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(54) Title: SURGICAL DEVICE FOR IOL EXCHANGE

(57) Abstract: A device for extraction of a deformable intraocular lens (IOL) from an eye during a surgical operation. The device includes a slit with an opening to a receiving chamber. The opening may be configured to receive an IOL situated within the eye. The device may be configured to receive solution from a syringe and the device may be inserted through an incision in the eye wall. The interface between the IOL with the slit, receiving chamber, and guide ridge may curl the IOL. The curled IOL may be further advanced into the receiving chamber and extracted from the eye through a small incision in the eye.

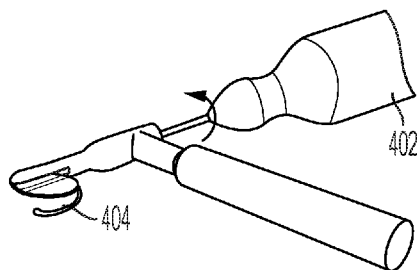


FIG. 6



SURGICAL DEVICE FOR IOL EXCHANGE

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Provisional Patent Application No. 62/792,790 to Young et al. filed on January 15, 2019 and entitled “Surgical Device For IOL Exchange Using Crescentic Contour And Guide Edges,” which is hereby incorporated by reference.

FIELD OF THE DISCLOSURE

[0002] The instant disclosure relates to surgical tools. More specifically, certain embodiments of this disclosure relate to surgical tools for intraocular lens (IOL) exchange.

BACKGROUND

[0003] An Intraocular lens (IOL) is placed inside the eye during cataract surgery to serve as a replacement for the native eye lens. Cataract surgery involves making a small incision into the eye, opening the capsule of the cataractous lens, removing the cataract inside the capsule, and implanting an IOL into the now empty capsular bag. The new lens provides focal power to the eye following removal of the cataract. There are a variety of circumstances requiring the IOL to be removed and/or exchanged after surgery. IOL exchange surgeries are technically challenging for the surgeon, and there are postoperative complications that may arise for the patient following the delicate procedure. IOL exchange

surgery typically requires a long period of recovery, increases the risk for zonular dehiscence and posterior capsule rupture, often requires suturing, increases the propensity for the development of astigmatism, and may lead to the development of intraocular inflammation. Current methods for IOL extraction include whole piece extraction, complete bisection, partial bisection, trisection, crisscross lensotomy, and refolding of the IOL using a fulcrum instrument. In general, the current IOL extraction procedure involves various technical complexities that involve the use of scissors to manipulate the IOL and a corneal incision large enough for the extraction of said IOL. There is a need in the art to develop a device and method to improve the ease of extracting an IOL in the presence of small corneal incision. In doing so, the IOL extraction procedure would be greatly simplified and the degree of patient complications reduced.

[0004] Shortcomings mentioned here are only representative and are included simply to highlight that a need exists for improvement of the strategies used for IOL exchange surgeries.

SUMMARY

[0005] Embodiments of a surgical tool device described herein overcome the shortcomings of the strategies currently in use for intraocular lens (IOL) exchange surgeries. The device applies a force during extraction of the IOL that causes the IOL to fit through an incision, such as by curling the IOL to reduce the cross-section of the IOL as the IOL exits the eye. With such a device the IOL may be extracted from the eye in one piece through a small corneal incision, which eliminates the need for intraocular scissors or an excessively long corneal incision.

[0006] When an intraocular lens (IOL) exchange is needed following cataract surgery or IOL implantation surgery, a device may be positioned near or within a corneal incision made in the eye to facilitate the extraction of an IOL situated upon an eye. The device is used to curl the IOL during extraction to allow removal of the IOL through a smaller incision in the cornea. The device may be configured to receive a solution or

ophthalmic viscosurgical device from a syringe and/or to receive grasping forceps to aid the surgeon before, during, or after the IOL exchange procedure. The device may comprise a handle attached to a surgical component. The surgical component may have a long axis oriented orthogonal to a long axis of the handle and have a first end. The first end of the handle may comprise a slit that provides an opening to a receiving chamber. The receiving chamber may extend a length of the long axis of the surgical component. An inner diameter wall of the receiving chamber may be configured to curl an IOL as the IOL is received by the surgical component. In some embodiments, the inner diameter walls may be smooth, and in other embodiments the walls may have ridges. The IOL may become curled upon interfacing with the opening of the first end and be further positioned into the receiving chamber for complete removal of the IOL from an eye.

[0007] In one embodiment is that the of the opening of the device is configured to curl the intraocular lens (IOL) without the use of an external object to curl the IOL prior to engagement of the IOL with the opening of the device. According to another embodiment, a method of manipulating the intraocular lens (IOL) may comprise the steps of applying a force to the IOL to cause a longitudinal movement of the IOL toward an opening of a device having a receiving chamber for the IOL. The placement of the IOL within the receiving chamber causes the IOL to continuously curl and move into the receiving chamber of the device until the IOL is extracted from an eye. According to one embodiment, the use of the device for intraocular lens (IOL) exchange surgeries removes the necessity of using intraocular scissors to excise the IOL and minimizes the risk of patient to develop deleterious post-operative effects.

[0008] The foregoing has outlined rather broadly certain features and technical advantages of embodiments of the present invention in order that the detailed description that follows may be better understood. Additional features and advantages will be described hereinafter that form the subject of the claims of the invention. It should be appreciated by those having ordinary skill in the art that the conception and specific embodiment disclosed may be readily utilized as a basis for modifying or designing other

structures for carrying out the same or similar purposes. It should also be realized by those having ordinary skill in the art that such equivalent constructions do not depart from the spirit and scope of the invention as set forth in the appended claims. Additional features will be better understood from the following description when considered in connection with the accompanying figures. It is to be expressly understood, however, that each of the figures is provided for the purpose of illustration and description only and is not intended to limit the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] For a more complete understanding of the disclosed system and methods, reference is now made to the following descriptions taken in conjunction with the accompanying drawings.

[0010] FIGURE 1 shows a cross-section of a device according to some embodiments of the disclosure illustrating the handle for the surgeon, the tip that is inserted into the eye, the slit with guide edges extending along the tip of the device to a receiving chamber, and the rear aperture.

[0011] FIGURE 2 shows a perspective view of a device according to some embodiments of the disclosure.

[0012] FIGURE 3 shows another perspective view of a device according to some embodiments of the disclosure.

[0013] FIGURE 4 shows an intraocular lens (IOL) moving toward the aperture of the first end of a device according to some embodiments of the disclosure.

[0014] FIGURE 5 illustrates how the forceps is inserted through the rear aperture of the device and is revealed past the apex of the tip of the device.

[0015] FIGURE 6 shows the curling of the intraocular lens (IOL) as the forceps is rotated, causing the lens to engage the guiding ridge of the device according to some embodiments of the disclosure.

[0016] FIGURE 7 shows the continuous curling of the intraocular lens (IOL) as the forceps are rotated multiple revolutions, which causes the lens to move into the receiving chamber of the device according to some embodiments of the disclosure.

[0017] FIGURE 8 illustrates the intraocular lens (IOL) received within the receiving chamber of the device according to some embodiments of the disclosure.

[0018] FIGURE 9 is a flow chart illustrating a method for manipulation of a deformable intraocular lens (IOL) according to some embodiments of the disclosure.

DETAILED DESCRIPTION

[0019] FIGURE 1 shows a cross-section of a device according to some embodiments of the disclosure illustrating the handle for the surgeon, the tip that is inserted into the eye, the slit with guide edges extending along the tip of the device to a receiving chamber, and an oblique view of a device with an opening to a receiving chamber and the rear aperture. An opening of the device is located at the first end tip apex 103 of a surgical component 110 of the device, and it may be the initial part of the device to enter the eye through a small incision. The first end tip apex 103 may include a slit containing guide ridges. The guide ridges may come in direct contact with the intraocular lens (IOL) as the IOL makes contact with the first end tip apex 103 of the device. The first end tip apex 103 of the device may lead into a receiving chamber 101 of the device. The receiving chamber 101 may be a portion of the tip that is hollow and provides space to receive the IOL. The guide ridges may be present on the inner wall of the receiving chamber 101 near the apex 103. In some embodiments, a smooth wall surface of the inner diameter of the receiving chamber 101 is the guide ridge. A rear aperture 106 located at an opposite end of the receiving chamber 101 from the apex 103 may be configured to receive solution. A ophthalmic viscoelastic

device (OVD) 'solution' is contained within a syringe with a long thin cannula; this cannula can be inserted via the aperture of the device into the lumen and injected to fill the lumen with the OVD. The solution may travel through the receiving chamber 101 and/or exit through the tip apex 103 opening of the device to make contact with an eye. The first end tip apex 103 of the device may be configured to function as a conduit or channel, whereby an intraocular lens (IOL) may be delivered into the receiving chamber 101. The handle 108 of the device is to be held by the surgeon and may be configured to be attached to the surgical component 110 without disturbing the continuous length of the receiving chamber 101.

[0020] The device shown in FIGURE 1 may be configured to be inserted through an eye wall and positioned anterior to a pupil by having appropriate dimensions for the surgical intraocular lens (IOL) exchange procedure. Example dimensions may have an opening tip apex to the portion of the slit closest to the rear with a length of approximately 6-10 mm, or more particularly approximately 8.5 mm, a wall thickness of the opening tip apex 103 of approximately 0.2-0.8 mm, or more particularly approximately 0.4 mm, and/or an inner diameter of the opening tip apex of approximately 1.5-4.5 mm, or more particularly approximately 2.5 mm. A total length from the first end tip apex 103 to the rear aperture 202 may be 10-20mm, or more particularly 15mm. The slit may be 0.5-2mm in width, or more particularly 1mm. The handle 108 may have a length of approximately 5-200mm, or more particularly 100mm. These listed dimensions provide for a device size that promotes the curling of IOL upon interaction with the IOL. For example, the slit cannot be too large; otherwise, during curling, the IOL may disengage and eject from the device. As another example, if the slit length is too short the IOL may protrude from the aperture tip and not properly curl.

[0021] FIGURE 2 is a side view of a device according to embodiments of the disclosure comprising an end configured to receive solution, a handle attached to the receiving chamber, and a receiving chamber. The rear aperture 202 may be configured to receive solution and allow for the solution to travel through the receiving chamber. In one embodiment, the aperture 202 may be a 2.4 mm circular hole. The receiving chamber may fit

an intraocular lens (IOL) or other object received through the tip 103. The tip 103 of the device 200 may be configured with a similar slit and guide ridges and other features as shown in FIGURE 1.

[0022] FIGURE 3 shows an oblique side view which highlights the slit 302. This slit may be continuous with the tip apex 103, and may be configured with similar features as shown in FIGURE 1. A wall thickness of the casing around the receiving chamber may be approximately 0.4mm.

[0023] FIGURE 4 shows grasping forceps 402 being inserted through the rear aperture, to extend through the receiving chamber, and extend out of the tip apex 103. The grasping forceps is positioned to be inserted through the rear aperture of the device. An arrow depicts the direction in which the forceps may be inserted. The forceps is then directed towards an intraocular lens (IOL) 404, which is then grasped. The IOL 404 may be held by a grasping tool and directed to the opening tip apex 103 of the device. The opening of the device may encompass a slit 302 and guide ridge that engages the IOL 404 upon contact with the opening of the device.

[0024] FIGURE 5 illustrates how the forceps, when retracted in the direction of the arrow past the tip apex 103, brings the IOL 404 into the slit 302 and positions the IOL 404 for curling by the slit and/or receiving chamber. In some embodiments, the forceps do not retract the IOL 404 further than the end of the slit 302.

[0025] FIGURE 6 shows the rotation of the forceps 402 in the direction of the arrow causing a curling of the intraocular lens (IOL) 404 as it engages guide ridges (e.g., the inner diameter of the receiving chamber 101 at or near the slit 302) of the device within the slit 302. The illustrated example depicts a clockwise motion of the forceps, but the motion can also be counterclockwise. The intraocular lens 404 deforms to change its original shape upon interacting with the guide ridge of the device. The guide ridge and the receiving chamber cause the folding of the IOL 404 as the IOL 404 is received from the eye. The structural combination of the slit, guide ridge, and/or the contour of the receiving chamber

may provide means by which the IOL 404 curls. The curling force applied by the device results in a reduced cross-section of the IOL 404 extending away from the device and into the eye allowing the lens to fit through a smaller incision. Thus, the incision in the eye may be made smaller when the IOL 404 is extracted with embodiments of the device shown in the figures.

[0026] FIGURE 7 shows the grasping forceps 402 rotated within the surgeon's hand, and the resulting revolutions causing continuous curling of the intraocular lens (IOL) 404 until the IOL 404 may be completely curled into the receiving chamber of the device. The intraocular lens 404 may interface with a grasping tool and receiving chamber simultaneously. The continuous curling of the IOL 404 occurs as a force is applied to the grasping tool 402 holding the IOL 404, whereby the IOL 404 then engages within the receiving chamber of the device. The IOL 404 may be partially interfacing with the receiving chamber as the IOL 404 continues to curl.

[0027] The lens held by the forceps is removed through the rear aperture in the direction depicted by the arrow shown in FIGURE 8. According to some embodiments of the disclosure, the entire device, lens, and forceps can be removed from the eye at the same time. FIGURE 8 illustrates the intraocular lens (IOL) 404 fitted within the receiving chamber of the device. The IOL 404 may be fully encapsulated as a rolled lens into the receiving chamber of the device. The rolled IOL 404 is then retracted into the receiving chamber by the continued grasp of the forceps and retraction force applied by or through the forceps. The retraction may continue until the forceps 402 and IOL 404 have been removed through the rear aperture. Alternatively, the device can be completely removed from the eye while the rolled IOL 404 and forceps 402 remain within the receiving chamber. In some embodiments, the receiving chamber does not receive or fit the entire IOL 404, and such a device may have smaller dimensions. The dimensions may depend on the thickness of the IOL (which is slightly different for each IOL) and the thickness of the forceps. An acceptable diameter of the inner should be based, at least in part, on these two factors. For some dimensions, the

entire IOL cannot be curled into a lumen, but partial curling of the IOL may still be possible with removal of the entire IOL performed with a part of the IOL left unfolded.

[0028] FIGURE 9 is a flow chart illustrating a method for manipulation of a deformable intraocular lens (IOL) prosthesis according to the embodiments of the disclosure. A method 900 may include introducing into the eye wall a device comprising a surgical component having a first end with opening through a slit to a receiving chamber to receive an IOL. The device used in the method of FIGURE 9 may be the device described above with respect to FIGURES 1-8. The method 900 may start at block 902 with the surgeon creating a small space in the eye wall to expose the IOL previously affixed to an eye. For example, an incision may be approximately 2-3 mm in length. The IOL may engage a slit opening to a receiving chamber of the device. Next, the IOL may be rotated into an anterior chamber, and an ophthalmic viscosurgical device is then inserted into the anterior chamber to elevate the IOL above the iris plane. In some embodiments, the ophthalmic viscosurgical device is inserted using the surgical tool described with reference to FIGURES 1-8.

[0029] At block 904, a force may be applied to the IOL to longitudinally move the IOL directionally toward the slit of the device. Upon interaction of the IOL with the slit of the device, turning of the forceps and the force applied by the receiving chamber and/or slit cause IOL to curl. After the curl is complete, the IOL may be further retracted into the receiving chamber. In some embodiments, the IOL may be folded to a degree by a partial insertion into the receiving chamber prior to removal of the device from the corneal incision. The lens need not be fully inserted into the device, but rather folded into a small enough dimension to allow it to fit through the small corneal incision. In some embodiments, grasping forceps can be inserted into the eye 180 degrees away from the device, come across the eye, and assist in alignment of the IOL into the slit and cause curling by revolutions of the forceps within the receiving chamber, and further insertion of the forceps can cause the complete insertion of the IOL into the device.

[0030] In some embodiments, the method may include manipulating haptics to curl such that leading and trailing haptics are also contained within a lumen of the device. In

some embodiments, the method may include amputating haptics and removing the haptics the eye prior to the insertion of the IOL into the device. In one embodiment, the haptic can be left unfolded and protruding from the device while the optic is curled, and removed from the eye 'trailing' outside of the device while still attached to the haptic.

[0031] There are many advantages to the use of embodiments of the disclosed device and method of IOL extraction and exchange. First, the potential downsides of intraocular scissors are avoided, which includes a potential of damaging the posterior capsule, iris, anterior capsule, corneal endothelium, and surrounding structures with the sharp blades. Certain embodiments also avoid malfunctioning moving parts or dull scissor blades that are incapable of cutting through the IOL material, which was not designed by the manufacturer to be cut, but rather designed to be folded. In contrast, embodiments described herein have no moving parts or sharp edges, and the disclosed use avoids the need to cut the IOL material entirely. Second, a large clear corneal incision used in semi-circular folding can be avoided, along with the associated higher risk of leaking, endophthalmitis, and irregular astigmatism. Third, the device acts as the agent that both folds the IOL and extracts it from the eye in one unified step, simplifying the procedure length and reducing surgical technique complexity. Fourth, the combination of the slit and receiving chamber configuration of the device allows the IOL to fold within a small diameter.

[0032] The described methods are generally set forth in a logical flow of steps. As such, the described order and labeled steps of representative figures are indicative of aspects of the disclosed method. Other steps and methods may be conceived that are equivalent in function, logic, or effect to one or more steps, or portions thereof, of the illustrated method. Additionally, the format and symbols employed are provided to explain the logical steps of the method and are understood not to limit the scope of the method. Although various arrow types and line types may be employed in the flow chart diagram, they are understood not to limit the scope of the corresponding method. Indeed, some arrows or other connectors may be used to indicate only the logical flow of the method. For instance, an arrow may indicate a waiting or monitoring period of unspecified duration

between enumerated steps of the depicted method. Additionally, the order in which a particular method occurs may or may not strictly adhere to the order of the corresponding steps shown.

[0033] Although the present disclosure and certain representative advantages have been described in detail, it should be understood that various changes, substitutions and alterations can be made herein without departing from the spirit and scope of the disclosure as defined by the appended claims. Moreover, the scope of the present application is not intended to be limited to the particular embodiments of the process, machine, manufacture, composition of matter, means, methods and steps described in the specification. As one of ordinary skill in the art will readily appreciate from the present disclosure, processes, machines, manufacture, compositions of matter, means, methods, or steps, presently existing or later to be developed that perform substantially the same function or achieve substantially the same result as the corresponding embodiments described herein may be utilized. Accordingly, the appended claims are intended to include within their scope such processes, machines, manufacture, compositions of matter, means, methods, or steps.

CLAIMS

What is claimed is:

1. An apparatus, comprising:
 - a surgical component comprising a first end, wherein the first end comprises a slit opening to a receiving chamber, and wherein the slit is configured to curl an intraocular lens (IOL) as the IOL is received into the receiving chamber; and
 - a handle attached to the surgical component and configured to allow for manipulation of the deformable intraocular lens (IOL).
2. The device of claim 1, wherein the slit exposes an inner diameter of the opening as guide ridges for curling the intraocular lens (IOL).
3. The device of claim 2, wherein the surgical component further comprises a rear aperture having a second opening to the receiving chamber.
4. The device of claim 3, wherein the rear aperture is configured to receive solution from a syringe.
5. The device of claim 3, wherein the rear aperture is configured to receive grasping forceps for manipulation of the deformable intraocular lens (IOL).
6. The device of claim 1, wherein the first end is configured to be inserted through an eye wall and positioned anterior to a pupil.
7. The device of claim 6, wherein the receiving chamber is approximately 10-20 mm in length.
8. The device of claim 6, wherein the slit is approximately 0.5-2mm in width and 6-10mm in length along an axis normal to a cross section of the opening.

9. The device of claim 6, wherein a wall thickness of the opening is approximately 0.2-0.8 mm.
10. The device of claim 6, wherein an inner diameter of the opening is approximately 1.5-4.5 mm.
11. A method for manipulation of the deformable intraocular lens (IOL), comprising the steps of:
 - applying a force to the IOL to cause a longitudinal movement of the IOL toward a slit of a device having a receiving chamber for the IOL; and
 - receiving the IOL in the receiving chamber of the device, wherein the receiving of the IOL into the slit causes guide ridges of the receiving chamber to cause the IOL to continuously curl.
12. The method of claim 11, further comprising creating a first and a second peripheral corneal incision, wherein the incisions are approximately 1.0-4.0 mm in length.
13. The method of claim 11, further comprising:
 - rotating the IOL into an anterior chamber of the eye;
 - elevating the IOL above the iris of the eye using an ophthalmic viscosurgical device that is inserted into the anterior chamber of the eye, wherein the ophthalmic viscosurgical device is inserted through the device having the receiving chamber.
14. The method of claim 11, wherein the receiving step results in removal of the IOL from the eye.

15. The method of claim 11, wherein receiving the IOL in the receiving chamber comprises folded the IOL to a degree by a partial insertion into the receiving chamber prior to removal of the device from the corneal incision.
16. The method of claim 11, further comprising inserting grasping forceps into an eye 180 degrees away from the device to assist in alignment of the IOL into the slit and cause curling by rotation of the grasping forceps within the receiving chamber.
17. The method of claim 16, further comprising continuing rotation of the grasping forceps to cause complete extraction of the IOL from an eye into the device.
18. The method of claim 11, further comprising manipulating haptics to curl such that leading and trailing haptics are also contained within a lumen of the device.
19. The method of claim 11, further comprising amputating haptics; and removing the haptics the eye prior to the insertion of the IOL into the device.

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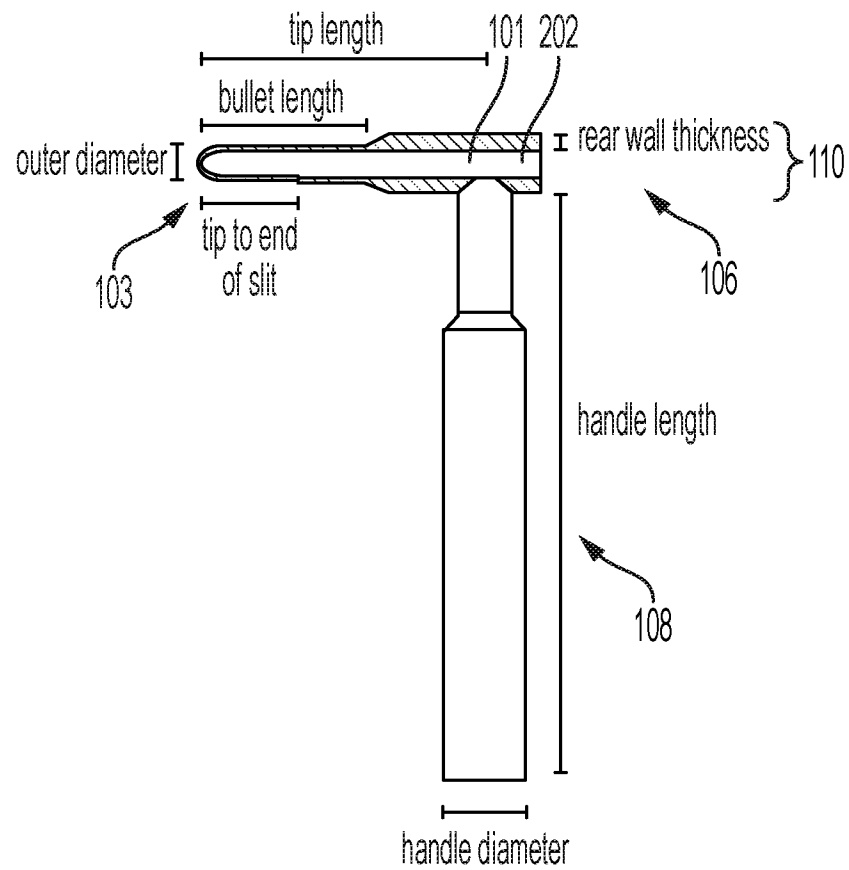


FIG. 1

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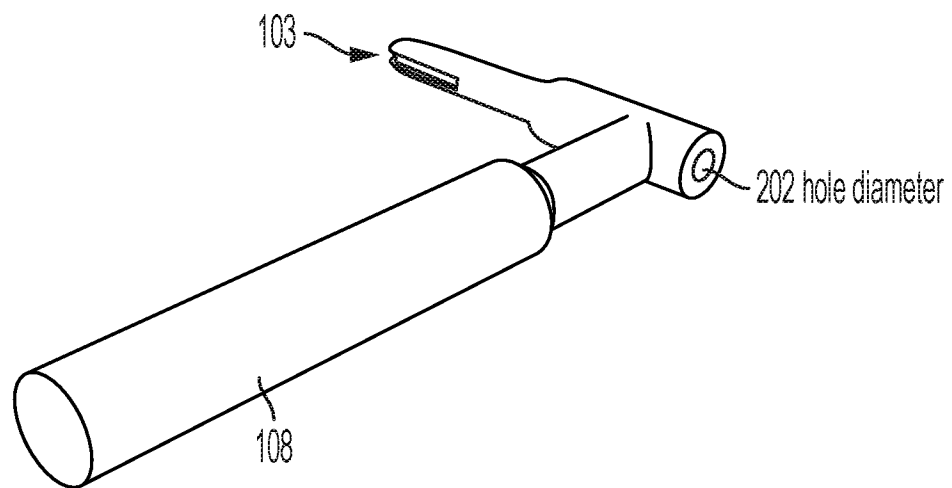


FIG. 2

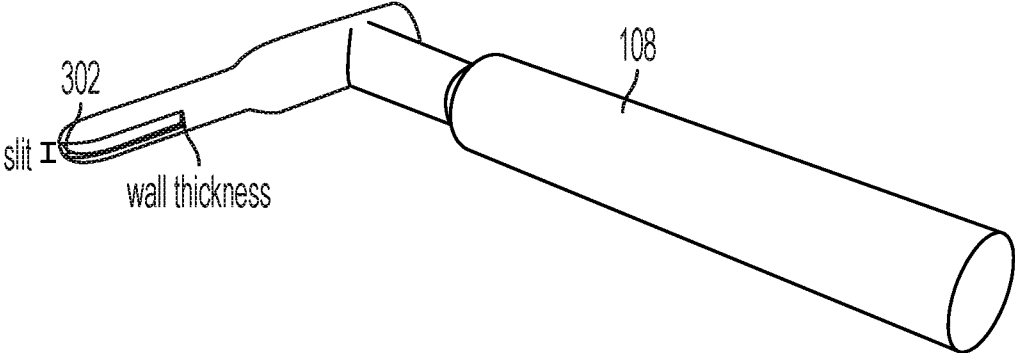


FIG. 3

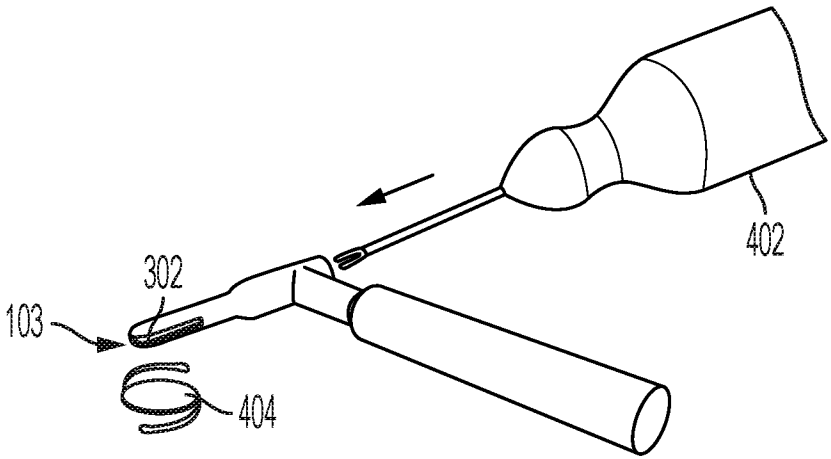


FIG. 4

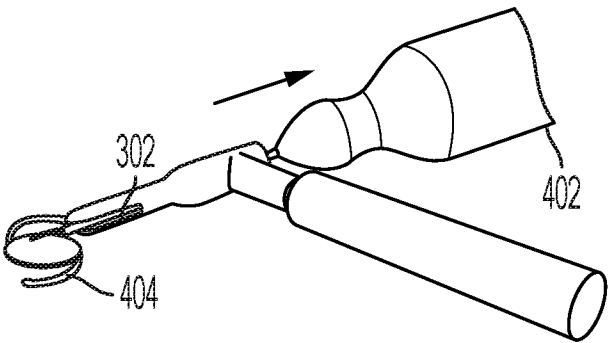


FIG. 5

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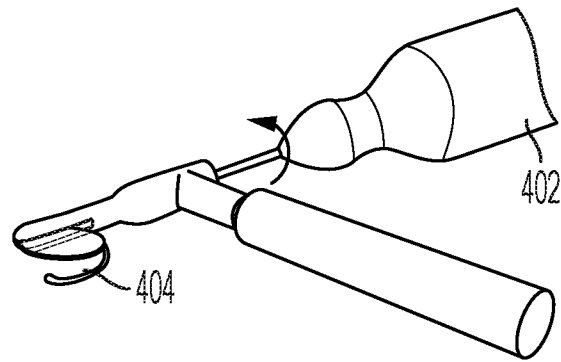


FIG. 6

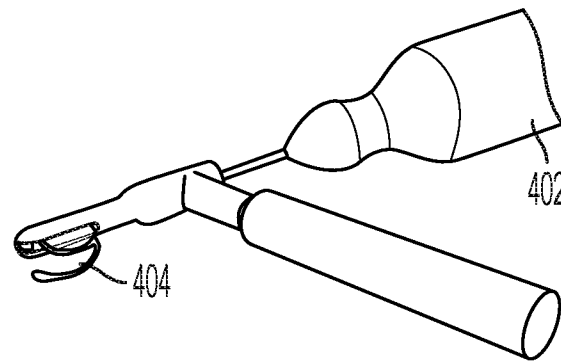


FIG. 7

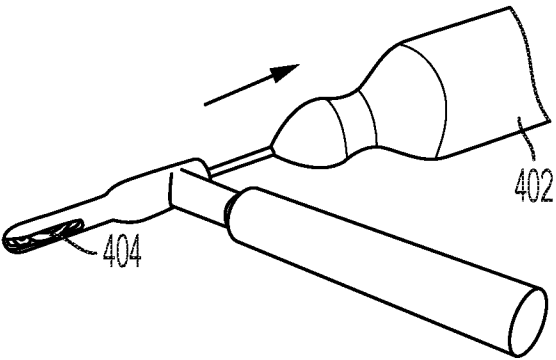


FIG. 8

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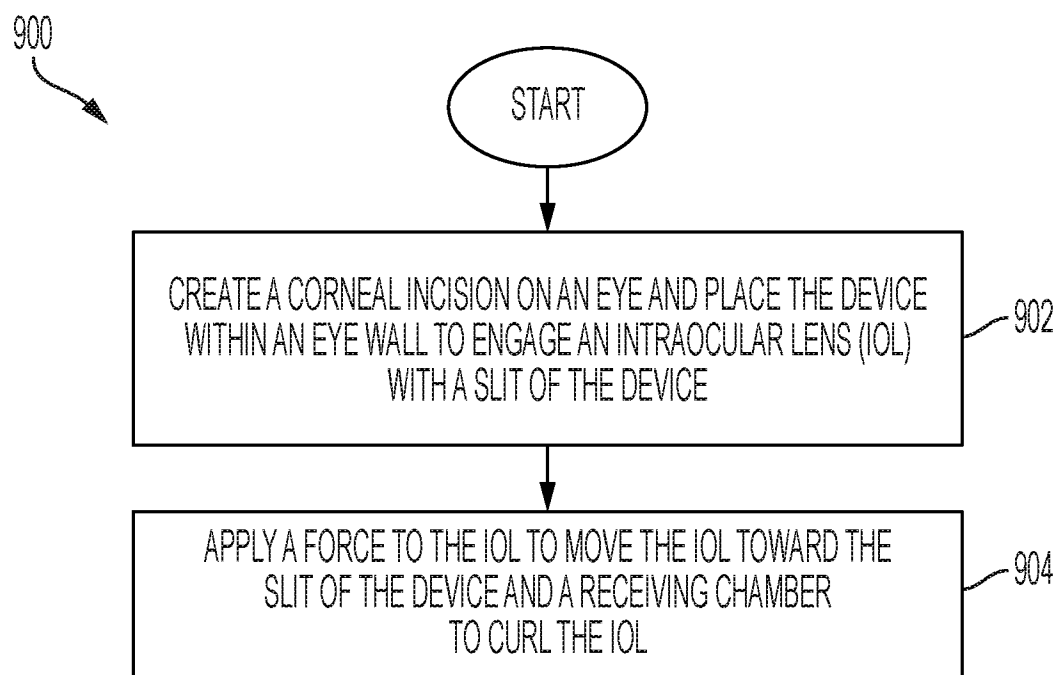


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2020/013476

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/16; A61F 2/14; A61F 9/00; A61F 9/007 (2020.01)

CPC - A61F 2/1662; A61F 2/14; A61F 2/16; A61F 9/00; A61F 9/007; A61F 2002/1681; A61F 2002/16902 (2020.02)

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)

See Search History document

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

USPC - 606/107; 623/4.1; 623/6.12; 623/6.11 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,836,201 A (PATTON et al) 06 June 1989 (06.06.1989) entire document	1-11
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Y		15, 18
Y	US 2009/0270876 A1 (HOFFMANN et al) 29 October 2009 (29.10.2009) entire document	15
Y	US 5,304,182 A (RHEINISH et al) 19 April 1994 (19.04.1994) entire document	18
A	US 5,562,676 A (BRADY et al) 08 October 1996 (08.10.1996) entire document	1-19
A	US 4,834,094 A (PATTON et al) 30 May 1989 (30.05.1989) entire document	1-19

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Date of the actual completion of the international search

23 February 2020

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