

by the insertion of the needle into the eye is self-sealing upon the removal of the needle. Particular orientations of the needle (e.g., bevel away from the surface of the cornea) during insertion can aid in self-sealing. For example, the penetrating step can comprise inserting the needle into the cornea with the bevel of the needle oriented 180° away from the surface of the eye or cornea. According to one embodiment, the method and apparatus as set forth herein are used to introduce an intraocular implant (or more particularly, an intracameral implant) into the anterior chamber of a patient's eye. The patient can be a human patient in need of treatment for a medical condition of the eye.

[0019a] One embodiment provides for a method of introducing an intraocular implant into the anterior chamber of a patient's eye using the apparatus as disclosed herein, the method comprising:

- (a) providing an intraocular implant delivery apparatus as disclosed herein;
- (b) penetrating the cornea of a patient's eye with the distal beveled end of the needle;
- (c) inserting the needle into the anterior chamber of the patient's eye;
- (d) ejecting the implant from the apparatus into the anterior chamber of the patient's eye;
- (e) and removing the needle from the patient's eye.

[0019b] One embodiment provides for a use of an intraocular implant in the manufacture of a medicament for treating an ocular condition, wherein the intraocular implant is to be introduced into the anterior chamber of a patient's eye using the apparatus as disclosed herein, wherein:

- (a) the cornea of a patient's eye is to be penetrated with the distal beveled end of the needle;
- (b) the needle is to be inserted into the anterior chamber of the patient's eye;
- (c) the implant is to be ejected from the apparatus into the anterior chamber of the patient's eye;
- (d) and the needle is to be removed from the patient's eye.

[0020] The needle tip can further be configured to have particular beveled designs which further aid in the self-sealing method. In some forms of the method, the patient can have glaucoma or ocular hypertension. One or more markings are optionally present on the exterior of the needle as an aid to measure needle advancement into the eye. In one form of the method, the needle is inserted into the anterior chamber of the eye by inserting the needle through the cornea at a point just anterior to the limbus (or corneo-scleral junction, where the cornea joins the sclera and the bulbar conjunctiva attaches to the eyeball). According to some embodiments, the needle is inserted into the anterior

chamber to a depth of about 4 mm to about 7.5 mm, as measured from the tip of the needle to the corneal surface where the needle first penetrates the eye. The needle may be pointed toward the inferior anterior chamber angle before ejecting the implant. In one embodiment, the needle is advanced into the eye to a length of about 4 mm, as measured from the tip of the needle to the outer surface of the eye where the needle first penetrates the eye, and the tip of the needle is pointed toward the inferior anterior chamber angle. The ejector button is then depressed to deploy the implant. The method may be effective for treating a medical condition of the eye. For example, the method may be effective for treating glaucoma, ocular hypertension (or elevated intraocular pressure), dry eye, or age-related macular degeneration.

[0021] An apparatus according to the present disclosure can include an implant holder for holding and retaining an implant during assembly and prior to activation of the ocular implant apparatus. Unlike some other devices, the implant is not stored in the lumen of the needle but is instead held in the lumen of an implant holder, a separately manufactured element located

CLAIMS

What is claimed is:

1. An apparatus for injecting an intraocular implant into the anterior chamber of a patient's eye, the apparatus comprising:

(a) an elongate housing having a longitudinal axis and having a proximal end and a distal end;

(b) an ejector button extending through an opening in the housing and moveable from a first position to a second position in a direction normal to the longitudinal axis of the housing;

(c) a needle having a proximal end and a distal beveled end, the needle extending longitudinally from the distal end of the housing, the needle having a lumen extending through a length of the needle such that an intraocular implant can be received within and translated through the lumen of the needle, the needle rotatable in clockwise and counter-clockwise directions about its long axis; and

(d) an implant holder having a proximal and a distal end and a lumen capable of receiving and holding an intraocular implant prior to activation of the apparatus, the implant holder located inside the housing, the implant holder further being capable of movement, upon activation of the apparatus, from a first position to a second position within the housing along the longitudinal axis of the housing and in a direction toward a distal end of the apparatus, the lumen of the implant holder aligned with the lumen of the needle such that an implant can slidably translate from the lumen of the implant holder into the lumen of the needle upon activation of the apparatus, the implant holder capped at its distal end with a cross-slit membrane,

wherein depression of the ejector button results in activation of the apparatus and ejection of the implant from the apparatus.

2. The apparatus of claim 1, further comprising an intraocular implant, the implant located entirely within the implant holder, wherein the intraocular implant is a solid, rod-shaped, biodegradable, intraocular implant comprising a biodegradable polymer matrix and a pharmaceutically active agent associated with the biodegradable polymer matrix, wherein the pharmaceutically active agent is effective for treating a medical condition of the eye, and wherein the implant is 150 μm to 300 μm in diameter or width, 0.50 mm to 2.5 mm in length, and 20 μg to 120 μg in total weight.

3. The apparatus of claim 1 or claim 2, wherein the length of the needle extending from the distal end of the housing is 4 mm to 8 mm.
4. The apparatus of any one of claims 1-3, further comprising a push rod having a proximal and a distal end, wherein prior to activation of the apparatus the distal end of the push rod is disposed in the lumen of the implant holder at the proximal end of the implant holder, and wherein the push rod is slidably receivable within the lumen of the implant holder and the lumen of the needle, and wherein the push rod is moveable along the longitudinal axis of the housing.
5. The apparatus of claim 4, further comprising a spring-driven assembly engageable with the push rod for forcing the push rod through the implant holder and the lumen of the needle following activation of the apparatus.
6. The apparatus of any one of claims 1-5 further comprising a needle-rotation knob located at the proximal end of the housing, whereby manual rotation of said knob in a clockwise or counter-clockwise direction relative to the longitudinal axis of the housing results in a corresponding clockwise or counter-clockwise rotation of the needle.
7. The apparatus of any one of claims 1-6 further comprising implant inspection windows located on the distal end of the housing, wherein said implant inspection windows are configured to permit visual observation of an implant inside the housing prior to activation of the apparatus.
8. The apparatus of any one of claims 1-7, further comprising an implant delivery feedback window located on the housing, wherein said feedback window is configured to allow observation of a visible signal that indicates activation of the apparatus.
9. The apparatus of any one of claims 1-8 wherein said needle is a 28 gauge needle with a wall that is 0.0381 mm (0.0015 inches) to 0.0572 mm (0.00225 inches) thick.

10. The apparatus of claim 2, wherein the pharmaceutically active agent is a steroid, a non-steroidal anti-inflammatory agent, an alpha 2 adrenergic receptor agonist, a prostamide, or a protein.

11. Use of an intraocular implant in the manufacture of a medicament for treating an ocular condition, wherein the intraocular implant is to be introduced into the anterior chamber of a patient's eye using the apparatus of claim 2, wherein:

(a) the cornea of a patient's eye is to be penetrated with the distal beveled end of the needle;

(b) the needle is to be inserted into the anterior chamber of the patient's eye;

(c) the implant is to be ejected from the apparatus into the anterior chamber of the patient's eye;

(d) and the needle is to be removed from the patient's eye.

12. The use of claim 11, wherein in step (a) the needle is to be inserted into the cornea with the bevel of the needle oriented 180° away from the surface of the eye.

13. The use of claim 11 or claim 12, wherein the needle is to be inserted into the anterior chamber through the cornea at a point just anterior to the limbus.

14. The use of any one of claims 11-13, wherein needle is to be inserted into the anterior chamber to a depth of about 4 mm to about 7.5 mm, as measured from a tip of the needle to the corneal surface where the needle first penetrates the eye, and wherein the needle is to be pointed toward the inferior anterior chamber angle before ejecting the implant.

15. The use of any one of claims 11-14, wherein the patient has glaucoma or ocular hypertension.