



(51) International Patent Classification:

A61F 9/007 (2006.01)

(21) International Application Number:

PCT/US2011/032884

(22) International Filing Date:

18 April 2011 (18.04.2011)

(25) Filing Language:

English

(26) Publication Language:

English

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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, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, 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, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, ML, MR, NE, SN, TD, TG).

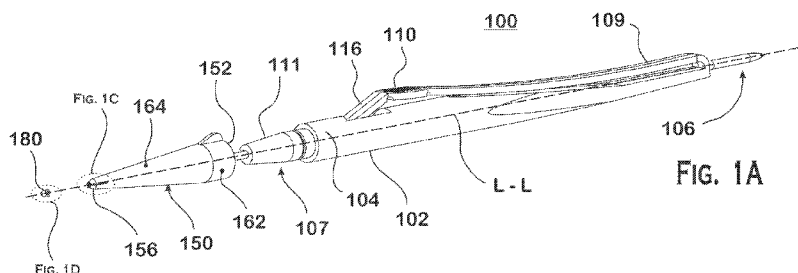
Declarations under Rule 4.17:

- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

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

(54) Title: IMPLANTATION INSTRUMENTS, SYSTEM, AND KIT FOR PUNCTAL IMPLANTS



(57) Abstract: Described and illustrated are various insertion instruments, cap, plug, method and kit. In one aspect, a cap (150) for a punctal insertion instrument (100) is shown and described. In a further aspect, a punctum plug insertion system that includes the instrument and the cap is provided. In yet a further aspect, a method of releasing a punctum plug (180) from a plug holder is provided. Additionally, a kit (700) that contains the plug insertion instrument, cap, plugs, and instructions for use (704) is provided.

IMPLANTATION INSTRUMENTS, SYSTEM, AND KIT FOR PUNCTAL IMPLANTS

BACKGROUND

[0001] One of the most common problems treated by eye physicians is dry eye syndrome.

It is believed that over ten million Americans suffer from this condition, which is usually caused by problems relating to the tear film that lubricates the eyes. Tears are formed in several glands around the eye. The water layer is produced in the lacrimal gland under the upper eyelid. Other glands in the lids make the oil and mucus layers. Blinking spreads the tears over the eye. Excess tears drain into ducts in the corner of the eye by the nose.

[0002] Problems with the tear film may occur due to the aging process. For example, a person produces less oil (up to 60% less) in the tear film at age 65 as compared to at age 18. The reduction of oil in the tear film may allow water in the film to evaporate faster, which leaves the cornea dry.

[0003] The use of plugs to block or reduce drainage into the tear ducts can be an effective step in treating moderate to severe dry eye that is incompatible with artificial tear drops and ointments. By blocking this outflow with a plug, called punctal or punctum plug, the tears tend to remain over the eye for a longer time. Punctal plugs have demonstrated to increase the comfort level and lower the frequency of artificial tear use in most dry eye patients.

[0004] The known punctum plugs are typically configured in the form of a cylindrical body with a blind hole extending from one end of the plug to allow the plug to be mounted over an insertion rod of an insertion tool, which is shown, for example, by US Patent Nos. 5,741,292; 5,643,280; 6,344,047; 6,527,780; and 5,335,871. Upon

insertion of the plug into the tear ducts, the insertion rod is used to release the plug from the tool.

[0005] While the plugs can be used as a technique to control outflow of tears, active agents are frequently administered at the same time to the eye for the treatment of ocular diseases and disorders. Several examples of punctum plug are shown and described in US Patent Publication No. 20070299516, which are hereby incorporated by reference herein to this application. In at least one example of such plug, an active agent is loaded into the blind bore of such plug.

SUMMARY OF THE DISCLOSURE

[0006] Utilizing the active agents with the punctum plug for greater efficacy in the treatment of dry eye syndromes and other related disorders of the eyes requires an effective insertion tool and those presently available are difficult to use or have performance limitations.

[0007] Accordingly, one aspect of the invention is an insertion instrument for implanting punctum plugs that lack a blind bore, including those plugs loaded with one or more active agents in a location where a blind bore would normally be formed.

[0008] In another aspect, an insertion instrument is provided. In another aspect, a cap for a punctal insertion instrument is shown and described. In a further aspect, punctum plug insertion system that includes the instrument and the cap is provided.

[0009] In yet a further aspect, a method of releasing a punctum plug from a plug holder is provided.

[0010] Additionally, a kit that contains the plug insertion instrument, cap, plugs, and instructions for use is provided.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0011] Figure 1A illustrates a perspective view of an exemplary embodiment of a punctum plug insertion system having a punctum plug, punctum cap, and insertion instrument.
- [0012] Figure 1B illustrates a sectional perspective view of the exemplary system of Figure 1A.
- [0013] Figure 1C illustrates a close-up perspective view of a distal portion of the insertion instrument of Figure 1A.
- [0014] Figure 1D illustrates a close-up perspective view of an exemplary punctal plug for use with the insertion instrument of Figure 1B.
- [0015] Figure 2A illustrates in a plan view of a variation of the instrument of Figure 1A whereby the plug illustrates mounted to the cap and unreleased from the instrument.
- [0016] Figure 2B illustrates a sectioned view of the components as viewed from sectional line 2B-2B.
- [0017] Figure 2C illustrates a plan view during a plug release sequence of the embodiment of Figure 2B.
- [0018] Figure 2D illustrates a sectioned view of the components as viewed from sectional line 2C-2C.
- [0019] Figures 3A and 3B illustrate respective schematic views of another variation of the exemplary system described and illustrated herein.
- [0020] Figure 4A illustrates a plan view of yet another variation of the embodiment of Figures 3A and 3B.
- [0021] Figure 4B illustrates a perspective view of the embodiment of Figure 4A.

- [0022] Figures 5A and 5B illustrate respective sectional side views of yet a further embodiment of an insertion instrument.
- [0023] Figures 6A-6C are exemplary perspective illustrations of various caps and plugs that can be utilized in the various exemplary instruments described herein to retain a punctum plug.
- [0024] Figure 7 illustrates an exemplary kit for the various embodiments described herein.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

- [0025] The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. As used herein, the term "punctal plug" refers to a device of a size and shape suitable for insertion into the inferior or superior lacrimal canaliculus of the eye through the inferior or superior lacrimal punctum. Additionally, the terms "about" or "approximately" for any numerical values or ranges indicate a suitable dimensional tolerance that allows the part or collection of components to function for its intended purpose as described herein. In addition, as used herein, the terms "patient," "host," "user," and "subject" refer to any human or animal subject and are not intended to limit the systems or methods to human use, although use of the subject invention in a human patient represents a preferred embodiment.
- [0026] Portions of the disclosure of this document contain material that is subject to copyright protection. The copyright owner reserves all copyright rights to these portions including, without limitation the instructions for use described herein.
- [0027] Referring to Figure 1A, a system 100 to deliver or insert a punctum plug 180 is shown in perspective view along a longitudinal axis L-L. The system 100 includes an insertion tool or instrument 102 that includes instrument body 104. The

instrument body 104 extends from a proximal end 106 (i.e., the end nearest an operator holding the instrument 102 for its intended use) to a distal end 107 (i.e., the end furthest away from an operator holding the instrument 102 for its intended use) along the longitudinal axis L-L. The instrument 102 has an actuator 110 disposed near the distal end 107. The actuator 110, in the form of a button, may be connected to an actuation member 112, which is configured to move along the longitudinal axis L-L through a body opening 114 provided in the instrument body. The actuation member 112 may be formed of any configuration as long as such configuration allows the actuation member 112 to reciprocate along the longitudinal axis L-L in the body opening 114. Preferably, the actuation member 112 is configured as a generally cylindrical rod. The actuation member 112 is connected to the actuator 110 via an arm 116 that is angled with respect to the longitudinal axis L-L. The arm 116 is coupled to the actuator 110 via at least one suitable hinge 105, such as, for example, an unbiased hinge, spring-biased hinge or preferably a living hinge 105.

[0028] Although the embodiment shown in Figure 1A is provided with one hinge, other embodiments may be provided with two or more hinges, as shown in Figures 3A, 3B, 4A, and 4B. At the proximal end 106 of such embodiments, a dilation member 108 can be provided to assist in the dilation of the tear ducts prior to insertion or implantation of the punctum plug 180. The dilation member 108 may be a conical taper with diameters ranging from about 1.5 mm to about 0.1 mm. The shaft attached to the dilation member 108 is generally cylindrical shaft with a diameter of about 0.1 cm to about 0.8 cm with a length of about 10 mm to about 100 mm. The dilation member 108 may be connected to the actuator 110 via a cantilever member 109, which provides a suitable bias for the actuator 110 to remain in the unreleased or non-actuated position. The stiffness modulus of the cantilever member 109 may

be of any suitable stiffness modulus sufficient to allow the instrument 102 to function for its intended purpose. For example, the stiffness modulus may be from about 0.7 mm⁴ to about 48 mm⁴, preferably from about 1.0 mm⁴ to about 4.5 mm⁴, more preferably about 4.5 mm⁴.

[0029] The instrument 102 includes cap support portion 111 to support a cap 150, which may be loaded with a punctum plug 180, shown here in close-up of Figure 1D. The cap support portion 111 has an outer support surface 120 that is generally complementary to the inner surface 160 of the cap 150. The support surface 120 can be provided with a ridge 169B to interlock with a recessed groove 169A formed in the inner surface 160 of the cap 150. The interlock secures the cap 150 to the instrument 102. Preferably, the support surface 120 of the cap support portion 111 is provided with a recessed annular groove 169B to interlock with an annular ridge 169A formed on the inner surface 160 of the cap 150.

[0030] With reference to Figures 1A and 1B, the cap 150 may have two portions on its outer surface 157. The first portion 162 proximate the first cap end 152 may be generally cylindrical in form. The second portion 164 extends proximate the first portion 162 to a second cap end 156 about and along the longitudinal axis L-L to define a generally tapered surface in the form of a cone. The inner surface 160, which is spaced from the outer surface 157 of the cap 150, may have generally similar configurations as the outer surface 157 to define a hollow cylinder contiguous to a hollow cone about and along the longitudinal axis L-L. The hollow cylinder may have a raised portion proximate the first end 152 of the cap 150 that extends towards the longitudinal axis L-L to preferably define an annular ridge.

[0031] As shown in Figure 1B, the first cap end 152 defines a first opening 154 about the longitudinal axis L-L, and the second cap end 156 defines a second opening 158

about the longitudinal axis L-L. The second opening 158 (Fig. 1D) is configured to be generally the same size or smaller as that of the body 182 of the plug 180 (Fig. 1E) so that the second opening 158, in the form of two half circles or retainer lips 174A and 174B, is able to capture the plug 180 with only the head 184 of the plug 180 protruding from the cap 150.

[0032] As shown in Figure 1C, the second cap end 156 has one or more slits 170 that extend along the longitudinal axis L-L such that the slits 170 provide a diametrical separation, shown here in Figs. 2B and 2D, between retainer lips 174A and 174B of the second cap end 156. The slits 170 provide first retainer lip 174A and second retainer lip 174B of the second cap end 156 with the ability to flare out in a tulip-like manner during a release of the plug 180.

[0033] In an alternative embodiment, shown here in Figure 3A, the cap 150 is integrated with the instrument 300 and fingers 302 may be added to the retainer lips 174A and 174B second opening to further ensure positive retention of the plug 180 on the cap 150.

[0034] The cap 150 will now be described with reference to Figures 1B and 1C. In Figure 1B, the cap 150 can be seen as an elongated body that extends along the longitudinal axis L-L from a proximal or first end 152 to a distal or second end 156. The second end 156 of the cap 150 defines a proximal or first cap opening 154 larger than a distal or second opening 158 defined by the second end 156. The second opening 158 may include at least two slits 170 that extend through a wall 172 of the cap 150 proximate the distal end 107 so that a punctum plug 180 is able to pass through the distal opening 158 upon expansion of the distal opening 158. Preferably, a portion of elongated body has a taper disposed about and along the longitudinal axis L-L to define a generally conic outer surface 157. The inner surface 160 of the elongated

body may be spaced apart from the outer surface 157 to define a suitable hollow surface (e.g., cylindrical, conic or combinations thereof).

- [0035] Preferably, the inner surface 160 defines a generally hollow cone. In the preferred embodiments, the cap 150 has three portions for its outer surface 157: (1) a generally planar tab 151 on (2) a generally cylindrical portion 162, which is integrated with (3) a generally conical portion 164. The inner surface 160 defines the corresponding hollow cylindrical and conic portions. One or more annular rings 169A (raised or recessed) oriented about the longitudinal axis L-L may be provided on the inner surface 160 of the cap 150 so that the ring may interlock with the corresponding annular ring (recessed or raised) 169B on the cap support portion 111. Alternatively, helical rings in the form of screw-on male and female threads may also be provided.
- [0036] Where the instrument 102 is reusable but the cap 150 and plug 180 are single-use components, several features are provided. A seal 200 can be formed proximate the first cap opening 154 to ensure that whenever the cap 150 is mounted to the instrument 102, there is clear physical indication that the sterility of the cap 150 is no longer assured due to the actuator member 112 piercing the seal 200, which may be hermetic in function. A separate actuator rod 202 can be mounted for engagement with the actuation member 112. The actuator rod 202 may be provided with a slight friction fit to the cap's inner surface 160 proximate the second cap opening 158 with serrated outer surfaces of the rod 202 to ensure that once the actuator rod 202 has been deployed, another plug 180 cannot be installed into the cap 150 due to the action of the serrated surfaces (not shown), which prevents backward movement of the rod 202 towards the proximal end 106.
- [0037] Referring to Figures 2A, 2B, 2C, and 2D, the release of the plug 180 from the cap 150 will now be described. As shown in Figure 2A, the plug 180 is mounted to the cap

150, which is mounted to the instrument 102 with the actuator 110 in the unreleased or non-actuated position shown in Figure 1A. In this position, the plug 180 is retained by the lip retainers 174A and 174B (Fig. 2B) of the second opening 158 of the cap 150. To release the plug 180 for its intended use, such as, for example, in the tear duct of a subject, the button 110 (Fig. 1A) is compressed radially towards the longitudinal axis L-L, which causes the actuator member 112 via the hinge 105 to move along the longitudinal axis L-L towards the distal second cap opening 158. Because the actuator member 112 is configured to be larger than the second opening 158, the retainer lips 174A and 174B are forced to move radially outward in a tulip like fashion. As the button 110 is further depressed towards the axis L-L, actuator member 112 continues moving along the longitudinal axis L-L towards the distal end 107 causing actuator 112 to engage against the tail portion of the plug 180. This forces the plug 180 out of the second opening 158. As the actuator member 112 continues moving in the distal direction, the plug 180 will no longer be constrained or retained to the cap 150 and therefore will be released from the cap 150 and into the tear duct.

[0038] It is noted that the action of pressing on the actuator 110 may cause the actuator member 112 to translate in a linear direction along the longitudinal axis L-L due to the constraint of the support body opening 114. The linear movement of the actuator member 112 may be simultaneous or in sequence depending on whether there is intentional slop built into the connection between the actuator 110 and the actuator member 112. In the preferred embodiment, both actions (pressing and sliding) are generally simultaneous with some overlaps between the two actions.

[0039] In the embodiment of Figures 3A and 3B, the retainers 174A and 174B are connected to corresponding cantilevered arms 306 and the cantilevered arms 306 are coupled to a dilation member 108 via angled arms 321. Actuation arms 312 and 314 are

connected to the cantilevered arms 306 to ensure that actuation member 316 is forced to move along the longitudinal axis L-L towards the tail portion 182 of the plug 180. Reinforcements 318 are provided between the retainers 174A and 174B and the cantilevered arms 306 to prevent or constrain a flexing of the retainers 174A and 174B relative to the cantilevered arms 306. The cantilevered arms 306 are connected to the angled arms 321 via a connecting hinge 320 for each pair of arms. As in the embodiments of Figures 1A and 2A, the connecting hinges 320 may be living hinges.

[0040] In a variation of the embodiment of Figure 3, a double or dual- lever instrument 400 is provided in Figures 4A and 4B which may include two cantilevered connecting arms 402 coupled to an actuator body 404. The actuator body 404 is connected to an elongated actuator element 406. Two connecting arm hinges 408 are provided at each end of each cantilevered arm 402. A plug 180 may be mounted on a cap 150. The cap 150 may be mounted to the double lever instrument 400 or integrated as a part of the double lever instrument 400. A dilation member 108 may also be provided in this embodiment to allow a physician to dilate a duct just prior to insertion of the plug 180. In operation, the plug 180 is released by applying forces radially towards the longitudinal axis L-L to compress the actuator 410. This causes each of the cantilevered arms 402 to rotate about its axis while translating along the longitudinal axis L-L, causing the actuator body 404 to force the elongated actuator element 406 to translate along the longitudinal axis L-L. As in the prior embodiments, the cross-section (e.g., circular, conical and the like) of the elongated actuator element 406 may be larger than the opening of the cap 150, which causes the opening 158 of the cap 150 to flare in a tulip-like manner upon entry of the actuator element 406, thereby releasing the plug 180 from the cap.

- [0041] Another variation, shown in Figures 5A and 5B, is provided in which two hinges 506 are utilized for instrument 500. In this instrument 500, the actuator arm 508 is connected to the actuator 504 via a hinge 506. The actuator arm 508 is connected to the actuator member 510 via a pin 322. The actuator member 510 is constrained to translate along the axis L-L due to the opening formed by boss 540. The actuator 504 may also have a hinge 506 for its connection to the dilation member 108. As in the prior embodiments, a cap 550 may also be provided with the plug 180 mounted thereon. Release of the plug 180 in this embodiment is similar to the other embodiments.
- [0042] It is believed that one of many advantages of the invention over the known system is the ability to switch between different sizes or different configurations of the plugs without the physician straining to find the right plug 180 in order to insert an actuation rod of the known insertion tool. That is, in the known tool, if the plug is not of the right size, the physician would have to either use another tool preloaded with the right size plug or the physician would have to pull the plug out of the known instrument and insert a new plug into an insertion rod of the known tool. In the latter case, the small size of the plug is a significant challenge for the physician to locate and insert the inserter rod of the known tool into the right size plug. In contrast, the embodiments taught herein would allow the physician to simply pull off a wrong-size cap 150 and mount the right size cap 150 without significant visual or physical difficulties in the attachment of the right size plug 180.
- [0043] To allow the physicians or health care provider ("HCP") with additional flexibility, the cap 150 and plug 180 may be provided in different configurations, such as, for example, shown in Figures 6A, 6B, and 6C. In Figure 6A, an extended length plug 600 can be utilized with the cap 150. The cap may be in the form of an axially clamped cap 602 (Fig. 6B) or split-seam cap 604 (Fig. 6C).

- [0044] To obtain even greater flexibility for the HCP, a suitable kit in the form such as, for example, Figure 7 may be provided for the HCP. In this kit 700, an enclosure (e.g., blow-molded case) is provided that contains at least one instrument 102 with a suitable sized plug 180 mounted to the cap 150. Additional caps with different sizes of the plugs (e.g., 0.3mm, 0.4mm, 0.5mm, 0.6mm, 0.7mm, 0.8mm, 0.9mm and so on with the appropriate size indicia printed on the caps) are provided in the enclosure within a single sterile packaging or within a sub-divided (i.e., multiple individual) sterile packaging. Instructions for use ("IFU") 704 of the kit 700 are provided in the form readable by a person, such as, for example, in the form of a paper medium or electronic medium (e.g., memory stick or CD-ROM). The entire enclosure and its contents can be sterilized using a regulatory approved sterilization technique.
- [0045] The IFU 704 would include, at a minimum the steps of ensuring that the cap 150 is securely attached to the instrument 102 with the right size plug 180 mounted in the tip of the cap 150; removing the cap 150 if the wrong size plug 180 or wrong tip configuration of the cap 150 is mounted to the instrument 102; securing the right cap 150 and plug 180 configurations to the instrument 102; dilating the tear duct, inserting the plug 180 into the duct and actuating the actuator 110 of the instrument 102 to release or implant the plug 180 into the duct of the subject.
- [0046] Preferably, the IFU 704 includes the following instructions: (1) Hold the applicator instrument (100) as with a pencil, between the thumb and fingers with the index finger just above the release button (110). At this point, the user should not depress the button. (2) Gently depress the release button (110) until a 'soft-stop' is felt; This is the pre-deployment position. The punctal plug (180) should partially protrude in this position so that the shaft (182) is exposed. (3) Using a gentle, downward, rotational motion, insert the plug until the rim (184) is flush against the punctal opening. Verify that the rim of the plug has not been buried below the punctal ring.

If so, gently pull the inserter upward until the rim is sealed properly. (4) With the plug (180) properly positioned, fully depress and hold the release button on the applicator. (5) Remove the applicator while holding the button down. Dispose of the used inserter in a "sharps" container. (6) Using a forceps, gently push down on the collar (186) of the plug (top of the plug) to ensure the plug is completely inserted and the collar is flush with the lid margin.

[0047] While preferred embodiments of the present invention have been shown and described herein such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. Various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

CLAIMS

WHAT IS CLAIMED IS:

1. An insertion instrument comprising:
a body extending along a longitudinal axis from a proximal end to a distal end;
an actuation member disposed to move along the longitudinal axis through a portion of the body near the distal end, the actuation member including an arm disposed at an angle relative to the longitudinal axis; and
an actuator connected to the actuation member with at least one hinge, the actuator being connected to the arm via the at least one hinge.
2. The system of claim 1, wherein the proximal end of the body includes a dilation member.
3. The system of claim 1, wherein the actuation member comprises a generally cylindrical rod.
4. The system of claim 4, wherein the at least one hinge comprises a living hinge.
5. The system of claim 1, wherein the actuator comprises a cantilevered member connected to the dilation member.
6. The system of claim 1, wherein the body includes a cap support portion having a truncated generally conical outer surface to support a complementary inner surface of

such cap.

7. The system of claim 1, wherein the body includes a cap support portion having an opening proximate the longitudinal axis that extends through the cap support to allow the actuation member to reciprocate along the longitudinal axis.

8. A cap for a punctal insertion instrument, the cap comprising:

an elongated body extending along a longitudinal axis from a proximal end to a distal end, the proximal end defining a proximal opening larger than a distal opening defined by the distal end, the distal opening including at least two slits that extend through a wall of the cap proximate the distal end so that a punctum plug is able to pass through the distal opening upon expansion of the distal opening.

9. The cap of claim 8, wherein at least a portion of the cap comprises a tapered outer cap surface that surrounds the longitudinal axis to define a generally conical outer surface.

10. The cap of claim 9, wherein cap comprises an inner surface spaced apart from the outer cap surface, the inner surface surrounds the longitudinal axis to define a generally hollow cone.

11. The cap of claim 10, wherein the inner surface of the cap comprises a raised portion proximate the first end of the cap that extends towards the longitudinal axis.

12. The cap of claim 8, wherein the second cap end comprises at least two retainers separated by on diametrically opposed sides of the second end cap.

13. The cap of claim 8, wherein the first opening includes a hermetic seal to prevent ingress of contaminant into the cap.
14. The cap of claim 13, further comprising an elongated actuator rod disposed proximate the second end.
15. The cap of claim 8, further comprising a punctum plug having a body connected to a body and a tail, the body being partially disposed in the cap proximate the second opening.
16. An insertion system comprising:
 - an insertion instrument including:
 - a body extending along a longitudinal axis from a proximal end to a distal end;
 - an actuator disposed proximate the distal end, the actuator including an actuation member disposed to move along the longitudinal axis and connected to the actuator with at least one hinge;
 - a cap disposed proximate the distal end of the body, the cap extending from a first cap end to a second cap end along the longitudinal axis, the first cap end defining a first opening about the longitudinal axis and the second cap end defining a second opening about the longitudinal axis, the second cap end further defining at least one slit that extends along the longitudinal axis; and
 - a punctum plug having a portion disposed inside the second opening of the cap such that the plug is retained to the cap.

17. The system of claim 16, wherein the proximal end of the body includes a dilation member.

18. The system of claim 16, wherein the actuation member comprises a generally cylindrical rod.

19. The system of claim 16, wherein the actuation member includes an arm disposed at an angle relative to the longitudinal axis and connected to actuator via the at least one hinge.

20. The system of claim 18, wherein the at least one hinge comprises a living hinge.

21. The system of claim 16, wherein the at least one hinge comprises two living hinges.

22. The system of claim 16, wherein the actuator comprises a cantilevered member connected to the dilation member.

23. The system of claim 16, wherein at least a portion of the cap comprises a tapered outer cap surface that surrounds the longitudinal axis to define a generally conical outer surface.

24. The system of claim 23, wherein cap comprises an inner surface spaced apart from the outer cap surface, the inner surface surrounds the longitudinal axis to define a generally hollow cone.

25. The system of claim 24, wherein the inner surface of the cap comprises a raised

portion proximate the first end of the cap that extends towards the longitudinal axis.

26. The system of claim 16, wherein the second cap end comprises at least two finger-like retainers separated by the slits.

27. A method of releasing a punctum plug from a plug holder, the plug having a body portion disposed along a longitudinal axis that extends from a head portion to a tail portion, the plug holder having at least two retainers in contact with at least an outer circumferential surface of the body portion of the punctum plug, the method comprising:
causing the retainers to move in a generally radial direction with respect to the longitudinal axis; and
moving the plug along the longitudinal axis away from the retainers.

28. The method of claim 27, wherein the moving comprises translating a member along the longitudinal axis against the tail portion of the plug.

29. The method of claim 27, wherein the causing comprises compressing cantilevered arms connected to respective retainers.

30. The method of claim 29, wherein the causing comprises translating a member along the longitudinal axis against the tail portion of the plug with actuation members connected to the cantilevered arms.

31. The method of claim 27, further comprising coupling the finger-like retainers to a dilation member via respective hinges.

32. The method of claim 28, wherein the hinges comprise living hinges.
33. An ocular implant kit comprising:
an enclosure to house a plurality of components, the plurality of components comprising:
(a) at least one insertion instrument including:
a body extending along a longitudinal axis from a proximal end to a distal end;
an actuator disposed proximate the distal end, the actuator including an actuation member disposed to move along the longitudinal axis and an actuator button coupled to the actuation member with a hinge;
(b) at least one cap disposed proximate the distal end of the body, the cap extending from a first cap end to a second cap end along the longitudinal axis, the first cap end defining a first opening about the longitudinal axis and the second cap end defining a second opening about the longitudinal axis, the second cap end further defining at least one slit that extends along the longitudinal axis; and
(c) a punctum plug having a plug portion disposed in the second opening of the at least one cap; and
(d) instructions for use of the at least one insertion instrument, cap and punctum plug.
34. The kit of claim 33, wherein the proximal end of the body includes a dilation member.
35. The kit of claim 33, wherein the actuation member comprises a generally cylindrical rod.

36. The kit of claim 33, wherein the actuation member includes an angled arm connected to actuator button via the at least one hinge.
37. The kit of claim 36, wherein the at least one hinge comprises a living hinge.
38. The kit of claim 33, wherein the at least one hinge comprises two living hinges.
39. The kit of claim 33, wherein the actuation member comprises a cantilevered member connected to the dilation member.
40. The kit of claim 33, wherein at least a portion of the cap comprises a tapered outer cap surface that surrounds the longitudinal axis to define a generally conical outer surface.
41. The kit of claim 40, wherein cap comprises an inner surface spaced apart from the outer cap surface, the inner surface surrounds the longitudinal axis to define a generally hollow cone.
42. The kit of claim 41, wherein the inner surface of the cap comprises a raised portion proximate the first end of the cap that extends towards the longitudinal axis.
43. The kit of claim 33, wherein the second cap end comprises at least two finger-like retainers separated by the slits.
44. The kit of claim 42, wherein the body includes a cap support portion having a

truncated generally conical outer surface to support the inner surface of the cap.

45. The kit of claim 44, wherein the cap support portion of the instrument comprises a recessed surface complementary to the raised portion of the cap so that the cap is generally retained to the cap support portion.

46. The kit of claim 33, wherein the body includes a cap support portion having an opening proximate the longitudinal axis that extends through the cap support to allow the actuation member to reciprocate along the longitudinal axis.

47. The kit of claim 33, wherein the actuation member comprises a rod having an outer diameter greater than an inside diameter of the second opening of the cap.

48. The kit of claim 33, wherein the instructions for use comprises information in a human-readable medium.

49. A method of using a punctal insertion system, in which the system includes an insertion instrument with a body extending along a longitudinal axis from a proximal end to a distal end, an actuator disposed proximate the distal end, the actuator including an actuation member disposed to move along the longitudinal axis and connected to the actuator with at least one hinge and a release button proximate the hinge, a cap disposed proximate the distal end of the body, the cap extending from a first cap end to a second cap end along the longitudinal axis, the first cap end defining a first opening about the longitudinal axis and the second cap end defining a second opening about the longitudinal axis, the second cap end further defining at least one slit that extends along the longitudinal axis, and a punctum plug having a portion disposed inside the second

opening of the cap such that the plug is retained to the cap, the method including the steps of:

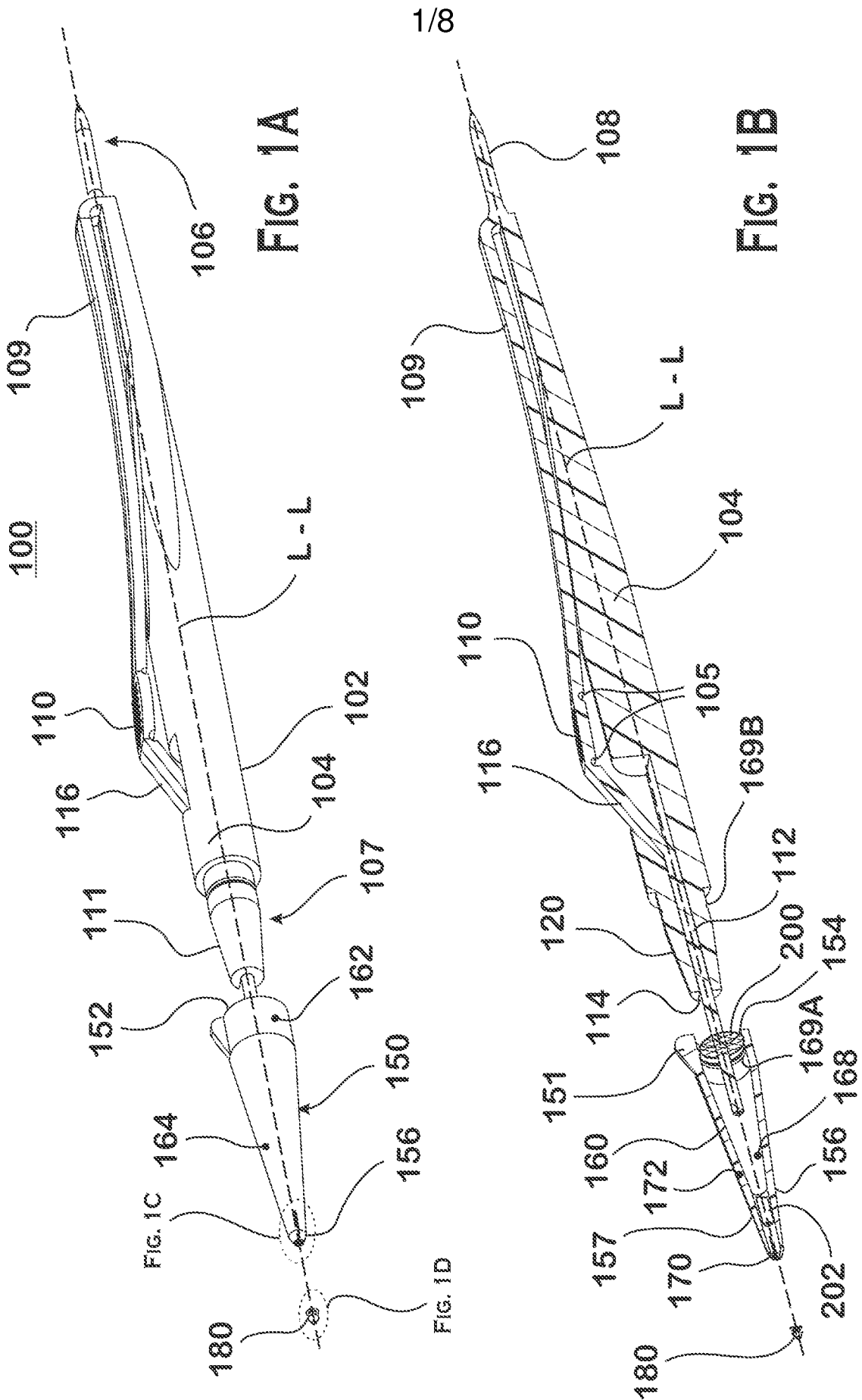
- holding the insertion instrument between a thumb and fingers with one finger just above the release button;

- gently depressing the release button until a soft-stop is felt;

- inserting the plug with a gentle, downward, rotational motion, until a portion of the plug is flush against a punctal opening;

- fully depressing and holding the release button on the applicator; and

- removing the applicator while holding the button down.



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FIG. 1C

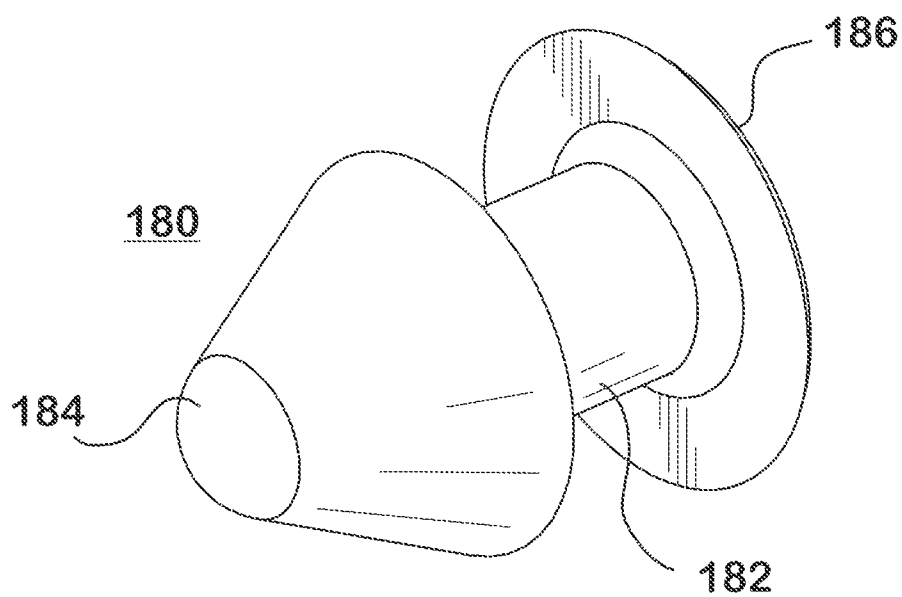
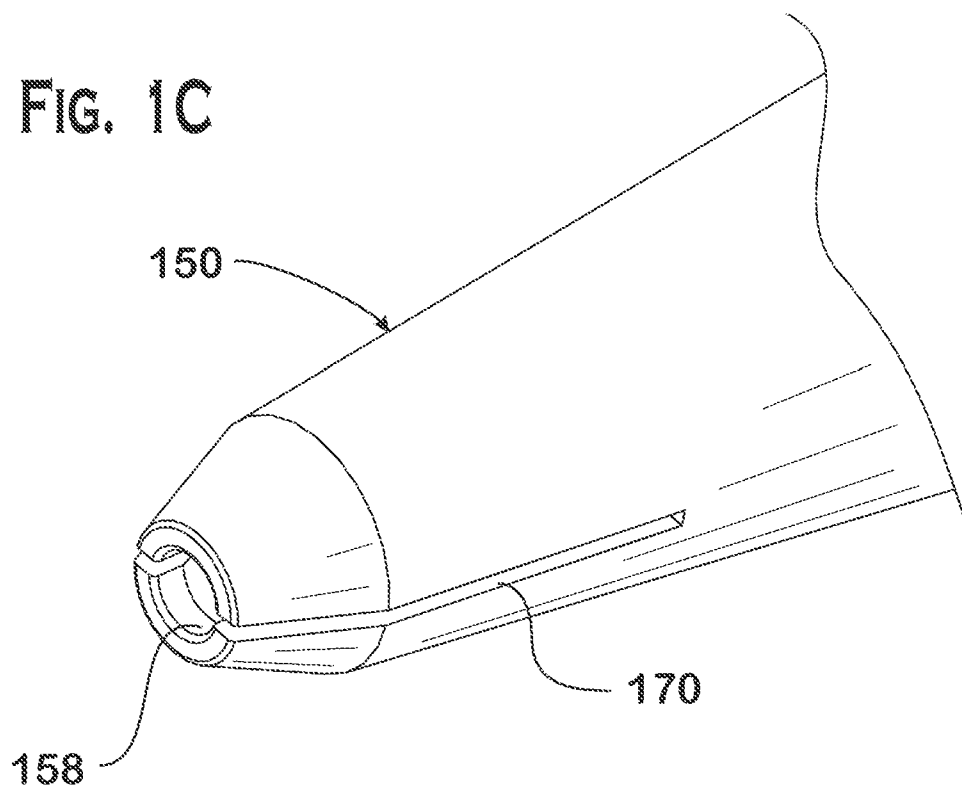
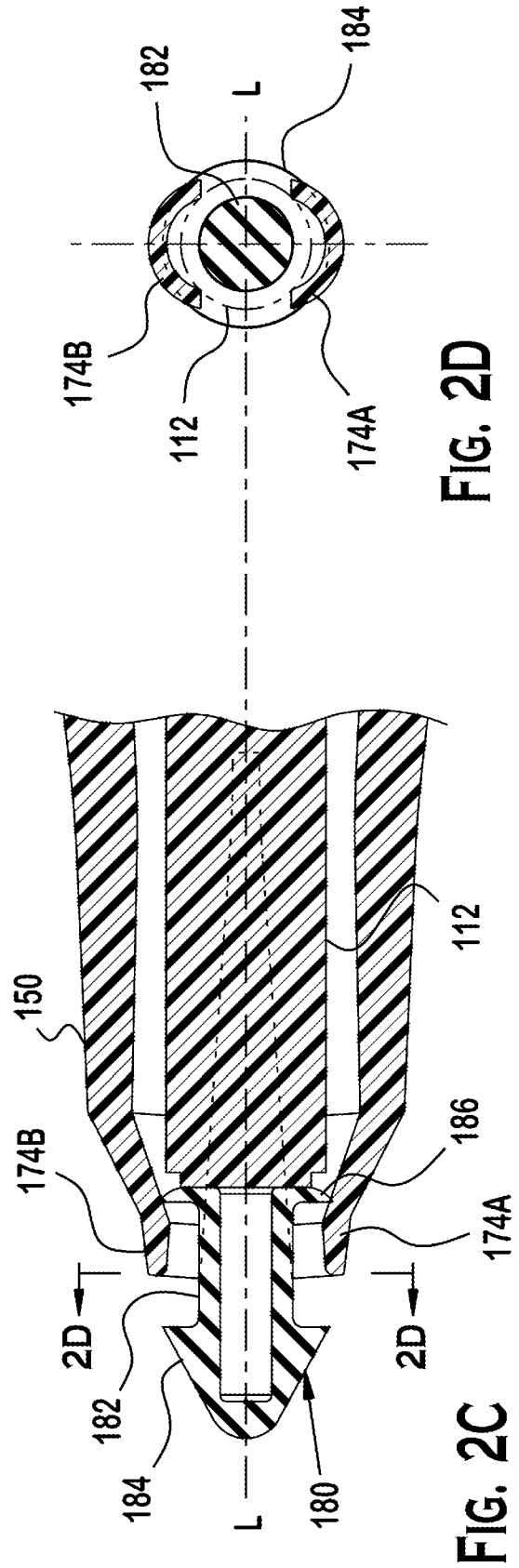
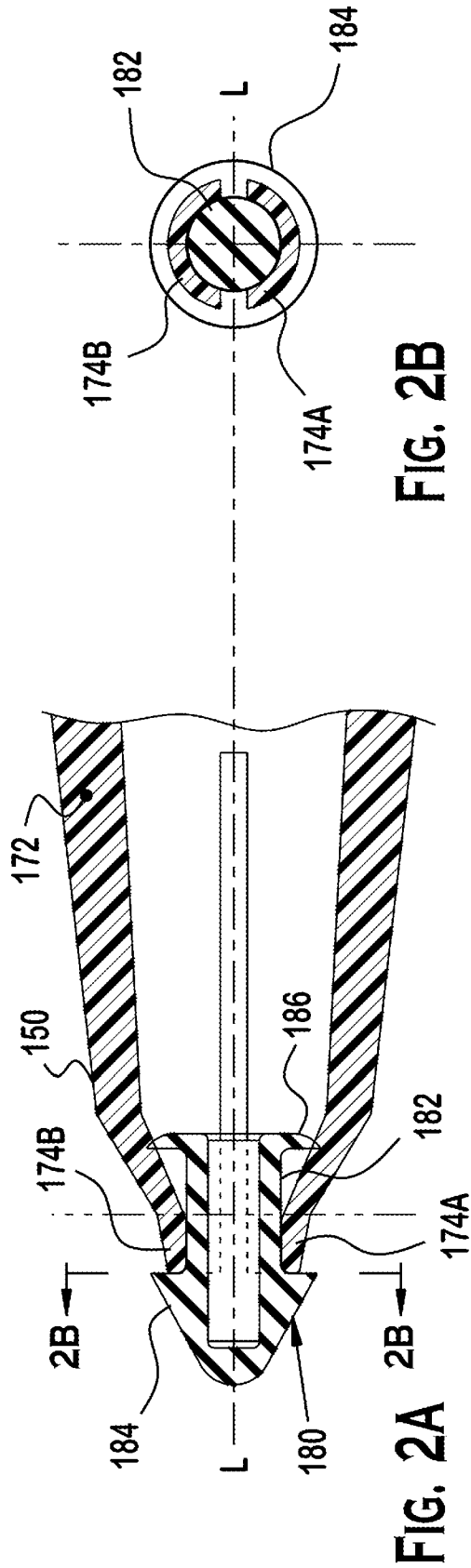


FIG. 1D



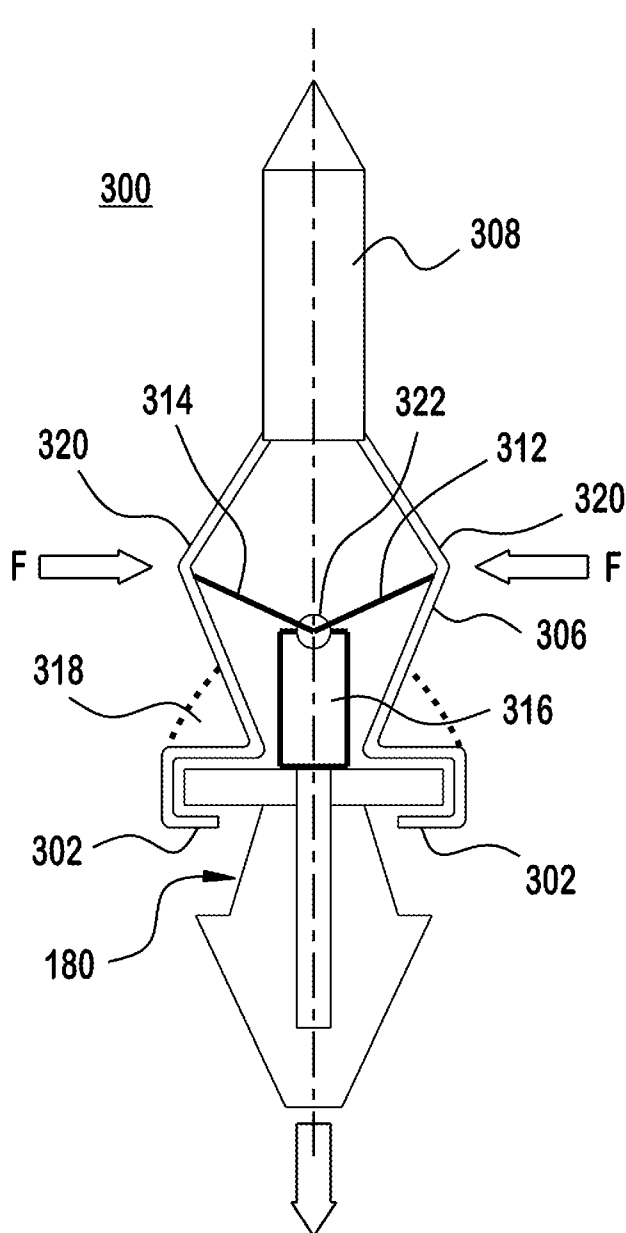


FIG. 3A

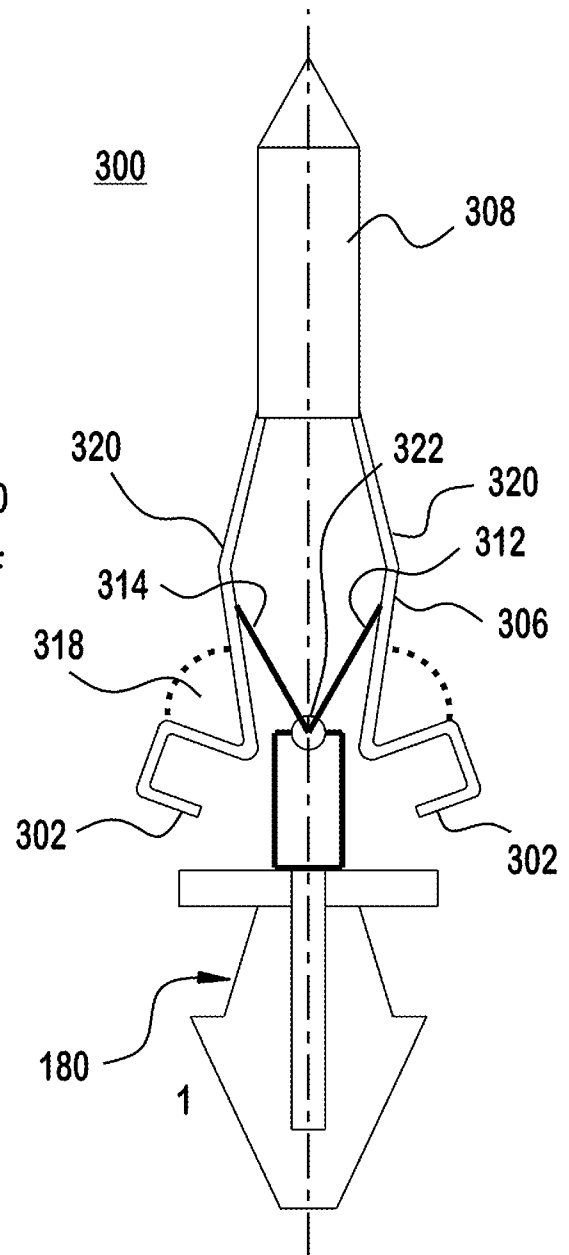
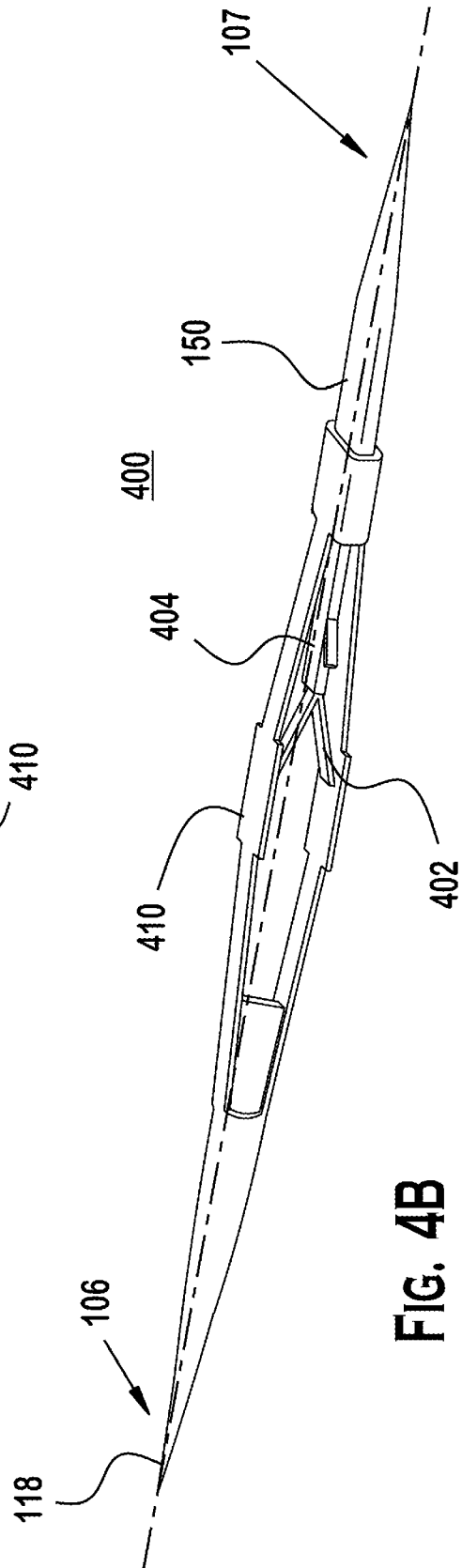
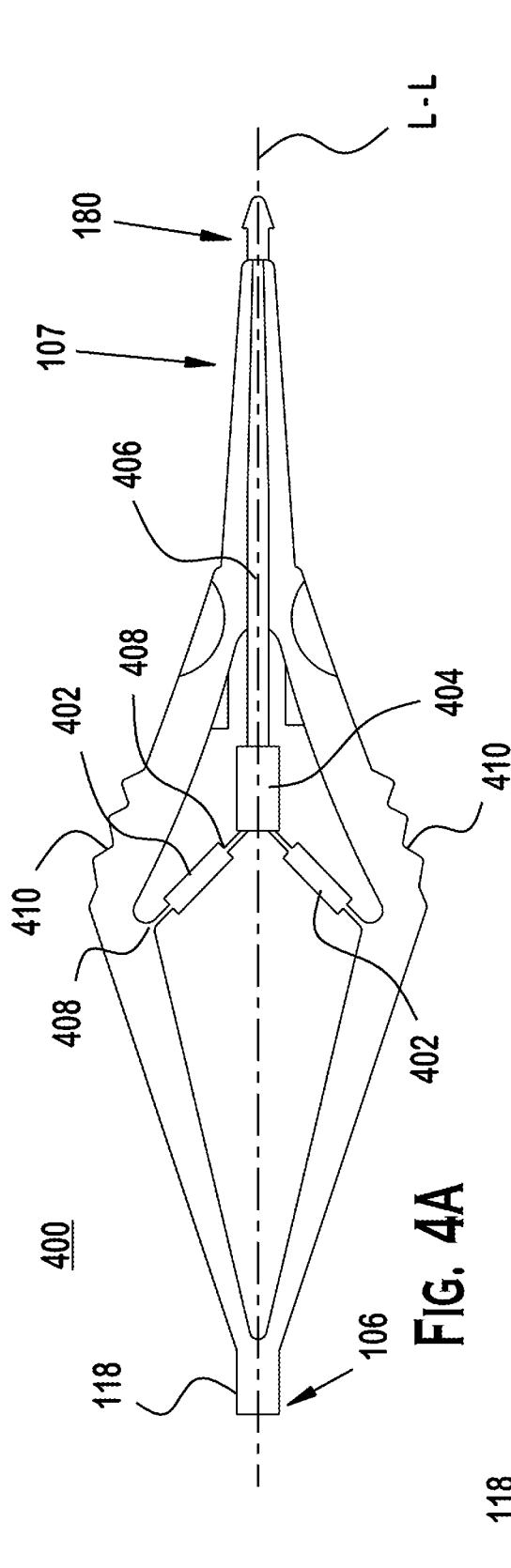


FIG. 3B

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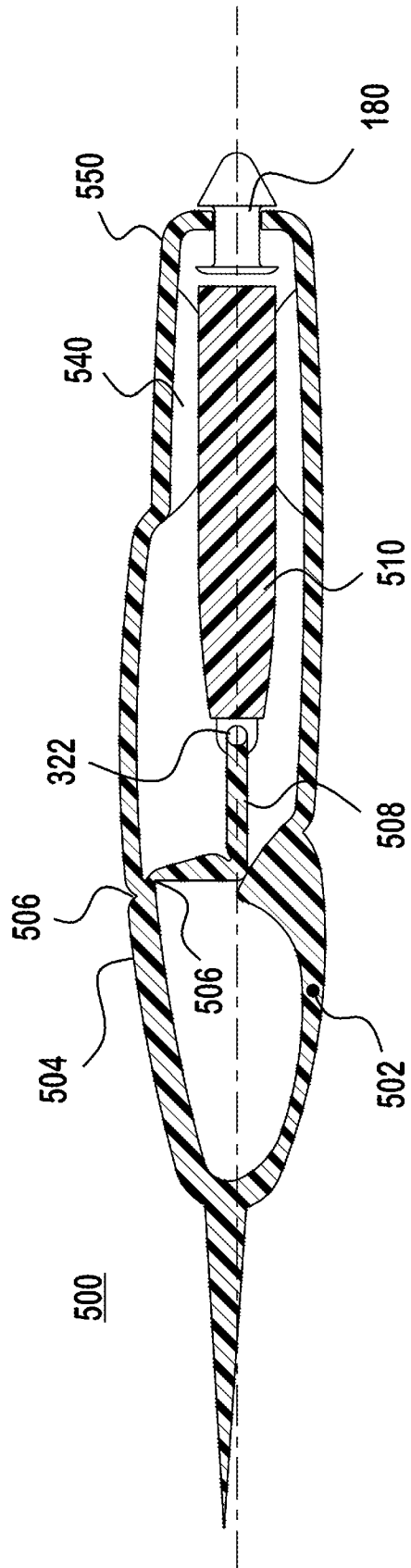


FIG. 5A

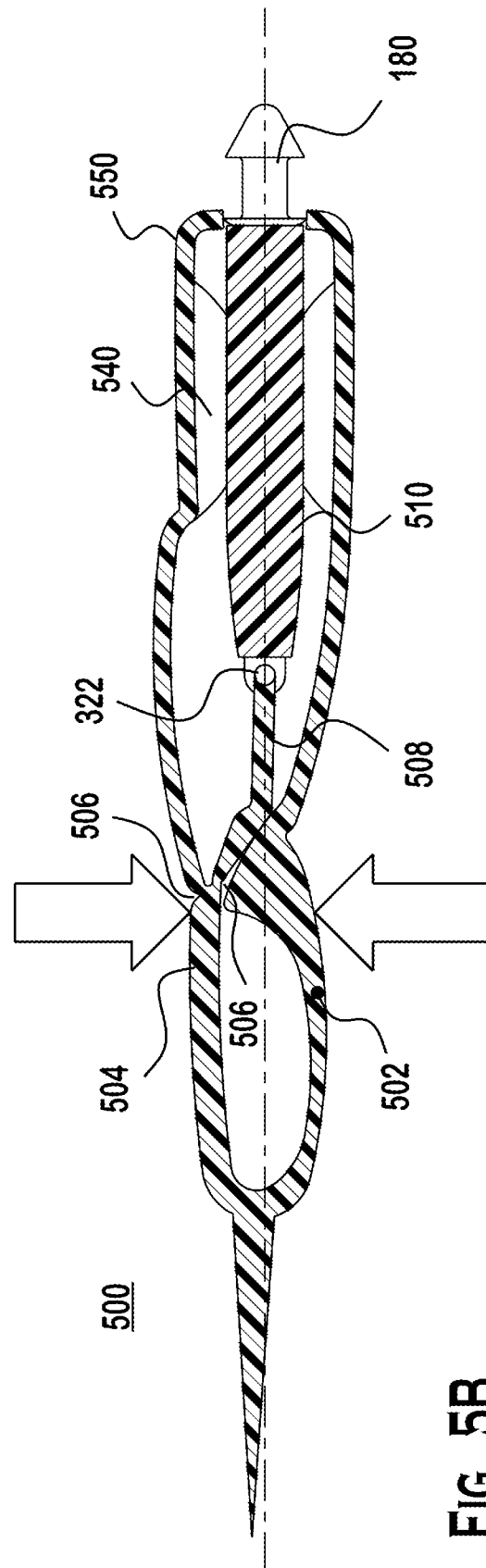
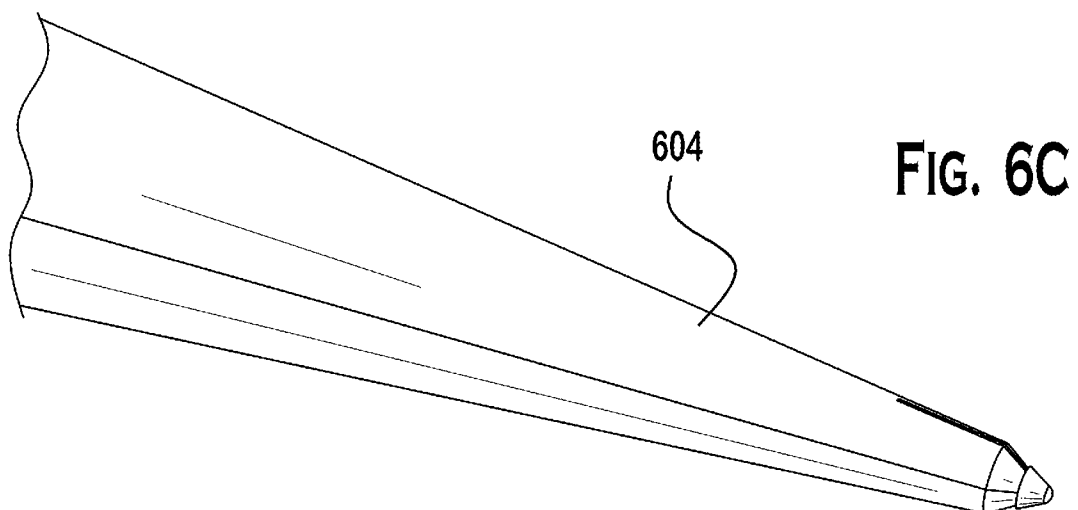
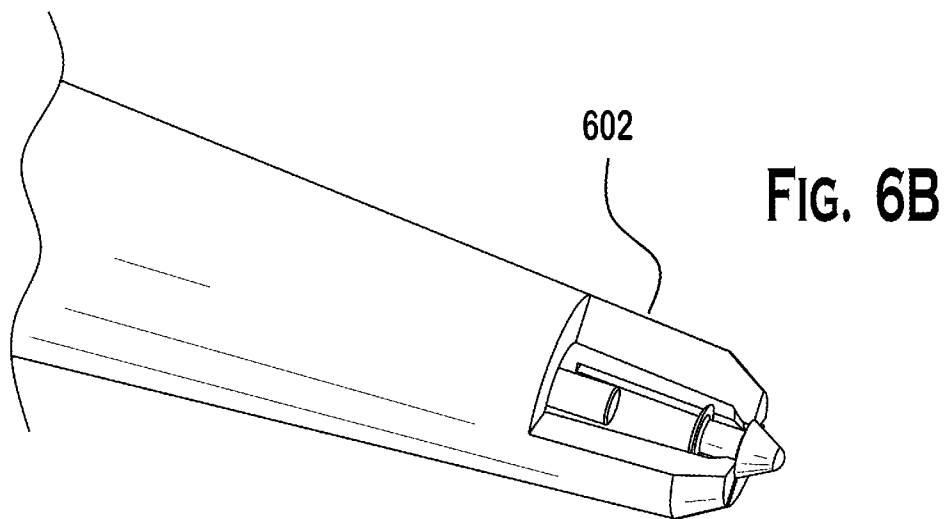
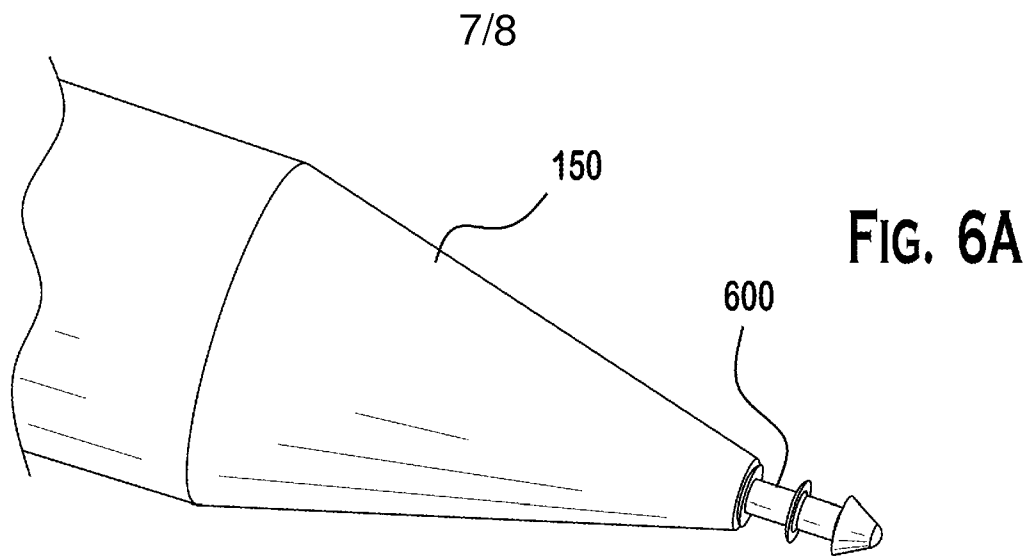


FIG. 5B



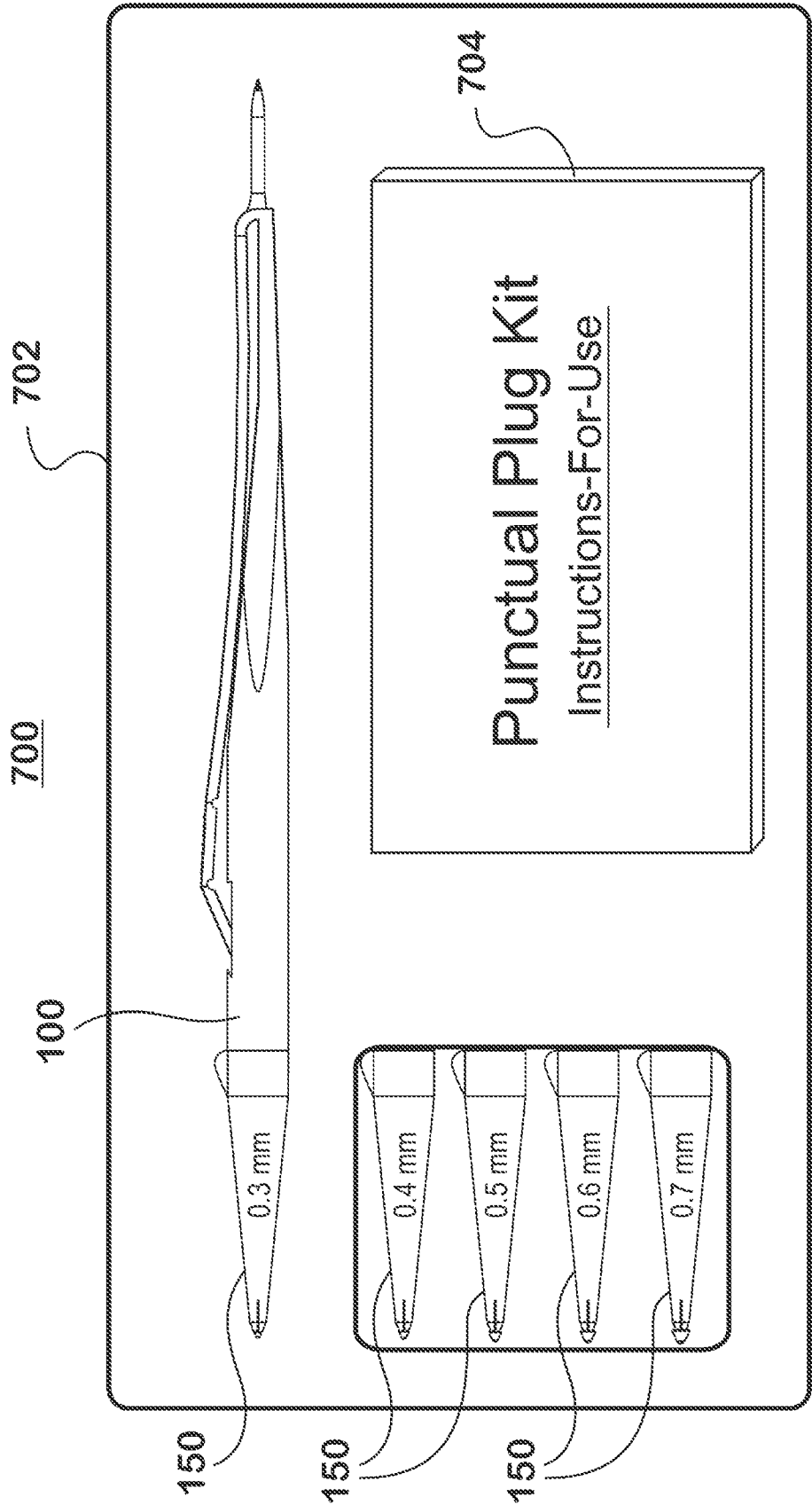


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/032884

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F9/007 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) A61F		
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.
E	US 2011/196317 A1 (LUST VICTOR [US] ET AL) 11 August 2011 (2011-08-11) the whole document -----	1-26, 33-48
X	US 2005/154399 A1 (WEBER DAVID A [US] ET AL) 14 July 2005 (2005-07-14) paragraph [0049] - paragraph [0059] paragraph [0091]; figures 1-9 -----	1-4,6,7
Y	paragraph [0049] - paragraph [0059] paragraph [0091]; figures 1-9 -----	16-21, 23-26
X	WO 2004/034518 A2 (EAGLE VISION INC [US]) 22 April 2004 (2004-04-22) page 6, line 22 - page 7, line 22 page 9, line 26 - page 10, line 4; figures 1-3,9-11 -----	1-4,6,7
Y	page 6, line 22 - page 7, line 22 page 9, line 26 - page 10, line 4; figures 1-3,9-11 -----	16-21, 23-26
----- -/--		
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 30 April 2012		Date of mailing of the international search report 09/05/2012
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Lega, A

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/032884

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 741 292 A (MENDIUS RICHARD [US]) 21 April 1998 (1998-04-21) cited in the application	1-4,6,7
Y	column 3, line 24 - page 4, line 32; figures 1-11	16-21, 23-26

X	US 2010/057024 A1 (BERNARD PASCAL [FR]) 4 March 2010 (2010-03-04)	8-10,12, 15
Y	the whole document	11,13, 14, 16-21, 23-26

X	US 2010/255061 A1 (DE JUAN JR EUGENE [US] ET AL) 7 October 2010 (2010-10-07) paragraph [0578]; figure 7G	33-48

Y	US 2007/027452 A1 (VARNER SIGNE E [US] ET AL) 1 February 2007 (2007-02-01)	11,14,25
A	paragraph [0071] paragraph [0080] - paragraph [0083] paragraph [0104]; figures 4,9a-9e	9,10,15

Y	US 2009/036842 A1 (PINEDJIAN RAFFI [US]) 5 February 2009 (2009-02-05) paragraph [0024] paragraph [0033]	11,13, 14,25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/032884

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.: 27-32, 49
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
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.:
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:

see additional sheet

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 an 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7

An insertion instrument comprising: a body extending along a longitudinal axis from a proximal end to a distal end;
an actuation member disposed to move along the longitudinal axis through a portion of the body near the distal end, the actuation member including an arm disposed at an angle relative to the longitudinal axis;
and an actuator connected to the actuation member with at least one hinge, the actuator being connected to the arm via the at least one hinge.

2. claims: 8-15

A cap for a punctal insertion instrument, the cap comprising: an elongated body extending along a longitudinal axis from a proximal end to a distal end, the proximal end defining a proximal opening larger than a distal opening defined by the distal end, the distal opening including at least two slits that extend through a wall of the cap proximate the distal end so that a punctum plug is able to pass through the distal opening upon expansion of the distal opening.

3. claims: 16-26

An insertion system comprising: an insertion instrument including:
a body extending along a longitudinal axis from a proximal end to a distal end;
an actuator disposed proximate the distal end, the actuator including an actuation member disposed to move along the longitudinal axis and connected to the actuator with at least one hinge;
a cap disposed proximate the distal end of the body, the cap extending from a first cap end to a second cap end along the longitudinal axis, the first cap end defining a first opening about the longitudinal axis and the second cap end defining a second opening about the longitudinal axis, the second cap end further defining at least one slit that extends along the longitudinal axis;
and a punctum plug having a portion disposed inside the second opening of the cap such that the plug is retained to the cap.

4. claims: 33-48

An ocular implant kit comprising: an enclosure to house a plurality of components.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

It should be noted, that with the wording "an enclosure to house a plurality of components" of claim 33, the components are not claimed. \$
Thus, this is the sole feature of claim 33. The same is valid for dependent claims 34-48

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 27-32, 49

Claims 27-32, 49 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT. Independent claim 49 comprises the step "inserting the plug ... until a portion of the plug is flush against a punctal opening" which clearly refers to a method for treatment of the human or animal body by surgery. Even if not explicitly directed to a method for treatment of the human or animal body by surgery, independent claim 27 refers to a method of releasing a punctum plug from a plug holder. The sole reasons for realising a punctum plug from a plug holder is to implant the plug into a patient. Therefore, claim 27 implicitly refers to a method for treatment of the human or animal body by surgery. The same is valid for claims 28-32 since they depend on claim 27.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2011/032884

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011196317	A1	11-08-2011	NONE
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US 2009036842	A1	05-02-2009	NONE