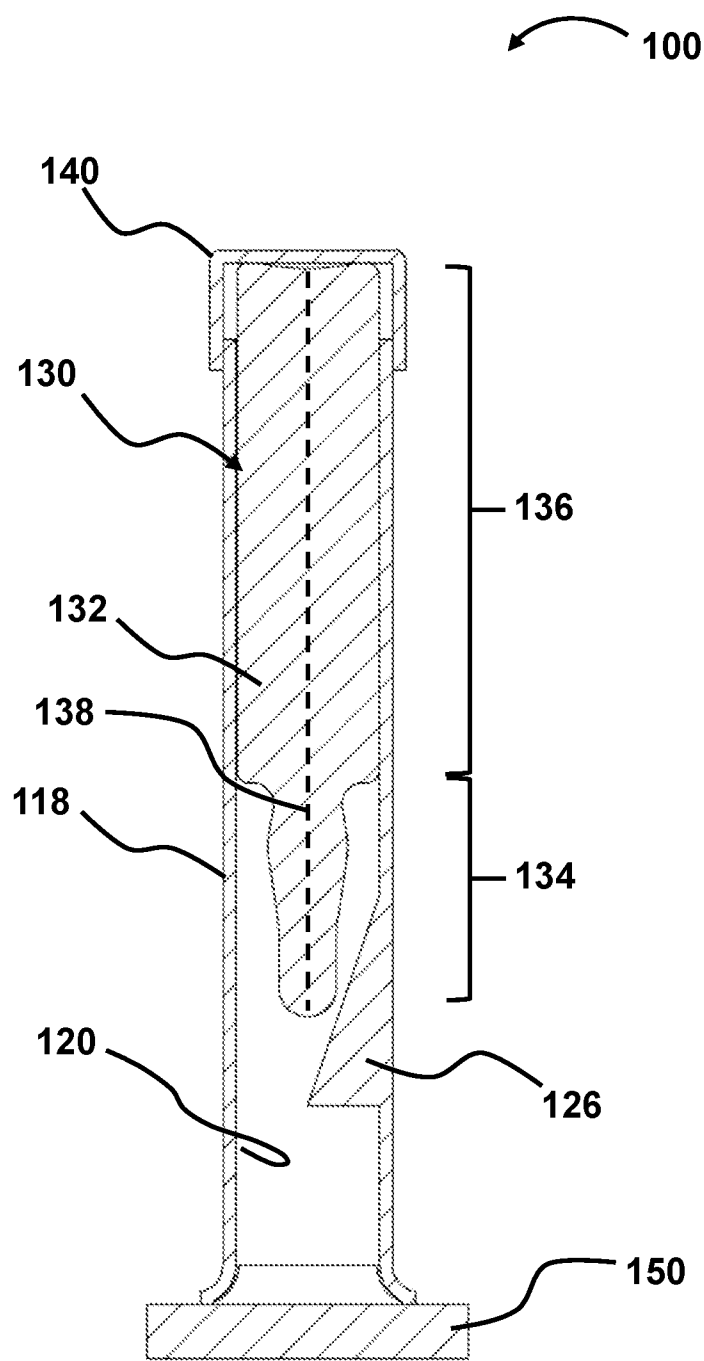


FIG. 7

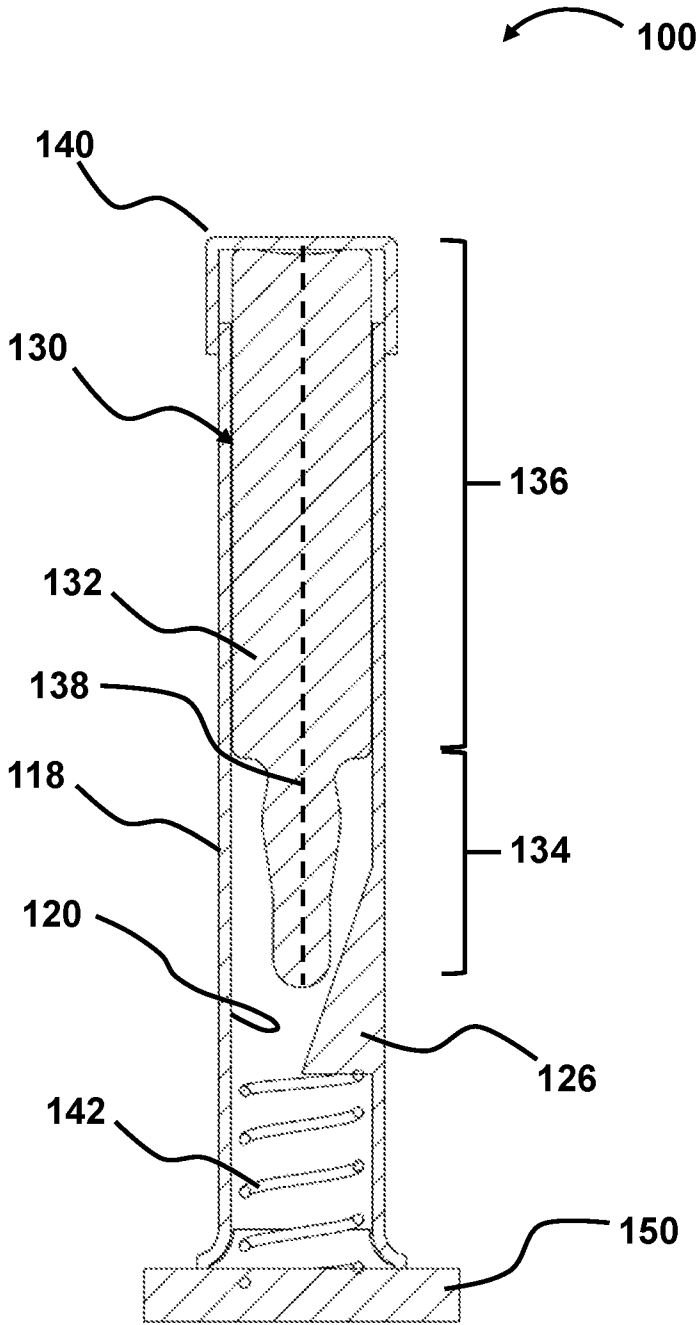


FIG. 8

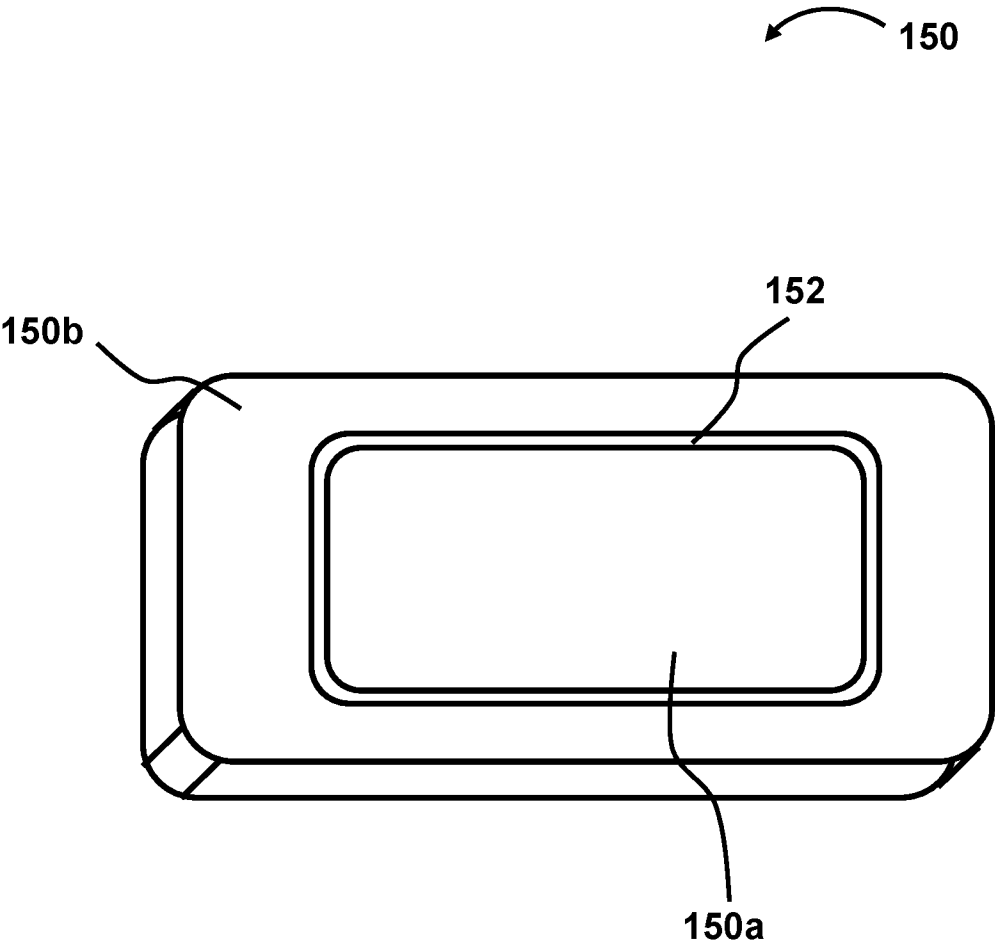


FIG. 9

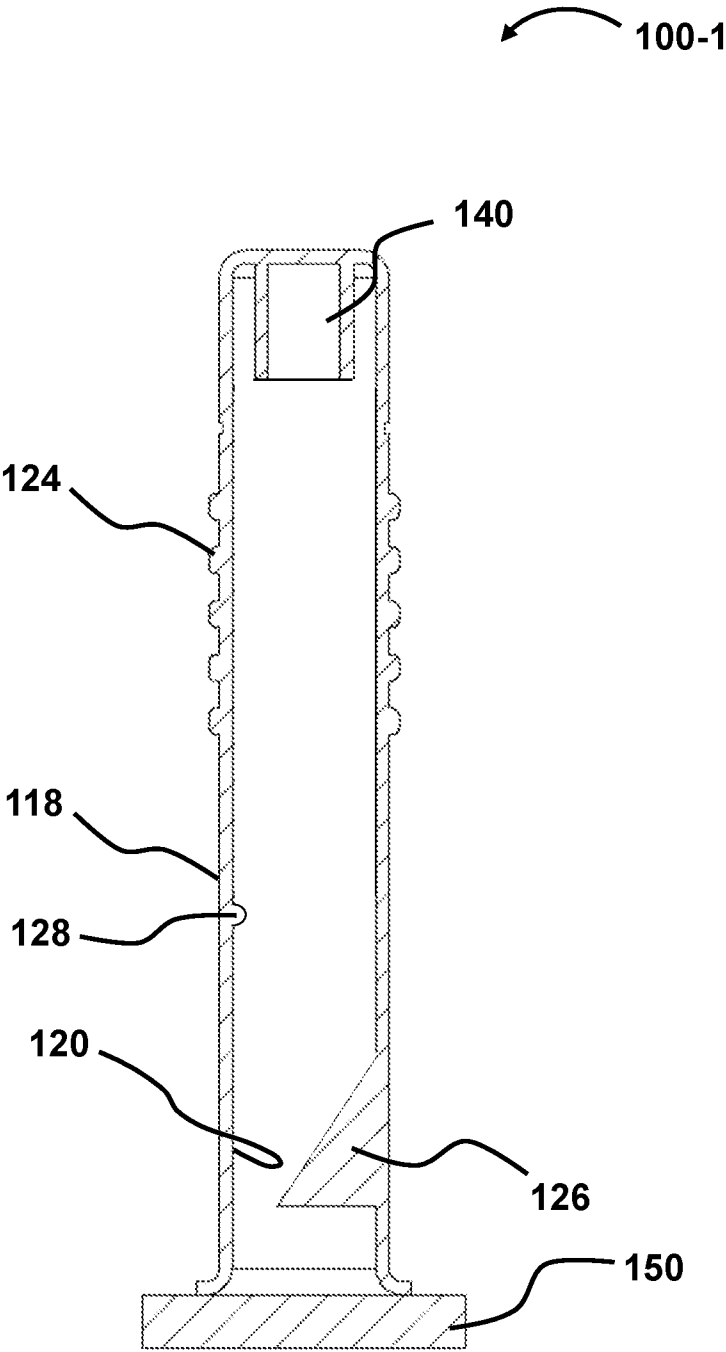


FIG. 10

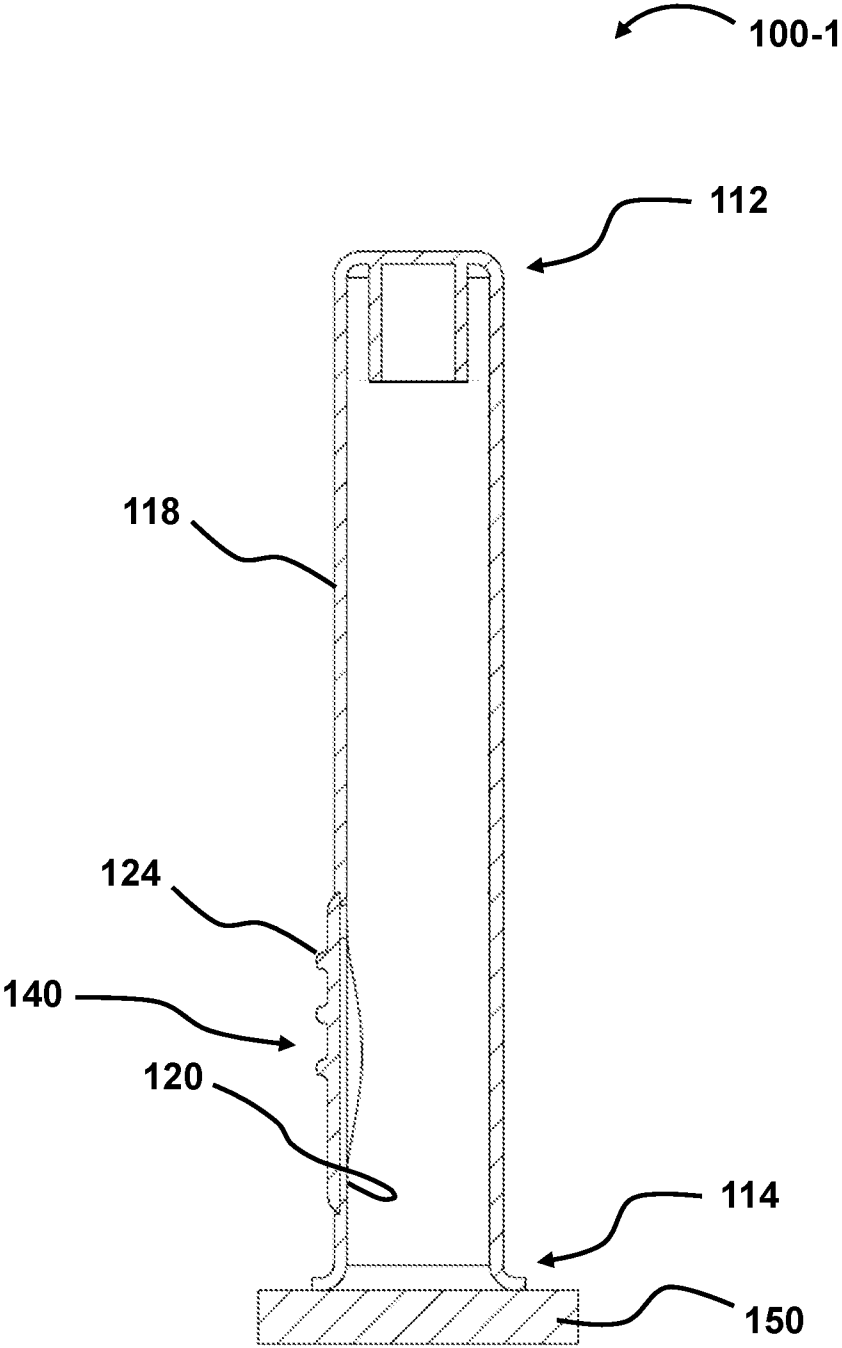


FIG. 11

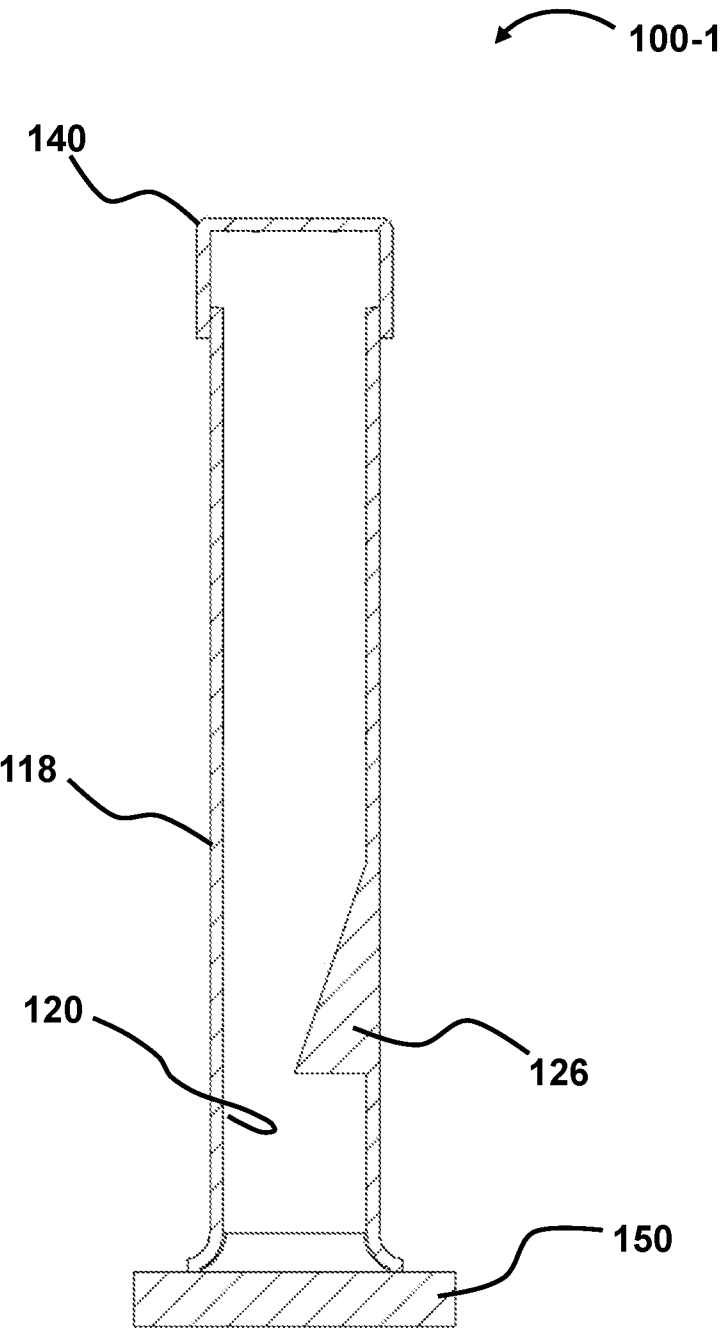


FIG. 12

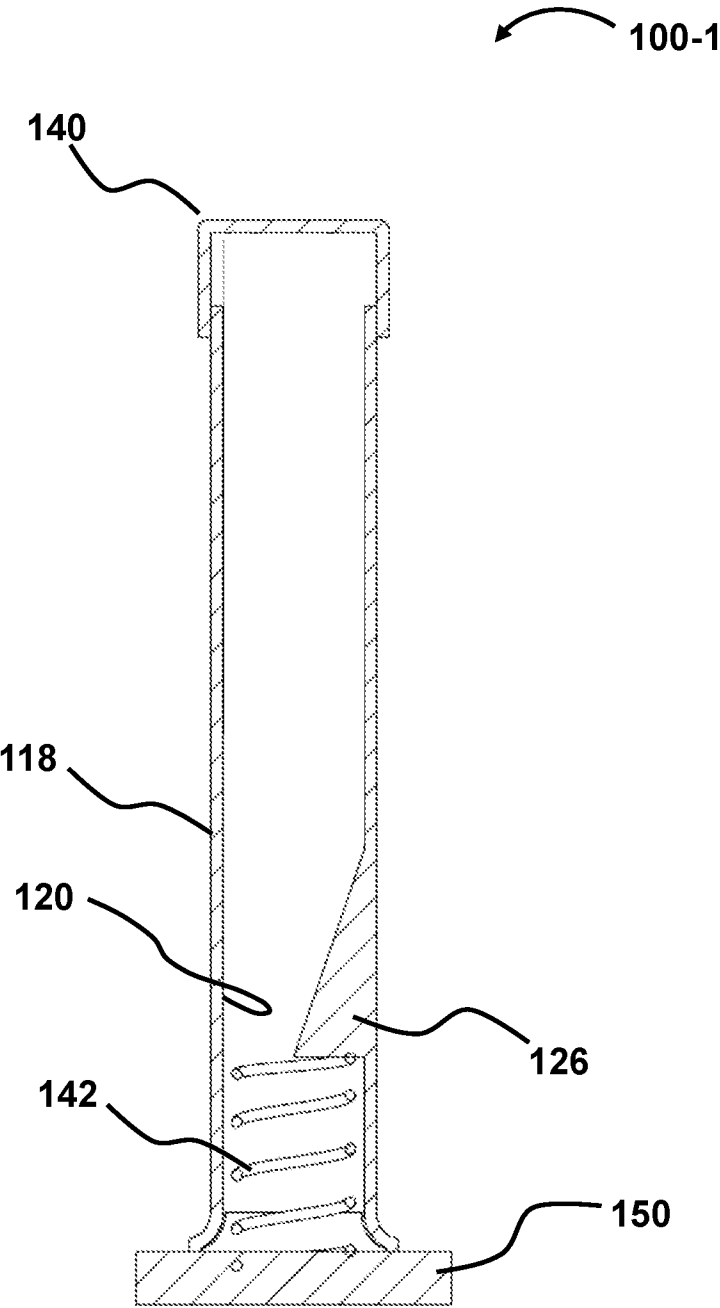


FIG. 13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/026714

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

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

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

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

3. ☒ Claims Nos.: 5-7, 12, 13, 18-20, 25-75
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

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

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2021/026714

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 35/00; A61B 17/00; A61F 13/40; A61M 35/006 (2021.01)

CPC - A61M 35/003; A61M 35/00; A61M 35/006 (2021.05)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

see Search History document

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

see Search History document

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

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,288,159 A (WIRT) 22 February 1994 (22.02.1994) entire document	1-4, 8-11, 14-17, 21-24
Y	JP 5128837 B2 (TYCO HEALTHCARE GROUP LP) 23 January 2013 (23.01.2013) machine translation	1-4, 8-11, 14-17, 21-24
A	US 2005/0054967 A1 (ASHE et al) 10 March 2005 (10.03.2005) entire document	1-4, 8-11, 14-17, 21-24
A	US 6,991,394 B2 (TUFTS et al) 31 January 2006 (31.01.2006) entire document	1-4, 8-11, 14-17, 21-24
A	US 10,478,851 B2 (ETTLIN) 19 November 2019 (19.11.2019) entire document	1-4, 8-11, 14-17, 21-24

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

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

24 June 2021

Date of mailing of the international search report

JUL 28 2021

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