TORQUE RING FOR SUBRETINAL INJECTION DEVICE

PRIORITY

[0001] This application claims the benefit of U.S. Pat. App. No. 63/570,372, entitled "Torque Ring for Subretinal Injection Device," filed March 27, 2024, the disclosure of which is incorporated by reference herein.

BACKGROUND

[0002] The human eye comprises several layers. The white outer layer is the sclera, which surrounds the choroid layer. The retina is interior to the choroid layer. The sclera contains collagen and elastic fiber, providing protection to the choroid and retina. The choroid layer includes vasculature providing oxygen and nourishment to the retina. The retina comprises light sensitive tissue, including rods and cones. The macula is located at the center of the retina at the back of the eye, generally centered on an axis passing through the centers of the lens and cornea of the eye (i.e., the optic axis). The macula provides central vision, particularly through cone cells.

[0003] Macular degeneration is a medical condition that affects the macula, such that people suffering from macular degeneration may experience lost or degraded central vision while retaining some degree of peripheral vision. Macular degeneration may be caused by various factors such as age (also known as age-related macular degeneration or "AMD") and genetics. Macular degeneration may occur in a "dry" (nonexudative) form, where cellular debris known as drusen accumulates between the retina and the choroid, resulting in an area of geographic atrophy. Macular degeneration may also occur in a "wet" (exudative) form, where blood vessels grow up from the choroid behind the retina. Even though people having macular degeneration may retain some degree of peripheral vision, the loss of central vision may have a significant negative impact on the quality of life. Moreover, the quality of the remaining peripheral vision may be degraded and, in some cases, may disappear as well. It may therefore be desirable to provide treatment for macular degeneration to prevent or reverse the loss of vision caused by macular degeneration. In some cases, it may be desirable to provide such treatment in a highly

localized fashion, such as by delivering a therapeutic substance in the subretinal layer (under the neurosensory layer of the retina and above the retinal pigment epithelium) directly adjacent to the area of geographic atrophy, near the macula. However, since the macula is at the back of the eye and underneath the delicate layer of the retina, it may be difficult to access the macula in a practical fashion.

[0004] While a variety of surgical methods and instruments have been made and used to treat an eye, it is believed that no one prior to the inventors has made or used the invention described in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] While the specification concludes with claims which particularly point out and distinctly claim this technology, it is believed this technology will be better understood from the following description of certain examples taken in conjunction with the accompanying drawings, in which like reference numerals identify the same elements and in which:

[0006] FIG. 1 depicts a perspective view of an example of an instrument for subretinal administration of a therapeutic agent from a suprachoroidal approach;

[0007] FIG. 2 depicts a perspective view of a distal portion of a cannula of the instrument of FIG. 1;

[0008] FIG. 3 depicts a front elevation view of the distal portion of the cannula of FIG. 2;

[0009] FIG. 4 depicts a top plan view of the distal portion of the cannula of FIG. 2;

[00010] FIG. 5 depicts a perspective view of the distal end of a cannula of FIG. 2, with a needle extending from the cannula;

[00011] FIG. 6 depicts an exploded perspective view of a portion of the instrument of FIG. 1, showing a needle actuation assembly of the instrument;

[00012] FIG. 7 depicts a perspective view of a rotary cam of the needle actuation assembly of FIG. 6;

[00013] FIG. 8 depicts a perspective view of a frame member of the needle actuation assembly of FIG. 6;

[00014] FIG. 9 depicts a perspective view of a needle driver of the needle actuation assembly of FIG. 6;

[00015] FIG. 10A depicts a cross-sectional view of the needle actuation assembly of FIG. 6, with the rotary cam of FIG. 7 at a first angular position and the needle driver of FIG. 9 in a proximal position;

[00016] FIG. 10B depicts a cross-sectional view of the needle actuation assembly of FIG. 6, with the rotary cam of FIG. 7 at a second angular position and the needle driver of FIG. 9 in a distal position;

[00017] FIG. 11 depicts a perspective view of a circuit board assembly of the instrument of FIG. 1;

[00018] FIG. 12 depicts a perspective view of the instrument of FIG. 1, mounted near a patient, with a combination of medical equipment;

[00019] FIG. 13A depicts a cross-sectional side view of an eye of a patient;

[00020] FIG. 13B depicts a cross-sectional side view of the eye of FIG. 13A, with a suture loop attached to the eye, and with a sclerotomy being performed;

[00021] FIG. 13C depicts a cross-sectional side view of the eye of FIG. 13A, with the cannula of FIG. 2 being inserted through the sclerotomy opening and in between the sclera and choroid of the eye;

[00022] FIG. 13D depicts a cross-sectional side view of the eye of FIG. 13A, with the distal end of the cannula being positioned adjacent to a target location;

[00023] FIG. 13E depicts a cross-sectional side view of the eye of FIG. 13A, with the needle of FIG. 5 being advanced through the choroid to access the subretinal space at the target location;

[00024] FIG. 13F depicts a cross-sectional side view of the eye of FIG. 13A, with the needle

of FIG. 5 dispensing a first volume of leading bleb fluid to provide separation between a region of the retina and the choroid at the target location;

[00025] FIG. 13G depicts a cross-sectional side view of the eye of FIG. 13A, with the needle of FIG. 5 dispensing a therapeutic agent between a region of the retina and the choroid at the target location;

[00026] FIG. 14 depicts a perspective view of another example of an instrument for subretinal administration of a therapeutic agent from a suprachoroidal approach, operatively coupled to an example of a fluid control unit;

[00027] FIG. 15 depicts a perspective view of a rotary knob assembly of the instrument of FIG. 14;

[00028] FIG. 16 depicts an exploded perspective view of the rotary knob assembly of FIG. 15;

[00029] FIG. 17 depicts a perspective view of a knob body of the rotary knob assembly of FIG. 15;

[00030] FIG. 18 depicts a perspective view of a torque ring of the rotary knob assembly of FIG. 15;

[00031] FIG. 19 depicts a perspective view of a slip clutch of the rotary knob assembly of FIG. 15;

[00032] FIG. 20 depicts a perspective view of a knob base of the rotary knob assembly of FIG. 15;

[00033] FIG. 21A depicts a partial side cross sectional view of the instrument of FIG. 14, taken along line 21-21 in FIG. 14, with the rotary knob assembly of FIG. 15 at a first angular position and the needle driver of FIG. 9 in a proximal position;

[00034] FIG. 21B depicts a partial side cross sectional view of the instrument of FIG. 14, taken along line 21-21 in FIG. 14, with the rotary knob assembly of FIG. 15 at a second angular position and the needle driver of FIG. 9 in a distal position;

[00035] FIG. 22A depicts a partial top cross sectional view of the instrument of FIG. 14, taken along line 22-22 in FIG. 14, with first and second valves of a fluid supply assembly of the instrument in respective closed states;

[00036] FIG. 22B depicts a partial top cross sectional view of the instrument of FIG. 14, taken along line 22-22 in FIG. 14, with the first valve of the fluid supply assembly in an open state for supplying a first fluid to a needle of the instrument, and with the second valve of the fluid supply assembly in the closed state;

[00037] FIG. 22C depicts a partial top cross sectional view of the instrument of FIG. 14, taken along line 22-22 in FIG. 14, with the first valve of the fluid supply assembly in the closed state, and with the second valve of the fluid supply assembly in an open state for supplying a second fluid to the needle of the instrument;

[00038] FIG. 23 depicts a schematic view of a circuit board assembly of the instrument of FIG. 14;

[00039] FIG. 24 depicts a perspective view of another example of a fluid control unit for use with either of the instruments of FIGS. 1 and 14, showing the fluid control unit operatively coupled to the instrument and to an offboard processor, and further showing the fluid control unit mounted to a wrist rest of FIG. 12;

[00040] FIG. 24A depicts a side elevation view of the fluid control unit of FIG. 24, showing the fluid control unit mounted to the wrist rest of FIG. 12 via a mounting assembly;

[00041] FIG. 25 depicts an exploded perspective view of the fluid control unit of FIG. 24, showing a control module and a cartridge of the fluid control unit;

[00042] FIG. 26 depicts a top plan view of the control module of FIG. 25;

[00043] FIG. 27 depicts a front elevation view of a distal end of the control module of FIG. 25;

[00044] FIG. 28 depicts an exploded perspective view of the control module of FIG. 25, showing upper and lower housing shells, first and second drive assemblies, and a circuit board assembly of the control module;

[00045] FIG. 29 depicts a perspective view of the first and second drive assemblies of FIG. 28;

[00046] FIG. 30 depicts a side elevation view of the first and second drive assemblies of FIG. 28;

[00047] FIG. 31 depicts a perspective view of the circuit board assembly and lower housing shell of FIG. 28;

[00048] FIG. 32 depicts a top plan view of the cartridge of FIG. 25;

[00049] FIG. 33 depicts a bottom plan view of the cartridge of FIG. 25;

[00050] FIG. 34 depicts a rear elevation view of a proximal end of the cartridge of FIG. 25; and

[00051] FIG. 35 depicts an exploded perspective view of the cartridge of FIG. 25.

[00052] The drawings are not intended to be limiting in any way, and it is contemplated that various embodiments of the technology may be carried out in a variety of other ways, including those not necessarily depicted in the drawings. The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present technology, and together with the description serve to explain the principles of the technology; it being understood, however, that this technology is not limited to the precise arrangements shown.

DETAILED DESCRIPTION

[00053] The following description of certain examples of the technology should not be used to limit its scope. Other examples, features, aspects, embodiments, and advantages of the technology will become apparent to those skilled in the art from the following description, which is by way of illustration, one of the best modes contemplated for carrying out the technology. As will be realized, the technology described herein is capable of other different and obvious aspects, all without departing from the technology. Accordingly, the drawings and descriptions should be regarded as illustrative in nature and not restrictive.

[00054] It is further understood that any one or more of the teachings, expressions,

embodiments, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, embodiments, examples, etc. that are described herein. The following-described teachings, expressions, embodiments, examples, etc. should therefore not be viewed in isolation relative to each other. Various suitable ways in which the teachings herein may be combined will be readily apparent to those skilled in the art in view of the teachings herein. Such modifications and variations are intended to be included within the scope of the claims.

[00055] For clarity of disclosure, the terms "proximal" and "distal" are defined herein relative to a surgeon or other operator grasping a surgical instrument having a distal surgical end effector. The term "proximal" refers the position of an element closer to the surgeon or other operator and the term "distal" refers to the position of an element closer to the surgical end effector of the surgical instrument and further away from the surgeon or other operator.

[00056] Furthermore, the terms "about," "approximately," and the like as used herein in connection with any numerical values or ranges of values are intended to encompass the exact value(s) referenced as well as a suitable tolerance that enables the referenced feature or combination of features to function for the intended purpose described herein.

[00057] I. Instrument for Subretinal Administration of Therapeutic Agent

[00058] FIG. 1 shows an example of an instrument (100) that is configured for use in a procedure for the subretinal administration of a therapeutic agent to an eye of a patient from a suprachoroidal approach. Instrument (100) comprises a pair of housing halves (110, 111), a pair of rocker plates (112, 114), a rotary knob (120), and a flexible cannula (130) extending distally from housing halves (110, 111). As also shown in FIG. 1, a tube set (140) extends proximally from instrument (100). Cannula (130) of the present example has a generally rectangular cross section, though any other suitable cross-sectional profile (e.g., elliptical, etc.) may be used. The generally rectangular cross-sectional profile of cannula (130) is configured to enable cannula (130) to be passed atraumatically along the suprachoroidal space, as will be described in greater detail below. Cannula (130) is generally configured to support a needle (150) that is slidable within cannula (130), as will

be described in greater detail below.

[00059] In the present example, cannula (130) comprises a flexible material such as Polyether block amide (PEBA), though any other suitable material or combination of materials may be used. In some versions, cannula (130) has a cross-sectional profile dimension of approximately 1.6 mm (width) by approximately 0.6 mm (height), with a length of approximately 80 mm. Alternatively, any other suitable dimensions may be used. Cannula (130) of the present example is flexible enough to conform to specific structures and contours of the patient's eye, yet cannula (130) has sufficient column strength to permit advancement of cannula (130) between the sclera and choroid of patient's eye without buckling. As best seen in FIGS. 2-5, cannula (130) includes a transversely oriented opening (134) near the distal end (132) of cannula (130). Opening (134) of the present example is formed by a U-shaped lateral recess (136) in cannula (130), which leads to an open distal end (138) of a needle guide lumen within cannula (130). Distal end (132) is atraumatic such that distal end (132) is configured to provide separation between the sclera and choroid layers via blunt dissection, as will be described in greater detail below, to thereby enable cannula (130) to be advanced between such layers while not inflicting trauma to the sclera or choroid layers.

[00060] By way of example only, cannula (130) may be configured and operable in accordance with at least some of the teachings of U.S. Pat. No. 10,226,379, entitled "Method and Apparatus for Subretinal Administration of Therapeutic Agent," issued March 12, 2019, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 10,646,374, entitled "Apparatus and Method to From Entry Bleb for Subretinal Delivery of Therapeutic Agent," issued May 12, 2020, the disclosure of which is incorporated by reference herein, in its entirety; and/or in any other suitable fashion.

[00061] As shown in FIG. 5, needle (150) may be advanced distally to protrude from opening (134). Needle (150) of the present example has a sharp distal tip (152) and defines a lumen (not shown). Distal tip (152) of the present example has a lancet configuration. In some other versions, distal tip (152) has a tri-bevel configuration or any other configuration as described in U.S. Pat. No. 10,226,379, the disclosure of which is incorporated by reference herein, in its entirety. Still other suitable forms that distal tip

(152) may take will be apparent to those skilled in the art in view of the teachings herein. In the present example, the generally rectangular, generally elliptical, or otherwise generally flat cross-sectional profile of cannula (130) prevents cannula (130) from rotating about the longitudinal axis of cannula (130) when cannula (130) is disposed in the suprachoroidal space as will be described in greater detail below. This provides a consistent and predictable orientation of opening (134), thereby providing a consistent and predictable exit path for needle (150) when needle (150) is advanced distally relative to cannula (130) as will be described in greater detail below.

[00062] By way of example only, the angle defined between the exposed portion of needle (150) and cannula (130), after needle (150) has been advanced distally relative to cannula (130), may be within the range of approximately 5° to approximately 30° relative to the longitudinal axis of cannula (130); or more particularly within the range of approximately 5° to approximately 20° relative to the longitudinal axis of cannula (130); or more particularly within the range of approximately 5° to approximately 10° relative to the longitudinal axis of cannula (130); or more particularly within the range of approximately 7° and approximately 9° relative to the longitudinal axis of cannula (130). In the present example, needle (150) is resiliently biased to assume a bent configuration to thereby provide an exit angle that varies based on the extent to which needle (150) is advanced distally relative to cannula (130). By way of further example only, needle (150) may include a preformed bend in accordance with at least some of the teachings of U.S. Pat. No. 10,478,553, entitled "Apparatus for Subretinal Administration of Therapeutic Agent via a Curved Needle," issued November 19, 2019, the disclosure of which is incorporated by reference herein, in its entirety.

[00063] Rotary knob (120) is rotatable relative to housing halves (110, 111) to thereby selectively translate needle (150) longitudinally relative to cannula (130). In particular, rotary knob (120) is rotatable in a first angular direction to drive needle (150) distally relative to cannula (130); and in a second angular direction to drive needle (150) proximally relative to cannula (130). In this regard, and as shown in FIG. 6, instrument (100) further includes a frame member (160), a circuit board assembly (170), and a needle driver/needle actuator (180). As shown in FIG. 6, rotary knob (120), frame member (160), and needle

actuator (180) are coupled together to form an assembly. Rotary knob (120) is operable to rotate relative to housing halves (110, 111). Frame member (160) is configured to be unitarily secured to housing halves (110, 111), such that frame member (160) remains stationary relative to housing halves (110, 111). Needle actuator (180) is operable to translate relative to housing halves (110, 111), in response to rotation of rotary knob (120) relative to housing halves (110, 111). As shown in FIG. 7, the underside of rotary knob (120) includes a spiral cam recess (124). As shown in FIG. 8, frame member (160) includes a pair of support rails (162) and a guide slot (164). As shown in FIG. 9, needle actuator (180) comprises a pair of guide wings (182) and a cam follower post (184). Guide wings (182) are sized and configured to engage support rails (162). This engagement provides vertical and lateral support to needle actuator (180), while permitting needle actuator (180) to slide longitudinally relative to frame member (160). Guide slot (164) is configured to receive cam follower post (184) and accommodate sliding movement thereof as needle actuator (180) slides longitudinally relative to frame member (160).

[00064] As shown in FIGS. 10A-10B, cam follower post (184) of needle actuator (180) is configured to fit in spiral cam recess (124) of rotary knob (120). Due to this engagement, and due to guidance provided to cam follower post (184) by guide slot (164), needle actuator (180) will translate from a proximal position (FIG. 10A) to a distal position (FIG. 10B) in response to rotation of rotary knob (120). Needle (150) is fixedly secured to needle actuator (180), such that needle (150) will translate longitudinally relative to cannula (130) in response to rotation of rotary knob (120). By way of example only, instrument (100) may provide such functionality through knob (120) in accordance with at least some of the teachings of U.S. Pat. No. 10,646,374, the disclosure of which is incorporated by reference herein, in its entirety. Other suitable ways in which rotary motion of knob (120) may be converted to linear translation of needle (150) will be apparent to those skilled in the art in view of the teachings herein. Similarly, other suitable ways in which needle (150) may be actuated (150) longitudinally relative to cannula (130) will be apparent to those skilled in the art in view of the teachings herein.

[00065] As shown in FIG. 11, an upper side of circuit board assembly (170) comprises a first tactile switch (172) and a linear sensor (176). First tactile switch (172) may be

positioned to be actuated by a dowel (173) that is positioned between first tactile switch (172) and a dowel seat (not shown) on the underside of upper rocker plate (114). The operator may provide such actuation of tactile switch (172) by pressing upper rocker plate (114) to cause upper rocker plate (114) to pivot about pivot posts (not shown), which will drive the dowel downwardly toward first tactile switch (172). First tactile switch (172) may communicate with a control module (not shown) via one or more of wires (175) contained in tube set (140). By way of example only, the control module may provide delivery of therapeutic agent (341) via needle (150) in response to actuation of first tactile switch (172).

[00066] While not shown, an underside of circuit board assembly (170) may include a second tactile switch positioned to be actuated by an integral post of lower rocker plate (112). The operator may provide such actuation of the second tactile switch by pivotably urging housing halves (110, 111) downwardly to cause housing halves (110, 111) to pivot about pivot posts (not shown), which will drive the second tactile switch downwardly toward the integral post. The second tactile switch may communicate with the control module via one or more of wires (175) contained in tube set (140). By way of example only, the control module may provide delivery of bleb fluid (340) via needle (150) in response to actuation of the second tactile switch.

[00067] Linear sensor (176) includes a slider (178) that is configured to slide unitarily with needle actuator (180) and thereby translate longitudinally relative to a body of linear sensor (176). Linear sensor (176) is configured to generate a varying data value based on the longitudinal position of slider (178) along the body of linear sensor (176). By way of example only, linear sensor (176) may comprise a linear potentiometer that generates a varying resistance value based on the longitudinal position of slider (178) along the body. Thus, the resistance value generated through linear sensor (176) will be indicative of the longitudinal position of needle (150) relative to cannula (130). By way of further example only, linear sensor (176) may comprise a sensor that senses rotation of knob (120), an optical sensor, or a sensor located in instrument (100) to directly monitor movement of needle actuator (180). Various other suitable ways in which movement of needle (150) may be sensed will be apparent to those of ordinary skill in the art in view of the teachings

herein. Linear sensor (176) is in communication with the control module via one or more of wires (175) contained in tube set (140). The control module may be configured to provide automated delivery of bleb fluid (340) via needle (150) in response to distal movement of needle (150) as sensed by linear sensor (176). By way of example only, instrument (100) may provide such functionalities through circuit board assembly (170) in accordance with at least some of the teachings of U.S. Pat. No. 10,646,374, the disclosure of which is incorporated by reference herein, in its entirety.

[00068] II. Procedure for Delivery of a Therapeutic Agent to Subretinal Space from a Suprachoroidal Approach

[00069] FIG. 12 shows a scenario where instrument (100) is positioned in relation to a patient. In this example, a conventional ophthalmic surgery wrist rest (also referred to as a wrist rail) (10) is positioned adjacent to and/or partially around the patient's head, to provide one or more resting points for the operator's wrists during operation of instrument (100). A drape (12) is disposed over the patient, with an opening (18) formed in drape (12) near the patient's eye (301). A speculum (16) is used to keep the eye (301) open. A fixture (14) is positioned adjacent to the eye (301). Fixture (14) may be used to secure instrumentation, such as a viewing scope, relative to the patient. A magnetic pad (30) is adhered to drape (12) near the opening (18) adjacent to the eye (301). Instrument (100) is placed on magnetic pad (30) and is removably secured thereto via magnetic attraction. In the present example, one or more permanent magnets (148) are positioned within housing halves (110, 111); and these magnets are magnetically attracted to one or more ferrous elements (not shown) contained within magnetic pad (30). By way of example only, these magnets and magnetic pad (30) may be configured in accordance with at least some of the teachings of U.S. Pat. No. 10,806,629, entitled "Injection Device for Subretinal Delivery of Therapeutic Agent," issued October 20, 2020, the disclosure of which is incorporated by reference herein, in its entirety. Instrument (100) is oriented to enable insertion of flexible cannula (130) of instrument (100) into the eye (301). An example of a process for inserting and positioning cannula (130) in the eye (301) is described in greater detail below with reference to FIGS. 13A-13F.

[00070] In the present example, instrument (100) is coupled with a fluid delivery system

(80) via tube set (140). In this example, fluid delivery system (80) comprises a bleb fluid source (82) and a therapeutic agent fluid source (84). Bleb fluid source (82) is coupled with a bleb fluid conduit (142) of tube set (140); and therapeutic agent fluid source (84) is coupled with a therapeutic agent conduit (144) of tube set (140). Conduits (142, 144) are in fluid communication with needle (150). In some versions, fluid sources (82, 84) comprise syringes. In some other versions, fluid sources (82, 84) comprise separate reservoirs and one or more associated pumps and/or valves, etc.

[00071] FIGS. 13A-13G show an example of a procedure that may be carried out using the above-described equipment, to deliver a therapeutic agent to the subretinal space of the eye (301) from a suprachoroidal approach. By way of example only, the method described herein may be employed to treat macular degeneration and/or other ocular conditions. Although the procedure described herein is discussed in the context of the treatment of age-related macular degeneration, no such limitation is intended or implied. For instance, in some alternative procedures, the same techniques described herein may be used to treat retinitis pigmentosa, diabetic retinopathy, and/or other ocular conditions. Additionally, the procedure described herein may be used to treat either dry or wet age-related macular degeneration, among other conditions.

[00072] In the present example, the procedure begins by an operator immobilizing tissue surrounding a patient's eye (301) (e.g., the eyelids) using an instrument such as speculum (16), and/or any other instrument suitable for immobilization. While immobilization described herein with reference to tissue surrounding eye (301), eye (301) itself may remain free to move. Once the tissue surrounding eye (301) has been immobilized, an eye chandelier port (314) is inserted into eye (301), as shown in FIG. 13A, to provide intraocular illumination when the interior of eye (301) is viewed through the pupil. In the present example, eye chandelier port (314) is positioned in the inferior medial quadrant such that a superior temporal quadrant sclerotomy may be performed. Eye chandelier port (314) is positioned to direct light onto the interior of eye (301) to illuminate at least a portion of the retina (308) (e.g., including at least a portion of the macula). As will be understood, such illumination corresponds to an area of eye (301) that is being targeted for delivery of therapeutic agent.

[00073] In the present example, only chandelier port (314) is inserted at the stage shown in FIG. 13A, without yet inserting an optical fiber (315) into port (314). In some other versions, an optical fiber (315) may be inserted into chandelier port (314) at this stage. In either case, a microscope may optionally be utilized to visually inspect the eye to confirm proper positioning of eye chandelier port (314) relative to the target site. Although FIG. 13A shows a certain positioning of eye chandelier port (314), eye chandelier port (314) may have any other suitable positioning as will be apparent to those skilled in the art in view of the teachings herein.

[00074] Once eye chandelier port (314) has been positioned, the sclera (304) may be accessed by dissecting the conjunctiva by incising a flap in the conjunctiva and pulling the flap posteriorly. After such a dissection is completed, the exposed surface of the sclera (304) may optionally be blanched using a cautery tool to minimize bleeding. Once conjunctiva dissection is complete, the exposed surface of the sclera (304) may optionally be dried using a WECK-CEL or other suitable absorbent device.

[00075] A template may then be used to mark the eye (301), as described in U.S. Pat. No. 10,226,379, the disclosure of which is incorporated by reference herein, in its entirety; and/or U.S. Pat. No. 11,000,410, entitled "Guide Apparatus for Tangential Entry into Suprachoroidal Space," issued May 11, 2021, the disclosure of which is incorporated by reference herein, in its entirety. The operator may then use a visual guide created using the template to attach a suture loop assembly (332) and to perform a sclerotomy, as shown in FIG. 13B, using a conventional scalpel (313) or other suitable cutting instrument. By way of example only, suture loop assembly (332) may be formed in accordance with at least some of the teachings of U.S. Pat. No. 10,226,379, the disclosure of which is incorporated by reference herein, in its entirety. Alternatively, in lieu of suture loop assembly (332), the operator may install a guide tack in accordance with at least some of the teachings of U.S. Pat. No. 11,000,410, the disclosure of which is incorporated by reference herein, in its entirety.

[00076] The sclerotomy procedure forms a small incision through sclera (304) of eye (301). The sclerotomy is performed with particular care to avoid penetration of the choroid (306). Thus, the sclerotomy procedure provides access to the space between sclera (304) and

choroid (306). Once the incision is made in eye (301), a blunt dissection may optionally be performed to locally separate sclera (304) from choroid (306). Such a dissection may be performed using a small blunt elongate instrument, as will be apparent to those skilled in the art in view of the teachings herein.

[00077] With the sclerotomy procedure performed, an operator may insert cannula (130) of instrument (100) through the incision and into the space between sclera (304) and choroid (306). As can be seen in FIG. 13C, cannula (130) is directed through suture loop assembly (332) and into the incision. Suture loop assembly (332) may stabilize cannula (130) during insertion. Additionally, suture loop assembly (332) maintains cannula (130) in a generally tangential orientation relative to the incision. Such tangential orientation may reduce trauma as cannula (130) is guided through the incision. As cannula (130) is inserted into the incision through suture loop assembly (332), an operator may use forceps or other instruments to further guide cannula (130) along an atraumatic path. Of course, use of forceps or other instruments is merely optional, and may be omitted in some examples. As noted above, a guide tack (or other device) may be used in lieu of suture loop assembly (332). Cannula (130) is advanced until distal end (132) is positioned near the targeted region of the subretinal space, on the opposite side of the choroid (306). Various suitable ways of visualizing distal end (132) to thereby observe proper positioning of distal end (132) will be apparent to those skilled in the art in view of the teachings herein.

[00078] Although not shown, in some examples, cannula (130) may include one or more markers on the surface of cannula (130) to indicate various depths of insertion. While merely optional, such markers may be desirable to aid an operator in identifying the proper depth of insertion as cannula (130) is guided along an atraumatic path. For instance, the operator may visually observe the position of such markers in relation to suture loop assembly (332) and/or in relation to the incision in the sclera (304) as an indication of the depth to which cannula (130) is inserted in eye (301). By way of example only, one such marker may correspond to an approximately 6 mm depth of insertion of cannula (130).

[00079] As shown in FIG. 13D, once cannula (130) is at least partially inserted into eye (301), an operator may insert an optical fiber (315) into eye chandelier port (314) if the fiber (315) had not yet been inserted at this stage. With eye chandelier port (314) in place

and assembled with optical fiber (315), an operator may activate eye chandelier port (314) by directing light through optical fiber (315) to provide illumination of eye (301) and thereby visualize the interior of eye (301). Further adjustments to the positioning of cannula (130) may optionally be made at this point to ensure proper positioning relative to the area of geographic atrophy of retina (308). In some instances, the operator may wish to rotate the eye (301), such as by pulling on suture loop assembly (332), to direct the pupil of the eye (301) toward the operator in order to optimize visualization of the interior of the eye (301) via the pupil.

[00080] FIGS. 13C-13D show cannula (130) as it is guided between sclera (304) and choroid (306) to position distal end (132) of cannula (130) at the delivery site for the therapeutic agent. In the present example, the delivery site corresponds to a generally posterior region of eye (301) adjacent to an area of geographic atrophy of retina (308). In particular, the delivery site of the present example is superior to the macula, in the potential space between the neurosensory retina and the retinal pigment epithelium layer. By way of example only, the operator may rely on direct visualization through a microscope directed through the pupil of eye (301) as cannula (130) is being advanced through the range of motion shown in FIGS. 13C-13D, with illumination provided through fiber (315) and port (314). Cannula (130) may be at least partially visible through a retina (308) and choroid (306) of eye (301). Visual tracking may be enhanced in versions where an optical fiber is used to emit visible light through the distal end of cannula (130).

[00081] Once cannula (130) has been advanced to the delivery site as shown in FIG. 13D, an operator may advance needle (150) of instrument (100) as described above by actuating knob (120). As can be seen in FIG. 13E, needle (150) is advanced relative to cannula (130) such that needle (150) pierces through choroid (306) without penetrating retina (308). Immediately prior to penetrating choroid (306), needle (150) may appear under direct visualization as "tenting" the surface of choroid (306). In other words, needle (150) may deform choroid (306) by pushing upwardly on choroid (306), providing an appearance like a tent pole deforming the roof of a tent. Such a visual phenomenon may be used by an operator to identify whether choroid (306) is about to be pierced and the location of any eventual piercing. The particular amount of needle (150) advancement sufficient to initiate

"tenting" and subsequent piercing of choroid (306) may be of any suitable amount as may be determined by a number of factors such as, but not limited to, general patient anatomy, local patient anatomy, operator preference, and/or other factors. As described above, an example of a range of needle (150) advancement may be between approximately 0.25 mm and approximately 10 mm; or more particularly between approximately 2 mm and approximately 6 mm.

[00082] In the present example, after the operator has confirmed that needle (150) has been properly advanced by visualizing the tenting effect described above, the operator infuses a balanced salt solution (BSS) or other similar solution as needle (150) is advanced relative to cannula (130). Such a BSS may form a leading bleb (340) ahead of needle (150) as needle (150) is advanced through choroid (306). Leading bleb (340) may be desirable for two reasons. First, as shown in FIG. 13F, leading bleb (340) may provide a further visual indicator to an operator to indicate when needle (150) is properly positioned at the delivery site. Second, leading bleb (340) may provide a barrier between needle (150) and retina (308) once needle (150) has penetrated choroid (306). Such a barrier may push the retinal wall outwardly, thereby minimizing the risk of retinal perforation as needle (150) is advanced to the delivery site. In some versions, a foot pedal is actuated in order to drive leading bleb (340) out from needle (150). Alternatively, other suitable features that may be used to drive leading bleb (340) out from needle (150) will be apparent to those skilled in the art in view of the teachings herein.

[00083] Once the operator visualizes leading bleb (340), the operator may cease infusion of BSS, leaving a pocket of fluid as can be seen in FIG. 13F. Next, a therapeutic agent (341) may be infused by actuating fluid delivery system (80) or some other fluid delivery device as described in various references cited herein. The delivered therapeutic agent (341) may be any suitable therapeutic agent configured to treat an ocular condition. Some merely illustrative examples of suitable therapeutic agents may include, but are not necessarily limited to, drugs having smaller or large molecules, therapeutic cell solutions, certain gene therapy solutions, tissue plasminogen activators, and/or any other suitable therapeutic agent as will be apparent to those skilled in the art in view of the teachings herein. By way of example only, the therapeutic agent (341) may be provided in accordance with at least

some of the teachings of U.S. Patent No. 7,413,734, entitled "Treatment of Retinitis Pigmentosa with Human Umbilical Cord Cells," issued August 19, 2008, the disclosure of which is incorporated by reference herein, in its entirety. In addition to, or as an alternative to, being used to deliver a therapeutic agent (341), instrument (100) and variations thereof may be used to provide drainage and/or perform other operations.

[00084] In the present example, the amount of therapeutic agent (341) that is ultimately delivered to the delivery site is approximately 50μL, although any other suitable amount may be delivered. In some versions, a foot pedal is actuated in order to drive agent (341) out from needle (150). Alternatively, other suitable features that may be used to drive agent (341) out from needle (150) will be apparent to those skilled in the art in view of the teachings herein. Delivery of therapeutic agent (341) may be visualized by an expansion of the pocket of fluid as can be seen in FIG. 13G. As shown, therapeutic agent (341) essentially mixes with the fluid of leading bleb (340) as therapeutic agent (341) is injected into the subretinal space.

[00085] Once delivery is complete, needle (150) may be retracted by rotating knob (120) in a direction opposite to that used to advance needle (150); and cannula (130) may then be withdrawn from eye (301). Because of the size of needle (150), the site where needle (150) penetrated through choroid (306) is self-sealing, such that no further steps need be taken to seal the delivery site through choroid (306). Suture loop assembly (332) and chandelier (314) may be removed, and the incision in the sclera (304) may be closed using any suitable conventional techniques.

[00086] As noted above, the foregoing procedure may be carried out to treat a patient having macular degeneration. In some such instances, the therapeutic agent (341) that is delivered by needle (150) may comprise cells that are derived from postpartum umbilicus and placenta. As noted above, and by way of example only, the therapeutic agent (341) may be provided in accordance with at least some of the teachings of U.S. Patent No. 7,413,734, the disclosure of which is incorporated by reference herein, in its entirety. Alternatively, needle (150) may be used to deliver any other suitable substance or substances, in addition to or in lieu of those described in U.S. Patent No. 7,413,734 and/or elsewhere herein. By way of example only, therapeutic agent (341) may comprise various kinds of drugs

including but not limited to small molecules, large molecules, cells, and/or gene therapies. It should also be understood that macular degeneration is just one merely illustrative example of a condition that may be treated through the procedure described herein. Other biological conditions that may be addressed using the instruments and procedures described herein will be apparent to those of ordinary skill in the art.

[00087] The procedure described above may be carried out in accordance with any of the teachings of U.S. Pat. No. 10,226,379, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 9,949,874, entitled "Therapeutic Agent Delivery Device with Convergent Lumen," issued April 24, 2018, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 9,925,088, entitled "Sub-Retinal Tangential Needle Catheter Guide and Introducer," issued March 27, 2018, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 10,322,028, entitled "Method and Apparatus for Sensing Position Between Layers of an Eye," issued June 18, 2019, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 10,064,752, entitled "Motorized Suprachoroidal Injection of Therapeutic Agent," issued September 4, 2018, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 10,219,936, entitled "Therapeutic Agent Delivery Device with Advanceable Cannula and Needle," issued March 5, 2019, the disclosure of which is incorporated by reference herein, in its entirety; U.S. Pat. No. 10,258,502, entitled "Therapeutic Agent Delivery Device," issued April 16, 2019, the disclosure of which is incorporated by reference herein, in its entirety; and/or International Pub. No. WO 2022/136913, entitled "Ocular Cannula Guide," published June 30, 2022, the disclosure of which is incorporated by reference herein, in its entirety.

[00088] III. Example of Alternative Instrument with Integrated Control and Knob Torque Ring

[00089] In some instances, it may be desirable to provide rotary knob (120) with one or more features that are configured to resist rotation of rotary knob (120), such that rotary knob (120) may only be rotated in response to application of a predetermined threshold rotational force (e.g., torque) to rotary knob (120) that is sufficient to overcome the rotational resistance imposed by such one or more features. It will be appreciated that such

rotational resistance may inhibit inadvertent rotation of rotary knob (120) (and thus inadvertent advancement and/or retraction of needle (150)) that might otherwise occur during handling of instrument (100) by the surgeon or other operator, such as if the operator were to accidentally bump rotary knob (120). In addition, or alternatively, the predetermined threshold rotational force required to overcome such rotational resistance may provide consistency and predictability to the manner in which rotation of rotary knob (120) is achieved.

[00090] In some instances, it may also be desirable to provide circuit board assembly (170) with additional features for controlling and/or monitoring the operation of instrument (100). In addition, or alternatively, it may be desirable to operatively couple instrument (100) to a compact fluid control unit that is configured to send and receive signals to and from circuit board assembly (170), and that is further configured to provide bleb fluid (340) and/or therapeutic agent (341) to needle (150).

[00091] FIGS. 14-22C show an example of an instrument (400) that may provide the features and functionalities described above. Instrument (400) is similar to instrument (100) described above, except as otherwise described below. In this regard, instrument (400) is configured for use in a procedure for the subretinal administration of a therapeutic agent to an eye of a patient from a suprachoroidal approach. Instrument (400) comprises a body (410), a pair of buttons (412, 414), a rotary knob assembly (420), and a flexible cannula (430) extending distally from body (410) to a distal end (432). As also shown in FIG. 14, a tube set (440) extends proximally from instrument (400). Cannula (430) is generally configured to support a needle (not shown), such as needle (150), that is slidable within cannula (430), as described in greater detail above. In this regard, instrument (400) also includes a needle actuator (416) having a cam follower post (418), similar to needle actuator (180) and cam follower post (184) described above, respectively, except as otherwise described below.

[00092] Rotary knob assembly (420) is rotatable relative to body (410) to thereby selectively translate needle (150) longitudinally relative to cannula (430). In particular, rotary knob assembly (420) is rotatable in a first angular direction to drive needle (150) distally relative to cannula (430); and in a second angular direction to drive needle (150)

proximally relative to cannula (430). In this regard, and as shown in FIG. 16, rotary knob assembly (420) of the present example includes a rotary knob body (421); a knob grip (422) fixedly secured to an exterior of knob body (421) for facilitating manual rotation of knob body (421) by the operator; a knob base (423) whose underside includes a spiral cam recess (424) (FIG. 20); a fastener in the form of a bolt or a screw (425) for rotatably coupling knob body (421) to knob base (423) and defining a rotational axis (RA) (FIG. 16) of rotary knob assembly (420); a knob cap (426) removably secured to knob body (421) for concealing screw (425); a torque ring (427) fixedly secured to an interior of knob body (421); a torque limiter in the form of a slip clutch (428) configured to selectively transmit rotary motion from knob body (421) to knob base (423) to facilitate driving of needle (150); and a compression spring in the form of a coil spring (429) interposed between knob body (421) and clutch (428) for resiliently biasing clutch (428) toward knob base (423) (e.g., downwardly).

[00093] As shown in FIGS. 14-17, knob body (421) of the present example includes a radially outer wall (450), a radially inner wall (452), and a radially intermediate wall (454). Any one or more of walls (450, 452, 454) may be generally cylindrical and/or generally frustoconical. In the example shown, inner wall (452) defines a central bore (456) that is sized and configured to rotatably receive a portion of knob base (423), as described in greater detail below. As shown, a plurality of fins (458) extends radially outwardly from an outer surface of inner wall (452) and are circumferentially spaced apart from each other at equal intervals, and a plurality of posts (459) extend at least partially radially inwardly from an inner surface of intermediate wall (454) and are circumferentially spaced apart from each other at equal intervals. As described in greater detail below, fins (458) and/or posts (459) may be configured to interlock with corresponding portions of other components of knob assembly (420) to fix such other components against rotation relative to knob body (421). While three fins (458) and three posts (459) are shown in the present example, it will be appreciated that any suitable number of fins (458) and/or posts (459) may be provided.

[00094] As shown in FIGS. 16 and 18, torque ring (427) of the present example includes an annular wall (460) having an outer surface that is configured to confront and/or frictionally

engage the inner surface of intermediate wall (454) of knob body (421). As shown, a plurality of upwardly-facing recesses (462) extend downwardly from an upper surface of annular wall (460) and are circumferentially spaced apart from each other at equal intervals for receiving corresponding posts (459) of knob body (421) while the outer surface of annular wall (460) confronts the inner surface of intermediate wall (454). In this manner, recesses (462) and posts (459) may be configured to interlock with each other to fix torque ring (427) against rotation relative to knob body (421), such that torque ring (427) may be rotatable together with knob body (421) about the rotational axis (RA) relative to body (410) of instrument (100). While three recesses (462) are shown in the present example, it will be appreciated that any suitable number of recesses (462) may be provided. As shown, a plurality of ledges (464) extend radially outwardly from the outer surface of annular wall (460) at or near a lower end of annular wall (460) and having respective upper surfaces for confronting a lower surface of intermediate wall (454) of knob body (421) while the outer surface of annular wall (460) confronts the inner surface of intermediate wall (454) of knob body (421) and recesses (462) receive the corresponding posts (459) of knob body (421).

[00095] In the example shown, a plurality of pairs of downwardly-facing recesses (466) extend upwardly from a lower surface of annular wall (460), with each pair of recesses (466) being spaced apart from each other to define respective deflectable members in the form of deflectable beams (468) that are circumferentially spaced apart from each other at equal intervals. As described in greater detail below, a detent (469) extends radially outwardly from an outer surface of each deflectable beam (468) for frictionally engaging a portion of body (410) of instrument (400). In this regard, each deflectable beam (468) is configured to deflect radially inwardly from the illustrated undeflected state to a respective deflected state (not shown), and is resiliently biased to assume the respective undeflected state. While three pairs of recesses (466) are shown in the present example to define three deflectable beams (468), it will be appreciated that any suitable number of pairs of recesses (466) may be provided to define any suitable number of deflectable beams (468).

[00096] As shown in FIGS. 16 and 19, clutch (428) of the present example includes an annular wall (470) having an inner surface that is configured to confront the outer surface of inner wall (452) of knob body (421). As shown, a plurality of upwardly-facing recesses

(472) extend downwardly from an upper surface of annular wall (470) and are circumferentially spaced apart from each other at equal intervals for receiving corresponding fins (458) of knob body (421) while the inner surface of annular wall (470) confronts the outer surface of inner wall (452). In this manner, recesses (472) and fins (458) may be configured to interlock with each other to fix clutch (428) against rotation relative to knob body (421), such that clutch (428) may be rotatable together with knob body (421) about the rotational axis (RA) relative to body (410) of instrument (100). While three recesses (472) are shown in the present example, it will be appreciated that any suitable number of recesses (472) may be provided.

[00097] In the example shown, an annular plate (474) extends radially outwardly from an outer surface of annular wall (470) at or near a lower end of annular wall (470). As shown, a plurality of generally triangular teeth (476) extend downwardly from a lower surface of annular plate (474) and are circumferentially spaced apart from each other at equal intervals for selectively engaging corresponding portions of knob base (423). Each tooth (476) may be defined by a pair of obliquely angled surfaces extending downwardly from the lower surface of annular plate (474) and converging with each other at a respective apex. While three teeth (476) are shown in the present example, it will be appreciated that any suitable number of teeth (476) may be provided. As shown, a plurality of protrusions (478) extend radially inwardly from an inner surface of annular plate (474) and are circumferentially spaced apart from each other at equal intervals. Protrusions (478) collectively define a central receptacle (479) that is sized and configured to rotatably receive a portion of knob base (423), as described in greater detail below. While three protrusions (478) are shown in the present example, it will be appreciated that any suitable number of protrusions (478) may be provided.

[00098] As shown in FIGS. 16 and 20, knob base (423) includes a central hub (480) that is configured to be received within central receptacle (479) of clutch (428) and central bore (456) of knob body (421). In this regard, central hub (480) has an outer surface that is configured to confront the inner surface of inner wall (452) of knob body (421) and inner surfaces of protrusions (478) of clutch (428). In the example shown, central hub (480) defines a central threaded bore (482) that is sized and configured to threadably receive

screw (425) for rotatably coupling knob body (421) to knob base (423).

[00099] In the example shown, an annular plate (484) extends radially outwardly from an outer surface of central hub (480) at or near a lower end of central hub (480), with spiral cam recess (424) being presented by a lower surface of annular plate (484). As best shown in FIG. 16, a circumferential array of generally triangular troughs (486) extend downwardly from an upper surface of annular plate (484) for selectively engaging teeth (476) of clutch (428). Each trough (486) may be defined by a pair of obliquely angled surfaces extending downwardly from the upper surface of annular plate (484) and converging with each other at a respective apex. In this manner, troughs (486) and teeth (476) may be configured to selectively interlock with each other to fix knob base (423) against rotation relative to clutch (428), and thus relative to knob body (421), such that knob base (423) may be rotatable together with knob body (421) about the rotational axis (RA) relative to body (410) of instrument (400).

[000100] Spiral cam recess (424) is configured and operable similarly to spiral cam recess (124) described above for converting rotation of knob base (423) about the rotational axis (RA) into longitudinal translation of needle (150), such as via cam follower post (418) of needle actuator (416). In this regard, and as shown in FIGS. 21A-21B, cam follower post (418) of needle actuator (416) is configured to fit in spiral cam recess (424) of knob base (423). Due to this engagement, needle actuator (416) will translate from a proximal position (FIG. 21A) to a distal position (FIG. 21B) in response to rotation of knob base (423).

[000101] As shown in FIGS. 21A-21B, detents (469) of deflectable beams (468) of torque ring (427) are configured to frictionally engage an internal annular ledge (490) of body (410) of instrument (400). In this regard, annular ledge (490) may be configured to urge deflectable beams (468) at least slightly radially inwardly via the respective detents (469) toward the respective deflected states. Due to the resilient biasing of deflectable beams (468) toward their respective undeflected states, deflectable beams (468) may remain frictionally engaged with annular ledge (490) to generate a predetermined amount of friction that opposes rotation of torque ring (427), and thus of knob body (421) and knob base (423), about the rotational axis (RA) relative to body (410) of instrument (400). In

this manner, deflectable beams (468) of torque ring (427) may resist rotation of knob body (421) and knob base (423), such that knob body (421) and knob base (423) may only be rotated about the rotational axis (RA) in response to application of a predetermined threshold rotational force to knob body (421) that is sufficient to overcome the rotational resistance imposed by deflectable beams (468).

[000102] As noted above, the rotational resistance provided by torque ring (427) may inhibit inadvertent rotation of knob body (421) and knob base (423) (and thus inadvertent advancement and/or retraction of needle (150)) that might otherwise occur during handling of instrument (400) by the surgeon or other operator. In addition, or alternatively, the predetermined threshold rotational force required to overcome such rotational resistance may provide consistency and predictability to the manner in which rotation of knob body (421) and knob base (423) is achieved. In some versions, the predetermined threshold rotational force may range from approximately 25 oz-in to approximately 50 oz-in. It will be appreciated that the predetermined threshold rotational force may be adjusted based on a variety of factors, such as the lengths and/or cross-sectional thicknesses of deflectable beams (468), the sizes of detents (469), and/or the material of torque ring (427).

[000103] While deflectable beams (468) of the present example are incorporated into torque ring (427) and bear against body (410) of instrument (400), it will be appreciated that deflectable beams (468) or any other suitable type of deflectable member(s) may alternatively be incorporated into body (410) of instrument (400) and bear against knob body (420) or any other suitable portion of knob assembly (420) to provide the desired rotational resistance, such as in an inverse arrangement of that shown. For example, torque ring (427) may be fixed against rotation relative to body (410) of instrument (400), and detents (469) of deflectable beams (468) may be configured to frictionally engage a surface of knob body (420). In some versions, torque ring (427) may be integrally formed together with either body (410) of instrument (400) or knob body (421) as a unitary (e.g., monolithic) piece.

[000104] In addition to being configured to selectively interlock with each other to fix knob base (423) against rotation relative to knob body (421), troughs (486) of knob base (423) and teeth (476) of clutch (428) may also be configured to selectively disengage from each

other to permit relative rotation (e.g., slipping) between knob base (423) and clutch (428), and thus between knob base (423) and knob body (421), such that knob base (423) may in some cases remain stationary about the rotational axis (RA) during rotation of knob body (421) about the rotational axis (RA) relative to body (410) of instrument (400). In this regard, coil spring (429) is vertically interposed between a downwardly-facing surface of knob body (421) and the upper surface of annular plate (474) of clutch (428), and is radially interposed between the inner surface of annular wall (460) of torque ring (427) and one or both of the outer surface of inner wall (452) of knob body (421) and/or the outer surface of annular wall (470) of clutch (428). Coil spring (429) is configured to resiliently bias clutch (428) downwardly toward knob base (423), such that teeth (476) of clutch (428) are resiliently biased by coil spring (429) into engagement with troughs (486) of knob base (423). Teeth (476) may thereby be configured to be engaged with troughs (486) via coil spring (429) in the absence of a threshold upwardly-directed force applied to clutch (428) that is sufficient to overcome the downward biasing of teeth (476) by coil spring (429).

[000105] In some versions, the threshold upwardly-directed force for overcoming the downward biasing of teeth (476) by coil spring (429) may generated by rotating knob body (421) in the first angular direction while needle (150) is already in a distal-most position relative to cannula (430); or in the second angular direction while needle (150) is already in a proximal-most position relative to cannula (430). In such cases, knob base (423) may be inhibited from rotating in the same angular direction in which knob body (421) is rotated (e.g., due to the interaction between an end of spiral cam recess (424) and cam follower post (418) of needle actuator (416)), such that troughs (486) may resist the rotation of teeth (476). Thus, knob base (423) may be configured to apply the threshold upwardly-directed force to clutch (428) via a camming interaction between the angled surfaces of troughs (486) and the angled surfaces of teeth (476) to urge teeth (476) upwardly out of troughs (486) so that knob body (421) may slip relative to knob base (423) and thereby prevent mechanical overloading of knob base (423).

[000106] As shown in FIGS. 22A-22C, instrument (400) of the present example includes a fluid supply assembly (500) that is at least partially retained within a chamber (505) of needle actuator (416). In the example shown, a retention pin (507) is received by a pair of

opposed bores (not shown) provided in needle actuator (416) for retaining various components of fluid supply assembly (500) within chamber (505).

[000107] Fluid supply assembly (500) of the present example includes first and second fluid supply tubes (511a, 511b), a fluid supply junction (512), first and second self-actuating check valves (513a, 513b), and a valve retainer (514). In the example shown, each fluid supply tube (511a, 511b) extends between an open proximal end (not shown) and an open distal end (516a, 516b), and defines a lumen (517a, 517b) extending therebetween for directing fluid therethrough. The open proximal end of each fluid supply tube (511a, 511b) is fluidly connected to a respective fluid conduit of tube set (440), and each open distal end (516a, 516b) is fluidly connected to fluid supply junction (512), as described in greater detail below.

[000108] As shown, fluid supply junction (512) and valve retainer (514) are each securely retained within chamber (505) of needle actuator (416). More particularly, retention pin (507) captures fluid supply junction (512) and valve retainer (514) within chamber (505). Therefore, fluid supply junction (512) and valve retainer (514) may be longitudinally translatable together with needle actuator (416) (and thus with needle (150)) relative to body (410) of instrument (400). Fluid supply junction (512) of the present example includes first and second proximal fluid supply passageways (518a, 518b) fluidly isolated from each other and configured to fluidly couple to open distal ends (516a, 516b) of first and second fluid supply tubes (511a, 511b), respectively. In the example shown, fluid supply junction (512) includes first and second generally annular valve seats (519a, 519b) defined about open distal ends of the respective fluid supply passageways (518a, 518b) and angled relative to each other to define a "V" shape, the purposes of which are described below. As shown, a generally obround groove (520) extends radially inwardly from a radially outer surface of fluid supply junction (512), and a proximal gasket in the form of a generally obround O-ring (521) is disposed within groove (520) for providing a fluid-tight seal between fluid supply junction (512) and a side of chamber (505).

[000109] Valve retainer (514) of the present example includes a single distal fluid supply passageway (522) fluidly coupled to the lumen of needle (150) (e.g., via bore (507) of needle actuator (416)) and configured to selectively fluidly couple to first and second

proximal fluid supply passageways (518a, 518b) of fluid supply junction (512). In this regard, valve retainer (514) also includes first and second generally dome-shaped recesses (523a, 523b) configured to confront first and second valve seats (519a, 519b), respectively, to define first and second fluid gateways (524a, 524b) therebetween. As shown, a generally circular groove (525) extends proximally from a distal surface of valve retainer (514), and a distal gasket in the form of a generally circular O-ring (526) is disposed within groove (525) for providing a fluid-tight seal between valve retainer (514) and a distal end of chamber (505).

[000110] As shown, each fluid gateway (524a, 524b) is configured to selectively fluidly couple a corresponding proximal fluid supply passageway (518a, 518b) to distal fluid supply passageway (522) for selectively directing fluid from the corresponding proximal fluid supply passageway (518a, 518b) to distal fluid supply passageway (522) through the respective fluid gateway (524a, 524b). In this regard, a corresponding portion of each valve (513a, 513b) is at least partially disposed within each fluid gateway (524a, 524b) for selectively placing the corresponding proximal fluid supply passageway (518a, 518b) into and out of fluid communication with distal fluid supply passageway (522). To that end, valve retainer (514) may include first and second valve retention slots; and each valve (513a, 513b) includes a generally frustoconical stem (528a, 528b) that may be securely received within a respective valve retention slot, and a generally disc-shaped flexible membrane (529a, 529b). In some versions, fluid supply junction (512) may capture stems (528a, 528b) within the respective valve retention slots. Each disc-shaped membrane (529a, 529b) is bendably coupled to the corresponding stem (528a, 528b) (e.g., via a corresponding living hinge), such that each membrane (529a, 529b) is bendable between respective open and closed states.

[000111] More particularly, membrane (529a) of first valve (513a) is bendable between a closed state (FIGS. 22A and 22C) and an open state (FIG. 22B). In the closed state, membrane (529a) sealingly engages first valve seat (519a) of fluid supply junction (512) to prevent fluid from flowing from first proximal fluid supply passageway (518a) through first fluid gateway (524a) to distal fluid supply passageway (522). In the open state, membrane (529a) disengages first valve seat (519a) of fluid supply junction (512) to permit

fluid to flow from first proximal fluid supply passageway (518a) through first fluid gateway (524a) to distal fluid supply passageway (522). Likewise, membrane (529b) of second valve (513b) is bendable between a closed state (FIGS. 22A and 22B) and an open state (FIG. 22C). In the closed state, membrane (529b) sealingly engages second valve seat (519b) of fluid supply junction (512) to prevent fluid from flowing from second proximal fluid supply passageway (518b) through second fluid gateway (524b) to distal fluid supply passageway (522). In the open state, membrane (529b) disengages second valve seat (519b) of fluid supply junction (512) to permit fluid to flow from second proximal fluid supply passageway (518b) through second fluid gateway (524b) to distal fluid supply passageway (522).

[000112] Each membrane (529a, 529b) of the present example is resiliently biased to assume the respective closed state and is configured to bend toward the respective open state in response to application of a threshold downstream-directed force to the respective membrane (529a, 529b), which may result from the presence of a threshold fluid pressure within the corresponding proximal fluid supply passageway (518a, 518b). For example, each membrane (529a, 529b) may be configured to immediately bend toward the respective open state in response to the fluid pressure within the corresponding proximal fluid supply passageway (518a, 518b) reaching the threshold fluid pressure to permit flow of fluid in the downstream direction, and may be configured to immediately resiliently return to the respective closed state in response to the fluid pressure within the corresponding proximal fluid supply passageway (518a, 518b) dropping below the threshold fluid pressure to prevent backflow of the fluid in the upstream direction. In this regard, each valve (513a, 513b) may comprise an elastomeric material, such as silicone. In some versions, each valve (513a, 513b) is configured as a Belleville valve, such as of the type sold by Minivalve International of Oldenzaal, the Netherlands or from any other suitable source. In addition, or alternatively, each valve (513a, 513b) may be configured and operable in accordance with one or more teachings of EP 1953432, entitled "Fluid Control Valve," granted on April 12, 2017.

[000113] As shown in FIG. 22B, when membrane (529a) of first valve (513a) is in the respective open state and membrane (529b) of second valve (513b) is in the respective

closed state, bleb fluid (340) may flow from the respective fluid conduit of tube set (440) through first lumen (517a) of first fluid supply tube (511a), through first proximal fluid supply passageway (518a) of fluid supply junction (512), through first fluid gateway (524a), through distal fluid supply passageway (522) of valve retainer (514), and into the lumen of needle (150) for delivery at distal tip (152). Due to the closure of membrane (529b) of second valve (513b), therapeutic fluid (341) may remain substantially isolated from bleb fluid (340) within instrument (400) during such delivery of bleb fluid (340).

[000114] As shown in FIG. 22C, when membrane (529b) of second valve (513b) is in the respective open state and membrane (529a) of first valve (513a) is in the respective closed state, therapeutic fluid (341) may flow from the respective fluid conduit of tube set (440) through second lumen (517b) of second fluid supply tube (511b), through second proximal fluid supply passageway (518b) of fluid supply junction (512), through second fluid gateway (524b), through distal fluid supply passageway (522) of valve retainer (514), and into the lumen of needle (150) for delivery at distal tip (152). Due to the closure of membrane (529a) of first valve (513a), bleb fluid (340) may remain substantially isolated from therapeutic fluid (341) within instrument (400) during such delivery of therapeutic fluid (341).

[000115] It will be appreciated that proximal O-ring (521) may assist with preventing fluid that is flowing through either fluid supply gateway (524a, 524b) from leaking proximally out of chamber (505) of needle actuator (416), and that distal O-ring (526) may assist with preventing fluid that is flowing between distal fluid supply passageway (522) and the lumen of needle (150) from leaking toward the side of chamber (505) of needle actuator (416).

[000116] While Belleville valves (513a, 513b) are used in the present example, any other suitable kind of valves may be used, such as umbrella valves. Other suitable ways in which valves may be incorporated into instrument (400) will be apparent to those skilled in the art in view of the teachings herein. For instance, instrument (400) may include an integral valve assembly that is configured and operable in accordance with at least some of the teachings of U.S. Pat. No. 10,226,379, entitled "Method and Apparatus for Subretinal Administration of Therapeutic Agent," issued on March 12, 2019, the disclosure of which

is incorporated by reference herein.

[000117] By way of example only, fluid supply assembly (500) may be configured and operable in accordance with at least some of the teachings of International Pub. No. WO 2024/013559, entitled "Transvitreal Subretinal Injector," published January 18, 2024, the disclosure of which is incorporated by reference herein, in its entirety.

[000118] Referring again to FIG. 14, instrument (400) is shown operatively coupled to an example of a fluid control unit (600) via tube set (440). Fluid control unit (600) may be substantially more compact than a typical vitrectomy machine. For example, fluid control unit (600) may be configured as a handheld device. Fluid control unit (600) may include a bleb fluid source, similar to bleb fluid source (82) described above, and a therapeutic agent fluid source, similar to therapeutic agent fluid source (84) described above. The bleb fluid source may be coupled with a bleb fluid conduit of tube set (440); and the therapeutic agent fluid source may be coupled with a therapeutic agent conduit of tube set (440). Such conduits may be in fluid communication with needle (150). Fluid control unit (600) may also include one or more suitable fluid dispensing mechanisms which may include, for example, one or more syringe plungers, pumps, valves, pneumatic actuators, and/or motors configured to selectively dispense bleb fluid (340) and therapeutic agent (341) from the respective sources.

[000119] Fluid control unit (600) may be operable to automatically dispense bleb fluid (340) and therapeutic agent (341) to instrument (400) via tube set (440). More particularly, fluid control unit (600) may include a processor in operative communication with the fluid dispensing mechanisms and with various components of instrument (400) for sending signals thereto and/or receiving signals therefrom.

[000120] In this regard, and as shown in FIG. 23, instrument (400) of the present example further includes a circuit board assembly (650), similar to circuit board assembly (170), disposed within body (410). An upper side of circuit board assembly (650) may include first and second user input elements in the form of tactile switches (652, 654), similar to the second tactile switch and first tactile switch (172) described above, respectively. First and second tactile switches (652, 654) may be positioned relative to respective buttons

(412, 414) such that the operator may provide actuation of first tactile switch (652) by pressing first button (412) and may provide actuation of second tactile switch (654) by pressing second button (414). First and second tactile switches (652, 654) may communicate with the processor of fluid control unit (600) via one or more wires (not shown), similar to wires (175), contained in tube set (440). By way of example only, fluid control unit (600) may be configured to provide delivery of bleb fluid (340) via needle (150) in response to actuation of first tactile switch (652), and/or to provide delivery of therapeutic agent (341) via needle (150) in response to actuation of second tactile switch (654).

[000121] For example, fluid control unit (600) may be configured to dispense bleb fluid (340) at a predetermined, fixed flow rate while first tactile switch (652) is actuated (e.g., while first button (412) is depressed), and may be configured to continuously monitor the volume of bleb fluid (340) delivered via needle (150), such as based on the fixed flow rate and the duration of time that the bleb fluid (340) is dispensed. Fluid control unit (600) may be configured to present a textual or graphical message (e.g., via a digital readout of fluid control unit (600)) to indicate the volume of bleb fluid (340) delivered via needle (150). In the present example, the flow rate of bleb fluid (340) is predetermined. By way of example only, the predetermined flow rate of bleb fluid (340) may range from approximately 100 μL per minute to approximately 300 μL per minute. For example, the predetermined flow rate of bleb fluid (340) may be approximately 200 μL per minute. In some other versions, fluid control unit (600) provides a user input where the operator may select a desired flow rate for bleb fluid (340) to be dispensed at while first tactile switch (652) is actuated. In addition, or in the alternative, the flow rate for bleb fluid (340) may vary during delivery, such as based on a predetermined sequence of flow rates selected by the operator, for example.

[000122] In addition, or alternatively, fluid control unit (600) may be configured to dispense therapeutic agent (341) at a precise, fixed flow rate while second tactile switch (654) is actuated (e.g., while second button (414) is depressed), and may be configured to continuously monitor the volume of therapeutic agent (341) delivered via needle (150), such as based on the fixed flow rate and the duration of time that the therapeutic agent

(341) is dispensed. For example, fluid control unit (600) may be configured to monitor the cumulative volume of therapeutic agent (341) delivered to the eye (301) by multiple discrete deliveries of therapeutic agent (341) via needle (150), such as in cases where second button (414) is depressed, released, and then depressed again. Fluid control unit (600) may be configured to present a textual or graphical message (e.g., via a digital readout of fluid control unit (600)) to indicate the volume of therapeutic agent (341) delivered via needle (150). In some versions, fluid control unit (600) provides a user input where the operator may select a desired flow rate for therapeutic agent (341) to be dispensed at while second tactile switch (654) is actuated. In addition, or in the alternative, the flow rate for therapeutic agent (341) may vary during delivery, such as based on a predetermined sequence of flow rates selected by the operator, for example.

[000123] The upper side of circuit board assembly (650) may also include a sensor, such as a linear sensor (656) similar to linear sensor (176) described above, or a rotary sensor such as a rotary potentiometer (not shown). For example, linear sensor (656) may include a slider that is configured to slide unitarily with needle actuator (416) and thereby translate longitudinally relative to a body of linear sensor (656). Linear sensor (656) may be configured to generate a varying data value based on the longitudinal position of the slider along the body of linear sensor (656). By way of example only, linear sensor (656) may comprise a linear potentiometer that generates a varying resistance value based on the longitudinal position of the slider along the body. Thus, the resistance value generated through linear sensor (656) will be indicative of the longitudinal position of needle (150) relative to cannula (430). By way of further example only, linear sensor (656) may comprise a sensor that senses rotation of knob base (423), an optical sensor, or a sensor located in instrument (400) to directly monitor movement of needle actuator (416). Various other suitable ways in which movement of needle (150) may be sensed will be apparent to those of ordinary skill in the art in view of the teachings herein. Linear sensor (656) may be in communication with the processor of fluid control unit (600) via one or more wires (not shown), similar to wires (175), contained in tube set (440). Fluid control unit (600) may be configured to present a textual or graphical message (e.g., via a digital readout of fluid control unit (600)) to indicate a length of needle (150) and/or a longitudinal position of needle (150) based on one or more signals received by the processor of fluid

control unit (600) from linear sensor (656). In addition, or alternatively, fluid control unit (600) may be configured to provide automated delivery of bleb fluid (340) via needle (150) in response to distal movement of needle (150) as sensed by linear sensor (656). For example, fluid control unit (600) may be configured to provide automated delivery of bleb fluid (340) via needle (150) at a predetermined, fixed flow rate as described above during distal advancement of needle (150) to promote safe penetration of the choroid (306) by distal tip (152) of needle (150) without perforating the retina (308). In addition, or in the alternative, the flow rate for bleb fluid (340) may vary based on the translation speed of needle (150). For instance, if needle (150) is being advanced rapidly, then bleb fluid (340) may be delivered at a relatively high rate; and if needle (150) is being advanced slowly, then bleb fluid (340) may be delivered at a relatively slow rate.

[000124] The upper side of circuit board assembly (650) may further include at least one user feedback element in the form of an illuminating element, such as an array of red-green-blue (RGB) programmable LEDs (658). LEDs (658) may be configured to selectively illuminate. Knob assembly (420), buttons (412, 414), and/or body (410) may be configured to enable viewing of light emitted by LEDs (658). LEDs (658) may be in communication with the processor of fluid control unit (600) via one or more wires (not shown), similar to wires (175), contained in tube set (440). Fluid control unit (600) may be configured to illuminate LEDs (658) differently based on the particular state of the system defined by instrument (400) and fluid control unit (600). For instance, fluid control unit (600) may be configured to send a signal to LEDs (658) to illuminate in yellow to indicate that the system is priming (e.g., that priming of the delivery line(s) for bleb fluid (340) and/or therapeutic agent (341) is being performed); in red to indicate an error within the system (e.g., such that the system is not ready for delivery of bleb fluid (340) and/or therapeutic agent (341)); in green when the system is primed and/or when needle (150) is in its fully retracted, proximal-most position (e.g., such that cannula (430) is ready for insertion into the eye (301)); and/or in indigo when needle (150) has been distally advanced from its fully retracted, proximal-most position. Other suitable ways in which LEDs (658) may be used will be apparent to those of ordinary skill in the art in view of the teachings herein.

[000125] Circuit board assembly (650) may also include at least one user feedback element

in the form of a speaker (660) configured to provide one or more audible tones. Speaker (660) may be in communication with the processor of fluid control unit (600) via one or more wires (not shown), similar to wires (175), contained in tube set (440). Fluid control unit (600) may be configured to provide different audible tones via speaker (660) based on the particular state of the system defined by instrument (400) and fluid control unit (600). For instance, fluid control unit (600) may be configured to send a signal to speaker (660) to provide a first unique audible tone or series of tones to indicate that needle (150) has been distally advanced to its fully extended, distal-most position; a second unique audible tone or series of tones during delivery of bleb fluid (340); a third unique audible tone or series of tones (e.g., a countdown) between actuation of second tactile switch (654) and the beginning of dispensing of therapeutic agent (341) from fluid control unit (600); a fourth unique audible tone or series of tones during delivery of therapeutic agent (341); a fifth unique audible tone or series of tones to indicate that delivery of therapeutic agent (341) has been completed; and/or a sixth unique audible tone or series of tones when needle (150) is in its fully retracted, proximal-most position. Other suitable ways in which speaker (660) may be used will be apparent to those of ordinary skill in the art in view of the teachings herein. While speaker (660) has been described as being incorporated into circuit board assembly (650), it will be appreciated that speaker (660) may be incorporated into fluid control unit (600) in some other versions.

[000126] By way of example only, instrument (400) may provide any one or more of such functionalities through circuit board assembly (650) in accordance with at least some of the teachings of U.S. Pat. No. 10,646,374, the disclosure of which is incorporated by reference herein, in its entirety.

[000127] IV. Example of Compact Fluid Control Unit

[000128] As noted above, it may be desirable to operatively couple an instrument, such as either instrument (100, 400) described above, to a compact fluid control unit that is configured to send and receive signals to and from circuit board assembly (170, 650) of instrument (100, 400), and that is further configured to provide bleb fluid (340) and/or therapeutic agent (341) to needle (150) of instrument (100, 400). It may be desirable for such a fluid control unit to be substantially more compact and/or substantially more

lightweight than a typical vitrectomy machine. For example, it may be desirable for such a fluid control unit to be configured as a handheld device. In addition, or alternatively, it may be desirable for such a fluid control unit to be configured for mounting to wrist rest (10) or another fixture adjacent to the patient, such as fixture (14).

[000129] FIGS. 24-35 show an example of a fluid control unit (700) that may provide the features and functionalities described above. Fluid control unit (700) is similar to fluid control unit (600) described above, except as otherwise described below. In the example shown, fluid control unit (700) includes a control module (702) and a cartridge (704) that is configured to hold a bleb fluid source in the form of a first syringe (706a) and a therapeutic agent fluid source in the form of a second syringe (706b). While first and second syringes (706a, 706b) are described as bleb and therapeutic agent fluid sources, respectively, it will be appreciated that first syringe (706a) may alternatively be a therapeutic agent fluid source and/or second syringe (706b) may alternatively be a bleb fluid source. Syringes (706a, 706b) may each have a capacity of about 500 μL, for example. Cartridge (704) is further configured to be removably coupled to control module (702) while holding syringes (706a, 706b) to define a loaded state of fluid control unit (700).

[000130] As described in greater detail below, fluid control unit (700) may be operatively coupled to an instrument, such as either instrument (100, 400), via a corresponding tube set (140, 440); and may be operable to automatically dispense bleb fluid (340) and therapeutic agent (341) from syringes (706a, 706b) to the instrument (100, 400) via fluid conduits (142, 144) of the tube set (140, 440) that are in fluid communication with the needle (150) of the instrument (100, 400). As also described in greater detail below, fluid control unit (700) may communicate with the instrument (100, 400) via one or more wires (175) of the tube set (140, 440) that are in operative communication with the circuit board assembly (170, 650) of the instrument (100, 400); and may communicate with an offboard processor (707) (e.g., of a host computer) wirelessly and/or via one or more wires (708).

[000131] FIG. 24 shows fluid control unit (700) mounted to wrist rest (10) such that wrist rest (10) substantially carries the weight of fluid control unit (700). In this regard, fluid control unit (700) of the present example has a substantially lightweight configuration, with

fluid control unit (700) having a total weight that is sufficiently small to allow wrist rest (10) to substantially carry the total weight of fluid control unit (700) without risk of fluid control unit (700) overburdening wrist rest (10). Fluid control unit (700) of the present example also has a substantially compact configuration, such that fluid control unit (700) may not interfere with the operator's performance of the procedure described above when fluid control unit (700) is mounted to wrist rest (10). For example, fluid control unit (700) may have a total physical volume (e.g., collectively defined by control module (702), cartridge (704), and syringes (706a, 706b)) that is less than about 150 mL. In other words, fluid control unit (700) may fit within a three dimensional space that has a volume that is less than about 150 mL.

[000132] Fluid control unit (700) may be mounted to wrist rest (10) in any suitable manner, such as via a mounting assembly (701) including a cradle (703) and/or clamp (705). For example, FIG. 24A shows fluid control unit (700) positioned on and at least partially received within cradle (703), and cradle (703) is shown removably coupled to wrist rest (10) via clamp (705). Clamp (705) may be adjustable to facilitate attachment of mounting assembly (701) to various different wrist rests (10) having a predetermined range of diameters. For example, clamp (705) may be compatible with wrist rests (10) having a diameter ranging from about 25 mm to about 30 mm. While fluid control unit (700) of the present example is shown mounted to wrist rest (10), the substantially compact and lightweight configuration of fluid control unit (700) may allow the fluid control unit (700) to be supported by various other objects and/or people during the procedure. For example, fluid control unit (700) may be readily mounted to fixture (14) described above. As another example, fluid control unit (700) may be hand-held by the surgeon or other operator during the procedure. Thus, unlike typical vitrectomy machines, fluid control unit (700) need not necessarily be positioned on a floor, or even on a tabletop (though such positionings of fluid control unit (700) may still be utilized, if desired).

[000133] As shown in FIGS. 24-31, control module (702) of the present example includes a housing (710) and a variety of components contained within housing (710), including a circuit board assembly (711), a power source in the form of a battery (712), and first and second drive assemblies (713a, 713b) for facilitating dispensing of fluids (340, 341) from

first and second syringes (706a, 706b), respectively. In the example shown, housing (710) is defined by upper and lower shells (714, 715), with circuit board assembly (711) being secured to lower shell (715), and with battery (712) and drive assemblies (713a, 713b) being secured to upper shell (714), though it will be appreciated that housing (710) may be defined in any other suitable manner; and that circuit board assembly (711), battery (712), and drive assemblies (713a, 713b) may be secured to housing (710) in any other suitable manners.

[000134] Referring primarily to FIGS. 25-28, in the example shown, upper shell (714) of housing (710) includes a top wall (716) that is configured to support battery (712) and drive assemblies (713a, 713b); and further includes a proximal wall (717), a distal wall (718), and first and second sidewalls (719a, 719b), each extending generally downwardly from top wall (716). Upper shell (714) of the present example also includes first and second generally U-shaped syringe receptacles (720a, 720b) extending both downwardly from an upper surface of top wall (716) and proximally from a distal surface of distal wall (718). First and second syringe receptacles (720a, 720b) are sized and configured to at least partially receive first and second syringes (706a, 706b), respectively, when cartridge (704) is removably coupled to control module (702). In the example shown, first and second syringe receptacles (720a, 720b) terminate proximally at first and second proximally-recessed walls (721a, 721b) of upper shell (714), respectively. First and second bores (722a, 722b) extend through first and second proximally-recessed walls (721a, 721b), respectively, for allowing respective portions of first and second drive assemblies (713a, 713b) to access the syringes (706a, 706b) received within the respective syringe receptacles (720a, 720b).

[000135] Upper shell (714) of the present example also includes first and second coupling members in the form of apertures (723a, 723b) that extend through distal wall (718) laterally outwardly of first and second receptacles (720a, 720b), respectively, and that are configured to interact with corresponding portions of cartridge (704) to removably couple cartridge (704) to control module (702). Upper shell (714) of the present example further includes a dock (724) that extends distally from distal wall (718) and that is configured to support cartridge (704) when cartridge (704) is removably coupled to control module (702).

More particularly, dock (724) includes first and second lower platforms (725a, 725b) that extend distally from portions of distal wall (718) substantially below the respective syringe receptacles (720a, 720b), and that are configured to confront the syringes (706a, 706b) received within the respective syringe receptacles (720a, 720b). First and second elongate slots (726a, 726b) extend through first and second lower platforms (725a, 725b), respectively, for communicating light from circuit board assembly (711) to the syringes (706a, 706b) received within the respective syringe receptacles (720a, 720b). In some versions, clear windows (not shown) may be positioned within elongate slots (726a, 726b) to protect circuit board assembly (711) from fluid spills or other environmental hazards.

[000136] In the example shown, dock (724) also includes a raised central platform (727) that extends distally from distal wall (718) and that bridges between lower platforms (725a, 725b). An array of bores (728) extend through raised central platform (727) for allowing respective portions of circuit board assembly (711) to access cartridge (704). Dock (724) further includes first and second guide members in the form of tracks (729a, 729b) that extend laterally outwardly from respective sides of raised central platform (727) over first and second lower platforms (725a, 725b) to define first and second grooves (730a, 730b), respectively. Tracks (729a, 729b) and grooves (730a, 730b) are configured to interact with corresponding portions of cartridge (704) to guide cartridge (704) into proper alignment with control module (702) during coupling of cartridge (704) to control module (702).

[000137] Upper shell (714) of the present example further includes a pair of bores (731, 732) that extend through top wall (716) and that are configured to receive a priming button (733) and a lightpipe (734), respectively. Priming button (733) extends downwardly through the interior of housing (710) to circuit board assembly (711), and is configured to be selectively depressed by the operator. Lightpipe (734) also extends downwardly through the interior of housing (710) to circuit board assembly (711) for communicating light from circuit board assembly (711) through top wall (716) of housing (710).

[000138] In the example shown, lower shell (715) of housing (710) includes a bottom wall (735) that is configured to support circuit board assembly (711); and further includes a proximal wall (736), a distal wall (737), and first and second sidewalls (738a, 738b), each extending generally upwardly from bottom wall (735). Lower shell (715) of the present

example also includes a pair of proximal recesses (739, 740) extending downwardly from an upper surface of proximal wall (736), and a distal recess (741) extending downwardly from an upper surface of distal wall (737). Recesses (739, 740, 741) are configured to allow access to corresponding portions of circuit board assembly (711).

[000139] Referring now primarily to FIGS. 28-30, first and second drive assemblies (713a, 713b) of the present example include first and second linear actuators (742a, 742b) that are configured to be independently driven by first and second electric motors (743a, 743b) to dispense fluids (340, 341) from first and second syringes (706a, 706b), respectively, when cartridge (704) is removably coupled to control module (702). In the example shown, linear actuators (742a, 742b) and the respective motors (743a, 743b) are supported by respective frames (744a, 744b) that are fixedly secured to a lower surface of top wall (716) of housing (710) via corresponding fasteners in the form of screws (745). Frames (744a, 744b) of the present example each include a generally horizontally-extending drive support plate (746a, 746b) fixedly secured to top wall (716) via the corresponding screws (745), and a pair of generally vertically-extending drive support brackets (747a, 747b, 748a, 748b) fixedly secured to a distal end of the respective drive support plate (746a, 746b) via corresponding fasteners in the form of screws (749) and spaced apart from each other via corresponding standoffs (750). In the example shown, each pair of drive support brackets (747a, 747b, 748a, 748b) retain a corresponding pair of bushings (751a, 751b) for movably supporting the respective linear actuator (742a, 742b).

[000140] First and second linear actuators (742a, 742b) of the present example include first and second leadscrews (752a, 752b) that are translatably supported by first and second pairs of bushings (751a, 751b), respectively, such that leadscrews (752a, 752b) are each configured to translate relative to the respective frame (744a, 744b) along a respective longitudinal axis (LA1, LA2). In this regard, each leadscrew (752a, 752b) of the example shown includes a flat key surface (753a, 753b) configured to interact with one or both of the corresponding bushings (751a, 751b) to inhibit rotation of the leadscrew (752a, 752b) about the respective longitudinal axis (LA1, LA2) while permitting translation of the leadscrew (752a, 752b) along the respective longitudinal axis (LA1, LA2). In the example shown, the first and second longitudinal axes (LA1, LA2) are substantially parallel to each

other, which may contribute to the substantially compact configuration of fluid control unit (700). First and second bores (722a, 722b) of housing (710) are aligned with first and second leadscrews (752a, 752b), respectively, along the respective longitudinal axis (LA1, LA2), for allowing leadscrews (752a, 752b) to access the syringes (706a, 706b) received within the respective syringe receptacles (720a, 720b). In the example shown, first and second plunger caps (754a, 754b) are coupled to distal ends of first and second leadscrews (752a, 752b) for dispensing fluids (340, 341) from first and second syringes (706a, 706b), respectively, during distal translation of the respective leadscrew (752a, 752b) along the respective longitudinal axis (LA1, LA2).

[000141] First and second linear actuators (742a, 742b) of the present example also include first and second gears (755a, 755b) that are rotatably supported by first and second pairs of bushings (751a, 751b) and/or by first and second leadscrews (752a, 752b), respectively, such that gears (755a, 755b) are each configured to rotate relative to the respective frame (744a, 744b), and thus relative to the respective leadscrew (752a, 752b), about the respective longitudinal axis (LA1, LA2). In this regard, each gear (755a, 755b) may include a threaded central bore that threadably engages with the respective leadscrew (752a, 752b), such that each leadscrew (752a, 752b) is configured to translate along the respective longitudinal axis (LA1, LA2) in response to rotation of the respective gear (755a, 755b) about the respective longitudinal axis (LA1, LA2). In other words, each gear (755a, 755b) may effectively define a lead nut of the respective linear actuator (742a, 742b). In some other versions, each gear (755a, 755b) may include an unthreaded central bore that fixedly retains a separate lead nut (not shown), and the separate lead nut may include a threaded central bore that threadably engages with the respective leadscrew (752a, 752b). In the example shown, each gear (755a, 755b) includes outer teeth (756a, 756b) for facilitating driving of the respective linear actuator (742a, 742b) by the respective motor (743a, 743b).

[000142] To that end, first and second motors (743a, 743b) of the present example are mounted to first and second drive support brackets (747a, 747b), respectively, and include first and second output shafts (not shown) carrying first and second pinions (757a, 757b), respectively. In the example shown, each pinion (757a, 757b) includes outer teeth (758a,

758b) that mesh with outer teeth (756a, 756b) of the corresponding gear (755a, 755b), such that each gear (755a, 755b) is configured to rotate about the respective longitudinal axis (LA1, LA2) in response to rotation of the output shaft of the respective motor (743a, 743b). While pinions (757a, 757b) are adjacent to each other in the example shown, it will be appreciated that outer teeth (758a, 758b) do not mesh with each other. Thus, each motor (743a, 743b) is configured to independently drive translation of the respective leadscrew (752a, 752b), together with the respective plunger cap (754a, 754b), along the respective longitudinal axis (LA1, LA2).

[000143] As shown in FIG. 30, first and second drive assemblies (713a, 713b) of the present example also each include a respective home switch (759) that is mounted to a lower surface of the respective drive support plate (746a, 746b) via corresponding fasteners in the form of screws (745). Each home switch (759) may be configured to be triggered by the respective leadscrew (752a, 752b) when the respective leadscrew (752a, 752b) is at a predetermined home position, such as a proximal-most position, along the respective longitudinal axis (LA1, LA2); and to generate a signal in response to the respective leadscrew (752a, 752b) being at the predetermined home position. Each home switch (759) may be in operative communication with offboard processor (707) via circuit board assembly (711), such that each home switch (759) may facilitate monitoring of the position of the respective leadscrew (752a, 752b) along the respective longitudinal axis (LA1, LA2) by offboard processor (707). For example, offboard processor (707) may be configured to determine whether each leadscrew (752a, 752b) is at the predetermined home position along the respective longitudinal axis (LA1, LA2) based on one or more signals received by offboard processor (707) from the respective home switch (759). In some versions, first and second drive assemblies (713a, 713b) may each include a respective linear sensor (not shown) in addition to or in lieu of the respective home switch (759). For example, such a linear sensor may be similar to either linear sensor (176, 656) described above, and may be configured to generate a varying data value based on the longitudinal position of the respective leadscrew (752a, 752b) along the respective longitudinal axis (LA1, LA2).

[000144] In some versions, first and second drive assemblies (713a, 713b) may each include a respective strain gauge (not shown) that is configured to detect the amount of strain

present in the respective drive assembly (713a, 713b). For example, such strain gauges may each be mounted to an upper surface of the respective drive support plate (746a, 746b) or at any other suitable location on the respective frame (744a, 744b). Such strain gauges may each be in operative communication with offboard processor (707) via circuit board assembly (711), such that each strain gauge may facilitate monitoring of the amount of strain present in the respective drive assembly (713a, 713b) by offboard processor (707).

[000145] While drive assemblies (713a, 713b) of the present example include linear actuators (742a, 742b) that are defined by leadscrews (752a, 752b) and corresponding lead nuts defined by gears (755a, 755b), it will be appreciated that any other suitable type of actuator, such as any other suitable type of linear actuator, may be provided in lieu of one or both linear actuators (742a, 742b).

[000146] Referring now primarily to FIGS. 28 and 31, circuit board assembly (711) of the present example includes a substrate (760) that is fixedly secured to an upper surface of bottom wall (735) of housing (710). In the example shown, circuit board assembly (711) also includes a proximal wired protocol control interface in the form of a Universal Serial Bus (USB) port (761) that is accessible via proximal recess (739) of lower shell (715), and that is configured to couple to wires (708) for placing circuit board assembly (711) in operative communication with offboard processor (707); and a distal wired protocol control interface in the form of a USB port (762) that is accessible via distal recess (741) of lower shell (715), and that is configured to couple to wires (175) for placing circuit board assembly (711) in operative communication with circuit board assembly (170, 650) of instrument (100, 400). In some cases, offboard processor (707) may be configured to supply power to circuit board assembly (711) of fluid control unit (700) via proximal USB port (761) (e.g., in addition to or in lieu of the power supplied to circuit board assembly (711) by battery (712)); and/or circuit board assembly (711) of fluid control unit (700) may be configured to supply power to circuit board assembly (170, 650) of instrument (100, 400) via distal USB port (762).

[000147] Circuit board assembly (711) also includes a wireless protocol control interface in the form of a Bluetooth Low Energy (BLE) module (763) for placing circuit board assembly (711) in operative communication with offboard processor (707). Thus, circuit

board assembly (711) may be placed in operative communication with offboard processor (707) via USB port (761) and/or via BLE module (763). In some versions, one of proximal USB port (761) or BLE module (763) may be omitted. For example, proximal USB port (761) may be omitted. In such cases, circuit board assembly (711) may still be placed in operative communication with offboard processor (707), such as via BLE module (763). In the example shown, circuit board assembly (711) further includes an array of spring-loaded pins (also referred to as pogo pins) (764) that extend through the array of bores (728) of upper shell (714), and that are configured to engage corresponding portions of cartridge (704) for placing circuit board assembly (711) in operative communication with cartridge (704).

[000148] Circuit board assembly (711) of the present example also includes a power switch (also referred to as an on/off switch) (765) that is accessible via proximal recess (740) of lower shell (715), and that is configured to selectively permit power to be supplied to circuit board assembly (711) and/or motors (743a, 743b) from battery (712). In the example shown, circuit board assembly (711) further includes a non-volatile memory storage device in the form of a Secure Digital (SD) card (766). SD card (766) may be configured to store event log data and/or instructions for offboard processor (707). For example, offboard processor (707) may be configured to perform any one or more of the functions described herein based on instructions stored by SD card (766).

[000149] Circuit board assembly (711) of the present example also includes a user input element in the form of a tactile switch (767) positioned relative to priming button (733) such that the operator may provide actuation of tactile switch (767) by pressing priming button (733). Tactile switch (767) may be in operative communication with offboard processor (707) via USB port (761) and/or via BLE module (763); and offboard processor (707) may in turn be in operative communication with one or both motors (743a, 743b) via USB port (761) and/or via BLE module (763), and may be configured to activate one or both motors (743a, 743b) in response to actuation of tactile switch (767), as described in greater detail below.

[000150] In the example shown, circuit board assembly (711) also includes at least one user feedback element in the form of an illuminating element, such as one or more red-green-

blue (RGB) programmable LEDs (768) (one shown). LED (768) may be configured to selectively illuminate, and is positioned relative to lightpipe (734) such that lightpipe (734) may communicate light emitted by LED (768) through top wall (716) of housing (710). LED (768) may be in operative communication with offboard processor (707) via USB port (761) and/or via BLE module (763); and offboard processor (707) may be configured to illuminate LED (768) differently based on the particular state of the system defined by instrument (100, 400) and fluid control unit (700), as described in greater detail below. While not shown, circuit board assembly (711) may include additional LEDs positioned relative to (e.g., below) elongate slots (726a, 726b) of housing (710) such that elongate slots (726a, 726b) may communicate light emitted by such additional LEDs through dock (724) of housing (710).

[000151] Circuit board assembly (711) of the present example further include at least one user feedback element in the form of a speaker (769) configured to provide one or more audible tones. Speaker (769) may be in operative communication with offboard processor (707) via USB port (761) and/or via BLE module (763); and offboard processor (707) may be configured to provide different audible tones via speaker (769) based on the particular state of the system defined by instrument (100, 400) and fluid control unit (700), as described in greater detail below.

[000152] While various components of circuit board assembly (711) have been described as being in operative communication with offboard processor (707), such components may additionally or alternatively be in operative communication with an onboard processor of fluid control unit (700), such as a microprocessor (not shown) that is disposed on substrate (760) or otherwise incorporated into circuit board assembly (711). Such an onboard processor may be configured to perform any one or more of the functions described herein in connection with offboard processor (707).

[000153] As shown in FIGS. 24-25 and 32-35, cartridge (704) of the present example includes a housing (770) and a variety of components contained within housing (770), including first and second syringe connectors (771a, 771b) for facilitating coupling of cartridge (704) with first and second syringes (706a, 706b), respectively. In the example shown, housing (771) is defined by upper and lower shells (772, 773).

[000154] Referring primarily to FIGS. 25 and 32-35, lower shell (773) of housing (770) includes a bottom wall (774) that is configured to support syringe connectors (771a, 771b); and further includes a proximal wall (775), a distal wall (776), and first and second sidewalls (777a, 777b), each extending generally upwardly from bottom wall (774). Lower shell (773) of the present example also includes first and second generally U-shaped syringe receptacles (778a, 778b) extending downwardly from an upper surface of bottom wall (774). First and second syringe receptacles (778a, 778b) are sized and configured to at least partially receive first and second syringes (706a, 706b), respectively, when syringes (706a, 706b) are coupled with cartridge (704). In the example shown, first and second syringe receptacles (778a, 778b) also accommodate respective portions of syringe connectors (771a, 771b).

[000155] Lower shell (773) of the present example also includes a channel (779) extending upwardly from a lower surface of bottom wall (774) and configured to receive raised central platform (727) of dock (724) of control module (702). Lower shell (773) further includes first and second guide members in the form of tracks (780a, 780b) that extend laterally inwardly below respective sides of channel (779) to define first and second grooves (781a, 781b). Tracks (780a, 780b) are configured to be slidably received with grooves (730a, 730b) of dock (724) of control module (702), respectively, and grooves (781a, 781b) are configured to slidably receive tracks (729a, 729b) of dock (724) of control module (702), respectively, to promote proper alignment of cartridge (704) with control module (702) during coupling of cartridge (704) to control module (702). For example, tracks (780a, 780b) and grooves (781a, 781b) of cartridge (704) may interact with the corresponding grooves (730a, 730b) and tracks (729a, 729b) of control module (702) to substantially align syringes (706a, 706b) along the respective longitudinal axes (LA1, LA2).

[000156] In the example shown, first and second grooves (781a, 781b) terminate distally at first and second stops (782a, 782b) of lower shell (773), respectively, such that stops (782a, 782b) may limit the advancement of tracks (729a, 729b) along grooves (781a, 781b). An array of bores (783) extend through bottom wall (774) to channel (779) for retaining an array of electrical contacts (784). Bores (783) and contacts (784) are arranged to align with

corresponding bores (728) and spring-loaded pins (764) of control module (702), such that each spring-loaded pin (764) may engage the corresponding contact (784) for placing circuit board assembly (711) in operative communication with cartridge (704).

[000157] First and second elongate slots (785a, 785b) extend through bottom wall (774) on respective sides of channel (779) and are arranged to align with first and second elongate slots (726a, 726b) of control module (702), respectively, for communicating light from the LEDs of circuit board assembly (711) to the syringes (706a, 706b) received within the respective syringe receptacles (778a, 778b), to thereby enhance visibility of syringes (706a, 706b) for the operator.

[000158] Lower shell (773) of the present example also includes first and second side recesses (786a, 786b) extending downwardly from upper surfaces of first and second sidewalls (777a, 777b), respectively, and first and second proximal recesses (787a, 787b) extending downwardly from upper surfaces of proximal wall (775), for accommodating first and second coupling members in the form of spring-loaded latches (788a, 788b). In this regard, latches (788a, 788b) each include a respective locking arm (789a, 789b) that extends through the corresponding proximal recess (787a, 787b) for engaging a periphery of the corresponding aperture (723a, 723b) of control module (702) to removably couple cartridge (704) to control module (702); and a respective release button (790a, 790b) that is accessible via the corresponding side recess (786a, 786b) for disengaging the respective locking arm (789a, 789b) from the periphery of the corresponding aperture (723a, 723b) to uncouple cartridge (704) from control module (702).

[000159] In the example shown, upper shell (772) of housing (770) includes a top wall (791); and further includes a proximal wall (792), a distal wall (793), and first and second sidewalls (794a, 794b), each extending generally downwardly from top wall (791). Upper shell (772) of the present example also includes first and second openings (795a, 795b) extending both downwardly through top wall (791) and distally from proximal wall (792), for at least partially receiving first and second syringes (706a, 706b), respectively.

[000160] First and second syringe connectors (771a, 771b) of the present example include first and second proximal fluid couplings in the form of female luer fittings (796a, 796b)

that are configured to couple with the distal ends of first and second syringes (706a, 706b), respectively; and first and second distal fluid couplings in the form of male luer fittings (797a, 797b) that are configured to couple with proximal ends of fluid conduits (142, 144), respectively. In some versions, first female luer fitting (796a) may be incapable of coupling with the distal end of second syringe (706b), and second female luer fitting (796b) may be incapable of coupling with the distal end of first syringe (706a), such that first syringe (706a) may only be coupled with first female luer fitting (796a), and such that second syringe (706b) may only be coupled with second female luer fitting (796b), to prevent inadvertent dispensing of bleb fluid (340) by second drive assembly (713b) and/or inadvertent dispensing of therapeutic agent (341) by first drive assembly (713a). In the example shown, syringe connectors (771a, 771b) include respective dead volume reduction inserts (798a, 798b) disposed within the corresponding male luer fittings (797a, 797b).

[000161] First and second syringe connectors (771a, 771b) of the present example also include first and second pressure transducers (799a, 799b), respectively, that are configured to detect the amount of fluid pressure present in the respective syringe connector (771a, 771b). Each pressure transducer (799a, 799b) may be in operative communication with circuit board assembly (711) via corresponding contacts (784) and spring-loaded pins (764), and may further be in operative communication with offboard processor (707) via circuit board assembly (711), such that each pressure transducer (799a, 799b) may facilitate monitoring of the amount of fluid pressure present in the respective syringe connector (771a, 771b) by offboard processor (707).

[000162] In an example of a method of use, syringes (706a, 706b) may initially each be equipped with a corresponding needle (not shown) coupled to the distal end of the respective syringe (706a, 706b), and with a corresponding plunger stem (not shown) that is threadably coupled to a stopper (also referred to as a piston) housed within the respective syringe (706a, 706b). In some versions, the stoppers may each include a tapered distal tip. Syringes (706a, 706b) may be filled with desired volumes of bleb fluid (340) and therapeutic agent (341), respectively, by inserting the corresponding needle into an appropriate vial of bleb fluid (340) or therapeutic agent (341) and withdrawing the corresponding plunger stem proximally to extract the desired volume of fluid (340, 341)

from the vial into the respective syringe (706a, 706b). The corresponding needle may then be uncoupled from the distal end of the respective filled syringe (706a, 706b), and the corresponding plunger stem may also be uncoupled from the stopper housed within the respective filled syringe (706a, 706b). The filled syringes (706a, 706b) may then be coupled with cartridge (704) by threading the distal end of each syringe (706a, 706b) onto the corresponding female luer fitting (796a, 796b).

[000163] Cartridge (704) may then be attached to control module (702) by sliding tracks (780a, 780b) and grooves (781a, 781b) of cartridge (704) along the corresponding grooves (730a, 730b) and tracks (729a, 729b) of control module (702), until spring-loaded latches (788a, 788b) of cartridge (704) engage the corresponding apertures (723a, 723b) of control module (702) to removably couple cartridge (704) to control module (702). In some versions, the engagement of spring-loaded latches (788a, 788b) of cartridge (704) with the corresponding apertures (723a, 723b) of control module (702) may provide audible feedback (e.g., a "click") to the operator indicating that the cartridge (704) is coupled to control module (702). With fluid control unit (700) in the loaded state, fluid control unit (700) may be operatively coupled to an instrument (100, 400) via the corresponding tube set (140, 440). For example, wires (175) may be plugged into distal USB port (762) to thereby place circuit board assembly (711) of fluid control unit (700) in operative communication with circuit board assembly (170, 650) of instrument (100, 400); and the proximal ends of fluid conduits (142, 144) may be threaded into the corresponding male luer fittings (797a, 797b).

[000164] With fluid control unit (700) in the loaded state and operatively coupled to instrument (100, 400), the operator may turn on power to fluid control unit (700) by switching power switch (765) to an "on" state. In some versions, an onboard processor (not shown) may be configured to send a signal to LED (768) to illuminate in a unique visible manner (e.g., solid white) to indicate that power is on; in another unique visible manner (e.g., flashing red) to indicate that battery (712) is low; and/or in yet another unique visible manner (e.g., solid red) to indicate a connection error between fluid control unit (700) and instrument (100, 400). In some other versions, such signals may be sent by offboard processor (707) (e.g., after fluid control unit (700) has been operatively coupled

to offboard processor (707)). In addition, or alternatively, the additional LEDs below elongate slots (726a, 726b) of control module (702) may illuminate upon powering on of fluid control unit (700) to emit light through elongate slots (726a, 726b) and through the corresponding elongate slots (785a, 785b) of cartridge (704) and thereby provide backlighting of syringes (706a, 706b), which may assist the operator with visually observing the levels of fluids (340, 341) within syringes (706a, 706b).

[000165] With fluid control unit (700) loaded, coupled to instrument (100, 400), and powered on, fluid control unit (700) may be operatively coupled to offboard processor (707). For example, wires (708) may be plugged into proximal USB port (761) to thereby place circuit board assembly (711) of fluid control unit (700) in operative communication with offboard processor (707). Circuit board assembly (711) may additionally or alternatively be placed in operative communication with offboard processor (707) via BLE module (763). In some versions, offboard processor (707) may also be operatively coupled to any one or more of a display, a microscope, and/or a video overlay system. For example, offboard processor (707) may be configured to present various textual or graphical messages via the display, and such messages by overlayed onto real time images of the patient's eye (301) that are captured by the microscope.

[000166] In order to prime the system, the operator may press priming button (733) to actuate tactile switch (767). Offboard processor (707) may be configured to send signals to motors (743a, 743b) to activate in response to actuation of tactile switch (767) for a predetermined duration that is sufficient to achieve priming of the system (e.g., priming of the delivery line(s) for bleb fluid (340) and/or therapeutic agent (341)). In some versions, offboard processor (707) may also be configured to send a signal to LEDs (658) of instrument (100, 400) to illuminate in a unique visible manner (e.g., solid green) to indicate that the system is priming (e.g., that priming of the delivery line(s) for bleb fluid (340) and/or therapeutic agent (341) is being performed). The operator may release priming button (733) in response to observing the green light emitted by LEDs (658) and/or in response to hearing the activation of motors (743a, 743b).

[000167] When activated, each motor (743a, 743b) drives distal translation of the respective leadscrew (752a, 752b) along the respective longitudinal axis (LA1, LA2), such that the

respective plunger cap (754a, 754b) engages the stopper housed within the corresponding syringe (706a, 706b) and urges the respective stopper distally. Each stopper may thereby drive a portion of the fluid (340, 341) from the respective syringe (706a, 706b) and into the respective fluid conduit (142, 144) via the corresponding syringe connector (771a, 771b). This may in turn provide priming of the system, purging any air from the fluid path between one or both syringes (706a, 706b) and the distal end of needle (150). In some instances, motors (743a, 743b) may be activated sequentially. In some other instances, both motors (743a, 743b) may be activated at substantially the same time. It should also be understood that, in some instances, an air gap may be provided between leading bleb (340) and therapeutic fluid (341) to prevent therapeutic fluid (341) from mixing with leading bleb (340). Various suitable ways in which the system may be primed with leading bleb (340) fluid, therapeutic fluid (341), and/or an intentional air gap will be apparent to those skilled in the art in view of the teachings herein. Offboard processor (707) may be configured to continuously monitor the priming status of the system during the priming process, such as based on the duration of time that each motor (743a, 743b) is activated. Offboard processor (707) may be configured to present a textual or graphical message (e.g., via the display) to indicate the current priming status. Offboard processor (707) may be configured to deactivate motors (743a, 743b) in response to determining that the system has been successfully primed, and/or to send a signal to speaker (769) to provide a unique audible tone or series of tones to indicate that the system is primed.

[000168] In some versions, offboard processor (707) may be configured to automatically perform a predetermined sequence of steps to prime the system in response to actuation of tactile switch (767). For example, offboard processor (707) may initially respond to actuation of tactile switch (767) by activating first motor (743a) to drive distal translation of first leadscrew (752a) along the first longitudinal axis (LA1) until first plunger cap (754a) engages the stopper housed within first syringe (706a). Offboard processor (707) may then activate second motor (743b) to drive distal translation of second leadscrew (752b) along the second longitudinal axis (LA2) until second plunger cap (754b) engages the stopper housed within second syringe (706b). Next, offboard processor (707) may again activate first motor (743a) to drive distal translation of first leadscrew (752a), together with first plunger (754a) and the stopper housed within first syringe (706a), along

the first longitudinal axis (LA1) sufficiently to at least partially (e.g., about halfway) prime the fluid path between first syringe (706a) and the distal end of needle (150). Offboard processor (707) may then again activate second motor (743b) to drive distal translation of second leadscrew (752b), together with second plunger cap (754b) and the stopper housed within second syringe (706b), along the second longitudinal axis (LA2) sufficiently to at least partially prime the fluid path between second syringe (706b) and the distal end of needle (150). Then, offboard processor (707) may again activate first motor (743a) to drive distal translation of first leadscrew (752a), together with first plunger (754a) and the stopper housed within first syringe (706a), along the first longitudinal axis (LA1) sufficiently to finish priming the fluid path between first syringe (706a) and the distal end of needle (150). Such a predetermined sequence of steps may inhibit backflow of the fluid (340, 341) from each syringe (706a, 706b) into the other syringe (706b, 706a).

[000169] Once the system is primed, the operator may advance needle (150) distally relative to the cannula (130, 430) of instrument (100, 400) to protrude from the corresponding opening (134) of the cannula (130, 430). For example, after cannula (130, 430) has been advanced to the delivery site as shown in FIG. 13D, the operator may advance needle (150) of instrument (100, 400) by rotating the corresponding knob/knob assembly (120, 420) such that needle (150) pierces through choroid (306) without penetrating retina (308) as shown in FIG. 13E. Offboard processor (707) may be configured to present a textual or graphical message (e.g., via the display) to indicate a longitudinal position of needle (150) based on one or more signals received by offboard processor (707) from the corresponding rotary or linear sensor (176, 656) of instrument (100, 400). In some versions, offboard processor (707) may be configured to activate first motor (743a) in response to distal movement of needle (150) as sensed by sensor (176, 656) to drive distal translation of first leadscrew (752a), together with first plunger (754a) and the stopper housed within first syringe (706a), along the first longitudinal axis (LA1). Offboard processor (707) may thereby provide automated delivery of bleb fluid (340) via needle (150) at a predetermined, fixed flow rate as described above during distal advancement of needle (150) to promote safe penetration of the choroid (306) by distal tip (152) of needle (150) without perforating the retina (308). In addition, or alternatively, offboard processor (707) may be configured to send a signal to LEDs (658) of instrument (100, 400) to illuminate in a unique visible

manner (e.g., solid blue) to indicate that needle (150) has been distally advanced to its fully extended, distal-most position, such that needle (150) is properly positioned for delivery of therapeutic agent (341).

[000170] With needle (150) properly positioned for delivery of therapeutic agent (341), the operator may first deliver bleb fluid (340) via needle (150) to form a pocket of bleb fluid (340) as shown in FIG. 13F. For example, after needle (150) has pierced through choroid (306) without penetrating retina (308), the operator may press lower rocker plate/first button (112, 412) of instrument (100, 400) to actuate the corresponding tactile switch (652). Offboard processor (707) may be configured to send a signal to first motor (743a) to activate in response to actuation of tactile switch (652) to drive distal translation of first leadscrew (752a), together with first plunger (754a) and the stopper housed within first syringe (706a), along the first longitudinal axis (LA1) to thereby dispense bleb fluid (340) at a predetermined, fixed flow rate while tactile switch (652) is actuated (e.g., while first button (412) is depressed). Offboard processor (707) may be configured to continuously monitor the volume of bleb fluid (340) delivered via needle (150), such as based on the fixed flow rate and the duration of time that the bleb fluid (340) is dispensed. Offboard processor (707) may be configured to present a textual or graphical message (e.g., via the display) to indicate the volume of bleb fluid (340) delivered via needle (150). In the present example, the flow rate of bleb fluid (340) is predetermined. By way of example only, the predetermined flow rate of bleb fluid (340) may range from approximately 100 μL per minute to approximately 400 μL per minute. For example, the predetermined flow rate of bleb fluid (340) may be approximately 200 μL per minute. In some other versions, fluid control unit (700) and/or the host computer provides a user input where the operator may select a desired flow rate for bleb fluid (340) to be dispensed at while first tactile switch (652) is actuated. In addition, or in the alternative, the flow rate for bleb fluid (340) may vary during delivery, such as based on a predetermined sequence of flow rates selected by the operator, for example. The operator may release lower rocker plate/first button (112, 412) when the desired volume of bleb fluid (340) has been delivered; and offboard processor (707) may be configured to deactivate first motor (743a) in response to the release of the corresponding tactile switch (652).

[000171] In some versions, offboard processor (707) may be configured to determine whether needle (150) is in its fully retracted, proximal-most position in response to actuation of tactile switch (652), prior to sending the signal to first motor (743a) to activate; and may only be configured to send the signal to first motor (743a) to activate if needle (150) is not in its fully retracted, proximal-most position. In other words, offboard processor (707) may be configured to refrain from sending the signal to first motor (743a) to activate when needle (150) is in its fully retracted, proximal-most position, to avoid inadvertent delivery of bleb fluid (340) prior to distal advancement of needle (150).

[000172] After the desired volume of bleb fluid (340) has been delivered, the operator may deliver therapeutic agent (341) via needle (150). For example, after a pocket of bleb fluid (340) has been formed as shown in FIG. 13F, the operator may press upper rocker plate/second button (114, 414) of instrument (100, 400) to actuate the corresponding tactile switch (654). Offboard processor (707) may be configured to send a signal to second motor (743b) to activate in response to actuation of tactile switch (654) to drive distal translation of second leadscrew (752b), together with second plunger (754b) and the stopper housed within second syringe (706b), along the second longitudinal axis (LA2) to thereby dispense therapeutic agent (341) at a precise, fixed flow rate while second tactile switch (654) is actuated (e.g., while second button (414) is depressed). Offboard processor (707) may be configured to continuously monitor the volume of therapeutic agent (341) delivered via needle (150), such as based on the fixed flow rate and the duration of time that the therapeutic agent (341) is dispensed. For example, offboard processor (707) may be configured to monitor the cumulative volume of therapeutic agent (341) delivered to the eye (301) by multiple discrete deliveries of therapeutic agent (341) via needle (150), such as in cases where second button (414) is depressed, released, and then depressed again. Offboard processor (707) may be configured to present a textual or graphical message (e.g., via the display) to indicate the volume of therapeutic agent (341) delivered via needle (150). In some versions, fluid control unit (700) and/or the host computer provides a user input where the operator may select a desired flow rate for therapeutic agent (341) to be dispensed at while second tactile switch (654) is actuated. By way of example only, the selected flow rate of therapeutic agent (341) may range from approximately 100 μL per minute to approximately 400 μL per minute. In addition, or in the alternative, the flow rate

for therapeutic agent (341) may vary during delivery, such as based on a predetermined sequence of flow rates selected by the operator, for example. The operator may release upper rocker plate/second button (114, 414) when the desired volume of therapeutic agent (341) has been delivered; and offboard processor (707) may be configured to deactivate second motor (743b) in response to the release of the corresponding tactile switch (654).

[000173] In some versions, offboard processor (707) may be configured to send a signal to second motor (743b) to activate in response to actuation of tactile switch (654) for a predetermined duration that is sufficient to achieve delivery of a predetermined volume of therapeutic agent (341). For example, the host computer may provide a user input where the operator may select a desired volume of therapeutic agent (341) to be dispensed, such as ranging from about 25 μL to about 300 μL; and offboard processor (707) may be configured to deactivate second motor (743b) in response to determining that the desired volume of therapeutic agent (341) has been successfully dispensed. In other words, fluid control unit (700) may automatically stop delivering therapeutic agent (341) once the desired volume of therapeutic agent (341) inputted into the host computer has been administered. In some instances, offboard processor (707) may be configured to sequentially activate and deactivate second motor (743b) to incrementally deliver the desired volume of therapeutic agent (341). For example, offboard processor (707) may be configured to deliver the desired volume of therapeutic agent (341) in increments of about 2 μL.

[000174] In some versions, offboard processor (707) may be configured to determine whether needle (150) is in its fully retracted, proximal-most position in response to actuation of tactile switch (654), prior to sending the signal to second motor (743b) to activate; and may only be configured to send the signal to second motor (743b) to activate if needle (150) is not in its fully retracted, proximal-most position. In other words, offboard processor (707) may be configured to refrain from sending the signal to second motor (743b) to activate when needle (150) is in its fully retracted, proximal-most position, to avoid inadvertent delivery of therapeutic agent (341) prior to distal advancement of needle (150).

[000175] Offboard processor (707) may be configured to continuously monitor the amount

of fluid pressure present in syringe connectors (771a, 771b), such as based on signals received by offboard processor (707) from pressure transducers (799a, 799b). In some versions, offboard processor (707) may compare the amount of fluid pressure present in each syringe connector (771a, 771b) to a threshold value, and may determine an error state of the system in response to the monitored amount of fluid pressure exceeding the threshold value. For example, offboard processor (707) may determine that an obstruction (e.g., a clog) is present within the fluid path between one of the syringes (706a, 706b) and the distal end of needle (150) in response to the monitored amount of fluid pressure present in the corresponding syringe connector (771a, 771b) exceeding the threshold value. Offboard processor (707) may be configured to present a textual or graphical message (e.g., via the display) to indicate the error state of the system; to send a signal to any of LEDs (658, 768) to illuminate in a unique visible manner (e.g., flashing or solid color) to indicate the error state of the system; and/or to send a signal to either speaker (660, 769) to provide a unique audible tone or series of tones to indicate the error state of the system. In addition, or alternatively, offboard processor (707) may be configured to cease and/or prevent delivery of either fluid (340, 341) when the system is in such an error state, such as by deactivating one or both motors (743a, 743b) until the system is no longer in such an error state.

[000176] In addition, or alternatively, offboard processor (707) may be configured to continuously monitor the amount of strain present in drive assemblies (713a, 713b), such as based on signals received by offboard processor (707) from the strain gauges of drive assemblies (713a, 713b). In some versions, offboard processor (707) may compare the amount of strain present in each drive assembly (713a, 713b) to a threshold value, and may determine an error state of the system in response to the monitored amount of strain exceeding the threshold value. For example, offboard processor (707) may determine that an obstruction (e.g., a clog) is present within the fluid path between one of the syringes (706a, 706b) and the distal end of needle (150) in response to the monitored amount of strain present in the corresponding drive assembly (713a, 713b) exceeding the threshold value. Offboard processor (707) may be configured to present a textual or graphical message (e.g., via the display) to indicate the error state of the system; to send a signal to any of LEDs (658, 768) to illuminate in a unique visible manner (e.g., flashing or solid color) to indicate the error state of the system; and/or to send a signal to either speaker

(660, 769) to provide a unique audible tone or series of tones to indicate the error state of the system. In addition, or alternatively, offboard processor (707) may be configured to cease and/or prevent delivery of either fluid (340, 341) when the system is in such an error state, such as by deactivating one or both motors (743a, 743b) until the system is no longer in such an error state.

[000177] In some cases where offboard processor (707) utilizes the data from such strain gauges to detect obstructions in the fluid paths, pressure transducers (799a, 799b) and the corresponding contacts (784) and spring-loaded pins (764) may be omitted. In addition, or alternatively, offboard processor (707) may be configured to determine a fill level of each fluid (340, 341) within the respective syringe (706a, 706b) based at least in part on the monitored amount of strain present in the corresponding drive assembly (713a, 713b); and may be configured to present a textual or graphical message (e.g., via the display) to indicate the fill level of each fluid (340, 341) within the respective syringe (706a, 706b).

[000178] While LEDs (658, 768) and speakers (660, 769) of instrument (400) and fluid control unit (700) have been described as being used by offboard processor (707) in various ways, other suitable ways in which LEDs (658, 768) and speakers (660, 769) may be used will be apparent to those of ordinary skill in the art in view of the teachings herein. For example, offboard processor (707) may utilize LEDs (658) and speaker (660) of instrument (400) in any of the ways described herein in connection with LED (768) and speaker (769) of fluid control unit (700), respectively; and/or may utilize LED (768) and speaker (769) of fluid control unit (700) in any of the ways described herein in connection with LEDs (658) and speaker (660) of instrument (400), respectively. In some instances, offboard processor (707) may utilize an external speaker, such as a built-in speaker of the display (not shown), in any of the ways described herein in connection with one or both speakers (660, 769), such that one or both speakers (660, 769) may be omitted.

[000179] V. Examples of Combinations

[000180] The following examples relate to various non-exhaustive ways in which the teachings herein may be combined or applied. It should be understood that the following examples are not intended to restrict the coverage of any claims that may be presented at

any time in this application or in subsequent filings of this application. No disclaimer is intended. The following examples are being provided for nothing more than merely illustrative purposes. It is contemplated that the various teachings herein may be arranged and applied in numerous other ways. It is also contemplated that some variations may omit certain features referred to in the below examples. Therefore, none of the aspects or features referred to below should be deemed critical unless otherwise explicitly indicated as such at a later date by the inventors or by a successor in interest to the inventors. If any claims are presented in this application or in subsequent filings related to this application that include additional features beyond those referred to below, those additional features shall not be presumed to have been added for any reason relating to patentability.

[000181] Example 1

[000182] An apparatus, comprising: (a) an instrument body; (b) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; (c) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position; (d) a rotary knob configured to rotate relative to the instrument body about a rotational axis and thereby drive translation of the needle between the proximal position and the distal position; and (e) at least one deflectable member fixed against rotation relative to one of the instrument body or the rotary knob, wherein the at least one deflectable member is configured to frictionally engage the other of the instrument body or the rotary knob to prevent rotation of the rotary knob about the rotational axis absent application of a predetermined threshold rotational force to the rotary knob.

[000183] Example 2

[000184] The apparatus of Example 1, wherein the at least one deflectable member is fixed against rotation relative to the rotary knob, wherein the at least one deflectable member is

configured to frictionally engage the instrument body to prevent rotation of the rotary knob about the rotational axis absent application of the predetermined threshold rotational force to the rotary knob.

[000185] Example 3

[000186] The apparatus of Example 2, wherein the at least one deflectable member is configured to deflect radially inwardly relative to the rotational axis from an undeflected state to a deflected state, wherein the at least one deflectable member is resiliently biased toward the undeflected state.

[000187] Example 4

[000188] The apparatus of any of Examples 2 through 3, wherein the instrument body is configured to urge the at least one deflectable member toward the deflected state.

[000189] Example 5

[000190] The apparatus of any of Examples 2 through 4, wherein the instrument includes a ledge, wherein the ledge is configured to urge the at least one deflectable member toward the deflected state.

[000191] Example 6

[000192] The apparatus of any of Examples 1 through 5, wherein the at least one deflectable member includes a plurality of deflectable members.

[000193] Example 7

[000194] The apparatus of Example 6, wherein the plurality of deflectable members are circumferentially spaced apart from each other at equal intervals.

[000195] Example 8

[000196] The apparatus of any of Examples 6 through 7, wherein the plurality of deflectable members include three deflectable members.

[000197] Example 9

[000198] The apparatus of any of Examples 1 through 8, wherein the at least one deflectable member includes at least one deflectable beam.

[000199] Example 10

[000200] The apparatus of Example 9, wherein the at least one deflectable beam is defined by at least one pair of recesses.

[000201] Example 11

[000202] The apparatus of any of Examples 9 through 10, wherein the at least one deflectable beam includes at least one detent extending radially outwardly from a radially outer surface of the at least one deflectable beam, wherein the at least one detent is configured to frictionally engage the instrument body.

[000203] Example 12

[000204] The apparatus of any of Examples 1 through 11, further comprising a torque ring, wherein the torque ring includes the at least one deflectable member.

[000205] Example 13

[000206] The apparatus of Example 12, wherein the rotary knob includes a first interlocking member, wherein the torque ring includes a second interlocking member configured to interlock with the first interlocking member to fix the torque ring against rotation relative to the rotary knob.

[000207] Example 14

[000208] The apparatus of Example 13, wherein one of the first or second interlocking members includes a post, wherein the other of the first or second interlocking members includes a recess configured to receive the post and thereby interlock with the post.

[000209] Example 15

[000210] The apparatus of any of Examples 12 through 14, wherein the rotary knob defines an interior, wherein the torque ring is at least partially disposed within the interior of the rotary knob.

[000211] Example 16

[000212] An apparatus, comprising: (a) an instrument body; (b) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; (c) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position; (d) a rotary knob configured to drive translation of the needle between the proximal position and the distal position; and (e) a torque ring configured to resist rotation of the rotary knob.

[000213] Example 17

[000214] The apparatus of Example 16, wherein the torque ring is fixed against rotation relative to one of the instrument body or the rotary knob.

[000215] Example 18

[000216] The apparatus of Example 17, wherein the torque ring is integrally formed together with the one of the instrument body or the rotary knob as a unitary piece.

[000217] Example 19

[000218] The apparatus of any of Examples 17 through 18, wherein the torque ring is fixed against rotation relative to the rotary knob.

[000219] Example 20

[000220] The apparatus of any of Examples 16 through 19, wherein the torque ring includes at least one deflectable member configured to provide friction between the rotary knob and the instrument body.

[000221] Example 21

[000222] An apparatus, comprising: (a) an instrument body; (b) a cannula extending distally

from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; (c) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position; (d) a knob configured to rotate relative to the instrument body and thereby drive translation of the needle between the proximal position and the distal position; (e) at least one deflectable member configured to frictionally engage one of the instrument body or the knob to prevent rotation of the knob absent application of a predetermined threshold rotational force to the knob; and (f) a fluid control unit configured to provide at least one fluid to the needle.

[000223] Example 22

[000224] The apparatus of Example 21, further comprising a sensor positioned on or within the instrument body, wherein the sensor is in operative communication with the fluid control unit, wherein the sensor is operable to detect a position of the needle relative to the cannula.

[000225] Example 23

[000226] The apparatus of Example 22, wherein the fluid control unit is configured to provide the at least one fluid to the needle in response to a signal received from the sensor.

[000227] Example 24

[000228] The apparatus of any of Examples 21 through 23, further comprising at least one user input element positioned on or within the instrument body, wherein the at least one user input element is in operative communication with the fluid control unit, wherein the fluid control unit is configured to provide the at least one fluid to the needle in response to at least one signal received from the at least one user input element.

[000229] Example 25

[000230] The apparatus of Example 24, wherein the at least one user input element includes

a first user input element, wherein the fluid control unit is configured to provide a first fluid to the needle in response to a first signal received from the first user input element.

[000231] Example 26

[000232] The apparatus of Example 25, wherein the at least one user input element includes a second user input element, wherein the fluid control unit is configured to provide a second fluid different from the first fluid to the needle in response to a second signal received from the second user input element.

[000233] Example 27

[000234] The apparatus of any of Examples 24 through 26, wherein the at least one user input element includes at least one tactile switch.

[000235] Example 28

[000236] The apparatus of any of Examples 21 through 27, further comprising at least one user feedback element positioned on or within the instrument body, wherein the at least one user feedback element is in operative communication with the fluid control unit, wherein the at least one user feedback element is configured to provide at least one form of user feedback in response to at least one signal received from the fluid control unit.

[000237] Example 29

[000238] The apparatus of Example 28, wherein the at least one user feedback element includes at least one illuminating element configured to illuminate in response to the at least one signal received from the fluid control unit.

[000239] Example 30

[000240] The apparatus of any of Examples 28 through 29, wherein the at least one user feedback element includes a speaker configured to provide an audible tone in response to the at least one signal received from the fluid control unit.

[000241] Example 31

[000242] A method, comprising: (a) inserting a flexible cannula having a needle retracted

therein into a space between a sclera and a choroid of an eye; (b) applying a predetermined threshold rotational force to a rotary knob associated with the needle that is sufficient to overcome a rotational resistance imposed upon the rotary knob by a deflectable member, to rotate the rotary knob and thereby advance the needle relative to the cannula while the cannula remains positioned between the sclera and the choroid, such that the needle pierces the choroid to access a subretinal space of the eye; and (c) delivering a therapeutic agent to the subretinal space via the advanced needle.

[000243] Example 32

[000244] The method of Example 31, wherein the deflectable member is fixed against rotation relative to the rotary knob.

[000245] Example 33

[000246] The method of any of Examples 31 through 32, further comprising tracking advancement of the needle via a sensor.

[000247] Example 34

[000248] The method of Example 33, further comprising automatically dispensing a leading bleb fluid through the needle while advancing the needle in response to at least one signal generated by the sensor.

[000249] Example 35

[000250] The method of any of Examples 31 through 34, further comprising actuating at least one user input element in operative communication with a fluid control unit.

[000251] Example 36

[000252] The method of Example 35, wherein delivering the therapeutic agent is automatically performed in response to at least one signal generated by the at least one user input element.

[000253] Example 37

[000254] The method of any of Examples 35 through 36, further comprising dispensing a

leading bleb fluid through the needle in response to at least one signal generated by the at least one user input element.

[000255] Example 38

[000256] The method of any of Examples 35 through 37, further comprising providing at least one form of user feedback in response to at least one signal generated by the fluid control unit.

[000257] Example 39

[000258] The method of Example 38, wherein providing at least one form of user feedback includes illuminating an illuminating element.

[000259] Example 40

[000260] The method of any of Examples 38 through 39, wherein providing at least one form of user feedback includes providing an audible tone.

[000261] Example 41

[000262] An apparatus, comprising: (a) a first fluid source including: (i) a first proximal end, (ii) a first distal end configured to dispense a bleb fluid, and (iii) a first piston disposed between the first proximal and distal ends; (b) a second fluid source including: (i) a second proximal end, (ii) a second distal end configured to dispense a therapeutic agent, and (iii) a second piston disposed between the second proximal and distal ends; (c) a cartridge including: (i) a first fluid source connector configured to couple the first distal end of the first fluid source to a first fluid conduit, and (ii) a second fluid source connector configured to couple the second distal end of the second fluid source to a second fluid conduit, and (d) a control module including: (i) a first drive assembly including a first electric motor, wherein the first drive assembly is configured to advance the first piston distally along a first longitudinal axis and thereby dispense the bleb fluid from the first distal end, and (ii) a second drive assembly including a second electric motor, wherein the second drive assembly is configured to advance the second piston distally along a second longitudinal axis and thereby dispense the therapeutic agent from the second distal end, the second longitudinal axis being substantially parallel to the first longitudinal axis.

[000263] Example 42

[000264] The apparatus of claim 41, wherein the control module further includes at least one user input element, wherein at least one of the first or second drive assemblies is configured to advance the respective first or second piston in response to actuation of the at least one user input element.

[000265] Example 43

[000266] The apparatus of claim 42, wherein the at least one user input element of the control module includes at least one tactile switch.

[000267] Example 44

[000268] The apparatus of any of claims 41 through 43, wherein the control module further includes at least one user feedback element, wherein the at least one user feedback element is configured to provide at least one form of user feedback indicative of a state of the apparatus.

[000269] Example 45

[000270] The apparatus of claim 44, wherein the at least one user feedback element includes at least one of an illuminating element configured to illuminate in a manner indicative of the state of the apparatus, or a speaker configured to provide an audible tone in a manner indicative of the state of the apparatus.

[000271] Example 46

[000272] The apparatus of any of claims 41 through 45, wherein the cartridge is removably coupled to the control module.

[000273] Example 47

[000274] The apparatus of any of claims 41 through 46, wherein the first and second drive assemblies include first and second linear actuators configured to be driven by the first and second electric motors, respectively.

[000275] Example 48

[000276] The apparatus of any of claims 41 through 47, wherein the first and second drive assemblies are configured to advance the first and second pistons, respectively, independently of each other.

[000277] Example 49

[000278] The apparatus of any of claims 41 through 48, wherein at least one of the cartridge or the control module includes first and second sensors configured to generate signals indicative of fluid pressure within the first and second fluid sources, respectively.

[000279] Example 50

[000280] The apparatus of claim 49, wherein the first and second sensors each include at least one of a strain gauge or a pressure transducer.

[000281] Example 51

[000282] The apparatus of any of claims 41 through 50, further comprising the bleb fluid disposed within the first fluid source.

[000283] Example 52

[000284] The apparatus of any of claims 41 through 51, further comprising the therapeutic agent disposed within the second fluid source.

[000285] Example 53

[000286] The apparatus of any of claims 41 through 52, wherein at least one of the first or second fluid sources includes a syringe.

[000287] Example 54

[000288] The apparatus of any of claims 41 through 53, wherein the first and second fluid sources, the cartridge, and the control module collectively have a total physical volume that is less than about 150 mL.

[000289] Example 55

[000290] A system, comprising: (a) the apparatus of any of claims 41 through 54; and (b) the

first and second fluid conduits, wherein the first and second fluid conduits are coupled to the first and second distal ends of the first and second fluid sources via the first and second fluid source connectors, respectively.

[000291] Example 56

[000292] The system of claim 55, further comprising an instrument, the instrument including: (i) an instrument body; (ii) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; and (iii) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position, wherein the needle is fluidly coupled with the first and second fluid conduits.

[000293] Example 57

[000294] The system of claim 56, wherein the instrument further includes a sensor positioned on or within the instrument body, wherein the sensor is operable to detect a position of the needle relative to the cannula.

[000295] Example 58

[000296] The system of claim 57, wherein one of the first or second drive assemblies is configured to advance the respective first or second piston in response to the sensor detecting translation of the needle relative to the cannula.

[000297] Example 59

[000298] The system of any of claims 56 through 58, wherein the instrument further includes at least one user input element positioned on or within the instrument body, wherein at least one of the first or second drive assemblies is configured to advance the respective first or second piston in response to actuation of the at least one user input element.

[000299] Example 60

[000300] The system of claim 59, wherein the at least one user input element of the instrument includes a first user input element, wherein the first drive assembly is configured to advance the first piston in response to actuation of the first user input element.

[000301] Example 61

[000302] The system of claim 60, wherein the at least one user input element of the instrument includes a second user input element, wherein the second drive assembly is configured to advance the second piston in response to actuation of the second user input element.

[000303] Example 62

[000304] The system of any of claims 59 through 61, wherein the at least one user input element of the instrument includes at least one tactile switch.

[000305] Example 63

[000306] The system of any of claims 56 through 62, wherein the apparatus is configured to supply electrical power to the instrument.

[000307] Example 64

[000308] The system of any of claims 55 through 63, further comprising a wrist rest, wherein the apparatus is mounted to the wrist rest.

[000309] Example 65

[000310] An apparatus, comprising: (a) a first fluid source including: (i) a first proximal end, (ii) a first distal end configured to dispense a bleb fluid, and (iii) a first piston disposed between the first proximal and distal ends, wherein the first piston is configured to be advanced distally along a first longitudinal axis for dispensing the bleb fluid from the first distal end; (b) a second fluid source including: (i) a second proximal end, (ii) a second distal end configured to dispense a therapeutic agent, and (iii) a second piston disposed between the second proximal and distal ends, wherein the second piston is configured to

be advanced distally along a second longitudinal axis for dispensing the therapeutic agent from the second distal end; (c) a cartridge including: (i) a first fluid source connector including: (A) a first proximal luer fitting configured to couple with the first distal end of the first fluid source, and (B) a first distal luer fitting configured to couple with a first fluid conduit, and (ii) a second fluid source connector including: (A) a second proximal luer fitting configured to couple with the second distal end of the second fluid source, and (B) a second distal luer fitting configured to couple with a second fluid conduit, the first and second proximal luer fittings being configured to orient the first and second fluid sources such that the first and second longitudinal axes are substantially parallel to each other; and (d) a control module including: (i) a first drive assembly, wherein the first drive assembly is configured to advance the first piston distally along the first longitudinal axis and thereby dispense the bleb fluid from the first distal end, and (ii) a second drive assembly, wherein the second drive assembly is configured to advance the second piston distally along the second longitudinal axis and thereby dispense the therapeutic agent from the second distal end.

[000311] Example 66

[000312] An apparatus, comprising: (a) a first fluid source containing a bleb fluid; (b) a second fluid source containing a therapeutic agent; (c) a cartridge configured to couple the first and second fluid sources to first and second fluid conduits, respectively; and (d) a control module including: (i) a first drive assembly including: (A) a first linear actuator including a first leadscrew, and (B) a first electric motor configured to drive the first linear actuator to translate the first leadscrew distally along a first longitudinal axis and thereby dispense the bleb fluid from the first fluid source, and (ii) a second drive assembly including: (A) a second linear actuator including a second leadscrew, and (B) a second electric motor configured to drive the second linear actuator to translate the second leadscrew distally along a second longitudinal axis and thereby dispense the bleb fluid from the second fluid source, the second longitudinal axis being substantially parallel to the first longitudinal axis.

[000313] Example 67

[000314] A method, comprising: (a) coupling first and second syringes to a cartridge, the first and second syringes being filled with a bleb fluid and a therapeutic agent, respectively; (b) sliding at least one guide member of the cartridge along at least one corresponding guide member of the control module; and (c) engaging at least one coupling member of the cartridge with at least one corresponding coupling member of the control module to thereby attach the cartridge to the control module, wherein the first and second syringes are aligned with first and second drive assemblies of the control module, respectively, when the cartridge is attached to the control module.

[000315] Example 68

[000316] The method of Example 67, wherein coupling the first and second syringes to the cartridge includes threading distal ends of the first and second syringes onto corresponding luer fittings of the cartridge.

[000317] Example 69

[000318] The method of any of Examples 67 through 68, wherein coupling the first and second syringes to the cartridge includes orienting the first and second syringes to be substantially parallel to each other.

[000319] Example 70

[000320] The method of any of Examples 67 through 69, further comprising filling at least one of the first or second syringes with the bleb fluid or therapeutic agent, respectively, prior to coupling the at least one of the first or second syringes to the cartridge.

[000321] Example 71

[000322] The method of Example 70, wherein filling the at least one of the first or second syringes includes withdrawing a corresponding plunger stem proximally to extract the bleb fluid or therapeutic agent from a vial into the at least one of the first or second syringes.

[000323] Example 72

[000324] The method of Example 71, further comprising uncoupling the corresponding plunger stem from a corresponding stopper housed within the at least one of the first or

second syringes after filling the at least one of the first or second syringes and prior to coupling the at least one of the first or second syringes to the cartridge.

[000325] Example 73

[000326] The method of any of Examples 70 through 72, wherein filling the at least one of the first or second syringes includes extracting the bleb fluid or therapeutic agent into the at least one of the first or second syringes via a corresponding needle.

[000327] Example 74

[000328] The method of Example 73, further comprising uncoupling the corresponding needle from a distal end of the at least one of the first or second syringes after filling the at least one of the first or second syringes and prior to coupling the at least one of the first or second syringes to the cartridge.

[000329] Example 75

[000330] The method of any of Examples 67 through 74, further comprising operatively coupling the control module to an instrument, the instrument including: (i) an instrument body; (ii) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; and (iii) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position.

[000331] Example 76

[000332] The method of Example 75, wherein operatively coupling the control module to the instrument includes placing a circuit board assembly of the fluid control module in operative communication with a circuit board assembly of the instrument.

[000333] Example 77

[000334] The method any of Examples 75 through 76, wherein operatively coupling the control module to the instrument includes fluidly coupling the needle with the first and second syringes.

[000335] Example 78

[000336] The method of any of Examples 67 through 77, wherein the at least one guide member of the cartridge or the at least one corresponding guide member of the control module includes at least one of a track or a groove.

[000337] Example 79

[000338] The method of any of Examples 67 through 78, wherein the at least one coupling member of the cartridge or the at least one corresponding coupling member of the control module includes a spring-loaded latch.

[000339] Example 80

[000340] The method of any of Examples 67 through 79, further comprising disengaging the at least one coupling member of the cartridge from the at least one corresponding coupling member of the control module to thereby detach the cartridge from the control module.

[000341] VI. Miscellaneous

[000342] It should be understood that any of the versions of the instruments described herein may include various other features in addition to or in lieu of those described above. By way of example only, any of the devices herein may also include one or more of the various features disclosed in any of the various references that are incorporated by reference herein.

[000343] It should be understood that any one or more of the teachings, expressions, embodiments, examples, etc. described herein may be combined with any one or more of the other teachings, expressions, embodiments, examples, etc. that are described herein. The above-described teachings, expressions, embodiments, examples, etc. should therefore not be viewed in isolation relative to each other. Various suitable ways in which the teachings herein may be combined will be readily apparent to those skilled in the art in view of the teachings herein. Such modifications and variations are intended to be included

within the scope of the claims.

[000344] It should be appreciated that any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

[000345] Versions described above may be designed to be disposed of after a single use, or they can be designed to be used multiple times. Versions may, in either or both cases, be reconditioned for reuse after at least one use. Reconditioning may include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, some versions of the device may be disassembled, and any number of the particular pieces or parts of the device may be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, some versions of the device may be reassembled for subsequent use either at a reconditioning facility, or by an operator immediately prior to a procedure. Those skilled in the art will appreciate that reconditioning of a device may utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

[000346] By way of example only, versions described herein may be sterilized before and/or after a procedure. In one sterilization technique, the device is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and device may then be placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation may kill bacteria on the device and in the container. The sterilized device may then be stored in the sterile container for later use. A device may

also be sterilized using any other technique known in the art, including but not limited to beta or gamma radiation, ethylene oxide, or steam.

[000347] Having shown and described various embodiments of the present invention, further adaptations of the methods and systems described herein may be accomplished by appropriate modifications by one of ordinary skill in the art without departing from the scope of the present invention. Several of such potential modifications have been mentioned, and others will be apparent to those skilled in the art. For instance, the examples, embodiments, geometrics, materials, dimensions, ratios, steps, and the like discussed above are illustrative and are not required. Accordingly, the scope of the present invention should be considered in terms of the following claims and is understood not to be limited to the details of structure and operation shown and described in the specification and drawings.

I/We claim:

1. An apparatus, comprising:
   (a) an instrument body;
   (b) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye;
   (c) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position;
   (d) a rotary knob configured to rotate relative to the instrument body about a rotational axis and thereby drive translation of the needle between the proximal position and the distal position; and
   (e) at least one deflectable member fixed against rotation relative to one of the instrument body or the rotary knob, wherein the at least one deflectable member is configured to frictionally engage the other of the instrument body or the rotary knob to prevent rotation of the rotary knob about the rotational axis absent application of a predetermined threshold rotational force to the rotary knob.

2. The apparatus of claim 1, wherein the at least one deflectable member is fixed against rotation relative to the rotary knob, wherein the at least one deflectable member is configured to frictionally engage the instrument body to prevent rotation of the rotary knob about the rotational axis absent application of the predetermined threshold rotational force to the rotary knob.

3. The apparatus of claim 2, wherein the at least one deflectable member is configured to deflect radially inwardly relative to the rotational axis from an undeflected state to a deflected state, wherein the at least one deflectable member is resiliently biased toward the undeflected state.

4. The apparatus of any of claims 2 through 3, wherein the instrument body is configured to urge the at least one deflectable member toward the deflected state.

5. The apparatus of any of claims 2 through 4, wherein the instrument includes a ledge, wherein the ledge is configured to urge the at least one deflectable member toward the deflected state.

6. The apparatus of any of claims 1 through 5, wherein the at least one deflectable member includes a plurality of deflectable members.

7. The apparatus of claim 6, wherein the plurality of deflectable members are circumferentially spaced apart from each other at equal intervals.

8. The apparatus of any of claims 6 through 7, wherein the plurality of deflectable members include three deflectable members.

9. The apparatus of any of claims 1 through 8, wherein the at least one deflectable member includes at least one deflectable beam.

10. The apparatus of claim 9, wherein the at least one deflectable beam is defined by at least one pair of recesses.

11. The apparatus of any of claims 9 through 10, wherein the at least one deflectable beam includes at least one detent extending radially outwardly from a radially outer surface of the at least one deflectable beam, wherein the at least one detent is configured to frictionally engage the instrument body.

12. The apparatus of any of claims 1 through 11, further comprising a torque ring, wherein the torque ring includes the at least one deflectable member.

13. The apparatus of claim 12, wherein the rotary knob includes a first interlocking member, wherein the torque ring includes a second interlocking member configured to interlock with the first interlocking member to fix the torque ring against rotation relative to the rotary knob.

14. The apparatus of claim 13, wherein one of the first or second interlocking members includes a post, wherein the other of the first or second interlocking members includes a recess configured to receive the post and thereby interlock with the post.

15. The apparatus of any of claims 12 through 14, wherein the rotary knob defines an interior, wherein the torque ring is at least partially disposed within the interior of the rotary knob.

16. An apparatus, comprising:

(a) an instrument body;

(b) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye;

(c) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position;

(d) a rotary knob configured to drive translation of the needle between the proximal position and the distal position; and

(e) a torque ring configured to resist rotation of the rotary knob.

17. The apparatus of claim 16, wherein the torque ring is fixed against rotation relative to one of the instrument body or the rotary knob.

18. The apparatus of claim 17, wherein the torque ring is integrally formed together with the one of the instrument body or the rotary knob as a unitary piece.

19. The apparatus of any of claims 17 through 18, wherein the torque ring is fixed against rotation relative to the rotary knob.

20. The apparatus of any of claims 16 through 19, wherein the torque ring includes at least one deflectable member configured to provide friction between the rotary knob and the instrument body.

21. An apparatus, comprising:

(a) an instrument body;

(b) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye;

(c) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position;

(d) a knob configured to rotate relative to the instrument body and thereby drive translation of the needle between the proximal position and the distal position;

(e) at least one deflectable member configured to frictionally engage one of the instrument body or the knob to prevent rotation of the knob absent application of a predetermined threshold rotational force to the knob; and

(f) a fluid control unit configured to provide at least one fluid to the needle.

22. The apparatus of claim 21, further comprising a sensor positioned on or within the instrument body, wherein the sensor is in operative communication with the fluid control unit, wherein the sensor is operable to detect a position of the needle relative to the cannula.

23. The apparatus of claim 22, wherein the fluid control unit is configured to provide the at least one fluid to the needle in response to a signal received from the sensor.

24. The apparatus of any of claims 21 through 23, further comprising at least one user input element positioned on or within the instrument body, wherein the at least one user input element is in operative communication with the fluid control unit, wherein the fluid control unit is configured to provide the at least one fluid to the needle in response to at least one signal received from the at least one user input element.

25. The apparatus of claim 24, wherein the at least one user input element includes a first user input element, wherein the fluid control unit is configured to provide a first fluid to the needle in response to a first signal received from the first user input element.

26. The apparatus of claim 25, wherein the at least one user input element includes a second user input element, wherein the fluid control unit is configured to provide a second fluid different from the first fluid to the needle in response to a second signal received from the second user input element.

27. The apparatus of any of claims 24 through 26, wherein the at least one user input element includes at least one tactile switch.

28. The apparatus of any of claims 21 through 27, further comprising at least one user feedback element positioned on or within the instrument body, wherein the at least one user feedback element is in operative communication with the fluid control unit, wherein the at least one user feedback element is configured to provide at least one form of user feedback in response to at least one signal received from the fluid control unit.

29. The apparatus of claim 28, wherein the at least one user feedback element includes at least one illuminating element configured to illuminate in response to the at least one signal received from the fluid control unit.

30. The apparatus of any of claims 28 through 29, wherein the at least one user feedback element includes a speaker configured to provide an audible tone in response to the at least one signal received from the fluid control unit.

31. A method, comprising:

(a) inserting a flexible cannula having a needle retracted therein into a space between a sclera and a choroid of an eye;

(b) applying a predetermined threshold rotational force to a rotary knob associated with the needle that is sufficient to overcome a rotational resistance imposed upon the rotary knob by a deflectable member, to rotate the rotary knob and thereby advance the needle relative to the cannula while the cannula remains positioned between the sclera and the choroid, such that the needle pierces the choroid to access a subretinal space of the eye; and

(c) delivering a therapeutic agent to the subretinal space via the advanced needle.

32. The method of claim 31, wherein the deflectable member is fixed against rotation relative to the rotary knob.

33. The method of any of claims 31 through 32, further comprising tracking advancement of the needle via a sensor.

34. The method of claim 33, further comprising automatically dispensing a leading bleb fluid through the needle while advancing the needle in response to at least one signal generated by the sensor.

35. The method of any of claims 31 through 34, further comprising actuating at least one user input element in operative communication with a fluid control unit.

36. The method of claim 35, wherein delivering the therapeutic agent is automatically performed in response to at least one signal generated by the at least one user input element.

37. The method of any of claims 35 through 36, further comprising dispensing a leading bleb fluid through the needle in response to at least one signal generated by the at least one user input element.

38. The method of any of claims 35 through 37, further comprising providing at least one form of user feedback in response to at least one signal generated by the fluid control unit.

39. The method of claim 38, wherein providing at least one form of user feedback includes illuminating an illuminating element.

40. The method of any of claims 38 through 39, wherein providing at least one form of user feedback includes providing an audible tone.

41. An apparatus, comprising:

(a) a first fluid source including:

(i) a first proximal end,

(ii) a first distal end configured to dispense a bleb fluid, and

(iii) a first piston disposed between the first proximal and distal ends;

(b) a second fluid source including:

(i) a second proximal end,

(ii) a second distal end configured to dispense a therapeutic agent, and

(iii) a second piston disposed between the second proximal and distal ends;

(c) a cartridge including:

(i) a first fluid source connector configured to couple the first distal end

of the first fluid source to a first fluid conduit, and

(ii) a second fluid source connector configured to couple the second distal end of the second fluid source to a second fluid conduit, and

(d) a control module including:

(i) a first drive assembly including a first electric motor, wherein the first drive assembly is configured to advance the first piston distally along a first longitudinal axis and thereby dispense the bleb fluid from the first distal end, and

(ii) a second drive assembly including a second electric motor, wherein the second drive assembly is configured to advance the second piston distally along a second longitudinal axis and thereby dispense the therapeutic agent from the second distal end, the second longitudinal axis being substantially parallel to the first longitudinal axis.

42. The apparatus of claim 41, wherein the control module further includes at least one user input element, wherein at least one of the first or second drive assemblies is configured to advance the respective first or second piston in response to actuation of the at least one user input element.

43. The apparatus of claim 42, wherein the at least one user input element of the control module includes at least one tactile switch.

44. The apparatus of any of claims 41 through 43, wherein the control module further includes at least one user feedback element, wherein the at least one user feedback element is configured to provide at least one form of user feedback indicative of a state of the apparatus.

45. The apparatus of claim 44, wherein the at least one user feedback element includes at least one of an illuminating element configured to illuminate in a manner indicative of the state of the apparatus, or a speaker configured to provide an audible tone in a manner indicative of the state of the apparatus.

46. The apparatus of any of claims 41 through 45, wherein the cartridge is removably coupled to the control module.

47. The apparatus of any of claims 41 through 46, wherein the first and second drive assemblies include first and second linear actuators configured to be driven by the first and second electric motors, respectively.

48. The apparatus of any of claims 41 through 47, wherein the first and second drive assemblies are configured to advance the first and second pistons, respectively, independently of each other.

49. The apparatus of any of claims 41 through 48, wherein at least one of the cartridge or the control module includes first and second sensors configured to generate signals indicative of fluid pressure within the first and second fluid sources, respectively.

50. The apparatus of claim 49, wherein the first and second sensors each include at least one of a strain gauge or a pressure transducer.

51. The apparatus of any of claims 41 through 50, further comprising the bleb fluid disposed within the first fluid source.

52. The apparatus of any of claims 41 through 51, further comprising the therapeutic agent disposed within the second fluid source.

53. The apparatus of any of claims 41 through 52, wherein at least one of the first or second fluid sources includes a syringe.

54. The apparatus of any of claims 41 through 53, wherein the first and second fluid sources, the cartridge, and the control module collectively have a total physical volume that is less than about 150 mL.

55. A system, comprising:

(a) the apparatus of any of claims 41 through 54; and

(b) the first and second fluid conduits, wherein the first and second fluid conduits are coupled to the first and second distal ends of the first and second fluid sources via the first and second fluid source connectors, respectively.

56. The system of claim 55, further comprising an instrument, the instrument including:

(i) an instrument body;

(ii) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; and

(iii) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position, wherein the needle is fluidly coupled with the first and second fluid conduits.

57. The system of claim 56, wherein the instrument further includes a sensor positioned on or within the instrument body, wherein the sensor is operable to detect a position of the needle relative to the cannula.

58. The system of claim 57, wherein one of the first or second drive assemblies is configured to advance the respective first or second piston in response to the sensor detecting translation of the needle relative to the cannula.

59. The system of any of claims 56 through 58, wherein the instrument further includes at least one user input element positioned on or within the instrument body, wherein at least one of the first or second drive assemblies is configured to advance the respective first or second piston in response to actuation of the at least one user input element.

60. The system of claim 59, wherein the at least one user input element of the instrument includes a first user input element, wherein the first drive assembly is configured to advance the first piston in response to actuation of the first user input element.

61. The system of claim 60, wherein the at least one user input element of the instrument includes a second user input element, wherein the second drive assembly is configured to advance the second piston in response to actuation of the second user input element.

62. The system of any of claims 59 through 61, wherein the at least one user input element of the instrument includes at least one tactile switch.

63. The system of any of claims 56 through 62, wherein the apparatus is configured to supply electrical power to the instrument.

64. The system of any of claims 55 through 63, further comprising a wrist rest, wherein the apparatus is mounted to the wrist rest.

65. An apparatus, comprising:

(a) a first fluid source including:

(i) a first proximal end,

(ii) a first distal end configured to dispense a bleb fluid, and

(iii) a first piston disposed between the first proximal and distal ends, wherein the first piston is configured to be advanced distally along a first longitudinal axis for dispensing the bleb fluid from the first distal end;

(b) a second fluid source including:

(i) a second proximal end,

(ii) a second distal end configured to dispense a therapeutic agent, and

(iii) a second piston disposed between the second proximal and distal ends, wherein the second piston is configured to be advanced distally along a second longitudinal axis for dispensing the therapeutic agent from the second distal end;

(c) a cartridge including:

(i) a first fluid source connector including:

(A) a first proximal luer fitting configured to couple with the first distal end of the first fluid source, and

(B) a first distal luer fitting configured to couple with a first fluid conduit, and

(ii) a second fluid source connector including:

(A) a second proximal luer fitting configured to couple with the second distal end of the second fluid source, and

(B) a second distal luer fitting configured to couple with a second fluid conduit,

the first and second proximal luer fittings being configured to orient the first and second fluid sources such that the first and second longitudinal axes are substantially parallel to each other; and

(d) a control module including:

(i) a first drive assembly, wherein the first drive assembly is configured to advance the first piston distally along the first longitudinal axis and thereby dispense the bleb fluid from the first distal end, and

(ii) a second drive assembly, wherein the second drive assembly is configured to advance the second piston distally along the second longitudinal axis and thereby dispense the therapeutic agent from the second distal end.

66. An apparatus, comprising:

(a) a first fluid source containing a bleb fluid;

(b) a second fluid source containing a therapeutic agent;

(c) a cartridge configured to couple the first and second fluid sources to first and second fluid conduits, respectively; and

(d) a control module including:

(i) a first drive assembly including:

(A) a first linear actuator including a first leadscrew, and

(B) a first electric motor configured to drive the first linear actuator to translate the first leadscrew distally along a first longitudinal axis and thereby dispense the bleb fluid from the first fluid source, and

(ii) a second drive assembly including:

(A) a second linear actuator including a second leadscrew, and

(B) a second electric motor configured to drive the second linear actuator to translate the second leadscrew distally along a second longitudinal axis and thereby dispense the bleb fluid from the second fluid source, the second longitudinal axis being substantially parallel to the first longitudinal axis.

67. A method, comprising:

(a) coupling first and second syringes to a cartridge, the first and second syringes being filled with a bleb fluid and a therapeutic agent, respectively;

(b) sliding at least one guide member of the cartridge along at least one corresponding guide member of the control module; and

(c) engaging at least one coupling member of the cartridge with at least one corresponding coupling member of the control module to thereby attach the cartridge to the control module,

wherein the first and second syringes are aligned with first and second drive assemblies of the control module, respectively, when the cartridge is attached to the control module.

68. The method of claim 67, wherein coupling the first and second syringes to the cartridge includes threading distal ends of the first and second syringes onto corresponding luer fittings of the cartridge.

69. The method of any of claims 67 through 68, wherein coupling the first and second syringes to the cartridge includes orienting the first and second syringes to be substantially parallel to each other.

70. The method of any of claims 67 through 69, further comprising filling at least one of the first or second syringes with the bleb fluid or therapeutic agent, respectively, prior to coupling the at least one of the first or second syringes to the cartridge.

71. The method of claim 70, wherein filling the at least one of the first or second syringes includes withdrawing a corresponding plunger stem proximally to extract the bleb fluid or therapeutic agent from a vial into the at least one of the first or second syringes.

72. The method of claim 71, further comprising uncoupling the corresponding plunger stem from a corresponding stopper housed within the at least one of the first or second syringes after filling the at least one of the first or second syringes and prior to coupling the at least one of the first or second syringes to the cartridge.

73. The method of any of claims 70 through 72, wherein filling the at least one of the first or second syringes includes extracting the bleb fluid or therapeutic agent into the at least one of the first or second syringes via a corresponding needle.

74. The method of claim 73, further comprising uncoupling the corresponding needle from a distal end of the at least one of the first or second syringes after filling the at least one of the first or second syringes and prior to coupling the at least one of the first or second syringes to the cartridge.

75. The method of any of claims 67 through 74, further comprising operatively coupling the control module to an instrument, the instrument including:

(i) an instrument body;

(ii) a cannula extending distally from the instrument body, wherein the cannula is flexible, wherein the cannula is sized and configured to advance between a sclera and a choroid of a patient's eye; and

(iii) a needle slidably disposed in the cannula, wherein the needle includes a sharp distal tip, wherein the needle is configured to translate relative to the cannula between a proximal position and a distal position, wherein the distal tip is configured to be positioned inside the cannula when the needle is in the proximal position, wherein the distal tip is configured to be positioned outside the cannula when the needle is in the distal position.

76. The method of claim 75, wherein operatively coupling the control module to the instrument includes placing a circuit board assembly of the fluid control module in operative communication with a circuit board assembly of the instrument.

77. The method any of claims 75 through 76, wherein operatively coupling the control module to the instrument includes fluidly coupling the needle with the first and second syringes.

78. The method of any of claims 67 through 77, wherein the at least one guide member of the cartridge or the at least one corresponding guide member of the control module includes at least one of a track or a groove.

79. The method of any of claims 67 through 78, wherein the at least one coupling member of the cartridge or the at least one corresponding coupling member of the control module includes a spring-loaded latch.

80. The method of any of claims 67 through 79, further comprising disengaging the at least one coupling member of the cartridge from the at least one corresponding coupling member of the control module to thereby detach the cartridge from the control module.