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(54) Title: OCULAR IMPLANTATION DEVICE

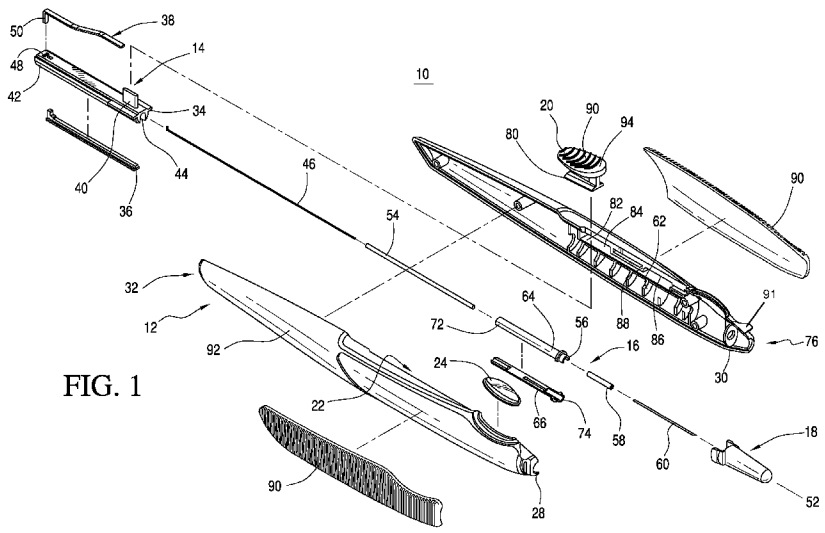


FIG. 1

(57) Abstract: An ocular implantation device comprises a housing having a longitudinal axis, a needle configured to receive an implant, and a plunger and a rod operatively coupled together. The plunger and the rod are disposed in the housing and are collectively, translationally moveable along the longitudinal axis of housing. The rod is configured to be receivable within at least a portion of the needle to enable the rod to move an implant therethrough. An actuator is operatively engaged with the plunger such that movement of the actuator in a direction aligned with the longitudinal axis of the housing results in translational movement of the plunger and the rod along the longitudinal axis of the housing in order to deliver the implant through the needle to a target site. An alternative embodiment of the device uses a retractable needle to deliver the implant.

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OCULAR IMPLANTATION DEVICE

RELATED APPLICATIONS

[0001] The present patent document claims the benefit of the filing date under 35 U.S.C. §119(e) of Provisional U.S. Patent Application Serial Nos. 60/986,464, filed November 8, 2007, and 61/075,786, filed June 26, 2008, which are hereby incorporated by reference in their entirety.

FIELD

[0002] The invention relates to a device for delivering ocular implants into the vitreous of the eye. Specifically, the invention relates to an ergonomically shaped injector containing a needle capable of puncturing the eye and delivering an implant into the vitreous of the eye.

BACKGROUND

[0003] A primary difficulty in treating diseases of the eye is the inability to introduce drugs or therapeutic agents into the eye and maintain these drugs or agents at a therapeutically effective concentration in the eye for the necessary duration. Systemic administration may not be an ideal solution because, often, unacceptably high levels of systemic dosing are needed to achieve effective intraocular concentrations thus increasing the incidence of unacceptable side effects of the drugs. Simple ocular instillation or application is not an acceptable alternative in many cases because the drug may be quickly washed out by tear-action or may otherwise be depleted from the eye into the general circulation. Suprachoroidal injections of drug solutions have been performed, but again the drug availability is short-lived. In summary, available methods make it difficult to maintain therapeutic levels of drug for adequate time periods.

[0004] Efforts to address this problem have lead to the development of drug delivery devices, or implants, which can be implanted into the eye such that a controlled amount of desired drug can be released constantly over a period of several days, weeks, or even months. Many such devices have been previously reported. See, for example, U.S. Patent No. 4,853,224, which discloses biocompatible implants for introduction into an anterior segment or a posterior segment of an eye for the treatment of an ocular condition. In addition, U.S. Patent No. 5,164,188 discloses a method of treating an ocular condition by introduction of a biodegradable implant comprising drugs of interest into the suprachoroidal space or pars plana of the eye. See also U.S. Patent Nos. 5,824,072; 5,476,511; 4,997,652; 4,959,217; 4,668,506; and 4,144,317.

Other methods include anchoring a plug or tack containing a drug into the sclera of the eye (see, e.g., U.S. Pat. No. 5,466,233).

[0005] Various sites exist in the eye for implantation of a drug delivery device or implant, such as the vitreous of the eye, anterior or posterior chambers of the eye, or other areas of the eye including intraretinal, subretinal, intrachoroidal, suprachoroidal, intrascleral, episcleral, subconjunctival, intracorneal or epicorneal spaces. Wherever the desired location of implantation, typical methods of implantation all require relatively invasive surgical procedures, pose a risk of excessive trauma to the eye, and require excessive handling of the implant. For example, in a typical method for placement in the vitreous, an incision is made through the sclera, and the implant is inserted into and deposited at the desired location in the vitreous, using forceps or other like manual grasping device. Once deposited, the forceps (or grasping device) is removed, and the incision is sutured closed. Alternatively, an incision can be made through the sclera, a trocar can be advanced through the incision and then the implant can be delivered through the trocar. Similar methods can be employed to deliver implants to other locations, e.g., implantation in the anterior chamber of the eye through an incision in the cornea.

[0006] There are numerous drawbacks of such techniques for implant delivery. Extensive handling of the implant is necessitated in these techniques, creating a risk that the implant will be damaged in the process. Many implants are polymer-based and are relatively fragile. If portions of the implants are damaged and broken-off, the effective therapeutic dose delivered by the implant once placed will be significantly altered. In addition, it becomes inherently difficult using these methods to achieve reproducible placement from patient to patient. Additionally, all of these techniques require an incision or puncture in the eye large enough to require suturing. Thus such techniques are typically performed in a surgical setting.

[0007] Many considerations affect the design and efficacy of an implant delivery device. First, it is important to ensure that the implant is consistently delivered to the subject with each application. Second, because implant therapy often requires numerous applications, the cost of providing the implant should also be considered.

[0008] Based on the foregoing, a need for a more facile, convenient, less invasive, and less traumatic means for delivering implants into the eye remains. In addition, a need for a more controlled means of delivering implants into the eye also remains.

BRIEF SUMMARY

[0009] The present invention is directed to a device and method for delivering ocular implants to desired locations in the eye. The device comprises a housing having an actuator that

is communicatively linked to a plunger. A force applied to the actuator in a direction parallel to the longitudinal axis of the housing is used to deliver the implant to the desired location of the eye. Prior to delivery of the implant, the status of the implant is visually observable to a user.

[0010] In an aspect of the invention, an ocular implantation device comprises a housing having a longitudinal axis and a needle extending from the housing, wherein a lumen of the needle is configured to receive an implant. The device further comprises a plunger longitudinally disposed within the housing and a longitudinally extending rod operatively coupled thereto. The plunger and the rod are collectively, translationally moveable along the longitudinal axis of the housing. The rod is configured to be receivable within at least a portion of the lumen. The device also comprises an actuator configured for controlled, guided movement, such movement being controlled and guided by a user and by a portion of the housing. The actuator is operatively engaged with the plunger such that movement of the actuator in a direction aligned with the longitudinal axis of the housing results in translational movement of the plunger and the rod along the longitudinal axis of the housing. Further, the actuator is capable of movement in a direction normal to the longitudinal axis of the housing that does not result in movement of the plunger and the rod.

[0011] In another aspect of the invention, an ocular implantation device comprises a housing having a longitudinal axis and a needle extending longitudinally from the housing, with the needle having a lumen extending therethrough. The needle lumen is configured to receive an implant. The device further comprises a plunger longitudinally positioned within the housing and a rod extending therefrom. The plunger and the rod are translationally moveable along the longitudinal axis of the housing from an initial position, and the rod is receivable within at least a portion of the needle lumen. The device also comprises a guide shaft that is fixedly positioned within the housing in communication with the needle, with the guide shaft cooperatively receiving the plunger and the rod upon translational movement thereof and an actuator communicatively linked to the plunger. The actuator is longitudinally moveable from a first position relative to the housing upon application to the actuator of a force aligned with the longitudinal axis of the housing. Movement of the actuator corresponds with translational movement of the plunger from the initial position. The housing has a window disposed therein for visually determining the status of an implant disposed in the housing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 is an exploded view of an ocular implantation device in accordance with an embodiment of the present invention.

[0013] FIG. 2 is a side elevational view of the ocular implantation device of FIG. 1 in an initial operational configuration with the left housing portion removed to better show internal components thereof.

[0014] FIG. 3 is a magnified partial view of FIG. 2 showing the implant in detail.

[0015] FIG. 4 is a side elevational view of the ocular implantation device of FIG. 1 in a subsequent operational configuration with the left housing portion removed to better show internal components thereof.

[0016] FIG. 5 is a magnified partial view of FIG. 4 showing the implant in detail.

[0017] FIG. 6 is a side elevational view of the ocular implantation device of FIG. 1 in another subsequent operational configuration with the left housing portion removed to better show internal components thereof.

[0018] FIG. 7 is a magnified partial view of FIG. 6 showing the implant in detail.

[0019] FIG. 8 is a side elevational view of the ocular implantation device of FIG. 1 in another subsequent operational configuration with the left housing portion removed to better show internal components thereof.

[0020] FIG. 9 is a magnified partial view of FIG. 8 showing the implant in detail.

[0021] FIG. 10 is a side elevational view of the ocular implantation device of FIG. 1 in another subsequent operational configuration with the left housing portion removed to better show internal components thereof.

[0022] FIG. 11 is a magnified partial view of FIG. 10 showing the implant in detail.

[0023] FIGS. 12-17 are perspective views of the ocular implantation device in accordance with alternative embodiments thereof.

[0024] FIG. 18 is an exploded view of an ocular implantation device in accordance with another embodiment of the present invention.

[0025] FIG. 19 is an exploded view of an ocular implantation device in accordance with another embodiment of the present invention, which embodiment is similar to the embodiment of FIG. 18.

[0026] FIGS. 20A-E are side elevational views of the ocular implantation device of FIG. 19 in various stages of operation, with the left housing portion removed to better show internal components thereof.

[0027] FIG. 21 is a magnified partial view of FIG. 20B showing the implant in detail.

[0028] FIG. 22 is a magnified partial view of FIG. 20C showing the implant in detail.

[0029] FIG. 23 is an exploded view of an ocular implantation device in accordance with another embodiment of the present invention.

[0030] FIGS. 24A-D are side elevational views of the ocular implantation device of FIG. 23 in various stages of operation, with the left housing portion removed to better show internal components thereof.

[0031] FIG. 25 is a magnified partial view of FIG. 24A showing the implant in detail.

[0032] FIGS. 26-27 are side elevational views of an ocular implantation device in accordance with another embodiment of the present invention in various stages of operation, with the right housing portion removed to better show internal components thereof.

[0033] FIG. 28 is a perspective view of an ocular implantation device in accordance with an alternative embodiment of the present invention, which embodiment is similar to the embodiment of FIG. 1.

[0034] FIG. 29 is a top plan view of the ocular implantation device of FIG. 28.

[0035] FIG. 30 is a side elevational view of the ocular implantation device of FIG. 28.

DETAILED DESCRIPTION

[0036] An ocular implantation device is disclosed that provides a user a visual indication of the status of an implant to be delivered to a target tissue prior to delivery. The device further provides a tactile indication of the status of the implant to be delivered prior to delivery.

[0037] As used herein, the term "implants" refers to ocular implants or drug delivery devices that can be implanted into any number of locations in the eye and that may release a controlled amount of a bioactive agent or therapeutic immediately or over time. The term implants may include microimplants that have a sufficiently small cross-sectional area that they can be delivered by methods and/or using devices according to the invention that result in self-sealing of the eye at the puncture site associated with the delivery.

[0038] Although many implantable devices may be suitable for use with the ocular implantation device disclosed herein, devices having a tube shape, such as those described in U.S. patent No. 6,375,972, the subject matter of which is incorporated herein in its entirety, are preferred. An example of a tube shaped device includes a polyimide tube with a drug core contained therein. The drug core may be made by intermixing polyvinyl alcohol (PVA) with a drug substance such as fluocinolone acetonide. The core may be injected as a slurry into the tube and heated to crosslink the PVA. The tube may be cut to an appropriate length before or after insertion of the drug core. At each end of the tube, a drug permeable coating, for example, PVA may be applied. Alternatively, a permeable coating may be used at one end and an impermeable member may be placed at the other for a reduced rate of release.

[0039] As used herein, "self-sealing" methods of delivering implants into the eye refers to methods of introducing implants through a needle and into target tissue of a patient's eye without the need for a suture, or other similar closure means, at the needle puncture site. Such self-sealing methods do not require that the puncture site completely seal immediately upon withdrawal of the needle, but rather that any initial leakage is minimal and dissipates quickly such that a surgeon or another person equally skilled in the art would not be compelled to suture or otherwise provide other similar closure means to the puncture site. It is preferred that all embodiments of the device of the present invention provide self-sealing methods of delivering implants.

[0040] Referring now to the drawings, various illustrative embodiments will be described. In the figures herein, an implant is shown preloaded into the various device embodiments for descriptive and explanatory purposes. FIG. 1 depicts an embodiment of the ocular implantation device **10** comprising a housing **12**, a plunger assembly **14**, a guide shaft assembly **16**, and an optional cap **18**. The device **10** further comprises an actuator **20** disposed in an elongated housing opening **22** and a transparent window **24** for viewing an implant **26** (perhaps best shown in FIGS. 3 or 5) within the housing **12**. The housing **12** may comprise a right housing portion **28** and a left housing portion **30**, which may be joined together to form the assembled housing **12**. The plunger assembly **14** is disposed within the housing **12** at a proximal end **32** thereof when the device **10** is assembled. It comprises a plunger **34**, an optional inserter plunger plug **36**, and a spring **38**. The plunger **34** and the optional inserter plunger plug **36** are configured to fit together. The plunger **34** is longitudinally disposed within the housing **12** and includes a plurality of radial projections **40**, a closed end **42**, and an open end **44** for receiving a longitudinally extending rod or wire **46**. The rod **46** and the plunger **34** are operatively coupled such that movement of the plunger **34** results in movement of the rod **46** thereby resulting in the plunger **34** and the rod **46** being collectively, translationally moveable along the longitudinal axis **52** of the housing **12**. An elongated opening or slot **48** is disposed near the closed end **42** of the plunger **34**. The spring **38** has a flange portion **50** that may be inserted into the slot **48** of the plunger **34** to enable the spring **38** and the plunger **34** to be operatively connected to one another.

[0041] The plunger assembly **14** and the guide shaft assembly **16** are aligned with a longitudinal axis **52** of the housing **12**. The guide shaft assembly **16** comprises the rod **46**, a guide tube **54**, a guide shaft **56**, a needle stop **58**, and a needle **60** and is disposed within the housing **12** when the housing **12** is assembled. When the device **10** is assembled, the plunger **34** and the rod **46** are translationally moveable along the longitudinal axis **52** of the housing **12**

from an initial position, wherein the rod **46** is receivable within at least a portion of a lumen **70** of the needle **60**. Additionally, the rod **46** is dimensioned to fit concentrically within the guide tube **54**, and the guide tube **54** is dimensioned to fit concentrically within at least a portion of the guide shaft **56**. The guide shaft **56** is fixedly positioned within and is supported by the housing **12**, in particular by ribs **62** of the housing **12** and is in communication with the needle **60** when the device **10** is assembled. In addition, when the device **10** is assembled, the guide shaft **56** cooperatively receives the plunger **34** and the rod **46** upon translational movement thereof. The guide shaft **56** may include an upper guide shaft portion **64** and a lower guide shaft portion **66**, with the lower guide shaft portion **66** optionally including a retention means for preventing the implant **26** from being unintentionally ejected from the device **10** or from being dislodged during shipping. In the exemplary embodiment, the retention means is a core dam **68** (perhaps best shown in FIGS. 3 or 5). While the core dam **68** may prevent the implant from being unintentionally dislodged, it does not span the entire travel path of the implant **26**. Thus during use of the device **10**, the implant **26** may be moved beyond the core dam **68** for ejection from the device **10** by exertion of sufficient force upon the implant **26** by the rod **46**.

[0042] The window **24** of the housing **12** enables a user to view the implant **26** in the housing **12** prior to its being moved into a lumen **70** (perhaps best shown in FIGS. 3 or 5) of the needle **60**, which is configured to receive the implant **26**. Thus a user may view the implant **26** to ensure that it has not been damaged during shipping and handling or unintentionally ejected. The user may also use the window **24** to ensure that the implant **26** has been moved into the lumen **70** of the needle **60** and thus may be delivered to the target tissue, i.e., a user may look through the window **24** to make sure that the implant **26** is no longer visible and thus has been moved into the lumen **70** of the needle **60**.

[0043] The guide shaft **56** is preferably open at both ends **72, 74**. One end **72** of the guide shaft **56** slidably receives the guide tube **54**, and the other end **74** is fitted with the needle stop **58**. The needle stop **58** is axially aligned with the rod **46**, the guide tube **54**, and the guide shaft **56** and is disposed at a distal end **76** of the housing **12** when the device **10** is assembled. The needle stop **58** is configured to receive the needle **60** therethrough such that the needle **60** is positioned within the needle stop **58** and projects from the distal end **76** of the housing **12** when the device **10** is assembled. The needle stop **58** is configured to receive the rod **46** and an implant **26** during operation of the device **10** such that the implant **26** can be driven into the lumen **70** of the needle **60** by the rod **46** during operation. The implant **26** may contain a bioactive agent. The optional cap **18** is frictionally attached to the housing **12** thereby shielding the needle **60** when the device **10** is not being used.

[0044] The actuator **20** is preferably positioned partially within the housing **12** and is translationally moveable along the elongated opening **22** in the housing **12**. The actuator **20** may be communicatively linked or operatively engaged with the plunger **34** such that movement of the actuator **20** in a direction aligned with the longitudinal axis **52** of the housing **12** results in translational movement of the plunger **34** and the rod **46** along the longitudinal axis **52** of the housing **12**. The operative engagement may also enable the actuator **20** to be capable of movement in a direction normal to the longitudinal axis **52** of the housing **12** that does not result in movement of the plunger **34** and the rod **46**. For example, the actuator **20** may be operatively engaged with the plunger **34** via one of the radial projections **40** of the plunger **34** and may be coupled to the flat spring **38** such that a force is applied to the actuator **20** by the spring **38**.

[0045] When the device **10** is assembled, the actuator **20** may be longitudinally moveable from a first position **96** relative to the housing **12** upon application to the actuator **20** of a force aligned with the longitudinal axis **52** of the housing **12**. The actuator **20** includes flanges **80** cooperatively engaging a portion of the housing **12** for controlling and guiding movement of the actuator **20**. In the exemplary embodiment, the portion of the housing **12** is a track **82** disposed in the housing **12** for controlling and guiding movement of the actuator **20** during operation of the device **10**. The track **82** is divided into continuous proximal and distal sections **84, 86** by a protrusion **88** disposed along the track **82**. The protrusion **88** aids in preventing inadvertent delivery of the implant **26** by preventing the actuator **20** from accidentally moving along the track **82** from the proximal section **84** to the distal section **86** thereof. Finger gripping means **90** are optionally disposed on an exterior surface **92** of the housing **12** and an upper surface **94** of the actuator **20**. The optional finger gripping means **90** aid in secure handling of the device **10** by a user.

[0046] The device **10** may further include a gauge or guide member **91** for assessing the location of the site of injection in relation to a landmark on the eye, preferably the limbus. FIGS. 28-30 show an embodiment of the ocular implantation device that is similar to the embodiment of FIG. 1 and that has a slightly different variation of the guide member than the guide member of FIG. 1. Preferably, an outer edge or a sight on the guide member **91** is aligned at or near the landmark, resulting in assessing a site for injection, which would be a predetermined distance from the landmark. Useful distances calibrated from a particular-sized guide member **91** are from about 10mm to about 0.5mm. Preferably from about 6mm to about 2mm. Most preferably about 4mm. In the present embodiment, the guide member **91** includes a wing-shaped planar member disposed at the distal end **76** of the housing **12** in horizontal alignment with the longitudinal axis **52** of the housing **12**. A user may use the guide member **91**

to assist in determining the location of various parts of the eye in relation to one another, e.g., the cornea, the limbus, and the sclera, and in relation to the needle **60** of the device **10** to aid in precisely and accurately injecting the needle **60** into the eye for delivery of the implant **26**.

[0047] FIGS. 2-11 show the device **10** in progressive stages of operation. In FIG. 2, the device **10** is in an initial configuration, with the actuator **20** positioned partially within the housing **12** at the proximal section **84** of the track **82**. In FIG. 2, the actuator **20** is in the first position **96**. In the first position **96**, the flanges **80** of the actuator **20** are disposed within the housing **12** while much of the remainder of the actuator **20** is disposed exterior to the housing **12**. In addition, the actuator flanges **80** are abutting the protrusion **88**. Thus in order to move the actuator **20** toward the distal end **76** of the housing **12** thereby delivering the implant **26** to the target tissue, the flanges **80** should clear the protrusion **88**. In the initial device configuration, the actuator **20** is acted upon by the flat spring **38** thereby maintaining the actuator **20** in the first position **96**. A user may view the implant **26** in the housing **12** when the actuator **20** is in the first position **96**, as shown in FIG. 3. Upon application of a downward force generally normal to the actuator **20**, flanges **80** of the actuator **20** are vertically displaced below the protrusion **88**, as shown in FIG. 4. In this configuration, more of the actuator **20** is disposed within the housing **12** than in the initial configuration shown in FIG. 2. Despite the fact that the actuator **20** moves downwardly relative to the longitudinal axis **52** of the housing **12**, the plunger **34**, which is operatively coupled to the actuator **20**, does not move downwardly relative to the longitudinal axis **52** of the housing **12**. In contrast, the plunger **34** remains vertically stationary with respect to the longitudinal axis **52** of the housing **12** throughout use and operation of the device **10**. A user may use the window **24** to view the implant **26** in the housing **12** in this configuration, as shown in FIG. 5. As can be seen in FIGS. 3 and 5, the implant **26** is in the same location in the housing **12** when the housing **12** is in its initial configuration, shown in FIG. 2 and the instant configuration, shown in FIG. 4, i.e., movement of the actuator **20** downward relative to the longitudinal axis **52** of the housing **12** does not affect the location of the implant **26** during this stage of operation. As shown in FIG. 6, once the actuator flanges **80** are below the protrusion **88**, a force applied to the actuator **20** in the direction of the distal end **76** of the housing **12** that is generally aligned with the longitudinal axis **52** of the housing **12** causes movement of the actuator **20**, which causes translational movement of the plunger **34** and the rod **46** from the initial position in the proximal section **84** of the track **82** toward the distal end **76** of the housing **12**. As described above, when the actuator **20** is in the first position **96**, the track **82** guides movement of the actuator **20** in a direction normal to the longitudinal axis **52** of the housing **12** prior to movement of the actuator **20** in a direction aligned with the

longitudinal axis **52** of the housing **12**, which results in translational movement of the plunger **24** and the rod **46** along the longitudinal axis **52** of the housing **12**.

[0048] During operation between the configurations of FIG. 4 and FIG. 6, the implant **26** is contacted by the rod **46**, which moves the implant **26** into the lumen **70** of the needle **60** such that the implant **26** is primed for delivery to the target tissue, as can be seen in FIG. 7. The needle **60** may be modified, for example, with indent(s) (not shown) in the lumen **70** of the needle **60** to retain the implant **26** and prevent or eliminate accidental ejection or loss of the implant. After the actuator flanges **80** have cleared the protrusion **88**, the spring **38** provides a tactile indication to the user that the implant **26** is primed for ejection as the actuator **20** is forced upwardly in a direction normal to the longitudinal axis **52** of the housing **12** to a second position **98** in the distal section **86** of the track **82** by the force of the spring **38**, as shown in FIG. 8. Further, the relative movement, or lack thereof of the implant **26** is observable in the transparent window **24** of housing **12**. More particularly, in FIGS. 2 to 5, the implant **26** is observable within the transparent window **24**, and in FIGS. 6 to 9, the implant **26** has been driven into the lumen **70** of the needle **60** and is therefore not observable through the transparent window **24**, thus indicating to a user that the implant **26** is primed to be delivered. In either event, the transparent window **24** aids in determining the location of the implant **26**. The transparent window **24** may contain a magnifying lens. In FIGS. 6-9, the implant **26** is disposed in the lumen **70** of the needle **60** and is ready for ejection into a target site. Once the implant **26** is disposed thusly, a force applied to the actuator **20** that is generally aligned with the longitudinal axis **52** of the housing **12** and in the direction of the distal end **76** of the housing **12** further translates the plunger **34** and the rod **46** through the distal section **86** of the track **82**, thereby driving the implant **26** through the lumen **70** of the needle **60** for ejection from the needle **60** and insertion into a target tissue. Thus, when the actuator **20** is in the second position **98**, the track **82** guides movement of the actuator **20** in a direction aligned with the longitudinal axis **52** of the housing **12** for further translational movement of the plunger **34** and the rod **46** to deliver the implant **26**.

[0049] To use the device **10**, a user may insert the needle **60** of the device **10**, when the device **10** is in the initial configuration shown in FIG. 2, into a subject's eye. In the initial configuration, the user may verify that the implant **26** is disposed in the housing **12** by using the window **24** of the device **10** to view the implant **26**. In FIG. 2, the actuator **20** is in the first position **96**. The user may apply a downward and a forward force to the actuator **20** to move the actuator **20** and hence the plunger **34** and rod **46** toward the distal end **76** of the housing **12**. As described above, the plunger **34** is operatively connected to the rod **46**, which drives the implant

26 through the lumen **70** of the needle **60** toward the target site as the actuator **20** is being moving toward the distal end **76** of the housing **12** by the user, ultimately resulting in the implant **26** being ejected from the device **10**.

[0050] In the first position **96**, the actuator **20** is disposed in the proximal section **84** of the track **82** in abutting relation with the protrusion **88**. A user may press downwardly on the actuator **20** to move the flanges **80** below the protrusion **88**. Once the flanges **80** clear the protrusion **88**, a user may press the actuator **20** toward the distal end of the housing **12** thereby moving the actuator flanges **80** beyond the protrusion **88** (FIG. 6). The actuator's movement along the longitudinal axis **52** of the housing **12** causes or translates to similar movement of the plunger **34** and the rod **46** along the longitudinal axis **52** of the housing **12** resulting in the rod **46** pushing the implant **26** into the lumen **70** of the needle **60** thereby priming the implant **26** for ejection. The user may verify that the implant **26** is no longer in the housing **12** by looking through the window **24** of the housing **12**. After the user has moved the actuator **20** beyond the protrusion **88**, the spring **38** forces the actuator **20** into the second position **98**, wherein the actuator **20** is disposed in the distal section **86** of the track **82** with the flanges **80** thereof disposed above the protrusion **88** (FIG. 8). The user may continue to press the actuator **20** toward the distal end **76** of the housing **12** thereby causing further translational movement of the plunger **34** and the rod **46** thus delivering the implant **26** to the target site, as shown in FIGS. 10 to 11. Preferably, the puncture site is self-sealing upon removal of the needle **60**.

[0051] FIGS. 12-17 are perspective views of the ocular implantation device in accordance with alternative embodiments thereof. Similarly to the embodiment shown in FIG. 1, the ocular implantation devices of FIGS. 12-17 comprise a housing **102**, an actuator **104** disposed in an elongated housing opening **128**, a transparent window **106** for viewing the implant **26** within the housing **102**, and an optional cap **112**. Components that are substantially similar to those of the embodiments of FIGS. 18 and 19 are designated with the same reference numerals as used in FIGS. 18 and 19. The devices include various embodiments of finger gripping means optionally disposed on an exterior surface of the housing and an upper surface of the actuator to aid in secure handling of the device by a user.

[0052] FIGS. 18 and 19 are exploded perspective views of the ocular implantation device in accordance with alternative embodiments thereof. The devices **100** of FIGS. 18 and 19 are substantially similar; however, the optional finger gripping means **170**, **172** present in the two embodiments are somewhat different. FIG. 18 substantially corresponds to the embodiment shown in FIG. 12 and FIG. 19 substantially corresponds to the embodiment shown in FIG. 13.

Components that are the same as one another or substantially similar in the devices of FIGS. 18 and 19 share the same reference numeral.

[0053] Both embodiments comprise a housing **102**, an actuator **104**, a window **106**, a plunger assembly **108**, a guide shaft assembly **110**, and an optional cap **112**. The housing **102** may comprise a right housing portion **114** and a left housing portion **116**, which may be joined together to form the assembled housing **102**. The plunger assembly **108** is disposed within the housing **102** at a proximal end **118** thereof when the device **100** is assembled. It comprises a plunger **120** and a spring **122**. The plunger **120** includes a plurality of radial projections **124**, a closed end **126** having an elongated opening or slot **128** formed therein, and an open end **130** for receiving an extendedly projecting rod or wire **132** and a rod holder **134**. In addition, the open end **130** of the plunger **120** is dimensioned to be slidably received by a guide shaft **136** of the guide shaft assembly **110**. The spring **122** has a flange portion **138** that may be inserted into the slot **128** of the plunger **120** to enable the spring **122** and the plunger **120** to be operatively connected to one another.

[0054] The plunger assembly **108** and the guide shaft assembly **110** are aligned with a longitudinal axis **140** of the housing **102**. The guide shaft assembly **110** comprises the rod **132**, the rod holder **134**, the guide shaft **136**, a needle stop **142**, and a needle **144** and is disposed within the housing **102** when the housing **102** is assembled. The rod **132** is dimensioned to fit concentrically within the guide shaft **136**. The guide shaft **136** is fixedly positioned within and is supported by the housing **102**, in particular by ribs **146** of the housing **102**.

[0055] The guide shaft **136** is preferably open at both ends **148, 150**. One end of the guide shaft **148** slidably receives the plunger **136**, and the other end **150** is fitted with the needle stop **142** for accommodating the rod **132** and an implant **152** prior to the implant **152** being moved into a lumen **154** (perhaps best shown in FIG. 21) of the needle **144**. The needle stop **142** is axially aligned with the rod **132**, the rod holder **134**, and the guide shaft **136**. The needle **144** is positioned in the needle stop **142** and projects from a distal end **156** of housing **102**. The needle stop **142** is configured to receive the rod **132** and the implant **152** during operation of the device **100** such that the implant **152** can be driven into the lumen **154** of the needle **144** by the rod **132** during operation. The implant **152** may contain a bioactive agent. The optional cap **112** is frictionally attached to the housing **102** thereby shielding the needle **144** when the device **100** is not being used.

[0056] The actuator **104** is preferably positioned partially within the housing **102** and is translationally moveable along an elongated opening **158** in the housing **102**. The actuator **104** may be operatively coupled to the plunger **120** via one of the radial projections **124** and may be

coupled to the flat spring **122** such that a force is applied to the actuator **104** by the spring **122**. The actuator **104** includes flanges **160** cooperatively engaging a track **162** disposed in the housing **102**. The track **162** aids in guiding the actuator **104** during operation of the device **100**. In the instant embodiment, the track **162** is divided into continuous proximal and distal sections **164, 166** by a protrusion **168** disposed along the track **162**. Finger gripping means **170, 172** are optionally disposed on an exterior surface **174** of the housing **102** and an upper surface **176** of the actuator **104**. The optional finger gripping means **170, 172** aid in secure handling of the device **100** by a user. As indicated previously, the finger gripping means **170, 172** of the embodiments shown in FIGS. 18 and 19 differ and thus have different reference numerals.

[0057] FIGS. 20A-E, 21, and 22 show the device **100** in progressive stages of operation. In FIG. 20A, the device **100** is in an initial configuration, with the actuator **104** positioned partially within the housing **102** in the proximal section **164** of the track **162**. In this initial configuration, the actuator **104** is acted upon by the flat spring **122** such that a force is applied to the actuator **104**. Upon application of a force that is generally normal to the actuator **104**, flanges **160** of the actuator **104** are vertically displaced below the protrusion **168**. Upon application of a force that is generally aligned with the longitudinal axis **140** of the housing **102**, the actuator **104** is moved from the proximal section **164** of the track **162** toward the distal end **156** of the housing **102** thereby clearing the protrusion **168**, as shown in FIG. 20B. During this operation, the implant **152** is contacted by the rod **132**, as shown in FIG. 21. An optional retention means **178** may be positioned distally from the implant **152** to prevent movement of the implant **152** during shipping or handling. Once the actuator **104** is beyond the protrusion **168**, the implant **152** is primed for ejection by introduction to the lumen **154** of the needle **144**, as shown in FIG. 22. The needle **144** may be modified, for example, with indent(s) **180** in the lumen **154** of the needle **144** to retain the implant **152** and prevent or eliminate accidental ejection or loss of the implant **152**. In this configuration, the spring **122** provides for a tactile indication to the user that the implant **152** is primed for ejection as the actuator **104** is forced upwardly into the distal section **166** of the track **162** by the applied force of the spring **122**. Further, the relative movement, or lack thereof of the implant **152** is observable in the transparent window **106** of housing **102**, as shown in FIGS. 21 and 22. The transparent window **106** may contain a magnifying lens. In FIG. 22, the implant **152** is disposed in the lumen **154** of the needle **144** and is ready for ejection into a target site. Once the implant **152** is disposed thusly, a force generally aligned with the longitudinal axis **140** of the housing **102** applied to the actuator **104** causes movement of the actuator **104**, which translates to movement of the plunger **120** and rod **132** from the distal

section **166** of the track **162**, thereby driving the implant **152** through the lumen **154** of needle **144** for ejection from the needle **144** and insertion into a target tissue, as shown in FIG. 20E.

[0058] Use of the embodiments of FIGS. 18 to 22 is substantially similar to that of the embodiment of FIGS. 1-11. To use the device **100**, a user may insert the needle **144** of the device **100**, when the device **100** is in the initial configuration, into a subject's eye. In the initial configuration, the user may verify that the implant **152** is disposed in the housing **102** by looking through the window **106** of the device **100**. The user may then apply a downward and then a forward force to the actuator **104** to move the actuator **104** and hence the plunger **120** and rod **132** toward the distal end **156** of the housing **102**. As described above, the plunger **120** is operatively connected to the rod **132**, which, in turn, pushes the implant **152** through the lumen **154** of the needle **144** toward the target site. Thus, as the actuator **104** is moved toward the distal end **156** of the housing **102** by the user, the implant **152** is being driven through the lumen **154** of the needle **144** until it is ejected from the device **100**.

[0059] From the initial configuration of FIG. 20A, the actuator **104** initially moves downwardly engaging the proximal section **164** of the track **162** when pressed by the user (FIG. 20B) and then moves toward the distal end **156** of the housing **102** under the protrusion **168** (FIG. 20C). Once the actuator **104** has moved beyond the protrusion **168**, the implant **152** is primed for ejection. The user may verify that the implant **152** is no longer in the housing **102** by looking through the window **106** of the housing **102**. After the user has moved the actuator **104** beyond the protrusion **168**, the spring **122** forces the actuator **104** back up into the distal section **166** of the track **162** (FIG. 20D). The user may continue to press the actuator **104** toward the distal end **156** of the housing **102** to deliver the implant **152** to the target site (FIG. 20E). Preferably, the puncture site is self-sealing upon removal of the needle **144**.

[0060] FIGS. 23 to 25 show the ocular implantation device in accordance with another alternative embodiment thereof wherein the actuator includes actuator tabs and the device does not include a spring. FIG. 23 is an exploded perspective view of the device and FIGS. 24A-D and 25 show the device in progressive stages of operation.

[0061] The device **200** comprises a housing **202**, an actuator **204**, a window **206**, a plunger **208**, a guide shaft assembly **210**, and an optional cap **212**. The housing **202** may comprise a right housing portion **214** and a left housing portion **216**, which may be joined together to form the assembled housing **202**. The plunger **208** is disposed within the housing **202** at a proximal end **218** thereof when the device **200** is assembled. The plunger **208** includes plunger openings **220**, a closed end **222**, and an open end **224** for receiving an extendedly projecting rod or wire

226. In addition, the open end 224 of the plunger 208 is dimensioned to be slidably received by a guide shaft 228.

[0062] The plunger 208 and the guide shaft assembly 210 are aligned with a longitudinal axis 230 of the housing 202. The guide shaft assembly 210 comprises the rod 206, the guide shaft 228, a needle stop 232, and a needle 234 and is disposed within the housing 202 when the housing 202 is assembled. The guide shaft 228 is fixedly positioned within and is supported by the housing 202, in particular by ribs 236 of the housing 202, when the device 200 is assembled. The rod 226 is dimensioned to fit concentrically within the guide shaft 228. The guide shaft 228 is preferably open at both ends 238, 240. One end 238 of the guide shaft 228 slidably receives the plunger 208 and the rod 226, and the other end 240 is fitted with the needle stop 232 for accommodating the rod 226 and an implant 242 prior to the implant 242 being moved into a lumen 244 (perhaps best shown in FIG. 25) of the needle 234. The needle stop 232 is axially aligned with the rod 226 and the guide shaft 228. The needle 234 is positioned within the needle stop 232 and projects from a distal end 246 of the housing 202. A retention means 248, shown in FIG. 25, may be disposed in the guide shaft 228 adjacent the implant 242 to prevent movement of the implant 242 during shipping or handling and to prevent inadvertent delivery of the implant 242. The optional cap 212 is frictionally attached to the housing 202 thereby shielding the needle 234 when the device 200 is not being used.

[0063] The actuator 204 is preferably positioned partially within the housing 202 and is translationally moveable along an elongated opening 250 in the housing 202. The actuator 204 may be operatively coupled to the plunger 208 via actuator tabs 252 positioned within the plunger openings 220. The actuator tabs 252 enable the actuator 204 to move in directions normal to the longitudinal axis of the housing 202 relative to the plunger 208 while the plunger 208 remains stationary in a plane of motion. The actuator 204 includes flanges 254 cooperatively engaging a track 256 disposed in the housing 202. The track 256 aids in guiding the actuator 204 during operation of the device 200. In the exemplary embodiment, the track 256 is divided into a continuous proximal upper section 258 and distal lower section 260. Because the proximal section 258 of the track 256 is relatively higher in the housing 202 than the distal section 260 of the track 256, an edge wall 266 demarcates the two sections 258, 260 along the track 256. Finger gripping means 262 are optionally disposed on an upper surface 264 of the actuator 204.

[0064] Referring to FIGS. 24A-D, in an initial configuration, (shown in FIG. 24A) the actuator 204 is initially positioned toward the proximal end 218 of the housing 202 with the actuator tabs 252 disposed within the plunger openings 220. During use, from the initial

configuration, a user applies a force to the actuator **204** in a direction toward the distal end **246** of the housing **202** and generally aligned with the longitudinal axis **230** of the housing **202** causing the actuator **204** to move, which translates to movement of the plunger **208** with the rod **226** extending therefrom toward the distal end **246** of the housing **202**. Movement is interrupted as the actuator flanges **254** reach the edge wall **266** of the track, as shown in FIG. 24B. Once the device **200** is in this configuration, the rod **226** is disposed adjacent the implant **242**. From this configuration, a force in a generally normal direction relative to the longitudinal axis **230** of the housing **202** vertically translates the actuator flanges **254** downwardly for engagement with the distal lower track section **260** while the actuator tabs **252** extend through the plunger openings **220**, as shown in FIG. 24C. Because the actuator tabs **252** are able to move relative to the plunger openings **220** in directions normal to the longitudinal axis **230** of the housing **202**, the plunger **208** remains stationary while the actuator **204** moves downwardly relative to the longitudinal axis **230** of the housing **202**. From this configuration, a force applied to the actuator **204** in a direction generally aligned with the longitudinal axis **230** of the housing **202** toward the distal end **246** of the housing **202** causes the rod **226** to urge the implant **242** from the retention means **248** and eject the implant **242** from the lumen **244** of needle **234**, as shown in FIG. 24D. This action results in insertion of the implant **242** into the target tissue. As with the previously described embodiments, implant **242** translation or lack thereof may be observed using the transparent window **206**.

[0065] To use the device **200**, a user may insert the needle **234** of the device **200**, when the device **200** is in the initial configuration, into a subject's eye. In the initial configuration, the user may verify that the implant **242** is disposed in the housing **202** by looking through the window **206** of the device **200**. The user may then apply a forward force to the actuator **204** to move the actuator **204** and hence the plunger **208** and rod **226** toward the distal end **246** of the housing **202**. As described above, the plunger **208** is operatively coupled to the rod **226**, which, in turn, pushes the implant **242** through the lumen **244** of the needle **234** toward the target site. Thus, as the actuator **204** is moved toward the distal end **246** of the housing **246** by the user, the implant **242** is being driven through the lumen **244** of the needle **234** until it is ejected from the device **200**.

[0066] From the initial configuration of FIG. 24A, the actuator **204** initially moves toward the distal end **246** of the housing **202** engaging the proximal upper section **258** of the track **256** when pressed by the user. Movement of the actuator **204** is interrupted when the actuator flanges **254** reach the edge wall **266** of the proximal upper track section **258**, as shown in FIG. 24B. The user may press downwardly on the actuator **204** to move the actuator flanges **254** into

engagement with the distal lower track section **260**, as shown in FIG. 24C. The user may then push the actuator **204** toward the distal end **246** of the housing **202** to deliver the implant **242** to the target site (FIG. 24D). The user may verify that the implant **242** is no longer in the housing **202** by looking through the window **206** of the housing **202**. Preferably, the puncture site is self-sealing upon removal of the needle **234**.

[0067] FIGS. 26-27 depict the ocular implantation device in accordance with another alternative embodiment thereof wherein the needle is retractable. These figures show the device **300** in progressive stages of operation. The device **300** of FIGS. 26-27 is structurally similar to the device **10** of FIGS. 1 to 11, thus the same reference numerals will be used to designate components of the instant embodiment that are substantially similar to or the same as those of the embodiment of FIGS. 1 to 11. It will be understood by one of skill in the art that the retractable needle device **300** may have configurations that vary from the configuration shown in FIGS. 26-27. For example, the retractable needle device **300** may be made without a window, may have a simplified track system, or may be made without a rod.

[0068] In contrast to the embodiment of FIGS. 1 to 11, the needle **302** of the instant embodiment may be retracted into the distal end **76** of the housing **12**. Thus, an implant **26** may be delivered with the instant device **300** by the needle **302** being retracted into the distal end **76** of the housing **12** rather than by the rod **46** pushing the implant **26** completely through the lumen of the needle **60** until it is delivered, as in previously described embodiments.

[0069] In FIG. 26, the device **300** is in an initial configuration, wherein the needle **302** is extended from the housing **12** with the implant **26** disposed in the lumen of the needle **302** ready for deployment into a target tissue. A user may apply a force to the actuator **20** that is generally aligned with the longitudinal axis **52** of the housing **12** but is in a direction moving away from the distal end **76** of the housing **12**. Movement of the actuator **20** away from the distal end **76** of the housing **12** retracts the needle **60** into the housing **12** thereby deploying the implant **26** into the target tissue, as shown in FIG. 27. The needle **302** simply retracts back into the housing **12** leaving the implant **26** disposed in the target tissue. The retractable needle device **300** is advantageous because it offers control and predictability for the delivery location of an implant. A user may place the needle **302** at the location for desired delivery. When the needle **302** is retracted, the implant is left behind in the location that the needle **302** was in previously. In contrast, in an ocular implantation device embodiment wherein an implant is delivered by being forced out of a needle by a rod, the implant delivery location may be affected by the force with which the rod presses the implant or by the distance from the needle that the rod extends to eject the implant.

[0070] To use the device **300**, a user may insert the needle **302** into a subject's eye. Then the user may press the actuator **20** away from the distal end **76** of the housing **12** to retract the needle **302** into the housing **12** thereby leaving the implant **26** in the target site (FIG. 27). Preferably, the puncture site is self-sealing upon removal of the needle **302**.

[0071] The ocular implantation device disclosed herein may be provided as a kit with the implant preloaded into the implantation device. A kit may be provided that includes an implantation device preloaded with an implantable tube including a drug core contained therein with permeable coatings applied to each end of the tube. Alternatively, a kit may be provided that includes an implantation device preloaded with an implantable tube including a drug core contained therein with a permeable coating at one end of the tube and an impermeable member at the other end of the tube. The kit may also include saleable packaging for distribution and sale of the kit. It may further include auxiliary components, including, but not limited to, for example, components for properly disposing of the device, components for assisting in sterilizing an area around the injection site, and/or instructions for using the device.

[0072] The above-described ocular implantation device enables a healthcare provider to consistently deliver an implant to a subject. The device further enables the implant to be properly lodged or positioned in the target tissue. Advantageously, the device also ensures that the implant is positioned for delivery immediately prior to or commensurate with entry of the device into the target tissue because the implant is visually observable prior to activating or manipulating the device. The capability to push the actuator forward along the longitudinal axis of the device, with the needle in the subject's target tissue, and to observe that the implant is properly positioned for ejection into the target tissue results in better placement of the implant. Without the ability to visually observe that the implant is properly positioned prior to delivery, it can be difficult or, at the least, time consuming for a user to ensure that the implant has been delivered.

[0073] It will be understood to those of ordinary skill in the art that the same can be performed within a wide and equivalent range of conditions, formulations, and other parameters without affecting the scope of the invention or any embodiment thereof. All patents, patent applications, and publications cited herein are fully incorporated by reference herein in their entirety.

CLAIMS

What is claimed is:

1. An ocular implantation device comprising:
   (a) a housing having a longitudinal axis;
   (b) a needle extending from said housing, wherein a lumen of said needle is configured to receive an implant;
   (c) a plunger longitudinally disposed within said housing and a longitudinally extending rod operatively coupled thereto, wherein said plunger and said rod are collectively, translationally moveable along the longitudinal axis of said housing, and wherein said rod is configured to be receivable within at least a portion of the lumen; and
   (d) an actuator configured for controlled, guided movement, such movement being controlled and guided by a user and by a portion of said housing,
   (e) wherein said actuator is operatively engaged with said plunger such that movement of said actuator in a direction aligned with the longitudinal axis of said housing results in translational movement of said plunger and said rod along the longitudinal axis of said housing, said actuator being capable of movement in a direction normal to the longitudinal axis of said housing that does not result in movement of said plunger and said rod.

2. The ocular implantation device of claim 1, further comprising a flat spring operatively interconnected with said actuator whereby said flat spring exerts a force on said actuator in a direction normal to the longitudinal axis of said housing.

3. The ocular implantation device of claim 1, further comprising an ocular implant, said implant comprising a bioactive agent.

4. The ocular implantation device of claim 3, wherein the bioactive agent is fluocinolone acetonide.

5. The ocular implantation device of claim 1, further comprising a window disposed in said housing for visually determining the status of an implant disposed in said housing.

6. The ocular implantation device of claim 1, further comprising retention means for preventing inadvertent delivery or displacement of an implant disposed in said housing.

7. The ocular implantation device of claim 6, wherein the retention means is a core dam.

8. The ocular implantation device of claim 1, wherein the portion of said housing guiding movement of said actuator comprises a track.

9. The ocular implantation device of claim 8, wherein when said actuator is in a first position, said track guides said movement of said actuator in a direction normal to the longitudinal axis of said housing prior to said movement of said actuator in a direction aligned with the longitudinal axis of said housing resulting in translational movement of said plunger and said rod along the longitudinal axis of said housing.

10. The ocular implantation device of claim 9, wherein a flat spring exerts a force upon said actuator thereby moving said actuator in a direction normal to the longitudinal axis of said housing to a second position after said movement of said actuator in a direction aligned with the longitudinal axis of said housing.

11. The ocular implantation device of claim 10, wherein when said actuator is in said second position, said track guides said movement of said actuator in a direction aligned with the longitudinal axis of said housing for further translational movement of said plunger and said rod.

12. The ocular implantation device of claim 11, wherein said further translational movement of said plunger and said rod results in ejection of an ocular implant from the device.

13. The ocular implantation device of claim 8, wherein said actuator has a first position in a proximal section of said track and a second position in a distal section of said track, said proximal section and said distal section being defined by a protrusion disposed in said track.

14. An ocular implantation device comprising:

(a) a housing having a longitudinal axis;

(b) a needle extending longitudinally from said housing, said needle having a lumen extending therethrough, said needle lumen configured to receive an implant;

(c) a plunger longitudinally positioned within said housing and having a rod extending therefrom, wherein said plunger and said rod are translationally moveable along the longitudinal axis of said housing from an initial position, wherein said rod is receivable within at least a portion of said needle lumen;

(d) a guide shaft fixedly positioned within said housing in communication with said needle, said guide shaft cooperatively receiving said plunger and said rod upon translational movement thereof;

(e) an actuator communicatively linked to said plunger, said actuator longitudinally moveable from a first position relative to said housing upon application to said actuator of a force aligned with the longitudinal axis of said housing, wherein movement of said actuator corresponds with translational movement of said plunger from said initial position; and

(f) a window disposed in said housing for visually determining the status of an implant disposed in said housing.

15. The ocular implantation device of claim 14, wherein said window comprises a magnifying lens.

16. The ocular implantation device of claim 14 further comprising:

(a) a track formed in said housing for controlling and guiding movement of said actuator, said track having a proximal section and a distal section defined by a protrusion; and

(b) a flat spring operatively interconnected with said actuator and said plunger whereby said flat spring exerts a force on said actuator thereby moving said actuator in a direction normal to the longitudinal axis of said housing.

17. A method of delivering an implant to an eye comprising:

(a) providing the device of claim 16 with said implant preloaded therein;

(b) inserting said needle of said device into said eye; and

(c) applying a force to said actuator of said device in order to deliver said implant to said eye.

18. A kit for delivering a tube shaped implant to an eye, comprising the device of claim 16 preloaded with a tube shaped implant including a drug core contained therein with permeable coatings applied to each end of the tube.

19. A kit for delivering a tube shaped implant to an eye, comprising the device of claim 16 preloaded with a tube shaped implant including a drug core contained therein with a permeable coating at one end of the tube and an impermeable member at the other end of the tube.

20. A method of delivering an implant to an eye comprising:
(a) providing said device of claim 1 with said implant preloaded therein;
(b) inserting said needle of said device into said eye; and
(c) applying a force to said actuator of said device in order to deliver said implant to said eye.

21. The method of claim 20, further comprising using said window disposed in said housing of said device to determine the status of said implant disposed in said housing.

22. The method of claim 20, wherein applying a force to said actuator comprises applying a force in a direction normal to the longitudinal axis of said housing in order to initiate movement of said actuator.

23. The method of claim 20, wherein applying a force to said actuator comprises applying a force in a direction aligned with the longitudinal axis of said housing in order to advance said actuator toward a distal end of said housing.

24. An ocular implantation device comprising:
(a) a housing having a longitudinal axis;
(b) a needle disposed at least partially within said housing, said needle extending from and being capable of retracting into said housing and having a lumen configured to receive an implant; and

(c) an actuator operatively interconnected with said needle whereby said actuator may be used for said retracting said needle into said housing in order to deliver an implant to a target tissue.

25. A method of delivering an implant to an eye comprising:

(a) providing said device of claim 24 having said implant to be delivered preloaded in said needle thereof;

(b) inserting said needle of said device into a site in said eye; and

(c) applying a force to said actuator of said device whereby said needle is retracted thereby delivering said implant into said eye.

26. The method of claim 25, wherein said insertion site of said eye is self-sealing.

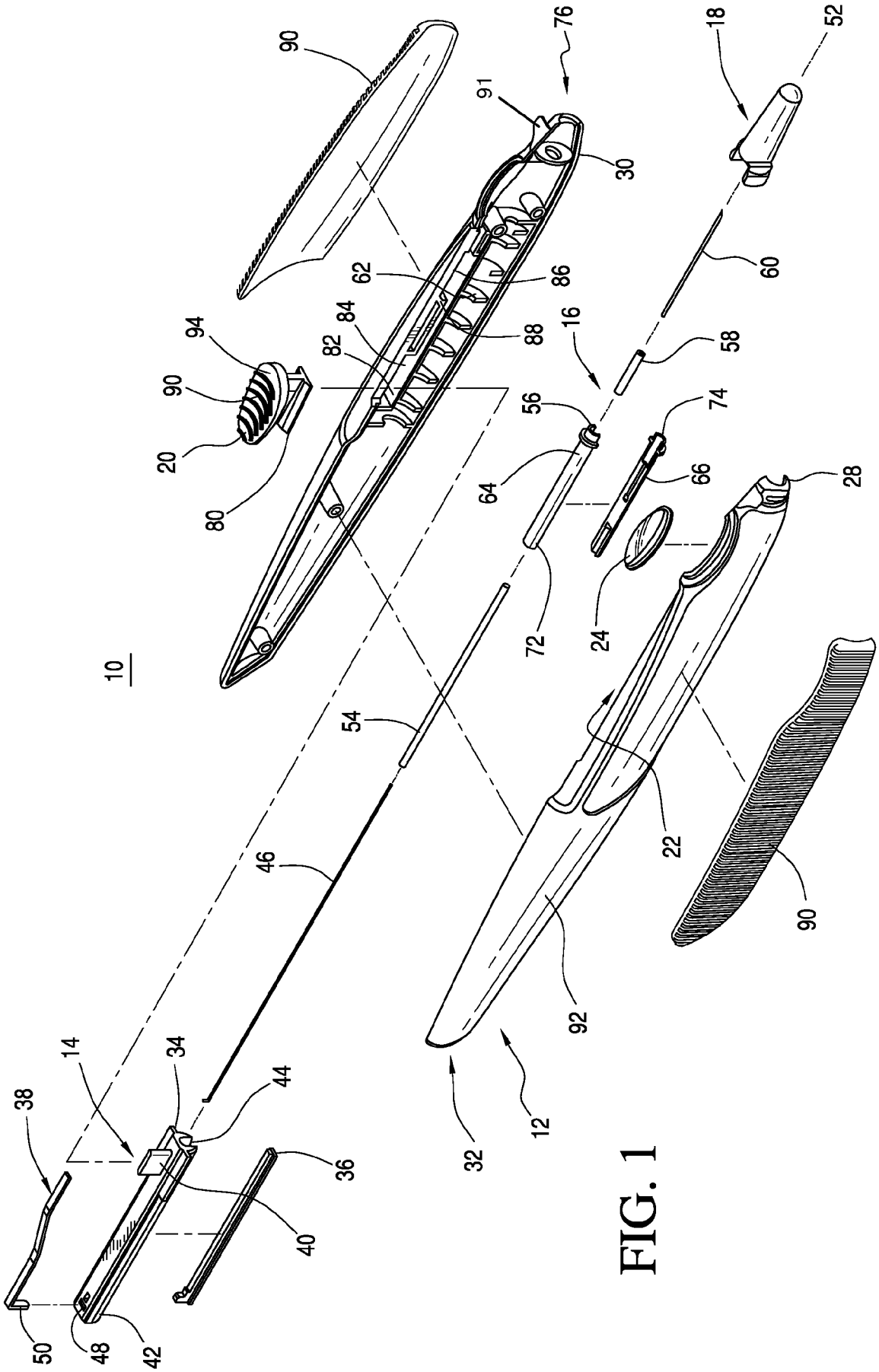

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FIG. 1

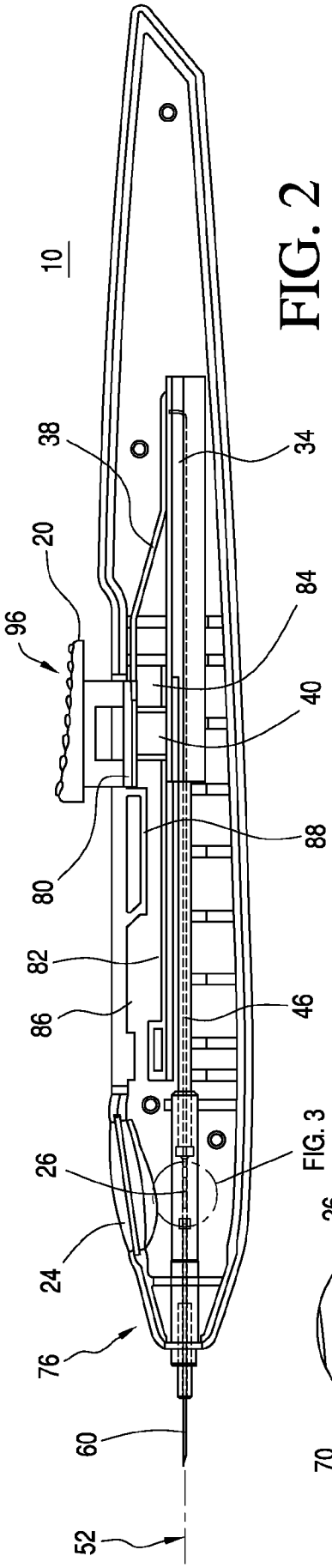


FIG. 2

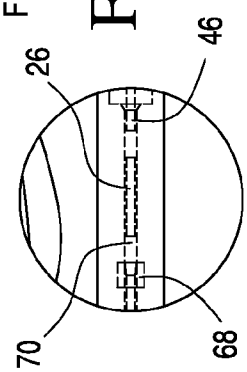


FIG. 3

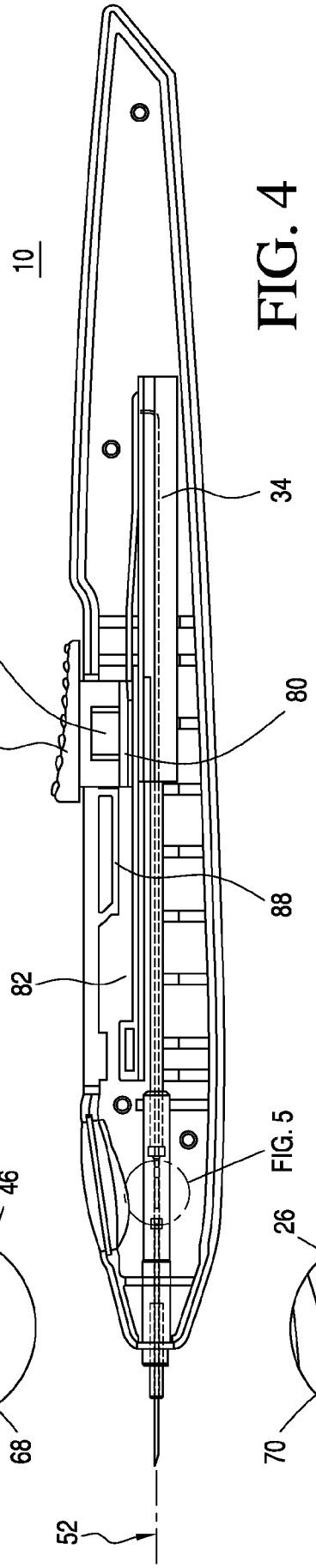


FIG. 4

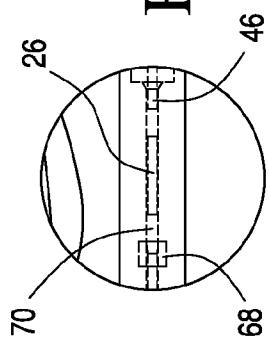


FIG. 5

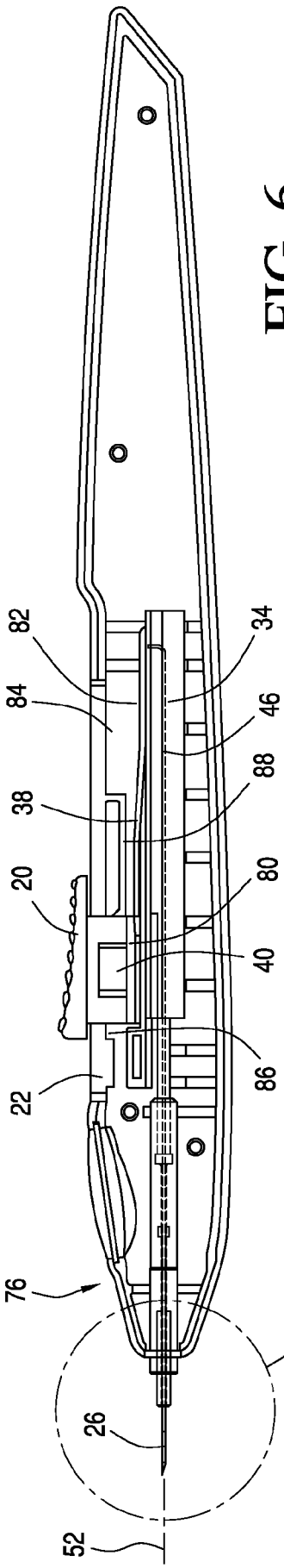


FIG. 6

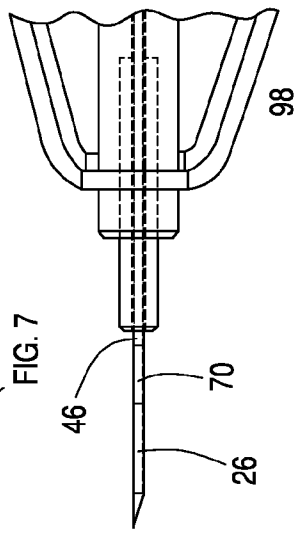


FIG. 7

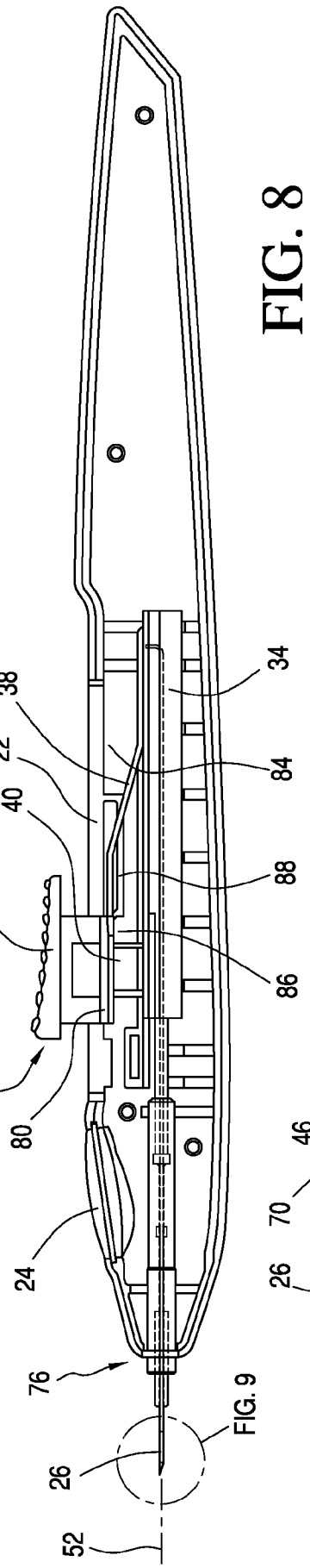


FIG. 8

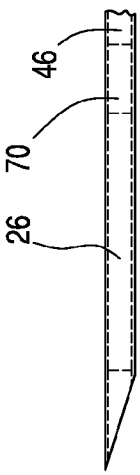


FIG. 9

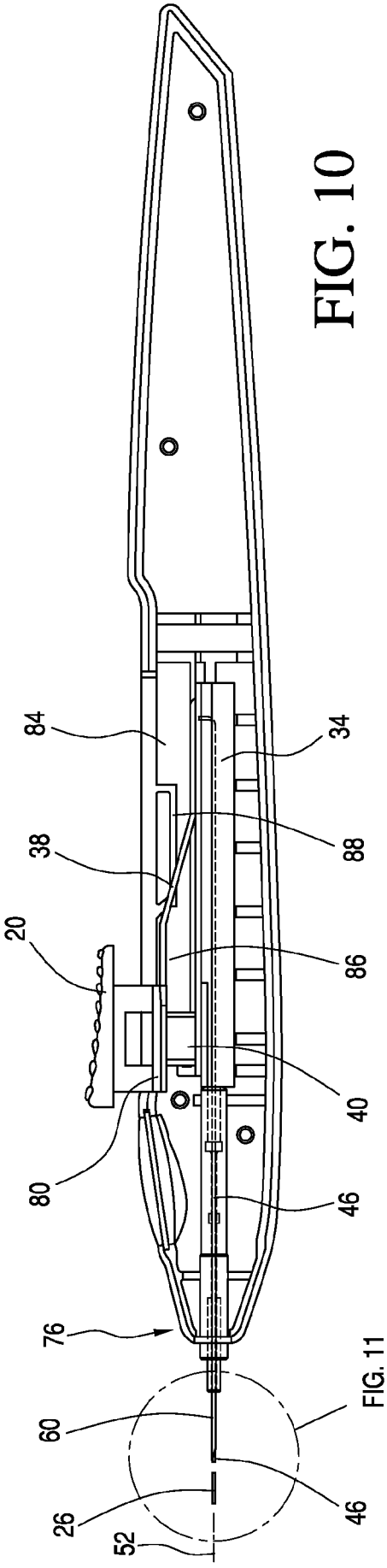


FIG. 10

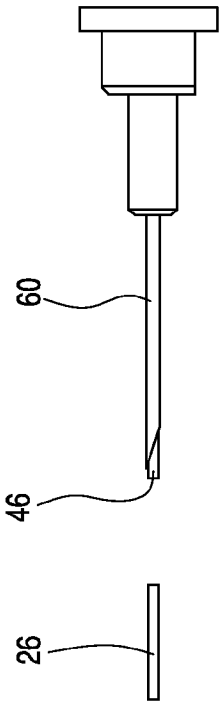


FIG. 11

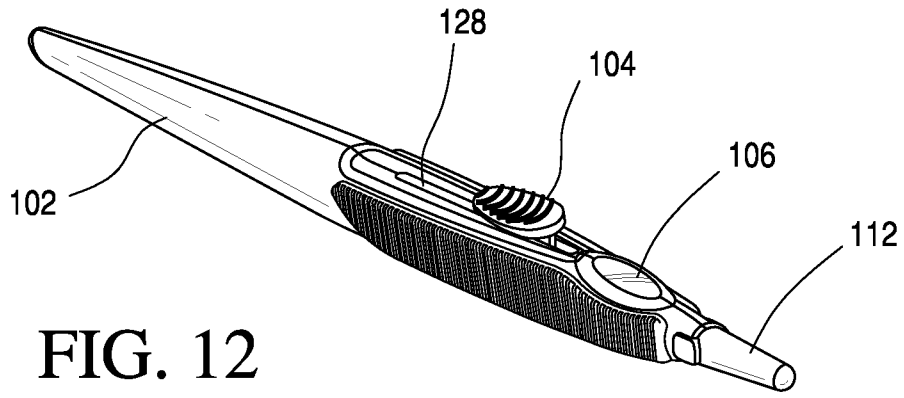


FIG. 12

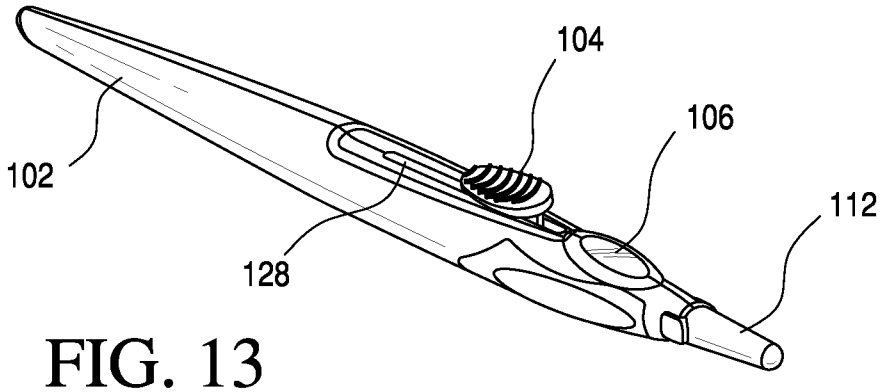


FIG. 13

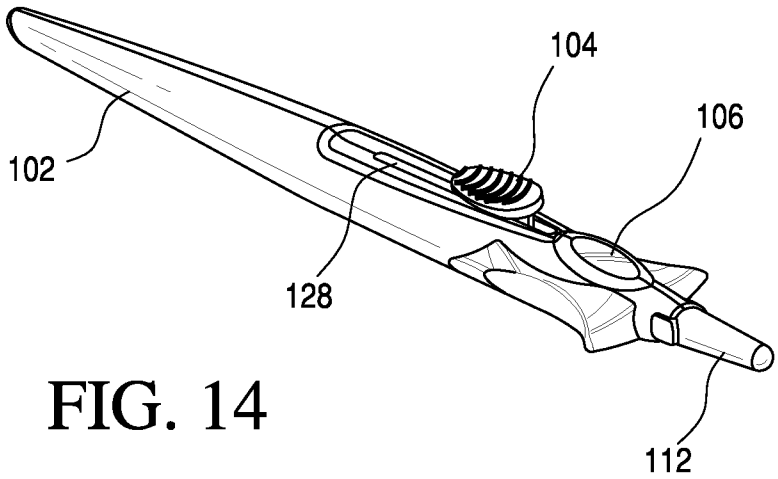


FIG. 14

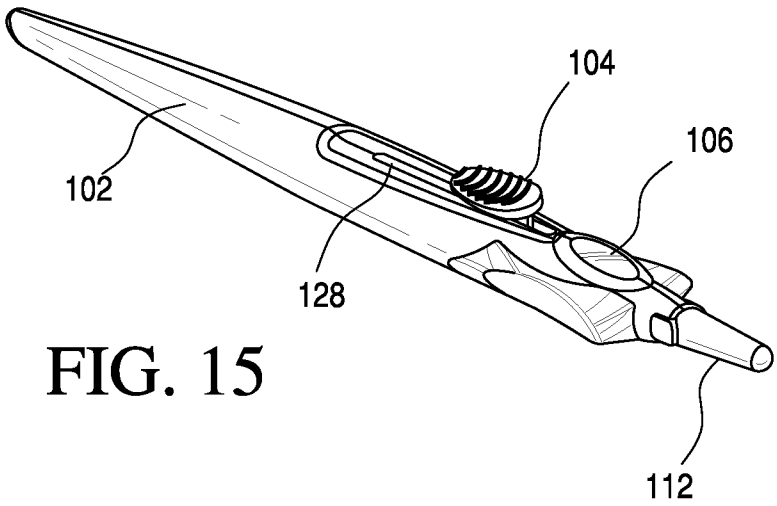


FIG. 15

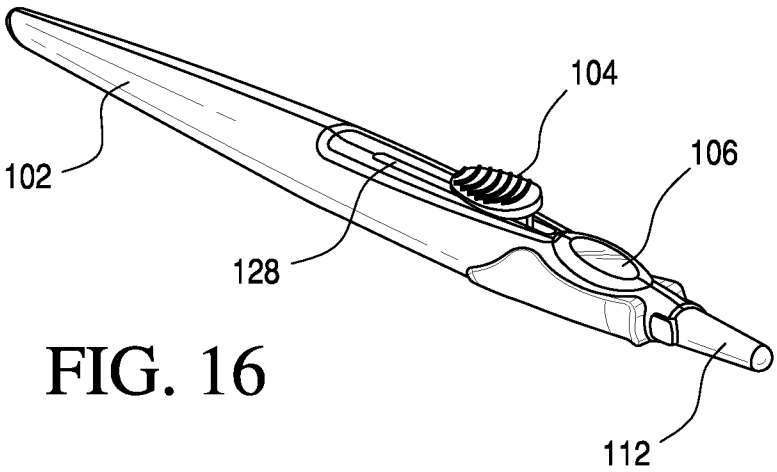


FIG. 16

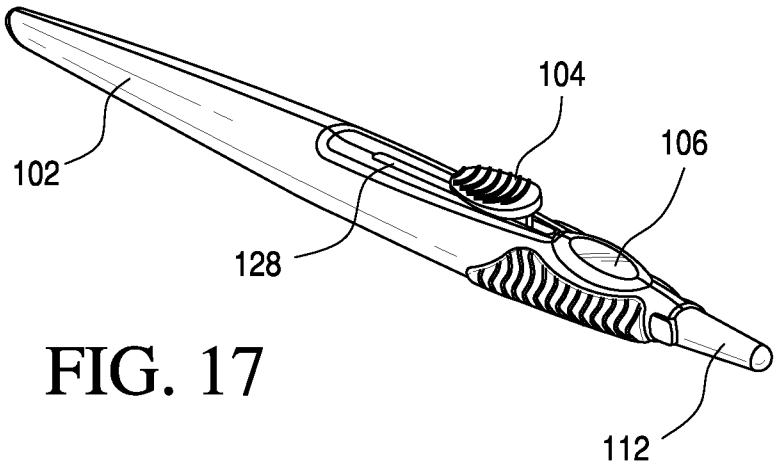


FIG. 17

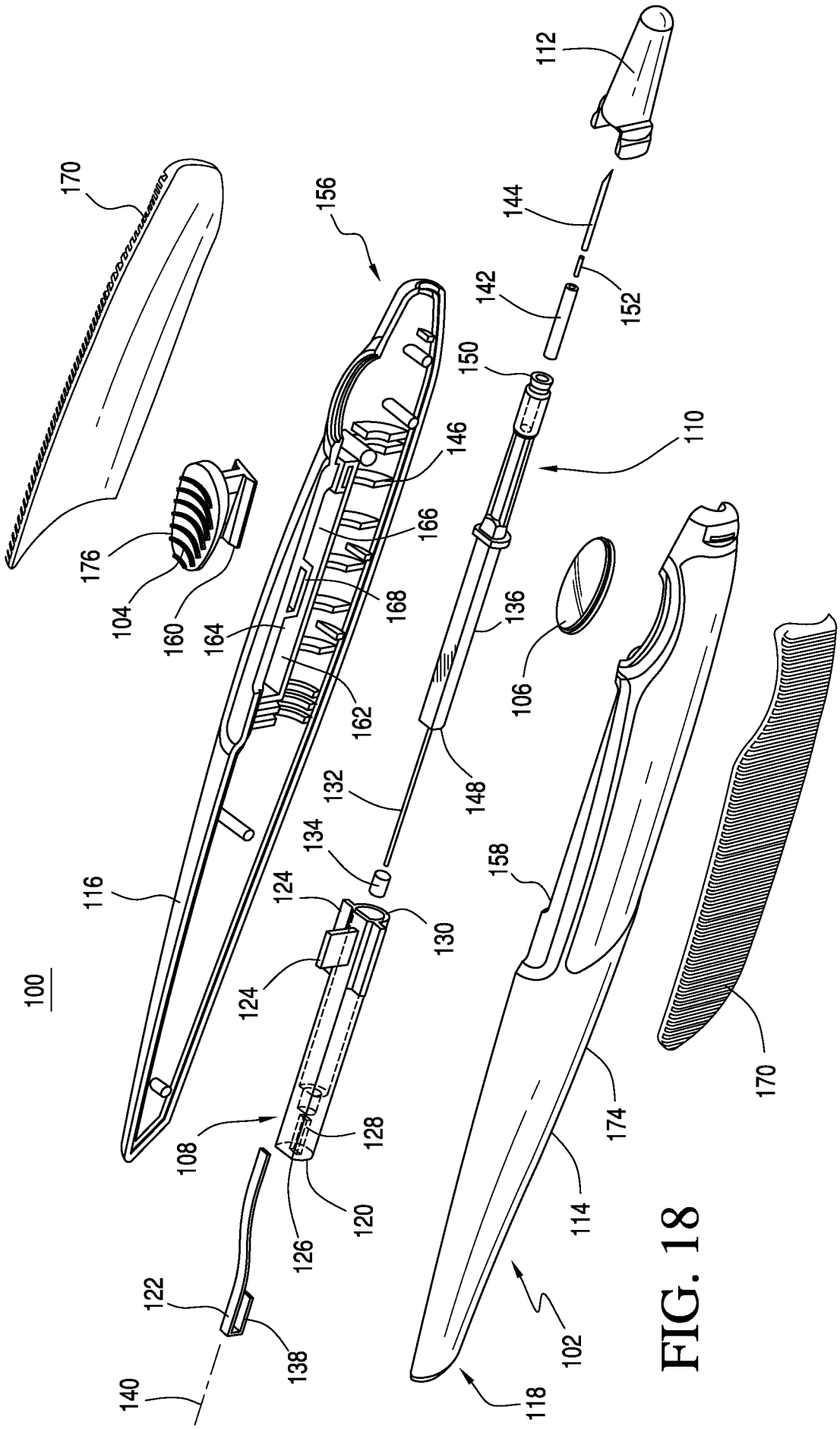

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FIG. 18

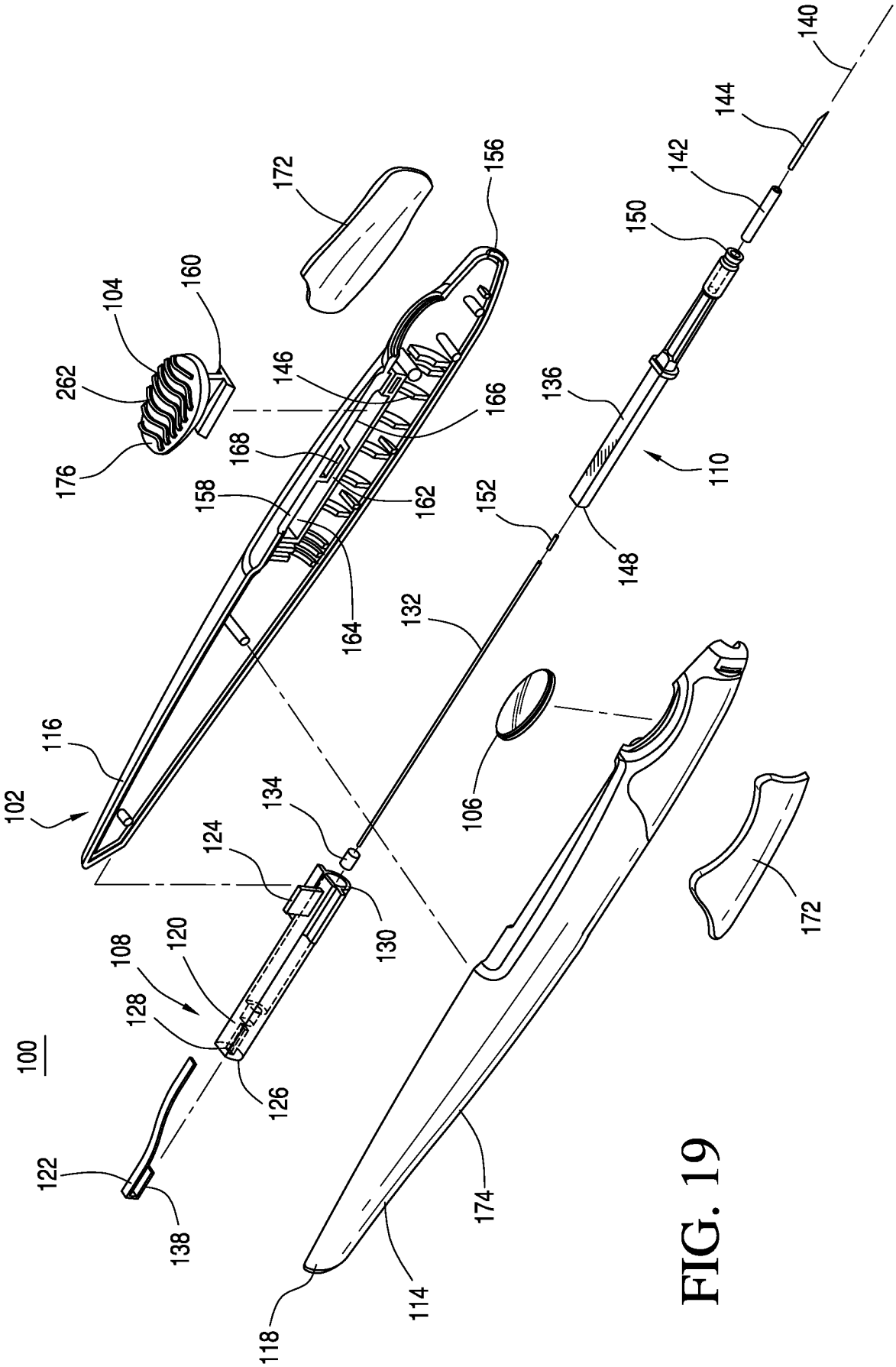

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FIG. 19

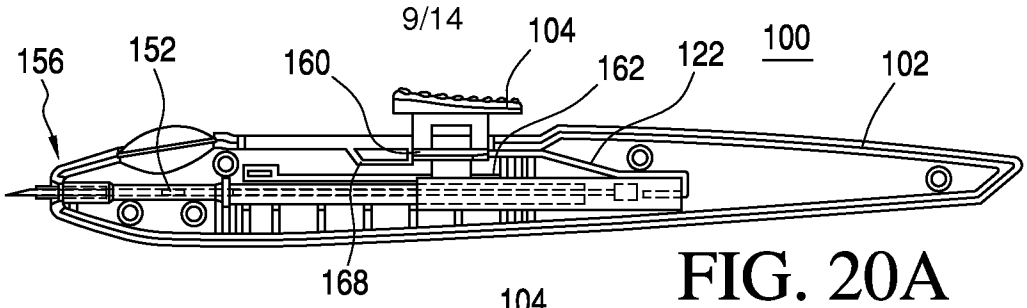


FIG. 20A

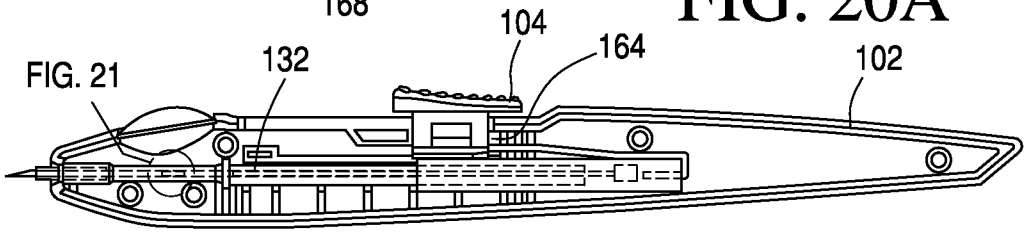


FIG. 20B

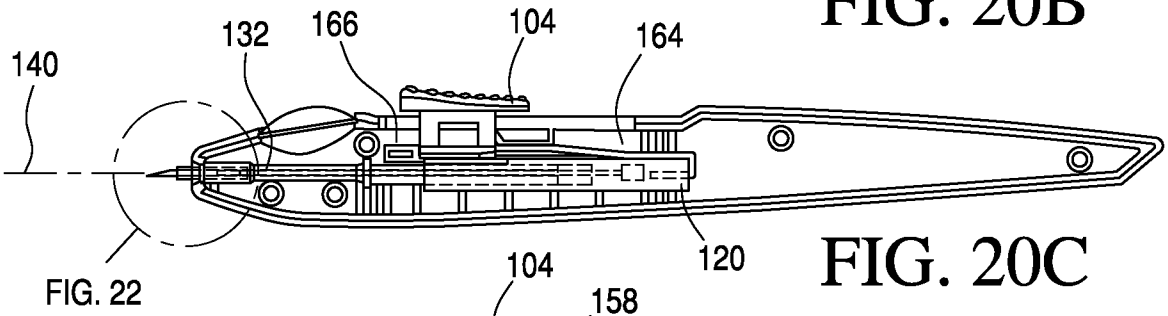


FIG. 20C

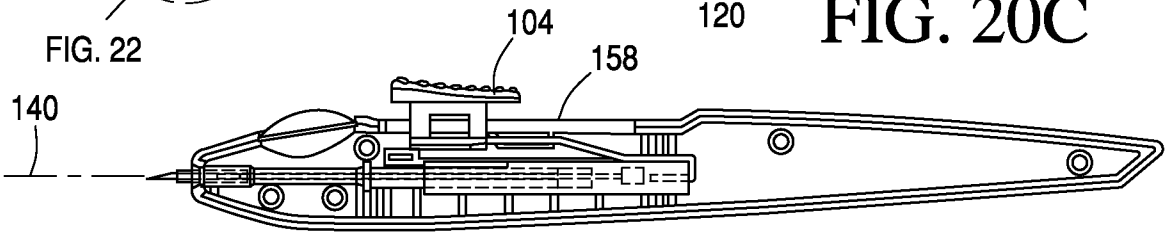


FIG. 20D

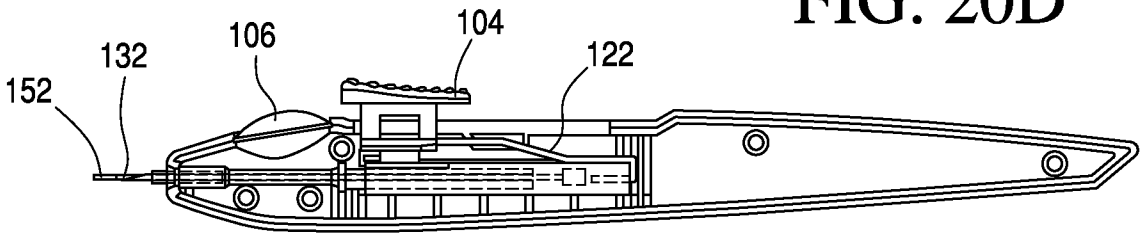


FIG. 20E

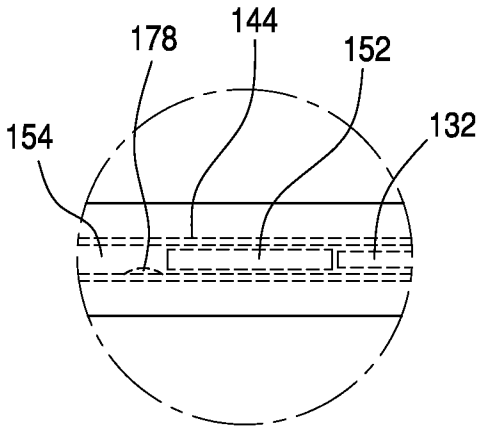


FIG. 21

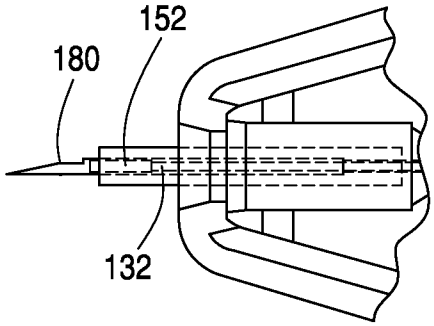


FIG. 22

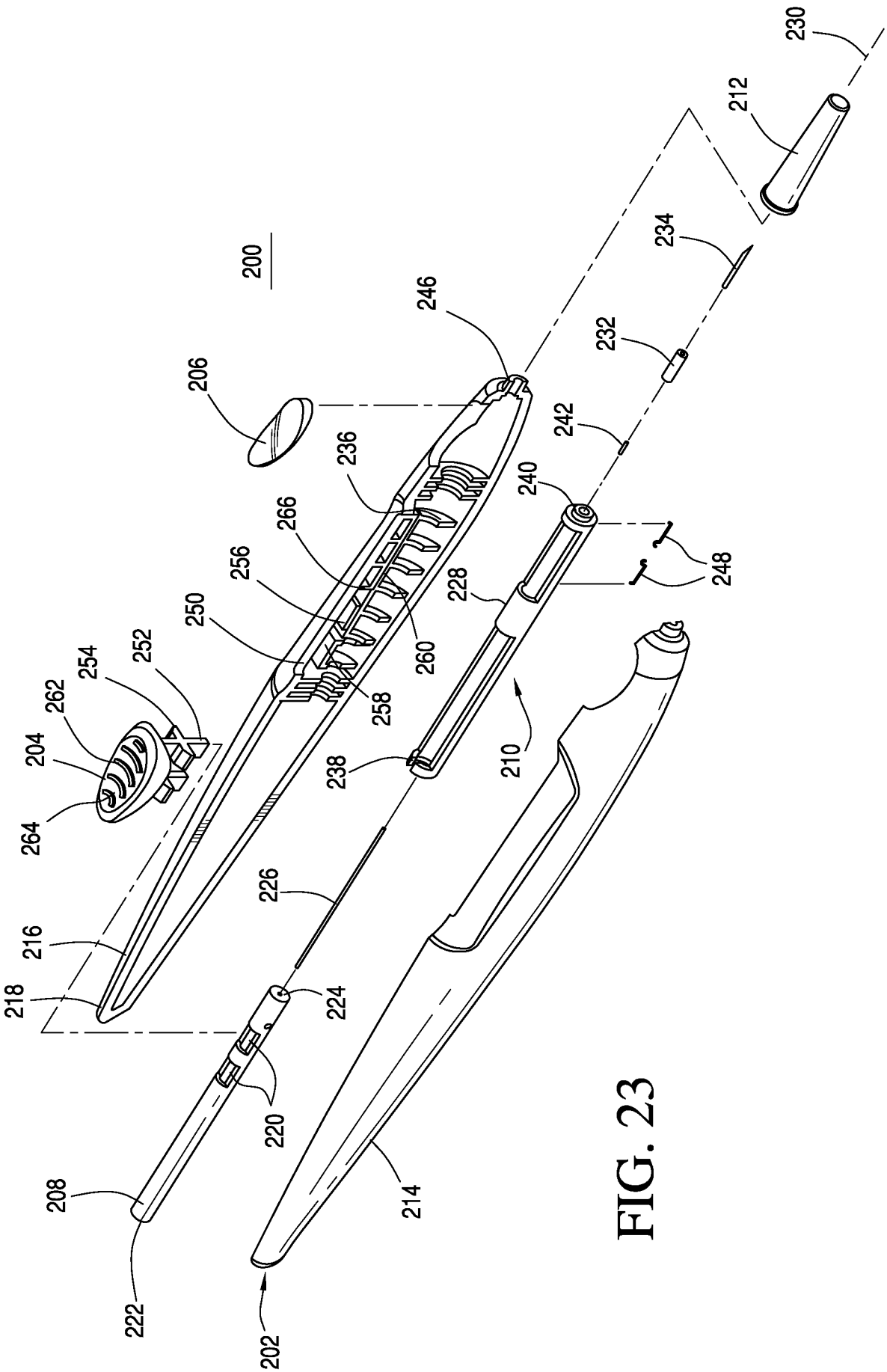

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FIG. 23

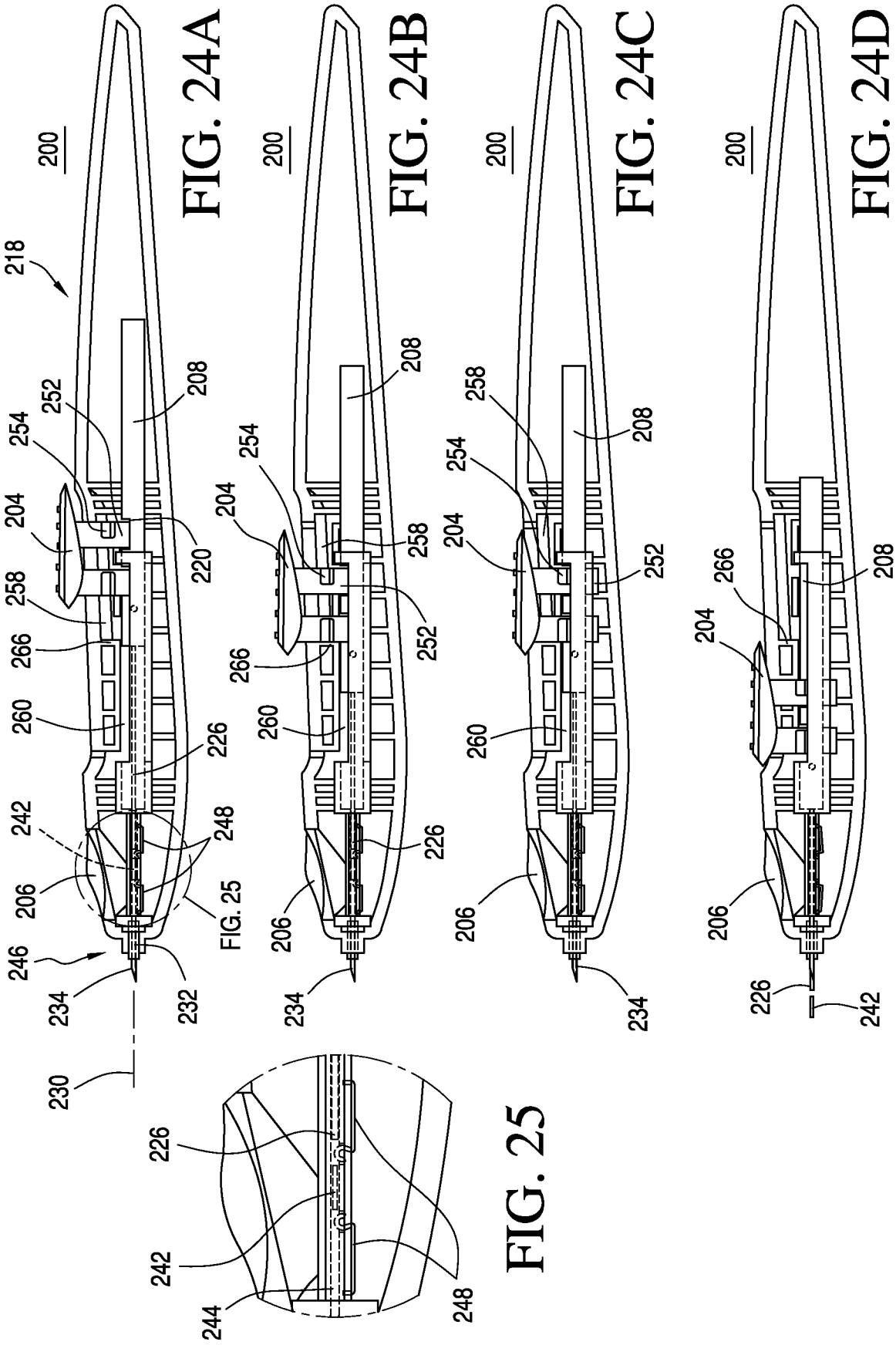


FIG. 24A

FIG. 24B

FIG. 24C

FIG. 24D

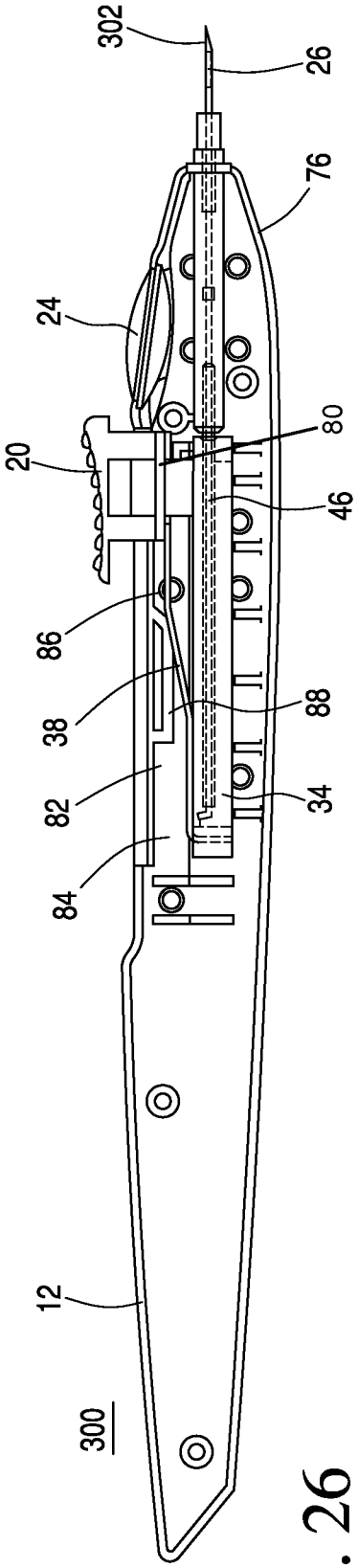

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FIG. 26

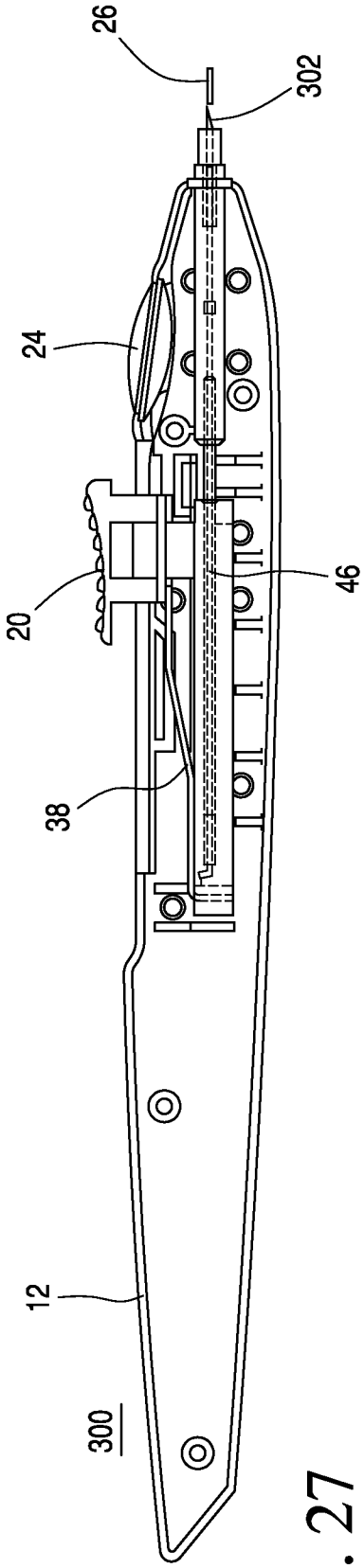

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FIG. 27

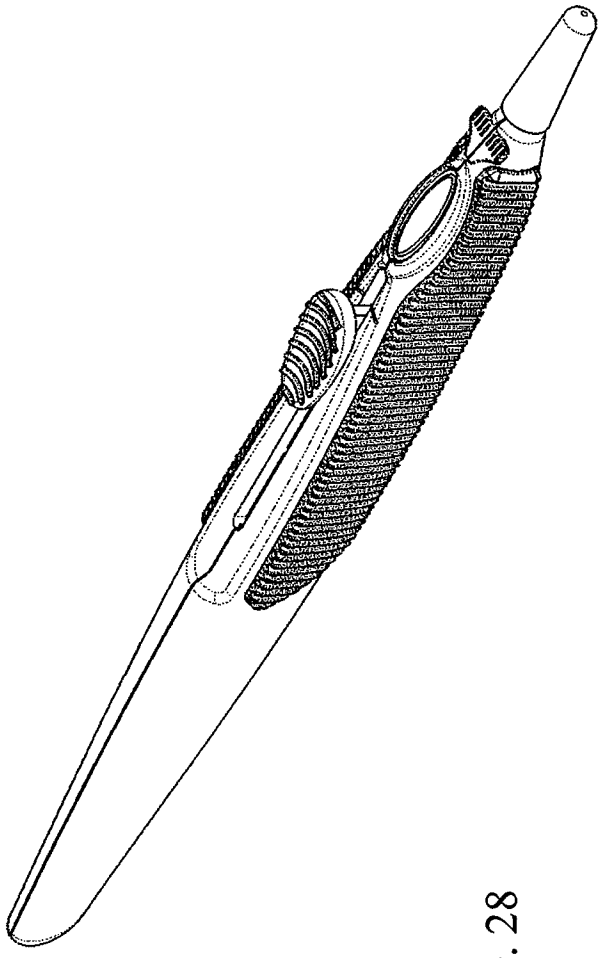


FIG. 28

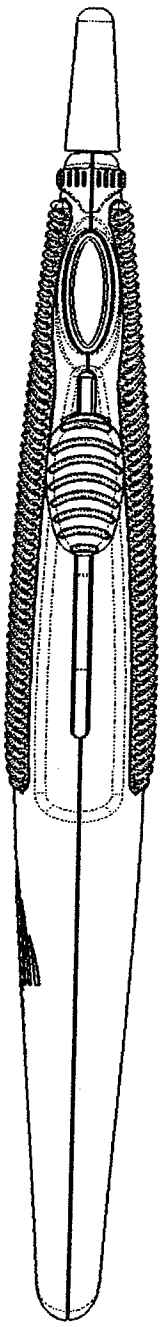


FIG. 29

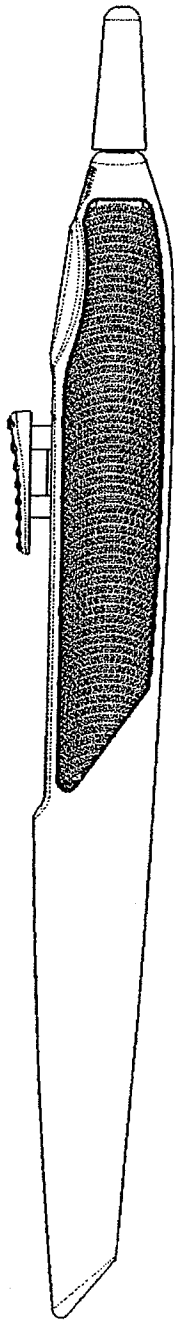


FIG. 30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/82735

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 9/007 (2009.01)
USPC - 606/107
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 9/007 (2009.01)
USPC - 606/107

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/521, 606/57, 606/59, 606/48;
IPC(8) - A61F 9/00, A61M 5/178, A61M 5/31, A61F 9/007 (2009.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST (PGPB, USPT, USOC, EPAB, JPAB)
GOOGLE (SCHOLAR, WEB, PATENTS)
Search Terms Used: eye, ocular, plunger, spring, needle, syringe, bioactive, actuator, drug core, permeable

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0211982 A1 (PRESTRELSKI et al.) 21 September 21 2006 (21.09.2006); see paragraphs [0085]-[0086]; [0098]; [0113]; [0120]-[0122]; [0126]-[0129]	1-26
Y	US 4,277,888 A (SZABO) 14 July 1981 (14.07.1981); see col. 4, ln 34-53; col. 5, ln 4-11	1-23
Y	US 7,147,644 B2 (WEBER et al.) 12 December 2006 (12.12.2006) see col. 3, ln 28-46	1-26
Y	US 6,439,276 B1 (WOOD et al.) 27 August 2002 (27.08.2002); see col. 5, ln 6-1	15
Y	US 2007/0243230 A1 (de JUAN Jr. et al.) 18 October 2007 (18.10.2007); see paragraph [0087], [0140]	18-19

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 January 2009 (06.01.2009)	16 JAN 2009

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Facsimile No. 571-273-3201

Authorized officer:
Lee W. Young
PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)