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**Andersen et al.** (43) **Pub. Date: Dec. 14, 2017**

(54) **PROTECTIVE CAP FOR AN INSERTION DEVICE AND OTHER INSERTION DEVICE FEATURES**

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(72) Inventors: **Steven R. Andersen**, Rancho Santa Margarita, CA (US); **David W. Gaylord**, Trabuco Canyon, CA (US); **David A. Ruddocks**, Mission Viejo, CA (US); **Mark S. Cole**, Trabuco Canyon, CA (US)

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(22) Filed: **Jun. 26, 2017**

**Related U.S. Application Data**

(62) Division of application No. 13/818,573, filed on Feb. 25, 2014, now Pat. No. 9,687,340, filed as application No. PCT/US2011/049029 on Aug. 24, 2011.

(60) Provisional application No. 61/500,564, filed on Jun. 23, 2011, provisional application No. 61/467,584, filed on Mar. 25, 2011, provisional application No. 61/376,661, filed on Aug. 24, 2010.

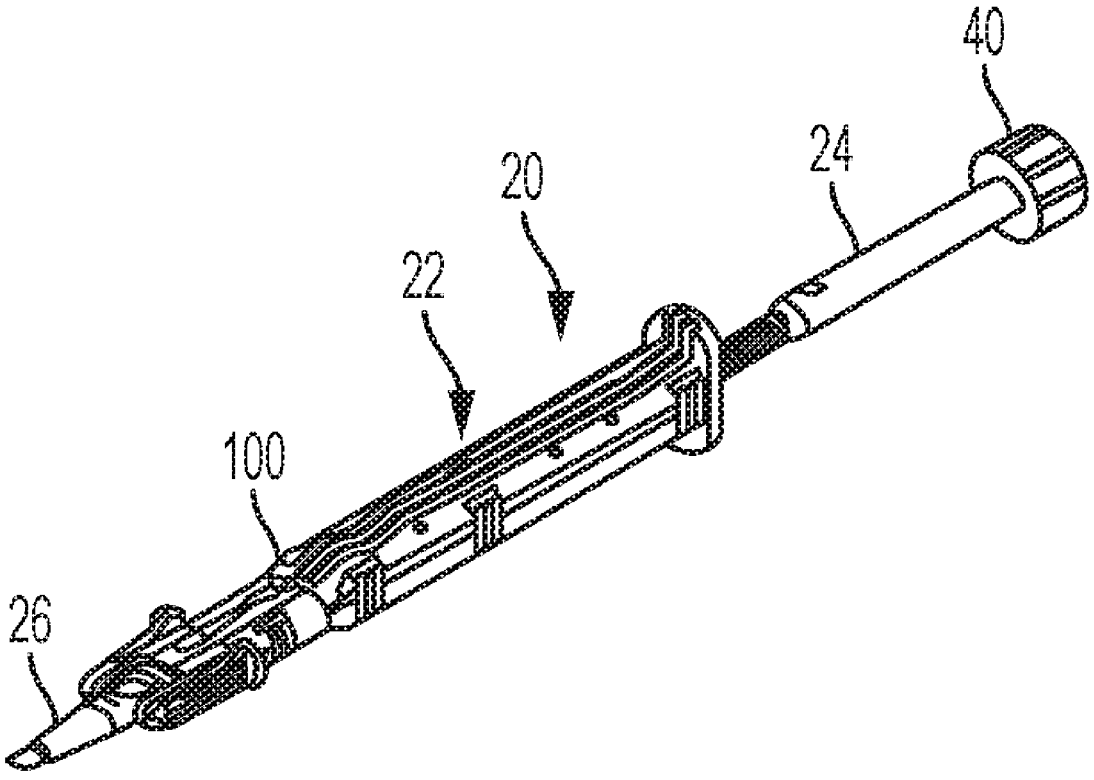
**Publication Classification**

(51) **Int. Cl.**
*A61F 2/16* (2006.01)

(52) **U.S. Cl.**
CPC ..... ***A61F 2/167*** (2013.01); ***A61F 2/1678*** (2013.01); ***A61F 2/1662*** (2013.01); ***A61F 2/1675*** (2013.01); ***A61F 2/1667*** (2013.01)

(57) **ABSTRACT**

A protective cap having finger grips, a window, and port. The protective cap may also have one or more clips (or snaps), one or more relief slots, and/or one or more guides. Protective cap 200 may also have a fill indicator and/or a material relief. An insertion system having a handpiece, a pushrod assembly, a cartridge, and a cap with a window and a port. The cap is configured and dimensioned to couple with the distal end of the cartridge. The insertion system may also have a pushrod with a plunger having a marker configured and dimensioned to indicate axially translation of the push-rod assembly within the handpiece.



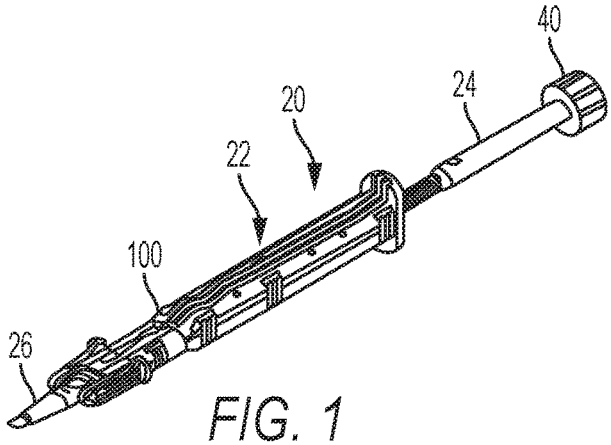



FIG. 1

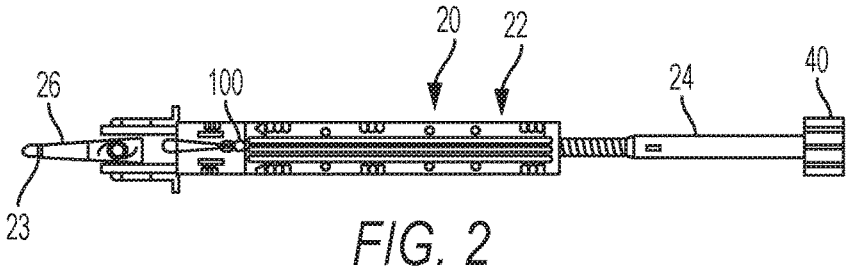



FIG. 2

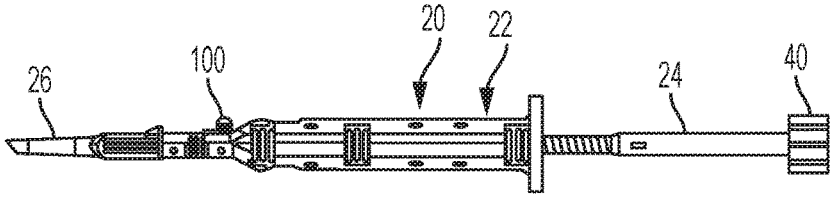



FIG. 3

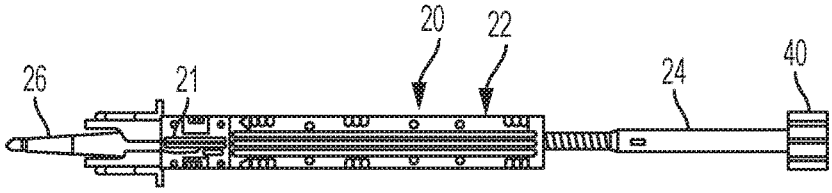



FIG. 4

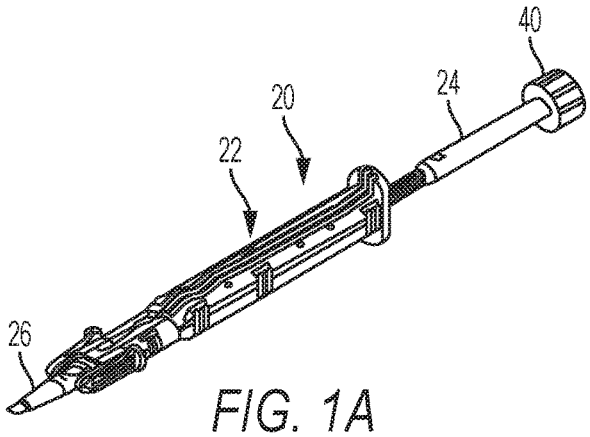



FIG. 1A

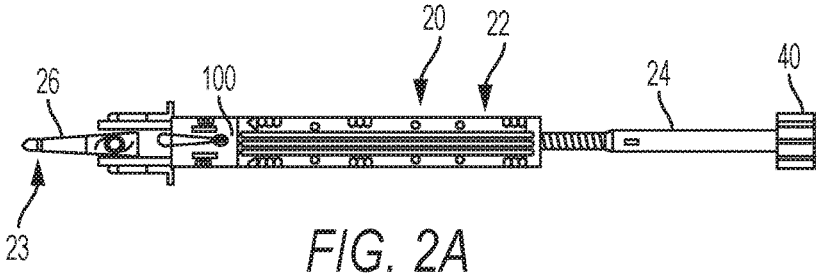



FIG. 2A

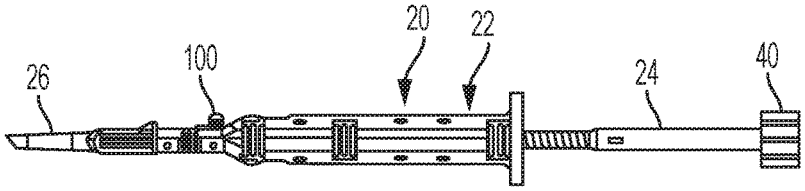



FIG. 3A

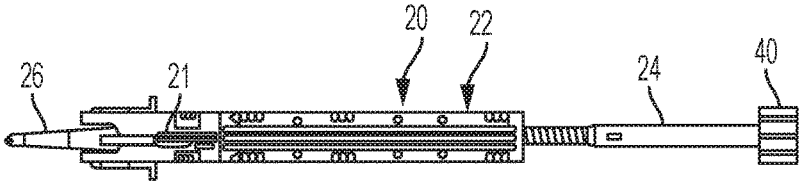



FIG. 4A

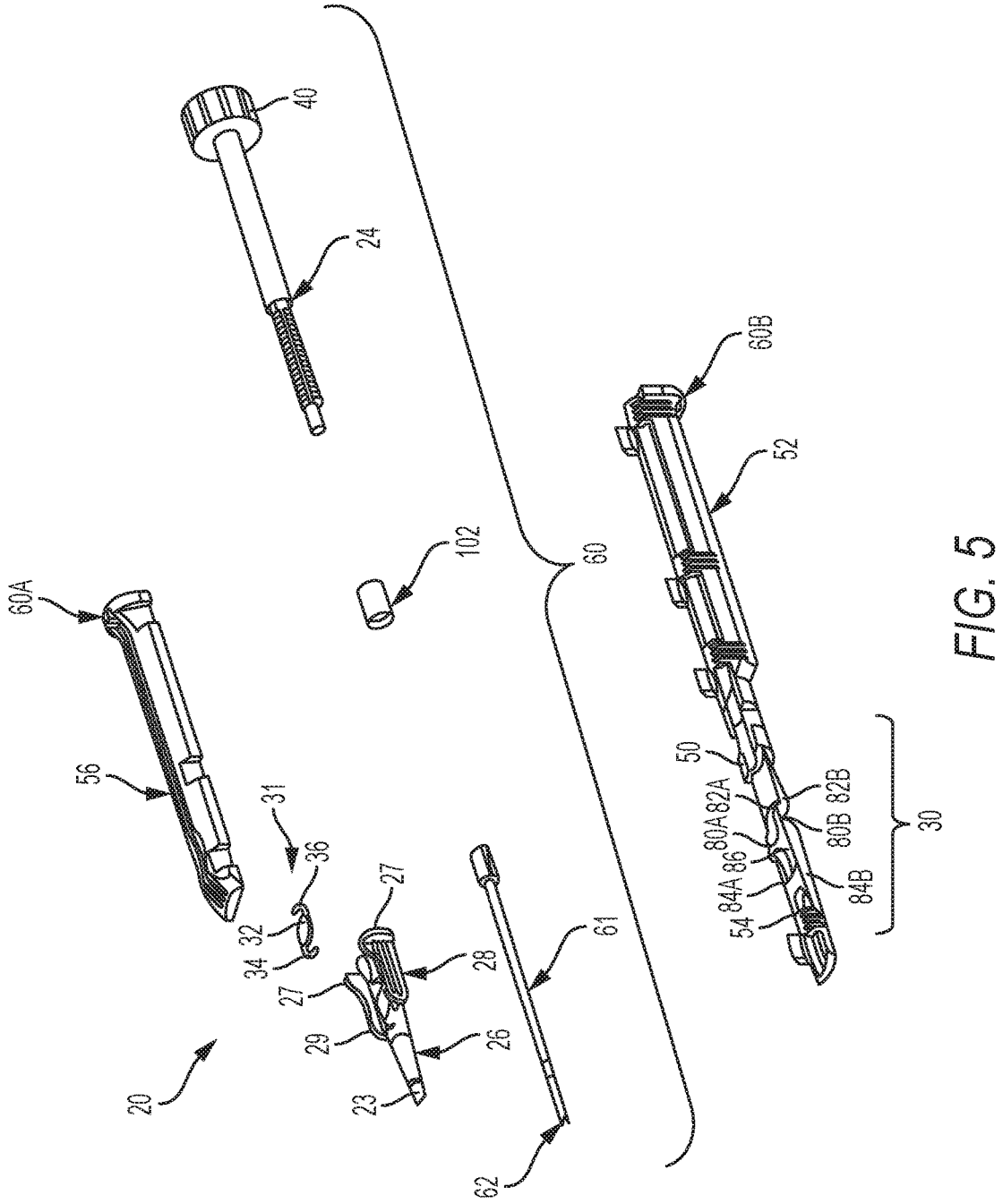

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FIG. 5

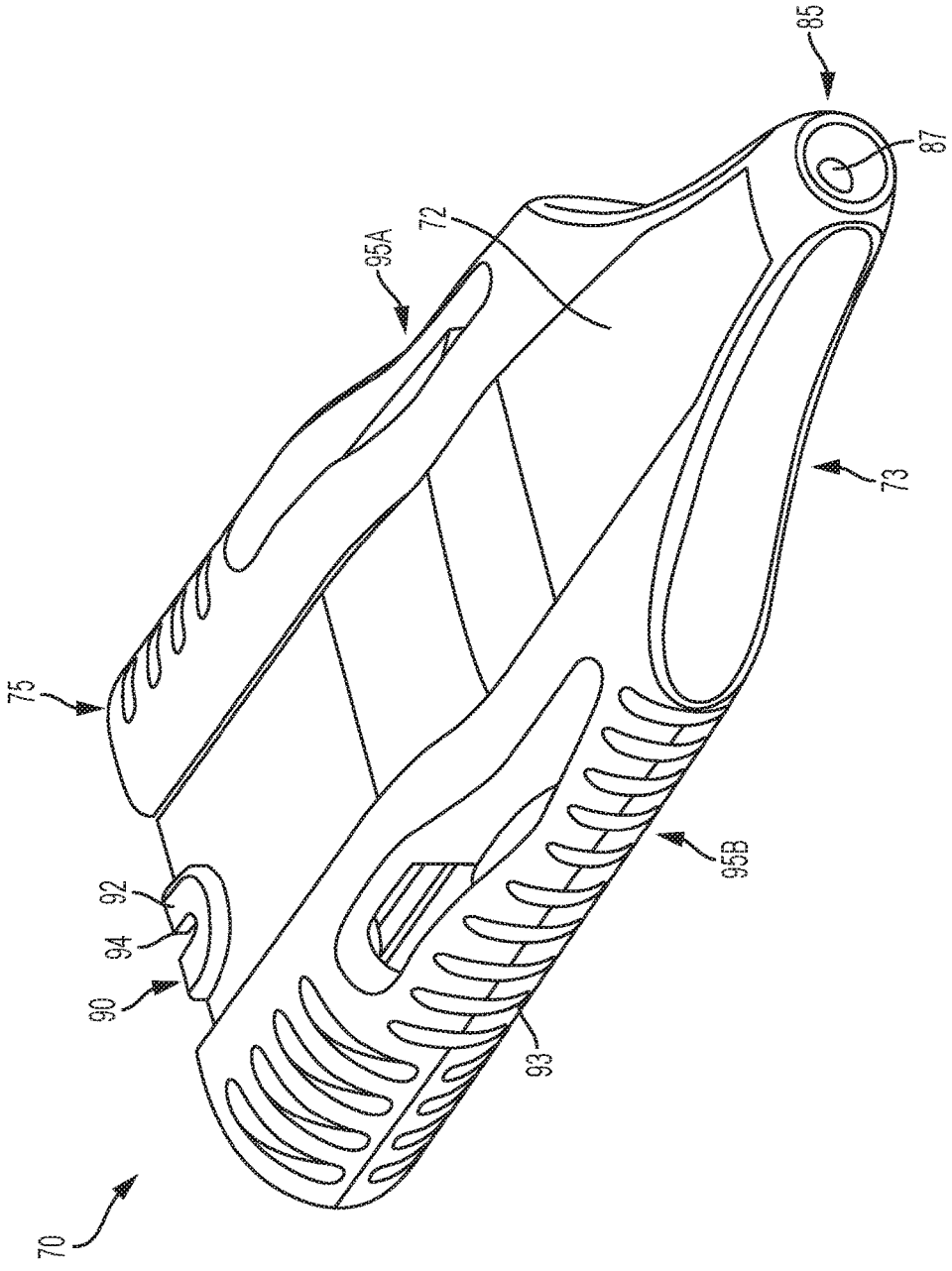



FIG. 6

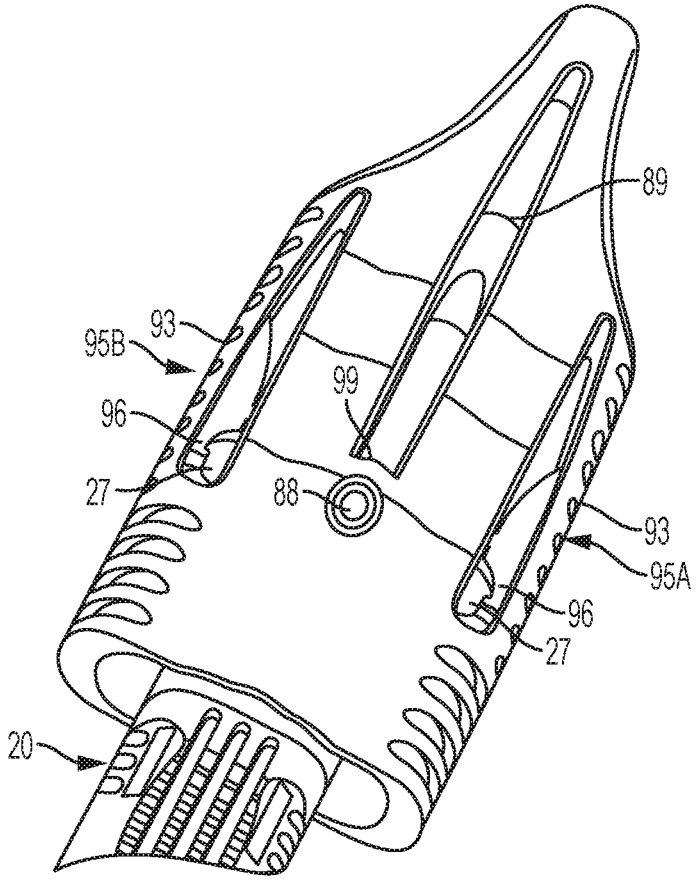



FIG. 7

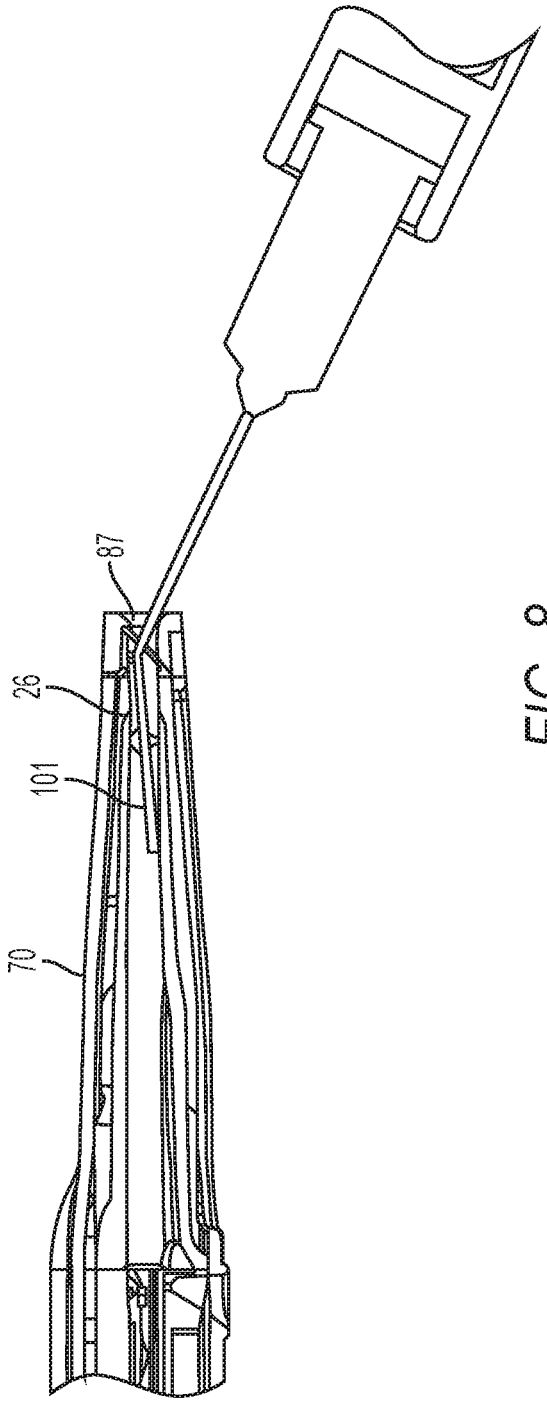



FIG. 8

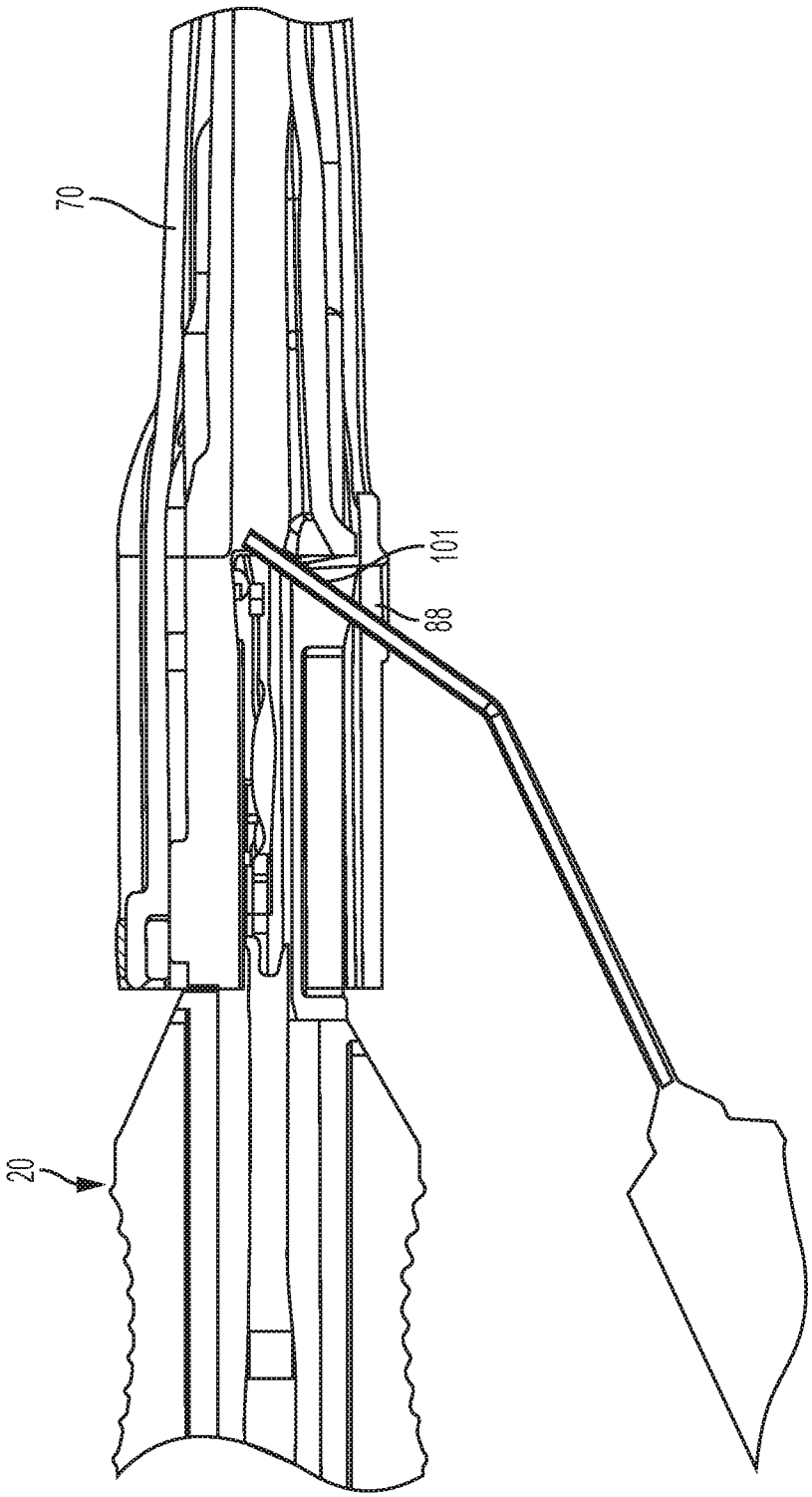



FIG. 9

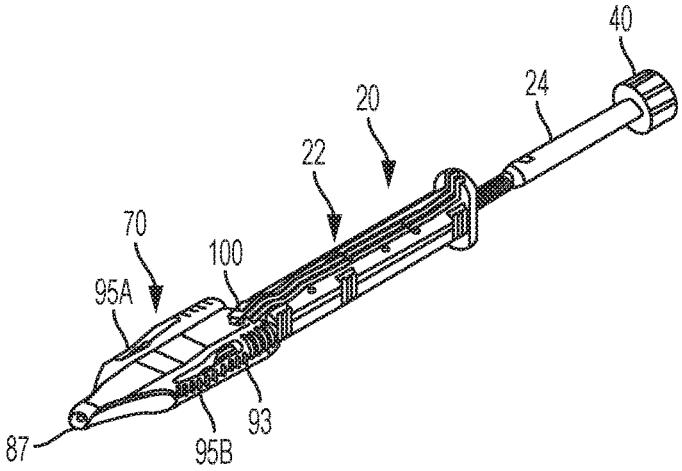



FIG. 10

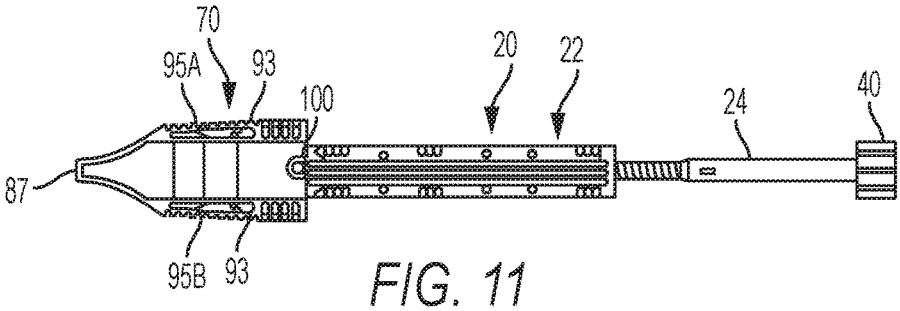



FIG. 11

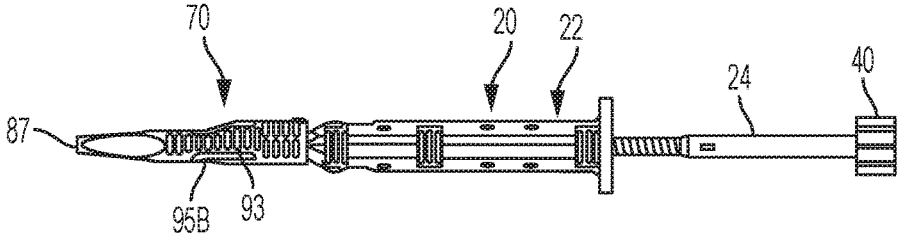



FIG. 12

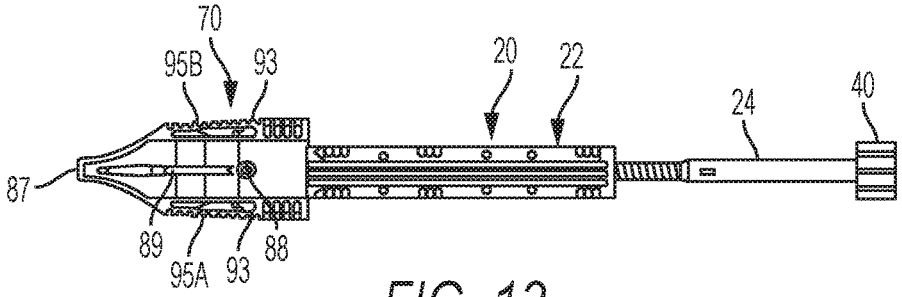



FIG. 13

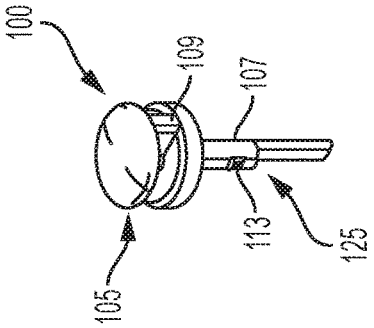



FIG. 14A

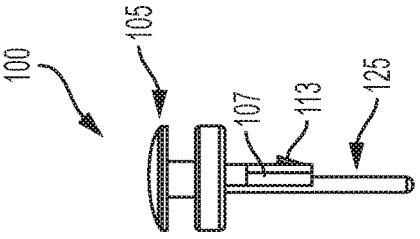



FIG. 14E

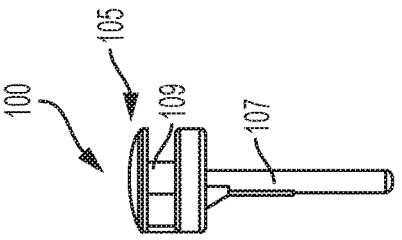



FIG. 14D

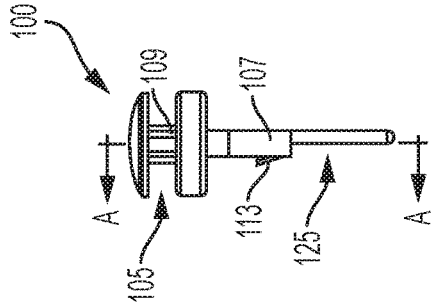



FIG. 14B

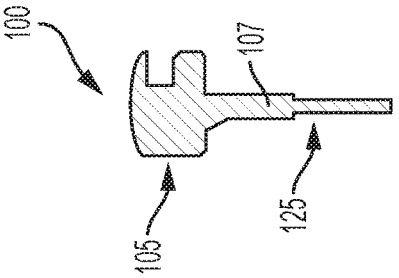



FIG. 14C

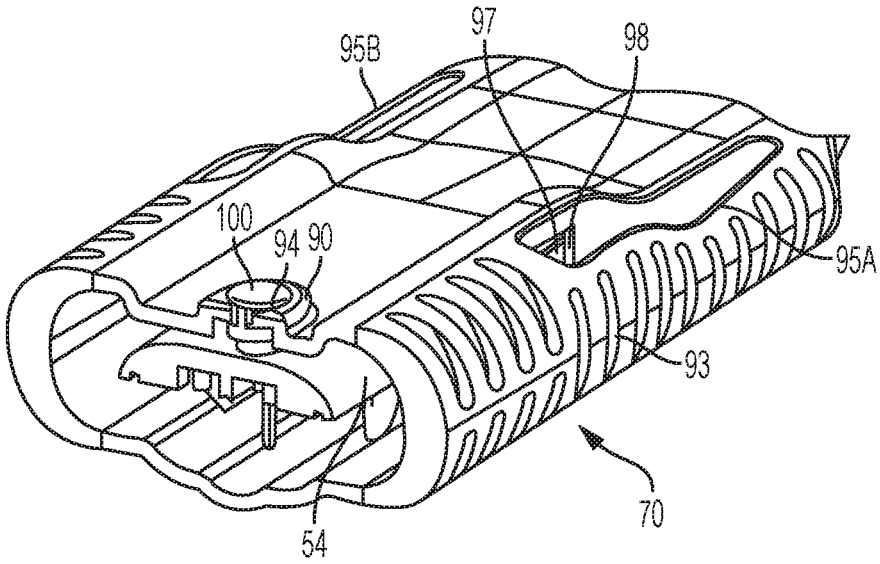



FIG. 15

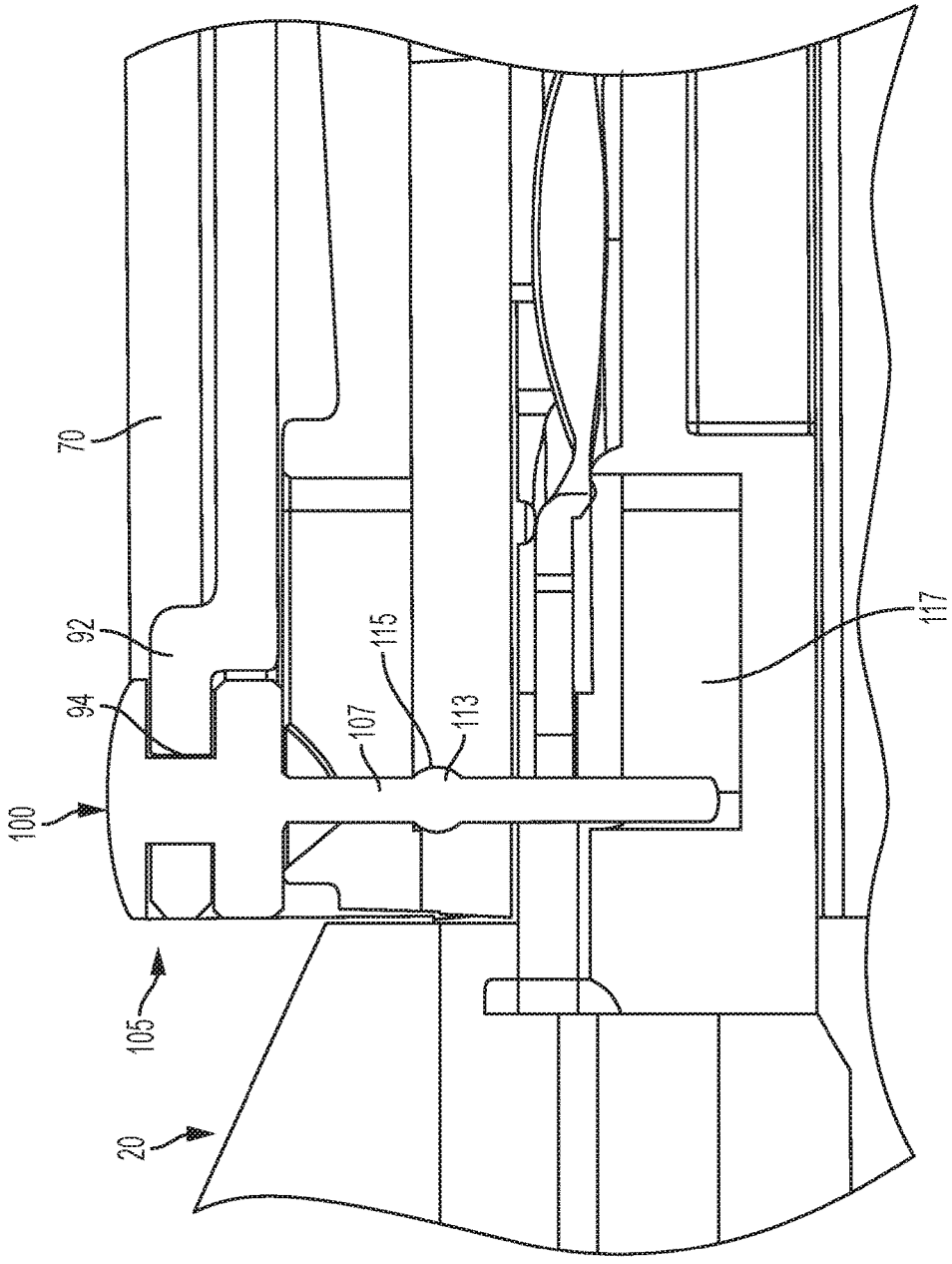



FIG. 15A

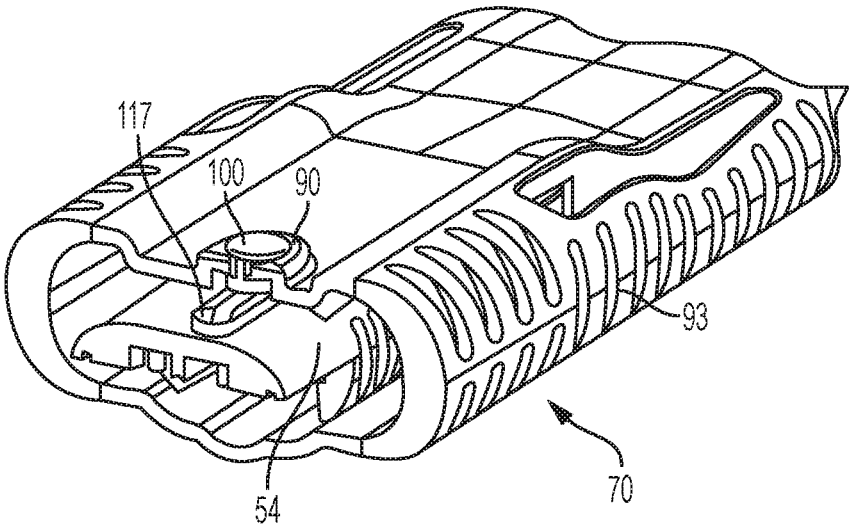



FIG. 16

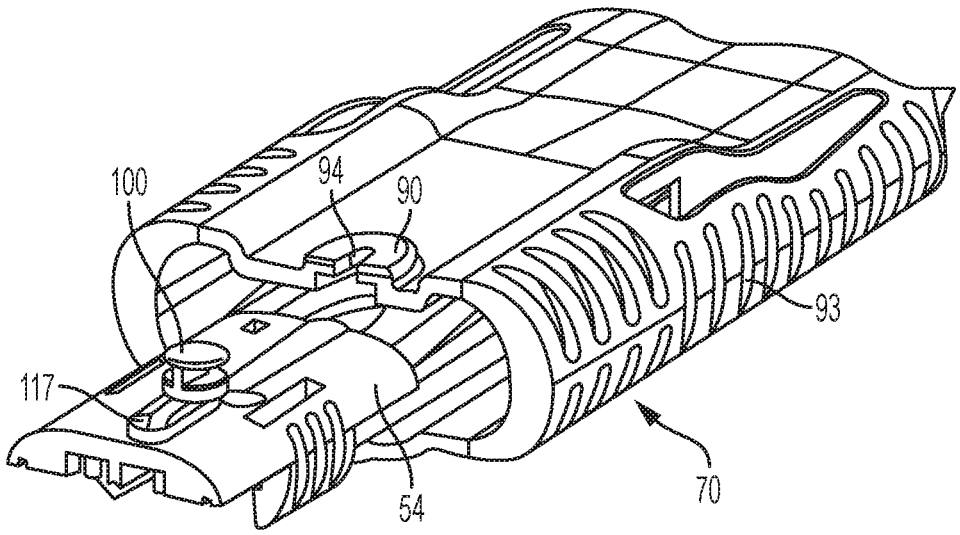



FIG. 17

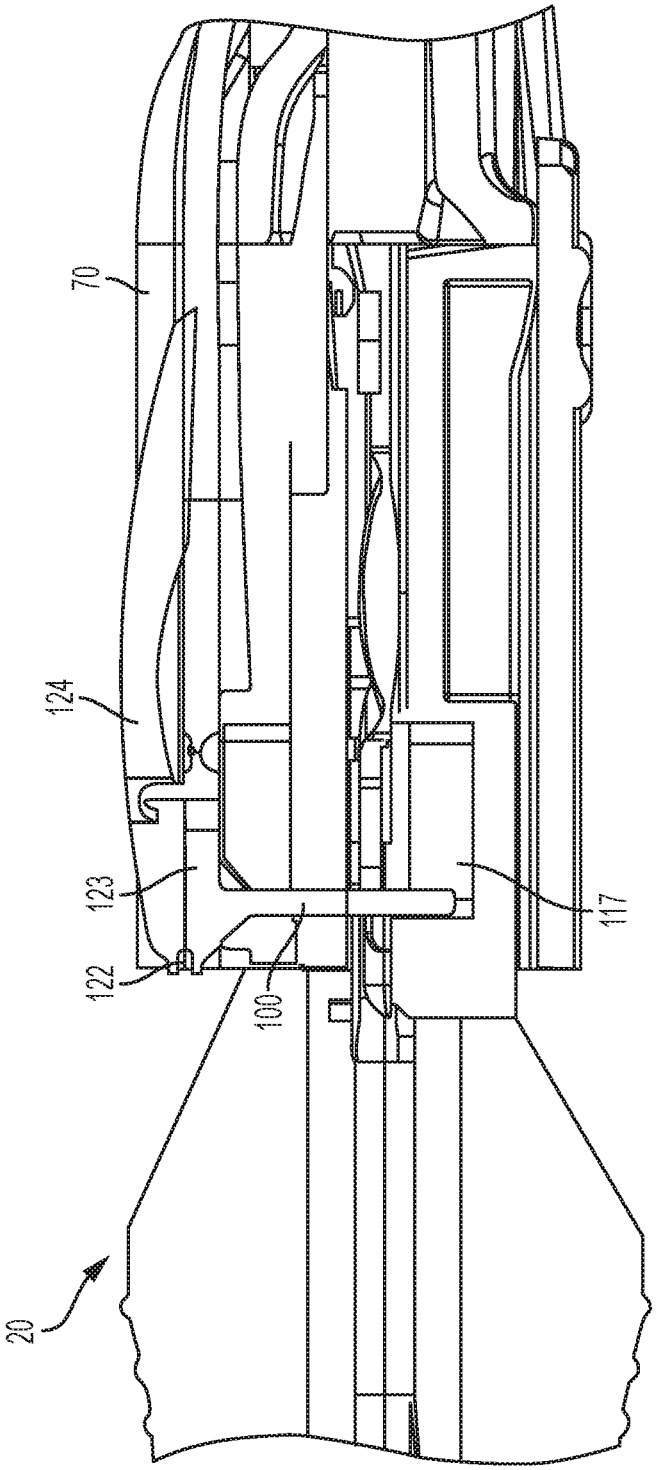



FIG. 18A

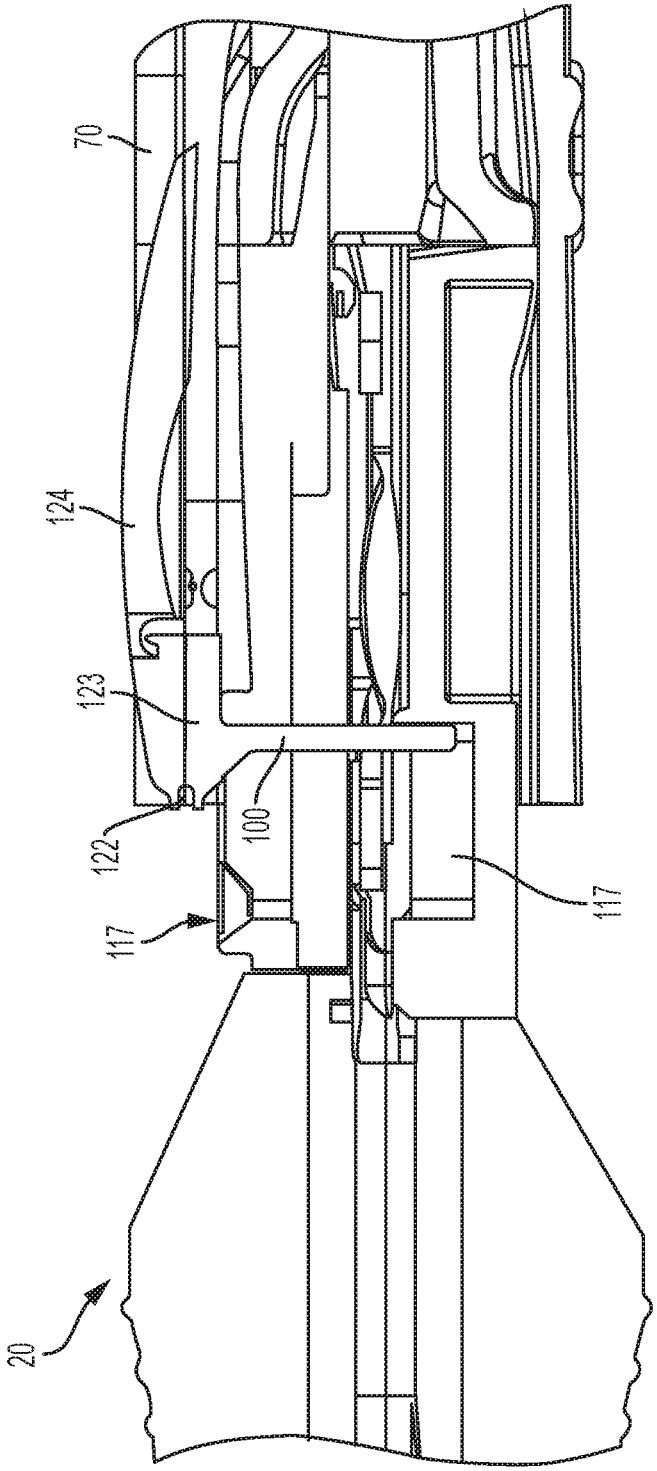



FIG. 18B

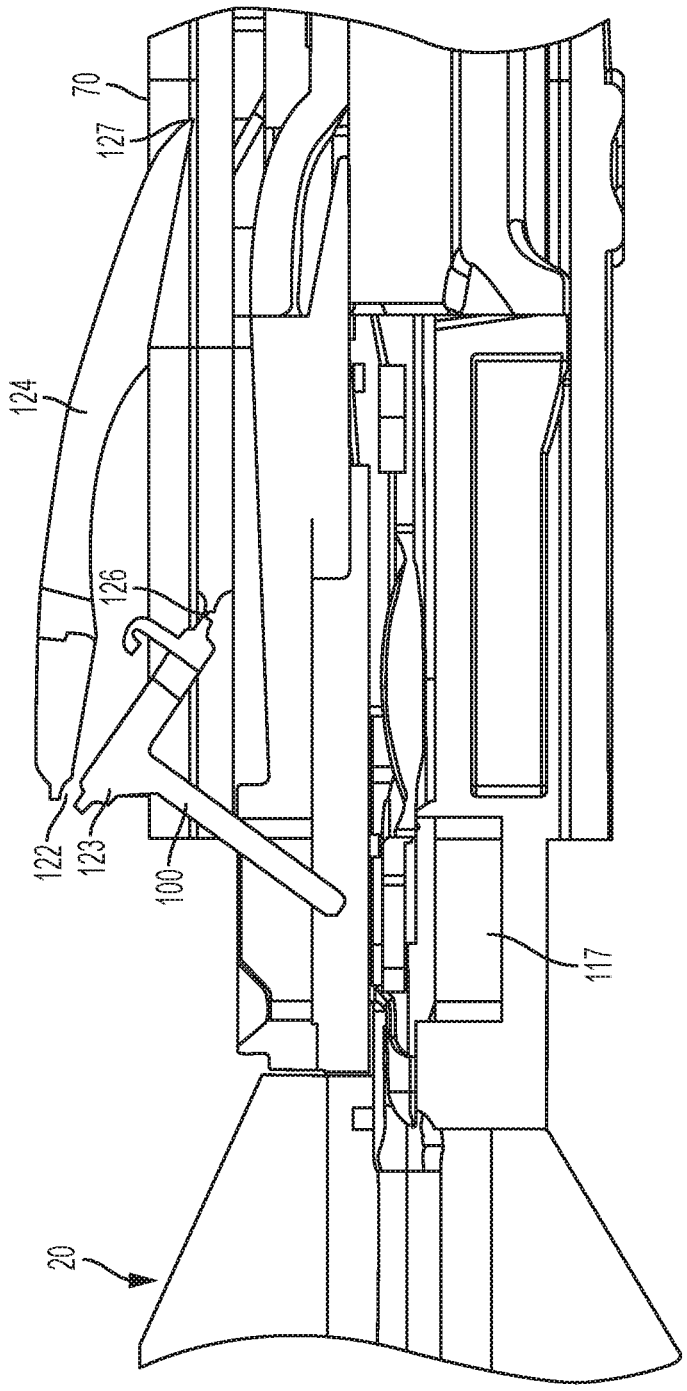



FIG. 18C

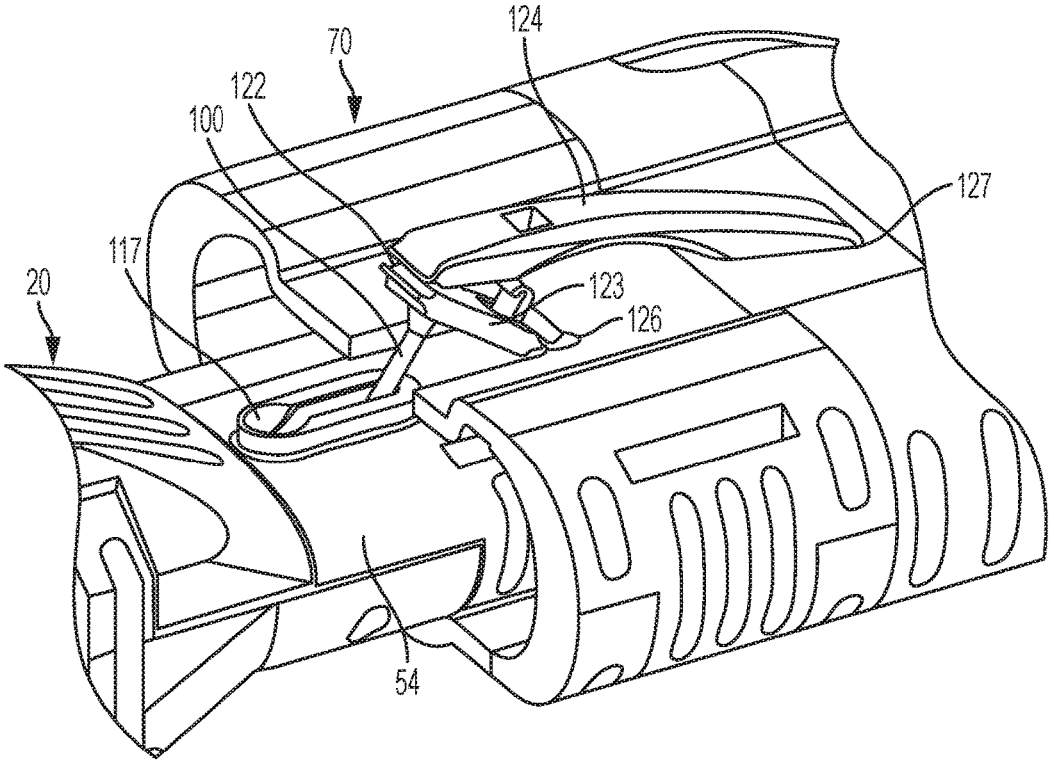



FIG. 18D

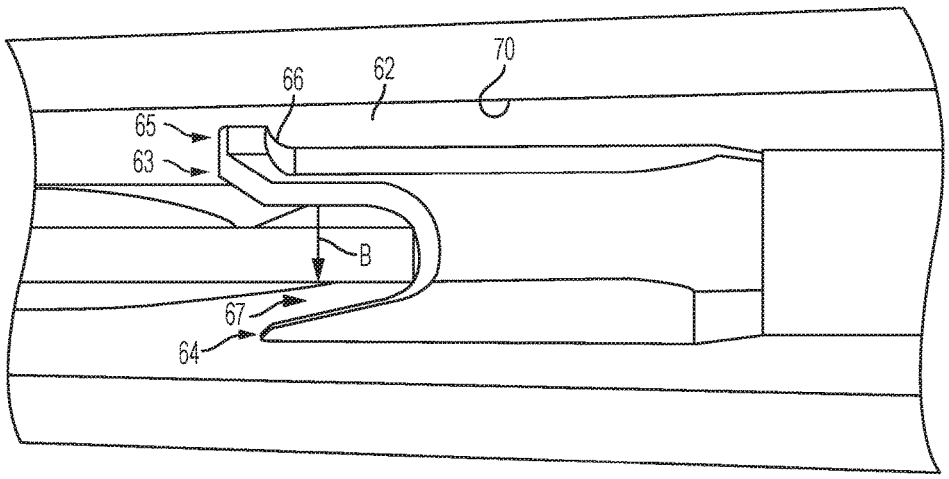



FIG. 19A

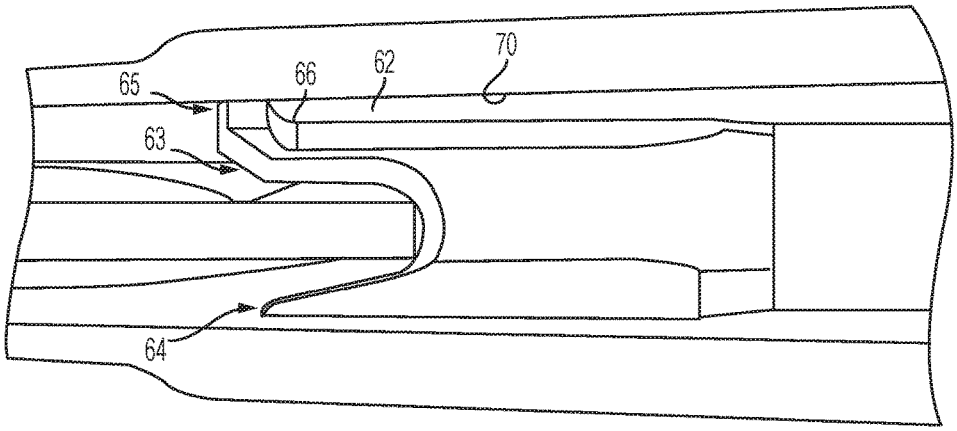



FIG. 19B

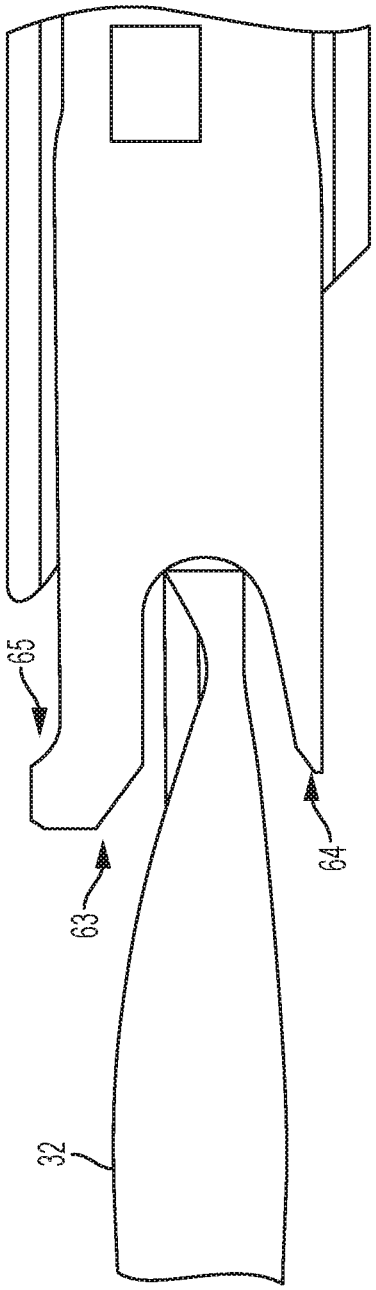



FIG. 19C

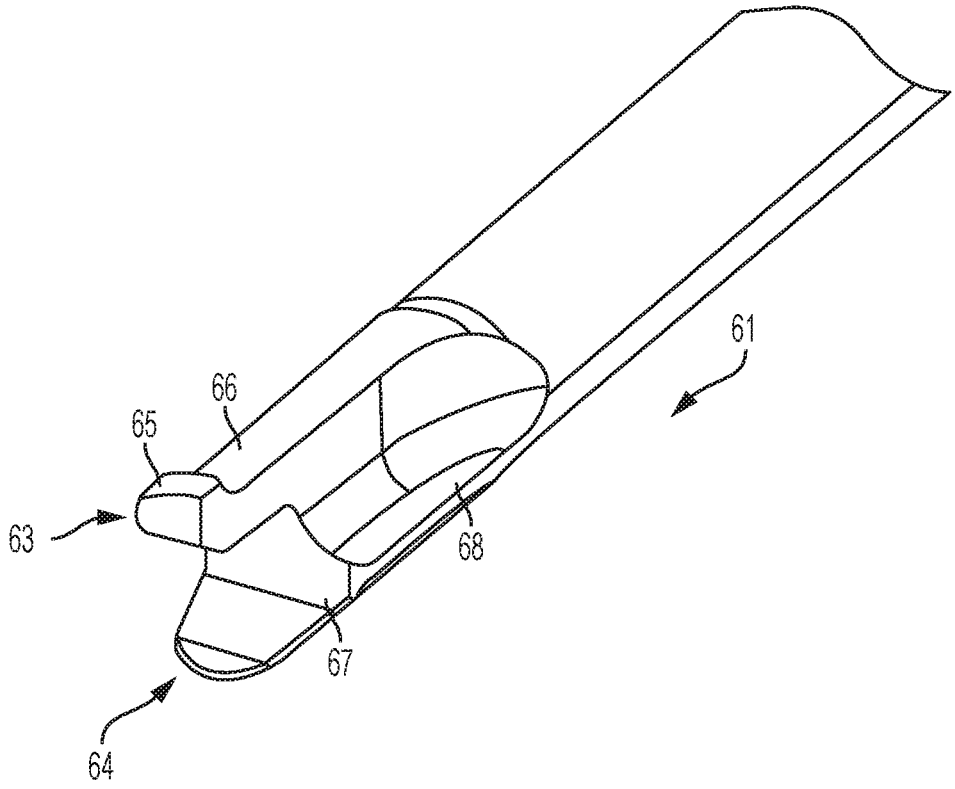



FIG. 19D

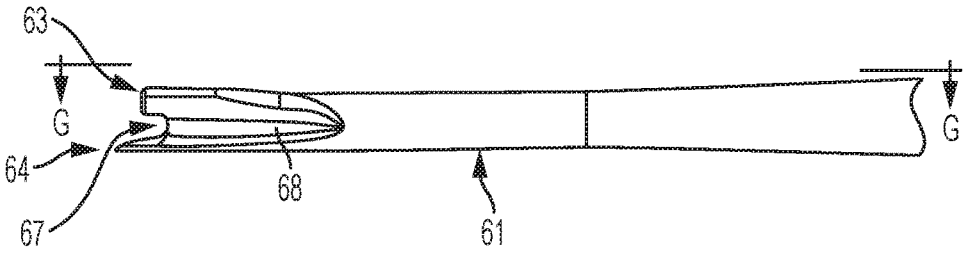
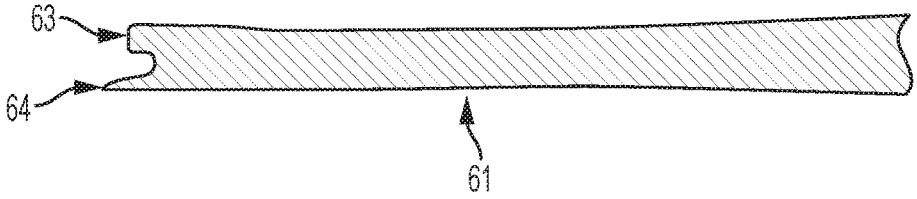



FIG. 19E




SECTION G-G

*FIG. 19F*

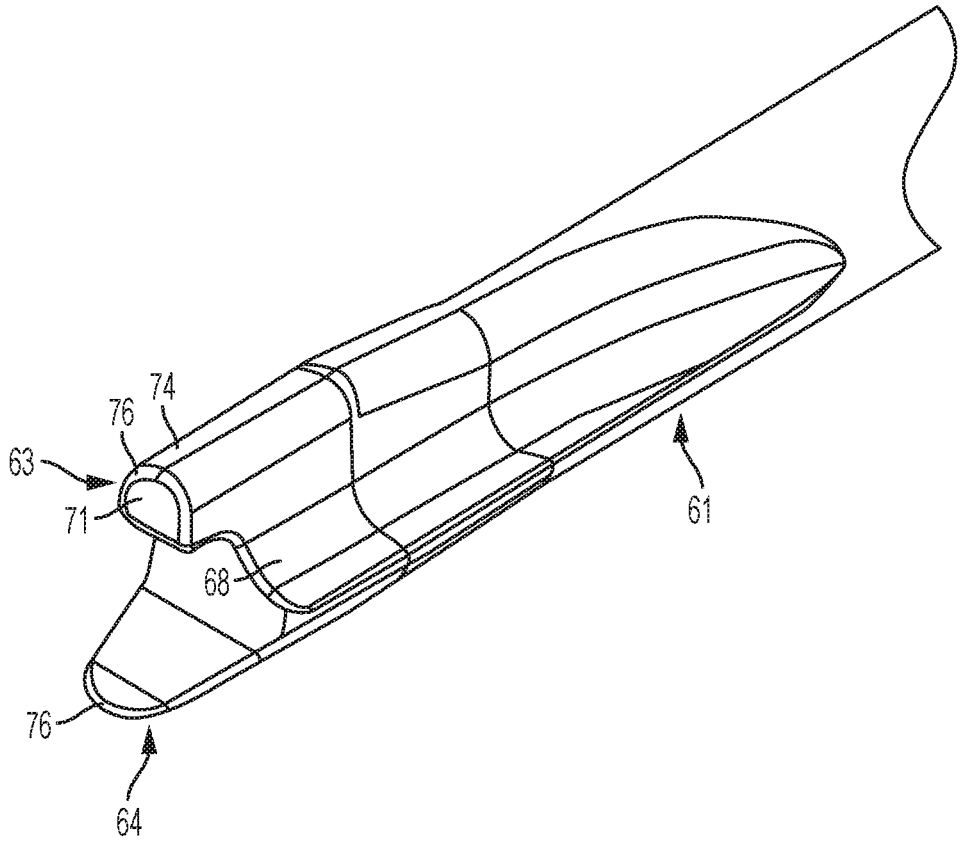



FIG. 19G

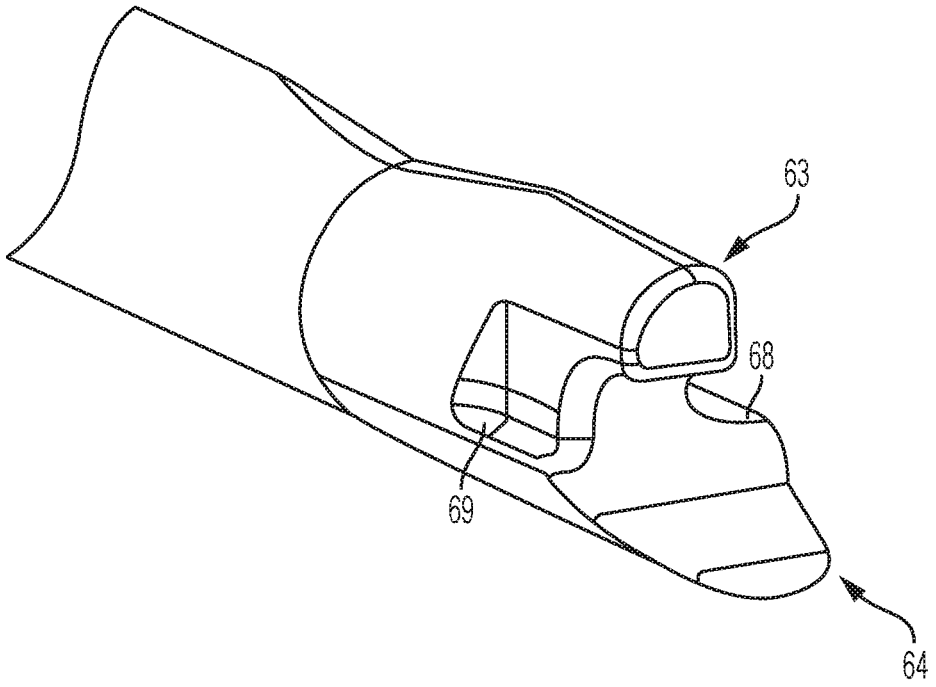



FIG. 19H

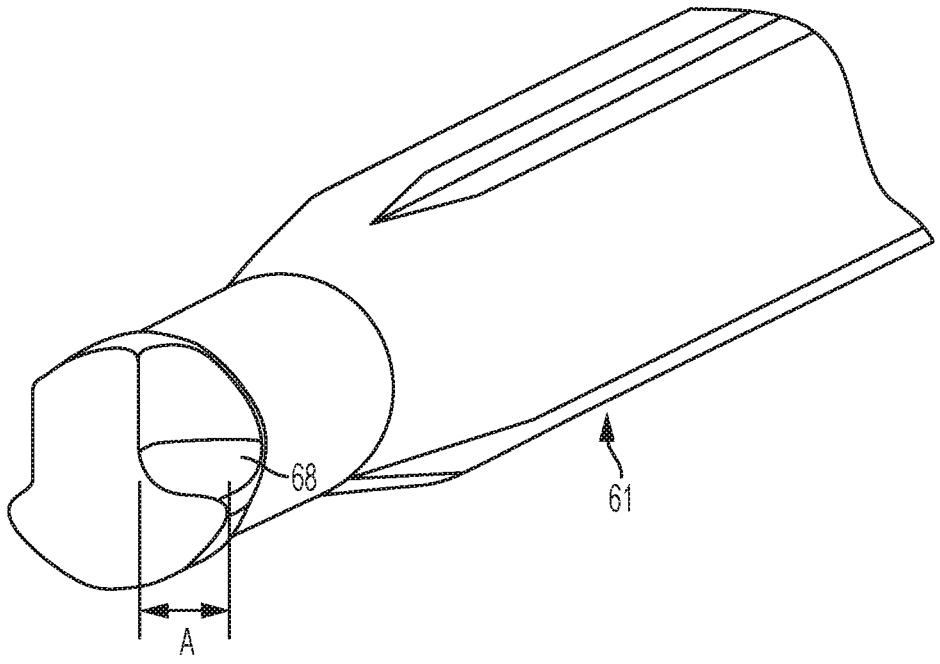



FIG. 20

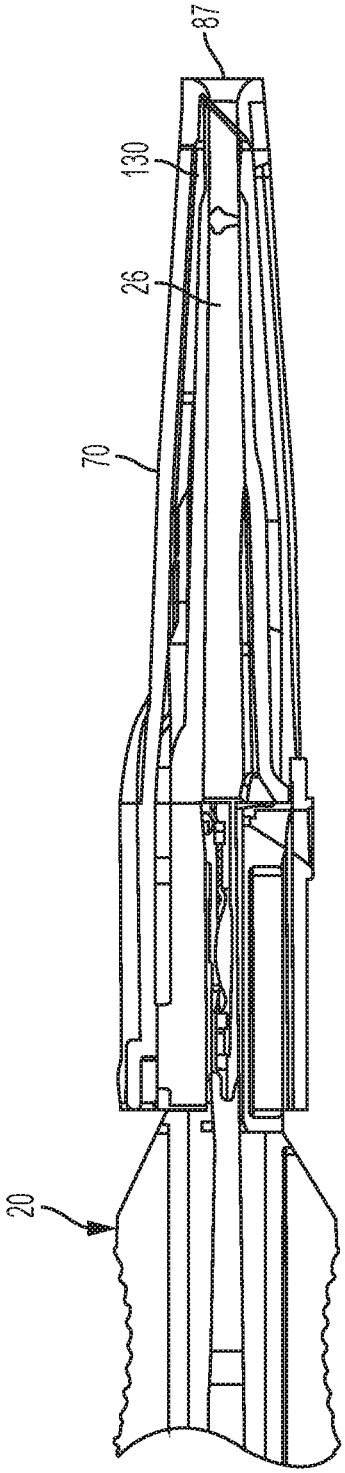



FIG. 21

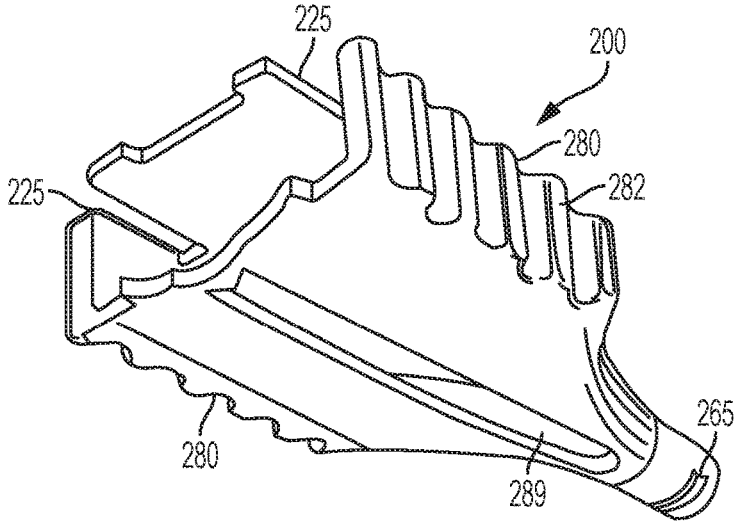



FIG. 22A

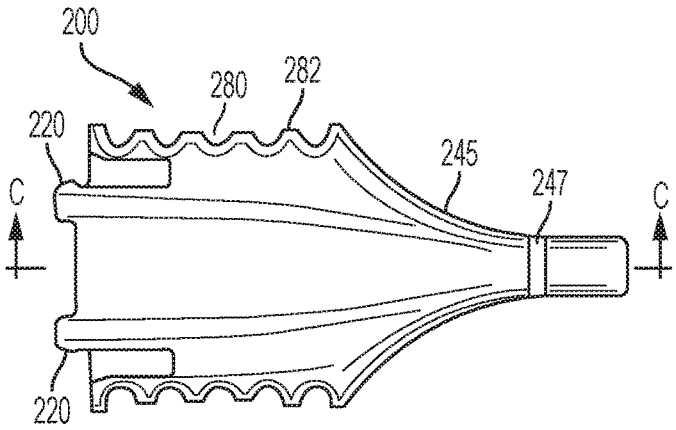



FIG. 22B

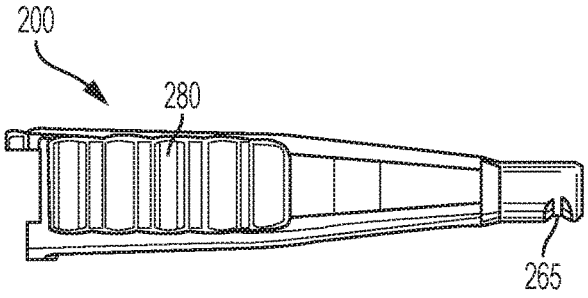



FIG. 22C

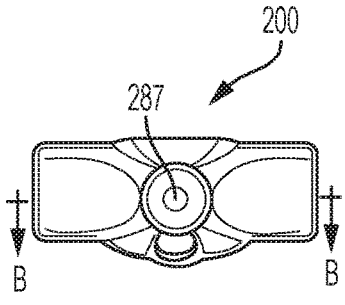



FIG. 22D

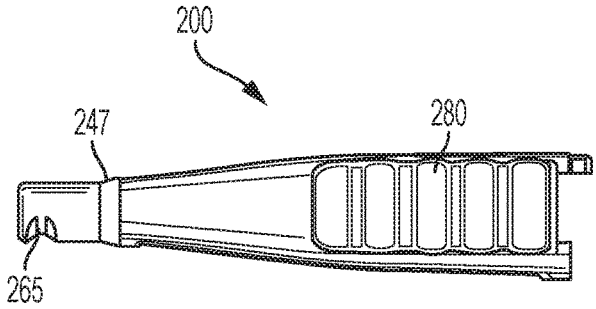



FIG. 22E

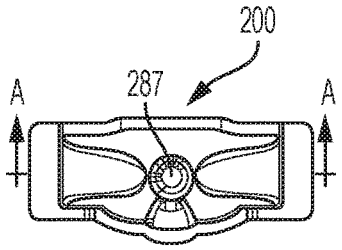



FIG. 22F

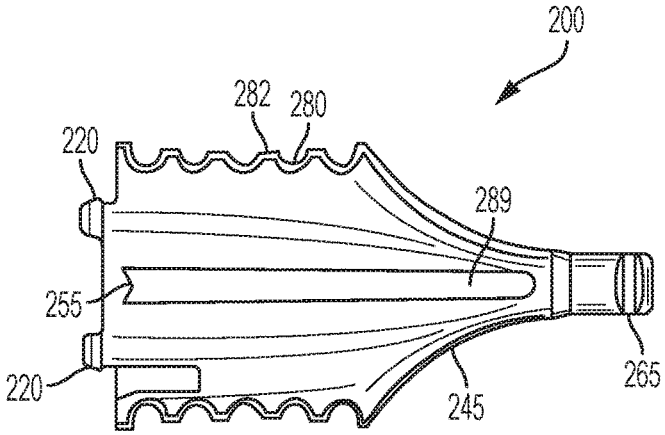
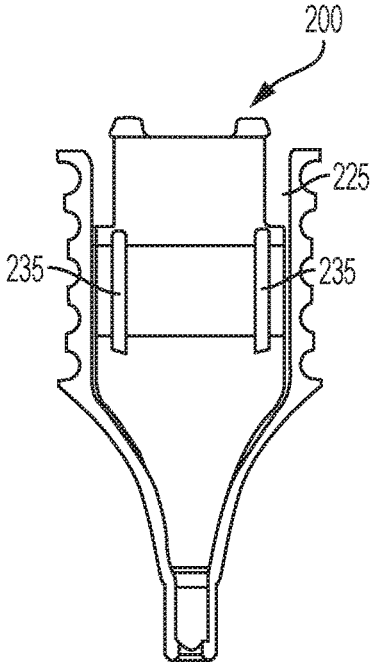
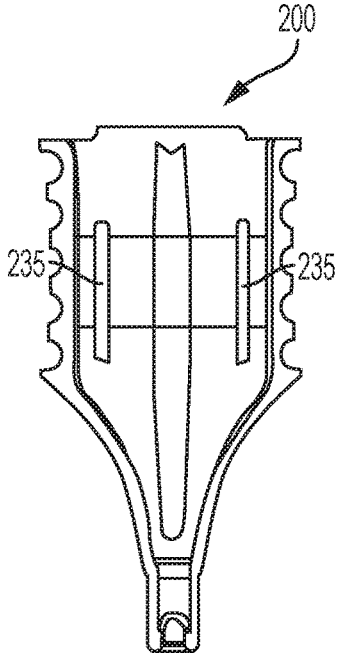



FIG. 22G



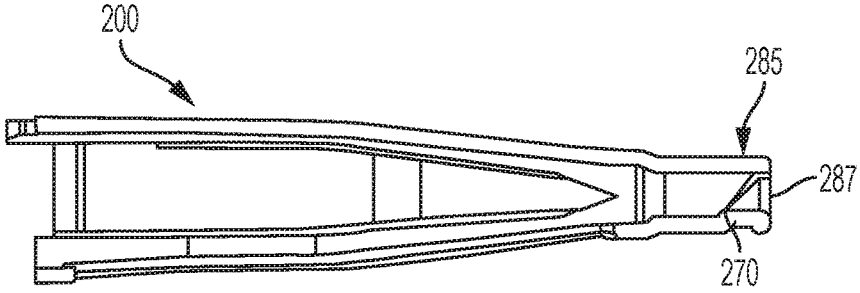

SECTION A-A

FIG. 23A




SECTION B-B

FIG. 23B




SECTION C-C

FIG. 24

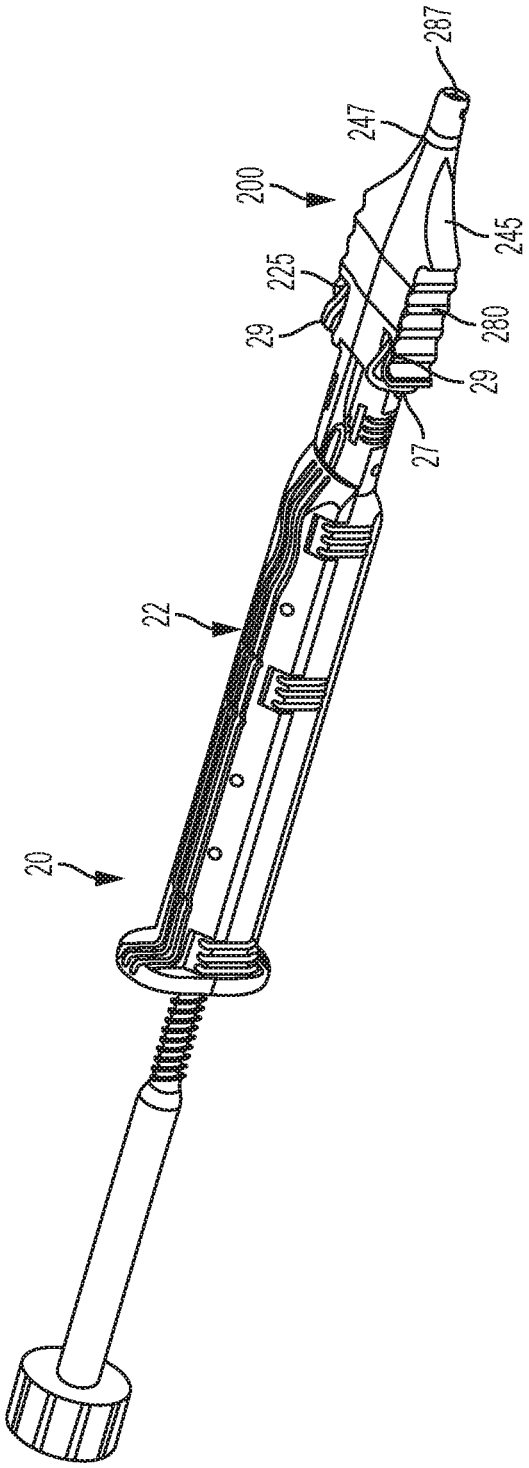



FIG. 25

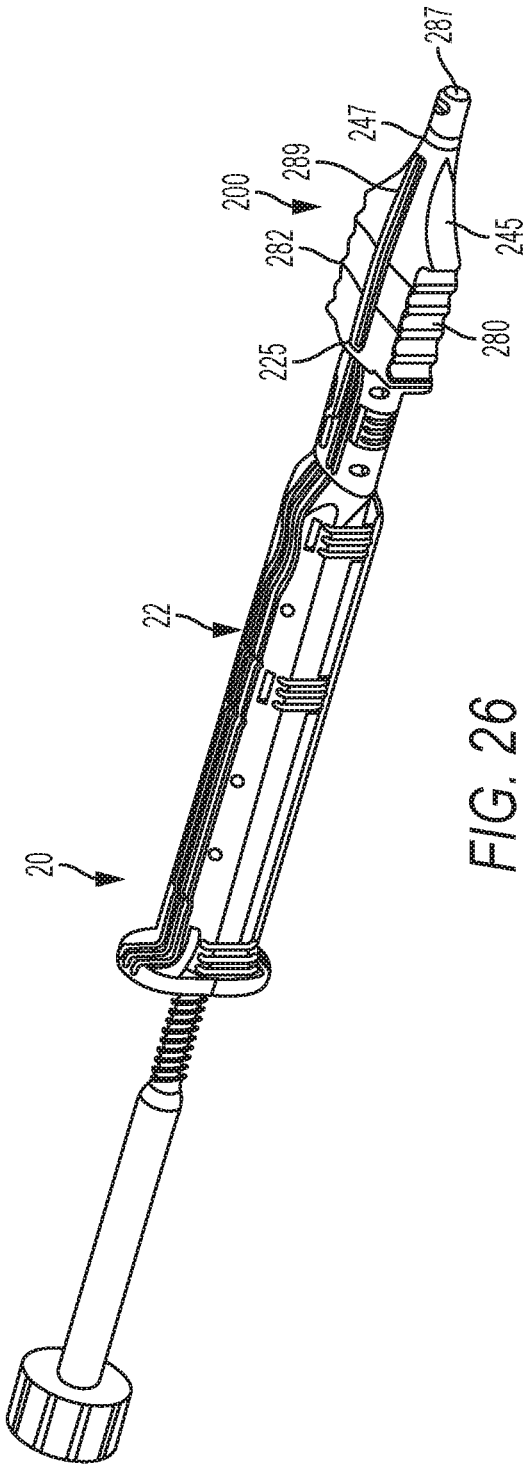



FIG. 26

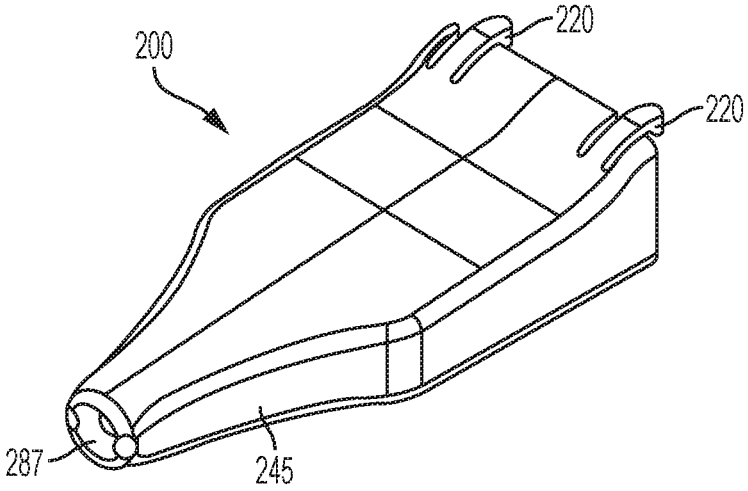



FIG. 27A

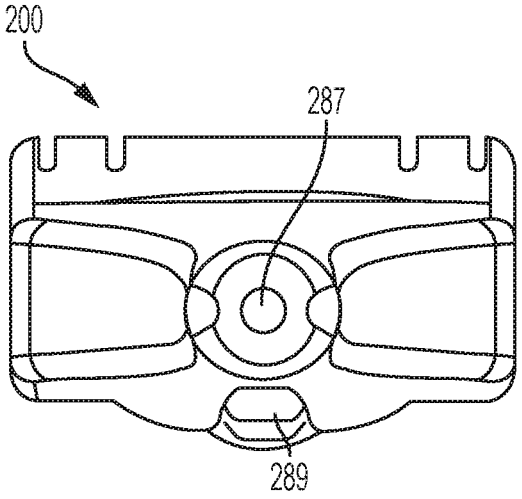



FIG. 27B

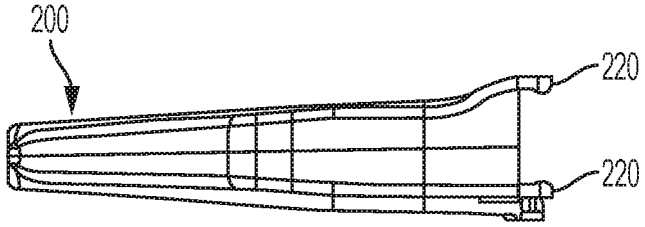



FIG. 27C

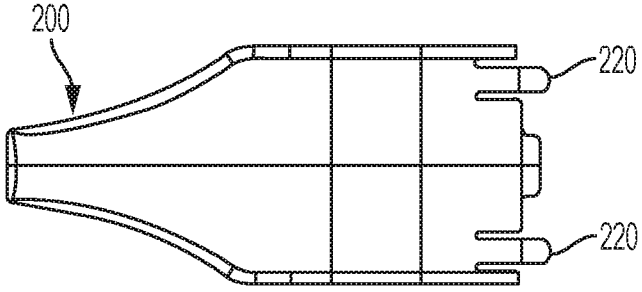



FIG. 27D

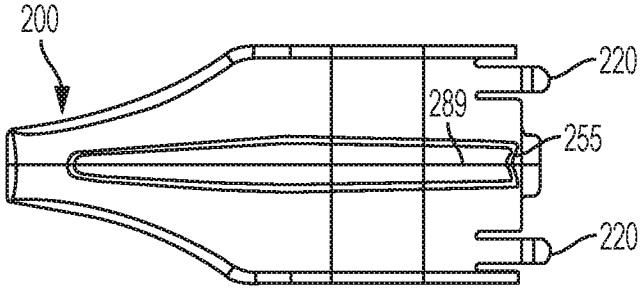



FIG. 27E

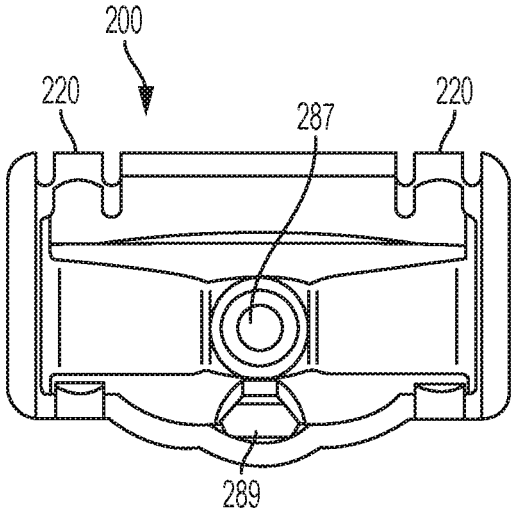



FIG. 27F

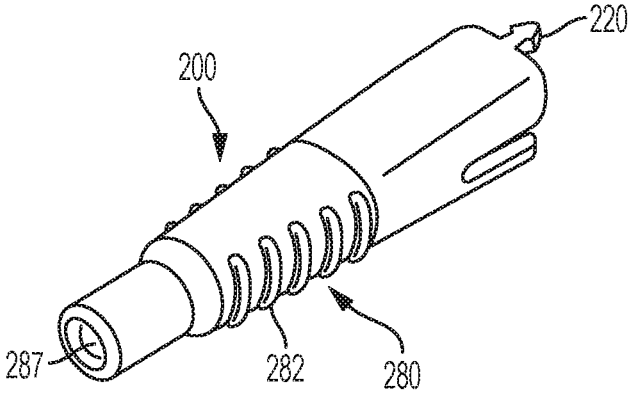



FIG. 28A

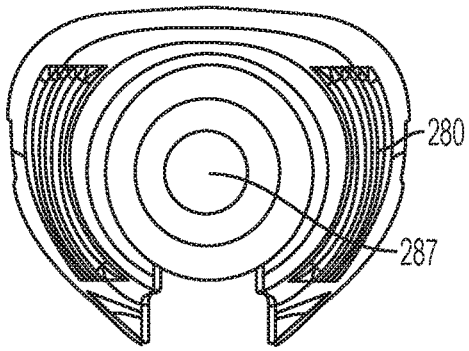



FIG. 28B

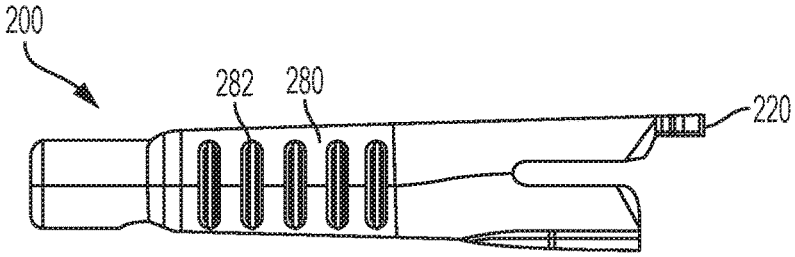



FIG. 28C

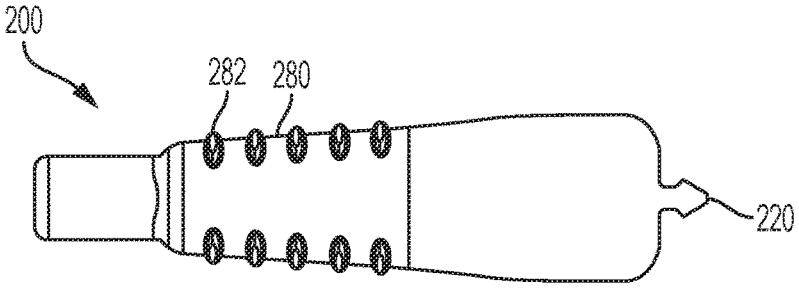



FIG. 28D

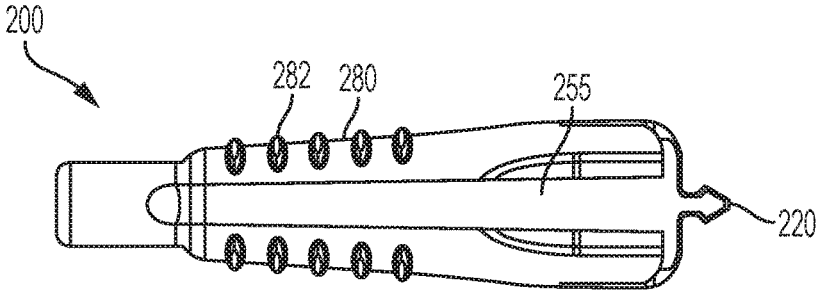



FIG. 28E

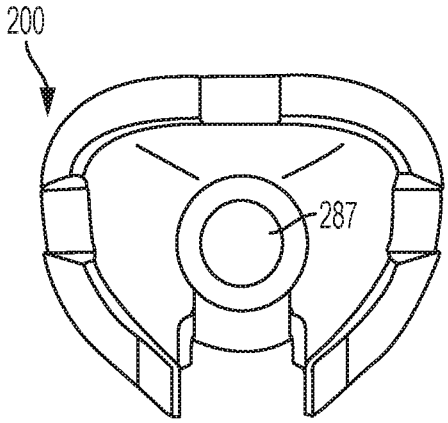



FIG. 28F

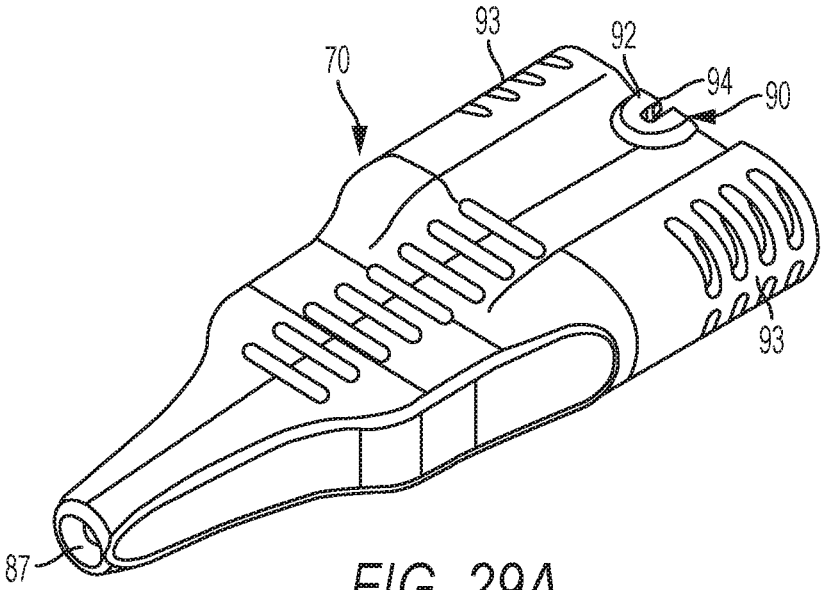



FIG. 29A

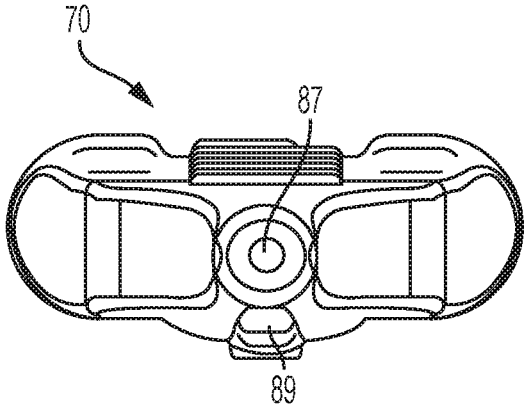



FIG. 29B

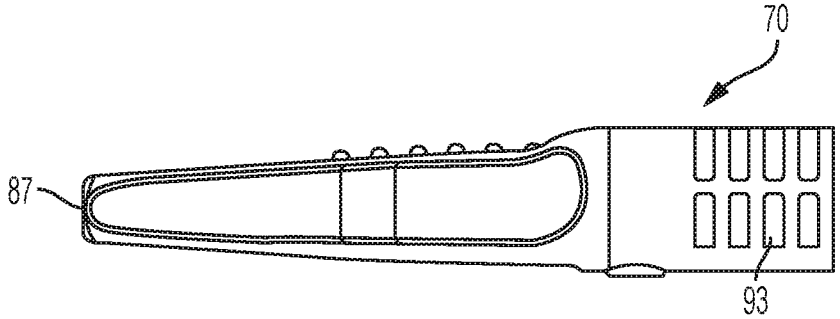



FIG. 29C

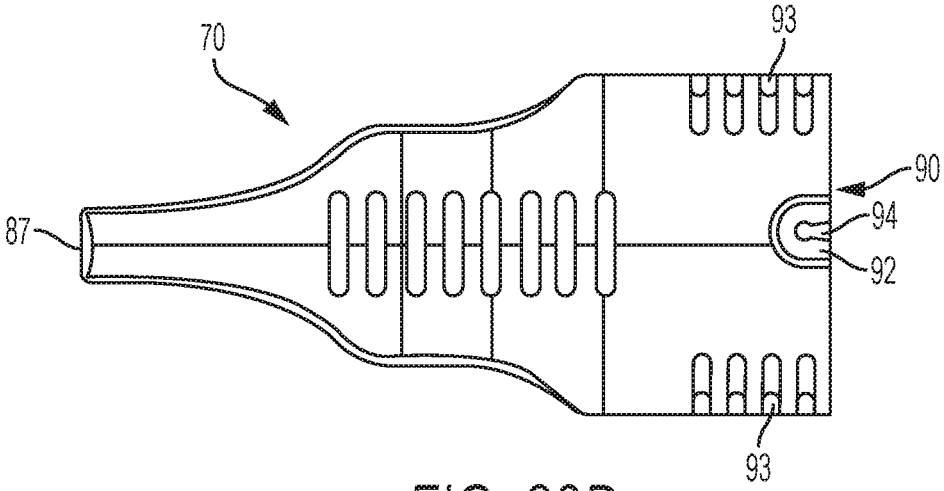



FIG. 29D

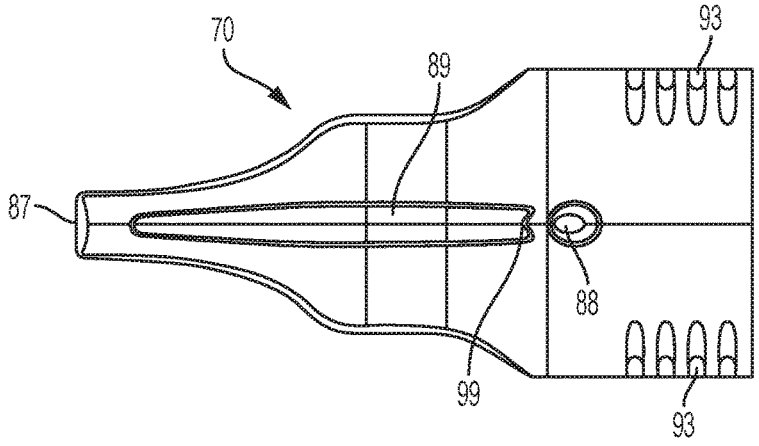



FIG. 29E

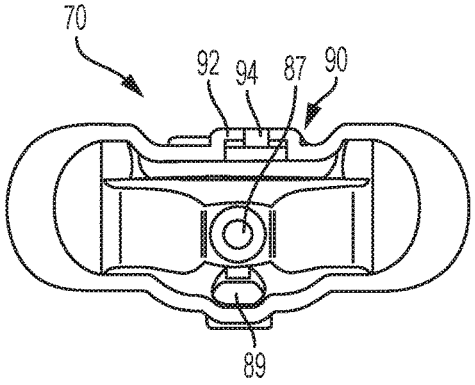



FIG. 29F

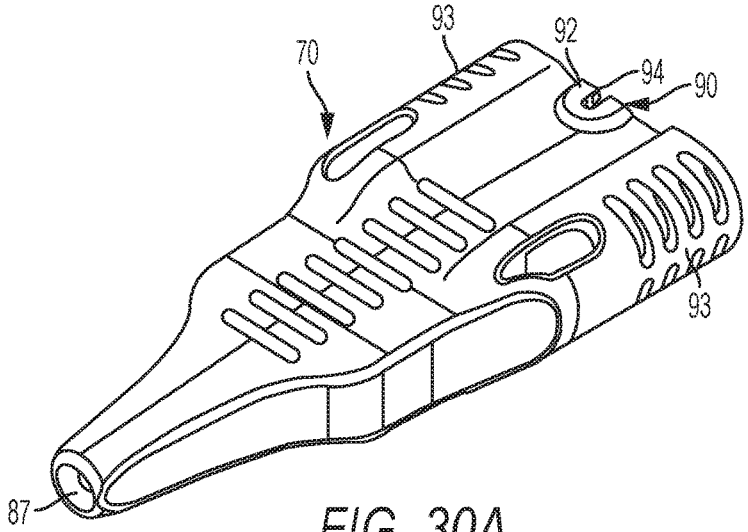



FIG. 30A

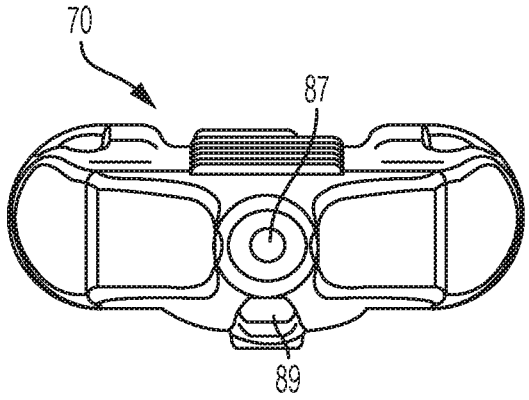



FIG. 30B

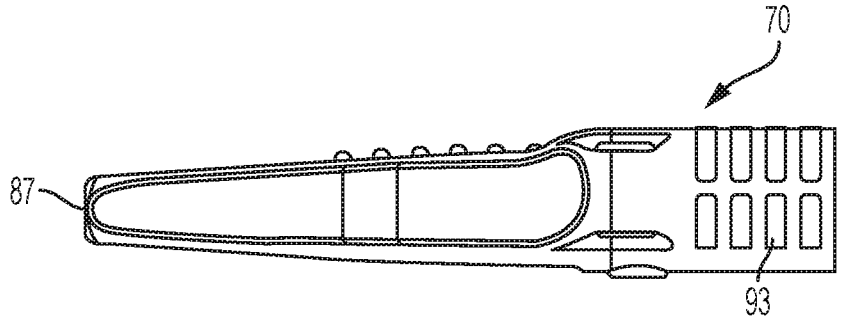



FIG. 30C

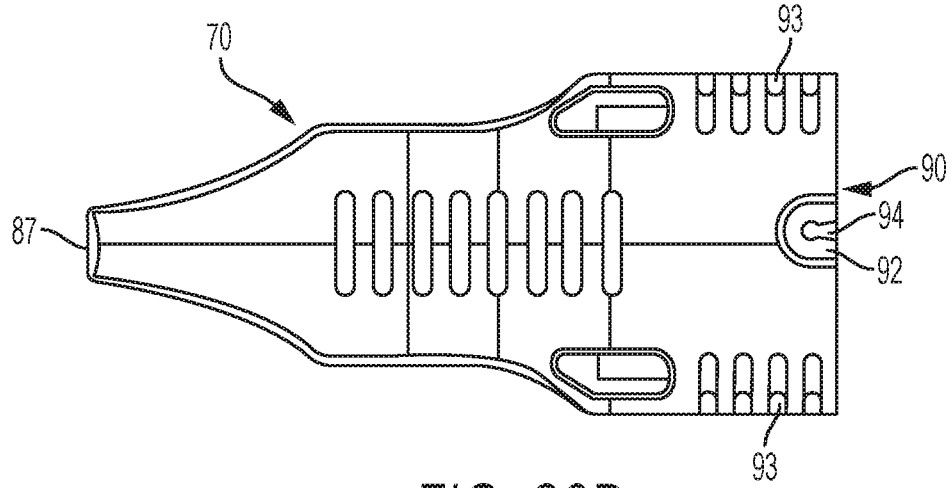



FIG. 30D

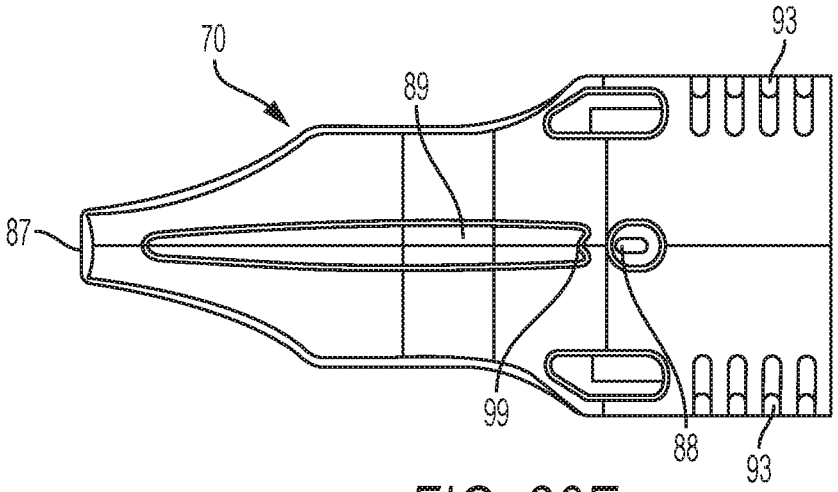



FIG. 30E

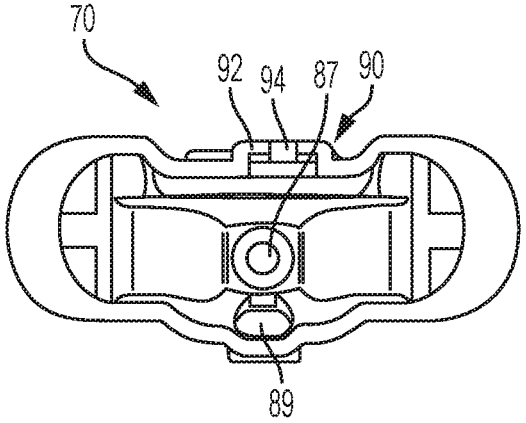



FIG. 30F

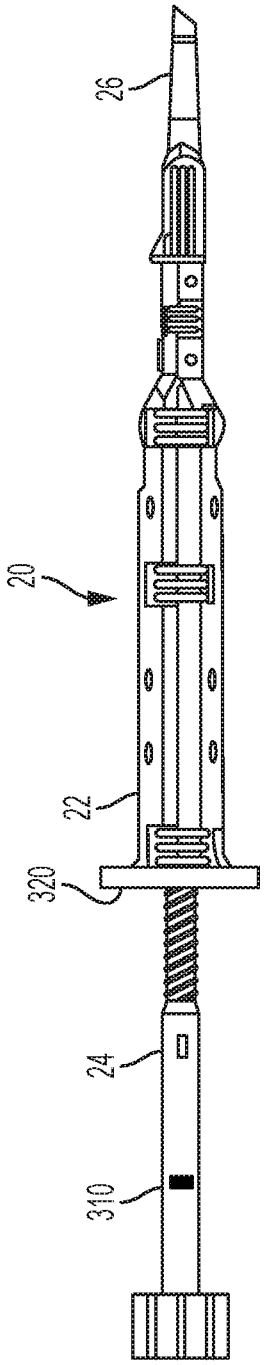



FIG. 31A

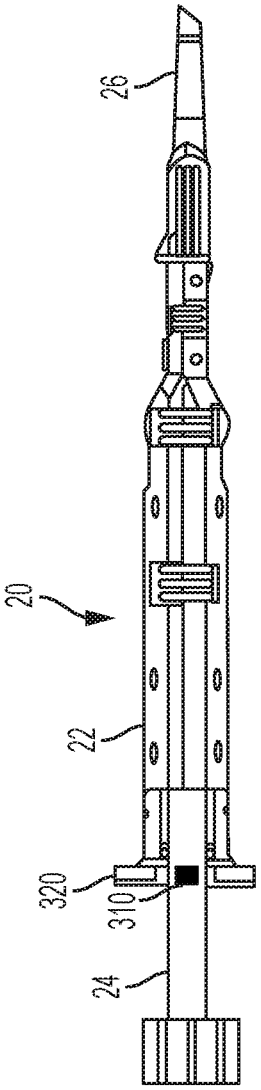



FIG. 31B

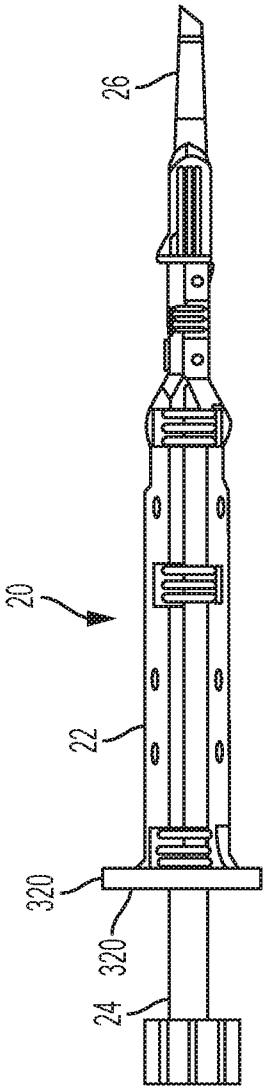



FIG. 31C

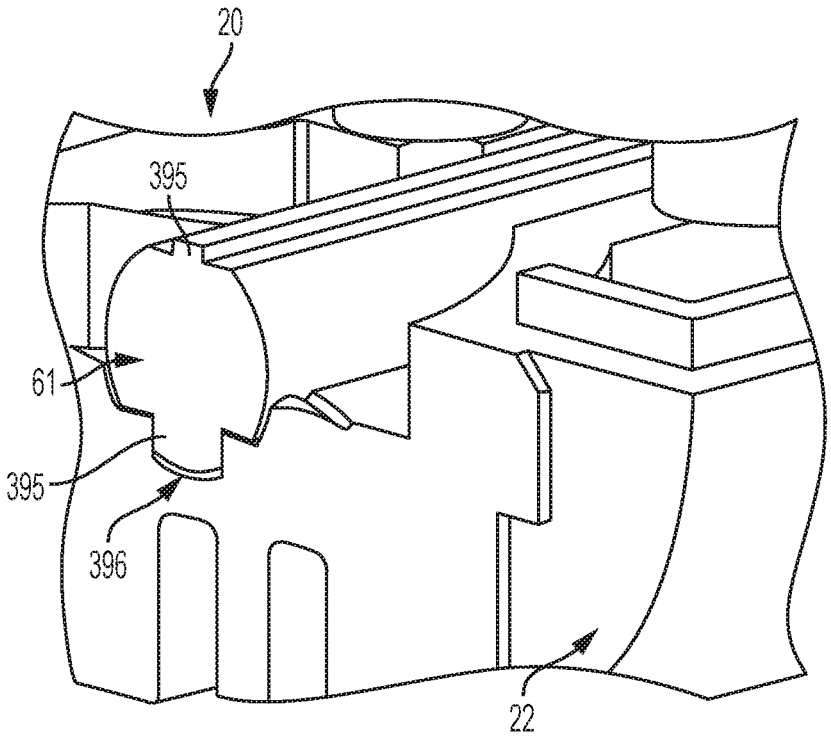



FIG. 32

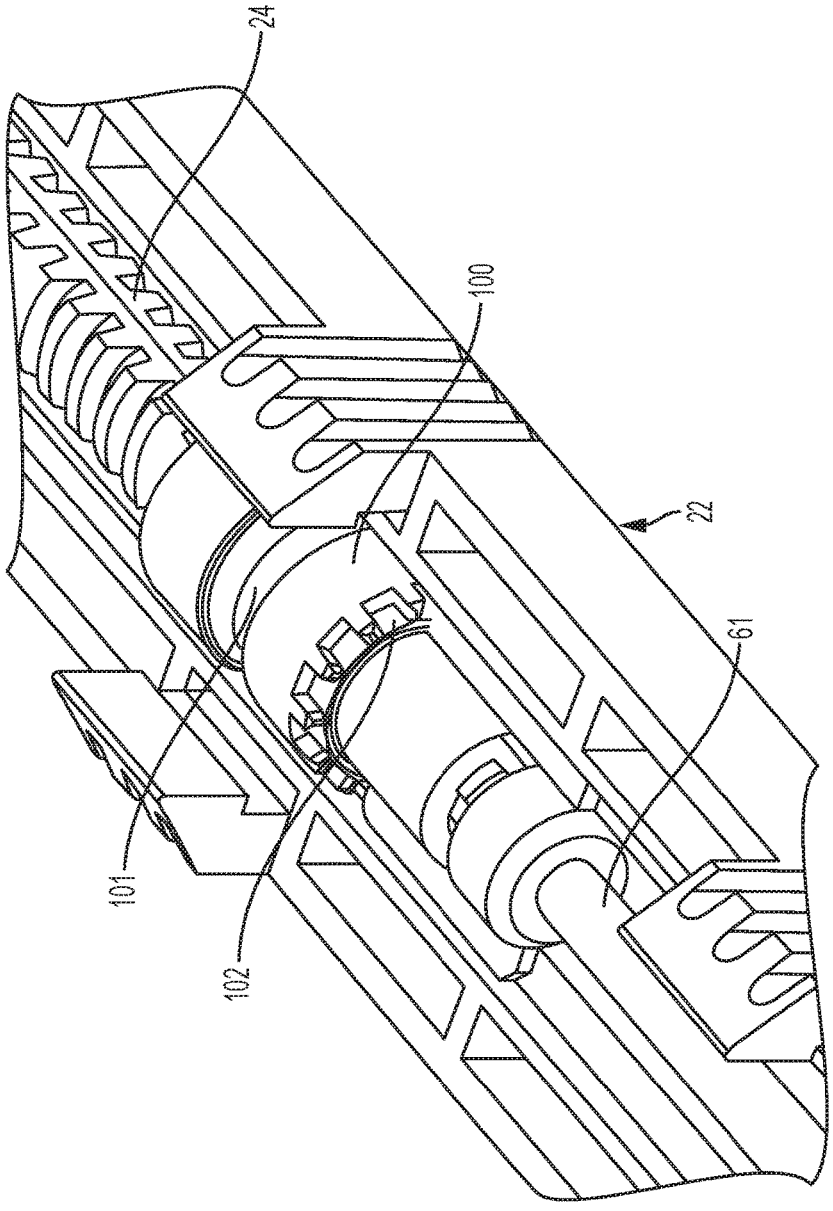



FIG. 33

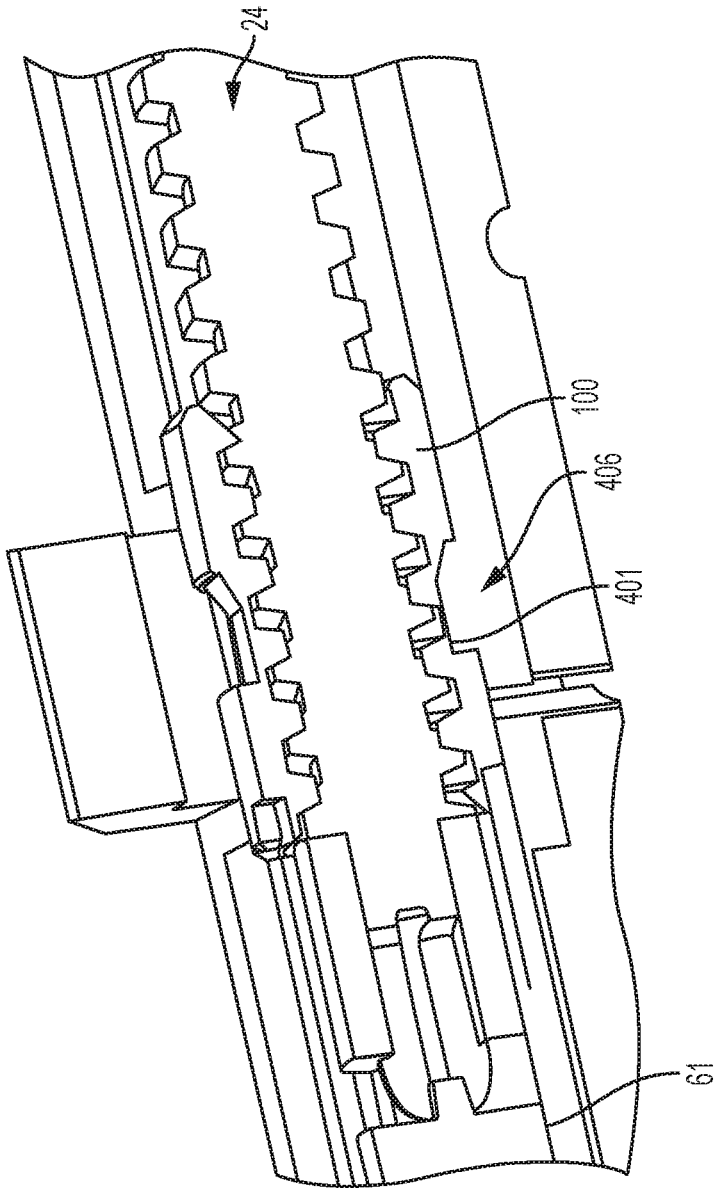



FIG. 33A

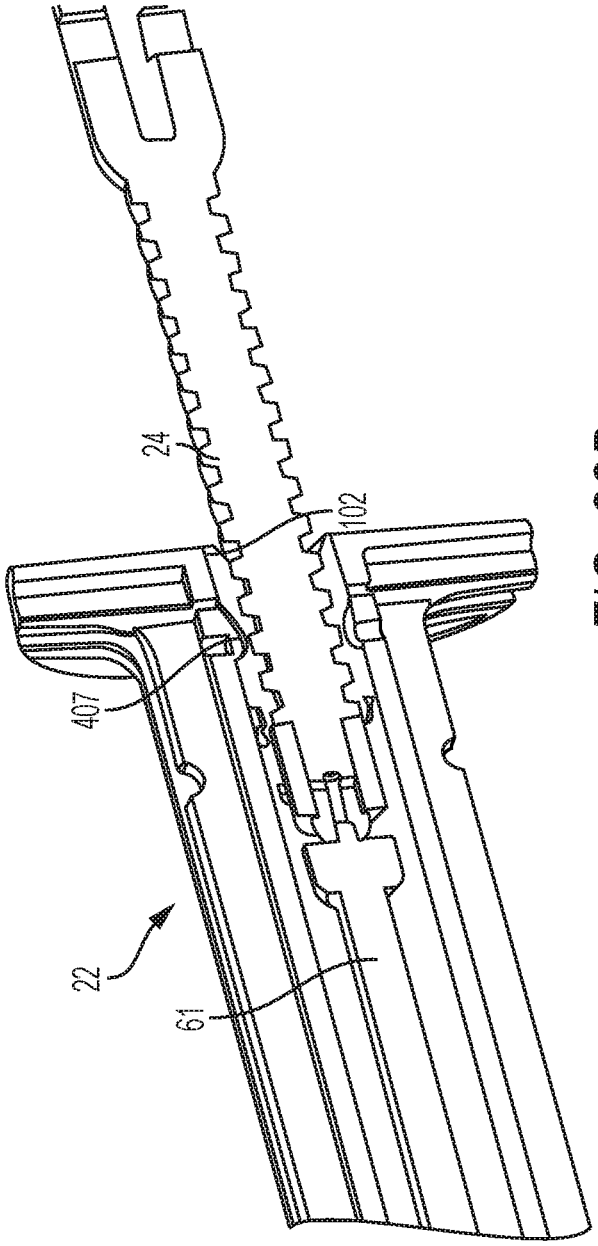



FIG. 33B

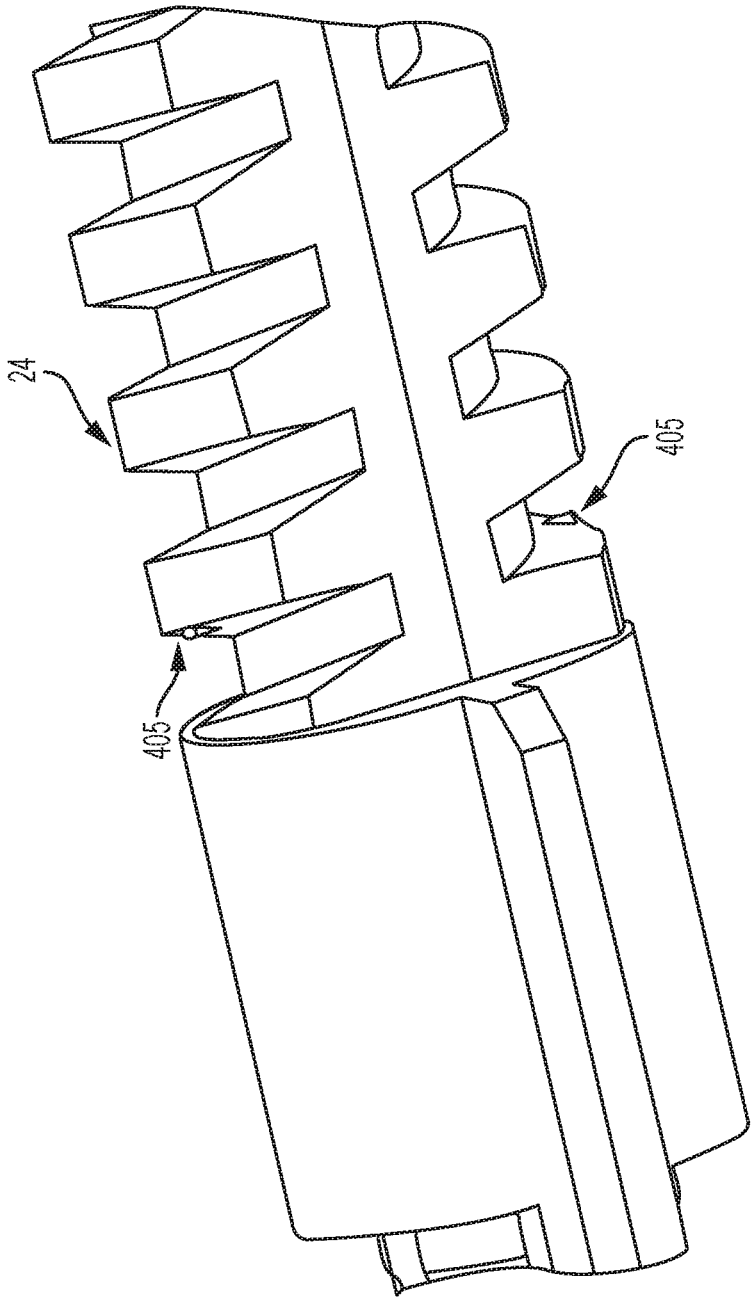



FIG. 34

# PROTECTIVE CAP FOR AN INSERTION DEVICE AND OTHER INSERTION DEVICE FEATURES

## CROSS-REFERENCE TO RELATED PATENTS AND APPLICATIONS

**[0001]** This application claims priority to and is a divisional of U.S. application Ser. No. 13/818,573, filed Feb. 25, 2014, which is a U.S. National Phase of PCT Application No. PCT/US2011/049029, filed Aug. 24, 2011, which claims priority to U.S. Provisional Application Nos. 61/376,661, filed on Aug. 24, 2010; 61/467,584, filed on Mar. 25, 2011; and 61/500,564, filed on Jun. 23, 2011, all of which are hereby incorporated by reference in their entirety.

## TECHNICAL FIELD OF THE INVENTION

**[0002]** The present invention relates to an inserter protective cap and other inserter features.

## BACKGROUND OF THE INVENTION

**[0003]** It is estimated that 73% of Americans between the ages of 65 to 74 get cataracts. A cataract is a clouding of the eye's lens that impairs a person's vision and, if left untreated, causes blindness. As a result, each year approximately 1.4 million people in the United States alone undergo cataract surgery, whereby the clouded natural crystalline lens is removed and replaced with an intraocular lens (IOL) implant.

**[0004]** Surgeons implant IOLs not only as a replacement for the natural crystalline lens but also to alter the optical properties of (provide vision correction to) an eye with an existing IOL or in which the natural lens remains. IOLs often include an optically clear disk-like optic of about 6 mm in diameter, and preferably at least one flexible fixation member or haptic which extends radially outward from the optic and becomes affixed in the eye to secure the lens in position.

**[0005]** The optics may be constructed of rigid biocompatible materials such as polymethyl methacrylate (PMMA) or deformable materials such as silicone polymeric materials, acrylic polymeric materials, hydrogel polymeric materials, and the like. The deformable materials allow the IOL to be rolled or folded for insertion through an injector or insertion cartridge and an incision into the eye. Once within the chamber of the eye, the IOL is expulsed from the injector and returns to its original shape.

**[0006]** Injectors or inserters for delivering IOLs into the eye typically employ a handpiece and a removable cartridge that receives the IOL and has a hollow insertion tube or cannula through which the folded IOL is passed using a pushrod. Some inserters do without the cartridge. The inserter may be wholly or partly reusable, in which case the inserter or handpiece is usually made of some type of metal alloy that can be sterilized. Alternatively, disposable inserters made of less expensive materials, such as plastics, remain in a sterile package until ready for use. In some cases, the IOL is stored separately and transferred to a load chamber in the inserter or cartridge just prior to delivery. One particularly useful arrangement wherein the cartridge folds over an IOL is disclosed in U.S. Pat. No. 4,681,102 to Bartell. A cartridge opens to receive an IOL in a load chamber, and then folds closed and fits into an injector. A syringe-like plunger in the injector pushes the IOL from the load chamber through a tapered tube into the eye. The IOL unfolds as it emerges from the tip of the tapered tube. Another such insertion system is disclosed in Makker et al., U.S. Pat. No. 5,942,277. An example of storing an IOL in an inserter component is seen in U.S. Pat. No. 7,156,854, filed May 28, 2003. In the '854 patent, a nozzle portion **12** along with a removable stop **26** retains the IOL therein during storage and has internal ramps that assist in folding the IOL optic during an implant procedure. Also, U.S. Patent Publication No. 2008/0058830, filed Jul. 17, 2007, discloses a number of configurations for pre-loading IOLs for transfer to an insertion apparatus, and is expressly incorporated herein. Another preloaded insertion system is illustrated in U.S. Patent Publication No. 2009/0318933, filed Jun. 23, 2008, which is hereby incorporated by reference in its entirety.

**[0007]** Despite the advances in the area of insertion devices, there remains a need for devices and systems that increase the ease of use of inserters, including facilitating the insertion of IOLs, while reducing the risk of damage to both the insertion device and the IOL.

## SUMMARY OF THE INVENTION

**[0008]** The present inventions disclose a protective cap having a window and a port at a distal end of the cap, wherein the cap is configured and dimensioned to couple with a distal end of an insertion system. The window of the protective cap may have a fill indicator. In an embodiment, the window is located on a top of the cap and wherein the window runs along at least a portion of a longitudinal axis of the cap. In an additional embodiment, the cap may have an internal bevel inside the cap at the distal end, wherein the internal bevel is configured and dimensioned to couple with a bevel at the distal end of an insertion system. Additionally, the cap may have at least two finger grips along at least a portion of a longitudinal axis of the cap and wherein the finger grips are located on opposite sides of the cap.

**[0009]** According to embodiment, the port of the protective cap comprises a funnel shape and is configured and dimensioned to couple with a lumen at a distal end of an insertion system to enable insertion of a fluid into the lumen of the insertion system. The distal end of the cap may also have a material relief to prevent distortion of a tip at a distal end of the cap during manufacturing of the cap. In another embodiment, one or more internal walls of the cap comprise one or more internal guides that run along at least a portion of a longitudinal axis of the cap, wherein the one or more internal guides are configured and dimensioned to couple with features on an outer portion of an insertion device. In an embodiment, the cap may also have two substantially parallel internal guides.

**[0010]** According to an embodiment, an insertion system may include a handpiece having a longitudinal axis, a distal end, and a proximal end; a pushrod assembly having a distal end and a proximal end, wherein the push rod assembly comprises a pushrod and a plunger, couples with the handpiece along the longitudinal axis; and wherein the pushrod is coupled with the plunger and the pushrod is located on the distal end of the push rod assembly and the plunger is located on the proximal end of the pushrod assembly. The insertion system may also include a cartridge having a delivery tube at a distal; wherein the cartridge is configured and dimensioned to couple with the distal end of the handpiece; and a cap having a window and a port; wherein the cap is configured and dimensioned to couple with the

distal end of the cartridge. In an embodiment, the cartridge further includes one or more wings and the cap further includes one or more clips, wherein the one or more clips are configured and dimensioned to couple with the one or more wings. In an embodiment, the cap further includes an internal bevel inside the cap at a distal end, wherein the internal bevel is configured and dimensioned to couple with a bevel at the distal end of the delivery tube. In another embodiment, the cap may include at least two finger grips along at least a portion of a longitudinal axis of the cap and wherein the finger grips are located on opposite sides of the cap. In an embodiment the window may have a fill indicator and the window may be located on a top of the cap, wherein the window runs along at least a portion of a longitudinal axis of the cap.

**[0011]** According to an embodiment the port may include a funnel shape that is configured and dimensioned to couple with a lumen at a distal end of an insertion system to enable insertion of a fluid into the lumen of the insertion system. In an embodiment, the distal end of the cap may have a material relief to prevent distortion of a tip at a distal end of the cap during manufacturing of the cap. In another embodiment, one or more internal walls of the cap comprise one or more internal guides that run along at least a portion of a longitudinal axis of the cap, wherein the one or more internal guides are configured and dimensioned to couple with features on an outer portion of an insertion device. The In an embodiment, the cap may also have two substantially parallel internal guides.

**[0012]** According to an embodiment, an insertion system may include a handpiece having a longitudinal axis, a distal end, and a proximal end; a pushrod assembly having a distal end and a proximal end, wherein the push rod assembly comprises a pushrod and a plunger, couples with the handpiece along the longitudinal axis; and wherein the pushrod is coupled with the plunger and the pushrod is located on the distal end of the push rod assembly and the plunger is located on the proximal end of the pushrod assembly. The plunger of the insertion system may also have a marker configured and dimensioned to indicate axially translation of the pushrod assembly within the handpiece; and a cartridge comprising a delivery tube at a distal end, wherein the cartridge is configured and dimensioned to couple with the distal end of the handpiece. In an embodiment, the marker is configured and dimensioned to indicate a location of a detent when the pushrod assembly is advanced toward the distal end of the handpiece.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0013]** The present invention is best understood with reference to the following detailed description of the invention and the drawings in which:

**[0014]** FIG. **1** is an assembled perspective view of an insertion system according to an embodiment of the invention;

**[0015]** FIG. **1**A is an assembled perspective view of an insertion system according to an embodiment of the invention;

**[0016]** FIG. **2** is a top view of an insertion system according to an embodiment of the invention;

**[0017]** FIG. **2**A is a top view of an insertion system according to an embodiment of the invention;

**[0018]** FIG. **3** is a side view of an insertion system according to an embodiment of the invention;

**[0019]** FIG. **3**A is a side view of an insertion system according to an embodiment of the invention;

**[0020]** FIG. **4** is a bottom view of an insertion system according to an embodiment of the invention;

**[0021]** FIG. **4**A is a bottom view of an insertion system according to an embodiment of the invention;

**[0022]** FIG. **5** is an exploded view of the insertion system according to FIGS. **1** and **1**A;

**[0023]** FIG. **6** is a perspective view of a puller cap according to an embodiment of the invention;

**[0024]** FIG. **7** is a perspective view of a puller cap according to an embodiment of the invention;

**[0025]** FIG. **8** is cross-sectional view of a puller cap and insertion system according to an embodiment of the invention;

**[0026]** FIG. **9** is cross-sectional view of a puller cap and insertion system according to an embodiment of the invention;

**[0027]** FIG. **10** is an assembled perspective view of an insertion system with a puller cap according to an embodiment of the invention;

**[0028]** FIG. **11** is an assembled perspective view of an insertion system with a puller cap according to an embodiment of the invention;

**[0029]** FIG. **12** is an assembled perspective view of an insertion system with a puller cap according to an embodiment of the invention;

**[0030]** FIG. **13** is an assembled perspective view of an insertion system with a puller cap according to an embodiment of the invention;

**[0031]** FIGS. **14**A-**14**E are multiple views of a pin according to an embodiment of the invention;

**[0032]** FIG. **15** is a cross-sectional perspective view of a puller cap and insertion system according to an embodiment of the invention;

**[0033]** FIG. **15**A is a cross-sectional view of a pin, puller cap, and insertion system according to an embodiment of the invention;

**[0034]** FIG. **16** is a cross-sectional perspective view of a puller cap and insertion system according to an embodiment of the invention;

**[0035]** FIG. **17** is a cross-sectional perspective view of a puller cap and insertion system according to an embodiment of the invention;

**[0036]** FIGS. **18**A-**18**C are cross-sectional views of an alternate embodiment of the puller cap;

**[0037]** FIG. **18**D is a perspective view of the alternative embodiment of the puller cap shown in FIGS. **18**A-**18**C;

**[0038]** FIG. **19**A is a side view of a pushrod according to an embodiment;

**[0039]** FIG. **19**B is a side view of a pushrod according to an embodiment;

**[0040]** FIG. **19**C is a side view of a pushrod according to an embodiment;

**[0041]** FIG. **19**D is a perspective view of pushrod according to an embodiment of the invention;

**[0042]** FIG. **19**E is a side view of a pushrod according to an embodiment;

**[0043]** FIG. **19**F is an alternate side view of a push rod according to an embodiment;

**[0044]** FIGS. **19**G and **19**H are alternative views of a portion of a push rod according to an embodiment;

**[0045]** FIG. **20** is a cross-sectional perspective view of the pushrod in FIG. **19**D;

**[0046]** FIG. **21** is a cross-sectional view of a puller cap and insertion system according to an embodiment of the invention;

**[0047]** FIG. **22**A is a perspective view of the protective cap according to an embodiment;

**[0048]** FIG. **22**B is a top view of the protective cap according to an embodiment;

**[0049]** FIG. **22**C is a side view of the protective cap according to an embodiment;

**[0050]** FIG. **22**D is a front view of the protective cap according to an embodiment;

**[0051]** FIG. **22**E is a side view of the protective cap according to an embodiment;

**[0052]** FIG. **22**F is a rear view of the protective cap according to an embodiment;

**[0053]** FIG. **22**G is bottom view of the protective cap according to an embodiment;

**[0054]** FIG. **23**A is a cross-sectional view of the protective cap shown in FIG. **22**F;

**[0055]** FIG. **23**B is a cross-sectional view of the protective cap shown in FIG. **22**D;

**[0056]** FIG. **24** is a cross-sectional view of the protective cap shown in FIG. **22**B;

**[0057]** FIG. **25** is an assembled perspective view of an insertion system with a protective cap according to an embodiment of the invention;

**[0058]** FIG. **26** is an assembled perspective view of an insertion system with a protective cap according to an embodiment of the invention

**[0059]** FIGS. **27**A-**27**F are additional embodiments of a protective cap;

**[0060]** FIGS. **28**A-**28**F are additional embodiments of a protective cap;

**[0061]** FIGS. **29**A-**29**F are additional embodiments of a puller cap;

**[0062]** FIGS. **30**A-**30**F are additional embodiments of a puller cap;

**[0063]** FIG. **31**A is a side view of an insertion system according to an embodiment;

**[0064]** FIG. **31**B is a side view with a cutout portion of an insertion system according to an embodiment;

**[0065]** FIG. **31**C is a side view of an insertion system according to an embodiment;

**[0066]** FIG. **32** is a cross-sectional view of a rails and channels embodiment;

**[0067]** FIG. **33** is a perspective view of a nut lock according to an embodiment;

**[0068]** FIG. **33**A is a cross-sectional view of a nut lock according to an embodiment;

**[0069]** FIG. **33**B is a cross-sectional view of a nut lock according to an embodiment; and

**[0070]** FIG. **34** is a perspective view of a detent safety embodiment.

## DETAILED DESCRIPTION OF THE INVENTION

**[0071]** Reference will now be made in detail to embodiments of the invention, examples of which are illustrated in the accompanying drawings. While the invention will be described in conjunction with the embodiments, it will be understood that they are not intended to limit the invention to those embodiments. On the contrary, the invention is intended to cover alternatives, modifications, and equivalents, which may be included within the spirit and scope of the invention as defined by the appended claims.

**[0072]** FIGS. **1-4** illustrate varying views of an exemplary IOL insertion system **20** of the present invention comprising a twist/syringe-style device having, generally, a handpiece **22**, a plunger **24**, and a delivery tube **26** on a distal end/portion thereof. As illustrated in FIGS. **1-3**, IOL insertion system **20** may also include puller pin **100**, which will be described in greater detail below. As illustrated in FIG. **4**, system **20** also may comprise port **21** to enable application or insertion of a fluid, such as water, balance salt solution, and/or viscoelastic. FIGS. **1**A-**4**A illustrates an alternative IOL insertion system **20** of the present invention. The IOL insertion system **20** illustrated in FIGS. **1**A-**4**A does not include puller pin **100** or port **21**. It is also envisioned that IOL insertion system **20** may include only one of the puller pin **100** or the port **21**. The system **20** is also shown in an exploded view in FIG. **5**.

**[0073]** IOL **31** is shown in FIG. **5** and may be positioned between two halves of a holding station **30**. IOL **31** may comprise a central circular optic **32** having a leading haptic **34** and a trailing haptic **36** generally spirally extending therefrom. One exemplary IOL as illustrated is a one piece acrylic Tecnis® brand of aspheric IOL available from Abbott Medical Optics Inc. of Santa Ana, Calif. It is also envisioned that any IOL may be used with the insertion system disclosed herein.

**[0074]** With reference to FIGS. **1-5** and FIGS. **1**A-**4**A, the system **20** defines a longitudinal axis from an end cap **40** of a pushrod assembly **60** at a proximal end to the delivery tube **26** at a distal end. The pushrod assembly **60** includes a plunger **24**, an end cap **40**, a nut lock **102**, and a pushrod **61**. Pushrod **61** may have a distal tip **62**. In an embodiment, a portion of distal tip **62** may be flexible as described in greater detail below. In the illustrated embodiment, the distal tip **62** is forked to enable reliable capture of a proximal edge of the IOL optic **32** and/or trailing haptic **36**. The plunger **24** and/or pushrod **61** translates axially through an elongate passage defined within the inserter handpiece **22** and is configured to urge the IOL from a holding station **30** through the distal delivery tube **26**. In a general sense, the plunger **24** represents any actuator capable of displacing the IOL from the holding station **30** in a distal direction through a delivery tube or other such device. The plunger **24** therefore may be generally termed an actuator so as to encompass other prime movers that can perform the same function, such as a rotary actuators, threaded actuators, levers, etc.

**[0075]** FIG. **5** is an exploded view of the components of the system **20** in the orientation in which they will be assembled. However, a preferred mold configuration results in a total of six (or possibly fewer) components for the entire system, not counting the IOL. It is also envisioned that the mold configuration results in a total of seven or more components for the entire system, not counting the IOL depending upon many factors, including but not limited to manufacturing requirements. The six components shown in FIG. **5** include the plunger **24**, the pushrod **61**, the cartridge **28**, the nut lock **102**, the upper body **56**, and the lower body **57**. Lower body **57** may include the holding station **30** and base portion **52**. Cartridge **28** comprises delivery tube **26** and wings **27**. It is possible that the handpiece upper body **56** could be formed along with the remainder of the handpiece, though the mold would be fairly complicated and expensive.

Likewise, the cartridge **28** could be incorporated into the handpiece **22**, but again for reasons of manufacturing economy they are separate.

**[0076]** The one half of the holding station **30** comprises a base **50** that, in a preferred embodiment, forms a distal extension of a base portion **52** of the handpiece **22**. The upper half of the holding station **30** comprises a cover **54** that abuts the upper body **56** of the inserter handpiece **22**. In the illustrated embodiment, as seen in FIG. **5**, the cover **54** and upper body **56** fit directly over the base **50** and base portion **52** to form the elongated handpiece **22**. The overall shape of handpiece **22** may be of any shape to accommodate proper gripping of the device. According to an embodiment, the holding station cover **54** may be connected by a pair of living hinges **80***a,* **80***b* to the base **50**. The base **50** includes a pair of bifurcated fingers **82***a,* **82***b* that meet a similar pair of bifurcated fingers **84***a,* **84***b* extending from the cover **54** at the living hinges **80***a,* **80***b*. The opposed pairs of aligned fingers **82**, **84** are shaped so as to form slots therebetween when folded about the living hinges **80** and a central cavity **86** (shown in FIG. **5**) for receiving a delivery tube **26**, the combination of which is best seen in the assembled view of FIGS. **1** and **1**A. In this regard, the delivery tube **26** desirably comprises a rear-loading cartridge as shown, and as described in co-pending U.S. Patent Publication No. 2009-0270876, filed on Apr. 28, 2008, which is hereby incorporated by reference in its entirety. In an embodiment, hinges **80***a* and **80***b* may be a snap feature instead of living hinges. In such an embodiment, holding station cover **54** may be molded as a separate part from base portion **52** and base **50**.

**[0077]** The handpiece may further include a pair of proximal finger tabs **60***a,* **60***b,* one on the base portion **52** and one on the upper body **56**. When an operator desires to depress the plunger **24**, he or she places the thumb of one hand on the end cap **40**, and index and middle fingers on respective finger tabs **60***a,* **60***b.* Squeezing the hand closed depresses the end cap **40** and moves the rest of pushrod assembly **60** along a lumen of the IOL insertion system **20** toward the distal end of the delivery tube **26**.

**[0078]** Puller Cap

**[0079]** FIGS. **10-13** illustrate different views of system **20** with puller cap **70**. Puller cap **70** fits over the holding station **30** and cartridge **28** in order to protect these components, and in particular the delivery tube **26**, while also facilitating the insertion of fluid as further described below.

**[0080]** FIGS. **6** and **7** show two views of puller cap **70** of the present invention. In FIG. **6**, puller cap **70** has a top **72**, a bottom **73**, a proximal end **75**, and a distal end **85**. Puller cap **70** includes lock **95**A, **95**B, grips **93**, snap **90**, and port **87**. Puller cap **70** may be made of any material known in the art, but preferably polypropylene, polycarbonate, polyethylene, or polyethylene terephthalate; more preferably polypropylene and polycarbonate; most preferably polypropylene. Puller cap **70** may also be of any color, preferably translucent or clear to enable a user to visualize the features inside puller cap **70** and anything housed within puller cap **70**. Puller cap **70** may be the shape as illustrated in the embodiment in FIG. **6**, but the invention also envisions that puller cap **70** may be of any shape or size to accommodate the needs of the insertion system the puller cap is used with or the needs of the user the puller cap is designed for. For example, the puller cap may be of an arrow shape as illustrated in the embodiment in FIG. **6**, may be more of a round shape, triangular shape, square shape, or shaped to meet the needs for shipping and/or handling. The puller cap may also include one or more hook features (not shown) to aid in the removal of the puller cap from an inserter. The hook feature may be located on any location on the puller cap, including but not limited to the top, bottom, on or near the snap, or near the distal or proximal ends. The hook feature may be of any shape or size to accommodate for the shape or size of the puller cap and may be of any shape or size to accommodate the fingers of a user.

**[0081]** The lock **95**A and **95**B may be of any design or configuration known in the art. According to an embodiment of the present invention, a portion **96** of locks **95**A, **95**B are configured and dimensioned to cam outwardly when external pressure is placed on the snaps in a perpendicular plane with respect to the longitudinal plane of system **20** from proximal end **75** to distal end **85**. (See FIG. **7**). Locks **95**A, **95**B may comprise a texture design or feature to ease gripping and/or actuation of the snaps and removal of puller cap **70** from an insertion system, such as insertion system **20** as illustrated in FIGS. **1-5** and **1**A-**4**A. In an embodiment, puller cap **70** may have one or more grips having a texture design or feature and the lock **95**A and **95**B are separated from the one or more grips, such that squeezing of the grips does not deactivate locks **95**A and **95**B.

**[0082]** As shown in FIG. **6**, the snap **90** is designed and configured to couple with pin **100** (see FIGS. **14** and **15**). Snap **90** may be of any shape or size as long as it is configured and dimensioned to mate with pin **100**. According to the embodiment in FIG. **6**, snap **90** comprises a canopy **92** and a keyway **94**. In another embodiment, snap **90** does not have a canopy and only has keyway **94**.

**[0083]** Puller cap **70** may include one or more ports **87** to aid in the insertion of a fluid, including but not limited to balanced salt solution, water, and/or viscoelastic. The one or more ports **87** mate with ports located on the insertion system **20** to assist with filling a portion of the system with fluid to provide lubrication to the internal features of the insertion system to aid in delivery of the IOL. With respect to port **87** as illustrated in FIG. **6**, port **87** acts a funnel mechanism into the distal end of delivery tube **26**. FIG. **7** illustrates a bottom view of puller cap **70** comprising port **88** and a window **89**. The puller cap may also comprise one or more windows to provide the users with a visual indicator of the amount of fluid inserted into a portion of the insertion system, as well as provide viewing of the distal end of a cannula tip, which is typically used to inject a fluid. In an embodiment, the one or more windows may be located on the top, bottom or sides of the puller cap, preferably on the top or the bottom. The one or more windows may also comprise a measuring devise such as a ruler to allow a user to measure or see the amount of fluid inserted into the inserter. The window **89** may also have a fill indicator **99** such that a user fills a portion of the insertion system until the fluid reaches fill indicator **99** indicating a proper and/or maximum fill has been reached. The one or more windows may also comprise a material such that when a fluid is inserted into the insertion system and viewed through the window light that is emitted through the window to the fluid is polarized providing a visual indicator of the fluid within the inserter.

**[0084]** As is well known in the art, the small nature of the ports of insertion systems known in the art can make it very difficult for doctors, nurses, and/or staff to locate openings for inserting fluids. The puller cap of the present invention

solves this problem by providing a larger port with a funnel feature that leads into the smaller ports of the insertion system. This enables a user to more easily direct a cannula tip **101** into a delivery tube **26** or ports **87**, **88** as illustrated in FIGS. **8** and **9**.

**[0085]** Pin and Haptic Sweep Slot

**[0086]** FIGS. **14**A-E shows pin **100** which includes top **105**, stem **107**, key **109**, and lock **113**. Top **105** comprises key **109** that may be of any shape or configuration so as to mate with snap **90**. Lock **113** may be of any shape or size and is configured to mate with grove **115** of haptic sweep slot **117** of cover **54** (see FIG. **16**). Lock **113** may also be located anywhere along stem **107** and the present invention also envisions more than one lock feature. Haptic sweep slot **117** may also be of any shape or size as long as it is configured to mate with pin **100**. According to an embodiment, haptic sweep slot **117** runs along the same longitudinal axis of system **20**. In an embodiment, the length of the haptic sweep slot is longer in length than the width the slot. In an embodiment, the length of the haptic sweep slot is between about 0.150 inches (in.) (3.81 millimeters (mm)) to about 0.170 in. (4.318 mm), preferably about 0.153 in. (3.8862 mm), more preferably about 0.165 in. (4.191 mm). In an embodiment, the width of the haptic sweep slot is about 0.028 in. (0.7112 mm) to about 0.040 in. (1.016 mm), preferably about 0.030 in. (0.762 mm), more preferably about 0.035 in. (0.889 mm). Pin **100** is configured and dimensioned to be inserted into haptic sweep slot **117** such that lock **113** and groove **115** are coupled together securing the two parts together, but still enabling the pin **100** to move within haptic sweep slot **117**. Groove **115** may also be of any shape or size as long as it is configured to mate with lock **113**. In an embodiment, there may be more than one groove in the haptic sweep slot. Groove **115** enables pin **100** to maintain a substantially perpendicular orientation with respect to the longitudinal axis of system **20**. According to an embodiment, the substantially perpendicular orientation assists with sweeping or folding of trailing haptic **36** as further described below.

**[0087]** Pin **100** may comprise leg feature **125** (see FIGS. **14**A-**14**E); such that pushrod **61** is capable of passing step **107** once pin **100** has been advanced forward to sweep trailing haptic **36**. The leg feature **125** results in stem **107** having a cut out or offset portion as shown in FIGS. **14**A, B, C and E. To ensure that this leg feature **125** is in the correct orientation during manufacture, lock **109** may comprise a one-way directional snap feature or poke-oke as illustrated in an embodiment in FIGS. **14**C and D.

**[0088]** In an embodiment, pin **100** is configured and dimensioned to penetrate or extend through cover **54** and base **50** or another portion of system **20** or similar device to sweep or fold a trailing or leading haptic or similar feature of an IOL.

**[0089]** Puller Cap and Pin Function

**[0090]** As shown in FIGS. **10** and **15**, as puller cap **70** is placed on system **20** to cover cartridge **28** and delivery tube **26**, snap **90** mates or couples with pin **100** via key **109** and keyway **94**. See FIG. **15**A for a cross-sectional view showing pin **100** coupled with snap **92** in keyway **94** and lock **113** coupled with groove **115**. In addition to the functions described above, puller cap **70** with pin **100** function to fold or sweep the trailing haptic **36** in the distal direction prior to folding or moving the IOL in the distal direction to insert the IOL into the eye. Folding or sweeping trailing haptic **36** in the distal direction controls the location of the haptic and prevents damage to the haptic during delivery of the IOL. Pin **100** may also sweep the trailing haptic **36** over a portion of optic **32** such that during movement of the IOL down the lumen of tube **26** at least a portion of the trailing haptic **36** is captured in the fold or folds of the optic **32**. Prior to the present invention a user would have to manually use the distal end of a cannula to fold or sweep the trailing haptic, which was difficult to do due to the small nature of the slot. Moreover, it was difficult to visualize whether the haptic was in fact in place once the cannula moved the haptic. The present invention overcomes these problems. Once puller cap **70** is coupled with pin **100** a user may use the easy to access one or more ports **87**, **88** to insert/inject fluid into system **20**. Next, to sweep trailing haptic **36** a user may grasp and squeeze locks **95**A, **95**B to release the internal lock features, e.g. portion **96** of lock **95**A, B from wings **27**. As puller cap **70** is advanced distally from system **20** along the longitudinal axis of system **20** pin **100** slides along haptic sweep slot **117** and lock **113** slides in groove **115** as shown in FIG. **16**. When pin **100** reaches the end of haptic sweep slot **117**, pin **100** will release from snap **90**, releasing puller cap **70** from system **20** as shown in FIG. **17**. At this point, trailing haptic **36** has been swept or folded into the proper position without the use of another tool and the IOL is now ready for insertion into the eye.

**[0091]** In an alternate embodiment, pin **100** may release from cover **54** with puller cap **70**. It is also envisioned that pin **100** may be connected to one or more arms and one or more hinges to aid in its connection to puller cap **70** and its release from system **20**. FIG. **18**A shows such an alternate embodiment of the present invention. In FIGS. **18**A-D, pin **100** is connected to arm **123** which is connected to arm **124** via hinge **122**. Arms **123** and **124** may further be coupled with puller cap **70** with hinge **126** and **127** (as shown in FIGS. **18**C and **18**D) or by any other mechanism known in the art. As puller cap **70** is moved distally along the longitudinal axis of system **20** to sweep trailing haptic **36** pin **100** is advanced along haptic sweep slot **117**. When pin **100** reaches the end of haptic sweep slot **117**, further advancement of puller cap **70** causes arm **124** to lift up thereby lifting arm **123** and lifting pin **100** from haptic sweep slot **117** and releasing puller cap **70** from system **20**. In an embodiment, haptic sweep slot **117** may comprise a ramp at one or both ends of the slot. In particular, a haptic sweep slot **117** may comprise a ramp at the distal end **121** of the slot to aid in the release of pin **100** and/or puller cap **70** after trailing haptic **36** has been swept or folded. According to another embodiment, only a single arm or a single hinge may be used with pin **100**. In another embodiment, one or more arms or one or more hinges may used with pin **100**.

**[0092]** In an embodiment, pin **100** maintains trailing haptic **36** in the proper orientation for delivery and even if a user decides to place puller cap **70** back onto system **20**, the internal features of system **20** still maintain trailing haptic **36** in the proper orientation. This allows a user to determine when she would like to use and/or the order in which she will use the haptic sweep feature, the port features, and the tip protection feature, which will be described further below.

**[0093]** Pushrod

**[0094]** FIG. **19**A illustrates a pushrod capable of being used with the system **20**. Pushrod **61** comprises a top jaw **63** and a bottom jaw **64** that form mouth **67**. Top jaw **63** may also comprise a lip **65** that protrudes from an upper portion

**66** of top jaw **63**. In an embodiment, lip **65** is configured and dimensioned to help catch trailing haptic **36** and keep trailing haptic **36** in a swept/folded configuration. FIG. **19**D illustrates an exemplary pushrod of the present invention modifying the features of FIG. **19**A. In FIG. **19**D a portion of the distal end of pushrod **61** is removed resulting in cutout portion or notch **68** to allow room for the IOL as it is folded and/or compressed during insertion of the IOL into an eye. The cutout portion **68** of pushrod **61** provides for less force on the walls of delivery tube **26** and less force on the IOL as it delivered preventing damage to the IOL and delivery tube **26**. In an embodiment, cutout portion **68** comprises approximately half the diameter of the top jaw **63** for a portion of the distal end including the lip **65**, while bottom jaw **63** remains intact. Cutout portion **68** may extend proximally beyond top jaw **63** into the body of pushrod **61**. In an embodiment, a notch or cutout portion may also extend or be placed into bottom jaw **64**. It is also envisioned that an additional notch or cutout similar to notch **68** can be made on the opposite side of top jaw **63**. Bottom jaw **64** may also have one or more notches. In an embodiment, a cross-section view of cutout portion **68** shows an L-shaped seat (see FIG. **20**).

**[0095]** In an embodiment, lip **65** is configured to ride along at least a portion of an internal channel or groove located within handpiece **22**. Lip **65** provides more stability for the pushrod **61** as it is advanced within a lumen of the handpiece **22** towards the distal end of the handpiece. By having the lip **65** engage at least a portion of the internal channel, the distal end of the pushrod is less likely to move from its desired location within the lumen as the pushrod is advanced towards the distal end of the handpiece.

**[0096]** According to an embodiment, the distal end of pushrod **61** may have a top jaw **63** and a bottom jaw **64** that form mouth **67** as illustrated in FIGS. **19**E-**19**H. As shown in FIG. **19**E, top jaw **63** is shorter in length than bottom jaw **64** and includes cutout portion **68**. For such an embodiment sweeping of the trailing haptic by pin **100** or another means is unnecessary because the design of the distal end of pushrod **61** causes the trailing haptic of an IOL to be swept or folded over the optic as the pushrod assembly **60** travels down the lumen of the insertion system towards the distal end of the delivery tube. In an embodiment, the top jaw is designed to engage the trailing haptic of an IOL before the bottom jaw engages the lens body or edge of the optic. In an embodiment, the height of the top jaw is such that it configured to couple with at least a portion of an internal channel of the handpiece, preferably the top jaw is configured to couple with at least a portion of an internal channel located in the staging area, more preferably the top jaw is configured to couple with an internal channel extending through the staging area. In another embodiment, the blunt tip may a height that is larger than the height of a haptic, e.g. a trailing haptic.

**[0097]** In an embodiment, the distal end of pushrod **61** may comprise another cutout portion **69** on the opposite side of the first cutout portion. The second cutout portion **69** may also provides for less force on the walls of delivery tube **26** and less force on the IOL as it delivered preventing damage to the IOL and delivery tube **26**. For example, as the IOL is advanced down the delivery tube, the IOL is compressed. The second cutout portion **69** provides space for an edge of the IOL to wrap around the top jaw **63** and tuck into the second cutout portion **69**. The second cutout portion may be shorter or longer in length than the first cutout portion **68**, preferably shorter than the first cutout portion **68**. The width of the second cutout portion may be larger or smaller than the width of the first cutout portion, preferably small that the width of the first cutout portion. The second cutout portion **69** may create a substantially L-shaped seat. In an embodiment, a notch or cutout portion may also extend or be placed into bottom jaw **64**. It is also envisioned that an additional notch or cutout similar to cutout portion **68** and **69** can be made on one or both sides of bottom jaw **64**.

**[0098]** Similar to the lip **65** discussed above, in an embodiment, the top jaw **63** illustrated in FIGS. **19**E-**19**H is configured to ride along at least a portion of an internal channel or groove located within handpiece **22**. Coupling of the top jaw **63** with at least a portion of an internal channel provides more stability for the pushrod **61** as it is advanced within a lumen of the handpiece **22** towards the distal end of the handpiece. By having the at least a portion of top jaw **63** engage at least a portion of the internal channel, the distal end of the pushrod is less likely to move from its desired location within the lumen as the pushrod is advanced towards the distal end of the handpiece. The forces generated by moving the IOL down the lumen of the staging area and/or lumen of the cartridge can have a tendency to push or offset the distal end of the pushrod. Coupling the top jaw **63** with at least a portion of the internal channel or groove helps to counter this movement and maintain the distal end of the pushrod in proper alignment, e.g. maintaining the distal end of the pushrod substantially on center of the lumen of the handpiece. In an embodiment, the internal channel or groove runs the length of the staging area.

**[0099]** In an embodiment, the top jaw **63** may have a blunt tip **71** and a rounded top portion **74**. The blunt tip **71** sweeps or folds the trailing haptic of an IOL over the optic as the pushrod assembly **60** travels down the lumen of the insertion system towards the distal end of the delivery tube. The top jaw **63** and the bottom jaw **64** may have a rounded leading edge **76**. Rounding the leading edge prevents damage to an IOL as it is moved down the lumen of an insertion system.

**[0100]** In an embodiment, pushrod **61** has a tapered portion around the circumference of the pushrod starting at or near the back of mouth **67** and extends a long a length of the pushrod. In an embodiment, the tapered portion extends approximately **2**/**3** the total length of pushrod **61**. As shown in FIG. **19**F, beginning at or proximally near the back of the mouth **67**, the diameter of the tapered portion gradually gets smaller until approximately the midline of the tapered portion and then begins to gradually get larger until it reaches the largest diameter of the pushrod **68**. The smallest diameter of the tapered portion may occur at the halfway point of the entire length of the tapered portion. In an embodiment, the smallest diameter occurs beyond the halfway point of the entire length of the tapered portion in the proximal direction. The length of the tapered portion may be between about 0.280 in. (7.122 mm) and about 0.325 in. (8.255 mm). The diameter of the pushrod at its largest diameter may be between about 0.080 in. (2.032 mm) and about 0.060 in. (1.524 mm), preferably 0.070 in. (1.778 mm); and the smallest diameter of the tapered portion may be between about 0.045 in. (1.143 mm) and about 0.060 in. (1.524 mm). The tapered portion provides for space and/or allows for a trailing haptic to wrap around the pushrod

should the haptic not fold over the optic, which prevents the IOL from being damaged or broken off from the rest of the IOL.

**[0101]** In an embodiment, cutout portion or notch **68** may extend into a portion of the tapered portion. Cutout portion **68** is designed as a safety feature to (1) provide space for the folding IOL as it is advanced down a tapered lumen; (1) allow for a trailing haptic to wrap around the pushrod and/or guide the trailing haptic around the tapered portion should the haptic not fold over the optic; (3) allow for extension of a trailing haptic that does not get folded; and/or (4) allow space for shoulder or bend that is created near the optic-haptic junction when the trailing haptic is folded over the optic, which prevents the IOL from being damaged or broken off from the rest of the IOL. In an embodiment, the cutout portion **68** may have a length between about 0.150 in. (3.81 mm) and about 0.300 in. (7.62 mm), a height between about 0.030 in. (0.762 mm) and about 0.050 in. (1.27 mm), and a width between about 0.040 in. (1.016 mm) and about 0.065 in. (1.651 mm). The length of the cutout portion **68** may also be longer or shorter than the full extension of an IOL haptic. Cutout portion **68** may begin at or near the tip of pushrod **61** or at or near the back of the mouth **67** and continue a length of the pushrod **61**. The cutout portion **68** may continue a length of the pushrod **61** with its width gradually tapering out or becoming smaller until it meets the side of the pushrod (see FIG. **19**G).

**[0102]** The features of pushrod **61** as shown in FIGS. **19**A-**19**D may have various dimensions. The length of the cutout portions **68** may be between about 0.145 in. (3.683 mm) to about 0.165 in. (4.191 mm), preferably between about 0.149 in. (3.7846 mm) to about 0.160 in. (4.064 mm), more preferably about 0.149 in. (3.7846 mm) or about 0.160 in. (4.068 mm). The width of upper portion **66** of top jaw **63** may range from about 0.015 in. (0.381 mm) to about 0.030 in. (0.762 mm), preferably about 0.023 in. (0.5842 mm). The diameter or width A of cutout portion **68** as shown in FIG. **20** may be between about 0.015 in. (0.381 mm) to about 0.025 in. (0.635 mm), preferably about 0.019 in. (0.4826 mm). According to an embodiment, the diameter A of cutout portion **68** may be inversely proportional to the width of the upper portion **66** of top jaw **63**. The height of lip **65** that protrudes up may be between about 0.003 in. (0.0762 mm) to about 0.012 in. (0.3048 mm), preferably about 0.006 in. (0.1524 mm). In an embodiment, there may be a radius on the back side of lip **65** where lip **65** and upper portion **66** meet. The radius may be sharp to 0.010R. In an embodiment, the radius of mouth **67** that engages a lens may range between 0.012R-0.020R, preferably about 0.014R. The length of top jaw **63** and the bottom jaw **64** from the back of mouth **67** may be between about 0.045 in. (1.143 mm) and about 0.070 in. (1.778 mm). In an embodiment the length of top jaw **63** is preferably about 0.054 in. (1.3716 mm). The top jaw length may have a relationship (ratio) to the bottom jaw which is about 1.3 to 1 (Top to Bottom). In an embodiment, the relationship may be 1 to 1 or 1 to 1.3 (Top to Bottom).

**[0103]** The features of pushrod **61** as shown in FIGS. **19**E-**19**H may have various dimensions. The length of the cutout portions **68** may be between about 0.150 in. (3.81 mm) to about 0.300 in. (7.62 mm), preferably between about 0.190 in. (4.826 mm) to about 0.250 in. (6.35 mm), more preferably about 0.190 in. (4.826 mm). The diameter or width of cutout portion **68** as shown may be between about 0.020 in. (0.508 mm) to about 0.030 in. (0.762 mm), preferably about 0.025 in. (0.635 mm). In an embodiment, the radius of mouth **67** that engages a lens may range between 0.010R-0.018R, preferably about 0.013R. The width of the top jaw may be between about 0.020 in. (0.508 mm) and about 0.030 in. (0.762 mm) and the width of the bottom jaw may be between about 0.060 in. (1.524 mm) and about 0.040 in. (1.016 mm). The top jaw may be offset from a centerline along the longitudinal axis of the pushrod. The top jaw length may have a relationship (ratio) to the bottom jaw which is about 1 to 2 (Top to Bottom). In an embodiment, the relationship may be 1 to 1 or 1 to 1.3 (Top to Bottom). The width of the top jaw may have a relationship to the width of the bottom jaw which is about 1 to 2 (Top to Bottom). In an embodiment, where the top portion of the top jaw meets the side wall of the notch, the radius of curvature or blending may be about 0.010R. Also, in another embodiment the length of the notch may be about 60% of the total length of the pushrod.

**[0104]** Pushrod Flex Tip

**[0105]** As discussed above, FIG. **5** shows an exploded view of pushrod assembly **60** which comprises pushrod **61**, plunger **24**, and nut lock **102**.

**[0106]** According to an embodiment of the present invention, pushrod **61** comprises distal tip **62** at the distal end of pushrod **61** that has a top jaw **63** and a bottom jaw **64**, which is shown in FIG. **19**A. Top jaw **63** of distal tip **62** is capable of flexing toward bottom jaw **64** shown by arrow "B" to allow the distal tip **62** (or distal end) of pushrod **61** to pass through the tapered lumen of delivery tube **26**. Top jaw **63** may comprise a lip **65** that protrudes from an upper portion **66** of top jaw **63** and is capable of making contact with the lumen of delivery tube **26**. FIG. **19**B illustrates lip **65** coming in contact with the lumen **70** of delivery tube **26** and top jaw **63** flexing toward bottom jaw **64**. Lip **65** may make continuous or substantially continuous contact with the lumen of delivery tube **26** while pushrod **61** is moved longitudinal through delivery tube **26** to eject the IOL out the distal end of the delivery tube. FIG. **19**C illustrates that once lip **65** of top jaw **63** exits delivery tube **26** at the distal end, top jaw **63** will flex substantially back into its original position. Lip **65** can be any configuration or shape that will allow for the flexing of top jaw **63** toward bottom jaw **64**. Preferably top jaw **63** is slightly longer or longer than bottom jaw **64** to prevent the IOL from being captured between the two jaws and held after the IOL exits from the delivery tube. According to an embodiment, bottom jaw **64** may remain substantially stationary with respect to the rest of pushrod **61**. In an embodiment, the flexible top jaw **63** allows for further folding of the trailing haptic of the IOL over the optic during implantation of the IOL. The distal tip keeps the trailing haptic in a stable position.

**[0107]** In an embodiment, lip **65** may be located on the bottom jaw **64** depending upon the geometry of the IOL and/or haptic. For example, if instead of the trailing haptic being in a "C" configuration if you look at the IOL in an insertion device from the top, the trailing haptic is in reversed "C" configuration, the lip **65** may function better or properly if it is located on the bottom jaw **64**.

**[0108]** In an embodiment, the bottom jaw **64** may also flex or be capable of flexing toward top jaw **63** to allow the distal tip (or distal end) of pushrod **61** to pass through the tapered lumen of delivery tube **26**. It is also envisioned that both the

top jaw **63** and bottom jaw **64** flex towards each other as the pushrod **61** is passed through the tapered lumen of delivery tube **26**.

**[0109]** Tip Protector

**[0110]** An advantage of puller cap **70** is it acts as a tip protector to prevent damage or deformation. As illustrated in FIG. **21**, a certain amount of clearance or space is provided around the distal end of delivery tube **26** when puller cap **70** is placed onto system **20**. The clearance or space **130** is maintained by contact between the internal structures of puller cap **70** at the proximal end and system **20**. In an embodiment, clearance or space **130** between delivery tube **26** and the distal end of puller cap **70** is maintained by contact between wall **98** through window **97** shown in FIG. **15** and wings **27** and portion **96** of lock **95**A, B shown in FIG. **7**. It is also envisioned that other similar structures may be used to maintain clearance **130** to protect the tip of delivery tube **26**.

**[0111]** Protective Cap

**[0112]** FIGS. **22**A-G, **23**A-B, **24**, **25**, and **26** illustrate a protective cap **200** of the present invention. Protective cap **200** has similar advantages of puller cap **70** of protecting the tip from damage or deformation. Protective cap **200** may be used instead of puller cap **70** when the trailing haptic is swept or folded by means of the pushrod or the trailing haptic does not require sweeping or folding. Protective cap **200** comprises finger grips **280**, window **289**, and port **287**. Protective cap **200** may also comprise one or more of the following: clips (or snaps) **220**, relief slots **225**, and/or guides **235**. Protective cap **200** may also comprise a fill indicator **255** and/or a material relief **265**.

**[0113]** Protective cap **200** may be made of any material known in the art, preferably polypropylene, polycarbonate, polyethylene, or polyethylene terephthalate; more preferably polypropylene and polycarbonate; most preferably polypropylene. Protective cap **200** may also be of any color, preferably translucent or clear to enable a user to visualize the features inside protective cap **200** and anything housed within protective cap **200**. Protective cap **200** may be the shape as illustrated in the embodiment in FIGS. **22**A-G, but the invention also envisions that protective cap **200** may be of any shape or size to accommodate the needs of the insertion system the protective cap is used with or the needs of the user the puller cap is designed for. For example, the protective cap may be of an arrow shape as illustrated in the embodiment in FIG. **22**B, may be more of a round shape, triangular shape, square shape, or shaped to meet the needs for shipping or handling.

**[0114]** The finger grips **280** may be of any design or configuration known in the art. According to an embodiment of the present invention, finger grips **280** may comprise a texture design or feature to ease gripping or actuation of the clip **220** and removal of protective cap **200** from an insertion system, such as system **20** as illustrated in FIGS. **1**-**5** and **1**A-**4**A. The protrusion **282** of finger grips **280** may also be of any shape, including but not limited to square, rounded, triangle, and any other shape known in the art that may assist in grasping protective cap **200**. Finger grips **280** may have inner walls that are sized and shaped to couple with at least a portion of the wings **27** that run along the longitudinal axis of cartridge **28**. The inner walls are configured and dimensioned to avoid damaging the distal end of the tip of the delivery tube **26** when protective cap **200** is placed on the insertion device. In an embodiment, finger grips **280** may have a radius of curvature that is similar to or mirrors the curvature of a user's finger to assist with gripping and removal of the protective cap **200**.

**[0115]** In an embodiment, protective cap **200** comprises tapered portion **245** (shown in FIGS. **22**B, **22**G, **25**, and **26**). Tapered portion **245** may be configured and dimensioned to mirror or substantially mirror the shape and size of the cartridge and/or insertion device. In an embodiment, tapered portion **245** comprises a bevel **247** which mirrors bevel **23** (shown in FIGS. **2**, **2**A, and **5**). The internal and external walls of tapered portion **245** may also remain uniform or substantially uniform with respect to each other from the beginning of the tapered portion to at or near the distal end of cartridge such that the walls run parallel to each other. It is also envisioned that the internal walls of the tapered portion mirror the external features of the cartridge or distal end of the insertion device and the external walls of the tapered portions remain substantial linear, for example without a bevel.

**[0116]** As shown in FIG. **24**, the distal end **285** of protective cap **200** may comprise internal bevel **270**. Internal bevel **270** is configured and dimensioned to match or substantially match or mate with the bevel of the tip (at the distal end) of delivery tube **26** of cartridge **28**. When protective cap **200** is placed on system **20**, internal bevel **270** is coupled with the bevel of the tip of delivery tube **26** of cartridge **28** and port **287**, and with its funnel feature it creates a larger opening. As discussed above, the small nature of ports can make it very difficult for doctors, nurses, and/or staff to locate openings for inserting fluids. Port **287** with internal bevel **270** enables a user to more easily direct a cannula tip **101** into a delivery tube **26** or port **87** as illustrated in FIG. **8**.

**[0117]** As illustrated in FIGS. **22**A, C, E, and G, the distal end of protective cap **200** may also comprise a material relief **265**. Material relief **265** helps prevent distortion of the tip at the distal end of protective cap **200** during the molding process. It is also envisioned, that the distal end of the protective cap **200** does not comprise a material relief.

**[0118]** As illustrated in FIG. **23**A, protective cap **200** may also have inner walls comprising one or more internal guides **235** that run along at least a portion of the longitudinal axis and are configured and dimensioned to mate or couple with features on the outer portions of the insertion device. Internal guides **235** help keep the protective cap substantially aligned in a horizontal and vertical direction when the cap is placed on or removed. This helps to protect the distal end or tip of cartridge **28** or insertion system **20**. The internal guides **235** may be of any width or of any length suitable to couple with external features of the insertion system and/or cartridge. According to an embodiment, there may be two internal guides on the internal wall of the protective cap along the longitudinal axis, and the distance between each of the guides may be any distance as long as it matches the external features on the insertion system. In an embodiment, the distance between the guides may be about 0.374 in. (9.4996 mm) apart. The width of a guide may be between about 0.023 in. (0.5842 mm) and about 0.028 in. (0.7112 mm), preferably about 0.025 in (0.635 mm). In an embodiment, the length of a guide may be between about 0.318 in. (8.0772 mm) to about 0.386 in. (9.8044 mm). The length of a guide may also be between about 0.318 in. (8.0772 mm) and about 0.328 in. (8.3312 mm), preferably about 0.323 in. (8.2042 mm) The length of the guide may also be between about 0.376 in. (0.5504 mm) and 0.386 in. (9.8044 mm),

preferably about 0.381 in. (9.6774 mm) In another embodiment, one or more guides may begin at or near the distal end of relief slot **225** (see FIG. **23**A) and extend for a distance toward the distal end of the protective cap.

**[0119]** As discussed above, the small nature of ports can make it very difficult for doctors, nurses, and/or staff to locate openings for inserting fluids. The protective cap **200** of the present invention solves this problem by providing a larger port **287** with a funnel feature that leads into the smaller port of the insertion device. This enables a user to more easily direct a cannula tip **101** into a delivery tube **26** or port **87** as illustrated in FIG. **8**. The protective cap may also include one or more additional ports.

**[0120]** Protective cap **200** may also have one or more windows **289** to provide the users with a visual indicator of the amount of fluid inserted into the insertion system, as well as provide viewing of the distal end of a cannula tip. The one or more windows may be located on the top, bottom or sides of the protective cap, preferably on the top or the bottom. The one or more windows may also comprise a measuring devise such as a ruler to allow a user to measure the amount of fluid inserted into the inserter. The one or more windows may also comprise a material such that when a fluid is inserted into the inserter and viewed through the window light that is emitted through the window to the fluid is polarized providing a visual indicator of the fluid within the inserter. The window **289** may also comprise a fill indicator **255** to provide a maximum fill line.

**[0121]** In order to secure protective cap **200** to an insertion system, such as the system **20** shown in FIGS. **1** and **1**A, clip **220** may be used. Clip **220** is configured and dimensioned to mate with a distal portion of wings **27** of cartridge **28** (cartridge **28** is shown in FIG. **5**). In an embodiment illustrated in FIG. **25**, relief slots **225** of protective cap **200** couple with the vertical elements **29** (shown in FIG. **5**) of wings **27** of cartridge **28**. Relief slots **225** may be of any shape or size to couple with the shape or size of the vertical elements **29**. Clip **220** may also extend beyond the proximal end of finger grips **280** as illustrated in FIG. **22**B.

**[0122]** In an embodiment, when the protective cap **200** is placed on the distal end of the system **20**, clips **220** act as a cantilever snap by riding along the vertical elements **29** of the wings **27** of cartridge **28** until the clips **220** are over center and then snapping down over the end of the wings **27**. In an embodiment, the clip **220** is not located on the grip **280** to allow for easier removal of the protective cap. It is also envisioned that clip **220** may be located or coupled with the grip **280** depending upon the design and/or function of the clip **220** and whether the grip **280** is an extension of the clip **220**.

**[0123]** FIGS. **27**A-F and **28**A-F illustrate additional embodiments of a protective cap with similar features as shown in FIGS. **22**A-**22**G, **23**A-**23**B, and **24**. FIGS. **29**A-F and FIGS. **30**A-F illustrate additional embodiments of a puller cap with similar features as shown in FIGS. **6-13**.

**[0124]** Plunger Marker

**[0125]** As illustrated in FIGS. **31**A and **31**B, plunger **24** may comprise a marker or indicator **310**. As discussed above, the plunger **24** and/or pushrod **61** (pushrod assembly **60**) translates axially through an elongate passage defined within the inserter handpiece **22** and is configured to urge the IOL from a holding station **30** through the distal delivery tube **26**. In an embodiment, system **20** may operate in a push and/or twist fashion. With a push and twist mechanism, the plunger **24** may first be advanced axially along the longitudinal axis to a predetermined point and then the plunger **24** may be rotated for further advancement. Such a further advancement via rotation may provide additional control in the delivery of the IOL. In such a scenario, it would be helpful to provide an indication of when the axial translation of the plunger **24** or pushrod assembly **60** has reached the predetermined point. In such an embodiment, a marker **310** is placed on plunger **24** such that when the plunger **24** is advanced or displaced along the longitudinal axis of the system **20** a user will be able to visualize that the plunger has reached the predetermined point when marker **310** lines up with the proximal end **320** of handpiece **22** (see FIG. **31**B) or disappears within handpiece **22** (see FIG. **31**C). Marker **310** may be placed on any location on plunger **24** and may be of any shape, size or color. The predetermined point may be the proximal end **320** as described in the above embodiment, but it is also envisioned to be any location along the handpiece **22**. This may be possible if handpiece **22** is made of a translucent or transparent material such that marker **310** is visible through handpiece **22**.

**[0126]** Pushrod Supports

**[0127]** According to an embodiment, the present invention provides one or more guide rails to provide support for the pushrod on the distal end of the inserter body. FIG. **32** shows a cross-sectional view of insertion system **20** with pushrod **61** and handpiece **22**. According to an embodiment, pushrod **61** may comprise one or more guide rails **395**, preferably a guide rail on opposite sides of pushrod **61**. To mate with guide rails **395**, one or more channels **396** on the upper and/or lower portions of lens holding station **30** may be included. The top and/or bottom channels **396** may be of any shape to mate with the shape of the one or more guide rails. Preferably the guide rails and channels are substantially rectangular in shape. Preferably, the lower channel is wider than the upper channel, although the width of the channels can be of any size and the channels can be of any shape. The guide rails on the pushrod mate to the channels and may have substantially the same shape. The guide rails may be on any portion of the pushrod and may make up any percentage of the pushrod. The channels may be located on other locations of the handpiece **22**, including but not limited to base **52** and/or delivery tube **26**.

**[0128]** According to an embodiment, it is also envisioned that one or more guide rails may be located on the handpiece **22** and corresponding channels may be located on the pushrod **61**. In an embodiment, the channels may be located a long a portion of the pushrod **61** and may be found on any location around the circumference of the pushrod. The one or more guide rails may be located anywhere within the handpiece such that the guide rails are configured and dimensioned to mate with the one or more channels located on the pushrod **61**.

**[0129]** Nut Lock

**[0130]** In insertion systems, advancing an IOL through a delivery tube involves a significant amount of force. To allow for advancement of an IOL from a lens storage area/holding station to a loading area the same mechanism described above can be used. For ease of use a pushing mechanism may be used to advance a lens from a storage/holding station into a delivery tube for insertion and then the same mechanism can be used to insert the IOL using a twisting mechanism. To allow for the push and twist and accommodate the high amount of force, the present inven-

tion incorporates a nut lock to prevent the pushrod from moving proximally as the pushrod is rotated to move the IOL distally.

**[0131]** FIG. **33** illustrates an embodiment of the present invention. Nut lock **102** may have an internal thread of a load bearing quality. Nut lock **102** may be cylindrical in shape and have a centrally located groove **401** that allows interlock and/or detent with external/internal features of handpiece **22**. On the distal portion of nut lock **102** there may be a series of radial keyways **402** that are capable of mating with keys (not shown) protruding inward from handpiece **22** that prevent it from counter rotating. Nut lock **102** may be made of any material known in the art, including but not limited to plastic, metal, and ceramic. Nut lock **102** may be coupled with the plunger **24** via load bearing threads and is sandwiched between plunger **24** and pushrod **61**, which may be snapped together or coupled together in any way known in the art.

**[0132]** According to an embodiment, nut lock **102** may comprise a single lead thread, but may comprise more (multiple). Nut lock **102** may also have varying thread pitch.

**[0133]** According to an embodiment, when the insertion system is delivered to a physician's office, pushrod assembly **60** is in a first position. In this first position, the pushrod assembly **60** is in its most proximal position and groove **401** of nut lock **102** mates with one or more proximal detents **407** located at or near the most proximal end of handpiece **22** and prevents accidental movement of pushrod assembly **60**. At this point, plunger **24** can be rotated in any direction without causing longitudinal movement of pushrod **61**. When the pushrod assembly is moved into a second position between the most proximal detent **407** and a second distal detent **406**, pushrod assembly **60** is movable in a longitudinal direction between detents, but rotation of plunger **24** in any direction does not longitudinally move pushrod **61**. When pushrod assembly **60** is moved distally in a longitudinal direction to a third position, wherein groove **401** of nut lock **102** mates with one or more distal detents **406** (second detent position) (see FIG. **33**A), pushrod assembly **60** is prevented from further distal or proximal movement by pushing or pulling on end cap **40**. Once in the second detent position, the pushrod assembly cannot be pulled from this position back to the first proximal position. At this point the only way to advance pushrod **61** longitudinally to insert the IOL is to rotate plunger **24** via end cap **40** in either a clockwise or counter-clockwise direction (depending upon the configuration of the threads). This is to prevent reuse of a one time use insertion system and/or improper activation of the pushrod.

**[0134]** The detents are one way snaps (cantilever snaps) that provide the strength to prevent the pushrod assembly **60** from being pulled back from the second detent **406** (see FIG. **33**A). The proximal detent(s) **407** also provide biasing for the proximal end of the plunger **24** as it is advanced longitudinally or rotated and provide a little resistance (see FIG. **33**B). The proximal detents **407** may be the same or similar to the second detent **406**. The proximal detents **407** may have a different configuration or shape from the second detent **406**. The detents may be of any shape or size suitable for its function.

Safety Detent for Plunger Threads

**[0135]** According to an embodiment, to help prevent advancing the pushrod with rotation of plunger **24** until desired, detents **405** are added to the plunger. Detents **405** are located on the distal end or portion of plunger **24**. According to an embodiment, the detents are located within the first two to three threads of plunger **24**. FIG. **34** illustrates detents **405** at the distal end or portion of plunger **24**. The number of detents can range between 1-6, preferably 4.

**[0136]** All references cited herein are hereby incorporated by reference in their entirety including any references cited therein.

**[0137]** The above presents a description of the best mode contemplated of carrying out the present invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use this invention. This invention is, however, susceptible to modifications and alternate constructions from that described above which are fully equivalent. Consequently, it is not the intention to limit this invention to the particular embodiments disclosed. On the contrary, the intention is to cover modifications and alternate constructions coming within the spirit and scope of the invention as generally expressed by the following claims, which particularly point out and distinctly claim the subject matter of the invention.

**1**. A cap, comprising:
a body having a distal end and a proximal end;
a window; and
a port located at the distal end of the cap;
wherein the cap is configured and dimensioned to couple with a distal end of an insertion system.

**2**. The cap of claim **1**, wherein the window comprises a fill indicator.

**3**. The cap of claim **1**, wherein the window is located on a bottom of the cap and wherein the window runs along at least a portion of a longitudinal axis of the cap.

**4**. The cap of claim **1**, wherein the cap further comprises an internal bevel inside the cap at the distal end, wherein the internal bevel is configured and dimensioned to couple with a bevel at the distal end of an insertion system.

**5**. The cap of claim **1**, wherein the cap further comprises at least two finger grips along at least a portion of a longitudinal axis of the cap and wherein the finger grips are located on opposite sides of the cap.

**6**. The cap of claim **1**, wherein the port comprises a funnel shape and is configured and dimensioned to couple with a lumen at a distal end of an insertion system to enable insertion of a fluid into the lumen of the insertion system.

**7**. The cap of claim **1**, wherein the distal end of the cap comprises a material relief to prevent distortion of a tip at a distal end of the cap during manufacturing of the cap.

**8**. The cap of claim **1**, wherein one or more internal walls of the cap comprise one or more internal guides that run along at least a portion of a longitudinal axis of the cap, wherein the one or more internal guides are configured and dimensioned to couple with features on an outer portion of an insertion device.

**9**. The cap of claim **8**, wherein the cap comprises two substantially parallel internal guides.

**10**. The cap of claim **1**, wherein the cap further comprises one or more clips, wherein the one or more clips are configured and dimensioned to couple with a distal end of an insertion device to secure the cap to the insertion device.

**11**. The cap of claim **10**, wherein the one or more clips are configured and dimensioned to act as a cantilever snap and couple with one or more wings of a cartridge.

**12**. The cap of claim **10**, wherein the cap is made of a clear or translucent material.

**13-22**. (canceled)

**23**. An insertion system, comprising:

a handpiece having a longitudinal axis, a distal end, and a proximal end,

a pushrod assembly having a distal end and a proximal end,

wherein the push rod assembly comprises a pushrod and a plunger;

wherein the pushrod assembly couples with the handpiece along the longitudinal axis;

wherein the pushrod is coupled with the plunger and the pushrod is located on the distal end of the push rod assembly and the plunger is located on the proximal end of the pushrod assembly;

wherein the plunger comprises a marker configured and dimensioned to indicate axially translation of the pushrod assembly within the handpiece; and

a cartridge comprising a delivery tube at a distal end;

wherein the cartridge is configured and dimensioned to couple with the distal end of the handpiece.

**24**. The insertion system of claim **23**, wherein the marker is configured and dimensioned to indicate a location of a detent when the pushrod assembly is advanced toward the distal end of the handpiece.

**25**. The insertion system of claim **22**, wherein the handpiece is made of a clear or translucent material.

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