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(54) Title: INTRAOCULAR LENS PERIPHERAL SURGICAL SYSTEMS

(57) Abstract: Peripheral surgical systems are used for insertion and filling of fluid- filled intraocular lenses, reaccessing and modifying fluid-filled intraocular lenses, and explantation of lenses. Although one peripheral surgical unit may perform all of these functions, in some embodiments different units perform different functions — i.e., each function may be performed by a separate unit, or the functions may be distributed over a smaller number of functional units.

INTRAOCULAR LENS PERIPHERAL SURGICAL SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to, and the benefits of, U.S. Serial Nos. 61/828,018 (filed on May 28, 2013), 61/829,607 (filed on May 31, 2013), 61/862,806 (filed on August 6, 2013), and 61/930,690 (filed on January 23, 2014). The entire disclosures of these priority documents are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] In various embodiments, the present invention relates generally to implantable intraocular lenses and, more specifically, to peripheral surgical systems relating to fluid-filled intraocular lenses.

BACKGROUND

[0003] The crystalline lens of a human's eye refracts and focuses light onto the retina. Normally the lens is clear, but it can become opaque (i.e., when developing a cataract) due to aging, trauma, inflammation, metabolic or nutritional disorders, or radiation. While some lens opacities are small and require no treatment, others may be large enough to block significant fractions of light and obstruct vision.

[0004] Conventionally, cataract treatment involves surgically removing the opaque lens matrix from the lens capsule using, for example, phacoemulsification and/or a femtosecond laser through a small incision in the periphery of the patient's cornea. An artificial intraocular lens (IOL) can then be implanted in a lens capsule bag (the so-called "in-the-bag implantation") to replace the crystalline lens. Generally, IOLs are made of a foldable material, such as silicone or acrylics, for minimizing the incision size and required stitches and, as a result, the patient's recovery time. The most commonly used IOLs are single-element lenses (or monofocal IOLs) that provide a single focal distance; the selected focal length typically affords fairly good distance vision. However, because the focal distance is not adjustable following implantation of the IOL, patients implanted with monofocal IOLs can no longer focus on

objects at a close distance (e.g., less than 25 cm); this results in poor visual acuity at close distances.

[0005] The insertion system for traditional IOLs typically involves an insertion device body and a small-diameter insertion tube through which the IOL travels. The insertion tube is placed into the surgical incision in the eye and the IOL is pushed from the insertion device body through the tube and inserted into the eye. Normally a viscoelastic, such as a hyaluronic acid or equivalent, is used to lubricate the lens as it passes through the insertion tube. After insertion, the IOL unfolds and is positioned into the correct anatomical location, most often the lens capsule.

[0006] Recently, liquid-filled intraocular lenses have been developed; these may be inserted into the eye and then filled. Advantages of this design include the ability to deploy through a small incision, following which the lens is inflated in situ. A small insertion diameter reduces post-operative healing times, allows the surgeon to avoid sutures for closing the incision, and reduces post-operative astigmatism. Therefore, incisions less than 3 mm, and preferably less than 2 mm, are desired by operating personnel for better surgical outcomes. In addition, certain liquid-filled intraocular lens designs can be adjustable after implantation to ensure accurate vision by refractive corrections through adjustment of the filling medium inside the lens. When made flexible, the fluid-filled lenses can provide adjustable focal distances (or accommodation), relying on the natural focusing ability of the eye (e.g., using contractions of ciliary muscles).

Unlike traditional intraocular lenses, which are not filled after insertion, liquid lenses designed to be deployed in a semi-deflated or completely deflated state (both cases referred to herein as a "deflated state") are both deployed into the eye and then inflated after deployment. Specialized insertion and filling systems are, therefore, generally required to implant these lenses. Additionally, these lenses can have the fluid contents adjusted after implantation. Therefore, there is a need for tools to access the fluidic contents of the fluid-filled IOL and to adjust the contents of the IOL before, during, and after implantation.

SUMMARY

[0007] Peripheral surgical systems in accordance herewith are used for insertion and filling of fluid-filled intraocular lenses, reaccessing and modifying the lenses, and explantation of the

lenses. Although one peripheral surgical unit may perform all of these functions, in some embodiments different units perform different functions — i.e., each function may be performed by a separate unit, or the functions may be distributed over a smaller number of functional units. The invention may also be used as a peripheral surgical system for other fluid-filled implantable devices such as a scleral buckle or breast implant.

[0008] In one aspect, the present invention relates to an intraocular lens insertion and filling system. Various embodiments contain a fluidic line in fluidic continuity with a deflated intraocular lens and an insertion system for deploying the intraocular lens into the eye. The fluidic system is used to fill the lens with a fluid after deployment of the lens into the eye. As used herein, the term "fluid" generally refers to a liquid, but in some instances may refer to or encompass a gas and/or a solute. For example, gases would not be suitable for implants as barometic changes would cause unwanted changes in accommodation.

[0009] The fluidics system may comprise an infusion pump, although an aspiration pump may be used alternatively or in addition. The infusion pump is responsible for dispensing fluid into a fluid-filled intraocular lens. In one embodiment, the infusion pump consists of or comprises a syringe pump capable of dispensing accurate volumes of fluid. This is especially suited for viscous fluids, such as silicone oils, where high pressures may be required in order to dispense at an adequate rate. Furthermore, a syringe pump reduces pressure surging that may occur with other pump technologies.

[0010] When present, the aspiration pump is responsible for removing media from the IOL. Suitable aspiration pumps include but are not limited to gear pumps, peristaltic pumps, venturi pumps, and syringe pumps. Certain pumps may be placed directly in line with the aspiration line without contaminating it. For example, a peristaltic pump can have the tubing from the aspiration side of the pump attached to it. Other pumps attach to a cassette, which is in fluidic contact with the aspiration line. Examples of this include pumps that operate with air, e.g., venturi pumps that are attached to a vacuum reservoir. The pump is used to evacuate air from the reservoir, which then drives fluid into the reservoir. However, fluid never contacts the pump in this implementation.

[0011] In certain embodiments, the infusion pump and aspiration pump have distinct fluidic lines connected to the handpiece. In one embodiment, two distinct lines carry infusion and

aspiration, respectively. In this configuration, the handpiece tip utilizes two cannulas, configured either side-by-side or concentrically. One cannula is used for injection of fluid into the IOL, while the other aspirates. Infusion and aspiration can occur simultaneously. This approach is advantageous for, e.g., fluid exchange of the IOL. One specific use of fluid exchange is removing fluid of one refractive index and replacing it with fluid of another refractive index. In certain embodiments, the refractive index of the lens filling fluid is monitored during lens fluid exchange and used to determine the amount of fluid to exchange. It is preferable to make the aspiration cannula larger than the infusion cannula because aspiration is limited to a maximum vacuum of one atmosphere, whereas infusion can occur at much larger pressure differentials.

[0012] In another embodiment, the aspiration line and the infusion line meet in a valve and are carried to the tip of the device through a single line. The tip typically has a single cannula. When infusion is active, it occurs through the tip of the device. When aspiration is active, the valve is in the opposite position, and fluid from the tip is aspirated. This provides the largest total area for both infusion and aspiration for a specific tip size. In a third position, the infusion and aspiration lines are in fluidic connection. This configuration is not limiting, of course, and other modes of switching between lines can be used — e.g., closing lines separately and remotely.

[0013] The aspiration line in this embodiment of the invention can be used to prime the line and remove air bubbles therefrom. The aspiration line and infusion line may meet in a valve or y-connection close to the distal end of the tip. With the aspiration and infusion line in fluidic connection, vacuum is applied to the aspiration line during fluid infusion. Infused fluid follows a path from the infusion side of the injector and then directly to the aspiration line, never moving to the most distal end of the tip. Therefore, no fluid travels out of the tip, keeping it clean from fluid residue while allowing all lines to be primed and purged of air. Maintaining a clean injector tip is desirable when accessing a valve of a liquid-filled IOL to prevent any liquid from contacting the external surface of the IOL. In addition, this is desirable when the lens is in fluidic contact with the tip. The lens can be put into fluidic contact with air in the lines, e.g., before attaching the fluidic system. Then the system is primed with the lens directly connected to the injection tip. For example, the lens may be mounted to the injection tip before the filling fluid is connected to the injector, following which the filling fluid is connected to the injector;

after connection of the filling fluid, the lines are primed by infusion fluid through the infusion line and aspiration through the aspiration line. Although vacuum is discussed as being used with the aspiration lines, this is not required. If the aspiration line has low fluidic resistance relative to other parts of the system, or if a valve closes the distal end of the tip, no vacuum is required to prime the line. In addition, the line may end in a reservoir in the handpiece to allow collection of the fluid. The reservoir may have a semipermeable membrane to allow fluid to fill the reservoir while air freely passes out of the reservoir.

[0014] In some embodiments, a selective filter, such as a degassing or debubbling filter, is used to remove air from the liquid and the lines. The selective filter acts to allow air, but not the fluid, to pass through. During priming of the lines and infusion of the fluid, the air and air bubbles are drawn from the lines through this selective filter. As an example, a semipermeable membrane tube may be used as a portion of the infusion line. Vacuum is applied externally to the semipermeable membrane tube. As air or the fluid passes through that portion of the filling tube, the external vacuum removes the air from the line. Alternatively or in addition, an air-capture device, such as an out-pocket in the infusion line, may be used to capture air bubbles as they pass through the infusion line, preventing air bubbles from entering the lens.

[0015] In various embodiments, a single pump is used for both aspiration and infusion through a single or multiple cannulas.

[0016] The tip of the handpiece may comprise one or more cannulas used to access the internal contents of the liquid-filled IOL. In one embodiment, the tip includes or consists of a blunt cannula, with a thin-walled, reduced-diameter polymer at the distal end. The polymer is selected to retain enough rigidity to access the lens, but a blunt end prevents damage to the lens walls. Suitable polymers include, but are not limited to, polyimide, TEFLON, PEEK, polyester, NYLON, polyethylene, and ABS.

[0017] In certain embodiments of the invention, the infusion and aspiration system is used to monitor the volume of fluid infused into or aspirated from the intraocular lens. Alternatively or in addition, the pressure inside the lens may be monitored. The refractive index of the filling fluid may also (or alternatively) be monitored, e.g., by an inline refractometer. Monitoring filling or aspiration, pressure inside the lens, or the refractive index of filling fluid can be used to determine the amount of lens fill, the amount of fluid to exchange, refractive properties of

exchange fluid, and optical properties of the lens. Therefore, this approach can be used to determine the appropriate refractive power of the implanted intraocular lens.

[0018] In certain embodiments, the IOL is loaded by inserting a sharp point into a valved portion of the lens or a polymeric membrane in the IOL. Then a cannula is inserted into the valved portion/polymeric membrane with the sharp point over the sharp point, similar to a trocar cannula insertion, or after the sharp point has been removed. If used in the manner of a trocar cannula insertion, the sharp point is removed after insertion of the cannula.

[0019] In a representative example of use, first the IOL is accessed via a sealing portion thereof with a sharp point, such as a sharpened nitinol wire protruding through the tip of the insertion and filling system. Next, the cannulated tip of the injection system is inserted through the sealing portion of the IOL. The nitinol wire is removed from the injector and the lens is tested for sealing using pressure, flow, optical, or visual monitoring of the lens. If the lens passes the sealing test, it is deflated and drawn into the insertion tube. The fluidics lines are attached to the lens. In certain embodiments, the lines are primed before attachment to the insertion system. In other embodiments, the lines are primed after attachment to the insertion system, while the lens is attached to the insertion and filling system.

[0020] In a representative system embodiment, an intraocular lens insertion and filling system according to the invention comprises a fluidic system in connection with the inside of an intraocular lens; the fluidic system is capable of filling or removing fluid from the intraocular lens after implantation into the eye. The intraocular lens is deployed from the insertion tip using a mechanical and/or fluidic force and is subsequently inflated by the insertion and filling system. The system may be configured to measure the pressure of the intraocular lens; the fluid flow and volume injected into or removed from the intraocular lens; and/or the refractive index of the fluid inside the intraocular lens. In some embodiments, a plunger is used to provide a seal around the lumen of the insertion system and insert the lens into the eye using a fluidic force created by the seal of the plunger.

[0021] In certain embodiments, a sheath wraps around the lens during loading and/or insertion of the lens. A mechanical gripping mechanism comprising two or more members may be used to draw the lens into and expel the lens from the insertion system. For example,

the gripping system may be used to re-access a sealing portion of the IOL after implantation of the intraocular lens.

[0022] In some embodiments, the insertion tube is translucent or clear for visualization of the loaded lens. The intraocular lens may be monitored for leakage by one or more of visual detection, optical detection, pressure monitoring, or flow monitoring.

[0023] In another aspect, the invention pertains to an intraocular lens-adjustment system for accessing an interior of an intraocular lens following implantation thereof. In various embodiments, the system comprises an access tip configured for mechanical interface with a valve of the lens via an exterior surface thereof, the access tip, when engaged with the valve, forming a fluidic seal therewith; one or more reservoirs used to store a fluid; and one or more fluidic lines for conducting the stored fluid between the reservoir and the access tip.

[0024] The system may further comprise a handpiece attached to the fluidics line and facilitating movement of the access tip relative to the intraocular lens valve. For example, the handpiece may comprise means for controlling a flow of fluid between the reservoir and the access tip. In some embodiments, the fluidics line has minimal wall compliance and is capable of carrying fluids at pressures over 10 PSI.

[0025] In various embodiments, the system further comprises a plurality of sensors and a controller connected thereto, the sensors measuring fluid flow in the one or more fluidic lines, a refractive state of the lens, and an internal pressure of the lens, the controller being responsive to the sensors and to a geometric shape of the lens. A portion of at least one fluidics line may have a diameter less than 4mm to allow reaccess to a previous main corneal incision without widening the incision. The access tip may have a diameter less than 3mm to allow self-sealing of a valve.

[0026] In a typical implementation, the system comprises at least one mechanical pump for driving fluid between the reservoir and the access tip. The system may include a metering device to monitor the fluid added or removed from the lens. In some embodiments, a flow sensor is located in proximity to the access tip to account for capacitive changes in the fluid or cavitation. A pressure sensor, if present, may be extendable past the access tip to directly monitor the pressure inside the lens. Alternatively or in addition, a pressure sensor may measure pressure outside the lens.

[0027] In various embodiments, the access tip comprises a locking feature for mechanically engaging the valve. For example, the locking feature may be a tether, a vacuum, a twist-lock, and/or a gripper.

[0028] In another aspect, the invention relates to an intraocular lens explantation system. In various embodiments, the system comprises an aspiration pump; a conduit fluidly coupled to the pump, the conduit having a distal end; an access member at the distal end of the conduit, the access member being configured to establish fluid communication between the pump and an interior of the lens, and including (i) an opening, (ii) a peripheral contact surface surrounding the opening, (iii) a passage fluidly coupling the opening to a lumen of the conduit, and a gripping member extending axially through the passage and beyond the opening, the gripping member including a mechanical feature for gripping an interior wall of the lens with the peripheral contact surface against an outer surface of the lens.

[0029] In some embodiments, the gripping member is retractable through the passage to pull the lens therein. The mechanical feature may be, for example, a barb or a pair of grippers in a forceps configuration.

[0030] Still another aspect of the invention relates to an intraocular lens explantation system. In various embodiments, the system comprises an aspiration pump; a conduit fluidly coupled to the pump, the conduit having a distal end; an access member at the distal end of the conduit, the access member establishing fluid communication between the pump and an interior of the lens and including an opening, a peripheral contact surface surrounding the opening, a passage fluidly coupling the opening to a lumen of the conduit, and a cutting member for cutting the lens to establish fluid communication between an interior of the lens and the pump.

[0031] In some embodiments, the the cutting member is disposed within the passage, suction created by the pump causing contact between the cutting member and the lens. The cutting member may be disposed telescopically within the passage and have a blade surrounding a central bore, the central bore being in fluid communication with the pump to apply suction to the lens. The cutting member may be configured for axial, rotary or reciprocating movement. In some embodiments, the cutting member is a laser.

[0032] Another representative system embodiment comprises a fluidic system in fluid communication with the inside of an intraocular lens and capable of filling the intraocular lens

after implantation into the eye. A second fluidic system is used to infuse fluid through the insertion tip and assist in deploying the intraocular lens into the eye, and the intraocular lens may be deployed from the insertion tip using a combination of mechanical and fluidic force. The lens is subsequently inflated by the insertion and filling system.

[0033] Yet another representative system embodiment includes a fluidic system in communication with the inside of an intraocular lens and capable of filling the intraocular lens after implantation into the eye. The system also includes one or more of an infusion system used to infuse fluid into the eye before, during, or after implantation of the intraocular lens; or an aspiration system used to infuse fluid into the eye before, during, or after implantation of the intraocular lens

[0034] Still another representative system embodiment comprises a fluidic system in communication with the inside of an intraocular lens and capable of filling the intraocular lens after implantation into the eye. The intraocular lens is deployed from the insertion tip and is subsequently inflated by the insertion and filling system. The system is configured to permit infusion and aspiration through a single or multiple lumens.

[0035] Yet another representative system embodiment comprises a fluidic system in communication with the inside of an intraocular lens and capable of filling the intraocular lens after implantation into the eye. The system is configured such that, after insertion of the intraocular lens and insertion tip, the insertion tip retracts from the intraocular lens and the intraocular lens is inflated.

[0036] Another representative intraocular lens insertion and filling system in accordance with the invention comprises a fluidic system in communication with the inside of an intraocular lens and capable of filling the intraocular lens after implantation into the eye. In this embodiment, the fluidic system comprises three separate fluidic lines: an infusion line, an aspiration or bleed off line, and a tip used to access the IOL. These three separate fluidic lines may connect by means of a y-connector or valve. During system priming, air and fluid pass from the infusion line to the aspiration or bleed-off line, and upon inflation of the IOL fluid passes from the infusion line to the aspiration line.

[0037] A representative method in accordance with the invention for preparing an IOL for implantation comprises inserting a fluidic line in the IOL, inflating the IOL using air or fluid,

and inspecting the IOL for leakage visually, optically, using pressure, and/or fluid flow. After the lens has been deemed not to leak, the IOL may be deflated and drawn into tube for insertion into the eye.

[0038] In another representative method, fluidic continuity is provided between the intraocular lens and a filling system, the intraocular lens is deployed into the eye using a mechanical and/or fluidic force, and the intraocular lens is inflated. For example, the intraocular lens and an insertion tip may be inserted into the eye, the insertion tip may be retracted around the intraocular lens, and the intraocular lens may be inflated.

[0039] In aspects, the invention is directed toward re-access to a fluid-filled intraocular lens through a valve or re-access port that may comprise or consist of a fluidic connection coupling the fluid-filled intraocular lens with either a valve or self-sealing medium in a tube. This re-access is performed to either inflate, deflate, or exchange fluid. When referring to inflating a fluid-filled intraocular lens, this could substantially refer to the process of injecting additional fluid into the lens which already contains a fluid, and injecting a soluble material or a non-soluble material or a pharmaceutical drug into the preexisting fluid. The primary purpose of injecting fluid that is identical in composition to that of fluid already existing in a fluid-filled intraocular lens is to change the volume of the lens. This then changes the curvatures of radius on either the anterior, posterior or both curvatures of the lens according to the design of the lens. This will then change the base power of the lens, thereby the index of refraction of the cornea. Base power change can similarly be accomplished by removing fluid from the fluid-filled intraocular lens.

[0040] In other embodiments, the anterior and posterior curvatures of the lens are not changed during filling but different properties of the lens are. One embodiment allows for changes of the intraocular lens size, allowing a better conformal fit between the intraocular lens and the surrounding lens capsule. In yet another embodiment in which the anterior and posterior curvatures are not changed, a fluid of different refractive index is injected, thereby altering the refractive index of the fluid-filled intraocular lens. A soluble example would be injecting a high concentration sugar water into a water based filled lens. Because refractive index is altered by the material compositions and may be altered by dopants (i.e. sugar concentration), a higher sugar concentration can be used to increase the refractive index of a filling fluid. Many other dopants sized below the scattering coefficient may be substituted.

Additional other factors including pressure of the liquid, temperature, and frequency of light further alter the refractive index.

[0041] In another embodiment, crosslinking agents are injected into an uncured or partially cured silicone filled lens. During the curing process of the silicone (i.e., baking, time, UV exposure), crosslinking occurs and the refractive properties of the silicone molecule change, thereby altering refractive index. In other embodiments, different crosslinking agents compatible with the curing methods of alternative materials besides silicone may be used. Specific examples include hydrogel, acrylic, phenyl-substituted silicone, or fluorosilicone. In other embodiments, the fluid injected into the lens is a chemically modified species to crosslink or chemically bond with the existing internal contents of the lens. As an example, phenyl-substituted silicones have a higher refractive index than non-phenyl-substituted silicones. The refractive index is proportional to the amount of phenyl-substituted entities in the silicone. Therefore, by taking a low level of phenyl-substituted silicone and adding monomers with phenyl-substitution into the internal contents of the lens, the refractive index can be increased. Likewise, by crosslinking in an unsubstituted, or low-level substituted silicone with an existing phenyl-substituted silicone, the refractive index can be decreased. Crosslinking may occur over a long period of time, longer than 6 hours, and in some embodiments longer than three months. In certain embodiments, crosslinking has been mostly completed by 90 days, thereby allowing the refractive properties of the lens to be adjusted up to 90 days by altering the inner composition until fully cured. In other embodiments, crosslinking is never complete, and a light crosslinking yields a gel that is capable of being modified throughout the life of the implant.

[0042] In other embodiments, insoluble liquid is injected to inflate the lens and increase the volume of the lens so it can either reshape the tissue around the lens or break existing bonds of tissue to the lens. This can be done by injecting air into the fluid-filled intraocular lens. The air can then diffuse out through the membrane of the lens. Other reasons for injecting a soluble or non-soluble into a fluid-filled intraocular lens is to reduce the amount of ultraviolet light that passes through the lens. A pharmaceutical drug can also be injected into the fluid-filled intraocular lens for extended drug delivery. In certain embodiments of the invention the pharmaceutical is injected into the lens periodically to ensure proper levels of intraocular drug are maintained in the eye. In certain embodiments of the invention there is a separate chamber

in the fluid-filled intraocular lens, into which the drug can be injected into and diffuse out into the eye over time, without altering the refractive index of the lens.

[0043] The tip of the re-access tool, which contains the component that accesses the fluid within the fluid-filled intraocular lens, depends on the valve or re-access port configuration which it is accessing. In one form the tip pierces the valve and then the valve self-seals after removal of the tip. This tip configuration would preferably have a sharp point to help pierce through the valve while having non-coring properties to minimize valve material removal. Another embodiment would be a semi-blunt or blunt tip that would be guided into a preexisting passage way. An example of a semi-blunt tip has a bevel like a sharp tip, however, instead of terminating at a sharp point, the tip of the bevel is manufactured to have a blunt end. This blunt end is designed to allow access to the valve while minimizing damage to the valve and surrounding intraocular lens, even when misguided by the user. This design mitigates the need to protect the remaining lens from a sharp tip to avoid damage or rupture to the intraocular lens. For example, the fluid-filled intraocular lens may be created in thinner embodiments, thereby altering the flexibility, refractive index, and accommodative properties, with minimal risk of rupture by instruments. Examples of the valve design include, but are not limited to a self-sealing hole, check valve, flap valve, or a tube with a valve or self-sealing medium.

[0044] Many of these re-access tool embodiments will benefit from a mechanism of alignment to align the tip with the access point. Alignment may be created in various ways. In one embodiment, there are one or more tubes. One tube pulls a vacuum to help grab the valve or tube. This configuration can be created by having concentric tubes, side-by-side tubes or some pre-designed shape that would be characteristic to the access point that the vacuum can hold on to in a certain orientation to line up the access tip to deliver or remove fluid. These redundant tubes may be multiple use, or single use in which case they may be sealed and removed after use.

[0045] The re-access tool in a broader sense may comprise or consist of an access tip, connected to a fluidic line or lines, which connects to a console that can have one or more fluid reservoirs for infusion into the lens, a vacuum mechanism for removing fluid from the intraocular lens or both. The filling process can be controlled by a foot pedal switch controlled by the surgeon to allow them to have both hands free to manipulate the tool and the fluid-filled intraocular lens. The switch can also be located on the tool itself and activated by the finger of

the surgeon. The amount of fluid injected or removed fluid will is monitored or metered in certain embodiments. This can be done with a flow sensor located on the fluidic line closer to the access tip. The closer to the distal end of the re-access tool, the more accurate the flow sensor. This is because the lines throughout the tool are subject to flexing, even minute amounts during infusion. This causes a capacitive ability of the lines. Therefore, flow from the infusion reservoir can be higher than flow out of the access tip during intraocular lens filling. Therefore, measurements at the proximal end of the line will overestimate the total flow into the intraocular lens as a certain amount of flow. During aspiration of intraocular lens contents, small bubbles in the airline can cavitate. This leads to fluid proximal to the console to be susceptible to erroneously higher aspiration levels than the actual fluid leaving the intraocular lens. For both situations, a flow sensor proximal to the lens is desired for high accuracy flow monitoring. Flow sensors, such as, but not limited to, those based upon thermal effects, time-of-flight, and/or pressure, may be used for monitoring/metering purposes.

[0046] The flow sensor can also accurately measure the amount of fluid coming in and out of the fluid-filled intraocular lens. In embodiments of injecting the fluid with a fluidic line that does not have compliance, a flow sensor may not be necessary as a syringe or some kind of accurate dispensing technique can be used to accurately inject fluid. Furthermore, the filling can be controlled by measuring the power of the lens within the patient while injecting or removing fluid. This measurement can then be used as real time feedback to a console that can then control the amount of fluid being injected or removed from the fluid-filled intraocular lens.

[0047] Other feedback mechanisms to control fluid infusion include monitoring the overall refractive power of the lens during lens adjustment, monitoring aberration of the lens and/or of the eye during lens adjustment, monitoring refractive index of the filling fluid, and monitoring pressure inside the lens.

[0048] In certain embodiments, fluid is altered to change the overall refractive state of the intraocular lens to achieve emmetropia. In other embodiments, lens aberrations, such as Zernicke coefficients, are monitored and adjusted to alter the overall refractive state of the lens as well as aberration of the intraocular lens. As a simple example, the aberration of the implanted lens is adjusted to reduce overall astigmatism of the eye, as in the case of an astigmatic cornea. In other embodiments, spherical aberration is adjusted and possibly

increased to increase depth of field of the implanted lens. In other embodiments, aberrations are reduced to increase overall visual acuity. This may occur through a single access valve in the intraocular lens, or multiple valves in the intraocular lens, these valves accessing separate portions or reservoirs of the intraocular lens. These separate portions of the intraocular lens are used to adjust the aberration of the lens as well as power of the lens. In the simplest form, one chamber is used for overall dioptric power of the lens, while a second chamber is used to adjust toricity of the intraocular lens to correct for astigmatism. The re-access tool may then be used to access one or both of the chambers. For example, it may be used to post-operatively adjust the toricity of an implanted intraocular lens for better astigmatic correction. This is important in the case of astigmatism induced by the surgical implantation process of the lens itself, which is difficult to predict. In another example, the re-access tip is used to increase spherical aberration to increase overall depth of field of an implanted intraocular lens. In yet another example, the re-access tool is used to adjust the lens based on unexpected corneal aberration post-operatively. The implanted IOL is adjusted to correct for aberration of the cornea to reduce overall aberration of the cornea-lens optical system of the eye.

[0049] Various aspects of the present invention relate to intraocular lens explantation, i.e., removal of liquid-filled IOLs from the eye. Explantation occurs by first removing the fluid from the liquid-filled IOL and then removing the lens in a deflated state. The advantage of this technique is that after removal of fluid, the deflated IOL has a small profile, allowing it to be removed through small incisions. More specifically, removal of the lens with incisions under 3 mm, and in some embodiments of the invention under 1 mm, is possible.

[0050] In one embodiment of the invention, a portion of the explantation tool retains the lens using suction. Once the lens is engaged to the explantation tool, a second portion of the tool is used to access the internal contents of the lens, e.g., through a special area of the lens such as a valve or through the wall of the lens. In one implementation a specialized hook is used to enter the lens and cause leakage to the outer member, where the internal liquid is aspirated out of the lens. In other implementations, no gripping tool is used; instead, a hollow cannulated tool is used to access the internal contents of the lens and aspirate the liquid. For example, the cannulated tool may have a sharp end to assist in accessing the liquid-filled intraocular lens. Alternatively, the cannulated tool may have a barb, hook, or

other device for mechanically retaining the lens after insertion into the liquid-filled intraocular lens.

[0051] In certain embodiments the deflated lens is drawn into the explantation tool for removal from the eye. In other embodiments the deflated lens is removed using a separate portion of the explantation system, which individually grasps and removes the deflated lens. This individual portion of the explantation system may have an aspiration or infusion aspiration component that is used to assist in gripping the lens, maintaining pressure in the anterior chamber of the eye, and in removing any residual liquid from the intraocular lens. Some implementations of the invention use a fluid exchange in the IOL before deflating the IOL and removing it. Aspiration comes from one portion of the explantation system while infusion is applied through the same portion of the IOL or from a separate portion of the lens.

[0052] In certain implementations a specific tool is used to open an aperture in the IOL and then aspirate liquid coming from the IOL. Other embodiments aspirate the intraocular lens by first using cautery, laser, ultrasonic power, or mechanical cutting to open an aperture in the device and then aspirate the contents of the intraocular lens.

[0053] One implementation of the invention uses a separate line to infuse fluid, such as BSS, viscoelastic, or air into the lens capsule while the lens is being deflated. This technique maintains the natural lens capsular shape, facilitating IOL removal from the lens capsule and subsequent IOL "in the bag" injection with a replacement IOL.

[0054] In certain aspects, therefore, the invention pertains to an intraocular lens explantation system. In various embodiments, the system comprises a portion that retains an intraocular lens using a mechanical, suction, or combination of mechanical and suction force to hold the lens, and a portion that accesses the internal contents of a fluid-filled intraocular lens; this latter portion removes or facilitates removal of the contents of the lens before lens removal from the eye. The portion that accesses the internal contents of the IOL may, for example, comprise or consist of a hooked or barbed member, and may be used to mechanically retain the lens against the retention portion of the explantation tool.

[0055] The portion that accesses the internal contents of the IOL may alternatively comprise or consist of a cannulated tool that aspirates the contents of the lens while the

lens is held by the gripping portion of the explantation tool. The portion that accesses the internal contents of the IOL may comprise or consist of an aspiration infusion portion that aspirates the contents of the lens and infuses a second fluid into the lens in order to fluidically exchange the internal contents of the lens with another fluid. After fluid exchange the lens is evacuated and drawn out of the eye. In still other embodiments, the retention portion may also aspirate fluid from the lens.

[0056] The explantation tool may have a feature to draw in the intraocular lens for removal thereof from the eye. A second independent portion of the explantation system, such as a forceps or other gripping member, may be designed specifically to interact and remove the deflated lens.

[0057] In another aspect, the invention relates to an intraocular lens explantation system comprising or consisting of two independent components. The first component is an intraocular lens gripper that uses a mechanical, suction, or combination of mechanical and suction force to hold the lens, and also accesses the internal contents of a fluid-filled intraocular lens in order to remove the contents of the lens before lens removal from the eye. The second component accesses a separate portion of the lens to infuse another fluid therein and/or to aspirate fluid from the lens.

[0058] An intraocular lens explantation system in accordance with the invention may comprises a tip used to open an aperture in the lens and allow fluid to escape while a second portion of the tip aspirates the fluid from the lens. A portion of the explantation tool may provide for infusion as well as aspiration.

[0059] An intraocular lens explantation system in accordance with the invention may comprise a portion that accesses the lens to deflate the lens while a second portion infuses fluid or viscoelastic into the lens capsule while the lens is deflated.

[0060] An intraocular lens explantation system in accordance with the invention may have an ultrasonically powered tip used to open an aperture in the side of the liquid-filled intraocular lens and aspirate the lens contents; the ultrasonically powered tip may have aspiration and infusion capability. In some embodiments, the tip contains a sharp portion to assist in rupturing the wall of the liquid-filled intraocular lens.

[0061] An intraocular lens explantation system in accordance with the invention may have a cautery tip to open an aperture in a liquid-filled intraocular lens, an aspiration portion to allow fluid from the IOL to be aspirated, and an optional infusion portion.

[0062] An intraocular lens explantation system in accordance with the invention may have a laser to open an aperture in a liquid-filled intraocular lens, an aspiration portion to allow fluid from the IOL to be aspirated, and an optional infusion portion. The laser may, for example, be endoscopically operated.

[0063] An intraocular lens explantation system in accordance with the invention may have means for cutting the edge of the liquid-filled intraocular lens and aspirating the contents of the intraocular lens. The cutting means may comprise or consist of a cutting tube telescopically received in an outer tube and having a cutting port on the distal end, with suction applied to the cutting port through the center of the inner cutting blade. The cutting tube may cut using one or a combination of reciprocating axial motion, reciprocating rotary motion, or rotary motion.

[0064] An intraocular lens explantation system in accordance with the invention may have a portion that accesses the internal contents of a fluid-filled intraocular lens, removing the contents of the lens before lens removal from the eye.

[0065] In another aspect, the invention relates to a method of explanting a fluid-filled intraocular lens. In various embodiments, the method consists of or comprises partially or fully emptying the intraocular lens and then removing the lens from the eye, either with the same tool used to empty the lens or a different tool.

[0066] A method of explanting a fluid-filled intraocular lens in accordance with the invention may comprise or consist of first exchanging the fluid in the intraocular lens with a second fluid, then partially or fully emptying the intraocular lens, and then removing the lens from the eye, either with the same tool used to empty the lens or a secondary tool. The fluid may be exchanged by means of a single access point in the lens. In some embodiments, the fluid is exchanged using one tool to remove fluid from the lens and a second tool to inflate the lens with a second fluid.

[0067] Reference throughout this specification to "one example," "an example," "one embodiment," or "an embodiment" means that a particular feature, structure, or characteristic described in connection with the example is included in at least one example of the present technology. Thus, the occurrences of the phrases "in one example," "in an example," "one embodiment," or "an embodiment" in various places throughout this specification are not necessarily all referring to the same example. Furthermore, the particular features, structures, routines, steps, or characteristics may be combined in any suitable manner in one or more examples of the technology. The headings provided herein are for convenience only and are not intended to limit or interpret the scope or meaning of the claimed technology. The term "substantially" or "approximately" means ±10% (e.g., by weight or by volume), and in some embodiments, ±5%.

BRIEF DESCRIPTION OF THE DRAWINGS

[0068] In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, with an emphasis instead generally being placed upon illustrating the principles of the invention. In the following description, various embodiments of the present invention are described with reference to the following drawings, in which:

[0069] FIG. 1A and 1B depict the IOL insertion and filling system.

[0070] FIG. 2A and FIG. 2B depict the insertion and filling system with a sealing member to deploy the IOL.

[0071] FIG. 3A and FIG. 3B depict an implementation of this invention with a protective sheath to assist in deploying the IOL.

[0072] FIG. 4A and FIG 4B depict an implementation with a mechanical gripping mechanism used to fold and deploy the lens.

[0073] FIG. 5 depicts an implementation with a fluidic line used to fluidically push the IOL out of the injector.

[0074] FIG. 6 depicts the access tip that is a dual cannula providing both infusion and aspiration.

[0075] FIG. 7 depicts the insertion and filling system with a separate infusion line and aspiration line attached to the access tip through a y-connector or valve.

[0076] FIG. 8 depicts the insertion and filling system with a debubbling filter used with the injection tip.

[0077] FIG. 9A-F depict the insertion and filling system with a specific method of checking the lens for leakage after insertion onto the injection and filling system.

[0078] FIG. 10 depicts the fully evacuated IOL fluidically connected to the access tip extending out of the insertion tube.

[0079] FIG. 11 illustrates a fluid-filled intraocular lens being accessed by an embodiment of a re-access tool.

[0080] FIG. 12 illustrates various embodiments of the access tip of the re-access tool.

[0081] FIG. 13 illustrates a dual-lumen access tip.

[0082] FIG. 14 illustrates various feedback mechanisms incorporated into the re-access tool.

[0083] FIG. 15 illustrates an explantation system interacting with an implanted lens.

[0084] FIG. 16 illustrates a view of the explantation system interacting with the lens.

[0085] FIG. 17 illustrates the deflated IOL in the explantation tool.

[0086] FIG. 18 illustrates an embodiment of the invention with a bimanual explantation tool.

[0087] FIG. 19 illustrates an explantation tool with a sharp portion that is used to open an aperture in the IOL before aspiration of the IOL contents.

[0088] FIG. 20 illustrates an implementation of the invention where the explantation system consists of a cutting tool used to cut a portion of the lens and aspirate the lens and filling fluid.

DETAILED DESCRIPTION

[0089] The peripheral surgical systems described below are used for insertion and filling of fluid-filled intraocular lenses, reaccessing and modifying the fluid-filled intraocular lens, and

explantation of the lens. Although one peripheral surgical unit may perform all of these features associated with the surgical manipulation of the fluid-filled intraocular lens, many different units may perform each separate functional feature. The invention may also be used as a peripheral surgical system for other fluid-filled implantable devices such as a scleral buckle or breast implant.

1. INSERTION/FILLING

[0090] Refer first to FIG. 1A, which depicts a representative IOL insertion and filling system 100. Fluidics line 104 connects the fluidics system 102 to an intraocular lens 112. Intraocular lens 112 is loaded into an insertion tube 110. During implantation, the insertion tube is inserted into the eye through a small incision. Then the intraocular lens 112 in pushed out of the insertion tube 110 into the correct location in the eye. The insertion tube 110 may be configured to be clear or translucent in order for the surgeon to visually inspect the lens during loading, while it is loaded, or during insertion. In FIG. 1A a slider 108 is used to deploy the IOL 112 by mechanically advancing the fluidics line 104 relative to the handpiece 114. However, this is not meant to be limiting and other configurations known to those skilled in the art can be used, including devices such as a lever, ball screw, switch or an automated deployment through an actuator 120 such as pneumatic, motor, or solenoid actuation. Alternatively, any known approach to pump fluid may be utilized. Combinations of one or more actuators 120 may be used in parallel such as one pneumatic pump and one vacuum pump. After filling, the lens is too large to withdraw back into the insertion tube 110, so simple retraction of the fluidics line 110 using the slider 108 pulls the end of the fluidics line out of the lens as it is retained against the outlet of the insertion tube. Furthermore, the insertion tube 110 may have a coating to prevent any damage in case of contacting the lens.

[0091] After deployment of the lens into the eye, the fluidics system 102 is used to fill the lens to the specified volume by actuating one or more fluids, gases, gels, or solutes from one or more reservoirs 124. If the fluidics system 102 is located remotely from the handpiece 114 a fluidics line 104 may be used to move the fluid from the fluidics system 102 to the IOL 112. Refer to FIG. 1B for the system block diagram of the IOL insertion and filling system. The fluidics system may include one or more feedback systems 122 used to monitor pressure with a pressure sensor 126, flow with a flow sensor 128, or refractive index with a refractometer 130 and can adjust one or more variables through actuation of the pump to provide the appropriate

refractive outcome of the lens. The pump actuation and feedback information is processed through a microcontroller 140 and appropriate software.

[0092] Deployment of the IOL occurs with the help of a viscoelastic in certain embodiments of the invention. The viscoelastic serves to reduce friction or stiction between the lens and the insertion tube. Likewise, in certain embodiments of the invention the viscoelastic is used as a carrier material that is pushed into the lens capsule by the injector and carries the lens along with it. In this manner, it supports the intraocular lens and assists the IOL to deploy into the lens capsule with the supported distal portions of the IOL entering first. The support of the viscoelastic prevents the flexible lens shell from buckling back on itself during insertion.

[0093] The viscoelastic assists in maintaining the lens capsule before insertion of the IOL. The viscoelastic is inserted into the lens capsule before or during IOL insertion and inflates the lens capsule to provide room for an inflatable IOL to be inflated. It displaces air from the injector and reduces or eliminates air bubbles from entering the eye that may be trapped in the folds of a deflated lens. The insertion tube 110 may be configured to be clear or translucent in order for the surgeon to visually inspect the lens during loading, while it is loaded, or during insertion. In FIG. 1 a slider 108 is used to deploy the IOL 112. However, this is not meant to be limiting and other approaches known to those skilled in the art can be used including other manual insertion devices such as a lever, ball screw, switch or an automated deployment through means such as pneumatic, motor, or solenoid actuation. After deployment of the lens into the eye, the fluidics system 102 is used to fill the lens to the specified volume. If the fluidics system 102 is located remotely from the handpiece 114 a fluidics line 104 may be used to move the fluid from the fluidics system 102 to the IOL 112.

[0094] Exemplary fluidics systems include a simple manual syringe or a fluidics pump, such as a syringe pump. The fluidics system 102 need not be an open-loop system; in certain implementations, feedback from a sensor is used to determine the fill volume, refractive properties of the lens as implanted in the eye, or pressure to fill to the correct volume. Fluidics system 102 may have the capability of both infusing fluid and aspirating fluid from the lens to reach the desired fill, refractive property, or lens pressure. In addition, fluidics system 102 may have the ability to monitor refractive properties of the lens filling fluid and adjust this.

[0095] Although the fluidics system is described as being remote from the handpiece, this is not essential. In certain implementations of the invention, the fluidics system is an integral part of the handpiece, any fluidic connections occurring within the handpiece. Other implementations that are within the spirit of the invention are possible to those skilled in the art.

[0096] Although insertion of the lens is described as the lens being pushed out of the insertion tube, it is also possible to retract the insertion tube 110 and fluidics line 104 and leave the lens 112 stationary. This has the distinct advantage of allowing the surgeon to place the IOL in the desired location, then retract the tube, exposing the IOL. Typically, in such embodiments, the fluidics line is 104 mechanically retracted before or along with the insertion tube. A blunt surgical tool, or another feature on the tip, may be used to hold the lens in place.

[0097] FIG. 2A illustrates an implementation with the IOL 212 deployed and FIG. 2B has the IOL 212 in the loaded configuration. In this implementation, a sealing plunger 210 forms a seal with the insertion tube 206. During loading a viscoelastic or other fluid, such as saline, balanced salt solution, or water may be used to assist in loading the lens. After the lens is loaded the intraluminal space 214 (which is bounded by the sealing plunger 210, the insertion tube 206, the IOL 212, and the end of the insertion tube 208) is filled with the fluid or viscoelastic. This filling fluid or viscoelastic is pushed out of the insertion tube 206 by the sealing plunger 210 along with the IOL 212 and fluidically pushes the lens from the insertion tube into the eye. In particular, forcing the fluid against the proximal side of the seal advances the plunger and pushes the lens out a known distance (until the seal has cleared the end of the insertion tube); again, a blunt surgical tool may be used to hold the lens and eject it from the fluidic line tip.

[0098] The filling fluid provides a fluidic force to assist in deployment the IOL 212 along with the mechanical force of the sealing plunger 210 along the proximal surface of the IOL 212. This is especially important for pushing out the unsupported distal end of the IOL 212 during lens deployment because it counteracts the tendency of the lens to become bunched up. The fluidic force also prevents the internal surfaces of the IOL 212 from being pushed against the access tip 216, which may cause damage to and possibly rupture of the IOL wall during deployment. The access tip 216 may be used to provide fluidic connection between the IOL 212 and fluidics system. The filling fluid reduces friction between the IOL 212 and the

insertion tube 206 during deployment, thereby preventing damage to the IOL 212 during insertion. In addition, the filling fluid displaces residual air surrounding the IOL 212 and prevents the air from being pushed into the eye with the IOL 212. Air inserted into the eye with the IOL may rise to the top of the eye, stick to the lens, or enter the lens capsule making visualization of the insertion process difficult. The sealing plunger 210 also prevents damage to the IOL by stopping the proximal end of the IOL 212 from folding back and becoming pinched between the plunger and the internal surface of the insertion tube 206.

[0099] FIGS. 3A and 3B depict an implementation with a protective sheath 304 to assist in deploying the IOL 312. The protective sheath 304 wraps around a portion or the entirety of the IOL, and extends along a portion of the length of the IOL. In certain implementations, the sheath extends and covers the IOL lengthwise and circumferentially. In FIG. 3A the insertion tool 300 is in the loaded configuration and prepared for deployment into the eye. FIG. 3B shows the insertion tool 302 after insertion of the IOL 212, but before inflation of the IOL. The protective sheath 304 serves to protect the IOL 312 against frictional forces from the insertion tube 306. This is especially useful when the IOL 312 is made from a material that adheres to the insertion tube 306 or other surrounding structures. During deployment or loading of the IOL 312, the sides of the IOL may stick to surrounding structures, causing damage to the IOL 312. The protective sheath 304 serves as a carrier, and sliding friction occurs between the protective sheath 304 and the insertion tube 306. In addition, during loading of the IOL 312, the protective sheath 304 serves to pre-fold and/or roll up the lens while it is drawn into the insertion tube 306.

[00100] The protective sheath 304 may span the full length of the IOL 312, or a partial length of the IOL 312. In certain implementations, the protective sheath 304 is short, extending around a valve in the IOL 312. The sheath is used to hold the IOL 312 by the valve while the IOL 312 is drawn into the injector. This assists in drawing the lens into the injector and folding the lens. Deployment of the protective sheath protects the lens from damage by the access tip 316 by supporting the back portion of the lens, not allowing the front of the lens to fold over as it is deployed. In addition, the protective sheath 304 can be used to secure the valve before, during, or after insertion. Then, while mechanically retaining the valve, an access tip can be used to access the valve, providing fluidic continuity between the IOL 312 and the fluidics system.

[00101] In certain implementations, the IOL 312 and protective sheath 304 are inserted together, then after insertion — but before, during, or after inflation of the IOL — the protective sheath 304 is retracted. In this manner, the protective sheath does not become trapped between the IOL 312 and the lens capsule after insertion and inflation. Likewise, the protective sheath may be used to load the lens into the insertion and filling system but is either partially deployed during lens insertion, or not deployed with the lens. In this implementation, the protective sheath 304 is used to fold and draw in the lens. To assist with this operation, the sheath may be shaped so as to promote folding of the lens (as described in greater detail in connection with FIG. 10). The material properties of the protective sheath 304 may be used to reduce friction between the IOL 312 and the insertion sheath 304 to allow smooth deployment. The protective sheath 304 then either does not come into direct contact with the lens capsule, or only slightly enters the lens capsule. In both cases this prevents damage to the lens capsule from the protective sheath 304.

[00102] Although the protective sheath 304 is described in connection with a liquid-filled IOL, this is not meant to be limiting. In certain implementations, this protective sheath is used with non-liquid-filled IOLs. When non-liquid-filled IOLs are used with the protective sheath, the fluidics system is not included in the design. Instead, a protective sheath is used in conjunction with an IOL injector to deploy the lens. This has the advantage of protecting the IOL during insertion from damage due to friction against the insertion tube, viscoelastic causing surface damage, or other damage from the compression experienced by the IOL during insertion. This type of sheath is especially important for micro incision IOL surgery, where IOLs are compressed to very small diameters, 2mm or less, during insertion. Therefore, this concept of a protective sheath can be used to reduce damage for non-liquid-filled IOLs as well to ensure a safe deployment of the lens.

[00103] FIGS. 4A and 4B show an implementation with a mechanical gripping mechanism used to fold and deploy the lens. FIG. 4A has the IOL 408 in the loaded position while FIG. 4B has the IOL 408 in the deployed position. A mechanical gripping mechanism 406 is used to retain the IOL 408 on the insertion tube 412. This is useful, for example, if a valve is employed to communicate with the fluidics lines. The mechanical gripping mechanism 406 prevents the lens valve from becoming unconnected to the fluidics portion of the insertion and injection system.

[00104] In addition, the mechanical gripping mechanism 406 may be used to protect the lens during insertion. In certain implementations, the mechanical gripping mechanism 406 is configured similar to a forceps. In other implementations, the mechanical gripping mechanism 406 is soft or flexible, made of a polymer (such as a silicone) to engage the IOL 408 without causing damage thereto. In addition, a soft material is preferable to prevent damage to the lens capsule after insertion of the IOL into the eye. The flexible gripping mechanism 406 may comprise or consist of two or more elements to grasp the IOL 408. As shown in FIG. 4B, the mechanical gripping mechanism 406 allows release of the IOL 408 after insertion. If the mechanical gripping mechanism 406 is configured like a forceps, upon deploying the lens, the gripping mechanism 406 automatically opens. For example, the grippers may be spring-loaded or include living hinges biased toward an open, spread-apart configuration, so that when they are deployed, they spread out. The gripping mechanism is structurally limited to only open a set distance which is large enough to release the lens, but smaller than the incision (less than 3mm, and in some cases less than 1mm). The mechanical gripping mechanism may be retracted after delivery of the IOL 408, before, during, or after filling the IOL 408.

[00105] In addition, a gripping mechanism may be used for accessing a deflated, partially inflated, or completely inflated IOL after insertion into the eye. When used in this manner, the gripping mechanism may be biased in the opposite direction or be configured to to draw the grippers toward each other; see, e.g., U.S. Serial No. 61/920,615 (filed on December 24, 2013), the entire disclosure of which is hereby incorporated by reference. The trippers may mechanically hold the lens while a valve in the IOL is accessed. At this point fluid can be added or removed from the IOL. This provides the possibility of implanting an unfilled IOL, then after implantation accessing the valve and inflating the lens. In this situation, the IOL is not in fluidic connection with the filling lines during implantation.

[00106] Other suitable gripping mechanisms access a valve in a fluid-filled IOL. One exemplary mechanism utilizes vacuum to retain the valve or by mechanical holding pressure; for example, the mechanism may utilize a pair of concentric tubes, the inner one extending beyond the outer one and being insertable into the lens, with the vacuum being applied through the outer lumen to draw the lens against the distal end of the outer tube. The valve may be accessed directly with a small tube or needle. Some implementations of the invention

mechanically retain the valve and then use a fluidic pressure to crack the valve open to either add or remove fluid from the liquid-filled IOL.

[00107] FIG. 5 shows an implementation with a fluidic line used to fluidically push the IOL 506 out of the injector. Fluid from an inlet 502 enters the insertion and filling system and exits through the insertion tube 508. During insertion of the IOL 506, the fluid flows the IOL out of the insertion tube 508 without forcing the IOL to fold onto itself. In addition, the fluid can be used to inflate the lens capsule. This fluid can be used instead of or in support of viscoelastic that is on or around the lens or inside the lens capsule. In certain implementations, the fluid displaces viscoelastic in the lens capsule after insertion of the IOL 506. This is especially important when an IOL is sized to fill most of the lens capsule. After inflation of a large lens-capsule-filling IOL, viscoelastic may become retained between the IOL wall and the lens capsule. Therefore, either avoiding use of viscoelastic or cleaning viscoelastic from the lens capsule during insertion and implantation may become appropriate.

[00108] Although FIG. 5 shows the additional fluidic line being coupled through the insertion tube, in other implementations the fluidic line is on the outside of the insertion tube and is used not as a source of fluidic force to push out the lens, but to inflate the lens capsule and/or clean out viscoelastic during insertion of the lens. In other implementations, an external aspiration line is used in conjunction with the external fluidic infusion line. Infusion and aspiration may be used together to remove any fluid, such as viscoelastic, from the eye. The infusion line may be coupled to the insertion tip, or may be external to the insertion tip. Likewise, the infusion and aspiration may be separated from the insertion tip, e.g., in the form of separate handpieces working together to exchange fluids in the eye.

[00109] Refer now to FIG. 6, which depicts an access tip in the form of a dual cannula providing both infusion and aspiration. The access tip 616 is placed from outside the lens 606 into the inside of the lens 604. An infusion portion of the injection tip 610 is used to infuse fluid 612 into the lens. A second port is used for aspiration 608 to aspirate the contents of the lens 614. This aspiration port 608 need not be located directly adjacent to the injection port 610. In certain implementations of the invention the access port and infusion port are located on opposing sides of the lens, and are put into the lens through two distinct access points. When infusion and aspiration are used together, it is possible to exchange fluid in the IOL. This is useful, for example, when changing the refractive index of the fluid filling the IOL. Likewise,

feedback systems in the handpiece can be used to monitor pressure, flow, or refractive index and the handpiece can adjust a single one or a combination of these to provide the appropriate refractive outcome of the lens.

[00110] Some implementations of the access tip utilize a blunt tip with multiple lumens configured in concentric or parallel orientations for infusing or aspirating fluid from the side of the tip. Still other implementations of the access tip involve features to prevent the IOL from collapsing over the aspiration hole. Exemplary access tip features include side ports, multiple lumens, and a rounded tip. This may be important, for example, when the IOL is evacuated prior to insertion into the eye. In this situation, a flexible wall of a liquid-filled IOL may cause lumen occlusion. However, a feature such as a protruding member or multiple lumens can be used to prevent lumen occlusion.

[00111] FIG. 7 depicts a separate infusion line 702 and aspiration line 704 attached to the access tip 706 through a y-connector or valve 708. An air bubble 710 travels through path 712 from the infusion line 710 and passes through the y-connector or valve 708, then passes out the aspiration line 704. Fluid traveling along this path does not enter the access tip 706. In this manner, the lines of the insertion and filling system can be primed up to the injection tip 706 without passing fluid into the injection tip 706. For example, the valve 708 may selectively connect the line 702 to the line 704 or line 706, so that air is cleared from the line 702 (via line 704) before it is connected to line 706. In some embodiments, the valve 704 is positioned higher than the line 706 so that the air travels out as gases tend to accumulate on the top of the line. Although FIG. 7 is shown with air bubbles, this approach also applies to any air in the line that can be removed.

[00112] Refer now to FIG. 8, which depicts a debubbling filter used with the injection tip. Liquid from the fluid reservoir moves through the infusion line 814 in a direction depicted by arrow 802. Air bubble 804 flows down the infusion line 814 until coming in contact with semipermeable membrane 806, which allows air to cross but blocks liquid from crossing. Air bubble 804 traverses the semipermeable membrane 806 via path 810. Air enters a separate chamber or line 812 after removal from the line. In this manner, liquid traveling out of the distal end of the infusion line 816 and into the IOL is free of air bubbles. Semipermeable membrane 806 may also be used to remove air during priming. Chamber 812 may be at ambient pressure (if the liquid in the line 814 is at higher pressure), or held under vacuum.

Likewise, the driving force for air to leave may be a pressure differential from the infusion line 814 and the chamber 812, or the process may be from diffusion.

[00113] FIG. 9 illustrates an exemplary method of inserting an IOL 902 onto the injector. The lens is checked for leakage after insertion onto the injection and filling system. In FIG. 9A, a sharp needle is first used to access or pierce a sealing portion 914 on the IOL. Then, as shown in FIG. 9B, the access tip 906 is inserted through the sealing membrane 914 into the IOL. Fluidic continuity between the fluidic system and the inside of the IOL 902 is achieved at this step. In FIG. 9C, the sharp needle is removed from the IOL. In FIG. 9D, the IOL is inflated with air or liquid to assume an inflated state 908. At this point the inflated IOL 908 is checked for leaks or damage to the IOL. This detection may be performed, for example, by optically inspecting the lens for deflation; by visually inspecting the lens for leakage; by monitoring pressure of the lens; or by monitoring fluid flow to and or from the lens. These techniques are not meant to be limiting and many other similar techniques known to those skilled in the art may be used to inspect the lens. In FIG. 9E the IOL is deflated and is in the deflated state 910. In FIG. 9F the IOL is inserted into the insertion tube 912. FIGS. 9A-9F illustrate an exemplary approach for checking the lens for leaks, but the illustrated steps are not meant to be limiting. For example, the lens may be accessed without a sharp tool 904 to check for leakage. In addition, the lens may be checked for leakage and subsequently removed from the injection and filling system for later use.

[00114] Viscoelastic can be used to deploy the IOL. Viscoelastics are used to maintain space between the IOL and the surrounding injection tubes. In addition, they assist in sealing portion of the injector when inserting the lens. This is true when a close fit is between a portion of the injector and the injector wall. In certain embodiments of the invention, the viscoelastic plugs a plunger used to deploy the lens. As the viscoelastic moves, it draws the light lens shell with it into the eye. In addition, the viscoelastic lowers friction and reduces stiction between the lens and surrounding insertion tube. Finally, during insertion into the lens capsule, the viscoelastic may enter the lens capsule before or simultaneously as the IOL enters the lens capsule. In this case the viscoelastic maintains the lens capsule in the inflated position and provides a space for the lens to sit inside the lens capsule. This is important during filling of the lens so there is a space for the lens to easily fill out, reducing wrinkling of the lens or lens capsule during insertion.

[00115] Viscoelastics are also used to fold thin walled injectable lenses. By placing a thin line of viscoelastic along a diameter of the lens corresponding to the fluidic line, the lens can be folded around this line enclosing the viscoelastic. The viscoelastic in this embodiment of the invention acts as a guide to roll up the thin walled IOL for retraction into the injector and injection into the eye. This prevents unwanted IOL folding during retraction into the injector and injection into the eye.

[00116] Suitable viscoelastics include, but are not limited to dispersive and cohesive viscoelastics or a combination of these. Exemplary viscoelastics include include hydroxypropyl methylcellulose solutions such as OcuCoat, sodium hyularonate solutions such as Provisc, chondroitin sulphate *I* sodium hyuronate soultions such as Viscoat. Other exemplary viscoelastics include HEALON, HEALON 5, HEALON GV, HEALON EndoCoat, Amvisc, Amvisc Plus, Medilon, Cellugel, BVI 1%, StaarVisc II, BioLon, and ltrax. Examples of combinations of viscoelastics include mixtures of dispersive and cohesive viscoelastics (e.g. DuoVise which contains separate syringes of Viscoat and Provisc) or HEALON Duet Dual (consisting of HEALON and HEALON EndoCoat). As an example, a dispersive viscoelastic may be used to cover the lens, while a cohesive viscoelastic is used around the dispersive to carry the IOL into the lens capsule. The IOL can be loaded into the injector in a number of ways known to those skilled in the art, including, but not limited to, front and back loading and closing the inserter around the IOL. Once loaded, the injector may be stored under standard IOL storage conditions until use.

[00117] In various loading embodiments, the lens is loaded using unique features of the IOL and the peripheral system. FIG. 10 depicts a fully evacuated fluid-filled intraocular lens. The access tip 1001 is used as a fluidic connection between the fluid-filled intraocular lens 1012 and the filling system. The access tip 1001 connects to the fluid-filled intraocular lens 1012 through a valve 1005 that creates a sealed fluidic connection thereto. The fluid-filled intraocular lens 1012 naturally conforms to a saddle shape, since that is theoretically the lowest surface-energy configuration due to its geometry. The access tip 1001 can protrude into the lens and flatten the curve though the center of the saddle slightly depending on how far the access tip extends. During loading, the edges 1002 and 1003 are folded over towards the center of the lens. This makes the lens form what is similar to a rolled tubular shape or a "taquito." There are ways to help the fluid-filled intraocular lens fold into this loaded position. One

technique is to lay a fluid (preferably a highly viscous liquid such as a viscoelastic) across the center channel of the lens, which starts at the end of the lens 1004 and extends through the center channel 1006 and up to the valve 1005. This allows the edges of the lens 1002 and 1003 to fold over a medium to prevent excess stresses to specific regions of the IOL during folding. Additionally, the surface tension of viscous fluid promotes the edges to fold over. The second technique uses the insertion tube 1007 in which the lens 1012 is loaded into to help it fold over itself during the loading process. The angled taper on the insertion tube 1007 helps first feed the valve portion 1005 of the fluid-filled intraocular lens first. As the lens is pulled farther and farther back into the insertion tube 1007, the tapered side walls of the tube opening slowly push the sides of the lens 1002 and 1003 over each other. This can also be achieved by placing a funnel in front of the insertion tube 1007 that will hold the lens. The funnel can then be detached after the lens is fully loaded into the insertion tube 1007. A third technique to help the lens load is to use a sheath that can wrap over the valve 1005 portion of the fluid-filled intraocular lens 1012. As the lens 1012 is pulled back into the insertion tube 1007, the sheath slowly curls over the lens and helps the lens fold over. The sheath also protects the fluidic connection by wrapping itself around the valve 1005 area of the lens. The sheath prevents the insertion tube 1007 from applying friction to the valve area. Such friction may prevent the valve from being loaded smoothly into the insertion tube 1007, subsequently causing the fluidic connection to be disconnected during loading or damage to the lens 1002.

[00118] A second embodiment back loads the intraocular lens 1012 through the insertion tube 1007. With this approach, the lens is pushed from the back of the tube to the front where it is ready to be injected. A funnel can be used to help guide the lens into the insertion tube 1007 in this approach as well. If the lens is back-loaded, a surgical tool with a grabbing mechanism such as forceps can be placed through the insertion tip from the front where the angled cut is. The grabbing mechanism can then go through the insertion tube tip and grab onto the end of the lens 1004. The lens can then be pulled through the insertion tube 1007 to be back loaded. This is to help the lens fold correctly and to prevent the lens from inappropriately folding within the insertion tube 1007. The end of the lens 1004 may have an additional segment to be preferably grabbed by the forceps. The forceps may be coated with a polymer such as silicone to prevent any damage to the lens 1012 during contact.

[00119] Either approach may be used to load a cartridge for storage. The cartridge may then be placed within an accessible portion of the insertion tube prior to implantation. The access tip 1001 is connected to the IOL 1002 to create a fluidic connection prior to the procedure.

2. RE-ACCESS

[00120] FIG. 11 illustrates a fluid-filled intraocular lens 1104 already implanted in a patient's capsular bag or in the cliliary sulcus. One or more access ports 1105 are located on the surface of the fluid-filled intraocular lens 1104, preferably outside of the field of vision. The access port 1105 allows an access tip 1103 to enter or pierce though and access the fluid within the fluid-filled intraocular lens 1104. In one embodiment, the access tip 1103 has an overall diameter less than 4mm, and ideally less than 2mm in order for the access port 1105 to maintain its self-sealing properties and to minimize leakage during or after access. This access tip 1103 can be manipulated using a handpiece 1107, allowing the surgeon to operate mechanisms to control the access tip 1103 orientation, length, and fluid transfer rate. One or more fluidic lines 1102 connect to the access tip 1103, and runs through the handpiece 1107. The fluidics line 1102, then connects to a console 1101. The console 1101 uses a pumping mechanism (e.g., a mechanical pump, syringe pump, peristaltic pump, or other pumping mechanism that is preferably meterable) to add fluid, remove fluid, or add and remove fluid sequentially or simultaneously. The surgeon can control the different injections and removal of fluid by a switch 1106, which can either be a foot pedal or pedals, hand controls, or some combination of both. To maintain convenient control of the handpiece, the line may be flexible, thereby allowing the surgeon to move the handpiece easily while accessing the intraocular lens. Due to the sensitivity and accuracy of fill that may be required of a fluid-filled intraocular lens 1104, the fluidics line 1102 may have minimal wall compliance and be designed for pressures above 10 psi. The fluidics line 1102 will endure high pressures (above 10 psi) during injection as most of the pressure drop occurs across the access tip 1103. The Hagen-Poiseulille equation, $\Delta P = \frac{8\mu LQ}{\pi r^2}$ (where ΔP is the pressure drop across the tube or pipe; μ is the dynamic viscosity; L is the length of the tube; Q is the volumetric flow rate; and r is the inner radius of the tube), shows that the majority of the pressure drop occurs through the access tip since the access tip has a much smaller inner diameter than the fluidic line. This means the fluidics line is under higher pressure while fluid is flowing through the line. More specifically, the line compliance may be designed for pressures between 10 psi and 1000 psi. These internal

pressures expand the inner diameter of the fluidics line, and this expansion creates the compliance in the line by changing its volume. These compliances can be estimated by using basic equations of thin-walled pressure vessels. In some cases, thick-walled open-ended pressure vessel equations may be used. Fluidic line compliance may be important in re-access operations that modify internal liquid quantities of 2μL or less. For example, if the fluidics line 1102 expands from an inner diameter of .010" to .011" and is 3' in length, the compliance in the system would be about 39 μL. Nominal total fill levels of the intraocular lens are between 10 μL and 700 μL, and preferably between 50 μL and 250 μL. This means the volumetric change within the fluid line is 39 μL from when the system is relaxed to pressurized. In this instance the surgeon must wait a designated amount of time after the injection has been made to account for fluid line compliance and/or monitor fluid flow or lens properties, such as refractive state, internal pressure, or refractive index of the fluid directly at the lens or proximal to the tip. This effect of waiting for the line to relax can be seen in the physiology compliance equations $\Delta P \times C = \Delta V$, where ΔP corresponds to the change in pressure, C is the compliance and ΔV is the change in volume. Waiting for the line to relax allows the fluid to reach equilibrium and stop flowing, making $\Delta P = 0$. Therefore the compliance has no effect of the volume change. In another approach, the wall of the fluidics line 1102 may have a negligible compliance. This means the walls of the line are stiff enough that they do not expand under pressure. The fluidics line 1102 would still have to maintain its flexibility to allow the surgeon to manipulate the access tip 1103.

[00121] In the configuration shown in FIG. 12, the fluidic line 1202 still runs through the handpiece 1207, but the figure illustrates some of the different configurations that an access tip can take. In the top form, the fluidics line 1202 connects directly to a smaller tube, which is the access tip 1208 that would either pierce through the valve or enter a passage. In this configuration, a corneal incision is made into the eye to allow the access tip 1208 and fluidics line 1202 to access the fluid-filled intraocular lens. The fluidics line 1202 may be less than 4mm in overall diameter so that the surgeon can either re-open the initial incision used to insert the fluid-filled intraocular lens or make a new incision small enough to avoid inducing astigmatism. The access tip 1208 may either have a locating device to position the access tip to go through an access port or may have a sharp point, permitting it to break through a valve membrane to access the fluid-filled intraocular lens. With reference to portion A in FIG. 12,

the access tip 1208 is incased and protected by an outer tube 1209. This tube has a sharp point at its end. This allows the surgeon to pierce the eye, e.g. through the cornea, and move the outer tube 1209 into position to access the fluid-filled intraocular lens. The access tip 1208 is then deployed from the outer tube 1209 and accesses the fluid-filled intraocular lens. In this configuration, the sharper outer tip 1209 does not contact the intraocular lens, but is used to create an incision in the eye. In the configurations associated with portion A of FIG. 12, the surgeon does not have to make a corneal incision. In the configurations associated with portion B of FIG. 12, a sharp point 1210 protrudes out of the access tip 1208 and helps cut through the eye to the fluid-filled intraocular lens. This configuration also does not need a corneal incision. The point may cut through statically (i.e., the surgeon pushes the point through the eye) or may cut dynamically. In the latter case, the sharp point 1210 may be excited by ultrasonic energy or reciprocate relative to the access tip 1208 to cut through the eye. In both configurations the sharp point may or may not also help access the fluid-filled intraocular lens through and access port or membrane.

[00122] Once the fluid-filled intraocular lens is accessed, the sharp point may be withdrawn and fluid removed, added, or exchanged. In certain embodiments, the sharp point 1210 is put in a first position in which it extends beyond the access tip 1208 upon entering the valve of the intraocular lens. Then, prior to accessing the intraocular lens valve, the sharp point 1210 is retracted to a second position inside the fluidics line 1202, thereby preventing flow obstruction in the access tip 1208 during infusion or aspiration of fluid. In other embodiments of the invention, the sharp point 1210 is used to keep the access tip 1208 rigid during insertion into the valve.

[00123] FIG. 13 illustrates a dual-lumen access tip 1303. In this configuration, the first lumen 1308 is further inserted within the IOL relative to the second lumen 1309, thereby facilitating proper fluid mixing when the internal contents of the IOL 1304 are exchanged by simultaneous or sequential infusion and extraction of fluid.

[00124] FIG. 14 illustrates a feedback configuration that allows a microprocessor to measure the amount of fluid that needs to removed, exchanged, or injected from fluid-filled intraocular lens 1404 through an access port 1405. A flow sensor 1411 or other metering device is placed near the access tip 1403. The position of the flow sensor is critical due to the compliance that may be in the fluidics line as explained previously. Alternatively, if fluid is being removed

through a vacuum, then due to cavitation and compliance of the lines the sensor 1411 should be placed as close to the access tip 1403 as possible. All of the fluid volume in the access tip 1403 and fluidics line represents dead volume. This dead volume may also be used a measurement. If a known amount of fluid needs to be removed, the access tip 1403 may be designed to accommodate exactly that much liquid; as soon as the liquid reaches the sensor 1411, the removal of fluid is complete.

[00125] Another useful feedback parameter is the pressure of the fluid-filled intraocular lens 1404. This may be measured by feeding a small pressure sensor through the access tip 1403 and into the fluid-filled intraocular lens 1404. A fiber-optic pressure sensor may be used for this purpose, for example. Another configuration is a probe 1413 that extends either from the fluidics line or the access tip and pushes against the wall of the fluid-filled intraocular lens 1404. The force, deflection, or both can be measured and fed back to a processor to help control the injection, exchange, or removal of fluid. In other embodiments, tonometry — such as applanation tonometry, Goldmann tomonetry, dynamic contour tonometry, indentation tonometry, rebound tonometry, pneumatonometry, impression tonometry, or non-contact tonometry using an optical device such as optical coherence tomography — may be used.

[00126] Another configuration not shown in FIG. 14 measures in real-time the power of the fluid-filled intraocular lens 1404 using wavefront aberrometry, refractometry, autorefractometry, ultrasound measurement of lens dimensions, and/or optical coherence tomography of lens dimensions. This parameter is fed back to a processor to help control the injection, exchange, or removal of fluid. For example, lens geometry may be used with a measured refractive index of the fluid. The refractive index may be adjusted to produce emmetropia of the patient. In another embodiment, the fluid amount is used with measurements of anterior and posterior lens curvature, position of the lens relative to the retina and cornea, a prior measurement of corneal power, and the fluid level, or refractive index is adjusted to produce emmetropia. In other embodiments of the invention, the pressure of the intraocular lens is monitored to ensure a conformal fit between the surrounding lens capsule, and the refractive index of the intraocular lens is monitored to adjust for emmetropia.

[00127] Not pictured in the figures is a locking or locating mechanism to secure the re-access connection during fluid exchange. This mechanism allows the access tip to pierce through and into the liquid filled intraocular lens and maintain such configuration. Suitable

locking mechanisms include but are not limited to snap locks, twist locks and slide locks. Suitable locating mechanisms include but are not limited to tethers, vacuum (onto a surface having a unique shape), grippers or pins with locating holes. One configuration utilizes an existing self-sealing hole; the access tip uses the locking and/ or locating mechanism to align with the hole, and is then be pushed through the hole to access the liquid inside the lens. In another configuration, the access tip pierces straight through a membrane or valve into the lens. In certain embodiments of the invention, a locking mechanism is used to prevent a pushing force during the valve access procedure from causing the lens to move and strain surrounding tissue. First the tool is locked to the locking mechanism, which allows the lens to be held in the appropriate position without straining surrounding tissue. Next the access tip is used to access the valve.

3. REMOVAL

[00128] Refer now to FIG. 15, which depicts an exemplary IOL explantation system 1504. The explantation system 1504 grabs onto and retains the side of the liquid-filled IOL 1502. Upon retention, an internal tip is used to access the inside of the IOL and aspirate the fluid 1508 from the IOL into the explantation aspiration tool through a fluid path1506.

FIG. 16 shows a close view of the explantation system. In the illustrated implementation, a mechanical gripper 1604 is used to hold onto the IOL lens wall 1602. The IOL lens wall 1602 may be a specific portion of the IOL meant to interact with the gripper. In certain implementations this portion of the IOL contains a locking mechanism that interacts with the gripper. In other implementations, the gripper interacts with a valve in the lens. Upon mechanically contacting the lens and retaining it, either through mechanical force or by suction, the lens-access portion 1606 of the explantation system is used to access the lens. This causes the silicone oil or other liquid inside the IOL to flow from the lens into the explantation tool along fluid path 1608. The explantation tool applies aspiration to remove the internal contents of the lens. The gripping and aspirating system allows the internal contents of the lens to be aspirated without coming into contact with other ocular structures.

[00129] In certain embodiments, the access portion 1606 is a barbed hook, sharp point, crescent hook, or forceps and is used to access the internal contents of the lens. In other

embodiments, the lens-access portion 1606 is a cannulated structure such as a cannulated hook or needle. Aspiration of the IOL contents occurs through the cannulated structure and/or through the surrounding explantation tool. In other embodiments, the access portion 1606 comprises a hollow structure that aspirates through a series of ports. When the flexible lens collapses on the access portion 1606, the other ports continue to aspirate. In one embodiment, features on the access portion, such as one or more small protrusions, prevent the deflated lens from closing off the apertures in the access portion 1606. The access portion 1606 of the device is not meant to be limited by descriptions above; it can be any cannulated on non-cannulated instrument that is used either to open an aperture in the lens or to sample the lens contents.

[00130] Refer now to FIG. 17. After aspirating all of the contents of the IOL, the IOL 1706 is brought into the explantation system 1704 in a deflated state. In certain embodiments, a mechanical retaining device, such as a hook or barb 1702, is used with or without aspiration to assist in drawing the deflated IOL 1706 into the explantation system 1704. In other implementations, a dual-lumen or coaxial access portion of the explantation tool is used to access the lens. One portion of the dual-lumen/coaxial tool infuses a liquid while the other removes the fluid inside the lens through aspiration. This allows the filling liquid to be replaced with another liquid, such as a lower-viscosity liquid, or a liquid that is better tolerated in the eye (such as a balanced saline solution or viscoelastic) before the lens is deflated. In this manner, the lens remains partially or totally inflated during removal of the internal contents of the lens. Then, after fluid exchange has occurred, the internal contents are aspirated out and the lens is removed.

[00131] FIG. 18 shows an embodiment of the invention with a bimanual explantation tool. Aspiration and removal of fluid from the lens is performed with the aspiration portion of the explantation tool 1802. This portion of the tool may be configured as described above. Fluid from inside the IOL travels along fluid path 1804 into the aspiration portion of the explantation tool. An infusion portion of the explantation tool 1810 is used to access another portion of the IOL 1806. While the lens contents are aspirated using the aspiration portion of the explantation tool 1802, the IOL 1806 volume is filled with fluid flowing along path 1808 from the aspiration portion. During this procedure, the contents of the IOL are exchanged with another fluid or fluids. Exemplary fluids include balanced

salt solution, viscoelastic, or air. After fluid exchange has occurred, the lens is emptied and brought out of the eye using either the explantation tool itself or a secondary tool such as a forceps.

[00132] In some embodiments the lens is partially deflated while a second tool is used to fill the lens capsule with viscoelastic to maintain the size of the lens capsule. In this manner, the lens capsule size is retained while the IOL is deflated. This procedure protects the lens capsule from damage while the IOL is removed and allows a second IOL to be implanted into the already full lens capsule. The large size of a fluid-filled IOL helps to maintain an open lens capsule, making lens exchange into the lens capsule an easier and safer procedure than with smaller-profile IOLs.

[00133] FIG. 19 illustrates an explantation tool with a sharp portion 1902 that is used to open an aperture in the IOL 1906. Aspiration from the lumen 1908 of the explantation tool is used to remove any fluid from the IOL. Fluid from the inside the IOL passes along a fluid path 1904 from the IOL to the explantation tool. In one embodiment, the explantation tool provides infusion and aspiration. Infusion maintains the intraocular pressure and stabilizes the anterior chamber while aspiration removes fluid from the IOL. In other embodiments, a sharpened tool, which is a separate part of the explantation system is used to open an aperture in the IOL while an aspiration or infusion-and-aspiration portion of the explantation tool is used to aspirate the contents of the IOL. Then the empty IOL is removed using a separate tool or through the aspiration portion of the explanation tool. In certain embodiments, the IOL is filled with a fluid less dense than the surrounding aqueous. This is advantageous because such fluid tends to rise to the top of the eye, easing removal of fluid. In addition, if the lens capsule is damaged during the explantation, the lens floats to the top of the eye, preventing fragments from entering the vitreous chamber.

[00134] Refer now to FIG. 20, which shows an explantation system 2008 comprising a cutting tool used to cut a portion of the lens and aspirate the lens and filling fluid. The explantation system 2008 has an outer tube 2002 with a cutting port 2012 and a cutting blade 2006 located telescopically within the outer tube 2002. In a configuration shown in FIG. 20, the cutting blade 2006 reciprocates linearly inside the outer tuber 2002. However, reciprocating linear motion, reciprocating rotary motion, rotary motion, or a combination of two or more of these motions are all within the scope of the invention. The lens 2010 is

opened by the cutting motion of the explantation system 2008. Then the liquid contents of the explantation system are aspirated out of the eye through the lumen 2004 of the cutting blade 2006. Suction is applied to the inner lumen 2004 of the cutting blade 2006 to draw in the lens and lens fluid. In certain implementations, the cutting blade 2006 contains a sharpened edge to assist in shearing a portion of the lens. In other implementations the cutting blade 2006 contains a bend or spring-loaded mechanism to create a shearing force between the cutting blade 2006 and the outer tube 2002.

[00135] Other techniques to open an aperture in the lens and aspirate out the lens fluid include using an ultrasonic probe along with a tube used as a cutting tip, and applying suction through the center of the tube. For example, an ultrasonic probe may be located coaxially and external to the cutting tip, which may include a feature for breaking the lens. In certain embodiments, the lens-breaking feature comprises or consists of a beveled edge, sharp point, angled point, or a sharp edge. Alternatively, a laser may be used to open an aperture in the IOL. The laser may be externally or endoscopically applied to the lens. Certain implementations of the invention include infusion and/or aspiration with the laser source to evacuate the contents of the lens before lens removal. Another approach uses cautery to open an aperture in the IOL and aspiration to remove the lens filling liquid. Likewise, certain implementations of the invention include infusion as well as aspiration. For the above-mentioned variations, it is possible to remove the lens with forceps or another manual tool, or with the extraction system and tool itself.

[00136] Certain embodiments of the present invention have described above. It is, however, expressly noted that the present invention is not limited to those embodiments, but rather the intention is that additions and modifications to what was expressly described herein are also included within the scope of the invention. Moreover, it is to be understood that the features of the various embodiments described herein were not mutually exclusive and can exist in various combinations and permutations, even if such combinations or permutations were not made express herein, without departing from the spirit and scope of the invention. In fact, variations, modifications, and other implementations of what was described herein will occur to those of ordinary skill in the art

without departing from the spirit and the scope of the invention. As such, the invention is not to be defined only by the preceding illustrative description.

CLAIMS

1. An intraocular lens insertion and filling system comprising:

a fluidic system including one or more pumps and one or more reservoirs for a liquid;

a conduit, fluidically connected to the pump and having a distal end configured for insertion into an intraocular lens;

an insertion mechanism including a handpiece terminating in an insertion tube, wherein:

the handpiece surrounds a distal portion of the conduit;

the insertion tube is configured to receive the lens in an at least partially deflated state; and

the handpiece includes an advancement mechanism for causing relative movement between the insertion tube and the lens received therewithin, whereby activation of the advancement mechanism causes the lens to be ejected from a distal end of the insertion tube.

2. The system of claim 1, wherein the pump is adapted to pump a liquid from the reservoir into the lens following ejection thereof from the insertion tube, thereby inflating the lens.

3. The system of claim 1, wherein the fluidic system comprises a pressure sensor for measuring an internal pressure of the intraocular lens during inflation thereof.

4. The system of claim 1, wherein the pump is a bidirectional pump, and further comprising a flow sensor for measuring an amount of liquid introduced into or withdrawn from the lens by the pump.

5. The system of claim 1, wherein the fluidic system further comprises an inline refractometer for measuring a refractive index of the fluid inside the intraocular lens.

6. The system of claim 1, wherein the advancement mechanism comprises:

a fluid channel within the handpiece at least partially surrounding the conduit; and

a plunger surrounding the conduit and sealingly disposed within the fluid channel, whereby the plunger is advanceable by pressure within the fluid channel so as to move the lens relative to the insertion tube.

7. The system of claim 1, further comprising a sheath disposed at the distal end of the conduit for containing at least a portion of the lens.

8. The system of claim 1, further comprising a mechanical gripping mechanism disposed at the distal end of the conduit for gripping the lens.

9. The system of claim 8, wherein the gripping mechanism is advanceable and retractable via the handpiece.

10. An intraocular lens insertion and filling system comprising:

a fluidic system including at least one pump and at least one reservoir for a liquid, gas, or solute; and

first and second conduits fluidically connected to the pump and having distal ends configured for (i) contact with an intraocular lens and (ii) cooperation in retaining and filling the lens.

11. The system of claim 10, wherein:

the first conduit extends beyond the second conduit;

a distal end of the first conduit is configured for insertion into the lens; and

the at least one pump is configured to (i) pump liquid from the reservoir through the first conduit and (ii) create a vacuum in the second conduit to retainably draw the lens against a distal end of the second conduit.

12. The system of claim 10, wherein the first and second conduits are concentric.

13. The system of claim 10, wherein the first and second conduits are adjacent.

14. A method of filling an intraocular lens, the method comprising the steps of:

providing a conduit having a distal end disposed within and movable relative to an insertion tube;

inserting the distal end of the conduit into the lens and positioning the lens within the insertion tube;

partially inflating the lens with liquid via the conduit;

causing ejection of the lens from the insertion tube; and

further inflating the lens with the liquid to achieve a target volume.

15. The method of claim 14, wherein the ejection step occurs by mechanically causing relative movement between the insertion tube and the lens therewithin.

16. The method of claim 15, wherein the conduit is advanced relative to the insertion tube.

17. The method of claim 14, wherein the ejection step occurs by fluidically causing relative movement between the insertion tube and the lens therewithin.

18. The method of claim 14, further comprising withdrawing the conduit from the lens following further inflation, whereby the lens has a diameter larger than a diameter of the insertion and is thereby prevented from entry therein.

19. The method of claim 14, wherein the lens is monitored for leakage using at least one of visual detection, optical detection, pressure monitoring, or flow monitoring.

20. A method of filling an intraocular lens, the method comprising the steps of:

providing an infusion conduit, an aspiration conduit and a lens-filling conduit selectably connectable via a valve;

introducing the lens-filling conduit into the lens;

connecting the infusion conduit to the aspiration conduit via the valve and flowing a filling liquid therethrough, whereby air-free liquid is advanced fluidically beyond the valve;

connecting the infusion conduit to the lens-filling conduit via the valve, whereby air-free liquid is introduced into the lens.

21. An intraocular lens adjustment system for accessing an interior of an intraocular lens following implantation thereof, the system comprising:

an access tip configured for mechanical interface with a valve of the lens via an exterior surface thereof, the access tip, when engaged with the valve, forming a fluidic seal therewith;

one or more reservoirs used to store a fluid; and

one or more fluidic lines for conducting the stored fluid between the reservoir and the access tip.

22. The system of claim 21, further comprising a handpiece attached to the fluidics line and facilitating movement of the access tip relative to the intraocular lens valve.

23. The system of claim 22, wherein the handpiece further comprises means for controlling a flow of fluid between the reservoir and the access tip.

24. The system of claim 22, where the fluidics line has minimal wall compliance and is capable of carrying fluids at pressures over 10 PSI.

25. The system of claim 21, further comprising a plurality of sensors and a controller connected thereto, the sensors measuring fluid flow in the one or more fluidic lines, a refractive state of the lens, and an internal pressure of the lens, the controller being responsive to the sensors and to a geometric shape of the lens.

26. The system of claim 21, wherein a portion of at least one said fluidics line has a diameter less than 4mm to allow reaccess to a previous main corneal incision without widening the incision.

27. The system of claim 21, wherein the access tip has a diameter less than 3mm to allow self-sealing of a valve.

28. The system of claim 21, further comprising at least one mechanical pump for driving fluid between the reservoir and the access tip.

29. The system of claim 25, further comprising a metering device to monitor the fluid added or removed from the lens.

30. The system of claim 25, wherein a flow sensor is located in proximity to the access tip to account for capacitive changes in the fluid or cavitation.

31. The system of claim 25, wherein a pressure sensor is extendable past the access tip to directly monitor the pressure inside the lens.

32. The system of claim 25, wherein the pressure sensor measures pressure outside the lens.

33. The system of claim 25, wherein the access tip comprises a locking feature for mechanically engaging the valve.

34. The system of claim 33, wherein the locking feature is a tether, a vacuum, a twist-lock, or a gripper.

35. An intraocular lens explantation system comprising:

an aspiration pump;

a conduit fluidly coupled to the pump, the conduit having a distal end;

an access member at the distal end of the conduit, the access member being configured to establish fluid communication between the pump and an interior of the lens, and including:

an opening;

a peripheral contact surface surrounding the opening;

a passage fluidly coupling the opening to a lumen of the conduit; and

a gripping member extending axially through the passage and beyond the opening, the gripping member including a mechanical feature for gripping an interior wall of the lens with the peripheral contact surface against an outer surface of the lens.

36. The system of claim 36, wherein the gripping member is retractable through the passage to pull the lens therein.

37. The system of claim 36, wherein the mechanical feature is a barb.

38. The system of claim 36, wherein the mechanical feature is a pair of grippers in a forceps configuration.

39. An intraocular lens explantation system comprising:

an aspiration pump;

a conduit fluidly coupled to the pump, the conduit having a distal end; and

an access member at the distal end of the conduit, the access member establishing fluid communication between the pump and an interior of the lens and including (i) an opening, (ii) a peripheral contact surface surrounding the opening, (iii) a passage fluidly coupling the opening to a lumen of the conduit, and (iv) a cutting member for cutting the lens to establish fluid communication between an interior of the lens and the pump.

40. The system of claim 39, wherein the cutting member is disposed within the passage, suction created by the pump causing contact between the cutting member and the lens.

41. The system of claim 40, wherein the cutting member is disposed telescopically within the passage and has a blade surrounding a central bore, the central bore being in fluid communication with the pump to apply suction to the lens.

42. The system of claim 39, wherein the cutting member is configured for axial, rotary or reciprocating movement.

43. The system of claim 39, wherein the cutting member is a laser.

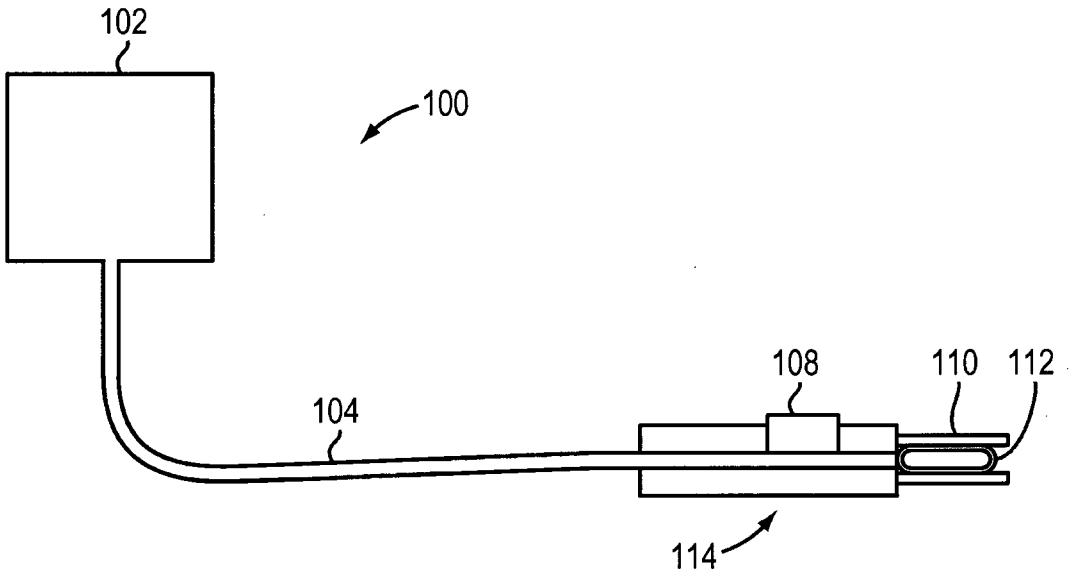

FIG. 1A

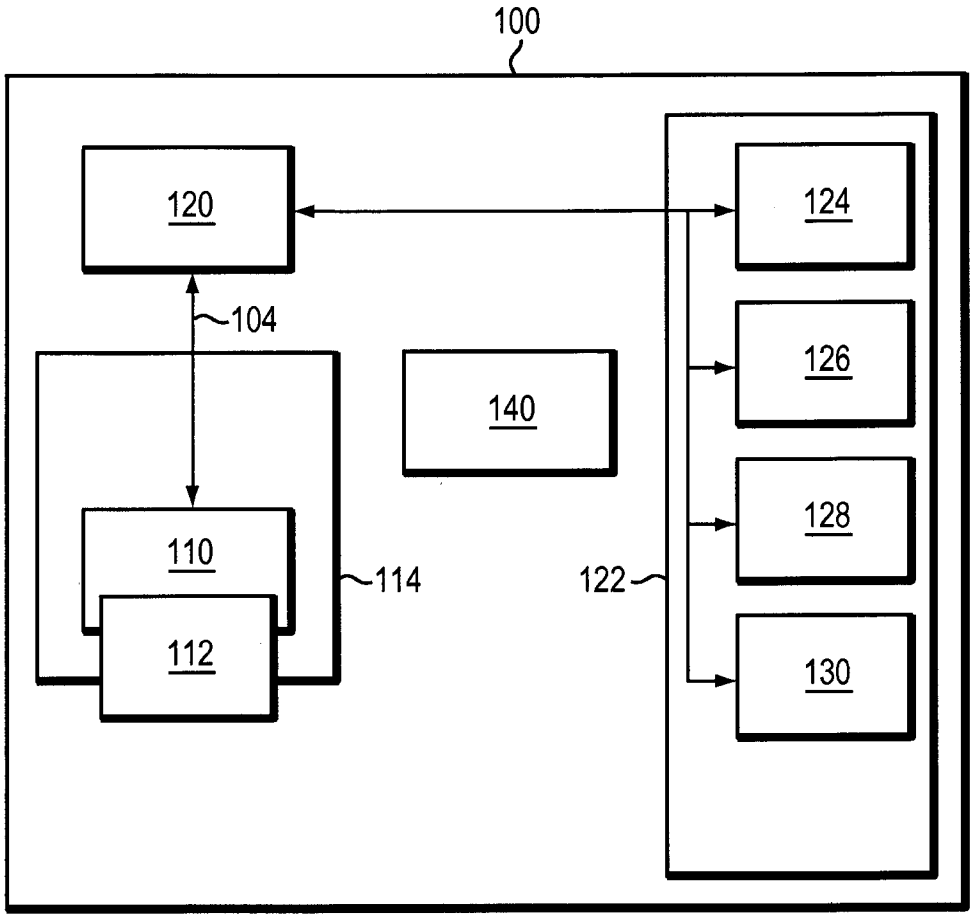

FIG. 1B

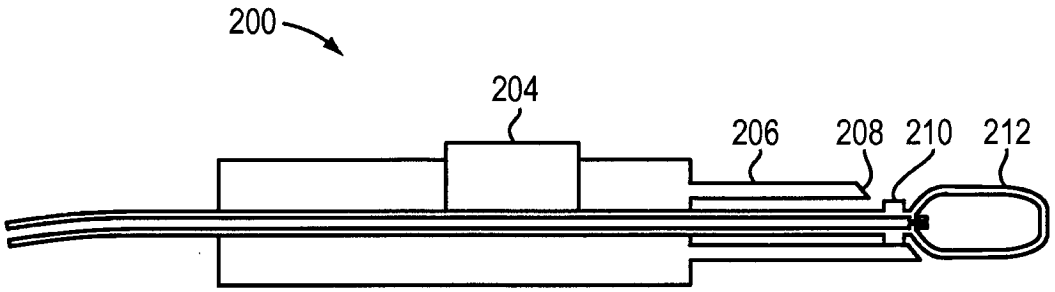

FIG. 2A

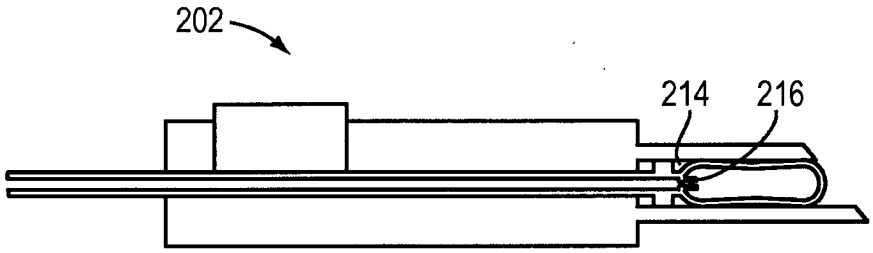

FIG. 2B

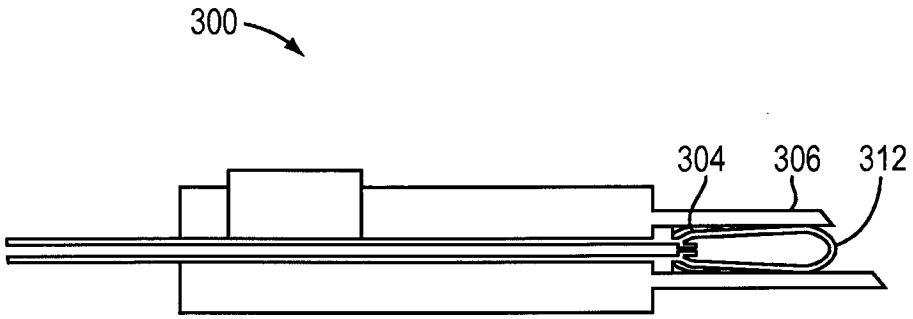

FIG. 3A

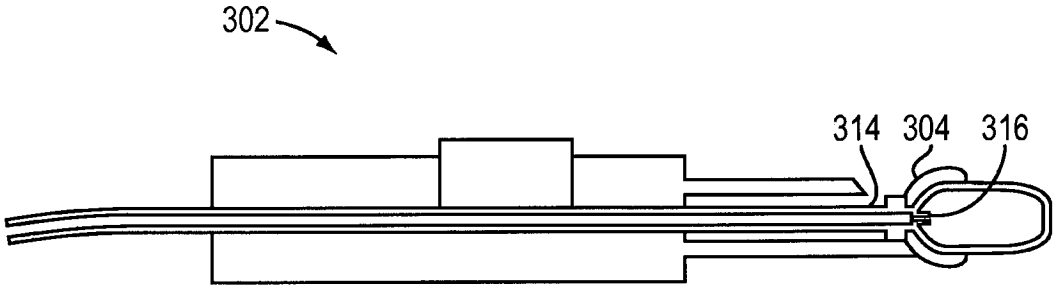

FIG. 3B

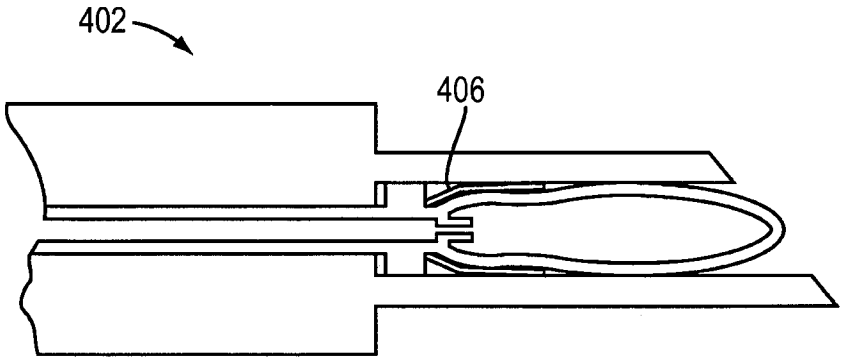

FIG. 4A

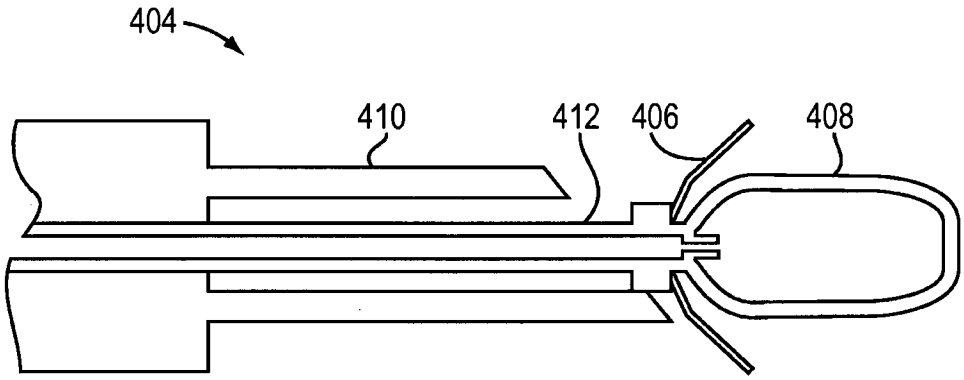

FIG. 4B

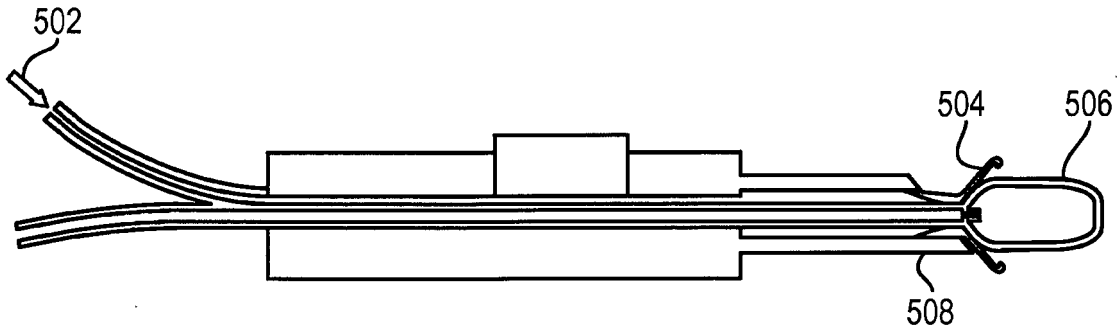

FIG. 5

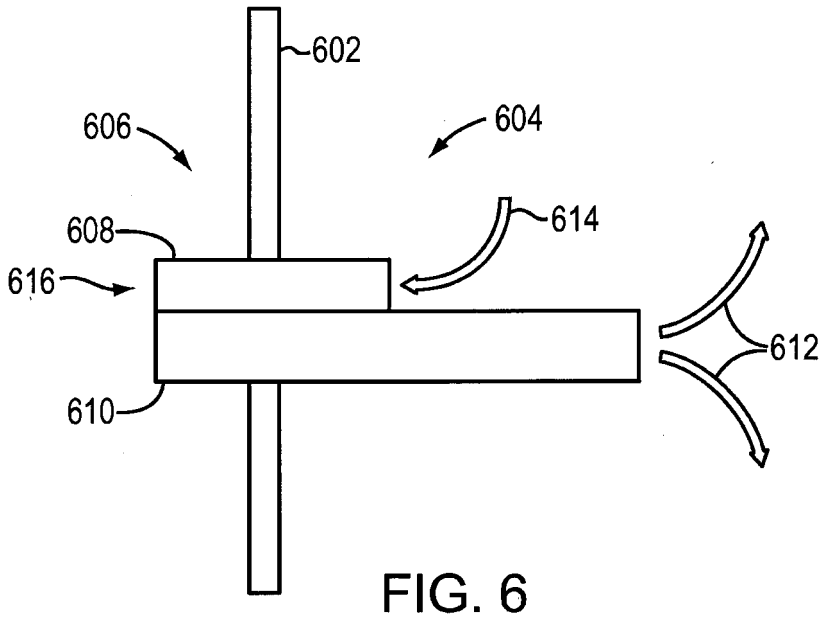

FIG. 6

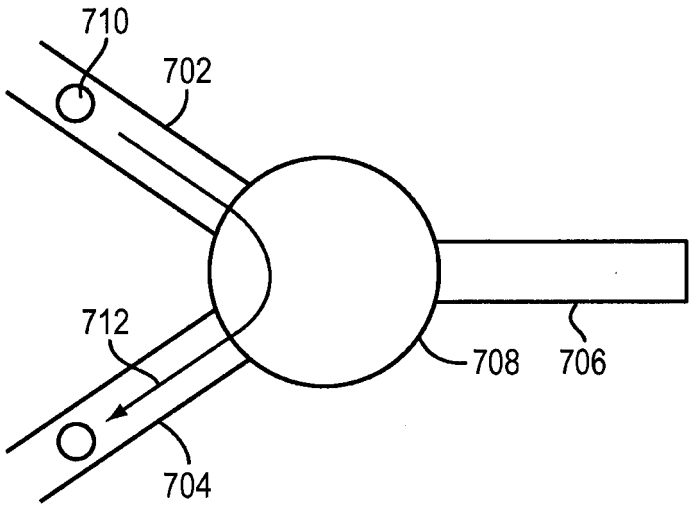

FIG. 7

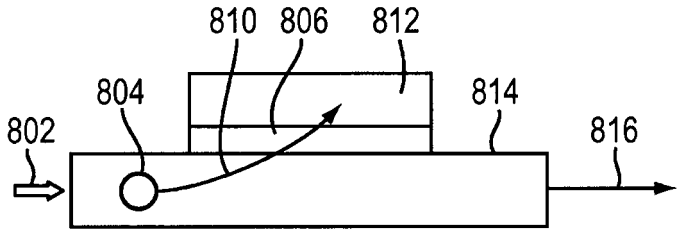

FIG. 8

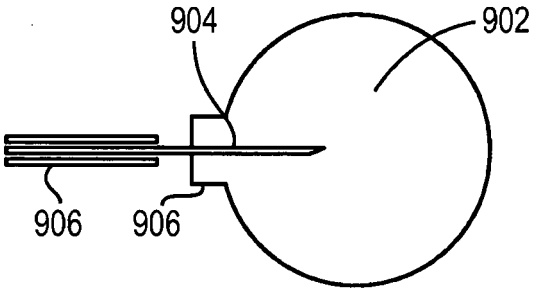

FIG. 9A

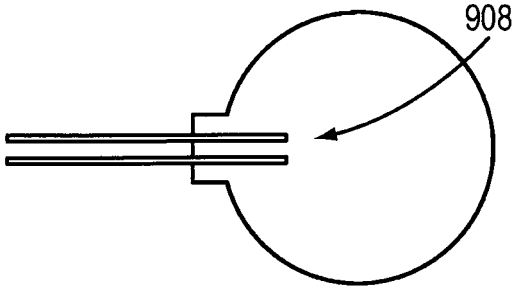

FIG. 9D

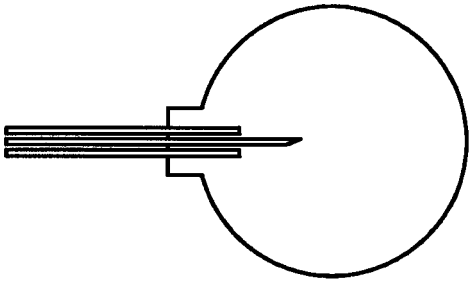

FIG. 9B

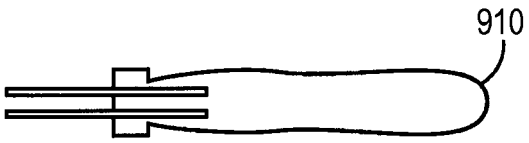

FIG. 9E

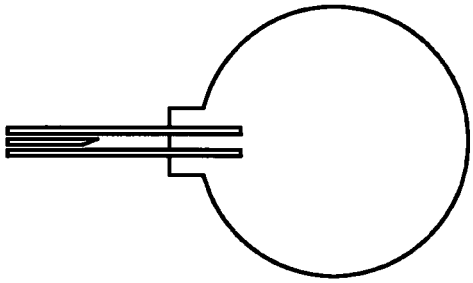

FIG. 9C

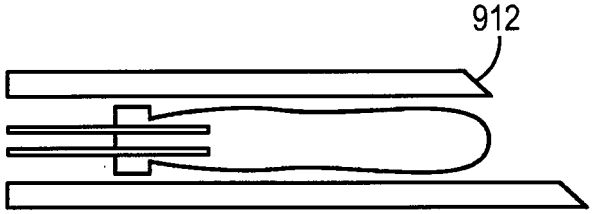

FIG. 9F

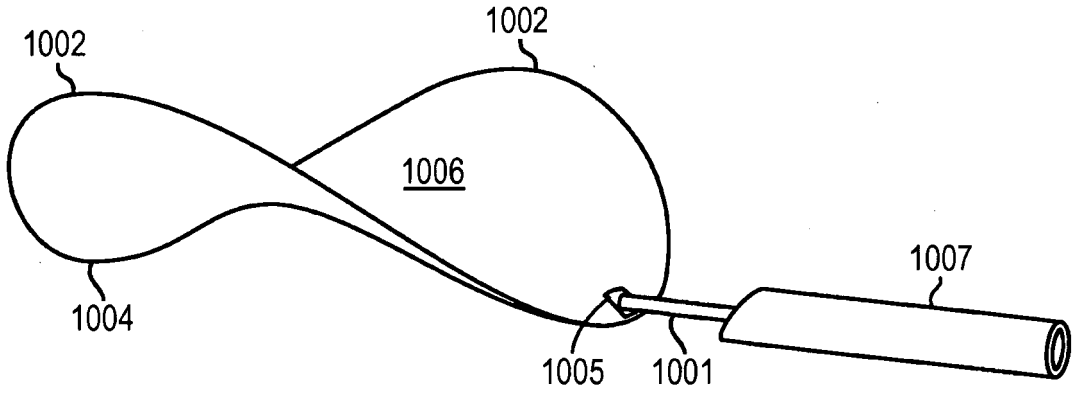

FIG. 10

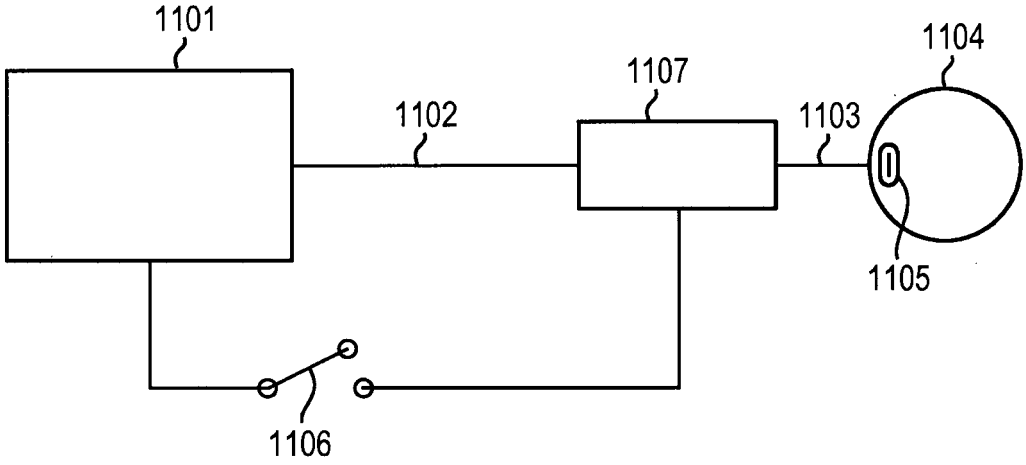

FIG. 11

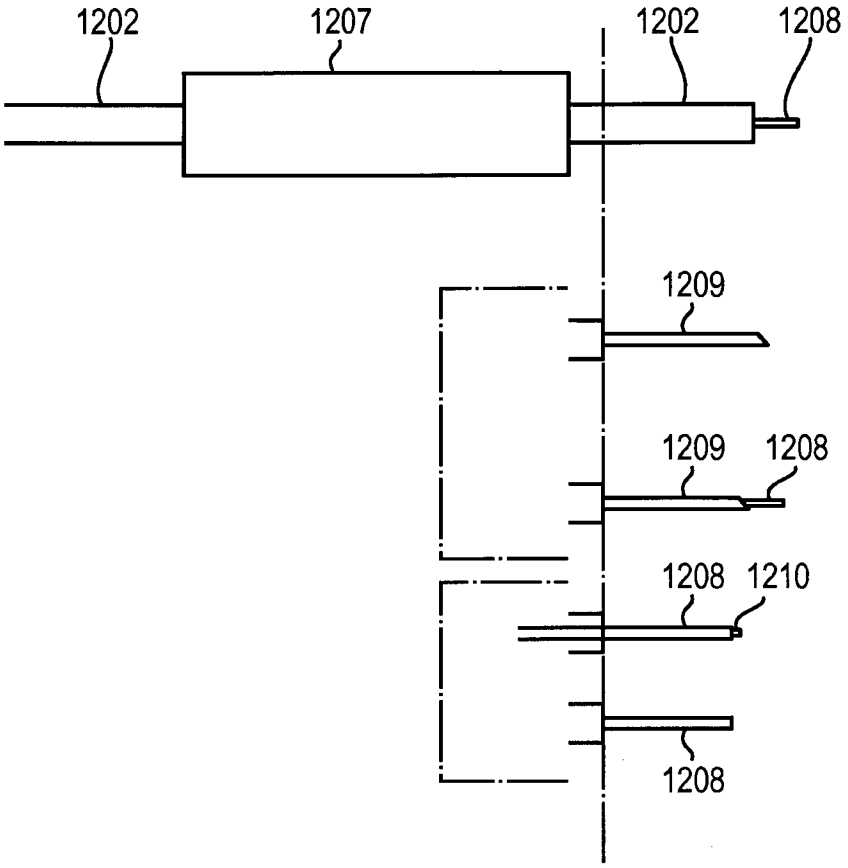
1202
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FIG. 12

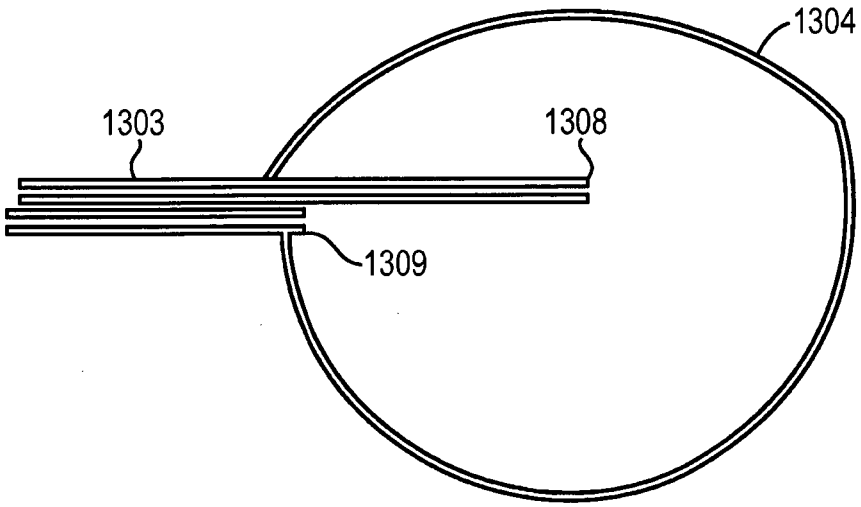
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FIG. 13

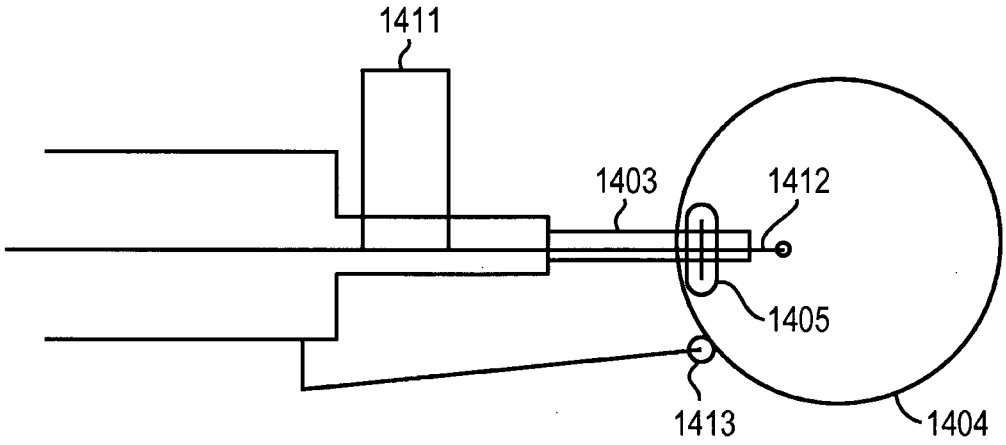

FIG. 14

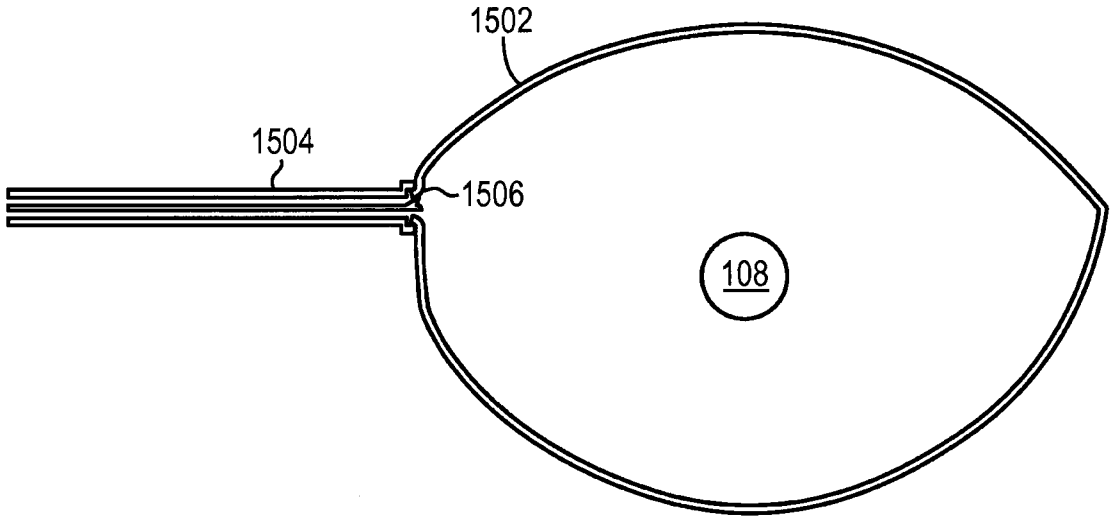

FIG. 15

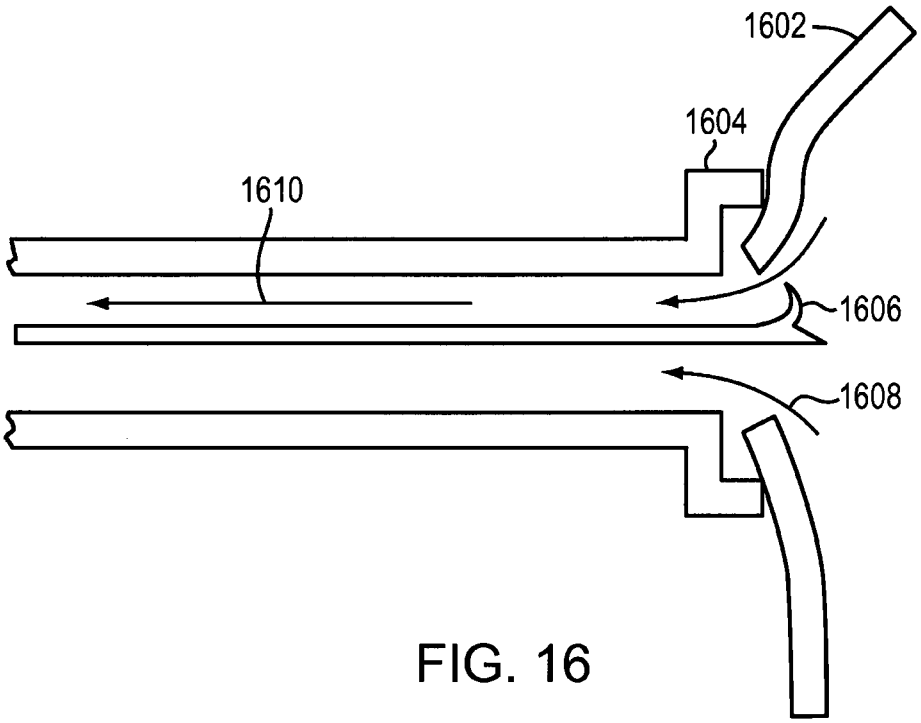

FIG. 16

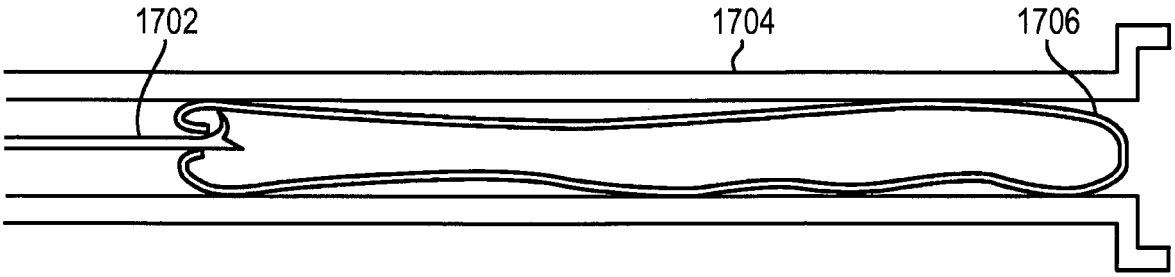

FIG. 17

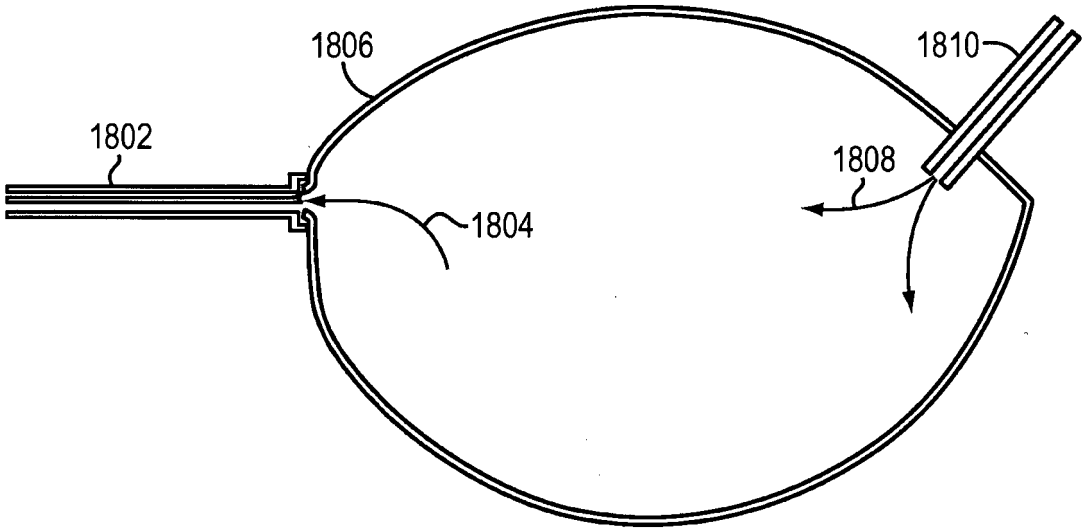

FIG. 18

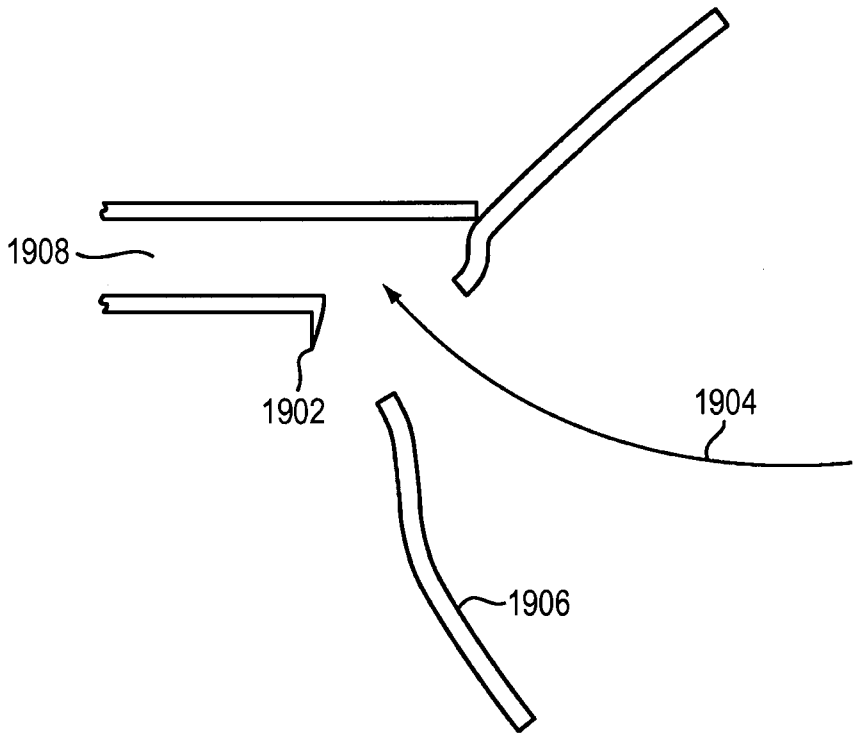

FIG. 19

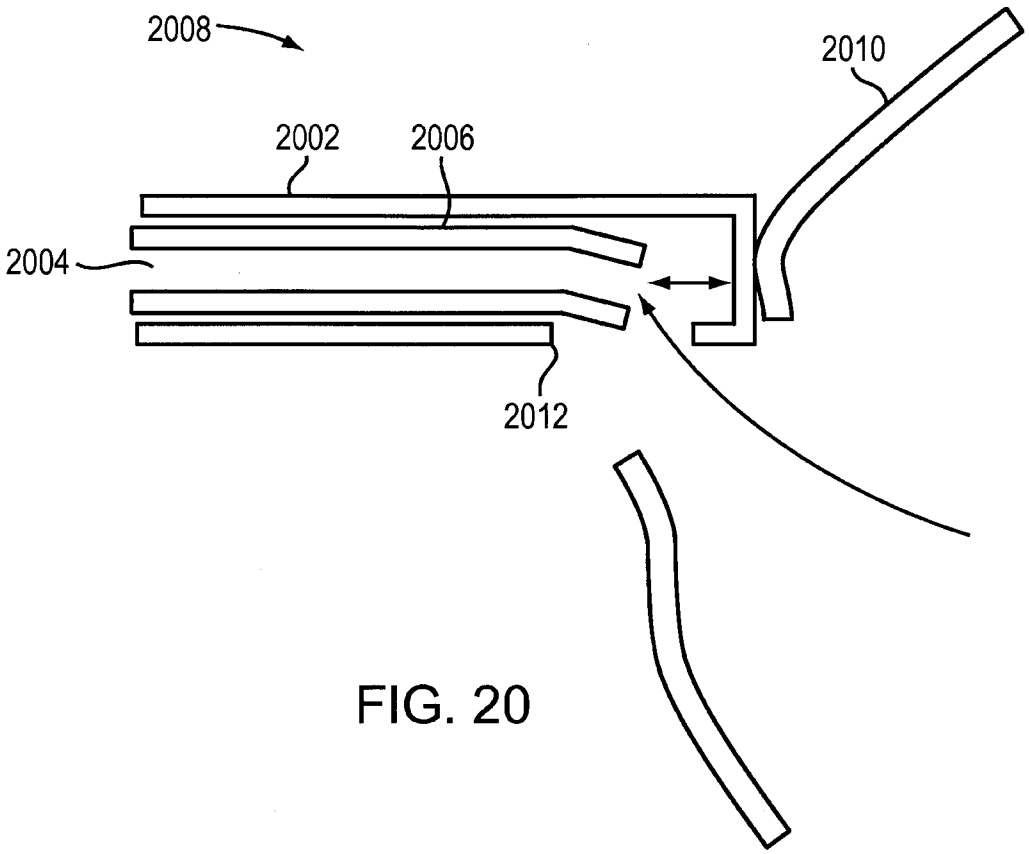

FIG. 20

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(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 December 2014 (04.12.2014)

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28 May 2014 (28.05.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

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61/829,607	31 May 2013 (31.05.2013)	US
61/862,806	6 August 2013 (06.08.2013)	US
61/930,690	23 January 2014 (23.01.2014)	US

(71) Applicant: **1CO, INC.** [US/US]; 3579 E. Foothill Blvd., #521, Pasadena, CA 91107 (US).

(72) Inventors: **DeBOER, Charles**; 704 Canyon Crest Drive, Sierra Madre, CA 91024 (US). **CABLE, Craig, Alan II**; 25192 Fairgreen, Mission Viejo, CA 92692 (US). **RIBEIRO, Ramiro, Magalhes**; 1638 Huntington Drive, Unit D, South Pasadena, CA 91030 (US). **MCCORMICK, Matthew**; 36876 Oak View Road, Yucaipa, CA 92399 (US). **CAFFEY, Sean**; 2645 Nina Street, Pasadena, CA 91107 (US). **TAI, Yu-chong**; 3191 E. California Boulevard, Pasadena, CA 91107 (US). **HUMAYUN, Mark**; 2757 Sleepy Hollow Place, Glendale, CA 91206 (US).

(74) Agents: **FRANK, Steven, J.** et al.; Bingham Mc Cutchen LLP, 2020 K Street, NW, Washington, DC 20003-1806 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM,

[Continued on next page]

(54) Title: INTRAOCULAR LENS PERIPHERAL SURGICAL SYSTEMS

(57) Abstract: Peripheral surgical systems are used for insertion and filling of fluid- filled intraocular lenses (100), reaccessing and modifying fluid-filled intraocular lenses, and explantation of lenses (1504). Although one peripheral surgical unit may perform all of these functions, in some embodiments different units perform different functions - i.e., each function may be performed by a separate unit, or the functions may be distributed over a smaller number of functional units.

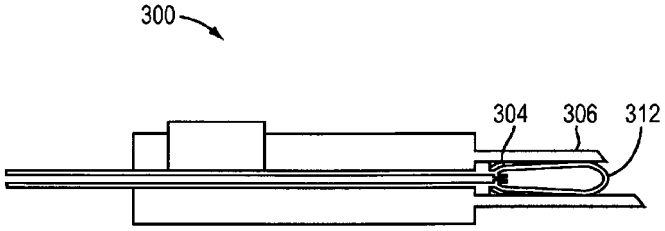

FIG. 3A

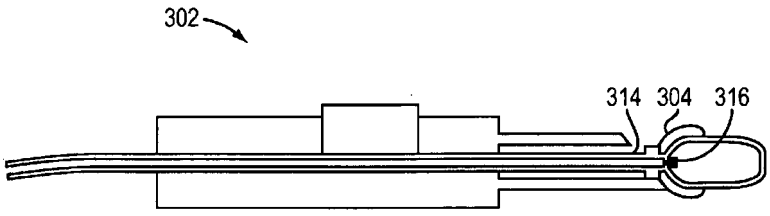

FIG. 3B

WO 2014/193953 A3

TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) **Date of publication of the international search report**:
26 February 2015

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/039792

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/16
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2012/296423 A1 (CAFFEY SEAN [US] ET AL) 22 November 2012 (2012-11-22) paragraph [0005] - paragraph [0053]; figures 1-8	1-5,8,9, 21-23, 25-33 6,7

X	US 2002/055776 A1 (JUAN EUGENE DE [US] ET AL DE JUAN JR EUGENE [US] ET AL) 9 May 2002 (2002-05-09) paragraph [0013] - paragraph [0051]; figures 2-6	1,2,8,9

X A	WO 92/17132 A1 (DAXER ALBERT [AT]) 15 October 1992 (1992-10-15) page 5, line 16 - page 7, line 27; figures 3b-6	21-23, 26-28 25

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 December 2014	07/01/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lega, A

Peripheral surgical systems are used for insertion and filling of fluid-filled intraocular lenses (100), reaccessing and modifying fluid-filled intraocular lenses, and explantation of lenses (1504). Although one peripheral surgical unit may perform all of these functions, in some embodiments different units perform different functions - i.e., each function may be performed by a separate unit, or the functions may be distributed over a smaller number of functional units.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/039792

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14-20
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [X] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

1-9, 21-34

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2014/039792

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/027460 A1 (KOBAYASHI KENICHI [JP] KOBAYASHI KENICHI [JP] ET AL) 31 January 2008 (2008-01-31) paragraph [0033] - paragraph [0044]; figures 1,2	6
Y	US 2004/097957 A1 (JAKER MARC [US] ET AL) 20 May 2004 (2004-05-20) paragraph [0041] - paragraph [0053]; figures 1-5	7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2014/039792

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012296423 A1	22-11-2012	EP 2709574 A2	26-03-2014
		US 2012296423 A1	22-11-2012
		WO 2012158773 A2	22-11-2012
US 2002055776 A1	09-05-2002	AU 7368301 A	21-01-2002
		US 2002055776 A1	09-05-2002
		WO 0205015 A2	17-01-2002
WO 9217132 A1	15-10-1992	NONE	
US 2008027460 A1	31-01-2008	EP 1800623 A1	27-06-2007
		JP 4234156 B2	04-03-2009
		JP 2007190360 A	02-08-2007
		US 2008027460 A1	31-01-2008
US 2004097957 A1	20-05-2004	US 2004097957 A1	20-05-2004
		US 2006178722 A1	10-08-2006

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-9

An intraocular lens insertion and filling system comprising: a fluidic system including one or more pumps and one or more reservoirs for a liquid; a conduit, fluidically connected to the pump and having a distal end configured for insertion into an intraocular lens; an insertion mechanism including a handpiece terminating in an insertion tube, wherein: the handpiece surrounds a distal portion of the conduit; the insertion tube is configured to receive the lens in an at least partially deflated state; and the handpiece includes an advancement mechanism for causing relative movement between the insertion tube and the lens received therewithin, whereby activation of the advancement mechanism causes the lens to be ejected from a distal end of the insertion tube.

---

2. claims: 10-13

An intraocular lens insertion and filling system comprising: a fluidic system including at least one pump and at least one reservoir for a liquid, gas, or solute; and first and second conduits fluidically connected to the pump and having distal ends configured for (i) contact with an intraocular lens and (ii) cooperation in retaining and filling the lens.

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3. claims: 21-34

An intraocular lens adjustment system for accessing an interior of an intraocular lens following implantation thereof, the system comprising: an access tip configured for mechanical interface with a valve of the lens via an exterior surface thereof, the access tip, when engaged with the valve, forming a fluidic seal therewith; one or more reservoirs used to store a fluid; and one or more fluidic lines for conducting the stored fluid between the reservoir and the access tip.

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4. claims: 35-38

An intraocular lens explanation system comprising: an aspiration pump; a conduit fluidly coupled to the pump, the conduit having a distal end; an access member at the distal end of the conduit, the access member being configured to establish fluid communication between the pump and an interior of the lens, and including: an opening; a peripheral contact surface surrounding the opening; a passage fluidly coupling the opening to a lumen of the conduit; and a gripping member extending axially through the

passage and beyond the opening, the gripping member including a mechanical feature for gripping an interior wall of the lens with the peripheral contact surface against an outer surface of the lens.

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5. claims: 39-43

An intraocular lens explanation system comprising: an aspiration pump; a conduit fluidly coupled to the pump, the conduit having a distal end; and an access member at the distal end of the conduit, the access member establishing fluid communication between the pump and an interior of the lens and including (i) an opening, (ii) a peripheral contact surface surrounding the opening, (iii) a passage fluidly coupling the opening to a lumen of the conduit, and (iv) a cutting member for cutting the lens to establish fluid communication between an interior of the lens and the pump.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 14-20

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery Claim 14 is specifying a method of filling an intraocular lens, comprising the steps of "causing ejection of the lens from the insertion tube" and "further inflating the lens with liquid to achieve a target volume". It is implicitly disclosed that the lens is implanted in the eye (first step) and from the description it is also clear, that inflating occurs after implantation. Claim 20 specifies a method of filling an intraocular lens, comprising the steps of "introducing the lens-filling conduit into the lens" and "whereby air-free liquid is introduced into the lens". From the description is clear, that the lens is already implanted. Thus, the first step necessitates introduction of the conduit within the eye and the liquid is introduced with the conduit within the eye. Therefore, these steps involves a surgical intervention. Pursuant to Art. 17 (2)(a)(i) PCT and Rule 39.1(iv) PCT, the subject-matter of independent claims 14 and 20 and of dependent claims 15-19 (which comprises all the features of claim 14) has not been searched.

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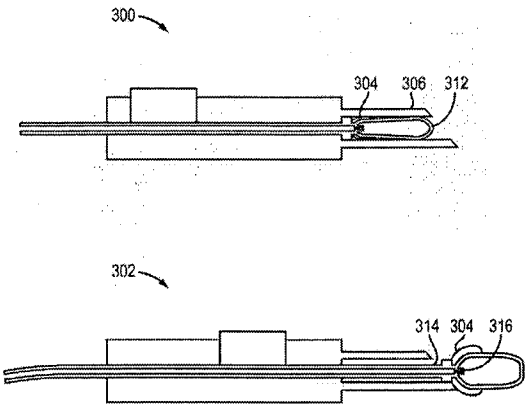
(54)发明名称

人工晶状体外围手术系统

(57)摘要

外围手术系统用于流体填充的人工晶状体的插入和填充(100),晶状体的再进入和改变,以及晶状体的移出(1504)。尽管一个外围手术单元可执行所有这些功能,在一些实施方式中,不同的单元执行不同的功能,即每个功能可由独立的单元执行,或各功能可分配在较少数量的功能单元上。



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1.一种人工晶状体插入和填充系统，其包括：

流体系统，其包括一个或多个泵以及液体的一个或多个贮存器；

导管，其流体地连接至所述泵并具有被配置为插入人工晶状体中的远端；

插入机构，其包括终止于插入管的手持件，其中：

所述手持件围绕所述导管的远端部分；

所述插入管被配置为容纳至少部分排空状态的晶状体；以及

所述手持件包括推进机构，其用于引起所述插入管和容纳在所述插入管中的晶状体之间的相对运动，由此所述推进机构的驱动使得晶状体从所述插入管的远端脱出。

2.根据权利要求1所述的系统，其中所述泵适合于在所述晶状体从所述插入管脱出后将液体从所述贮存器泵送进入所述晶状体，进而膨胀所述晶状体。

3.根据权利要求1所述的系统，其中所述流体系统包括压力传感器，用于在所述人工晶状体膨胀期间测量所述人工晶状体的内部压力。

4.根据权利要求1所述的系统，其中所述泵是双向泵，并且还包括流量传感器，用于测量通过所述泵引入所述晶状体或从所述晶状体抽出的液体量。

5.根据权利要求1所述的系统，其中所述流体系统还包括内联的屈光计，用于测量所述人工晶状体内的流体的屈光指数。

6.根据权利要求1所述的系统，其中所述推进机构包括：

至少部分地围绕所述导管的所述手持件内的流体通道；以及

柱塞，其围绕所述导管并密封地布置在所述流体通道内，由此所述柱塞能够通过压力在流体通道内推进，从而相对于所述插入管移动所述晶状体。

7.根据权利要求1所述的系统，还包括护套，其布置在所述导管的远端，用于包含晶状体的至少一部分。

8.根据权利要求1所述的系统，还包括机械抓取机构，其布置在所述导管的远端用于抓取所述晶状体。

9.根据权利要求8所述的系统，其中所述抓取机构是能够经由所述手持件推进和缩回的。

10.一种人工晶状体插入和填充系统，其包括：

流体系统，其包括至少一个泵和用于液体、气体、或溶质的至少一个贮存器；以及

第一导管和第二导管，其流体连接至所述泵并具有被配置为用于如下的远端：(i)接触人工晶状体以及(ii)在保持和填充晶状体时协作。

11.根据权利要求10所述的系统，其中：

所述第一导管延伸超过所述第二导管；

所述第一导管的远端被配置为用于插入所述晶状体内；以及

所述至少一个泵被配置为：(i)通过所述第一导管从所述贮存器泵送液体以及(ii)在所述第二导管内产生真空以能够抵靠所述第二导管的远端保持地吸引所述晶状体。

12.根据权利要求10所述的系统，其中所述第一导管和所述第二导管是同心的。

13.根据权利要求10所述的系统，其中所述第一导管和所述第二导管是相邻的。

14.一种填充人工晶状体的方法，该方法包括如下步骤：

提供具有远端的导管，所述远端布置在插入管内并能够相对于插入管移动；

将所述导管的远端插入晶状体内并将晶状体定位在所述插入管内；

经由所述导管用液体部分地膨胀所述晶状体；

使所述晶状体从所述插入管脱出；以及

用所述液体进一步膨胀所述晶状体以实现目标体积。

15.根据权利要求14所述的方法，其中所述脱出步骤通过机械地产生所述插入管和所述插入管内的晶状体之间的相对运动来发生。

16.根据权利要求15所述的方法，其中所述导管相对于所述插入管推进。

17.根据权利要求14所述的方法，其中所述脱出步骤通过流体地产生所述插入管和所述插入管内的晶状体之间的相对运动来发生。

18.根据权利要求14所述的方法，还包括在进一步膨胀后从所述晶状体抽出所述导管，由此所述晶状体具有比插入管的直径大的直径并进而被阻止进入插入管中。

19.根据权利要求14所述的方法，其中使用视觉检测、光学检测、压力监测、或流量监测中的至少一种来监视所述晶状体的泄露。

20.一种填充人工晶状体的方法，该方法包括如下步骤：

提供可选择地经由阀连接的输注导管、抽吸导管以及晶状体填充导管；

将晶状体填充导管引入所述晶状体内；

经由所述阀将所述输注导管连接至所述抽吸导管并使填充液体从中流经，由此无空气的液体被流体地推进越过所述阀；

经由所述阀将所述输注导管连接至所述晶状体填充导管，由此无空气的液体被引入所述晶状体内。

21.一种用于在人工晶状体植入后进入人工晶状体内部的人工晶状体调节系统，该系统包括：

进入尖端，其被配置为经由其外表面与晶状体的阀机械地配合，所述进入尖端在与所述阀啮合时形成与其的流体密封；

一个或多个贮存器，用于储存流体；以及

一个或多个流体线路，用于在所述贮存器和所述进入尖端之间引导所储存的流体。

22.根据权利要求21所述的系统，还包括手持件，所述手持件连接至所述流体线路并促进所述进入尖端相对于人工晶状体阀的运动。

23.根据权利要求22所述的系统，其中所述手持件还包括用于控制所述贮存器和所述进入尖端之间的流体流量的部件。

24.根据权利要求22所述的系统，其中所述流体线路具有最小壁顺应性并能够在超过10PSI的压力下承载流体。

25.根据权利要求21所述的系统，还包括多个传感器和连接至传感器的控制器，所述传感器测量一个或多个流体线路内的流体流量、晶状体的屈光状态、以及晶状体的内部压力，所述控制器响应于所述传感器和所述晶状体的几何形状。

26.根据权利要求21所述的系统，其中至少一个所述流体线路的一部分具有小于4mm的直径以允许再进入先前的主要角膜切口而不会加宽所述切口。

27.根据权利要求21所述的系统，其中所述进入尖端具有小于3mm的直径以允许阀的自密封。

28.根据权利要求21所述的系统，还包括至少一个机械泵用于驱动所述贮存器和所述进入尖端之间的流体。

29.根据权利要求25所述的系统，还包括计量设备，用于监视添加至所述晶状体或从晶状体移除的流体。

30.根据权利要求25所述的系统，其中流量传感器被定位在所述进入尖端附近以解释流体的电容变化或气穴现象。

31.权利要求25所述的系统，其中压力传感器能够延伸穿过所述进入尖端以直接监视所述晶状体内的压力。

32.根据权利要求25所述的系统，其中所述压力传感器测量所述晶状体外的压力。

33.根据权利要求25所述的系统，其中所述进入尖端包括用于机械地啮合所述阀的锁定特征。

34.根据权利要求33所述的系统，其中所述锁定特征是绳索、真空、转锁、和/或夹持器。

35.一种人工晶状体移出系统，其包括：

抽吸泵；

流体地耦合至泵的导管，所述导管具有远端；

所述导管的远端处的进入构件，所述进入构件被配置为建立所述泵和所述晶状体内部之间的流体连通，并且包括：

开口；

围绕所述开口的外围接触表面；

将所述开口流体地耦合至所述导管的管腔的通道；以及

抓取构件，其通过通道轴向地延伸并超出所述开口，所述抓取构件包括用于抓取所述晶状体的内壁的机械特征，所述外围接触表面抵靠所述晶状体的外表面。

36.根据权利要求36所述的系统，其中所述抓取构件能够通过所述通道缩回以将所述晶状体牵拉至其中。

37.根据权利要求36所述的系统，其中所述机械特征是倒钩。

38.根据权利要求36所述的系统，其中所述机械特征是以镊配置的一对夹持器。

39.一种人工晶状体移出系统，其包括：

抽吸泵；

流体地耦合至泵的导管，该导管具有远端；以及

所述导管的远端处的进入构件，所述进入构件建立所述泵和所述晶状体内部之间的流体连通，并包括(i)开口，(ii)围绕所述开口的外围接触面，(iii)将所述开口流体地耦合至所述导管的管腔的通道，以及(iv)切割构件，其用于切割所述晶状体以建立所述晶状体内部和所述泵之间的流体连通。

40.根据权利要求39所述的系统，其中所述切割构件被布置在所述通道内，由所述泵产生的抽吸引起所述切割构件和所述晶状体之间的接触。

41.根据权利要求40所述的系统，其中所述切割构件可伸缩地布置在所述通道内并具有围绕中心孔的刀片，所述中心孔与所述泵流体连通以对所述晶状体施加抽吸。

42.根据权利要求39所述的系统，其中所述切割构件被配置为轴向、旋转、或往复运动。

43.根据权利要求39所述的系统，其中所述切割构件是激光器。

人工晶状体外围手术系统

[0001] 相关申请的交叉引用

[0002] 本申请要求美国序列号No.61/828,018(于2013年5月28日提交)、61/829,607(于2013年5月31日提交)、61/862,806(于2013年8月6日提交)、以及61/930,690(于2014年1月23日提交)的优先权和权益。这些优先权文件的全部公开内容通过引用包含于此。

技术领域

[0003] 在各个实施方式中,本发明总体上涉及可植入人工晶状体,以及更加具体而言,涉及关于流体填充的人工晶状体的外围手术系统。

背景技术

[0004] 人体眼睛的晶状体将光线屈光并聚焦到视网膜上。通常晶状体是透明的,但它由于衰老、损伤、炎症、代谢和营养失调、或辐射会变得混浊(即,在患白内障时)。虽然一些晶状体混浊是小的且不需要治疗,而其他的会足够大以致阻碍光线的相当一部分并妨碍视力。

[0005] 通常,白内障治疗包括通过患者角膜外围中的小切口例如使用超声乳化术和/或飞秒激光从晶状体囊手术地移除混浊晶状体本体。然后,人造的人工晶状体(IOL)能够被植入晶状体囊袋(所谓的"袋内植入")中以替代人眼晶状体。通常,IOL是由可折叠材料制成,诸如硅树脂或丙烯酸树脂,用于最小化切口尺寸和所需的缝线、并因此最小化患者的康复时间。最通常使用的IOL是提供单个焦距的单元件晶状体(或单焦点IOL);所选择的焦距通常提供相当好的远距视力。然而,由于该焦距在IOL植入后不可调节,植有单焦点IOL的患者不再能够聚焦在近距离(例如,小于25cm)处的物体上;这导致近距离处的差的视力。

[0006] 用于传统IOL的插入系统通常包括插入设备主体和IOL行进所穿过的小直径插入管。插入管被置于眼睛中的手术切口内并且IOL从插入设备主体被推进穿过管并插入到眼睛内。通常,随着晶状体穿过插入管,使用粘弹性物质、诸如透明质酸或等效物润滑晶状体。在插入后,IOL展开并被定位在准确的解剖位置,最常见的在晶状体囊中。

[0007] 最近,已经开发了液体填充的人工晶状体;它们可以被插入到眼睛内然后被填充。该设计的优点包括通过小切口部署的能力,然后晶状体在原位膨胀。小的插入直径减少了手术后恢复时间,允许外科医生避免使用缝合来闭合切口,并减少了术后散光。因此,为了较好的手术结果,小于3mm,并优选小于2mm的切口是手术人员所期望的。另外,某些液体填充的人工晶状体设计在植入后能够被调节以确保通过晶状体内的填充介质的调节的屈光校正的精确视力。在做成柔性的时,流体填充的晶状体能够依靠眼睛的自然聚焦能力(例如,使用睫状肌的收缩)来提供可调节的焦距(或适应性调节)。

[0008] 不像传统的在插入后不可填充的人工晶状体,被设计为以半排空或完全排空状态部署(两种情形在本文中均称为"排空状态")的液体晶状体均被部署到眼睛内并在部署后膨胀。因此通常需要专用的插入和填充系统来植入这些晶状体。

[0009] 另外,这些晶状体能够具有在植入后被调节的流体内容物。因此,需要一种在植入

之前、植入期间、和植入之后进入流体填充的IOL的流体内容物并且调节IOL的内容物的工具。

发明内容

[0010] 根据本文的外围手术系统用于流体填充的人工晶状体的插入和填充、晶状体的再进入和改变、以及晶状体的移出。尽管一个外围手术单元可执行所有这些功能，但是在一些实施方式中，不同的单元执行不同的功能—即，每个功能可由单独的单元执行，或各功能可以在较少数量的功能单元上分配。本发明还可以用作为用于诸如巩膜扣压或隆胸的其他流体填充的可植入设备的外围手术系统。

[0011] 在一个方面，本发明涉及人工晶状体插入和填充系统。各个实施方式包含与排空的人工晶状体流体连续的流体线路以及用于将人工晶状体部署在眼睛内的插入系统。流体系统用于在将晶状体部署在眼睛内之后用流体填充晶状体。如本文中所使用的，术语“流体”通常指代液体，但在一些情形中也指代或包含气体和/或溶质。例如，由于气压变化将引起适应性调节的不期望变化，气体将不适用于植入物。

[0012] 流体系统可以包括输注泵，但是可以可替代地或另外地使用抽吸泵。输注泵负责将流体分配到流体填充的人工晶状体内。在一个实施方式中，输注泵由注射泵组成或包含注射泵，注射泵能够分配精确体积的流体。这尤其适用于粘性流体，诸如硅油，这里需要高压力从而以足够的速度分配。此外，注射泵减少了使用其他泵送技术可能会发生的压力冲击。

[0013] 在存在抽吸泵时，抽吸泵负责从IOL移除介质。合适的抽吸泵包括但不限于齿轮泵、蠕动泵、文丘里泵、以及注射泵。某些泵可以被放置为直接与抽吸线路一致但不污染抽吸线路。例如，蠕动泵能够具有从泵的抽吸侧附接至它的管。其他泵附接至与抽吸线路流体接触的盒。其示例包括用空气操作的泵，例如连接至真空贮存器的文丘里泵。泵用于从贮存器抽出空气，然后将流体驱动进入贮存器。然而，在该实现方式中流体从不接触泵。

[0014] 在某些实施方式中，输注泵和抽吸泵具有连接至手持件的不同流体线路。在一个实施方式中，两个不同线路分别承载输注和抽吸。在该配置中，手持件尖端利用并排配置或同心配置的两个套管。一个套管用于将流体注射进入IOL中，而另一个用于抽吸。输注和抽吸能够同时地发生。该方法有利于例如IOL的流体交换。流体交换的一个特定用途是将一种屈光指数的流体移除并替换为另一种屈光指数的流体。在某些实施方式中，在晶状体流体交换期间监视晶状体填充流体的的屈光指数并用于确定用于交换的流体的量。优选的是使得抽吸套管大于输注套管，这是因为抽吸被限定为一个大气压的最大真空，而输注能够在大得多的压差下发生。

[0015] 在另一实施方式中，抽吸线路和输注线路在阀内汇合并通过单个线路运载至设备的尖端。尖端通常具有单个套管。在输注激发时，它通过设备的尖端发生。在抽吸激发时，阀处于相反位置，并且抽吸来自尖端的流体。这提供了用于特定尖端尺寸的输注和抽吸二者的最大总面积。在第三个位置，输注和抽吸线路是流体连接的。该配置当然是非限制性的，并且能够使用在线路之间的其他切换模式——例如，独立且远程地闭合线路。

[0016] 在本发明的该实施方式中的抽吸线路能够用于填装线路并将气泡从中移除。抽吸线路和输注线路可在靠近尖端远端的阀或Y型连接器内汇合。随着抽吸和输注线路流体地

连接，在流体输注期间给抽吸线路施加真空。输注的流体沿着来自注射器输注侧的路径并直接至抽吸线路，但决不会移动至尖端的最远端。因此，没有流体行进离开尖端，保持尖端清洁不受流体残留物影响而允许所有线路被填装并清除空气。在进入液体填充的IOL的阀内时期望保持清洁的注射器尖端以阻止任何液体接触IOL的外表面。另外，这在晶状体与尖端流体接触时是期望的。晶状体能够例如在连接流体系统之前与线路内的空气流体接触。然后通过晶状体直接连接至输注尖端来填装系统。例如，晶状体可以在填充流体连接至注射器之前安装至注射尖端，随后填充流体连接至注射器；在填充流体的连接后，线路被穿过输注线路的输注流体和穿过抽吸线路的抽吸所填装。尽管讨论了真空与抽吸线路一起使用，但这并非必需的。如果抽吸线路具有相对于系统的其他部件的低流体阻力，或者如果阀封闭尖端的远端，不需要真空来填装该线路。另外，线路可终止于手持件中的贮存器以允许流体的收集。贮存器可具有半透膜以允许流体填充贮存器而气体自由地流出贮存器。

[0017] 在一些实施方式中，诸如除气或除泡过滤器的选择性过滤器用于从液体和线路中移除空气。选择性过滤器用于允许空气而不是流体穿过。在线路的填装和流体的输注期间，空气和空气泡通过该选择性过滤器从线路抽出。作为示例，半透膜管可用作为输注线路的一部分。在外部对半透膜管施加真空。随着空气或流体穿过填充管的该部分，外部真空从线路移除空气。可替代地或另外地，空气捕获设备，诸如输注线路中的外袋，可用于随着空气泡穿过输注线路而捕获空气泡，防止空气泡进入晶状体。

[0018] 在各个实施方式中，单个泵用于通过单个或多个套管的抽吸和输注。

[0019] 手持件的尖端可包括用于进入液体填充的IOL的内部内容物的一个或多个套管。在一个实施方式中，尖端包括钝头套管或由钝头套管组成，其在远端具有薄壁、缩减直径的聚合物。该聚合物被选择以保持足够的刚性以进入晶状体，但钝头末端防止对晶状体壁的破坏。合适的聚合物包括但不限于聚酰亚胺、特氟纶、PEEK、聚酯、尼龙、聚乙烯、和ABS。

[0020] 在本发明的某些实施方式中，输注和抽吸系统用于监视被输注进入人工晶状体或被抽吸离开人工晶状体的流体的体积。可替代地或另外地，可以监视晶状体内的压力。还可以(或可替代地)例如通过内联的屈光计监视填充流体的屈光指数。监视填充或抽吸、晶状体内的压力、或填充流体的屈光指数能够用于确定晶状体填装的量、交换的流体的量、交换流体的屈光属性、以及晶状体的光学属性。因此，该方法能够用于确定所植入人工晶状体的合适屈光度。

[0021] 在某些实施方式中通过将尖锐的点插入晶状体的阀部分或IOL中的聚合膜来装载IOL。然后随着尖锐的点对尖锐的点将套管插入阀部分/聚合物膜中，类似于穿刺套管插入，或者在移除尖锐的点之后将套管插入阀部分/聚合物膜中。如果使用穿刺套管插入的方式，那么在套管插入之后移除尖锐的点。

[0022] 在代表性的应用示例中，首先使用尖锐的点经由IOL的密封部进入IOL，例如突出通过插入和填充系统的尖端的尖锐的镍钛诺丝。接下来，注射系统的管状尖端被插入通过IOL的密封部分。镍钛诺丝从注射器移除并且使用晶状体的压力、流量、光学、或视觉监视来测试晶状体的密封。在晶状体通过密封测试时，其被排空并引入插入管内。流体线路连接至晶状体。在某些实施方式中，在连接至插入系统前填装线路。在其他实施方式中，在连接至插入系统后填装线路，而晶状体连接至插入和填充系统。

[0023] 在代表性的系统实施方式中，根据本发明的人工晶状体插入和填充系统包括流体

系统，其与人工晶状体的内部连接；流体系统能够在植入眼睛内之后从人工晶状体填充或移除流体。使用机械和/或流体力从插入尖端部署人工晶状体，并随后通过插入和填充系统使人工晶状体膨胀。该系统可以被配置为测量人工晶状体的压力；注射进入人工晶状体或从人工晶状体移除的流体流量和体积；和/或人工晶状体内部的流体的屈光指数。在一些实施方式中，柱塞用于提供插入系统的管腔的周围的密封并使用由柱塞的密封产生的流体力将晶状体插入眼睛内。

[0024] 在某些实施方式中，护套在晶状体装载和/或插入期间环绕晶状体。包括两个或多个构件的机械抓取机构可用于将晶状体引入插入系统中和从插入系统中排出。例如，抓取系统可用于在植入人工晶状体后再进入IOL的密封部分。

[0025] 在一些实施方式中，插入管是透明的或半透明的用于所加载晶状体的可视化。人工晶状体可通过视觉检测、光学检测、压力监测、或流量监测中的一个或多个来监视泄露。

[0026] 在另一个方面，本发明涉及用于在人工晶状体植入后进入人工晶状体内部的人工晶状体调节系统。在各个实施方式中，该系统包括进入尖端，其被配置为通过其外表面与晶状体的阀机械配合，进入尖端在于阀啮合时形成与其的流体密封；一个或多个贮存器，用于储存流体；以及一个或多个流体线路，用于在贮存器和进入尖端之间引导所储存的流体。

[0027] 该系统还可包括手持件，其连接至流体线路并促进进入尖端相对于人工晶状体阀的运动。例如，手持件可以包括用于控制贮存器和进入尖端之间流体的流量的工具。在一些实施方式中，流体线路具有最小壁顺应性并能够在超过10PSI的压力下承载流体。

[0028] 在各个实施方式中，该系统还包括多个传感器和连接至传感器的控制器，所述传感器测量一个或多个流体线路内的流体流量、晶状体的屈光状态、以及晶状体的内部压力，控制器响应于传感器和晶状体的几何形状。至少一个流体线路的一部分可具有小于4mm的直径以允许再进入先前的主要角膜切口而不会加宽切口。进入尖端可具有小于3mm的直径以允许阀的自密封。

[0029] 在典型的实现方式中，该系统包括至少一个机械泵用于驱动贮存器和进入尖端之间的流体。该系统可包括计量设备，用于监视添加至晶状体或从晶状体移除的流体。在一些实施方式中，流量传感器被定位在进入尖端附近以解释流体的电容变化或气穴现象。压力传感器在存在时可延伸穿过进入尖端以直接监视晶状体内的压力。可替代地或另外地，压力传感器可测量晶状体外的压力。

[0030] 在各个实施方式中，进入尖端包括用于机械地啮合阀的锁定特征。例如，锁定特征可以是绳索、真空、转锁、和/或夹持器。

[0031] 在另一个方面，本发明涉及人工晶状体移出系统。在各个实施方式中，该系统包括抽吸泵；流体地耦合至泵的导管，该导管具有远端；导管远端处的进入构件；该进入构件被配置为建立泵和晶状体内部之间的流体连通，并包括(i)开口，(ii)围绕开口的外围接触表面，(iii)将开口流体地耦合至导管的管腔的通道，以及抓取构件，其通过通道轴向地延伸并超出开口，抓取构件包括用于抓取晶状体的内壁的机械特征，外围接触表面抵靠晶状体的外表面。

[0032] 在一些实施方式中，抓取构件能够通过通道缩回以将晶状体牵拉至其中。该机械特征例如可以是倒钩或以镊配置的一对夹持器。

[0033] 本发明的又一方面涉及一种人工晶状体移出系统。在各个实施方式中，该系统包

括抽吸泵；流体地耦合至泵的导管，该导管具有远端；导管远端处的进入构件，该进入构件建立泵和晶状体内部之间的流体连通，并包括开口、围绕开口的外围接触表面、将开口流体地耦合至导管的管腔的通道，以及切割构件，其用于切割晶状体以建立晶状体内部和泵之间的流体连通。

[0034] 在一些实施方式中，切割构件被布置在通道内，由泵产生的抽吸引起切割构件和晶状体之间的接触。切割构件可以伸缩地布置在通道内并具有围绕中心孔的刀片，中心孔与泵流体连通以对晶状体施加抽吸。切割构件可以被配置为轴向、旋转、或往复运动。在一些实施方式中，切割构件是激光器。

[0035] 另一代表性系统实施方式包括流体系统，其与人工晶状体内部流体连通并能够在植入眼睛后填充人工晶状体。第二流体系统用于通过插入尖端输注流体并辅助将人工晶状体部署于眼睛内，并且可使用机械和流体力组合从插入尖端部署人工晶状体。晶状体随后通过插入和填充系统膨胀。

[0036] 又一代表性系统实施方式包括流体系统，其与人工晶状体内部流体连通并能够在植入眼睛后填充人工晶状体。该系统还包括一个或多个输注系统，其用于在人工晶状体植入之前、期间、或之后将流体输注进入眼睛内；或抽吸系统，其用于在人工晶状体植入之前、期间、或之后将流体输注进入眼睛内。

[0037] 又一代表性系统实施方式包括流体系统，其与人工晶状体内部流体连通并能够在植入眼睛后填充人工晶状体。人工晶状体从插入尖端被部署并随后由插入和填充系统膨胀。该系统被配置为允许通过单个或多个管腔输注和抽吸。

[0038] 又一代表性系统实施方式包括流体系统，其与人工晶状体内部流体连通并能够在植入眼睛后填充人工晶状体。该系统被配置为使得在插入人工晶状体和插入尖端之后，插入尖端从人工晶状体缩回并且人工晶状体被膨胀。

[0039] 根据本发明的另一代表性人工晶体插入和填充系统包括流体系统，其与人工晶状体内部流体连通并能够在植入眼睛后填充人工晶状体。在该实施方式中，流体系统包括三条单独流体线路：输注线路、抽吸或排放线路、以及用于进入IOL的尖端。这三个单独的流体线路可通过Y连接器或阀连接。在系统填装期间，空气和流体从输注线路传输至抽吸或排放线路，并且在IOL膨胀后，流体从输注线路传输至抽吸线路。

[0040] 根据本发明的用于制备用于植入的IOL的代表性方法包括在IOL中插入流体线路，使用空气或流体膨胀IOL，以及使用压力和/或流体流量视觉地、光学地检查IOL的泄露。在晶状体被认定为不泄露后，IOL可以被膨胀并引入管中用于插入到眼睛内。

[0041] 在另一代表性方法中，在人工晶状体和填充系统之间提供流体连续性，使用机械和/或流体力将人工晶状体部署在眼睛内，以及膨胀人工晶状体。例如，人工晶状体和插入尖端可插入到眼睛内，插入尖端可在人工晶状体附近缩回，以及人工晶状体可以膨胀。

[0042] 在多个方面，本发明涉及通过阀或再进入端口再进入流体填充的人工晶状体，阀或再进入端口可包括流体连接件或由流体连接件组成，流体连接件将流体填充的人工晶状体与阀或管内的自密封介质耦合。执行该再进入以膨胀、排空、或交换流体。在涉及膨胀流体填充的人工晶状体时，这基本涉及将另外的流体注射进入已经包含流体的晶状体内的过程，以及将可溶性物质或不可溶物质或药物注射进入已存在的流体中。注射与流体填充的人工晶状体内已经存在的流体的成分相同的流体的主要目的是改变晶状体的体积。然后根

据晶状体设计改变晶状体前部、后部或两者的曲率。这将改变晶状体的基本屈光度，进而改变角膜的屈光指数。基本屈光度变化能够类似地通过从流体填充的人工晶状体移除流体来实现。

[0043] 在其他实施方式中，晶状体的前部和后部曲率在填充期间不改变但晶状体的不同属性改变。一个实施方式允许人工晶状体尺寸的变化，允许人工晶状体和周围晶状体囊之间的更好的保形适配。在前部和后部曲率不变化的又一实施方式中，注射不同屈光指数的流体，进而改变流体填充的人工晶状体的屈光指数。可溶解示例是将高浓度糖水注射到基于水的填充晶状体内。由于屈光指数通过材料成分改变并可以通过掺质剂(即，糖浓度)改变，较高的糖浓度能够用于增加填充流体的屈光指数。尺寸低于散射系数的许多其他掺杂剂可以替代。包括液体压力、温度、及光频率的额外的其他因素也改变屈光指数。

[0044] 在另一实施方式中，将交联剂注射进入非固化或局部固化的硅树脂填充晶状体内。在硅树脂的固化过程期间(即，烘干、时间、UV曝光)，发生交联以及硅树脂分子的屈光属性变化，进而改变屈光指数。在其他实施方式中，可以使用与除了硅树脂的可替代材料的固化方法兼容的不同的交联剂。具体示例包括水凝胶、丙烯酸树脂、苯基代硅树脂、或氟硅氧烷。在其他实施方式中，注射进入晶状体内的流体是化学改性的种属以交联或化学键合晶状体的现有内部内容物。作为示例，苯基代硅树脂比非苯基代硅树脂具有更高的屈光指数。屈光指数与硅树脂中的苯基代实体的量成比例。因此，通过采用低水平的苯基代硅树脂或者在晶状体的内部内容物中增加具有苯基取代的单体，能够增加屈光指数。类似地，通过非取代的、或低水平取代的硅树脂与现有苯基取代的硅树脂交联，能够减小屈光指数。交联可在很长一段时间上发生，长于6小时，以及在一些实施方式中长于三个月。在某些实施方式中，交联通过90天基本完成，进而允许通过改变内部成分直至完全固化而调节晶状体的屈光指数达90天。在其他实施方式中，交联绝不完整，以及轻度交联产生能够在植入物的寿命期间改性的凝胶。

[0045] 在其他实施方式中，非可溶性液体被注射以膨胀晶状体并增加晶状体的体积，从而它能够再成形晶状体周围的组织或破坏组织与晶状体的现有结合。这能够通过将空气注射进入流体填充的人工晶状体来实现。空气然后能够通过晶状体的膜扩散出。用于注射可溶物或不可溶物进入流体填充的人工晶状体的其他原因是减少穿过晶状体的紫外光的量。药物也可以被注射进入流体填充的人工晶状体内用于延长药物输送。在本发明的某些实施方式中，周期地将药物注射至晶状体内以确保在眼睛内维持眼部药物的合适水平。在本发明的某些实施方式中，在流体填充的人工晶状体内具有单独腔室，药物能够被注射到单独腔室内并经过一段时间向外扩散到眼睛内，而不会改变晶状体的屈光指数。

[0046] 再进入工具的尖端，其包含进入流体填充的人工晶状体内的流体的组件，取决于其正在进入的阀或再进入端口的配置。在一种形式中，尖端刺穿阀以及随后在移除尖端后阀自密封。该尖端配置将优选具有尖锐的点以帮助刺穿阀而同时具有无芯属性以最小化阀材料的移除。另一实施方式将是半钝头或钝头尖端，其将被引导进入先前存在的通道内。另一示例的半钝头尖端具有类似尖锐尖端的斜面，然而，不是终止于尖锐的点，而是斜面的尖端被制造为具有钝头末端。该钝头末端被设计为即使被使用者错误引导时也允许进入阀同时最小化对阀的损害并围绕人工晶状体。该设计减轻了防护剩余的晶状体不受尖锐尖端的影响以避免对人工晶状体的破坏或破裂的需求。例如，流体填充的人工晶状体可以较薄实

施方式产生，进而改变柔性、屈光指数、和适应性调节属性，被器械破坏的风险最小。阀设计的示例包括但不限于自密封孔、止回阀、瓣阀、或具有阀或自密封介质的管。

[0047] 许多这些再进入工具的实施方式得益于将尖端与进入点对准的对准机构。可以多种方式产生对准。在一个实施方式中，具有一条或多条管。一个管抽真空以帮助抓住阀或管。该配置能够通过如下制造：具有同心管、并排管或一些预先设计形状的管，该预先设计形状的管对于进入点的特征是真空能够在某方向上保持以排列进入尖端用于输送或移除流体，这些冗余管可以被多次使用、或单次使用，在该情形中它们可以在使用后密封并移除。

[0048] 在更广泛意义上，再进入工具可包括进入尖端或由进入尖端组成，其连接至一条或多条流体线路，流体线路连接至控制台，控制台能够具有用于输注进入晶状体的一个或多个流体贮存器、用于从人工晶状体移除流体的真空机构、或两者。填充过程能够由外科医生控制的脚踏开关控制，以允许他们双手自由以操纵工具和流体填充的人工晶状体。该开关还能够被定位在工具自身上并由外科医生的手指驱动。在某些实施方式中将监视或计量注射或移除的流体量。这能够通过置于更加靠近进入尖端的流体线路上的流量传感器实现。越靠近再进入工具的远端，流量传感器越精确。这是因为贯穿工具的线路在输注期间经受弯曲，即使是微小量。这引起线路的电容性能。因此，在人工晶状体填充期间，来自输注贮存器的流量相比离开进入尖端的流量更高。因此，在线路近端处的测量将高估进入人工晶状体的总流量为作为流量的一定量。在人工晶状体内容物抽吸期间，空气线路内的小气泡会形成气穴。这导致靠近控制台的流体相比离开人工晶状体的实际流体更易于受到错误的较高抽吸水平的影响。在两种情形中，期望靠近晶状体的流量传感器用于高精度的流量监视。诸如但非限定于那些基于热效应的、渡越时间的、和/或压力的流量传感器可用于监视/计量目的。

[0049] 流量传感器还能精确地测量进入和离开流体填充的人工晶状体的流体量。在通过不具有顺应性的流体线路注射流体的实施方式时，流量传感器可能不是必须的，因为能够使用注射器或一些类型的精确分配技术来精确地注射流体。此外，能够通过在注射或移除流体时测量患者内晶状体的屈光度来控制填充。该测量然后能够用作为对控制台的实时反馈，然后能够控制从流体填充的人工晶状体注射或移除的流体的量。

[0050] 控制流体输注的其他反馈机制包括监视晶状体调节期间的晶状体的总屈光度，监视晶状体调节期间晶状体和/或眼睛的像差，监视填充流体的屈光指数，以及监视晶状体内的压力。

[0051] 在某些实施方式中，改变流体以改变人工晶状体的整体屈光状态，从而实现正视眼。在其他实施方式中，监视并调节晶状体像差，诸如Zernicke系数，从而改变晶状体的整体屈光状态以及人工晶状体的像差。作为简单示例，调节所植入晶状体的像差以减小眼睛的整体散光，如在散光角膜的情形中那样。在其他实施方式中，调节并可能地增加球面像差以增加所植入晶状体的景深。在其他实施方式中，减小像差以增加整体视力。这可以通过人工晶状体中的单个进入阀、或人工晶状体的多个阀来发生，这些阀进入人工晶状体的单独的部分或贮存器。人工晶状体的这些单独的部分用于调节晶状体的像差以及晶状体的屈光度。在最简单形式中，一个腔室用于晶状体的整体屈光本领，而第二个腔室用于调节人工晶状体的复曲面度以校正散光。该再进入工具然后可用于进入一个或两个腔室。例如，它可用

于手术后调节所植入人工晶状体的复曲面度以用于更好的散光校正。这在通过晶状体自身的手术植入过程诱发的散光的情形中是重要的，这种情形是难以预测的。在另一示例中，再进入尖端用于增加球面像差以增加所植入人工晶状体的整体景深。在又一示例中，再进入工具用于基于手术后非期望的角膜像差来调节晶状体。调节所植入的IOL以校正角膜的像差，从而减少眼睛的角膜晶状体光学系统的整体像差。

[0052] 本发明的多个方面涉及人工晶状体移出，即从眼睛移除液体填充的IOL。通过首先从液体填充的IOL移除流体并随后移除排空状态的晶状体来进行移出。该技术的优势是在流体移除后，排空的IOL具有小轮廓，允许它通过小的切口移除。更加具体而言，能够以低于3mm以及在本发明的一些实施方式中，低于1mm的切口移除晶状体。

[0053] 在本发明的一个实施方式中，移出工具的一部分使用吸力保持晶状体。一旦晶状体啮合至移出工具，工具的第二部分就用于进入晶状体的内部内容物，例如通过晶状体的诸如阀的特定区域，或通过晶状体的壁。在一个实现方式中，专用的钩用于进入晶状体并引起外侧构件的泄露，其中内部液体从晶状体抽吸出。在其他实现方式中，不使用抓取工具；而是使用空心套管来进入晶状体的内部内容物并抽吸液体。例如，套管工具可具有尖锐的末端以辅助进入液体填充的人工晶状体。可替代地，套管工具可具有倒钩、钩、或其他设备，用于在插入液体填充的人工晶状体后机械地保持晶状体。

[0054] 在某些实施方式中，排空的晶状体被拉入移出工具用于从眼睛移除。在其他实施方式中，使用移出系统的单独部分来移除排空的晶状体，该部分单独地抓住并移除排空的晶状体。移出系统的该单独部分具有抽吸或输注抽吸组件用于辅助抓取晶状体，保持眼睛前腔室内的压力，以及从人工晶状体移除任意残留的液体。本发明的一些实施方式在排空IOL并移除它之前使用IOL中的流体交换。抽吸来自移出系统一个部分，而输注通过IOL的相同部分或从晶状体的单独部分来施加。

[0055] 在某些实施方式中，特定工具用于打开IOL中的孔并随后抽吸来自IOL的液体。其他实施方式通过首先使用烧灼、激光、超声能量、或机械切割以打开设备中的孔来抽吸人工晶状体，并随后抽吸人工晶状体的内容物。

[0056] 在晶状体正处于排空时，本发明的一个实施方式使用单独线路来输注诸如BSS、粘弹性物质、或空气的流体进入晶状体囊中。该技术保持了自然晶状体囊形状，促进了IOL从晶状体囊的移除，并随后通过置换的IOL进行IOL“袋内”注射。

[0057] 因此，在某些方面，本发明涉及一种人工晶状体移出系统。在各个实施方式中，该系统包括如下：保持人工晶状体的部分，其使用机械、吸力、或机械和吸力的组合来保持晶状体；以及进入流体填充的人工晶状体的内部内容物的部分；后一部分在从眼睛移除晶状体之前移除或促进移除晶状体的内容物。进入IOL的内部内容物的部分例如可包括钩或倒钩构件或由其组成，并可用于机械地保持晶状体抵靠移出工具的保持部分。

[0058] 进入IOL内部内容物的部分可替代地包括抽吸晶状体内容物的套管工具或由其组成，而晶状体通过移出工具的抓取部保持。进入IOL内部内容物的部分可包括抽吸输注部分或由其组成，其抽吸晶状体的内容物并将第二流体输注进入晶状体以通过另一流体来流体地交换晶状体的内部内容物。在流体交换后，晶状体被抽空并从眼睛中拉出。在又一其他实施方式中，保持部分也可从晶状体抽吸流体。

[0059] 移出工具可具有吸入人工晶状体以将其从眼睛移除的特征。移出系统的第二独立

部分，诸如镊子或其他抓取构件，可以被特别设计为相互作用并移除排空的晶状体。

[0060] 在另一方面，本发明涉及人工晶状体移出系统，其包括两个独立组件或由其组成。第一部件是人工晶状体夹持器，其使用机械力、吸力、或机械力和吸力组合来保持晶状体，并且还进入流体填充的人工晶状体的内部内容物以在从眼睛移除晶状体之前移除晶状体的内容物。第二组件进入晶状体的单独部分以在其中输注另一流体和/或从晶状体抽吸流体。

[0061] 根据本发明的一种人工晶状体移出系统可包括用于打开晶状体内开口的尖端并允许流体溢出，而尖端的第二部分从晶状体抽吸流体。移出工具的一部分可提供输注以及抽吸。

[0062] 根据本发明的一种人工晶状体移出系统可包括进入晶状体以排空晶状体的部分，而第二部分在晶状体排空时将流体或粘弹性物质输注进入晶状体囊。

[0063] 根据本发明的一种人工晶状体移出系统可具有超声供能的尖端，其用于打开液体填充的人工晶状体侧面的孔并抽吸晶状体内容物；超声供能的尖端可具有抽吸和输注性能。在一些实施方式中，尖端包含尖锐的部分以辅助裂开液体填充的人工晶状体的壁。

[0064] 根据本发明的一种人工晶状体移出系统可具有打开液体填充的人工晶状体的孔的烧灼尖端，允许流体从IOL中被抽吸的抽吸部分，以及可选的输注部分。

[0065] 根据本发明的一种人工晶状体移出系统可具有打开液体填充的人工晶状体内的孔的激光器，允许流体从IOL中被抽吸的抽吸部分，以及可选的输注部。激光器例如可以是通过内窥镜操作的。

[0066] 根据本发明的一种人工晶状体移出系统可具有用于切割流体填充的人工晶状体的边缘并抽吸人工晶状体的内容物的部件。切割部件可包括切割管或由其组成，其伸缩地接收在外管内并在远端上具有切割端口，其中通过内部切割刀片的中心给切割端口施加吸力。切割管可使用往复轴向运动、往复旋转运动、或旋转运动中的一个或组合来切割。

[0067] 根据本发明的一种人工晶状体移出系统可具有进入流体填充的人工晶状体的内部内容物的部分，其在从眼睛移除晶状体之前移除晶状体的内容物。

[0068] 在另一方面，本发明涉及移出流体填充的人工晶状体的方法。在各个实施方式中，该方法包括或由如下组成：部分地或完全地清空人工晶状体并随后使用与清空晶状体所使用的工具相同或不同的工具从眼睛中移除晶状体。

[0069] 根据本发明的移出流体填充的人工晶状体的方法包括或由如下组成：首先以第二流体与人工晶状体内的流体交换，然后部分地或完全地清空人工晶状体并随后使用与清空晶状体所使用的工具相同的工具或或辅助工具从眼睛中移除晶状体。通过晶状体中的单独进入点来交换流体。在一些实施方式中，通过如下交换流体：使用一个工具从晶状体移除流体以及使用第二工具以第二流体膨胀晶状体。

[0070] 在整个说明书中提及“一个示例”、“示例”、“一个实施方式”、“实施方式”指代的是结合该示例所描述的特定特征、结构、或特性包含在本技术的至少一个示例中。因此，措辞“在一个示例中”、“在示例中”、“一个实施方式”、“实施方式”在整个说明书的多个地方的出现并非必须全部指代相同示例。此外，特定特征、结构、程序、步骤、或特性可在本技术的一个或多个示例中以任意合适方式组合。本文提供的标题仅出于方便目的且并非旨在限制或解释所要求保护的技术的范围或意义。术语“基本上”或“大约”意指±10%（例如，以重量或

以体积)，以及在一些实施方式中意指±5%。

附图说明

[0071] 在附图中，相似参考标记通常指代整个不同视图中的相同部件。并且，附图并非必须按比例绘制，而重点通常是在于示意本发明的原理。在下述说明中，参照如下附图描述本发明的各个实施方式，其中：

[0072] 图1A和1B描绘了IOL插入和填充系统。

[0073] 图2A和2B描绘了具有密封构件以部署IOL的插入和填充系统。

[0074] 图3A和3B示意了具有防护护套以辅助部署IOL的本发明的实现方式。

[0075] 图4A和4B描绘了具有用于折叠和部署晶状体的机械抓取机构的实现方式。

[0076] 图5描绘了具有用于将IOL流体地推出于注射器的流体线路的实现方式。

[0077] 图6描绘了进入尖端，其是提供输注和抽吸的双套管。

[0078] 图7描绘了插入和填充系统，其中单独的输注线路和抽吸线路通过Y连接器或阀连接至进入尖端。

[0079] 图8描绘了插入和填充系统，其中除泡过滤器与注射尖端一起使用。

[0080] 图9A-F描绘了插入和填充系统，其使用在插入到注射和填充系统上后检查晶状体泄露的特定方法。

[0081] 图10描绘了完全抽空的IOL，其流体连接至延伸至插入管外的进入尖端。

[0082] 图11示意了通过再进入工具的实施方式进入的流体填充的人工晶状体。

[0083] 图12是以了再进入工具的进入尖端的多个实施方式。

[0084] 图13示意了双管腔进入尖端。

[0085] 图14示意了结合至再进入工具的多个反馈机构。

[0086] 图15示意了与所植入晶状体相互作用的移出系统。

[0087] 图16示意了与晶状体相互作用的移出系统的视图。

[0088] 图17示意了移出工具内的排空的IOL。

[0089] 图18示意了本发明的具有双手移出工具的实施方式。

[0090] 图19示意了具有尖锐部分的移出工具，尖锐部分用于在IOL内容物的抽吸前打开IOL的孔。

[0091] 图20示意了本发明的由切割工具组成的移出系统的实现方式，切割工具用于切割晶状体的一部分并抽吸晶状体和填充的流体。

具体实施方式

[0092] 下文描述的外围手术系统用于插入并填充流体填充的人工晶状体，再进入及改变流体填充的人工晶状体，以及移出晶状体。尽管一个外围手术单元可执行与流体填充的人工晶状体的手术操作相关的所有这些特征，但是许多不同的单元可执行每个单独的功能特征。本发明还可用作为用于诸如巩膜扣压或隆胸的其他流体填充的可植入设备的外围手术系统。

[0093] 1、插入/填充

[0094] 首先参照图1A，其描绘了代表性的IOL插入和填充系统100。流体线路104将流体系

统102连接至人工晶状体112。人工晶状体112被装载在插入管110内。在植入期间，插入管通过小切口插入眼睛内。然后人工晶状体112被推出插入管110进入眼睛中的准确位置。插入管110可以被配置为是透明的或半透明的以用于外科医生在装载时的装载期间、或插入期间视觉地检查晶状体。在图1A中，滑块108用于通过相对于手持件114机械地推进流体线路104来部署IOL 112。然而，这并不意味着是限制性的，并且能够使用本领域技术人员所公知的其他配置，包括诸如杠杆、滚珠螺杆、开关的设备或通过诸如气动、电动、或螺线管驱动的致动器120的自动部署。可替代地，可以利用任意公知的方法来泵送流体。一个或多个致动器120的组合可并行地使用，诸如一个气动泵或一个真空泵。在填充后，晶状体太大以至于不能撤回到插入管110中，从而由于晶状体保持抵靠于插入管的出口，使得使用滑块108的流体线路110的简单缩回将流体线路的末端拉出晶状体。此外，插入管110可具有涂层以防止接触晶状体的情形中的任意破坏。

[0095] 在晶状体被部署在眼睛内之后，流体系统102用于通过驱动来自一个或多个贮存器124的流体、气体、凝胶、或溶质来填充晶状体至特定体积。如果流体系统102距手持件114远程地布置，流体线路104可用于将流体从流体系统102移动至IOL 112。参照图1B的针对IOL插入和填充系统的系统方框图。流体系统可包括一个或多个反馈系统122，其用于以压力传感器126监视压力、以流量传感器128监视流量、或以屈光计130监视屈光指数，并能够通过泵的驱动来调节一个或多个变量以提供晶状体的合适屈光结果。通过微控制器140和合适的软件来处理泵驱动和反馈信息。

[0096] 在本发明的某些实施方式中，借助于粘弹性物质进行IOL的部署。粘弹性物质用于减小晶状体和插入管之间的摩擦或静摩擦。类似的，在本发明的某些实施方式中，粘弹性物质用作为通过注射器推入晶状体囊内并连同晶状体囊一起承载晶状体的载体材料。这样，它支撑人工晶状体并通过首先进入的IOL的被支持的远端部分辅助IOL部署进入晶状体囊内。粘弹性物质的支持防止插入期间柔性晶状体壳弯曲回自身上。

[0097] 粘弹性物质辅助在IOL插入之前保持晶状体囊。在IOL插入之前或期间将粘弹性物质插入晶状体囊内并膨胀晶状体囊以提供用于待膨胀的可膨胀IOL的空间。它排除来自注射器的空气并减少或消除进入眼睛的可能会陷获在排空的晶状体的折痕中的空气泡。插入管110可以被配置为是透明的或半透明的从而用于临床医生在装载时的装载期间、或插入期间视觉地检查晶状体。在图1中，滑块108用于部署IOL 112。然而，这并不意味着是限制性的，并且能够使用本领域技术人员所公知的其他配置，包括诸如杠杆、滚珠螺杆、开关的其他手动插入设备或通过诸如气动、电动、或螺线管驱动的部件的自动部署。在将晶状体部署在眼睛内以后，流体系统102用于填充晶状体至特定体积。如果流体系统102距手持件114远程地布置，流体线路104可用于将来自流体系统102的流体移动至IOL 112。

[0098] 例证性流体系统包括简单的手动注射器或流体泵，诸如注射泵。流体系统102并非必须是开环系统；在某些实现方式中，来自传感器的反馈用于确定植入眼睛内的晶状体的填充体积、屈光属性、或填充至准确体积的压力。流体系统102可具有注入流体和从晶状体抽吸流体以达到期望的填充、屈光属性、或晶状体压力的性能。另外，流体系统102可具有监视晶状体填充流体的屈光属性并调节它的能力。

[0099] 尽管流体系统被描述为远离手持件，但这不是必需的。在本发明的某些实现方式中，流体系统是手持件的集成部件，在手持件内发生任意的流体连接。对于本领域技术人员

来说，在本发明的精神内的其他实现方式也是可能的。

[0100] 尽管晶状体的插入被描述为晶状体被推出插入管，但是也能够缩回插入管110和流体线路104并留下晶状体112不动。这具有显著的优点，即允许临床医生将IOL置于期望位置，然后缩回管，露出IOL。通常，在该实施方式中，流体线路104在插入管之前或连同插入管一起被机械地缩回。可以使用钝头的手术工具、或尖端上的另一特征来保持晶状体就位。

[0101] 图2A示意了被部署的IOL 212的实现方式以及图2B具有处于装载配置的IOL 212。在该实现方式中，密封柱塞210形成插入管206的密封件。在装载期间，诸如生理盐水、平衡盐溶液、或水的粘弹性物质或其他流体可用于辅助装载晶状体。在晶状体被装载后，腔内空间214(其通过密封柱塞210、插入管206、IOL 212、以及插入管208的末端界定)被流体或粘弹性物质填充。通过密封柱塞210将填充流体或粘弹性物质连同IOL 212推出插入管206，并且将晶状体从插入管流体地推动进入眼睛内。特别地，迫使流体抵靠密封件的近侧使柱塞推进并将晶状体推出已知距离(直至密封件已经通过了插入管的末端)；再次，钝头手术工具可用于保持晶状体并将晶状体从流体线路尖端脱出。

[0102] 填充流体提供了辅助IOL 212的部署的流体力以及沿IOL 212近侧表面的密封柱塞210的机械力。这对于晶状体部署期间推出IOL 212的无支撑的远端尤其重要，这是因为它阻碍了晶状体聚成一团的趋势。流体力还防止了IOL 212的内表面被抵靠进入尖端216推进，这会引起部署期间对IOL壁的破坏和可能的断裂。进入尖端216可用于提供IOL 212和流体系统之间的流体连接。填充流体减小了部署期间IOL 212和插入管206之间的摩擦，进而防止了插入期间对IOL 212的破坏。另外，填充流体将IOL 212周围的残留空气排除并防止空气随着IOL 212被推进到眼睛内。随着IOL插入眼睛内的空气会上升到眼睛的顶部，粘附于晶状体，或进入晶状体囊，使得插入过程的可视化困难。密封柱塞210还通过阻止IOL 212的近端向后折叠并在柱塞和插入管206的内表面之间变得皱褶而防止对IOL的破坏。

[0103] 图3A和3B描绘了通过防护套304辅助部署IOL 312的实现方式。防护套304环绕IOL的一部分或全部，并沿IOL的长度的一部分延伸。在某些实现方式中，护套在纵向上和周向上延伸并覆盖IOL。在图3A中，插入工具300处于装载配置并准备部署在眼睛内。图3B示出了IOL 212被插入之后但是IOL膨胀之前的插入工具302。防护套304用于防止IOL 312受到来自插入管306的摩擦力。这在IOL 312是由粘附至插入管306或其他周围结构的材料制成时是尤其有用的。在IOL 312的部署或装载期间，IOL的侧面会附着至周围结构，引起对IOL 312的破坏。防护套304用作为载体，并且在防护套304和插入管306之间发生滑动摩擦。另外，在IOL312的装载期间，防护套304用于在晶状体被拉入插入管306时预折叠和/或卷起晶状体。

[0104] 防护套304可以跨越IOL 312的整个长度、或IOL 312的部分长度。在某些实现方式中，防护套304是短的，绕IOL 312中的阀延伸。在IOL 312被拉入注射器时，护套用于通过阀保持IOL 312。这帮助将晶状体拉入注射器内并折叠晶状体。防护套的部署通过支撑晶状体的后部而不允许晶状体的前部随着其部署而折叠防止晶状体被进入尖端316损伤。另外，防护套304能够用于在插入之前、期间、或之后固定阀。那么，当机械地保持阀时，进入尖端能够用于进入阀，提供IOL 312和流体系统之间的流体连续性。

[0105] 在某些实现方式中，IOL 312和防护套304一起插入，接着在插入后，但在IOL膨胀之前、期间、或之后，防护套304缩回。这样，防护套不会在插入和膨胀之后被困在IOL 312和

晶状体囊之间。同样，防护套可用于将晶状体装载在插入和填充系统中，但在晶状体插入期间被局部地部署，或不随着晶状体被部署。在该实现方式中，防护套304用于折叠并吸入晶状体。为了辅助该操作。护套可被成形为使得促进晶状体的折叠(如结合图10更加详细描述的)。防护套304的材料属性可用于减小IOL 312和插入护套304之间的摩擦，以允许平滑部署。防护套304则不直接接触晶状体囊，或仅稍微进入晶状体囊。在两种情形中，这防止了防护套304对晶状体囊的损害。

[0106] 尽管结合液体填充的IOL对防护套304进行描述，但这并不意味着限制性的。在某些实现方式中，该防护套与非液体填充的IOL一起使用。在非液体填充的IOL与防护套一起使用时，流体系统不包括在该设计中。取而代之的是，防护套结合IOL注射器一起使用以部署晶状体。这具有防止IOL在插入期间受到由于与插入管的摩擦而引起的损害、粘弹性物质引起的表面损害、或来自插入期间由IOL经受的压缩引起的其他损害的优势。该类型的护套对于微切口IOL手术尤其重要，其中IOL在插入期间被压缩至非常小的直径，2mm或更小。因此，防护套的该概念能够用于减小对非流体填充的IOL的损害以及确保晶状体的安全部署。

[0107] 图4A和4B示出了其中使用机械抓取机构折叠和部署晶状体的实现方式。图4A的IOL 408处于装载位置，而图4B的IOL 408处于部署位置。机械抓取机构406用于将IOL 408保持在插入管412上。例如在利用阀与流体线路联通时，这是有用的。机械抓取机构406防止晶状体阀与插入和注射系统的流体部分分离。

[0108] 另外，机械抓取机构406可用于在插入期间保护晶状体。在某些实现方式中，机械抓取机构406被配置为类似于镊子。在其他实现方式中，机械抓取机构406是软的或柔性的，由聚合物(诸如硅树脂)制成，用于啮合IOL 408而不会对其产生损害。另外，为了防止IOL插入眼睛之后对晶状体囊的损害，软材料是优选的。柔性抓取机构406可包括两个或多个元件或由两个或多个元件组成以抓住IOL 408。如图4B所示，机械抓取机构406允许插入后IOL 408的释放。如果机械抓取机构406被配置为类似镊子，在部署晶状体时，抓取机构406自动地打开。例如，夹持器可以是弹簧加载的，或包括朝向一敞开、伸展的配置偏置的活动铰链，从而在它们被部署时，它们会展开。抓取机构在结构上被限制为仅打开足够释放晶状体但小于切口(小于3mm，以及在一些情形中小于1mm)的设定距离。机械抓取机构可在IOL 408的输送后、在IOL 408的填充之前、期间、或之后缩回。

[0109] 另外，抓取机构可用于在插入眼睛之后进入排空的、部分膨胀的、或完全膨胀的IOL。在用于该方式时，抓取机构可在相反方向上偏置或被配置为将夹持器拉向彼此；例如参见美国系列号No.61/920,615(于2013年12月24日提交的)，其全部公开内容通过引用包含于此。夹持器可机械地保持晶状体而进入IOL中的阀。在该点，能够从IOL添加或移除流体。这为植入非填充的IOL提供了可能性，然后在植入后进入阀并膨胀晶状体。在该情形中，IOL在植入期间不与填充线路流体连接。

[0110] 其他合适的抓取机构进入流体填充的IOL内的阀。一个例证性机构利用真空来保持阀或通过机械保持压力保持阀；例如，该机构可利用一对同心管，内管延伸超出外管并可插入晶状体内，其中通过外部腔施加真空以吸引晶状体抵靠外管的远端。可通过小管或针直接进入阀。本发明的一些实现方式机械地保持阀然后使用流体压力使阀裂开以从液体填充的IOL添加或移除流体。

[0111] 图5示出了其中使用流体线路将IOL 506流体地推出注射器的实现方式。来自入口

502的流体进入插入和填充系统并通过插入管508离开。在IOL 506的插入期间，流体使IOL流出插入管508，而不会迫使IOL自身折叠。另外，流体能够用于膨胀晶状体囊。流体能够用于替代或支撑晶状体上或晶状体周围或晶状体囊内部的粘弹性物质。在某些实现方式中，在IOL 506插入后，流体排除晶状体囊中的粘弹性物质。这在IOL的尺寸大小为填充大部分晶状体囊时尤其重要。在大的晶状体囊填充的IOL的膨胀后，粘弹性物质会保持在IOL壁和晶状体囊之间。因此，在插入和植入期间避免粘弹性物质的使用或从晶状体囊清除粘弹性物质是合适的。

[0112] 尽管图5示出了通过插入管耦接的另外的流体线路，在其他实施方式中，流体线路位于插入管的外侧上并且不用作推出晶状体的流体力源，但在晶状体插入期间膨胀晶状体囊和/或清除粘弹性物质。在其他实施方式中，外部抽吸线路结合外部流体输注线路一起使用。输注和抽吸可一起使用来从眼睛移除任意流体，诸如粘弹性物质。输注线路可耦接至插入尖端，或可以在插入尖端外部。同样，输注和抽吸可以与插入尖端间隔，例如以一起工作以交换眼睛内的流体的独立手持件的形式。

[0113] 现在参照图6，其描绘了以提供输注和抽吸的双套管形式的进入尖端。进入尖端616被从晶状体的外部606放置至晶状体的内部604。注射尖端610的输注部分用于将流体612注入晶状体。第二端口用于抽吸608，以抽吸晶状体614的内容物。该抽吸端口608无需直接邻近注射端口610定位。在本发明的某些实施方式中，进入端口和输注端口置于晶状体的相对侧面上，并通过两个不同的进入点被放入晶状体内。在输注和抽吸一起使用时，能够交换IOL内的流体。例如在改变填充IOL的流体的屈光指数时，这是有用的。同样，手持件内的反馈系统能够用于监视压力、流量、或屈光指数，并且手持件能够调节这些中的单独一个或组合以提供晶状体的合适的屈光结果。

[0114] 进入尖端的一些实现方式利用钝头尖端，其中多个管腔同心地或平行方向地配置以用于从尖端的侧面输注或抽吸流体。进入尖端的又一实现方式包括防止IOL塌陷在抽吸孔上的特征。例证性的进入尖端特征包括侧端口、多个管腔、以及圆头尖端。例如在IOL在插入眼睛之前被抽空时，这是重要的。在该情形中，液体填充的IOL的柔性壁可引起管腔闭塞。然而，诸如突出构件或多个管腔的特征能够用于防止管腔闭塞。

[0115] 图7描绘了通过Y连接器或阀708连接至进入尖端706的单独的输注线路702和抽吸线路704。空气泡710从输注线路710行进穿过路径712并穿过Y连接器或阀708，然后离开抽吸线路704。沿该路径行进的流体不会进入到进入尖端706。这样，插入和填充系统的线路能够填装至注射尖端706而不会使流体进入注射尖端706。例如，阀708可以选择性地将线路702连接至线路704或线路706，从而在线路702连接至线路706之前(通过线路704)清除来自线路702的空气。在一些实施方式中，阀704被定位为高于线路706以使得空气离开，这是因为气体倾向于聚集在线路的顶部。尽管图7示出了具有空气泡，该方法也适用于线路中能够被移除的任意空气。

[0116] 现在参照图8，其描绘了与注射尖端一起使用的除泡过滤器。来自流体贮存器的液体在由箭头802指示的方向上移动通过输注线路814。空气泡804从输注线路814向下流动直至接触半透膜806，半透膜806允许空气通过但阻止液体通过。空气泡804经由路径810穿过半透膜806。空气在从线路移除后进入单独的腔室或线路812。这样，离开输注线路816远端并进入IOL的液体没有空气泡。半透膜806也可用于在填装期间移除空气。腔室812可处于环

境压力(在线路814中的液体处于更高压力时),或在真空下保持。同样,用于空气离开的驱动力可以是输注线路814和腔室812的压差,或该过程可以源于扩散。

[0117] 图9示意了将IOL 902插入到注射器上的例证性方法。在插入到注射和填充系统上之后检查晶状体的泄露。在图9A中,首先使用尖锐的针进入或穿刺IOL上的密封部914。然后,如图9B所示,进入尖端906通过密封膜914插入到IOL中。在该步骤中实现流体系统和IOL 902内部之间的流体连续性。在图9C中,从IOL移除尖锐的针。在图9D中,以空气或液体膨胀IOL来呈现膨胀状态908。在该点,检查膨胀的IOL 908的泄露或对IOL的破坏。可以例如通过光学地检查晶状体排空、通过视觉地检查晶状体泄露、通过监视晶状体的压力、或通过监视流动至晶状体或者从晶状体流出的流体来执行该检测。这些技术不意指为限制性的,并且本领域技术人员已知的其他类似技术可用于检查晶状体。在图9E中,IOL被排空并且处于排空状态910。在图9F中,IOL被插入到插入管912内。图9A-9F示意了用于检查晶状体泄露的例证性方法,但所示意的步骤并不意指为限制性的。例如,晶状体可不被尖锐的工具904进入以检查泄露。另外,检查晶状体的泄露并随后从注射和填充系统移除晶状体以用于后面使用。

[0118] 粘弹性物质能够用于部署IOL。粘弹性物质用于保持IOL和周围注射管之间的空间。另外,它们在插入晶状体时辅助密封注射器的一部分。这在注射器的一部分和注射器壁之间紧密配合时是真的。在本发明的某些实施方式中,粘弹性物质塞住用于部署晶状体的柱塞。随着粘弹性物质的移动,它将轻的晶状体壳与其一起引入眼睛内。另外,粘弹性物质减小了晶状体和周围插入管之间的摩擦和静摩擦。最终,在插入晶状体囊期间,粘弹性物质可在IOL进入晶状体囊之前或与其同时地进入晶状体囊。在该情形中,粘弹性物质将晶状体囊保持在膨胀位置并为晶状体提供位于晶状体囊内的空间。这在晶状体填充期间是重要的,从而具有用于晶状体容易膨胀的空间,减小了晶状体或晶状体囊在插入期间的褶皱。

[0119] 粘弹性物质还用于折叠薄壁的可注射晶状体。通过沿对应于流体线路的晶状体直径布置粘弹性物质的细线,晶状体能够绕含有粘弹性物质的该线折叠。在本发明的该实施方式中,粘弹性物质作为引导物以卷起薄壁的IOL,从而缩入注射器及注射至眼睛内。这防止了缩入注射器和注射入眼睛内期间的不期望的IOL折叠。

[0120] 合适的粘弹性物质包括但不限于弥散的和黏合的粘弹性物质或这些的组合。例证性粘弹性物质包括诸如OcuCoat的羟丙基甲纤维素溶液、诸如Provisc的透明质酸钠溶液、诸如Viscoat的硫酸软骨素/透明质酸钠溶液。其他例证性粘弹性物质包括HEALON、HEALON 5、HEALON GV、HEALON EndoCoat、Amvisc、Amvisc Plus、Medilon、Cellugel、BVI1%,StaarVisc II、BioLon、以及Itrax。粘弹性物质的组合示例包括弥散的和黏合的粘弹性物质的混合物(例如,Duo Vise,其包含Viscoat和Provisc的单独的注射器)或HEALON Duet Dual(由HEALON和HEALON EndoCoat组成)。作为示例,离散的粘弹性物质可用于覆盖晶状体,而黏合的粘弹性物质用于在离散的粘弹性物质周围以将IOL运载至晶状体囊内。IOL能够以本领域技术人员公知的多种方式装载至注射器内,包括但不限于前装载和后装载以及绕IOL包封插入物。一旦装载,注射器可以被存储在标准的IOL存储条件下直至使用。

[0121] 在多个装载实施方式中,使用IOL和外围系统的独有特征来装载晶状体。图10描绘了完全抽空的流体填充人工晶状体。进入尖端1001用作为流体填充的人工晶状体1012和填充系统之间的流体连接件。进入尖端1001通过阀1005连接至流体填充的人工晶状体1012以

产生与流体填充的人工晶状体1012的密封的流体连接。流体填充的人工晶状体1012自然地符合马鞍形，这是因为由于其几何形状这是理论上最低表面能的配置。进入尖端1001能够突出进入晶状体内并基于进入尖端延伸多远而使穿过马鞍的中心的曲线稍微变平。在装载期间，边缘1002和1003朝向晶状体的中心折叠。这使得晶状体形成类似于卷绕管状或“塔奎多(taquito)”。具有许多方法来帮助流体填充的人工晶状体折叠至该装载位置。一个技术是越过晶状体的中心通道铺设流体(优选为高粘性液体，诸如粘弹性物质)，其在晶状体的末端1004处开始并延伸穿过中心通道1006直至阀1005。这允许晶状体的边缘1002和1003在一媒介处折叠以防止折叠期间对IOL特定区域的过多应力。另外，粘性流体的表面张力促进边缘折叠。第二种技术使用装载晶状体1012的插入管1007以帮助晶状体1012在装载过程期间自身折叠。插入管1007上的成角度锥首先帮助供给流体填充人工晶状体的阀部分1005。随着晶状体被越来越向后拉以进入插入管1007内，缓慢打开的管的锥形侧壁将晶状体的侧面1002和1003推进到彼此上。这也能够通过在保持晶状体的插入管1007的前方放置漏斗来实现。该漏斗然后能在晶状体被完全装载至插入管1007中之后被拆卸。第三种帮助晶状体装载的技术是使用护套，其能够缠绕在流体填充人工晶状体1012的阀部分1005上。随着晶状体1012被牵拉回插入管1007，护套缓慢地卷曲在晶状体上并帮助晶状体折叠。该护套还通过围绕晶状体的阀1005区域缠绕自身来保护流体连接。该护套防止插入管1007对阀区域施加摩擦。该摩擦会阻止阀被平滑地装载至插入管1007中，随后引起装载期间流体连接的断开或对晶状体1002的破坏。

[0122] 第二实施方式通过插入管1007后装载人工晶状体1012。通过该方法，晶状体从管的后方推进至准备被注射的前方。在该方法中，漏斗也能够用于帮助引导晶状体进入插入管1007。如果晶状体被后装载，具有诸如镊子的抓取机构的手术工具能够通过插入尖端从成角度切割的前方布置。抓取机构然后能够通过插入管尖端并抓住晶状体的末端1004。然后能够通过插入管1007牵拉晶状体以被后装载。这帮助晶状体准确折叠并防止晶状体在插入管1007内不合适地折叠。晶状体的末端1004可具有优选地由镊子抓取的附加段。镊子可涂覆有诸如硅树脂的聚合物以防止接触期间对晶状体1012的任何损害。

[0123] 可使用任意方法来装载用于存储的容器。该容器然后可在植入前置于插入管的可进入部分中。在该过程前，进入尖端1001连接至IOL 1002以产生流体连接。

[0124] 2、再进入

[0125] 图11示意了已经植入在患者囊袋内或睫状沟内的流体填充的人工晶状体1104。一个或多个进入端口1105置于流体填充的人工晶状体1104的表面上，优选地在视场的外侧。进入端口1105允许进入尖端1103进入或穿刺通过并进入流体填充的人工晶状体1104内的流体。在一个实施方式中，进入尖端1103具有小于4mm、并且理想地小于2mm的总直径，以用于进入端口1105保持其自密封属性以及最小化进入期间或之后的泄露。该进入尖端1103能够使用手持件1107操纵，允许外科医生操作机构以控制进入尖端1103的方向、长度、和流体传输速率。一条或多条流体线路1102连接至进入尖端1103，并贯穿手持件1107。流体线路1102然后连接至控制台1101。控制台1101使用泵送机构(例如，机械泵、注射泵、蠕动泵、或其他泵送机构，其优选为可计量的)来添加流体、移除流体、或者顺序地或同时地添加和移除流体。外科医生能够通过开关1106控制流体的不同注射和移除，开关1106可以是一个或多个脚踏开关、手持控制器、或两者的一些组合。为了维持手持件的方便控制，线路可以是

柔性的，进而在进入人工晶状体时允许外科医生方便地移动手持件。由于流体填充的人工晶状体1104所需的填充物的敏感性和精确性，流体线路1102可具有最小的壁顺应性并被设计用于高于10psi的压力。流体线路1102将在注射期间忍耐高压(高于10psi)，这是因为在进入尖端1103上发生多数压降。Hagen-Poiseulille公式，$\Delta P=8\mu LQ/\pi r^2$(其中ΔP是跨过管或管道的压降；μ是动态粘性；L是管的长度；Q是体积流速；以及r是管的内半径)，示出了通过进入尖端发生大多数压降，这是因为进入尖端具有比流体线路小的多的内直径。这意味着在流体流经线路时流体线路处于较高的压力下。更加具体而言，线路顺应性可以被设计为用于10psi和1000psi之间的压力。这些内部压力扩展流体线路的内直径，并且该扩展通过改变线路的体积来产生线路的顺应性。这些顺应性能够通过使用薄壁压力容器的基本公式来评估。在一些情形中，可使用厚壁开口压力容器公式。流体线路顺应性在改变2μL或更少的内部液体量的再进入操作中是重要的。例如，如果流体线路1102从内直径0.010″扩展至内直径0.011″并且长度为3'，系统的顺应性将是约39μL。人工晶状体的标称总填充水平在10μL和700μL之间，以及优选在50μL和250μL之间。这意味着从系统松弛至受压流体线路内的体积变化是39μL。在该情形中，外科医生需要在已经注射后等待指定量的时间以说明流体线路顺应性和/或监视流体流量或晶状体属性，诸如屈光状态、内部压力、或直接在晶状体处或尖端附近的流体的屈光指数。在生理顺应性公式$\Delta P\times C=\Delta V$中可以看出等待线路松弛的效果，其中ΔP对应压力的变化，C是顺应性，以及ΔV是体积变化。等待线路松弛允许流体达到平衡并停止流动，使得$\Delta P=0$。因此，顺应性不受体积变化的影响。在另一方法中，流体线路1102的壁可具有可忽略的顺应性。这意味着线路的壁足够硬以至于它们不会在压力下扩展。流体线路1102将仍保持其柔性以允许外科医生操纵进入尖端1103。

[0126] 在图12所示的配置中，流体线路1202仍然贯穿手持件1207，但该图示意了进入尖端能够采用的一些不同的配置。在最佳状态，流体线路1202直接连接至较小的管，该较小的管是将穿刺通过阀或进入通道的进入尖端1208。在该配置中，在眼睛内做出角膜切口以允许进入尖端1208和流体线路1202进入流体填充的人工晶状体。流体线路1202的总直径可以小于4mm以使得外科医生能够再次打开用于插入流体填充的人工晶状体的原始切口或做出足够小的新切口以避免诱发散光。进入尖端1208可以具有定位设备来将进入尖端定位以穿过进入端口或者可以具有尖锐的点，允许它穿破阀膜以进入流体填充的人工晶状体。参照图12中的部分A，进入尖端1208由外管1209封装并保护。该管在其末端具有尖锐的点。这允许外科医生穿刺眼睛，例如通过角膜，以及移动外管1209就位以进入流体填充的人工晶状体。进入尖端1208然后从外管1209部署并进入流体填充的人工晶状体。在该配置中，更尖锐的外尖端1209不会接触人工晶状体，但用于产生眼睛内的切口。在与图12的部分A有关的配置中，外科医生无需做出角膜切口。在与图12的部分B有关的配置中，尖锐的点1210从进入尖端1208突出并帮助刺穿眼睛至流体填充的人工晶状体。该配置也无需角膜切口。该点可静态地(即，外科医生推动该点通过眼睛)刺穿或动态地刺穿。在后者情形中，尖锐的点1210可通过超声能量来激励或相对于进入尖端1208往复运动以刺穿眼睛。在两种配置中，尖锐的点可以帮助或不帮助进入流体填充的人工晶状体和进入端口或膜。

[0127] 一旦进入了流体填充的人工晶状体，尖锐的点可以被撤回并移除、添加、或交换流体。在某些实施方式中，尖锐的点1210被置于第一位置，在该位置，在进入人工晶状体的阀时尖锐的点延伸超出进入尖端1208。然后，在进入人工晶状体的阀之前，尖锐的点1210缩回

至流体线路1202内的第二位置，进而阻止流体输注或抽吸期间进入尖端1208内的流体阻塞。在本发明的其他实施方式中，尖锐的点1210用于保持进入尖端1208在插入阀内期间的刚性。

[0128] 图13示意了双腔进入尖端1303。在该配置中，第一管腔1308相对于第二管腔1309进一步插入IOL内，进而当通过流体的同时或顺序输注和抽取来交换IOL 1304的内部内容物时促进合适的流体混合。

[0129] 图14示意了反馈配置，其允许微处理器测量需要通过进入端口1405从流体填充的人工晶状体1404移除、交换、或注射的流体的量。流量传感器1411或其他计量设备靠近进入尖端1403布置。由于先前所述的可能存在于流体线路中的顺应性，流量传感器的位置是关键的。可替代地，如果通过真空移除流体，那么由于线路的气穴现象和顺应性，传感器1411应当尽可能地靠近进入尖端1403放置。进入尖端1403和流体线路中的总流体体积代表死体积。该死体积还可用于测量。如果需要移除已知量的流体，进入尖端1403可以被设计为精确地容纳那么多液体；只要液体到达传感器1411，就完成液体移除。

[0130] 另一个有用的反馈参数是流体填充的人工晶状体1404的压力。这可以通过提供小的压力传感器穿过进入尖端1403并进入流体填充的人工晶状体1404来测量。例如，光纤压力传感器可用于该目的。另一配置是探针1413，其从流体线路或进入尖端延伸并抵靠流体填充的人工晶状体1404的壁推进。力、偏转、或两者能够被测量并反馈回处理器以帮助控制流体的注射、交换、或移除。在其他实施方式中，可以使用眼压测量计，诸如压平眼压测量计、Goldmann眼压测量计、动态轮廓眼压测量计、刻痕眼压测量计、回弹式眼压测量计、气动眼压测量计、压痕眼压测量计、或使用诸如光学相干层析照相的光学设备的非接触眼压测量计。

[0131] 图14中未示出的另一配置使用波前像差计、屈光计、自动屈光计、晶状体尺寸的超声测量、和/或晶状体尺寸的光学相干层析照相来实时地测量流体填充的人工晶状体1404的屈光度。该参数被反馈回处理器以帮助控制流体的注射、交换、或移除。例如，晶状体的几何形状可与所测量的流体屈光指数一起使用。屈光指数可以被调节以产生患者的正视眼。在另一实施方式中，流体量与晶状体的前曲率和后曲率的测量值、晶状体相对于视网膜和角膜的位置、角膜屈光度的先前测量值、以及流体水平一起使用，或者屈光指数被调节以产生正视眼。在本发明的其他实施方式中，监视人工晶状体的压力以确保周围晶状体囊之间的保形适配，以及监视人工晶状体的屈光指数来调节正视眼。

[0132] 附图中未图示的是用于在流体交换期间固定再进入连接的锁定或定位机构。该机构允许进入尖端穿刺并进入流体填充的人工晶状体并维持该配置。合适的锁定机构包括但不限于弹簧锁、扭锁、和滑动锁。合适的定位机构包括但不限于绳索、真空(在具有独特形状的表面上)、夹持器、具有定位孔的销钉。一个配置利用现有的自密封孔；进入尖端使用锁定和/或定位机构来与孔对齐，并随后被推进穿过孔以进入晶状体内的液体。在另一配置中，进入尖端直接穿刺通过膜或阀进入晶状体。在本发明的某些实施方式中，锁定机构用于防止阀进入过程期间的推进力使晶状体移动并拉紧周围组织。工具首先被锁定至锁定机构，其允许晶状体保持在合适位置而不会拉紧周围组织。接下来进入尖端用于进入阀。

[0133] 3、移除

[0134] 现在参照图15，其描绘了例证性IOL移出系统1504。移出系统1504抓取并保持液体

填充的IOL 1502的侧面。在保持时，内部尖端用于进入IOL内并从IOL抽吸流体1508通过流体路径1506进入移出抽取工具。图16示出了移出系统的近视图。在所示意的实现方式中，机械夹持器1604用于保持住IOL晶状体壁1602。IOL晶状体壁1602可以是旨在与夹持器相互作用的IOL的特定部分。在某些实现方式中，IOL的该部分包含与该夹持器相互作用的锁定机构。在其他实现方式中，夹持器与晶状体内的阀相互作用。在通过机械力或通过吸力机械地接触晶状体并保持它时，移出系统的晶状体进入部分1606用于进入晶状体。这引起IOL内的硅油或其他液体以从晶状体沿流体路径1608流入移出工具。移出工具施加抽吸以移除晶状体的内部内容物。抓取和抽吸系统允许抽吸晶状体的内部内容物而不会接触其他眼科结构。

[0135] 在某些实施方式中，进入部分1606是倒钩、尖锐的点、新月钩、或镊子，并用于进入晶状体的内部内容物。在其他实施方式中，晶状体进入部分1606是套管结构，诸如套管钩或针。IOL内容物的抽吸通过套管结构和/或通过周围的移出工具发生。在其他实施方式中，进入部分1606包括空心结构，其通过一系列端口抽吸。在柔性晶状体折叠在进入部分1606上时，其他端口继续抽吸。在一个实施方式中，进入部分上的特征，诸如一个或多个小的突出，防止排空的晶状体堵住进入部分1606的孔。设备的进入部分1606不旨在被上面的描述限制，它可以是任意套管或非套管器械，其用于打开晶状体内的孔或采样晶状体内容物。

[0136] 现在参照图17。在抽吸IOL的所有内容物之后，IOL 1706以排空状态被引入移出系统1704内。在某些实施方式中，机械保持设备，诸如钩或倒钩1702，与抽吸一起使用或不一起使用来辅助将排空的IOL 1706吸入移出系统1704内。在其他实现方式中，移出系统的双腔或共轴进入部分用于进入晶状体。双腔/共轴工具的一个部分输注液体而另一部分通过抽吸移除晶状体内的流体。这允许填充液体在晶状体被排空前用另一液体替换，诸如低粘度液体，或眼睛内良好耐受的液体(诸如平衡盐溶液或粘弹性物质)。这样，在晶状体的内部内容物移除期间，晶状体保持局部地或完全地排空。然后，在流体交换发生后，抽吸出内部内容物并且移除晶状体。

[0137] 图18示出了本发明的具有双手移出工具的实施方式，从晶状体的流体抽吸和移除通过移出工具1802的抽吸部分来执行。该工具的该部分被如上所述地配置。来自IOL内的流体沿流体路径1804行进至移出工具的抽吸部分内。移出工具1810的输注部分用于进入IOL 1806的另一部分。当使用移出工具1802的抽吸部分来抽吸晶状体内容物时，随着流体从抽吸部分沿路径1808流动，IOL 1806的体积被填充。在该过程期间，IOL的内容物与另一种或多种流体交换。例证性流体包括平衡盐溶液、粘弹性物质、或空气。在发生流体交换后，晶状体被清空并使用移出工具本身或诸如镊子的辅助工具移出眼睛。

[0138] 在一些实施方式中，晶状体局部地排空而第二工具用于使用粘弹性物质填充晶状体囊以维持晶状体囊尺寸。这样，保持了晶状体囊尺寸而IOL被排空。该过程防止在IOL被移除时晶状体囊受损害，并允许第二IOL被植入已充满的晶状体囊内。大尺寸的流体填充的IOL帮助维持开口的晶状体囊，使得相比较小轮廓的IOL，晶状体被交换至晶状体囊内成为更加方便和更加安全的过程。

[0139] 图19示意了具有用于打开IOL 1906内的孔的尖锐部分1902的移出工具。来自移出工具的管腔1908的抽吸用于从IOL移除任意流体。来自IOL内的流体从IOL穿过流体路径1904至移出工具。在一个实施方式中，移出工具提供输注和抽吸。输注维持了眼内压力并稳

定了前腔室，而抽吸从IOL移除流体。在其他实施方式中，作为移出系统的单独部件的尖锐工具用于打开IOL内的孔，而移出工具的抽吸部分或输注和抽吸部分用于抽吸IOL的内容物。然后使用单独工具或通过移出工具的抽吸部分移除空的IOL。在某些实施方式中，IOL用相比周围的水密度更低的流体填充。这是有利的，因为该流体趋于上升至眼睛的顶部，便于流体的移除。另外，如果在移出期间晶状体囊被破坏，晶状体漂浮至眼睛的顶部，防止了碎片进入玻璃体腔。

[0140] 现在参照图20，其示出了移出系统2008，包括用于切开晶状体的一部分并抽吸晶状体和填充流体的切割工具。移出系统2008具有外管2002，其中切割端口2012和切割刀片2006可收缩地定位在外管2002内。在图20所示的配置中，切割刀片2006在外管2002内线性地往复运动。然而，往复线性运动、往复旋转运动、旋转运动、或这些运动的两个或多个的组合也全部在本发明的范围内。晶状体2010可通过移出系统2008的切割运动打开。然后移出系统的液体内容物通过切割刀片2006的管腔2004被抽吸出眼睛。对切割刀片2006的内腔2004施加吸力以吸入晶状体和晶状体流体。在某些实现方式中，切割刀片2006包含尖锐边缘以辅助剪切晶状体的一部分。在其他实现方式中，切割刀片2006包含完曲或弹簧加载的机构，以产生切割刀片2006和外管2002之间的剪切力。

[0141] 打开晶状体内的孔并抽吸出晶状体流体的其他技术包括使用超声探头连同作为切割尖端的管，以及通过管的中心施加吸力。例如，超声探头可与切割尖端同轴地定位并在其外侧，切割尖端可包括用于破坏晶状体的特征。在某些实施方式中，晶状体破坏特征包括斜切的边缘、尖锐的点、成角的点、或尖锐的边缘或由其组成。可替代地，激光可用于打开IOL内的孔。激光可从外部或在内窥镜下施加至晶状体。本发明的某些实现方式包括使用激光源输注和/或抽吸以在晶状体移除前抽空晶状体的内容物。另一方法使用烧灼以打开IOL内的孔并抽吸以移除晶状体填充液体。同样，本发明的某些实现方式包括输注以及抽吸。针对上述变形，能够通过镊子或另一手动工具、或通过抽取系统和工具本身来移除晶状体。

[0142] 上面已经描述了本发明的某些实施方式。然而，应该明确指出的是本发明不限于这些实施方式，而是对这里明确描述的内容的添加和修改也包括在本发明的范围内。此外，应该理解的是，在不偏离本发明的精神和范围的情况下，这里描述的各个实施方式的特征不相互排斥并能够以各种组合和置换而存在，即使该组合或置换未在这里明确说明。事实上，在不偏离本发明范围的情况下，这里描述的变形、修改、和其他实现方式对本领域技术人员将是显而易见的。这样，本发明不仅仅由前述的示意描述所限定。

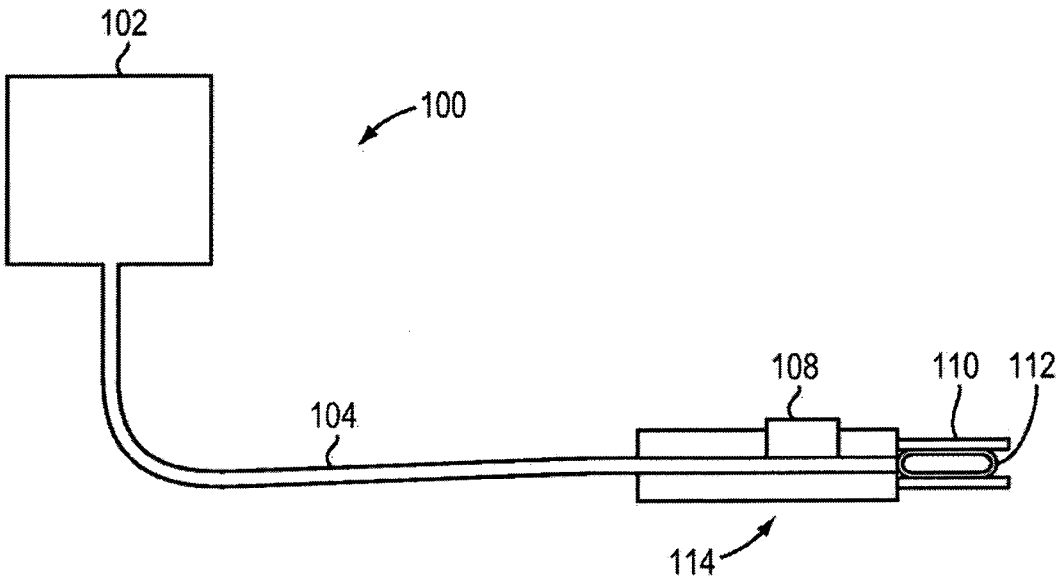
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图1A

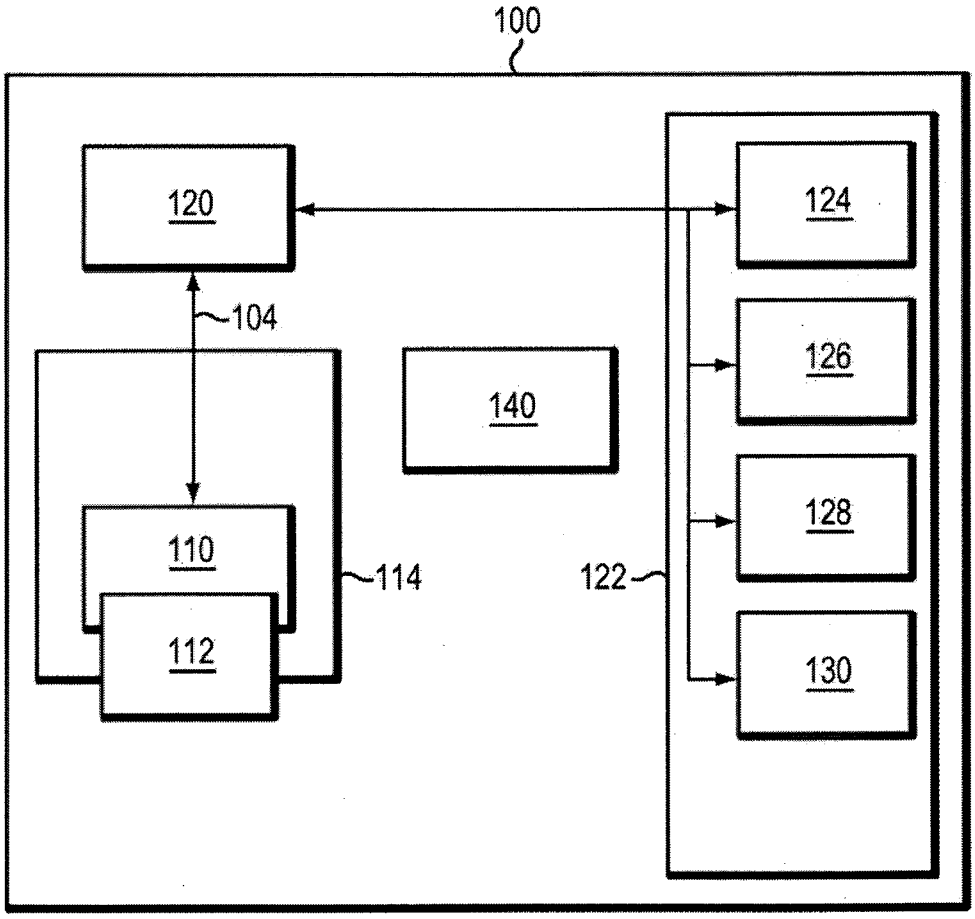
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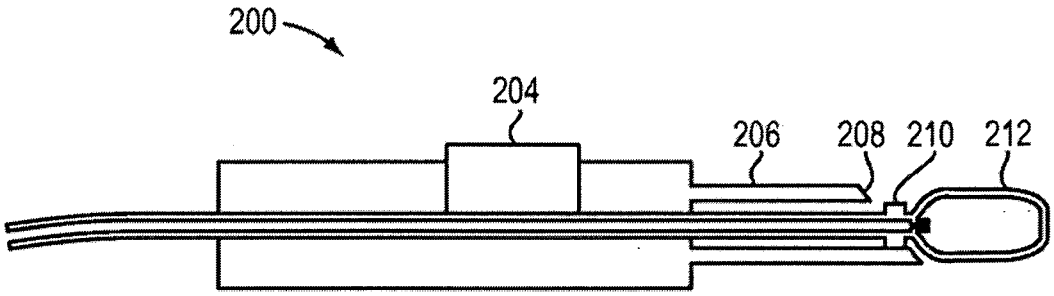
图1B



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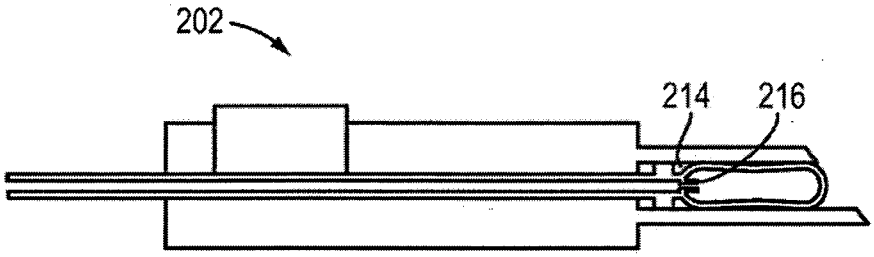

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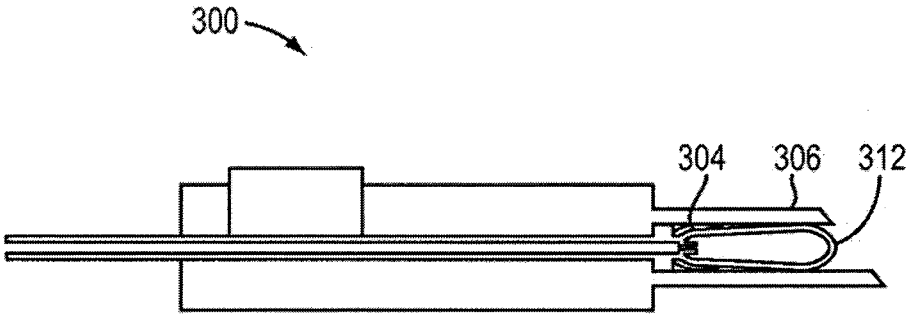

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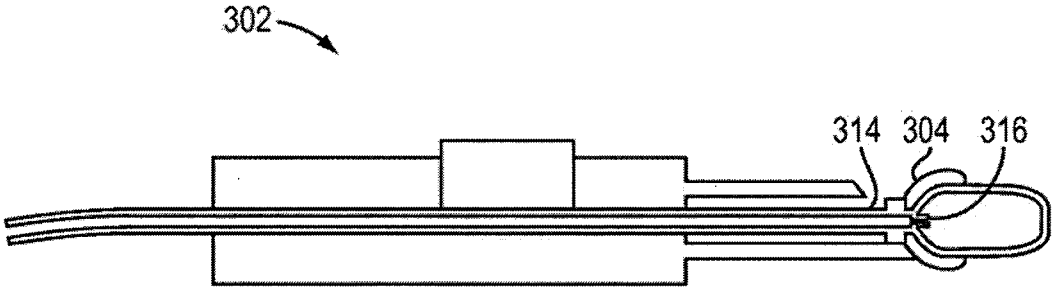

图3B

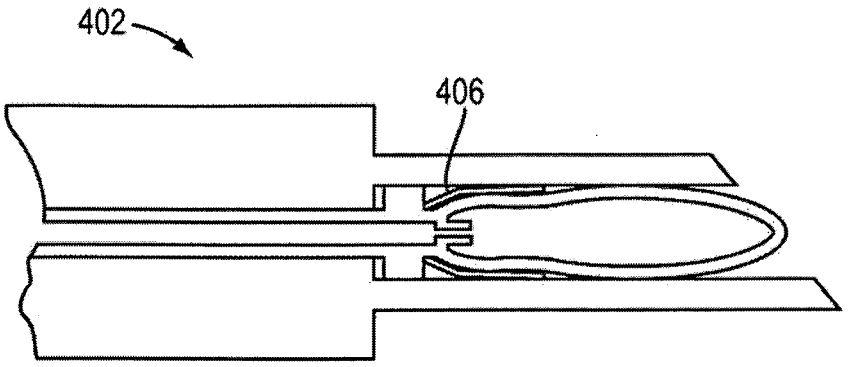

图4A

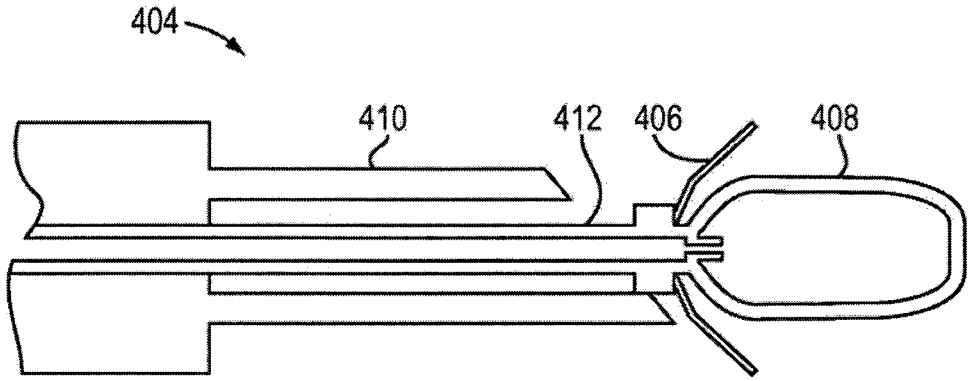

图4B

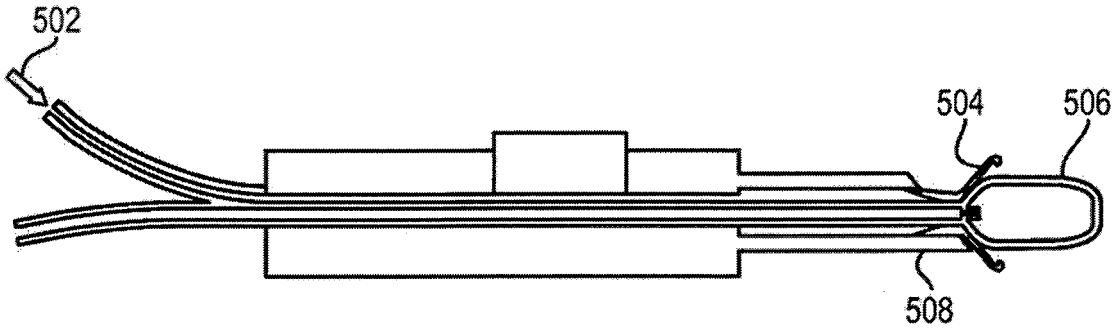

图5

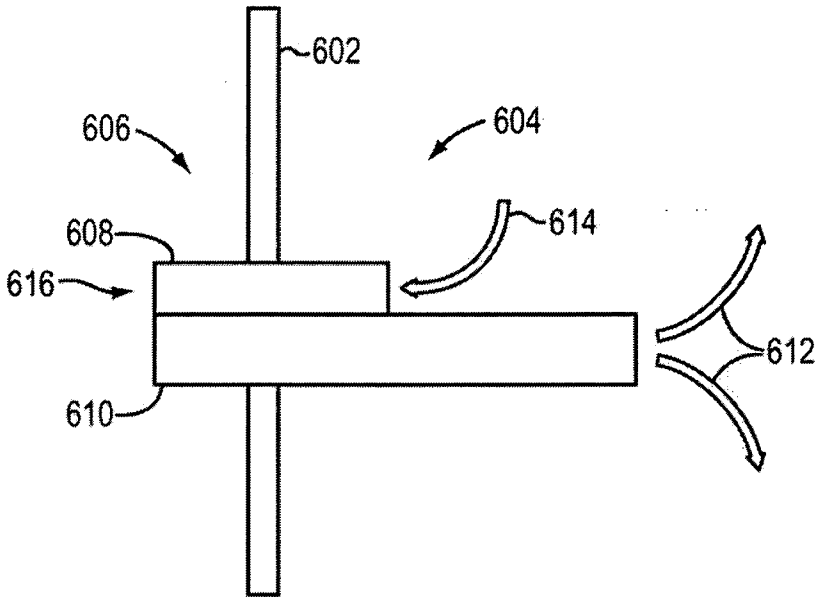
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图6

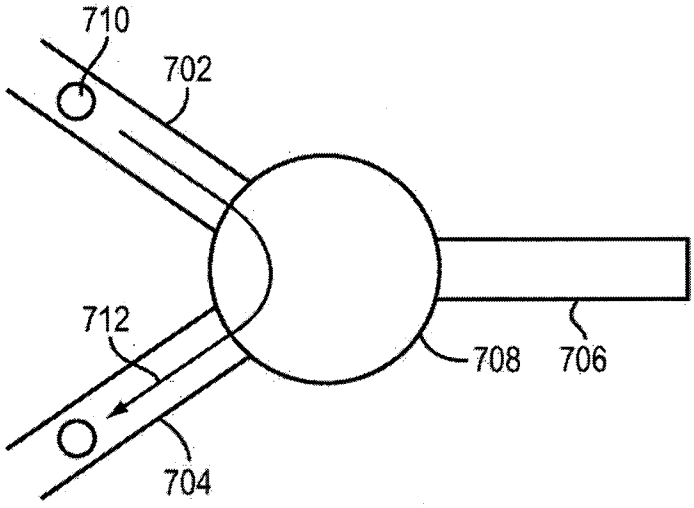
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图7

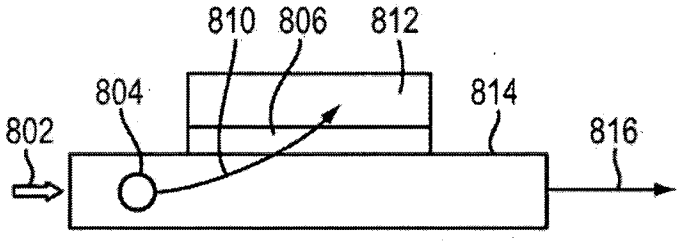
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图8

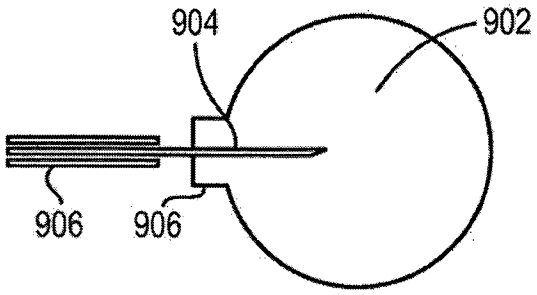


图9A

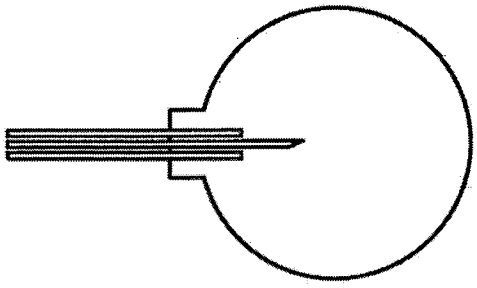
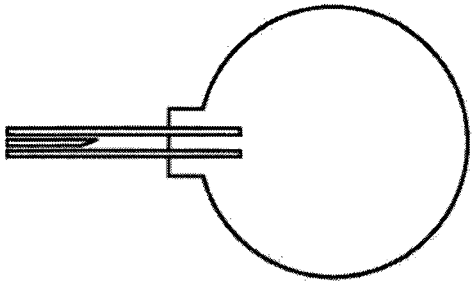


图9B



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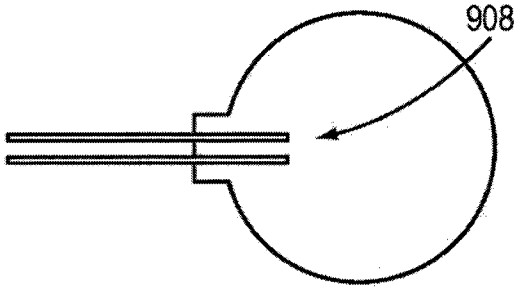

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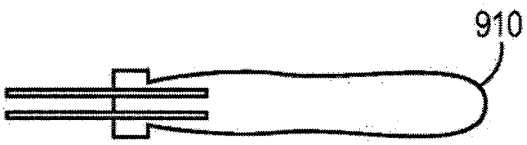

图9E

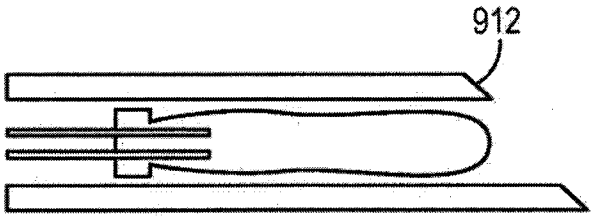

图9F

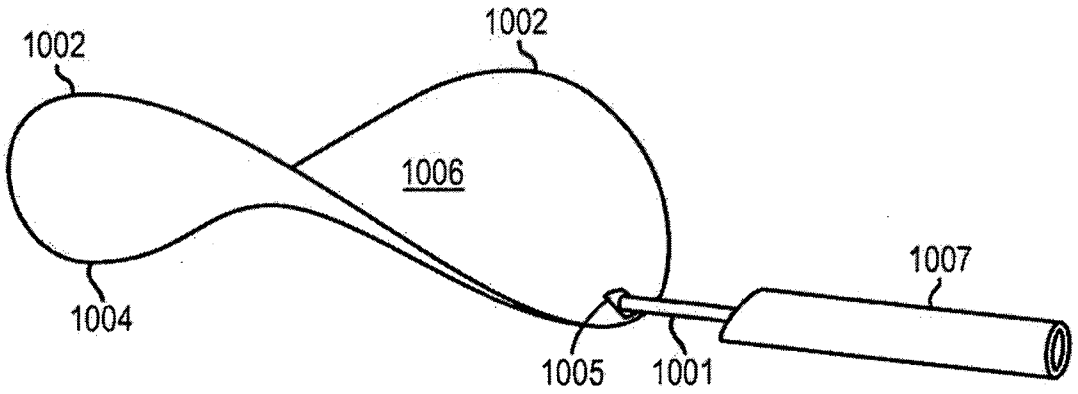

图10

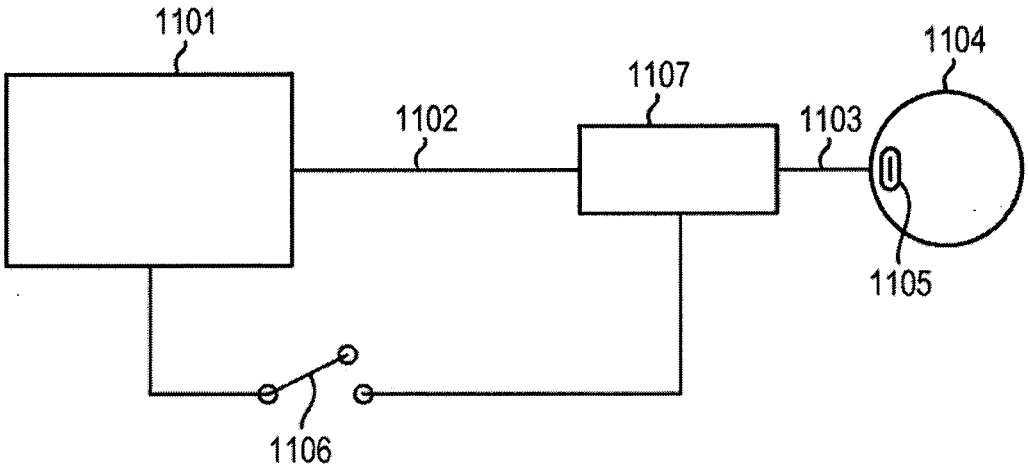
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图11

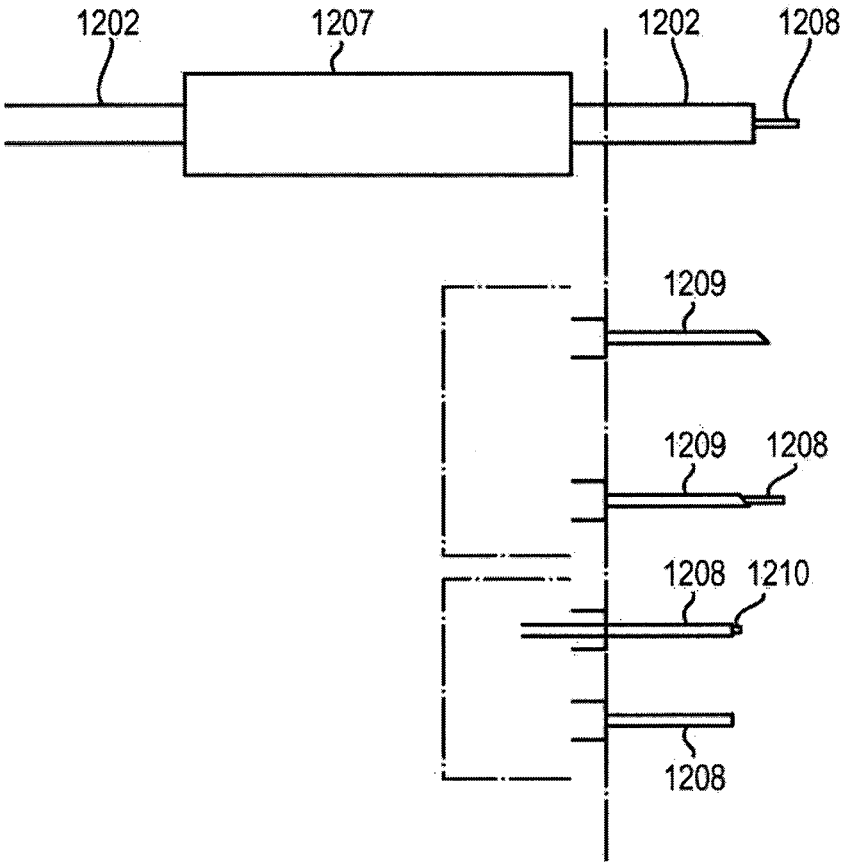
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图12

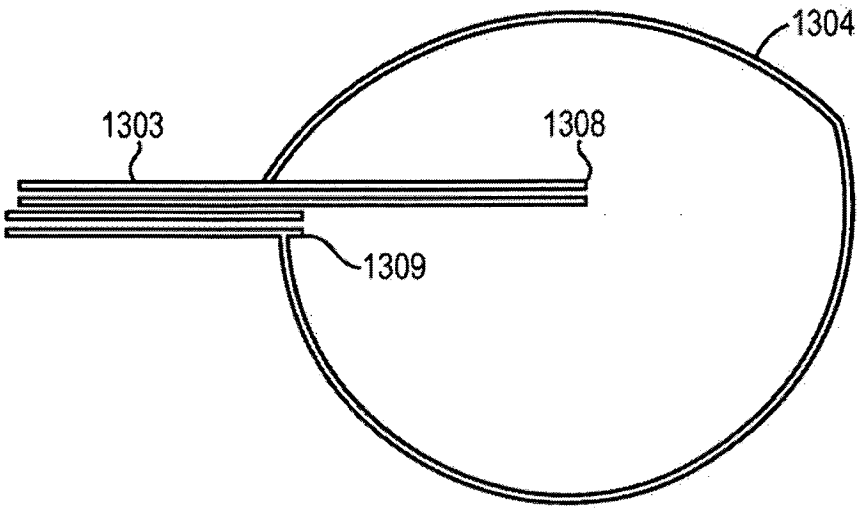

图13

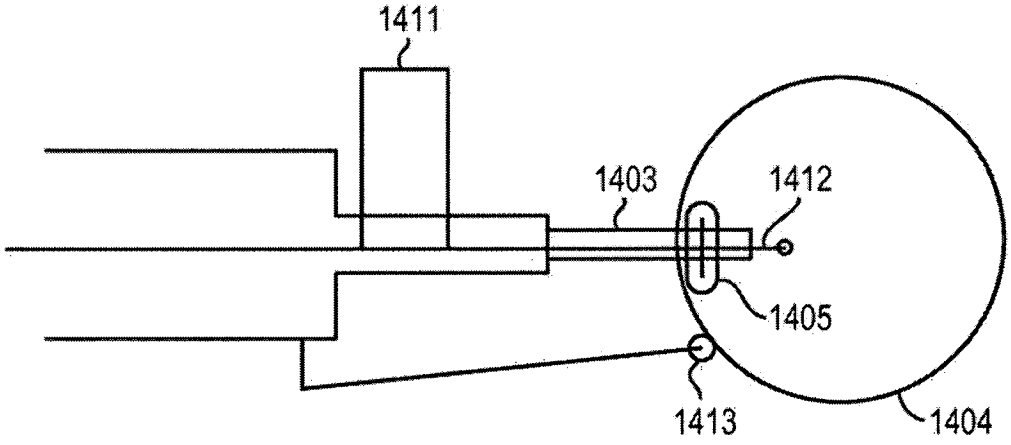

图14

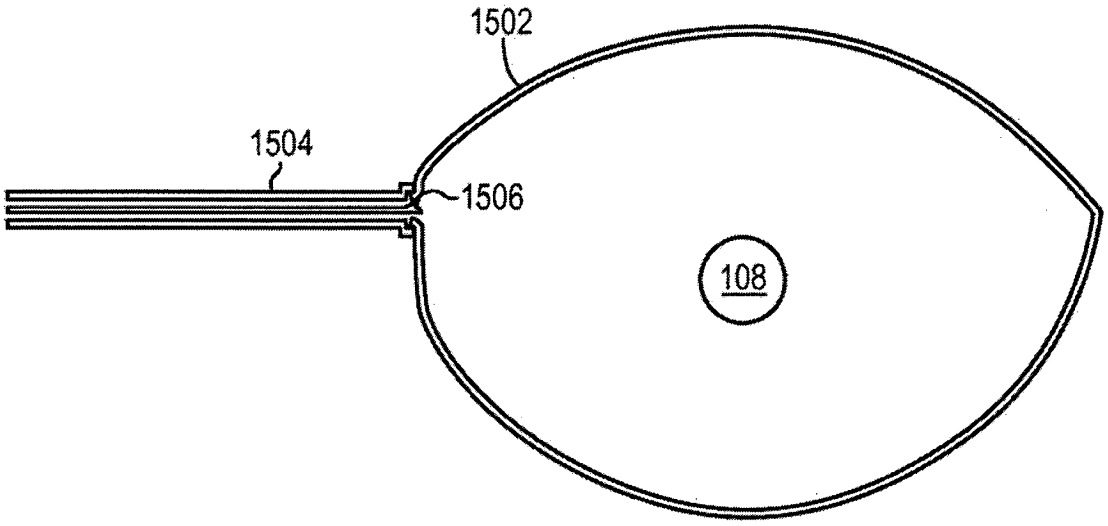

图15

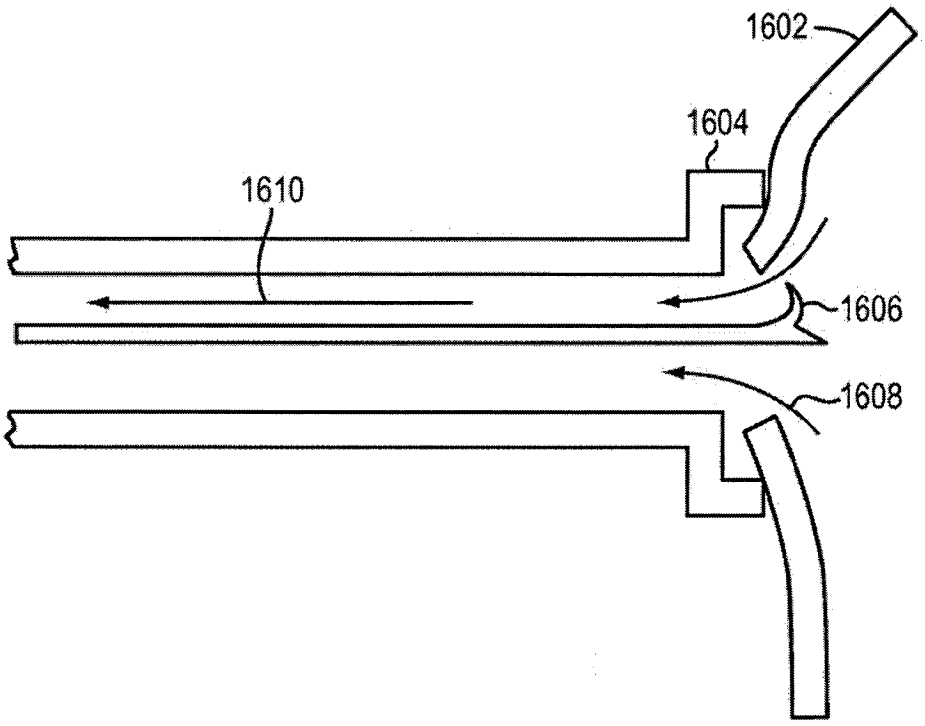

图16

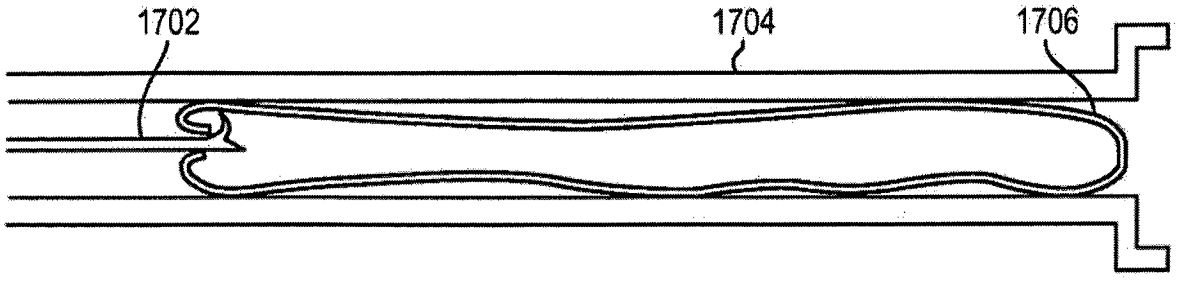

图17

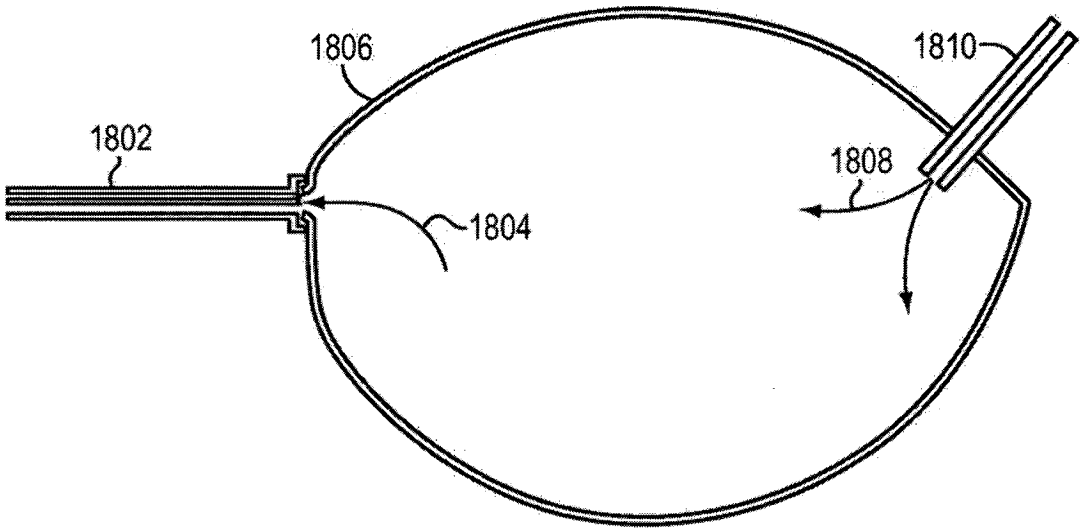

图18

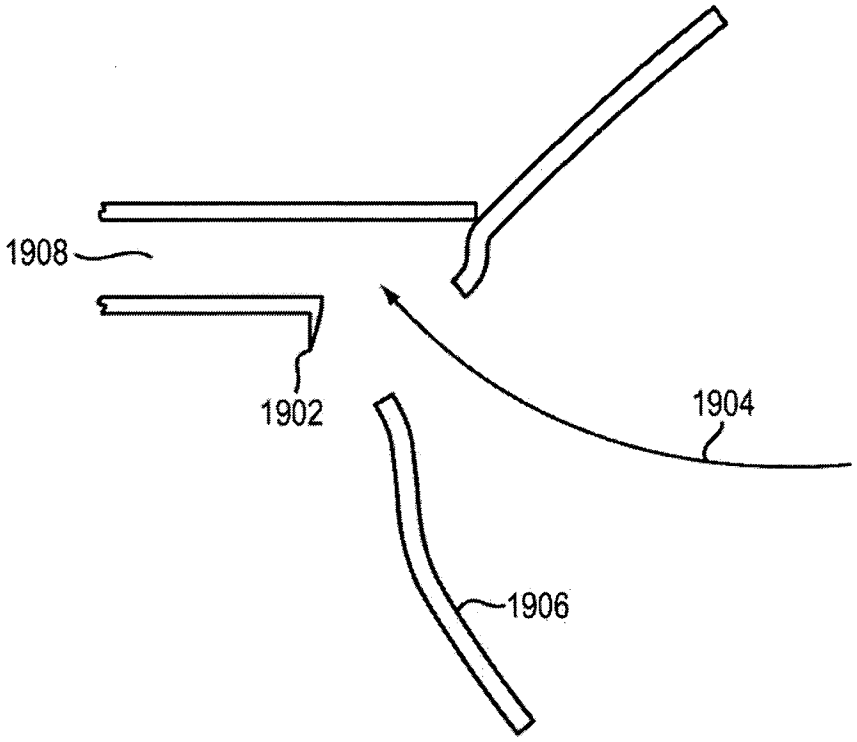

图19

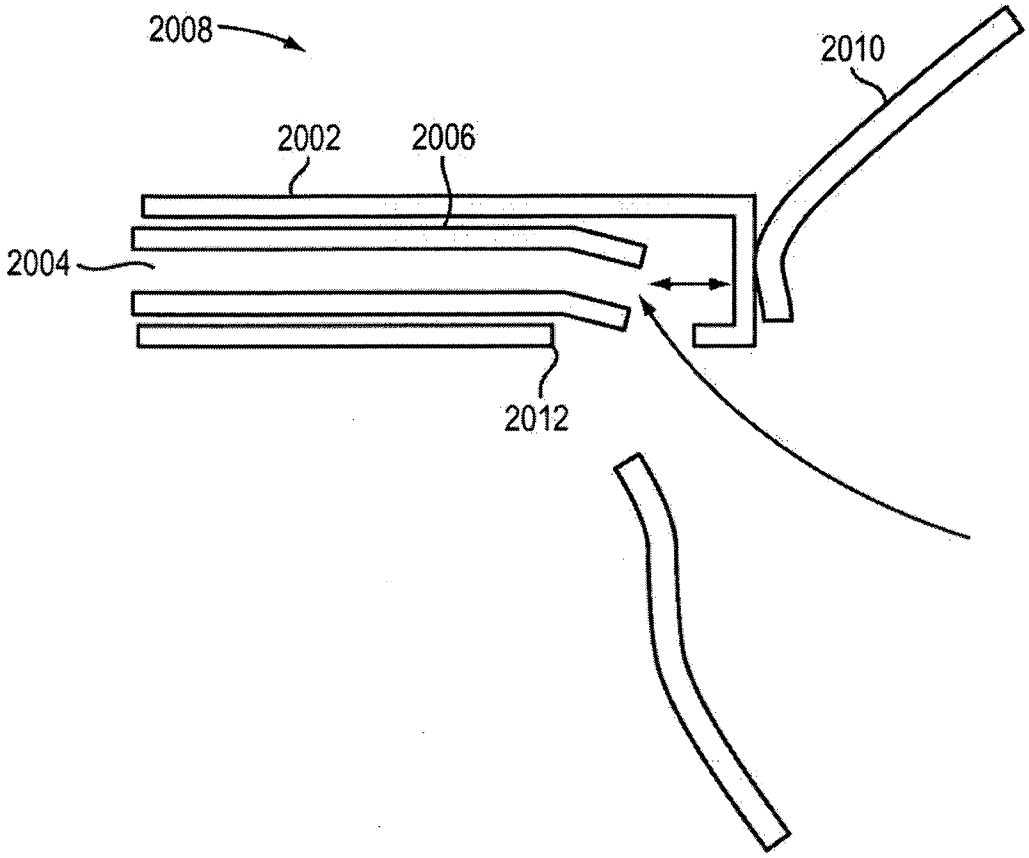

图20

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摘　要

外围手术系统用于流体填充的人工晶状体的插入和填充(100)，晶状体的再进入和改变，以及晶状体的移出(1504)。尽管一个外围手术单元可执行所有这些功能，在一些实施方式中，不同的单元执行不同的功能，即每个功能可由独立的单元执行，或各功能可分配在较少数量的功能单元上。