

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

HOYA CORPORATION, HOYA	)	
SURGICAL OPTICS, INC., HOYA	)	
LAMPHUN LTD., and HOYA MEDICAL	)	
SINGAPORE PTE LTD.,	)	
	)	
Plaintiffs,	)	<b>Civil Action No. 3:20-cv-03629</b>
	)	
v.	)	<b>JURY TRIAL DEMANDED</b>
	)	
ALCON INC., ALCON LABORATORIES,	)	
INC., ALCON RESEARCH, LLC, and	)	
ALCON VISION, LLC,	)	
	)	
Defendants.	)	
	)	
	)	
ALCON LABORATORIES, INC. and	)	
ALCON RESEARCH, LLC,	)	
	)	
Counterclaim Plaintiffs,	)	
	)	
v.	)	
	)	
HOYA CORPORATION and HOYA	)	
SURGICAL OPTICS, INC.	)	
	)	
Counterclaim Defendants.	)	

**FIRST AMENDED COMPLAINT**

Plaintiffs HOYA Corporation, HOYA Surgical Optics, Inc., HOYA Lamphun Ltd., and HOYA Medical Singapore Pte Ltd. (collectively “HOYA” or “Plaintiffs”) file this Original Complaint against Defendants Alcon Inc., Alcon Laboratories, Inc., Alcon Research, LLC, and Alcon Vision, LLC (collectively “Alcon” or “Defendants”) and hereby allege as follows:

### **NATURE OF ACTION**

1. HOYA alleges that Alcon has infringed and continues to infringe at least one claim of U.S. Patent Nos. 9,901,442 (“the ’442 Patent”); 9,980,811 (“the ’811 Patent”); 9,655,718 (“the ’718 Patent”); 9,877,826 (“the ’826 Patent”); 9,907,647 (“the ’647 Patent”); and 10,039,668 (“the ’668 Patent”) (collectively, “Patents-in-Suit”).

2. HOYA has been at the forefront of intraocular lens (“IOL”) technology since 1987, when it produced its first IOL. An IOL is a synthetic lens implanted in the eye as part of a treatment for cataracts. A cataract is the clouding of the eye’s natural lens and is the leading cause of vision loss for people over the age of 40.

3. Cataract surgery is one of the most commonly conducted surgical procedures in the United States, and in the world, and it is essential to restoring vision and improving the quality of life of patients suffering from cataracts. In cataract surgery, an IOL is implanted inside the anterior segment of the eye once the eye’s natural lens has been removed. As the number of cataract patients has increased with time, there has been an increased need for improved technologies that allow surgeons to safely and effectively treat these patients.

4. For several decades, HOYA has been a leading developer of IOL technology. HOYA’s IOLs and IOL insertion devices dramatically improved cataract surgery because they allow surgeons greater control and precision when implanting the IOL, eliminate the need for manual folding of the lens, and reduce the risk of infection as a result of the device’s sterile packaging. HOYA has secured numerous patents on its revolutionary inventions in this technology space, including the Patents-in-Suit, which cover methods and apparatuses for IOL insertion.

5. Alcon infringes the Patents-in-Suit through the manufacture, use, sale, offer for sale, and/or import of at least Alcon’s UltraSert Preloaded Delivery System (“UltraSert”). Alcon’s

UltraSert is a disposable IOL injector with a preloaded intraocular lens. Alcon has marketed and sold UltraSert to others in the medical industry, including hospitals, medical centers, clinicians, doctors, nurse practitioners, and care providers, with knowledge of HOYA's intellectual property asserted herein. As a result of such actions, Alcon infringes, contributes to the infringement of, and/or induces the infringement of each of the Patents-in-Suit.

### **PARTIES**

6. Plaintiff HOYA Corporation is a corporation organized under the laws of Japan with its principal place of business at 20F Nittochi Nishishinjuku Building, 6-10-1 Nishi-Shinjuku, Shinjuku-ku, Tokyo 160-8347 Japan.

7. Plaintiff HOYA Surgical Optics, Inc. is a corporation organized under the laws of the state of Delaware with its principal place of business at 15335 Fairfield Ranch Road, Suite 250, Chino Hills, CA 91709. HOYA Surgical Optics, Inc. is a subsidiary of HOYA Corporation.

8. Plaintiff HOYA Lamphun Ltd. is a company organized and existing under the laws of the Kingdom of Thailand with its principal office at Northern Region Industrial Estate, 75/2 Moo 4, Tambol Banklang, Amphur Muang, Lamphun, 51000 Thailand.

9. Plaintiff HOYA Medical Singapore Pte Ltd. is a corporation organized and existing under the laws of Singapore, having its principal office at 455A Jalan Ahmad Ibrahim Singapore 639939.

10. Plaintiff HOYA Corporation owns a number of subsidiaries incorporated and headquartered in the United States, including in the state of Texas. For example, HOYA Corporation, through a subsidiary, owns and operates a large facility at 651 E. Corporate Dr., Lewisville, TX 75057.

11. Plaintiffs HOYA Medical Singapore Pte Ltd. and HOYA Lamphun Ltd. are subsidiaries related to HOYA Corporation.

12. Plaintiff HOYA Medical Singapore Pte Ltd. manufactures HOYA IOL insertion devices and distributes HOYA IOL insertion devices in the United States as an exclusive licensee of the patents in suit.

13. Defendant Alcon Inc. is organized under the laws of Switzerland with its principal place of business at Chemin de Blandonnet 8, 1214 Vernier-Geneva, Switzerland. Alcon Inc.'s principal office for U.S. operations is located in Fort Worth, Texas. Alcon Inc. is the ultimate parent company of Alcon Laboratories, Inc., Alcon Research, LLC, and other Alcon entities.

14. Defendant Alcon Laboratories, Inc. is a corporation organized under the laws of the state of Delaware, with its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134. Alcon Laboratories, Inc. is licensed with the Texas Department of Health to manufacture and/or distribute medical devices in the State of Texas. Alcon Laboratories, Inc. is a wholly-owned subsidiary of Alcon Inc.

15. Defendant Alcon Research, LLC (formerly known as Alcon Research, Ltd.) (“Alcon Research”) is a corporation organized under the laws of the state of Delaware, with its principal place of business at 6201 South Freeway, Fort Worth, Texas 76134. Alcon Research is licensed with the Texas Department of Health to manufacture and/or distribute medical devices in the State of Texas. Alcon Research is a wholly-owned subsidiary of Alcon Inc.

16. Defendant Alcon Vision, LLC (“Alcon Vision”) is a corporation organized under the laws of the state of Delaware, with its principal place of business at 6201 South Freeway, Fort Worth, Texas, 76134. Alcon Vision is licensed with the Texas Department of Health to

manufacture and/or distribute products in the State of Texas. Alcon Vision, LLC is an affiliate of Alcon Inc.

### **JURISDICTION AND VENUE**

17. This Court has subject matter jurisdiction over the patent infringement claims asserted in this case under 28 U.S.C. §§ 1331 and 1338.

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400 because Alcon has committed, and continues to commit, acts of infringement in this District and has a regular and established place of business in this District. Alcon maintains regular and established places of business in the District at: 6201 South Freeway, Fort Worth, Texas 76134; 250 E. Altamesa Boulevard, Fort Worth, Texas 76134; 101 E. Altamesa Boulevard, Fort Worth, Texas 76134; 13155 Noel Rd., Dallas, Texas 75240; 777 Taylor St., Suite 900, Fort Worth, TX 76102; and 6551 South Freeway, Fort Worth, Texas 76134.

19. This Court has personal jurisdiction over each named Alcon entity. Alcon was founded in 1945 within the Northern District of Texas. Alcon Inc.'s global headquarters was located in the Northern District of Texas until 2019. Alcon Inc.'s U.S. headquarters is currently located in the Northern District of Texas. Additionally, Alcon Laboratories, Inc.'s and Alcon Research's principal place of business is currently located in the Northern District of Texas.

20. Alcon's largest production and research and development facility is located in the Northern District of Texas.

21. Alcon Inc., Alcon Laboratories, Inc., Alcon Research, and Alcon Vision employ thousands of individuals within the Northern District of Texas, including sales managers, engineers, scientists, materials specialists, legal counsel, and financial analysts.

22. Alcon conducts business extensively within the Northern District of Texas. For example, Alcon employees within this District solicit orders for Alcon's products; demonstrate Alcon's products; maintain an inventory of Alcon's products; and/or fill orders from their inventory of Alcon's products within this District.

23. Alcon has created a manufacturing, sales, and distribution system comprising substantial resources within the Northern District of Texas. Through this distribution channel, Alcon introduces infringing products into the stream of commerce with the knowledge, expectation, and intent that they will be sold and used in the United States, including in the State of Texas and in this District.

#### **THE HOYA PATENTS**

24. On February 27, 2018, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,901,442 ("the '442 Patent"), entitled "Intraocular Lens Insertion Device," to inventors Kazunori Kudo and Masahiro Noda. HOYA owns all rights to the '442 Patent necessary to bring this action. A true and correct copy of the '442 Patent is attached hereto as Exhibit 1 and incorporated herein by reference.

25. On May 29, 2018, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,980,811 ("the '811 Patent"), entitled "Ocular Implant Insertion Apparatus and Methods," to inventors Kazunori Kudo and Masahiro Noda. HOYA owns all rights to the '811 Patent necessary to bring this action. A true and correct copy of the '811 Patent is attached hereto as Exhibit 2 and incorporated herein by reference.

26. On May 23, 2017, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,655,718 ("the '718 Patent"), entitled "Intraocular Lens Insertion Device," to inventors Kazunori Kudo and Masahiro Noda. HOYA owns all rights to the '718 Patent necessary

to bring this action. A true and correct copy of the '718 Patent is attached hereto as Exhibit 3 and incorporated herein by reference.

27. On January 30, 2018, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,877,826 (“the '826 Patent”), entitled “Intraocular Lens Insertion Device,” to inventors Kazunori Kudo and Masahiro Noda. HOYA owns all rights to the '826 Patent necessary to bring this action. A true and correct copy of the '826 Patent is attached hereto as Exhibit 4 and incorporated herein by reference.

28. On March 6, 2018, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,907,647 (“the '647 Patent”), entitled “Intraocular Lens Insertion Device and Method for Controlling Movement of the Intraocular Lens,” to inventor Masanobu Inoue. HOYA owns all rights to the '647 Patent necessary to bring this action. A true and correct copy of the '647 Patent is attached hereto as Exhibit 5 and incorporated herein by reference.

29. On August 7, 2018, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 10,039,668 (“the '668 Patent”), entitled “Ocular Implant Insertion Apparatus and Methods,” to inventors Kazunori Kudo and Masahiro Noda. HOYA owns all rights to the '668 Patent necessary to bring this action. A true and correct copy of the '668 Patent is attached hereto as Exhibit 6 and incorporated herein by reference.

### **FACTUAL BACKGROUND**

30. For nearly three decades, HOYA has been a leading innovator in the design and manufacture of IOLs and IOL insertion devices, including HOYA's iSert® injector system. One of HOYA's revolutionary innovations is its IOL injector technology, which has increased the safety and effectiveness of cataract surgery as we know it today.

31. Cataracts are a major cause of blindness worldwide, and cataract surgery is one of the most commonly performed eye surgeries in the world. Cataract surgery typically involves removing the cloudy natural lens and replacing it with an IOL, which is implanted in the anterior chamber of the eye after the natural lens has been removed.

32. To perform cataract surgery today, a physician typically makes an incision in the periphery of the cornea (the clear outer covering of the eye) and removes the diseased lens using phacoemulsification. The physician then implants the new lens through the same incision. The new lens that is implanted in the patient's eye is typically an IOL that is made of hydrogel, soft acrylic, silicone, or the like.

33. Prior to the introduction of IOL injectors, a surgeon performing cataract surgery would have to insert a rigid polymethylmethacrylate ("PMMA") lens or manually fold a soft foldable lens and place it in the patient's eye using forceps. *See, e.g.*, '718 Patent at 1:25-2:4; '826 Patent at 1:28-3:18; '647 Patent at 1:25-3:07. Performing cataract surgery in this manner was difficult and potentially problematic for several reasons. First, the physician's use of forceps to place the lens in the patient's eye often caused damage to the IOL. Second, performing cataract surgery in this manner required the physician to make large incisions in the cornea in order to be able to place and position the lens on the eye. These large incisions often had to be closed using sutures, which increased the duration of the procedure. Although the size of the incision could be minimized by using foldable lenses, which unfold after insertion, manually folding an IOL requires a high level of skill and presents additional room for error by the physician and possible infection. For example, an uneven fold could cause the lens to be positioned improperly on the eye, which typically could only be remedied by enlarging the incision or making an additional incision. *See, e.g.*, '718 Patent at 1:25-2:4; '826 Patent at 1:28-3:18; '647 Patent at 1:25-3:07. Assistive devices



were eventually developed to help with the challenges presented as a result of having to manually fold the lens during surgery. Although these assistive devices aided with standardizing the proportions of the fold, none of these devices eliminated the use of forceps or provided a method for more controlled and consistent lens insertion.

34. The 1990s saw the development of reusable IOL injectors for soft deformable lenses, allowing physicians to inject an IOL into smaller incisions in the eye. These injectors generally used a cartridge into which the physician loaded the IOL using forceps, and the cartridge was subsequently attached to the injector body. The physician then slowly manipulated the plunger of the injector to advance the loaded IOL out of the injector cartridge and into the capsular sac of the eye. Because physicians had to manually load the IOLs into these injectors, there was the potential for contamination and damage to the optic (round lens portion) or the haptics (*e.g.*, the arm-like supports attached to the optic) of the IOLs. *See, e.g.*, '718 Patent at 1:60-65; '811 Patent at 1:47-57; '647 Patent at 1:60-64. Use of such injectors in certain circumstances could result in damage to the IOL due to the plunger riding up onto the rear haptic and optic, resulting in deformation of the IOL. *See, e.g.*, '718 Patent at 1:66-2:23; '826 Patent at 1:58-2:6; '647 Patent at 1:65-2:20.

35. In the 2000s, HOYA developed disposable, preloaded IOL injectors, which solved many of the challenges that existed with the prior cataract surgery methods and IOL injectors. *See, e.g.*, '718 Patent at 2:57-3:14; '826 Patent at 3:21-67; '647 Patent at 2:50-4:51. To date, HOYA has sold more than nine million preloaded IOL injector systems.

**ALCON'S ACCUSED PRODUCTS**

**A. Alcon Makes, Imports, Uses, Sells, and/or Offers for Sale Products that Infringe the Patents-in-Suit.**

36. Alcon makes, imports, uses, sells, and/or offers for sale IOL insertion devices that infringe at least one claim of each of the Patents-in-Suit (“Accused Products”).

37. For example, Alcon manufactures, imports, tests, uses, offers for sale, and sells an IOL delivery system called UltraSert, which is preloaded with an IOL. An image of the UltraSert injector is shown below:



<https://2.myalcon.com/professional/cataract-surgery/intraocular-lens/ultrasert-preloaded-delivery-system/features-specifications> (last visited 12/10/20).

38. Alcon received FDA approval for the UltraSert.

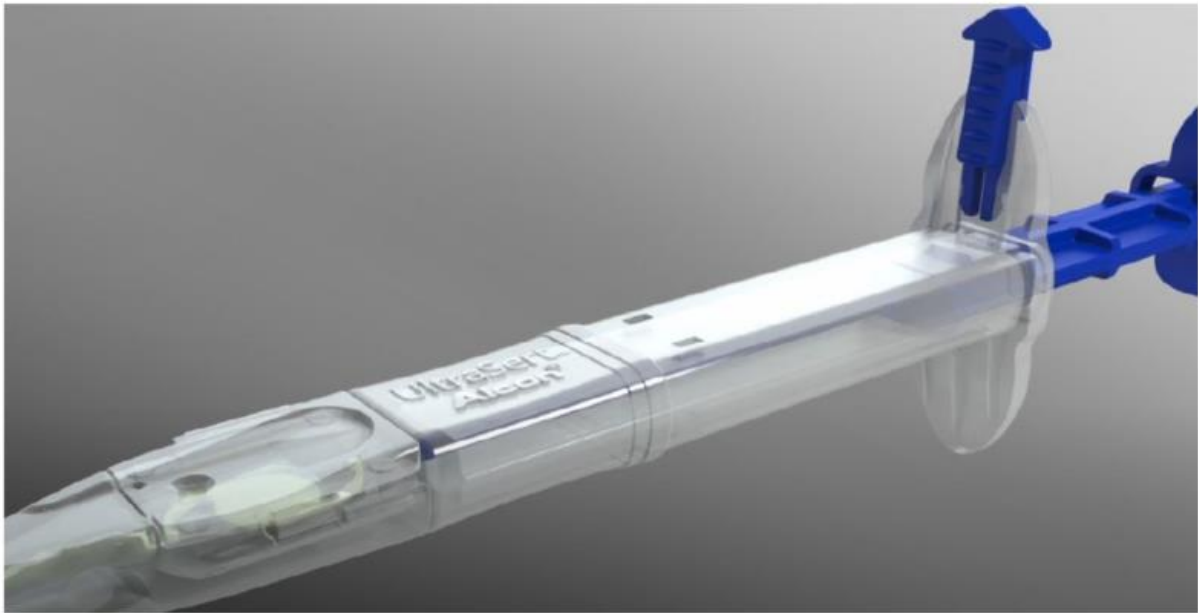
39. Alcon manufactures UltraSert in the United States. See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=181244> (last visited 12/10/2020); <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=148530> (last visited 12/10/2020).

40. Alcon markets, sells, and/or provides UltraSert to hospitals, medical centers, clinics, surgeons, and/or nurses in the United States directly, or through sales representatives or

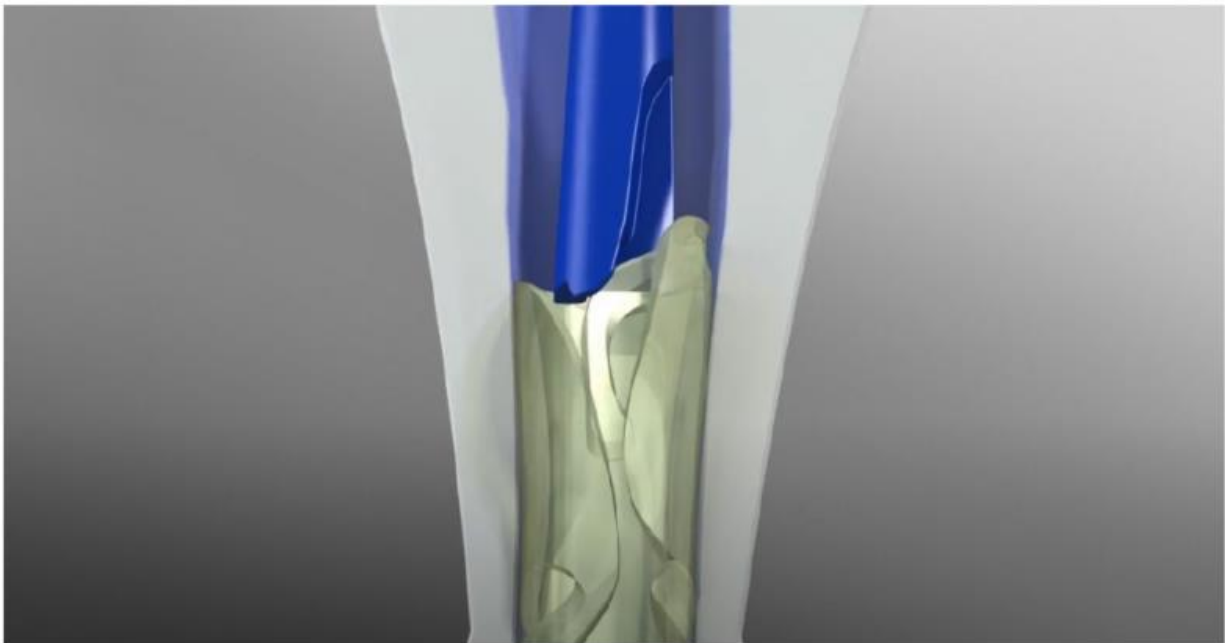
distributors, and provides instructions on how to use UltraSert. For example, Alcon advertises its UltraSert product on public webpages registered to Alcon Inc. and using public videos branded and/or sponsored by Alcon Inc. *See, e.g.,* <https://professional.myalcon.com/cataract-surgery/intraocular-lens/> (last visited 12/10/20); <https://www.alcon.com/media-release/alcon-introduces-newly-optimized-ultrasertr-pre-loaded-intraocular-lens-delivery> (last visited 12/10/20); <https://www.opthalmologytimes.com/view/ultrasert-pre-loaded-delivery-system-surgical-pearls> (last visited 12/10/20). Alcon Inc.'s recent SEC filings also include repeated mentions of its UltraSert product. *See* Alcon Inc., Registration Statement (Form 20-F) at 100, 107-108, 110-11, 136 (Mar. 21, 2019).

41. Alcon also regularly includes information concerning the production and sale of UltraSert in Alcon Inc.'s SEC filings and presentations to Alcon's investors. *See, e.g.,* [https://www.alcon.com/sites/g/files/rbvwei496/files/2019-04/Feb\\_Roadshow\\_Presentation\\_2.12.19.pdf](https://www.alcon.com/sites/g/files/rbvwei496/files/2019-04/Feb_Roadshow_Presentation_2.12.19.pdf) (last visited 12/10/20); [https://s1.q4cdn.com/963204942/files/doc\\_financials/2019/q4/Alcon-Form-20-F-2019.pdf](https://s1.q4cdn.com/963204942/files/doc_financials/2019/q4/Alcon-Form-20-F-2019.pdf) (last visited 12/10/20).

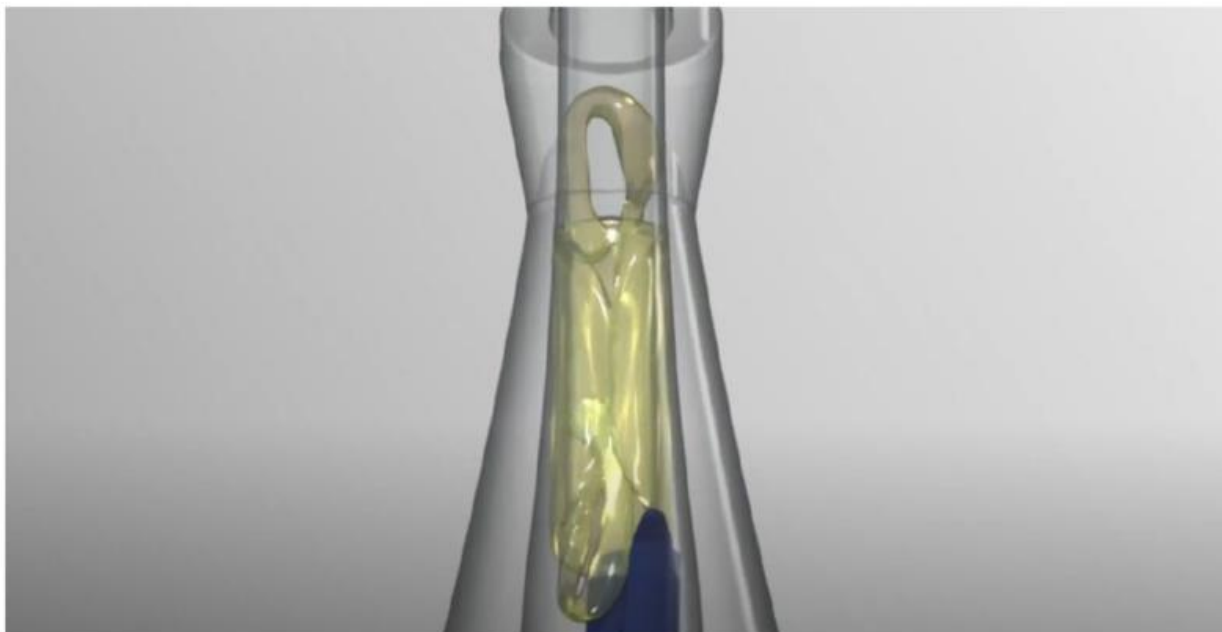
42. Use of UltraSert is depicted in a video titled "Alcon UltraSert preloaded IOL delivery system," available at <https://www.youtube.com/watch?v=uXWhS-BVcz4> (last visited 12/10/20). The following images of UltraSert are screenshots captured from this video.



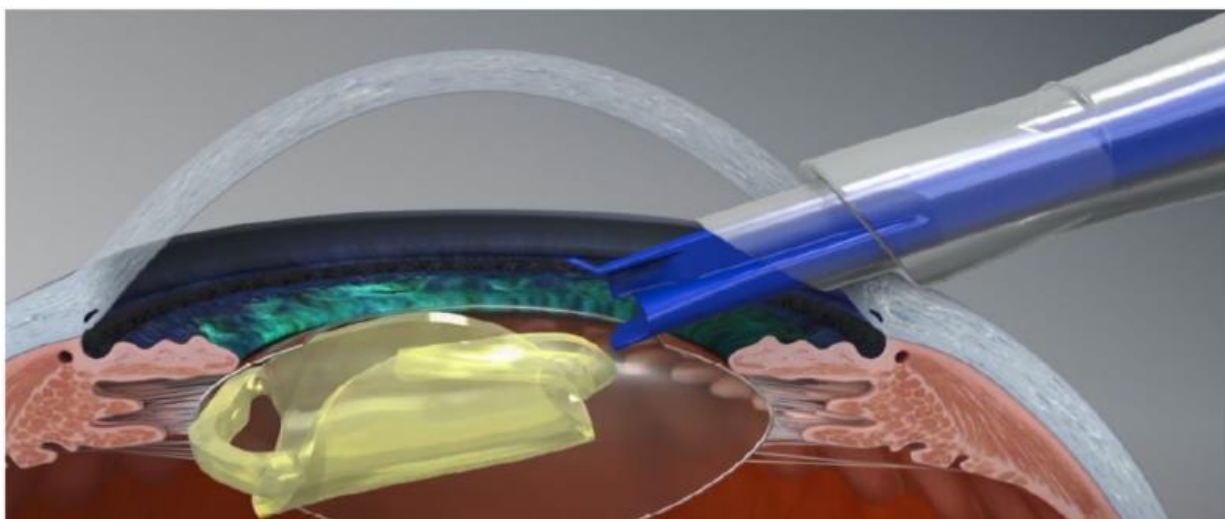
*Id.* at 0:34.



*Id.* at 1:08.



*Id.* at 1:14.



*Id.* at 6:36.

43. UltraSert is preloaded with an IOL that is comprised of a foldable optic, a bendable distal (*e.g.*, towards the eye) haptic that is attached to the optic at one end and free at another end, and a bendable proximal (*e.g.*, away from the eye) haptic that is attached to the optic at one end and free at another end. The preloaded IOL is positioned within a chamber atop lens supporting

surfaces within the UltraSert injector. The UltraSert also has a main body, a nozzle through which the IOL exits the device, and a tapered transition portion connecting the main body to the nozzle.

44. UltraSert contains a plunger that the user can depress to move the plunger in the distal direction towards the eye. The plunger has top, bottom, and side walls that form a recess, as well as a lens contacting portion. As the plunger moves distally, it first contacts the unfolded proximal haptic and bends it distally in an upward direction such that the free end of the proximal haptic passes over an unfolded portion of the optic. At least a portion of the proximal haptic enters the plunger recess as this occurs. The lens contacting portion of the plunger contacts the optic as the plunger moves distally through the main body. The sides of the optic fold in an upwards direction as the optic approaches the nozzle, and the free end of the upwardly bent proximal haptic enters the space in between the folded portions of the optic. As the IOL is pushed through the nozzle and into the eye by the plunger, the IOL is in a folded configuration with the free end of the proximal haptic pointing in the distal direction and positioned in the space between the folded portions of the optic.

45. When used or tested, UltraSert, and any other Alcon products that operate in substantially the same manner, either alone or in combination, directly infringe at least one claim of each of the Patents-in-Suit.

46. UltraSert is designed and sold to be used only to deliver an intraocular lens in a specific way, as directed by the instructions in the manuals delivered with UltraSert and promotional materials concerning UltraSert. The manuals and promotional materials provide specific instructions for using UltraSert in a way that infringes at least one claim of each of the Patents-in-Suit, and they do not contemplate any non-infringing uses.

**GENERAL ALLEGATIONS RELATED TO INFRINGEMENT**

47. Alcon has infringed and continues to directly and indirectly infringe at least one claim of each of the Patents-in-Suit by engaging in acts constituting infringement under 35 U.S.C. § 271(a), (b), (c) and/or (f), including but not limited to one or more of making, using, selling, offering for sale, importing, exporting, and inducing and contributing to infringement by others, the Accused Products in this District and elsewhere in the United States.

48. As a result of Alcon's infringement, HOYA has suffered and will continue to suffer harm in the form of reasonable royalties and/or lost profits. HOYA seeks damages for infringing acts beginning as early as six years prior to the filing of this Original Complaint.

49. HOYA also seeks an injunction prohibiting further acts of infringement. Each of Alcon's acts of infringement has caused and will continue to cause HOYA irreparable harm for which there is no adequate remedy at law. Such injunctive relief would not disserve the public interest, and is warranted when considering the balance of equities.

50. Alcon had actual or constructive knowledge and notice of infringement as to each of the Patents-in-Suit. Alcon is a direct competitor of HOYA in the IOL insertion device market. As such, Alcon knew, should have known, or was willfully blind as to the existence of the Patents-in-Suit at the time of Alcon's infringing acts. Additionally, Alcon's patents cite a number of patent applications and publications by the named inventors of the Patents-in-Suit and/or within the same family as the Patents-in-Suit, thereby confirming that Alcon is familiar with HOYA's intellectual property and knew, should have known, or was willfully blind as to the existence of the Patents-in-Suit at the time of Alcon's infringing acts. *See, e.g.*, U.S. Patent Nos. 9,463,089; 9,724,191; 10,010,408; 10,172,706; 10,188,506; 10,568,735; 10,588,780.

51. Alcon's infringement of the Patents-in-Suit has been, and continues to be, willful because Alcon has committed and continues to commit acts of infringement even though Alcon knew or should have known that its actions constituted an unjustifiably high risk of infringement.

52. Alcon's infringement of the Patents-in-Suit has been, and continues to be, without permission, consent, authorization, or license.

**COUNT I: PATENT INFRINGEMENT OF THE '442 PATENT**

53. HOYA incorporates by reference the preceding paragraphs as though fully set forth herein.

54. Alcon infringes, contributes to the infringement of, and/or induces infringement of the '442 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '442 Patent.

55. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one of more claims of the '442 Patent. Alcon makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the '442 Patent.

56. For example, Claim 1 of the '442 Patent is reproduced below:

1. An intraocular lens insertion apparatus, comprising:

a main body;

an intraocular lens including an optic and haptics, each haptic having a free end, stored in the main body in such a manner that one of the haptics is a proximal haptic and one of the haptics is a distal haptic;

a nozzle associated with the main body and configured to be inserted into an eye; and

a plunger, carried within the main body and movable relative to the main body from a first position to a second position at the nozzle, including a lens contact portion and a recess that is located above



the lens contact portion, that extends proximally from the lens contact portion, that has a first lateral side that is open, a second lateral side that is closed by a lateral wall, and an open distal end, wherein the plunger is configured to hold a portion of the proximal haptic in the recess when the proximal haptic is bent such that the free end of the proximal haptic is positioned over the optic.

57. As a non-limiting example, UltraSert is an intraocular lens insertion apparatus. This insertion apparatus includes a main body.

58. UltraSert includes an intraocular lens including an optic and haptics, each haptic having a free end, stored in the main body in such a manner that one of the haptics is a proximal haptic and one of the haptics is a distal haptic.

59. UltraSert includes a nozzle associated with the main body and configured to be inserted into an eye.

60. UltraSert includes a plunger that is carried within the main body and movable relative to the main body from a first position to a second position at the nozzle.

61. UltraSert includes a plunger including a lens contact portion and a recess that is located above the lens contact portion.

62. UltraSert includes a plunger including a recess that extends proximally from the lens contact portion, that has a first lateral side that is open, a second lateral side that is closed by a lateral wall, and an open distal end.

63. UltraSert includes a plunger wherein the plunger is configured to hold a portion of the proximal haptic in the recess when the proximal haptic is bent such that the free end of the proximal haptic is positioned over the optic.

64. Alcon also indirectly infringes claims of the '442 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Alcon's distributors, customers, and end users, in this District and elsewhere in the United States. For example, Alcon's customers and end

users directly infringe through their use of the inventions claimed in the '442 Patent. Alcon induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions, documentation, online technical support, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. As a result of Alcon's inducement, Alcon's customers and end users use the Accused Products in the way Alcon intends and directly infringe the '442 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '442 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '442 Patent.

65. Alcon also indirectly infringes claims of the '442 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. Alcon's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Alcon's customers' and end users' use of the Accused Products, such that the '442 Patent is directly infringed. The accused components within the Accused Products are material to the invention of the '442 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Alcon to be especially made or especially adapted for use in infringement of the '442 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '442 Patent and with intent, or willful blindness, that they cause the direct infringement of the '442 Patent.

**COUNT II: PATENT INFRINGEMENT OF THE '811 PATENT**

66. HOYA incorporates by reference the preceding paragraphs as though fully set forth herein.

67. Alcon infringes, contributes to the infringement of, and/or induces infringement of the '811 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '811 Patent.

68. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '811 Patent. Alcon makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the '811 Patent.

69. For example, Claim 1 of the '811 Patent is reproduced below: 1. An intraocular lens insertion apparatus, comprising:

an outer body including a lens placement section and a nozzle and defining a lens movement direction;

an intraocular lens, having an optic with a diameter and haptics with respective free ends, stored in the lens placement section in such a manner that the optic diameter is perpendicular to the lens movement direction, one of the haptics is a proximal haptic and one of the haptics is a distal haptic; and

a plunger, at least a portion of which is carried within the outer body, that is movable relative to the outer body and which has a distal region that defines a longitudinal axis, the distal region including

a bottom wall having an upper surface and defining a width in a direction transverse to the longitudinal axis of the distal region,

a lens contact surface extending downwardly from the bottom wall upper surface,

a top wall defining a width in a direction transverse to the longitudinal axis of the distal region that is less than the width of the bottom wall, and

a lateral wall that extends from the bottom wall to the top wall in a direction perpendicular to the optic diameter that is perpendicular to the lens movement direction,

the top wall, bottom wall and lateral wall together defining a recess that is located above the bottom wall, that extends proximally from the lens contact surface, that has a first lateral side that is open, a second lateral side that is closed by the lateral wall, and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end is positioned over the optic.

70. As a non-limiting example, UltraSert is an intraocular lens insertion apparatus. This insertion apparatus includes an outer body including a lens placement section and a nozzle and defining a lens movement direction.

71. UltraSert includes an intraocular lens including an optic with a diameter and haptics with respective free ends, stored in the lens placement section in such a manner that the optic diameter is perpendicular to the lens movement direction, one of the haptics is a proximal haptic and one of the haptics is a distal haptic.

72. UltraSert includes a plunger, at least a portion of which is carried within the outer body, that is movable relative to the outer body and which has a distal region that defines a longitudinal axis.

73. UltraSert includes a plunger with a distal region including a bottom wall having an upper surface and defining a width in a direction transverse to the longitudinal axis of the distal region, a lens contact surface extending downwardly from the bottom wall upper surface, a top wall defining a width in a direction transverse to the longitudinal axis of the distal region that is less than the width of the bottom wall, and a lateral wall that extends from the bottom wall to the top wall in a direction perpendicular to the optic diameter that is perpendicular to the lens movement direction, the top wall, bottom wall and lateral wall together defining a recess that is located above the bottom wall, that extends proximally from the lens contact surface, that has a

first lateral side that is open, a second lateral side that is closed by the lateral wall, and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end is positioned over the optic.

74. Alcon also indirectly infringes claims of the '811 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Alcon's distributors, customers, and end users, in this District and elsewhere in the United States. For example, Alcon's customers and end users directly infringe through their use of the inventions claimed in the '811 Patent. Alcon induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions, documentation, online technical support, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. As a result of Alcon's inducement, Alcon's customers and end users use the Accused Products in the way Alcon intends and directly infringe the '811 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '811 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '811 Patent.

75. Alcon also indirectly infringes claims of the '811 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. Alcon's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Alcon's customers' and end users' use of the Accused Products, such that the '811 Patent is directly infringed. The accused components within the Accused Products are material to the invention of the '811 Patent, are not staple articles or commodities of commerce, have no

substantial non-infringing uses, and are known by Alcon to be especially made or especially adapted for use in infringement of the '811 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '811 Patent and with intent, or willful blindness, that they cause the direct infringement of the '811 Patent.

**COUNT III: PATENT INFRINGEMENT OF THE '718 PATENT**

76. HOYA incorporates by reference the preceding paragraphs as though fully set forth herein.

77. Alcon infringes, contributes to the infringement of, and/or induces infringement of the '718 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '718 Patent.

78. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '718 Patent. Alcon makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the '718 Patent.

79. For example, Claim 1 of the '718 Patent is reproduced below:

1. A method for use with an intraocular lens, including an optic, a forward haptic having an end and a rear haptic having an end, that is located within an insertion device defining a lens travelling axis and including a nozzle, a transition section and a plunger that moves forwardly toward the nozzle and includes a forward region with a side wall and a bottom wall that together define a slot that extends rearwardly and is configured to receive a portion of the rear haptic, the method comprising the steps of:

pushing the end of the rear haptic upwardly and forwardly relative to the optic;

pushing the end of the rear haptic over the optic, while the portion of the optic over which the rear haptic passes remains unfolded, with the forward region of the plunger such that a portion of the rear haptic is bent and received in the slot that extends rearwardly;

folding the optic such that there is a space between folded portions of the optic; and

pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic.

80. As a non-limiting example, UltraSert is used according to a method of use with an intraocular lens. UltraSert is used with an intraocular lens including an optic, a forward haptic having an end and a rear haptic having an end.

81. UltraSert is used according to a method in which the intraocular lens is located within an insertion device defining a lens travelling axis and including a nozzle, a transition section, and a plunger that moves forwardly toward the nozzle.

82. UltraSert has a plunger which includes a forward region with a side wall and a bottom wall that together define a slot that extends rearwardly and is configured to receive a portion of the rear haptic.

83. UltraSert is operated by pushing the end of the rear haptic upwardly and forwardly relative to the optic.

84. UltraSert provides for pushing the end of the rear haptic over the optic, while the portion of the optic over which the rear haptic passes remains unfolded, with the forward region of the plunger such that a portion of the rear haptic is bent and received in the slot that extends rearwardly.

85. The implantation method of UltraSert provides for folding the optic such that there is a space between folded portions of the optic.

86. The implantation method of UltraSert provides for pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic.

87. Alcon also indirectly infringes claims of the '718 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Alcon's distributors, customers, and end users, in this District and elsewhere in the United States. For example, Alcon's customers and end users directly infringe through their use of the invention claimed in the '718 Patent. Alcon induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions, documentation, online technical support, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. As a result of Alcon's inducement, Alcon's customers and end users use the Accused Products in the way Alcon intends and directly infringe the '718 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '718 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '718 Patent.

88. Alcon also indirectly infringes claims of the '718 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. Alcon's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Alcon's customers' and end users' use of the Accused Products, such that the '718 Patent is directly infringed. The accused components within the Accused Products are material to the invention of the '718 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Alcon to be especially made or especially adapted for use in infringement of the '718 Patent. Alcon has performed and continues to perform



these affirmative acts with knowledge of the '718 Patent and with intent, or willful blindness, that they cause the direct infringement of the '718 Patent.

**COUNT IV: PATENT INFRINGEMENT OF THE '826 PATENT**

89. HOYA incorporates by reference the preceding paragraphs as though fully set forth herein.

90. Alcon infringes, contributes to the infringement of, and/or induces infringement of the '826 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '826 Patent.

91. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '826 Patent. Alcon makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the '826 Patent.

92. For example, Claim 1 of the '826 Patent is reproduced below:

1. A method performed by an intraocular lens insertion device on an intraocular lens, the intraocular lens including an optic, a forward haptic having an end and a rear haptic having an end, the insertion device including a nozzle, a transition section and a plunger having a forward region with a side wall and a bottom wall that together define an indentation and is configured to receive a portion of the rear haptic, the method comprising the steps of:

pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic;

pushing the rear haptic such that the end of the rear haptic passes over the optic, while the portion of the optic over which the rear haptic passes remains unfolded, with the forward region of the plunger in such a manner that the rear haptic is bent and a portion of the rear haptic is received in the indentation;

folding a portion of the optic such that there is a space between folded portions of the optic; and

pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic.

93. As a non-limiting example, UltraSert is used according to a method of using an intraocular lens insertion device on an intraocular lens. UltraSert is used according to a method in which the intraocular lens includes an optic, a forward haptic having an end and a rear haptic having an end, the insertion device including a nozzle, a transition section and a plunger having a forward region with a side wall and a bottom wall that together define an indentation and is configured to receive a portion of the rear haptic.

94. UltraSert is used according to a method which includes pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic.

95. UltraSert is used according to a method which includes pushing the rear haptic such that the end of the rear haptic passes over the optic, while the portion of the optic over which the rear haptic passes remains unfolded, with the forward region of the plunger in such a manner that the rear haptic is bent and a portion of the rear haptic is received in the indentation.

96. UltraSert is used according to a method which includes folding a portion of the optic such that there is a space between folded portions of the optic.

97. UltraSert is used according to a method which includes pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic.

98. UltraSert is operated by moving the free end of the rear haptic, from a position rearward of the optic, over the optic and into a space between folded portions of the optic with the plunger.

99. Alcon also indirectly infringes claims of the '826 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Alcon's customers, and end users,

in this District and elsewhere in the United States. For example, Alcon's customers and end users directly infringe through their use of the inventions claimed in the '826 Patent. Alcon induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions, documentation, online technical support, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. As a result of Alcon's inducement, Alcon's customers and end users use the Accused Products in the way Alcon intends and directly infringe the '826 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '826 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '826 Patent.

100. Alcon also indirectly infringes claims of the '826 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. Alcon's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Alcon's customers' and end users' use of the Accused Products, such that the '826 Patent is directly infringed. The accused components within the Accused Products are material to the invention of the '826 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Alcon to be especially made or especially adapted for use in infringement of the '826 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '826 Patent and with intent, or willful blindness, that they cause the direct infringement of the '826 Patent.

**COUNT V: PATENT INFRINGEMENT OF THE '647 PATENT**

101. HOYA incorporates by reference the preceding paragraphs as though fully set forth herein.

102. Alcon infringes, contributes to the infringement of, and/or induces infringement of the '647 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '647 Patent.

103. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '647 Patent. Alcon makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States, the Accused Products and thus directly infringes claims of the '647 Patent.

104. For example, Claim 1 of the '647 Patent is reproduced below:

1. A method of operating an insertion device including a main body, a nozzle, and a tapered transition portion proximal of the nozzle, the method comprising the steps of:

applying force to an intraocular lens, located within the main body and having an optic, a leading loop haptic with a fixed end at the optic and a free end, and a trailing loop haptic with a fixed end at the optic and a free end, with a plunger, including a distal portion with a lens contact surface and a slot that extends proximally from the lens contact surface, in such a manner that a portion of the trailing loop haptic is located within the slot while being bent toward the nozzle by the distal portion and the free end of the trailing loop haptic points toward the nozzle; and

pushing the intraocular lens into the nozzle with the plunger.

105. As a non-limiting example, UltraSert is used according to a method of operating an insertion device. The insertion device includes a main body, a nozzle, and a tapered transition portion proximal of the nozzle.

106. UltraSert is used according to a method in which force is applied to an intraocular lens, located within the main body and having an optic, a leading loop haptic with a fixed end at

the optic and a free end, and a trailing loop haptic with a fixed end at the optic and a free end, with a plunger.

107. UltraSert is used according to a method which includes a plunger, including a distal portion with a lens contact surface and a slot that extends proximally from the lens contact surface.

108. UltraSert is operated by applying a force to the intraocular lens with a plunger in such a manner that a portion of the trailing loop haptic is located within the slot while being bent toward the nozzle by the distal portion and the free end of the trailing loop haptic points toward the nozzle.

109. UltraSert is operated by pushing the intraocular lens into the nozzle with the plunger.

110. Alcon also indirectly infringes claims of the '647 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Alcon's customers, and end users, in this District and elsewhere in the United States. For example, Alcon's customers and end users directly infringe through their use of the inventions claimed in the '647 Patent. Alcon induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions, documentation, online technical support, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. As a result of Alcon's inducement, Alcon's customers and end users use the Accused Products in the way Alcon intends and directly infringe the '647 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '647 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '647 Patent.

111. Alcon also indirectly infringes claims of the '647 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. Alcon's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Alcon's customers' and end users' use of the Accused Products, such that the '647 Patent is directly infringed. The accused components within the Accused Products are material to the invention of the '647 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Alcon to be especially made or especially adapted for use in infringement of the '647 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '647 Patent and with intent, or willful blindness, that they cause the direct infringement of the '647 Patent.

**COUNT VI: PATENT INFRINGEMENT OF THE '668 PATENT**

112. HOYA incorporates by reference the preceding paragraphs as though fully set forth herein.

113. Alcon infringes, contributes to the infringement of, and/or induces infringement of the '668 Patent by making, using, selling, offering for sale, and/or importing into the United States the Accused Products that are covered by one or more claims of the '668 Patent.

114. The Accused Products directly infringe, literally and/or by the doctrine of equivalents, one or more claims of the '668 Patent. Alcon makes, uses, sells, offers for sale, and/or imports, in this District and elsewhere in the United States the Accused Products and thus directly infringes claims of the '668 Patent.

115. For example, Claim 1 of the '668 Patent is reproduced below:

1. An intraocular lens insertion apparatus, comprising:

an outer body that defines a lens movement direction, that includes a nozzle and a lens placement section with lens supporting surfaces having portions that are spaced from one another in a spacing direction that is perpendicular to the lens movement direction, and that is configured to store an intraocular lens, having an optic with a diameter and haptics with respective free ends in such a manner that diametrically opposed portions of the optic are on the lens supporting surface portions that are spaced in the spacing direction that is perpendicular to the lens movement direction, one of the haptics is a proximal haptic, and one of the haptics is a distal haptic; and

a plunger, at least a portion of which is carried within the outer body, that is movable relative to the outer body and which has a distal region that defines a longitudinal axis, the distal region including a bottom wall having an upper surface and defining a width in a direction transverse to the longitudinal axis of the distal region, a lens contact surface extending downwardly from the bottom wall upper surface, a top wall defining a width in a direction transverse to the longitudinal axis of the distal region that is less than the width of the bottom wall, and a lateral wall that extends from the bottom wall to the top wall in a direction perpendicular to the spacing direction that is perpendicular to the lens movement direction, the top wall, bottom wall and lateral wall together defining a recess that is located above the bottom wall, that extends proximally from the lens contact surface, that has a first lateral side that is open, second lateral side that is closed by the lateral wall and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end is positioned over the optic.

116. As a non-limiting example, UltraSert is an intraocular lens insertion apparatus. This insertion apparatus includes an outer body and a plunger.

117. UltraSert includes an outer body that defines a lens movement direction, that includes a nozzle and a lens placement section with lens supporting surfaces having portions that are spaced from one another in a spacing direction that is perpendicular to the lens movement direction, and that is configured to store an intraocular lens, having an optic with a diameter and haptics with respective free ends in such a manner that diametrically opposed portions of the optic are on the lens supporting surface portions that are spaced in the spacing direction that is

perpendicular to the lens movement direction, one of the haptics is a proximal haptic, and one of the haptics is a distal haptic.

118. UltraSert includes a plunger, at least a portion of which is carried within the outer body, that is movable relative to the outer body and which has a distal region that defines a longitudinal axis, the distal region including a bottom wall having an upper surface and defining a width in a direction transverse to the longitudinal axis of the distal region, a lens contact surface extending downwardly from the bottom wall upper surface, a top wall defining a width in a direction transverse to the longitudinal axis of the distal region that is less than the width of the bottom wall, and a lateral wall that extends from the bottom wall to the top wall in a direction perpendicular to the spacing direction that is perpendicular to the lens movement direction, the top wall, bottom wall and lateral wall together defining a recess that is located above the bottom wall, that extends proximally from the lens contact surface, that has a first lateral side that is open, second lateral side that is closed by the lateral wall and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end is positioned over the optic.

119. Alcon also indirectly infringes claims of the '668 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as Alcon's customers, and end users, in this District and elsewhere in the United States. For example, Alcon's customers and end users directly infringe through their use of the inventions claimed in the '668 Patent. Alcon induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Products, and providing instructions, documentation, online technical support, marketing, product manuals, advertisements, and other information to customers and end users suggesting they use the Accused Products in an infringing manner. As a result of



Alcon's inducement, Alcon's customers and end users use the Accused Products in the way Alcon intends and directly infringe the '668 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '668 Patent and with the intent, or willful blindness, that the induced acts directly infringe the '668 Patent.

120. Alcon also indirectly infringes claims of the '668 Patent, as provided by 35 U.S.C. § 271(c), by contributing to direct infringement committed by others, such as customers and end users, in this District and elsewhere in the United States. Alcon's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to Alcon's customers' and end users' use of the Accused Products, such that the '668 Patent is directly infringed. The accused components within the Accused Products are material to the invention of the '668 Patent, are not staple articles or commodities of commerce, have no substantial non-infringing uses, and are known by Alcon to be especially made or especially adapted for use in infringement of the '668 Patent. Alcon has performed and continues to perform these affirmative acts with knowledge of the '668 Patent and with intent, or willful blindness, that they cause the direct infringement of the '668 Patent.

#### **PRAYER FOR RELIEF**

WHEREFORE, HOYA respectfully requests that this Court enter judgment in its favor as follows and award HOYA the following relief:

- (a) an award of damages adequate to compensate HOYA for infringement of the Patents-in-Suit by Alcon, in an amount to be proven at trial, including supplemental post-verdict damages until such time as Alcon ceases its infringing conduct;
- (b) a permanent injunction prohibiting Alcon and its officers, directors, employees, agents, consultants, contractors, suppliers, distributors, all affiliated entities, and

all others acting in privity with Alcon, from committing further acts of infringement;

- (c) enhanced damages for willful infringement;
- (d) the costs of this action, as well as attorneys' fees as provided by 35 U.S.C. § 285;
- (e) pre-judgment and post-judgment interest at the maximum amount permitted by law;
- (f) all other relief, in law or equity, to which HOYA is entitled.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a jury trial for all issues so triable.

Dated: July 30, 2021

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# **EXHIBIT 1**

(12) **United States Patent**  
**Kudo et al.**

(10) **Patent No.:** **US 9,901,442 B2**  
 (45) **Date of Patent:** **\*Feb. 27, 2018**

(54) **INTRAOCULAR LENS INSERTION DEVICE**

(56) **References Cited**

(71) Applicant: **Hoya Corporation**, Tokyo (JP)

U.S. PATENT DOCUMENTS

(72) Inventors: **Kazunori Kudo**, Saku (JP); **Masahiro Noda**, Toda (JP)

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(73) Assignee: **Hoya Corporation**, Tokyo (JP)

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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This patent is subject to a terminal disclaimer.

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(21) Appl. No.: **15/600,684**

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(22) Filed: **May 19, 2017**

(65) **Prior Publication Data**

*Primary Examiner* — Kathleen Holwerda

US 2017/0252150 A1 Sep. 7, 2017

*Assistant Examiner* — Socrates L Boutsikaris

**Related U.S. Application Data**

(74) *Attorney, Agent, or Firm* — Henricks, Slavin & Holmes LLP

(63) Continuation of application No. 14/099,989, filed on Dec. 8, 2013, now Pat. No. 9,655,718, which is a (Continued)

(30) **Foreign Application Priority Data**

(57) **ABSTRACT**

Jan. 7, 2009 (JP) ..... 2009-001493

There is provided an intraocular lens insertion device capable of appropriately regulating the motion of a rear supporting portion during a process of moving an intraocular lens, and reducing the possibility of reoperation being required after the intraocular lens is inserted into an eye. An intraocular lens insertion device **1** comprises a main body **2**, and a slider **3** and a plunger **4** that are attached to the main body **2**. Further, the intraocular lens insertion device **1** is of a preset type in which an intraocular lens **5** is placed inside the main body **2** in advance. The slider **3** includes a first abutting portion **21** for pushing up a supporting portion **7** (rear supporting portion **7a**) arranged on a rear side of an optical part **6** with respect to a lens advancement axis A, and second abutting portions **22a**, **22b** abutting against an outer edge of a rear portion of the optical part **6**.

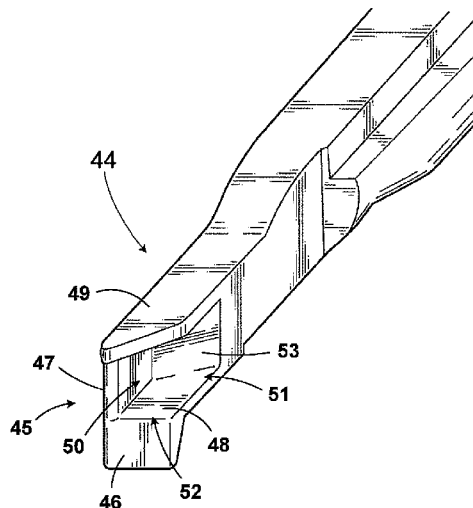
(51) **Int. Cl.**  
**A61F 2/16** (2006.01)

(52) **U.S. Cl.**  
 CPC ..... **A61F 2/167** (2013.01); **A61F 2/1672** (2013.01)

(58) **Field of Classification Search**  
 CPC ..... A61F 2/167; A61F 2/1662; A61F 2/1672; A61F 2/1675; A61F 2/1678; A61F 2/14; A61F 2/16

(Continued)

**27 Claims, 9 Drawing Sheets**



US 9,901,442 B2

**Related U.S. Application Data**

continuation of application No. 13/143,322, filed as application No. PCT/JP2010/050029 on Jan. 5, 2010, now Pat. No. 8,603,103.

(58) **Field of Classification Search**

USPC ..... 606/107; 623/6.12  
See application file for complete search history.

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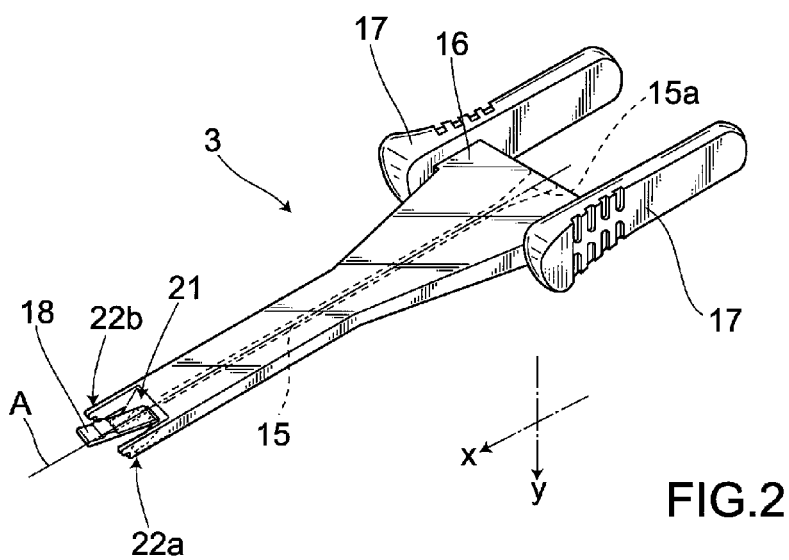
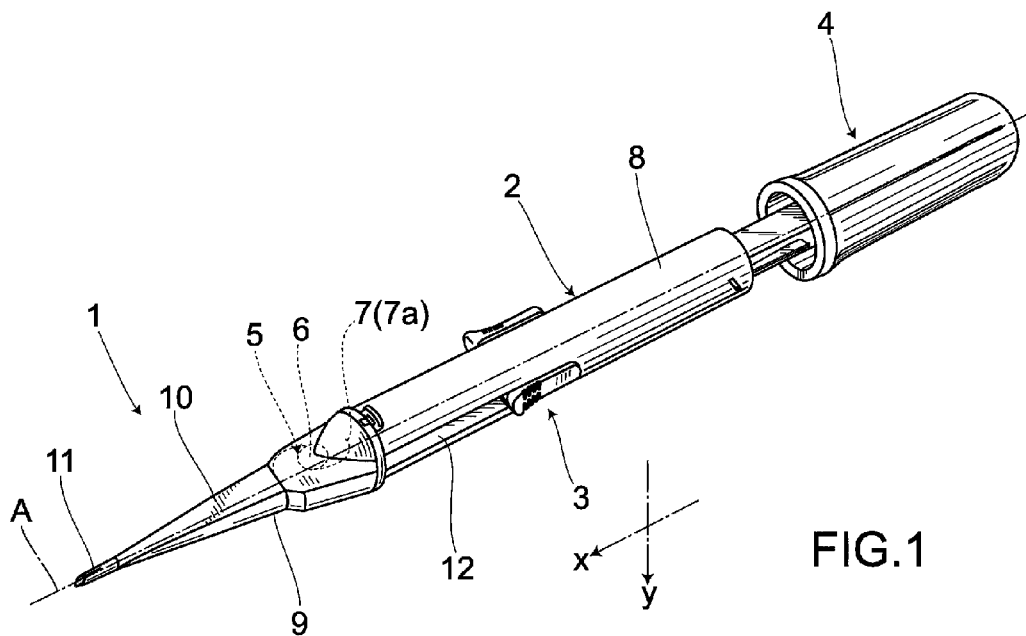
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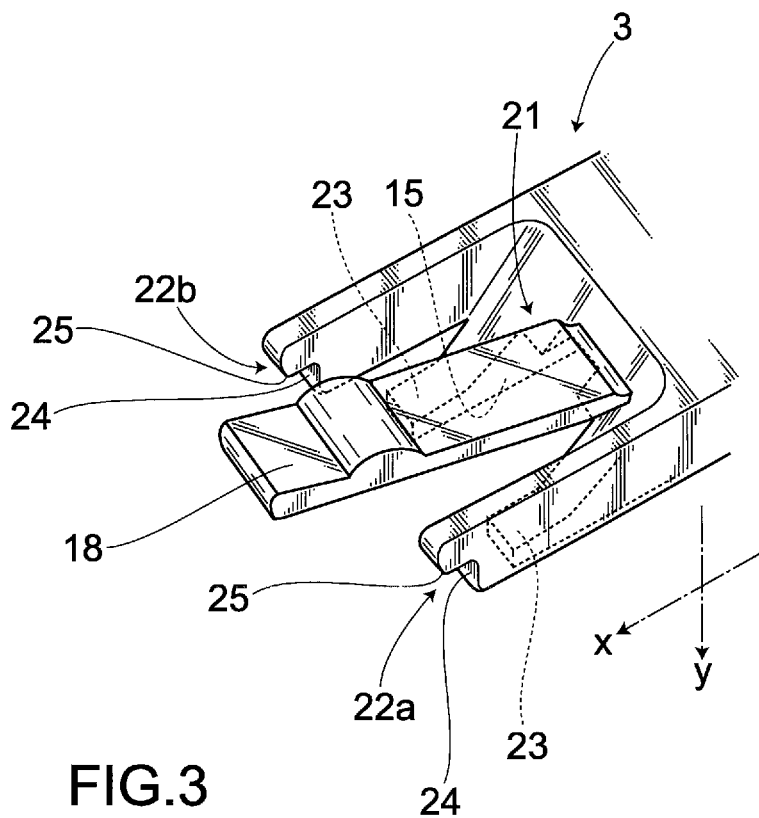
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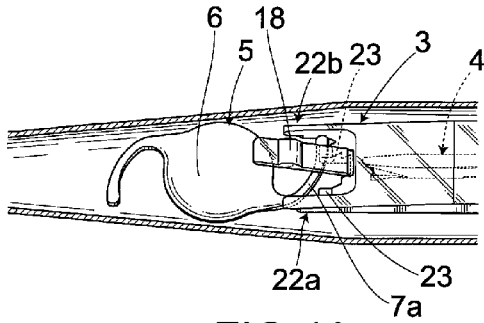


FIG. 4A

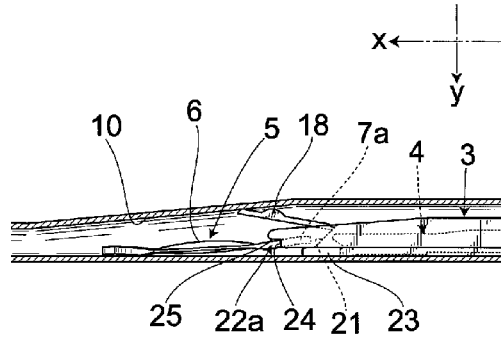


FIG. 4B

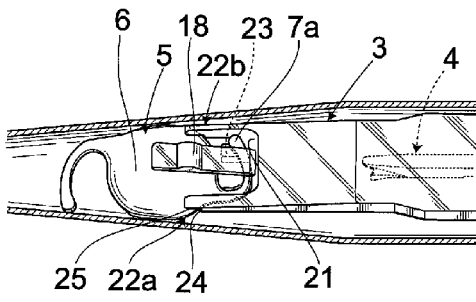


FIG. 5A

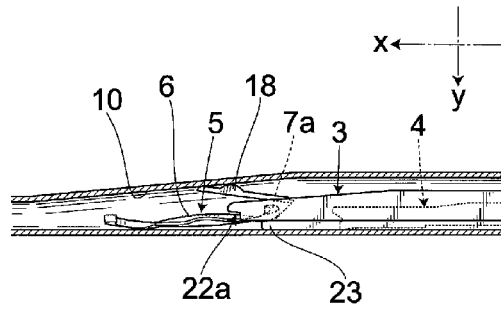


FIG. 5B

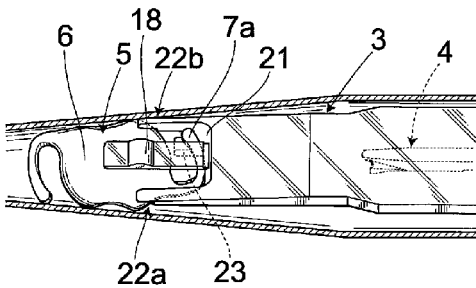


FIG. 6A

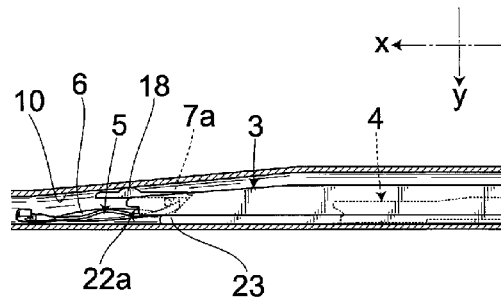


FIG. 6B

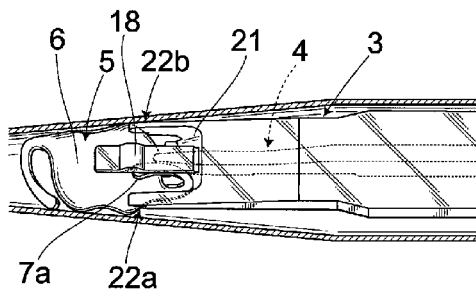


FIG. 7A

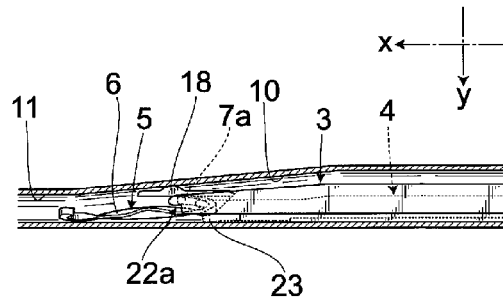


FIG. 7B

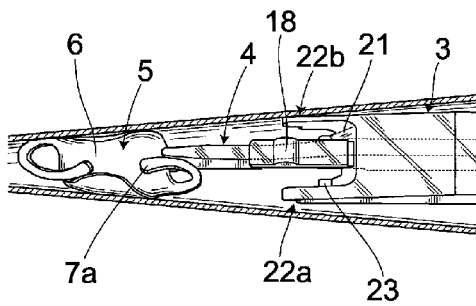


FIG. 8A

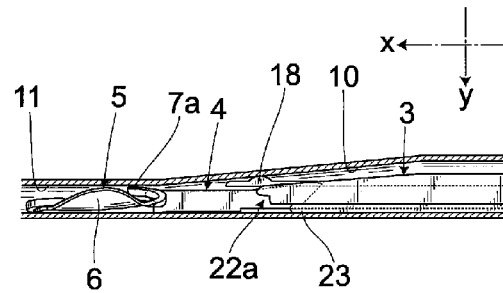


FIG. 8B

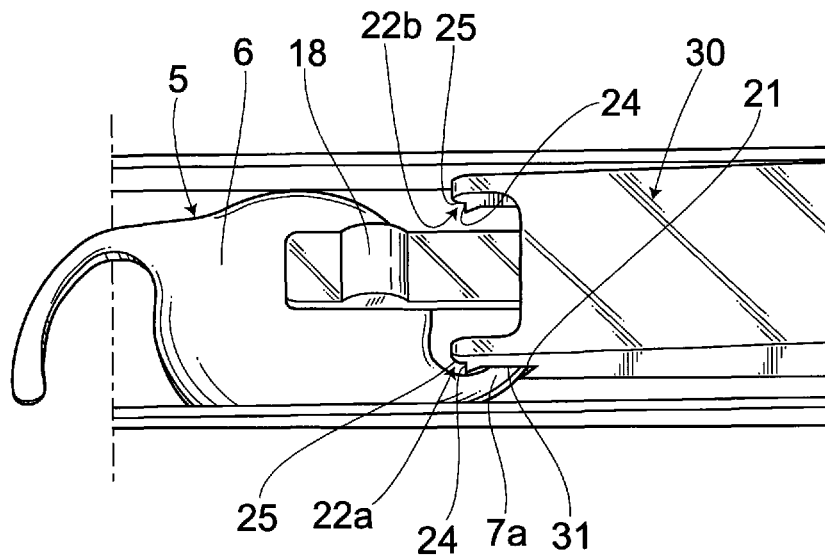


FIG.9

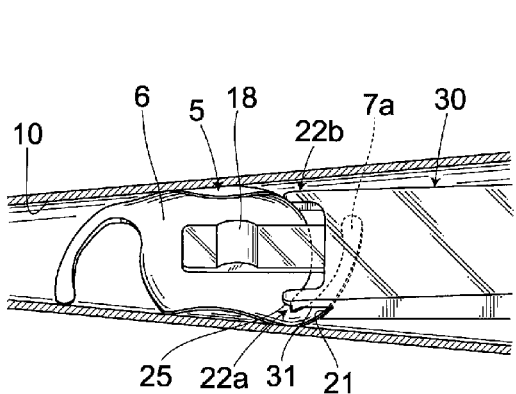


FIG. 10A

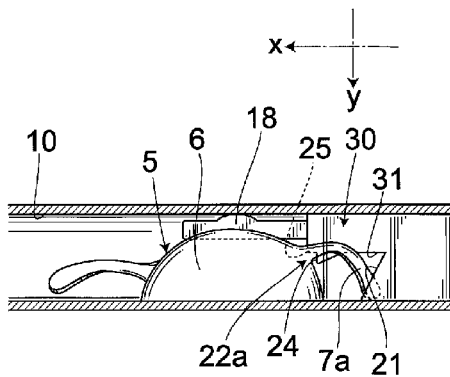


FIG. 10B

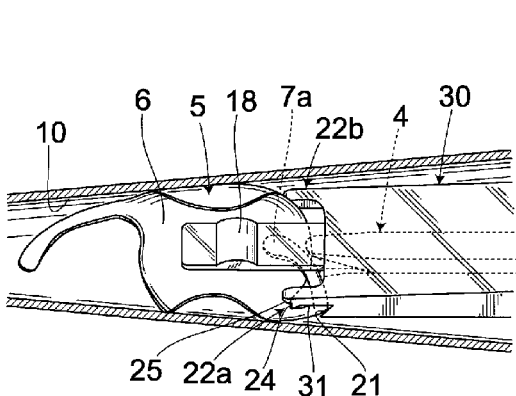


FIG. 11A

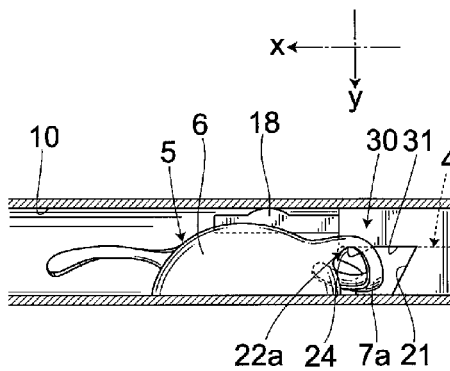


FIG. 11B

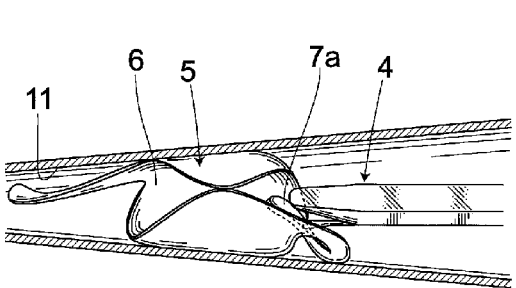


FIG. 12A

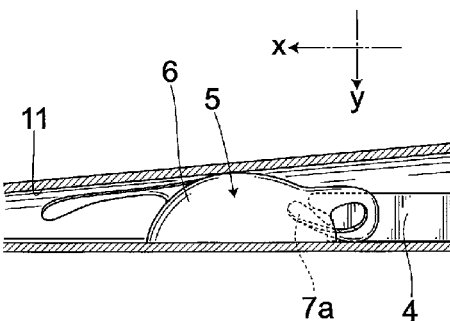
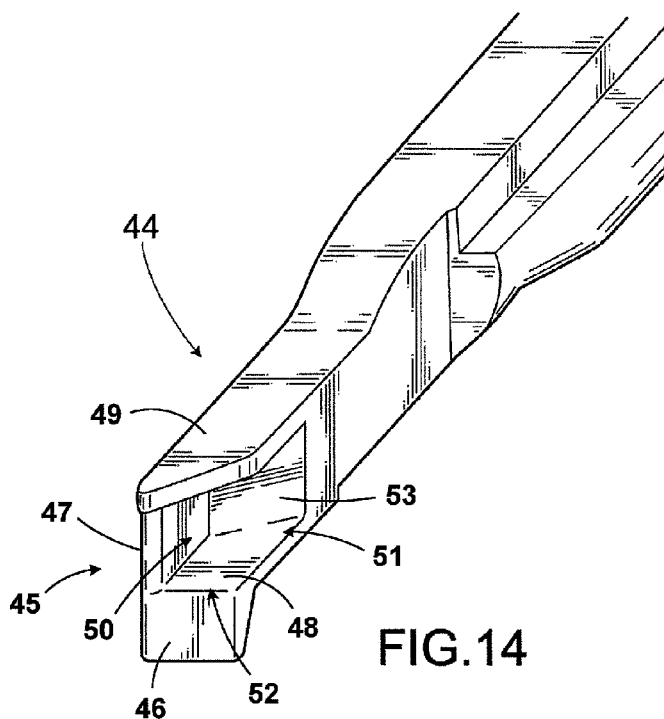
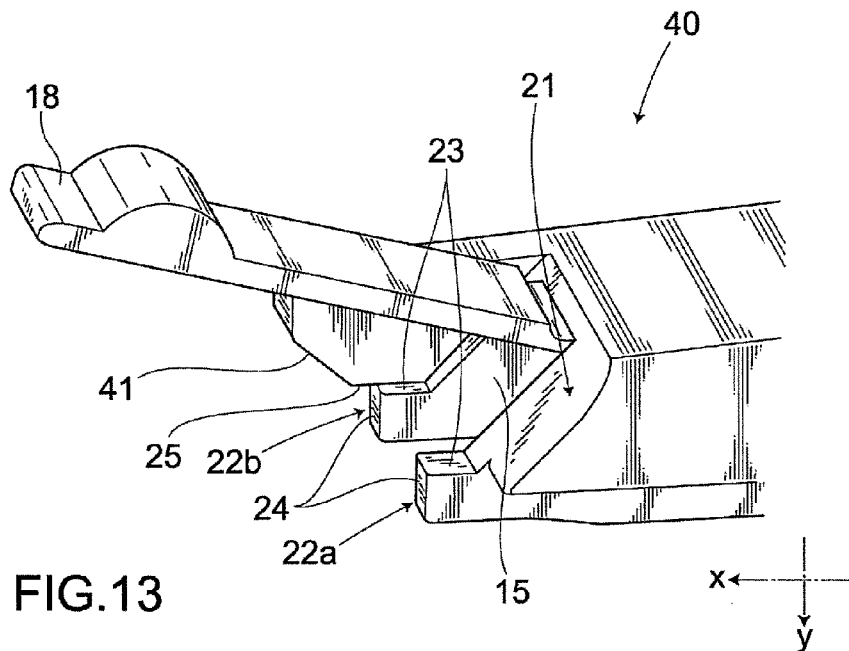


FIG. 12B



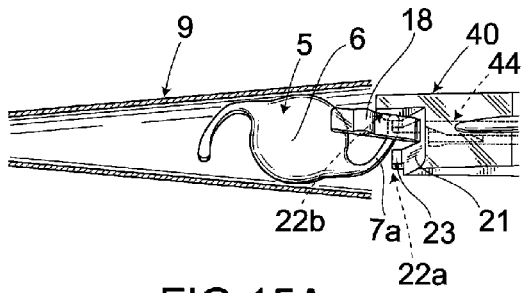


FIG. 15A

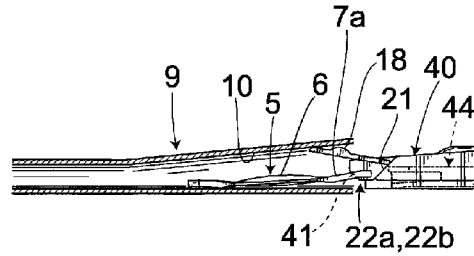


FIG. 15B

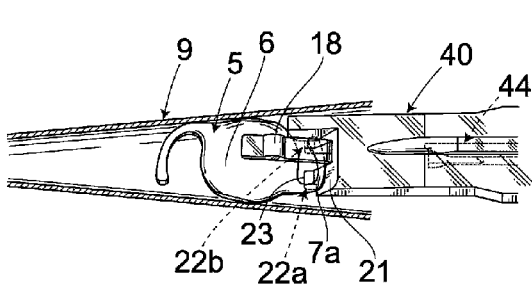


FIG. 16A

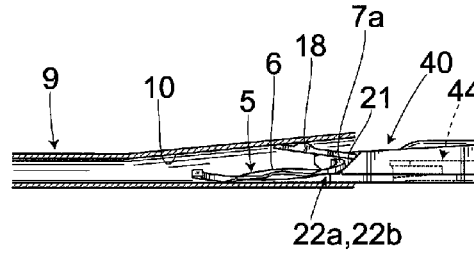


FIG. 16B

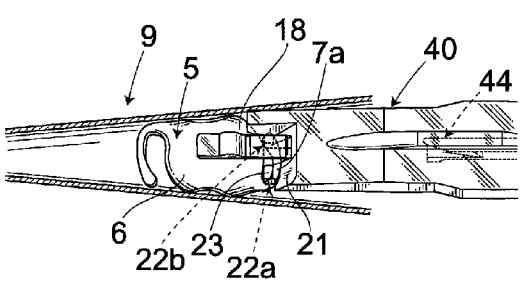


FIG. 17A

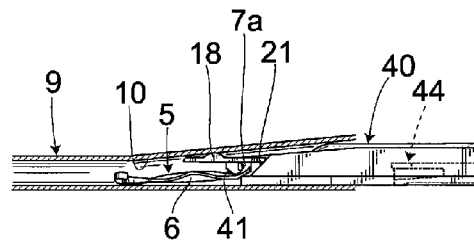


FIG. 17B



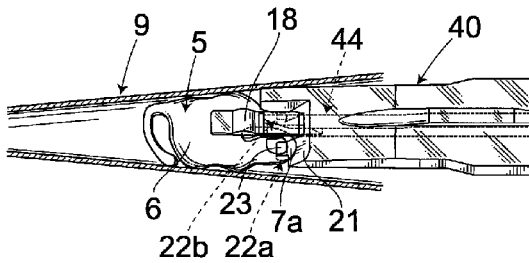


FIG. 18A

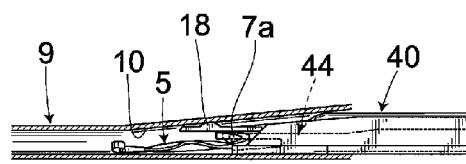


FIG. 18B

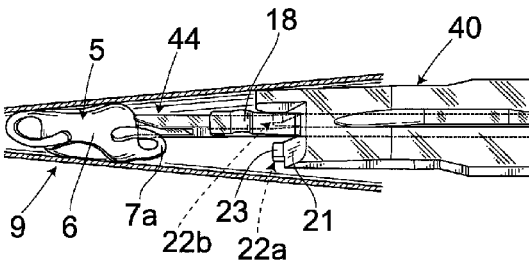


FIG. 19A

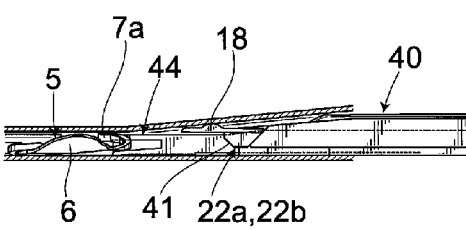


FIG. 19B

US 9,901,442 B2

1

**INTRAOCULAR LENS INSERTION DEVICE****CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 14/099,989, filed Dec. 8, 2013, now U.S. Pat. No. 9,655,718, which is a continuation of U.S. application Ser. No. 13/143,322, filed Jul. 5, 2011, now U.S. Pat. No. 8,603,103, which is a U.S. national phase application under 35 U.S.C. §371 of International Patent Application No. PCT/JP2010/050029 filed Jan. 5, 2010, which claims priority to Japanese patent application No. 2009-001493, filed Jan. 7, 2009. The International Application was published in Japanese on Jul. 15, 2010 as International Publication No. WO 2010/079780A1. The content of each application is incorporated herein in its entirety.

**TECHNICAL FIELD**

The present invention relates to an intraocular lens insertion device for inserting an intraocular lens into an eyeball as a substitute of a crystalline lens exenterated through cataract surgery.

**BACKGROUND ART**

Cataract surgery often involves removing an opacified crystalline lens through phacoemulsification (PEA), and implanting an intraocular lens after the crystalline lens has been removed. Intraocular lenses include hard intraocular lenses whose optical parts are made of hard materials such as PMMA or the like, and soft intraocular lenses whose optical parts are made of soft materials such as silicon elastomer, soft acrylic, hydrogel or the like.

When inserting a hard intraocular lens, there has to be formed on the cornea or the sclera an incision substantially as wide as the diameter of the optical part of the corresponding hard intraocular lens. In contrast, a soft intraocular lens can be inserted through an incision smaller than the diameter of the optical part thereof by allowing the corresponding optical part to be folded.

An intraocular lens is preferably inserted through a small incision in order to reduce the possibilities of corneal astigmatism and infection after the surgery. In this sense, soft intraocular lenses tend to be preferred nowadays. Types of soft intraocular lens include: a soft intraocular lens having an optical part made of a soft material and supporting portions made of a hard material such as PMMA or the like (the supporting portions of this type of intraocular lens are usually two thin filamentary members); a soft intraocular lens whose optical part and supporting portions are made of a same soft material (the supporting portions of this type are usually plate members); or a soft intraocular lens employing a plurality of thin strips as supporting portions, and the like.

Further, in order to insert an intraocular lens into an eye, there has also been used a dedicated intraocular lens insertion device having a structure for introducing the intraocular lens into the eye through an elongated tube. This type of intraocular lens insertion device allows an intraocular lens to be inserted through an incision smaller than 3 mm.

Furthermore, in recent years, there has been developed a type of intraocular lens insertion device which has an intraocular lens placed therein in advance and can be packaged and stored, in order to exclude the possibilities of bacteria contamination and errors in operation at the time of handling the intraocular lens (e.g., patent document 1).

2

However, this type of intraocular lens insertion device may cause a supporting portion (referred to as a rear supporting portion, hereunder) arranged on a rear side with respect to a lens advancement axis to slip in between a plunger for pushing out the intraocular lens and a passage inner wall surface of the insertion device, or be tangled with the corresponding plunger, during a process of moving the intraocular lens. These problems are particularly noticeable with soft intraocular lenses employing thin filamentary members as supporting portions and intraocular lenses employing thin strips as supporting portions.

Further, this type of intraocular lens insertion device may cause the rear supporting portion to be stretched during the process of moving the intraocular lens. Accordingly, the corresponding rear supporting portion may then be left outside an eye ball at the time of performing insertion through a small incision on the eyeball, thereby requiring an additional operation for inserting such rear supporting portion into the eye ball after pushing out the intraocular lens with the plunger, and thus making the surgery troublesome.

In this sense, when using an intraocular lens insertion device to insert an intraocular lens into an eye, the motion of the rear supporting portion of the intraocular lens has to be appropriately regulated during the process of moving the intraocular lens.

In view of the aforementioned problems, there has been disclosed a device in which a clearance is formed on a front end side portion of a plunger, for allowing the rear supporting portion to be kept therein and thus preventing the same from being damaged (e.g., patent document 2). Further, there has been disclosed a device in which a rear supporting portion receiving passage for receiving the rear supporting portion is provided on a lower side portion of a plunger (e.g., patent document 3). Furthermore, there has also been disclosed a device in which the rear supporting portion is pushed up on a lump portion by means of a plunger, thereby allowing the corresponding haptic to be bended upward and eventually positioned higher than an IOL (e.g., patent document 4). Accordingly, all the devices disclosed in the aforementioned patent documents serve to reduce holding pressures applied to the rear supporting portions of intraocular lenses employing thin filaments or strips as supporting portions.

**REFERENCE**

- Patent document 1: WO2007/037223
- Patent document 2: Japanese Unexamined Patent Application Publication (Translation of PCT Application) No. 1999-506357
- Patent document 3: U.S. Pat. No. 6,733,507
- Patent document 4: Japanese Unexamined Patent Application Publication No. 2004-351196

**DISCLOSURE OF THE INVENTION****Problem to be Solved by the Invention**

However, according to the patent documents 2 and 3, the rear supporting portion received in the clearance formed on the front end side portion of the plunger and in the rear supporting portion receiving passage is stretched, thereby still incurring a problem in which the corresponding rear supporting portion may be left outside a small incision formed on an eye ball when inserting an intraocular lens therethrough. Particularly, with regard to intraocular lenses employing thin strips as supporting portions, reoperation is

US 9,901,442 B2

3

often troublesome because the corresponding supporting portions are composed of soft members that are thick in sizes. Further, according to the patent document 4, the supporting portion is pushed by a small plunger front end matched to a nozzle front end with a small aperture diameter, thus causing the rear supporting portion to be compressed into an unexpected shape when bending the supporting portion upward so as to position the same higher than an optical part or when allowing an intraocular lens to pass through a passage.

Here, in view of the aforementioned problems, it is an object of the present invention to provide an intraocular lens insertion device capable of appropriately regulating the motion of a rear supporting portion during a process of moving an intraocular lens, and reducing the possibility of reoperation being required after the intraocular lens has been inserted into an eye.

#### Means for Solving the Problem

The invention according to a first aspect of the present invention is an intraocular lens insertion device comprising: a lens placement section for placing an intraocular lens having an optical part and one or more supporting portions provided on an outer edge of the optical part; a transition section for deforming the intraocular lens; a nozzle section for releasing the intraocular lens; a slider for pushing out the intraocular lens placed in the lens placement section; and a plunger for releasing the intraocular lens pushed out by the slider from the nozzle section, in which the slider includes: a first abutting portion for pushing up a supporting portion disposed in a rear direction of a lens advancement axis; and one or more second abutting portions abutting against an outer edge of a rear portion of the intraocular lens.

According to the invention described in a second aspect of the present invention, the second abutting portions are provided outside the first abutting portion with respect to the lens advancement axis.

According to the invention described in a third aspect of the present invention, the first abutting portion slants downward in a lens advancement direction.

According to the invention described in a fourth aspect of the present invention, at least one of the second abutting portions includes: an x-direction abutting surface substantially perpendicular to a surface of the optical part; and a y-direction abutting surface substantially parallel with the surface of the optical part.

The invention according to a fifth aspect of the present invention comprises a guiding portion for guiding the outer edge of the optical part to the second abutting portions.

According to the invention described in a sixth aspect of the present invention, the second abutting portions are provided as a left-right pair centered about the lens advancement axis.

#### Effects of the Invention

According to the present invention, the first abutting portion provided on the slider serves to push up the supporting portion arranged on the rear side with respect to the lens advancement axis, thereby allowing the motion of the rear supporting portion to be appropriately regulated during the process of moving the intraocular lens, and thus reducing the possibility of reoperation being required after the intraocular lens is inserted into the eye.

4

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view showing an overall structure of an intraocular lens insertion device of a first embodiment of the present invention.

FIG. 2 is a perspective view showing a structure of a slider of the first embodiment of the present invention.

FIG. 3 is a partially enlarged perspective view showing the structure of the slider of the first embodiment of the present invention.

FIGS. 4A and 4B are diagrams showing a usage state (1) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 4A is a cross sectional top view, and FIG. 4B is a longitudinal sectional view.

FIGS. 5A and 5B are diagrams showing a usage state (2) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 5A is a cross sectional top view, and FIG. 5B is a longitudinal sectional view.

FIGS. 6A and 6B are diagrams showing a usage state (3) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 6A is a cross sectional top view, and FIG. 6B is a longitudinal sectional view.

FIGS. 7A and 7B are diagrams showing a usage state (4) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 7A is a cross sectional top view, and FIG. 7B is a longitudinal sectional view.

FIGS. 8A and 8B are diagrams showing a usage state (5) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 8A is a cross sectional top view, and FIG. 8B is a longitudinal sectional view.

FIG. 9 is a partially enlarged perspective view showing a structure of a slider of a second embodiment of the present invention.

FIGS. 10A and 10B are diagrams showing a usage state (1) of an intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 10A is a cross sectional top view, and FIG. 10B is a longitudinal sectional view.

FIGS. 11A and 11B are diagrams showing a usage state (2) of the intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 11A is a cross sectional top view, and FIG. 11B is a longitudinal sectional view.

FIGS. 12A and 12B are diagrams showing a usage state (3) of the intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 12A is a cross sectional top view, and FIG. 12B is a longitudinal sectional view.

FIG. 13 is a partially enlarged perspective view showing a structure of a slider of a third embodiment of the present invention.

FIG. 14 is a partially enlarged perspective view showing a structure of a plunger of the third embodiment of the present invention.

FIGS. 15A and 15B are diagrams showing a usage state (1) of an intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 15A is a cross sectional top view, and FIG. 15B is a longitudinal sectional view.

FIGS. 16A and 16B are diagrams showing a usage state (2) of the intraocular lens insertion device of the third

5

embodiment of the present invention, in which FIG. 16A is a cross sectional top view, and FIG. 16B is a longitudinal sectional view.

FIGS. 17A and 17B are diagrams showing a usage state (3) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 17A is a cross sectional top view, and FIG. 17B is a longitudinal sectional view.

FIGS. 18A and 18B are diagrams showing a usage state (4) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 18A is a cross sectional top view, and FIG. 18B is a longitudinal sectional view.

FIGS. 19A and 19B are diagrams showing a usage state (5) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 19A is a cross sectional top view, and FIG. 19B is a longitudinal sectional view.

## BEST MODE FOR CARRYING OUT THE INVENTION

### 1. First Embodiment

#### (1) Basic Structure

An embodiment of the present invention is described hereunder in detail and with reference to the accompanying drawings.

An intraocular lens insertion device 1 shown in FIG. 1 comprises a main body 2, and a slider 3 and a plunger 4 that are attached to the main body 2. The intraocular lens insertion device 1 is of a preset type in which an intraocular lens 5 is placed inside the main body 2 in advance. Here, the intraocular lens 5 includes an optical part 6 and a pair of supporting portions 7 (or "haptics") provided on an outer edge of the optical part 6. As the supporting portions 7, there can be employed various types of members including, for example, members of a thin strip type.

In the following descriptions, an axis extending through the center of the intraocular lens 5 moving inside the main body 2 is referred to as a lens advancement axis A. Further, a direction to which the intraocular lens 5 moves is referred to as an "advancement direction x," and a downward direction is referred to as a "direction y."

The main body 2 is composed of a base end portion 8 and an insertion tube 9 connected to a front end of the base end portion 8 in the advancement direction x. Although not shown, a lens placement section made of a plate type member is formed on the front end of the base end portion 8 in the advancement direction x. The intraocular lens 5 is placed in the corresponding lens placement section. On side surfaces of the base end portion 8, there are provided slits 12 formed in parallel with the lens advancement axis A and extending to the front end of the base end portion 8. Further, the insertion tube 9 is integrally connected to the front end of the base end portion 8, thereby allowing the intraocular lens 5 placed in the lens placement section of the base end portion 8 to be disposed internally.

The insertion tube 9 comprises a transition section 10 and a nozzle section 11 that are successively disposed along the lens advancement axis A. The transition section 10 is formed into a tapered shape in which an inner wall of the transition section 10 tapers toward a front end thereof, such front end being further communicated with the nozzle section 11. The nozzle section 11 is so formed that an outer shape thereof can be inserted into an incision (not shown).

6

According to this intraocular lens insertion device 1, the intraocular lens 5 placed in the lens placement section is at first moved to the transition section 10 after being pushed out by the slider 3, thereby allowing the intraocular lens 5 to be reliably folded into a given shape. Next, the intraocular lens 5 is further moved to the nozzle section 11 after being pushed out by the plunger 4, thereby causing the intraocular lens 5 to be folded even smaller, and thus allowing the intraocular lens 5 to be inserted into an eye from a front end of the nozzle section 11. Accordingly, the intraocular lens insertion device 1 allows the intraocular lens 5 to be moved in the advancement direction x in two stages involving successively the slider 3 and the plunger 4, thus causing the intraocular lens 5 to be folded into a given shape and releasing the same to the outside.

#### (2) Structure of Slider

Next, the slider 3 attached to the main body 2 is described. As shown in FIG. 2, the slider 3 serves to push out the intraocular lens 5 placed in the lens placement section to the transition section 10 without imposing a local load thereon, and fold the intraocular lens 5 into the given shape. The slider 3 includes a guiding groove 15, a wing portion 16, operation portions 17 and a lens pressing member 18.

The guiding groove 15 is so configured that the plunger 4 can be supported thereby along the lens advancement axis A. Specifically, the guiding groove 15 allows the plunger 4 to slide, and a front end of the plunger 4 to protrude from a front end of the slider 3. According to the present embodiment, the guiding groove 15 is longitudinally formed over an entire length of a surface of the slider 3 in a manner such that the guiding groove 15 is substantially located in the center of the surface of the slider 3. Accordingly, the guiding groove 15 serves as a groove parallel to the lens advancement axis A. A cross-sectional surface of the guiding groove 15 is substantially formed into a same shape as an outer shape of the plunger 4. A wedge guiding path 15a is formed on a base end of the guiding groove 15. In this way, the plunger 4 is allowed to be inserted into the guiding groove 15 formed on the slider 3, and slide within the guiding groove 15 in a longitudinal direction of the slider 3.

The wing portion 16 is inserted into the slits 12 provided on the main body 2, and serves to support the slider 3 along the lens advancement axis A. By inserting the wing portion 16 into the slits 12, the slider 3 is allowed to not only be held in a substantial center portion of the main body 2, but also move along the lens advancement axis A. In this sense, the plunger 4 can also be held in the center portion of the main body 2 and move along the lens advancement axis A, when inserted into the guiding groove 15 formed on the slider 3. The slider 3 can be easily moved by means of the operation portions 17.

The operation portions 17 are provided as a left-right pair centered about the lens advancement axis A. Further, the operation portions 17 are connected to side end portions of the wing portion 16, and protrude from each side of the base end portion 8.

The lens pressing member 18 serves to fold the intraocular lens 5 in a given direction by pressing a surface of the intraocular lens 5 only when the intraocular lens 5 is being pushed out. According to the present embodiment, the lens pressing member 18 serves to press a surface of the intraocular lens 5 to the direction y, thereby causing the intraocular lens 5 to be folded inside the nozzle section 11 with the foregoing surface being folded inwardly, such surface being a front surface when releasing the intraocular lens 5 into the eye. The lens pressing member 18 is made of a strip type

member provided on the front end of the slider **3**, and is capable of swinging freely to the direction *y*.

In addition to the structure described so far, the slider **3** of the present embodiment, as shown in FIG. **3**, further includes a first abutting portion **21** for pushing up a supporting portion **7** arranged on a rear side with respect to the lens advancement axis *A* with respect to the optical part **6** (referred to as a rear supporting portion *7a*, hereunder), and second abutting portions **22a**, **22b** abutting against a rear outer edge of the optical part **6**.

The first abutting portion **21** has a slanting surface formed in the center of the front end of the slider **3** and slanting toward a direction between the advancement direction *x* and the direction *y*. The guiding groove **15** is opened in the center of the first abutting portion **21**, and a front end of the plunger **4** is thus allowed to protrude from the guiding groove **15** in the advancement direction *x*. Further, restriction portions **23** are formed on front ends of the first abutting portion **21**. The restriction portions **23** serve to prevent the rear supporting portion *7a* from entering in between the slider **3** and the main body **2** and thus being damaged, as the rear supporting portion *7a* deforms in the direction *y*. According to the present embodiment, the restriction portions **23** protrude from lower ends of the slanting surface to the advancement direction *x*.

The second abutting portions **22a**, **22b** are respectively provided on both sides of the first abutting portion **21**, and are configured to be able to abut against the outer edge of the optical part **6** of the intraocular lens **5**. According to the present embodiment, the second abutting portions **22a**, **22b** protrude from the front end of the slider **3** to the advancement direction *x*, and at least **22a** is allowed to abut against, along the lens advancement axis *A*, an outer edge of a section of the optical part **6**, such section of the optical part **6** being located outward from a connecting portion of the supporting portion **7** and the optical part **6**.

Further, the second abutting portions **22a**, **22b** have *x*-direction abutting surfaces **24** and *y*-direction abutting surfaces **25**. The *x*-direction abutting surfaces **24** are perpendicular to a surface of the optical part **6**, and are thus capable of pushing out the outer edge of the optical part **6**. The *y*-direction abutting surfaces **25** are parallel with the surface of the optical part **6**, and are thus able to restrict a surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded before the rear supporting portion *7a* has been sufficiently deformed.

As described above, according to the intraocular lens insertion device **1** of the present embodiment, the first abutting portion **21** and the second abutting portions **22a**, **22b** are provided on the slider **3** allowing the intraocular lens **5** to be in contact therewith through a contact area larger than that of the plunger **4**. Accordingly, the motion of the rear supporting portion *7a* can be appropriately regulated during the process of moving the intraocular lens **5**. Further, there can be reduced the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

### (3) Operation and Effect

According to the intraocular lens insertion device **1** having the aforementioned structure, the intraocular lens **5** is placed internally in a manner such that the optical part **6** thereof is arranged in parallel with the lens advancement axis *A* (FIGS. **4A** and **4B**). The slider **3** is at first moved to the advancement direction *x* in order to release the intraocular lens **5** internally placed in advance to the outside from the front end of the nozzle section **11**. In this way, the first

abutting portion **21** formed on the front end of the slider **3** is caused to abut against the rear supporting portion *7a* (FIGS. **5A** and **5B**).

Since the first abutting portion **21** has the slanting surface, the rear supporting portion *7a* is pushed up therealong as the slider **3** is further moved to the advancement direction *x* (FIGS. **6A** and **6B**). At the same time, the *x*-direction abutting surfaces **24** of the second abutting portions **22a**, **22b** are caused to abut against as well as push out the optical part **6**, thereby moving the intraocular lens **5** from the lens placement section to the transition section **10**. At that time, the outer edge of the optical part **6** is pushed by the inner wall of the transition section **10**. Further, the lens pressing member **18** is also pushed by the inner wall of the transition section **10**, and is thus caused to push down the surface of the optical part **6** to the direction *y*. In this way, the optical part **6** of the intraocular lens **5** is valley folded.

Next, as the plunger **4** is moved to the advancement direction *x*, the front end of such plunger **4** supported by the guiding groove **15** of the slider **3** is caused to abut against the outer edge of the optical part **6** (FIGS. **7A** and **7B**). The rear supporting portion *7a* pushed up by the first abutting portion **21** is thus caused to deform along the plunger **4** in a manner such that a front end of the rear supporting portion *7a* eventually points to the advancement direction *x*. In this way, the front end of the rear supporting portion *7a* deformed due to the first abutting portion **21**, is tucked into the surface of the valley-folded optical part **6**.

Here, the *y*-direction abutting surfaces **25** of the second abutting portions **22a**, **22b** are configured to restrict the surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded, thereby preventing the outer edge of the optical part **6** from interfering with the rear supporting portion *7a* during a deformation process of the rear supporting portion *7a*. Accordingly, the intraocular lens insertion device **1** allows the rear supporting portion *7a* to further reliably enter a space formed by the valley-folded surface of the optical part **6**, thereby making it possible to further reliably deform the intraocular lens **5** into the given shape.

Further, the restriction portions **23** provided on the first abutting portion **21** serve to prevent the rear supporting portion *7a* from deforming to the direction *y*. In this sense, the intraocular lens insertion device **1** allows the intraocular lens **5** to be further reliably deformed into the given shape.

Next, by further moving the plunger **4** to the advancement direction *x*, the intraocular lens **5** is moved from the transition section **10** to the nozzle section **11** (FIGS. **8A** and **8B**), followed by being released to the outside from the front end of the nozzle section **11** with the intraocular lens **5** itself being folded even smaller.

As described earlier, the intraocular lens insertion device **1** allows the rear supporting portion *7a* to be pushed up by the first abutting portion **21**, thereby making it possible to appropriately regulate the motion of the rear supporting portion *7a* during the process of moving the intraocular lens **5** and reduce the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

Further, since the first abutting portion **21** is provided on the slider **3**, the rear supporting portion *7a* is allowed to come into contact with the first abutting portion **21** through a large contact area. Accordingly, the intraocular lens insertion device **1** of the present embodiment allows the rear supporting portion *7a* to be further stably deformed, thereby making it possible to further appropriately regulate the rear supporting portion *7a*.

## 2. Second Embodiment

A second embodiment of the present invention is described hereunder with reference to the accompanying drawings. Here, the second embodiment differs from the first embodiment only in the structure of the front end portion of the slider **3**. Therefore, same symbols are used to describe the same members as those in the first embodiment, and the descriptions of the corresponding members are thus omitted for the sake of convenience.

According to a slider **30** shown in FIG. **9**, at least **22a** of second abutting portions **22a**, **22b** is configured to abut against an outer edge of a section of the optical part **6** between the connecting portion of the rear supporting portion **7a** and the optical part **6**, and the lens advancement axis **A**. Further, this slider **30** has a cutout hole **31** formed on a side surface thereof, such cutout hole **31** allowing the rear supporting portion **7a** to be inserted therethrough inwardly from the outside.

According to the present embodiment having the aforementioned structure, the slider **30** is at first moved to the advancement direction **x** by gripping operation portions **17**. As a result, a first abutting portion **21** formed on a front end of the slider **30** is caused to abut against the rear supporting portion **7a**.

As the slider **30** is further moved to the advancement direction **x**, the rear supporting portion **7a** is pushed up with **x**-direction abutting surfaces **24** of the second abutting portion **22** abutting against and pushing out the optical part **6**, at the same time, thus allowing the intraocular lens **5** to be moved from a lens placement section to a transition section **10**. In this way, the optical part **6** is pushed by an inner wall of the transition section **10**, and a surface of the optical part **6** is pushed down to the direction **y** by means of a lens pressing member **18**, thus allowing the optical part **6** to be valley folded (FIGS. **10A** and **10B**).

Next, as a plunger **4** is moved to the advancement direction **x**, the front end of such plunger **4** supported by a guiding groove **15** of the slider **3** is caused to abut against the outer edge of the optical part **6** (FIGS. **11A** and **11B**). The supporting portion **7** pushed up by the first abutting portion **21** is thus caused to deform along the plunger **4** in a manner such that a front end of the supporting portion **7** eventually points to the advancement direction **x**. In this way, a front end of the supporting portion **7** deformed due to the first abutting portion **21**, is tucked into the surface of the valley-folded optical part **6**.

Next, by further moving the plunger **4** to the advancement direction **x**, the intraocular lens **5** is moved from the transition section **10** to a nozzle section **11** (FIGS. **12A** and **12B**), followed by being released to the outside from a front end of the nozzle section **11** with the intraocular lens **5** itself being folded even smaller.

Due to the aforementioned structure of the present embodiment, the present embodiment, as is the case in the first embodiment, allows the motion of the rear supporting portion **7a** to be appropriately regulated during the process of moving the intraocular lens **5**, and reduces the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

## 3. Third Embodiment

As shown in FIG. **13**, a slider **40** of the present embodiment includes a first abutting portion **21**, second abutting portions **22a**, **22b** and a guiding portion **41** for guiding the optical part **6** to the second abutting portion **22b**. The second

abutting portion **22b** is provided on a location opposite to the connecting portion of the rear supporting portion **7a** and the optical part **6**, and is configured to be able to abut against the optical part **6** or the outer edge thereof. Further, the second abutting portion **22b** has an **x**-direction abutting surface **24** and a **y**-direction abutting surface **25**. In contrast, the second abutting portion **22a** only has the **x**-direction abutting surface **24**.

Here, the **y**-direction abutting surface **25** of the second abutting portion **22b** may be arranged substantially on the same plane as restriction portions **23**, or beyond the restriction portions **23** in the direction **y**. According to the present embodiment, the **y**-direction abutting surface **25** is arranged on the same plane as the restriction portions **23**.

The guiding portion **41** has a slanting surface slanting toward a direction between the advancement direction **x** and an opposite direction of the direction **y**. A lower end of the guiding portion **41** is communicated with the **y**-direction abutting surface **25**. Here, a plunger having a shape shown in FIG. **14** can be used as a plunger **44**. The plunger **44** includes a distal end **45** with a lens contact portion **46**, a lateral wall **47**, a bottom wall **48**, and a top wall **49**. A recess **50** has a first lateral side **51** that is open, a second lateral side that is closed by the lateral wall **47**, and an open distal end **52**. The recess **50** is located above, and extends proximally from, the lens contact portion **46**. The proximal end of the recess **50** is defined by a slanted wall **53**.

Next, there are described an operation and effect of the slider **40** having the aforementioned structure. The intraocular lens **5** is placed in a lens placement section (not shown) in a manner such that the optical part **6** thereof is arranged in parallel with the lens advancement axis **A** (FIGS. **15A** and **15B**). The slider **40** is at first moved to the advancement direction **x** in order to release such intraocular lens **5** to the outside from a front end of a nozzle section **11**. As a result, the first abutting portion **21** formed on a front end of the slider **40** is caused to abut against the rear supporting portion **7a** (FIGS. **16A** and **16B**).

Since the first abutting portion **21** has a slanting surface, the rear supporting portion **7a** is pushed up therealong as the slider **40** is further moved to the advancement direction **x** (FIGS. **17A** and **17B**). At the same time, the guiding portion **41** serves to push down a surface of the optical part **6** to the direction **y**, thereby guiding the corresponding optical part **6** to the second abutting portion **22b**. As a result, the **x**-direction abutting surface **24** of the second abutting portion **22b** and the **x**-direction abutting surface **24** of the second abutting portion **22a** are caused to abut against and then push out the optical part **6**, thus allowing the intraocular lens **5** to be moved from the lens placement section to a transition section **10**.

Here, the slider **40** allows the optical part **6** to be guided to the second abutting portion **22b** by means of the guiding portion **41**, thereby causing the second abutting portion **22b** to further reliably abut against the optical part **6**, and thus allowing the intraocular lens **5** to be further reliably pushed out.

In this way, the outer edge of the optical part **6** is pushed by an inner wall of the transition section **10**. Further, at that time, a lens pressing member **18** is also pushed by the inner wall of the transition section **10**, thus pushing down the surface of the optical part **6** to the direction **y**. As a result, the optical part **6** of the intraocular lens **5** is valley folded.

Next, as the plunger **44** is moved to the advancement direction **x**, the front end of such plunger **44** supported by a guiding groove **15** of the slider **40** is caused to abut against the outer edge of the optical part **6** (FIGS. **18A** and **18B**).

11

The rear supporting portion 7a pushed up by the first abutting portion 21 is thus caused to deform along the plunger 44 in a manner such that a front end of the rear supporting portion 7a eventually points to the advancement direction x and a part of the rear supporting portion 7a is in the recess. In this way, the front end of the rear supporting portion 7a deformed due to the first abutting portion 21, is enclosed by the valley-folded surface of the optical part 6.

Here, the y-direction abutting surface 25 of the second abutting portion 22b is configured to restrict the surface of the optical part 6 in the vicinity of the outer edge thereof from being valley folded, thereby preventing the outer edge of the optical part 6 from interfering with the rear supporting portion 7a during the deformation process of the rear supporting portion 7a.

Particularly, according to the present embodiment, since the y-direction abutting surface 25 is arranged on the same plane as the restriction portions 23, the outer edge of the optical part 6 is restricted from deforming to the opposite direction of the direction y, particularly, from deforming beyond the restriction portions 23 and the rear supporting portion 7a deformed due to the first abutting portion 21. In this sense, the slider 40 can further reliably prevent the outer edge of the optical part 6 from interfering with the rear supporting portion 7a, thereby allowing the intraocular lens 5 to be further reliably deformed into the given shape.

Next, by further moving the plunger 44 to the advancement direction x, the intraocular lens 5 is moved from a transition section 10 to a nozzle section 11 (FIGS. 19A and 19B), followed by being released to the outside from a front end of the nozzle section 11 with the intraocular lens 5 itself being folded even smaller.

Since the slider 40 of the present embodiment includes the first abutting portion 21 and the restriction portions 23, there can be achieved the same effects as those of the first embodiment.

4. Modified Embodiment

The present invention is not limited to the aforementioned embodiments. As a matter of fact, appropriate modifications are possible within the scope of the gist of the present invention. For example, in each one of the aforementioned embodiments, there are provided two second abutting portions in total. However, the present invention is not limited to this configuration. Particularly, the number of the second abutting portions can be one, three or more than three.

Further, in each one of the aforementioned embodiments, the second abutting portions 22 are provided as a symmetrical pair. However, the present invention is not limited to this configuration. The second abutting portions 22 can actually be provided in an asymmetrical manner. For example, one of the second abutting portions 22 may be formed longer than the other second abutting portion 22 in the advancement direction x, thereby making it possible to slightly rotate the intraocular lens 5 about an optical axis, and thus making it easier to regulate a supporting portion disposed forward.

DESCRIPTION OF SYMBOLS

- 1 intraocular lens insertion device
- 2 main body
- 3 slider
- 4 plunger
- 5 intraocular lens
- 6 optical part
- 7 supporting portion

12

- 7a rear supporting portion
- 21 first abutting portion
- 22 second abutting portion
- x advancement direction
- y direction (downward direction)
- A lens advancement axis

The invention claimed is:

1. An intraocular lens insertion apparatus, comprising:
  - a main body;
  - an intraocular lens including an optic and haptics, each haptic having a free end, stored in the main body in such a manner that one of the haptics is a proximal haptic and one of the haptics is a distal haptic;
  - a nozzle associated with the main body and configured to be inserted into an eye; and
  - a plunger, carried within the main body and movable relative to the main body from a first position to a second position at the nozzle, including a lens contact portion and a recess that is located above the lens contact portion, that extends proximally from the lens contact portion, that has a first lateral side that is open, a second lateral side that is closed by a lateral wall, and an open distal end, wherein the plunger is configured to hold a portion of the proximal haptic in the recess when the proximal haptic is bent such that the free end of the proximal haptic is positioned over the optic.
2. An intraocular lens insertion apparatus as claimed in claim 1, wherein
  - the plunger includes a top wall that extends over at least a portion of the recess.
3. An intraocular lens insertion apparatus as claimed in claim 1, wherein
  - the plunger includes a portion with a slanted wall and the slanted wall defines a proximal end of the recess.
4. An intraocular lens insertion apparatus as claimed in claim 3, wherein
  - the plunger defines a longitudinal axis; and
  - the slanted wall is oriented at a non-perpendicular angle with respect to the longitudinal axis.
5. An intraocular lens insertion apparatus as claimed in claim 3, wherein
  - the slanted wall extends from the lateral wall to the first lateral side that is open.
6. An intraocular lens insertion system as claimed in claim 1, further comprising:
  - a slider movable relative to the plunger from a pre-use slider position to a second slider position.
7. An intraocular lens insertion apparatus as claimed in claim 6, wherein
  - movement of the slider from the pre-use slider position to the second slider position moves the free end of the proximal haptic towards the optic.
8. An intraocular lens insertion apparatus as claimed in claim 1, wherein
  - the plunger includes a rotatable handle.
9. An intraocular lens insertion apparatus as claimed in claim 1, wherein
  - the plunger includes a thumb rest.
10. An intraocular lens insertion apparatus as claimed in claim 1, wherein
  - the lens contact portion is planar.
11. An intraocular lens insertion apparatus as claimed in claim 1, wherein
  - the main body includes a base portion and an insertion tube.

13

12. An intraocular lens insertion apparatus as claimed in claim 11, wherein the insertion tube includes a tapered transition section and the nozzle.

13. An intraocular lens insertion apparatus, comprising:  
a main body;

an intraocular lens including an optic and haptics, each haptic having a free end, stored in the main body in such a manner that one of the haptics is a proximal haptic and one of the haptics is a distal haptic;

a nozzle associated with the main body and configured to be inserted into an eye; and

a plunger, carried within the main body and movable relative to the main body, including a lens contact portion and a recess that extends proximally from the lens contact portion, that has a first lateral side that is open, a second lateral side that is closed by a lateral wall, and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end of the proximal haptic is positioned over the optic;

wherein the insertion apparatus defines an x-direction and a y-direction that is perpendicular to the x-direction, the plunger moves in the x-direction, the lens contact portion and the recess are offset from one another in the y-direction, and the first and second lateral sides are offset from one another in a lateral direction that is perpendicular to both the x-direction and the y-direction.

14. An intraocular lens insertion apparatus as claimed in claim 13, wherein

the plunger includes a top wall that extends over at least a portion of the recess.

15. An intraocular lens insertion apparatus as claimed in claim 13, wherein

the plunger includes a portion with a slanted wall and the slanted wall defines a proximal end of the recess; and the plunger defines a longitudinal axis.

16. An intraocular lens insertion apparatus as claimed in claim 15, wherein

the slanted wall is oriented at a non-perpendicular angle with respect to the longitudinal axis.

17. An intraocular lens insertion apparatus as claimed in claim 15, wherein

the slanted wall extends from the lateral wall to the first lateral side that is open.

18. An intraocular lens insertion system as claimed in claim 13, further comprising:

14

a slider movable relative to the plunger from a pre-use slider position to a second slider position.

19. An intraocular lens insertion apparatus as claimed in claim 18, wherein

movement of the slider from the pre-use slider position to the second slider position moves the free end of the proximal haptic towards the optic.

20. An intraocular lens insertion apparatus as claimed in claim 13, wherein

the plunger includes a rotatable handle.

21. An intraocular lens insertion apparatus as claimed in claim 13, wherein

the plunger includes a thumb rest.

22. An intraocular lens insertion apparatus as claimed in claim 13, wherein

the lens contact portion is planar.

23. An intraocular lens insertion apparatus as claimed in claim 13, wherein

the main body includes a base portion and an insertion tube.

24. An intraocular lens insertion apparatus as claimed in claim 23, wherein the insertion tube includes a tapered transition section and the nozzle.

25. An intraocular lens insertion apparatus, comprising:

a main body;  
an intraocular lens including an optic and haptics, each having a free end, stored in the main body in such a manner that one of the haptics is a proximal haptic and one of the haptics is a distal haptic;

a nozzle associated with the main body and configured to be inserted into an eye; and

a plunger, carried within the main body and movable relative to the main body, including a lens contact portion and means for holding a portion of the proximal haptic when the proximal haptic is bent such that the free end of the proximal haptic is positioned over the optic.

26. An intraocular lens insertion system as claimed in claim 25, further comprising:

a slider movable relative to the plunger from a pre-use slider position to a second slider position.

27. An intraocular lens insertion apparatus as claimed in claim 26, wherein

movement of the slider from the pre-use slider position to the second slider position moves the free end of the proximal haptic towards the optic.

\* \* \* \* \*



# **EXHIBIT 2**

(12) **United States Patent**  
**Kudo et al.**

(10) **Patent No.:** **US 9,980,811 B2**  
 (45) **Date of Patent:** **May 29, 2018**

(54) **OCULAR IMPLANT INSERTION APPARATUS AND METHODS**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 12 days.

(21) Appl. No.: **15/608,895**

(22) Filed: **May 30, 2017**

(65) **Prior Publication Data**

US 2017/0258582 A1 Sep. 14, 2017

**Related U.S. Application Data**

(63) Continuation of application No. 15/071,880, filed on Mar. 16, 2016, which is a continuation of application (Continued)

(30) **Foreign Application Priority Data**

Jun. 10, 2010 (JP) ..... 2010-132952

(51) **Int. Cl.**

**A61F 2/16** (2006.01)  
**A61F 2/14** (2006.01)

(52) **U.S. Cl.**

CPC ..... **A61F 2/1672** (2013.01); **A61F 2/167** (2013.01); **A61F 2/1664** (2013.01); (Continued)

(58) **Field of Classification Search**

CPC ..... A61F 2/148; A61F 9/0008; A61F 2/167; A61F 2/1662

See application file for complete search history.

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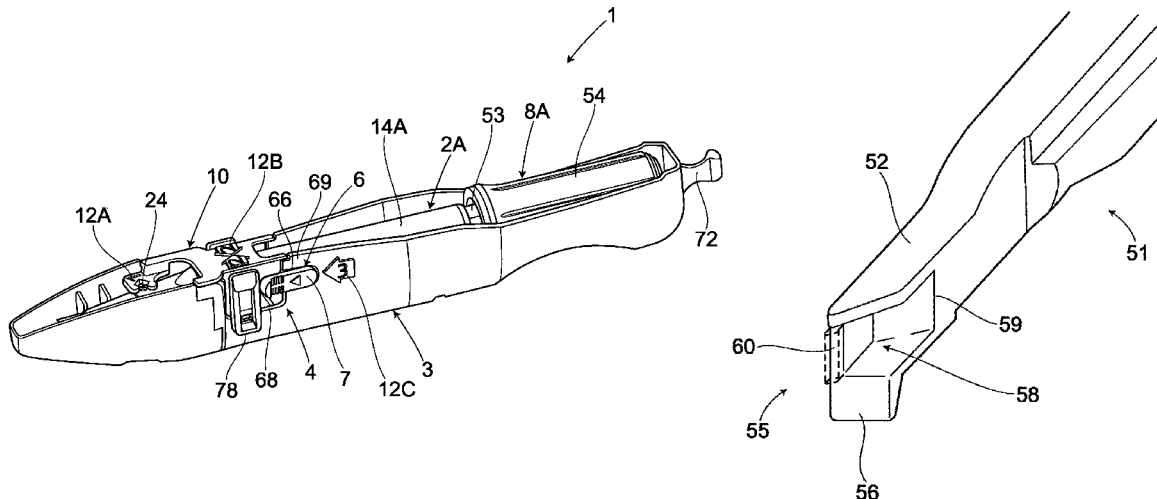
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(57)

**ABSTRACT**

An exemplary ocular implant insertion system includes a case and a preloaded ocular implant insertion apparatus. The apparatus includes first and second movable structures that move the ocular implant in a predetermined sequence. The respective configurations of the case and the ocular implant insertion apparatus are such that the ocular implant insertion apparatus is not removable from the case when the ocular implant insertion apparatus is in the pre-use state and is removable after the first movable structure has moved at least a portion of the optical implant.

**17 Claims, 12 Drawing Sheets**



## US 9,980,811 B2

Page 2

**Related U.S. Application Data**

No. 14/145,846, filed on Dec. 31, 2013, now Pat. No. 9,314,373, which is a continuation of application No. 13/699,708, filed as application No. PCT/JP2011/063747 on Jun. 8, 2011, now Pat. No. 8,647,382.

(52) **U.S. Cl.**

CPC ..... *A61F 2/1678* (2013.01); *A61F 2/148* (2013.01); *A61F 2/1662* (2013.01); *A61F 2002/16903* (2015.04)

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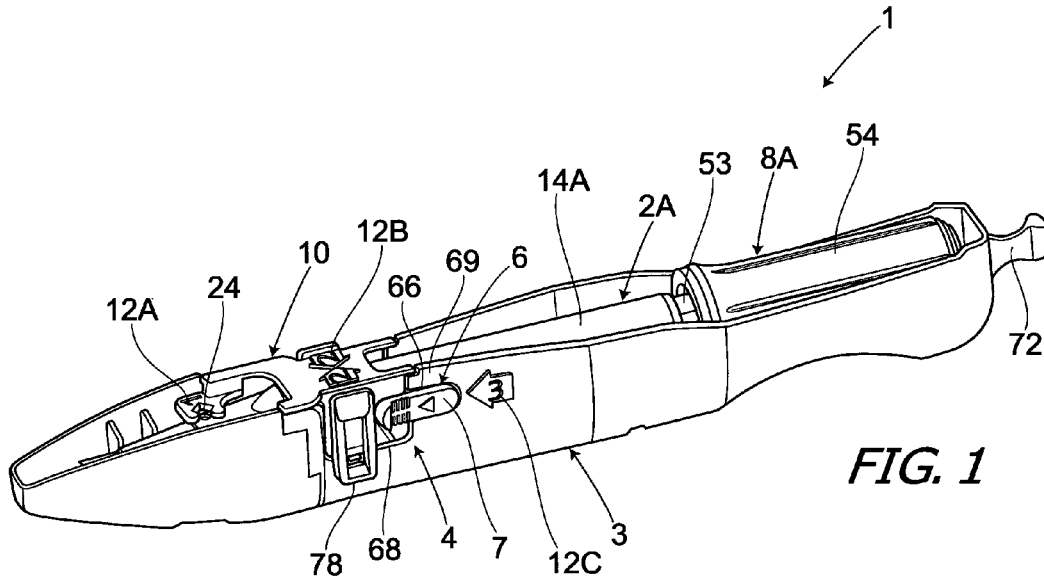


FIG. 1

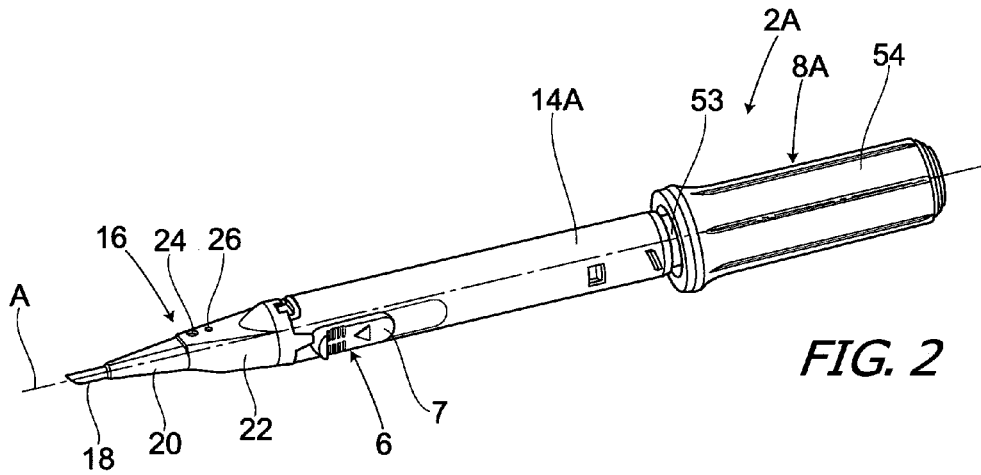


FIG. 2

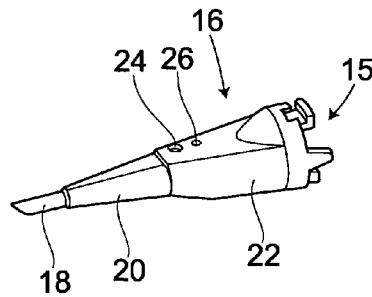
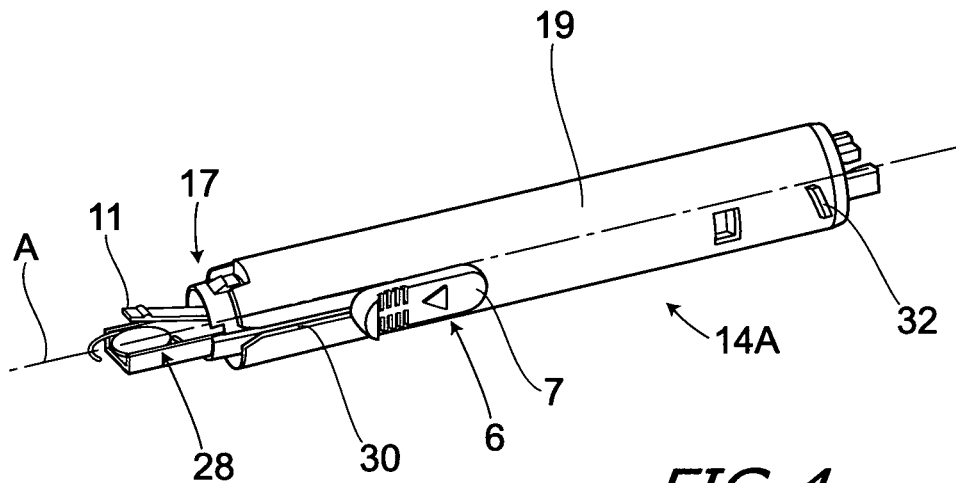
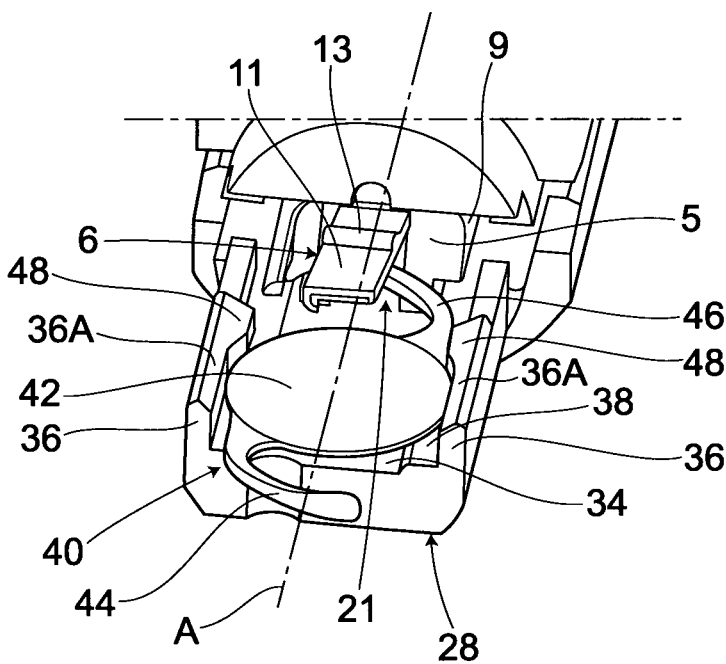


FIG. 3



**FIG. 4**



**FIG. 5**



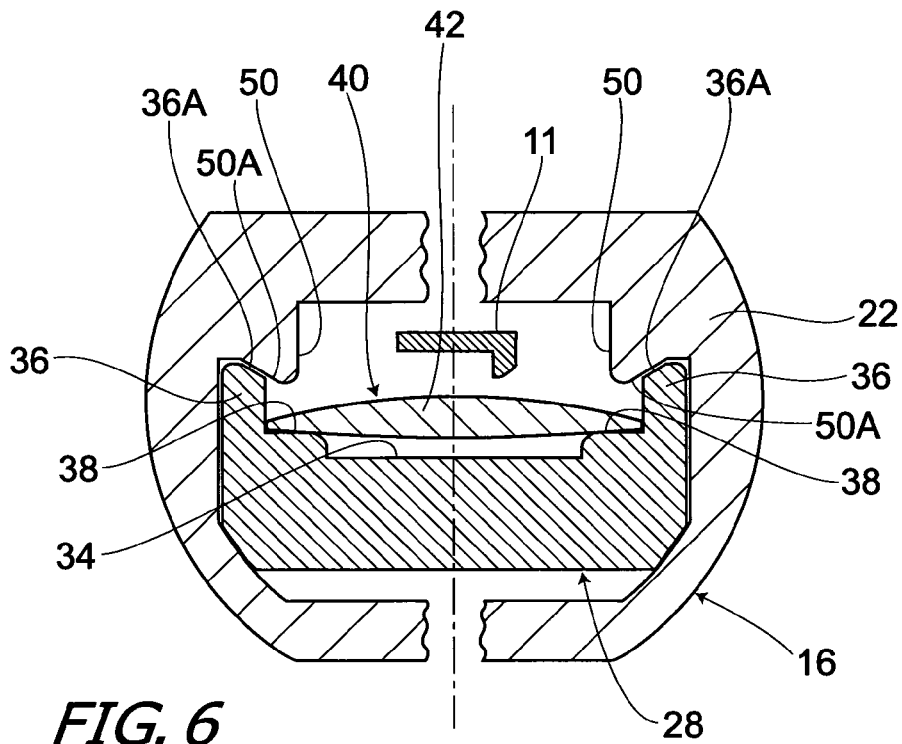


FIG. 6

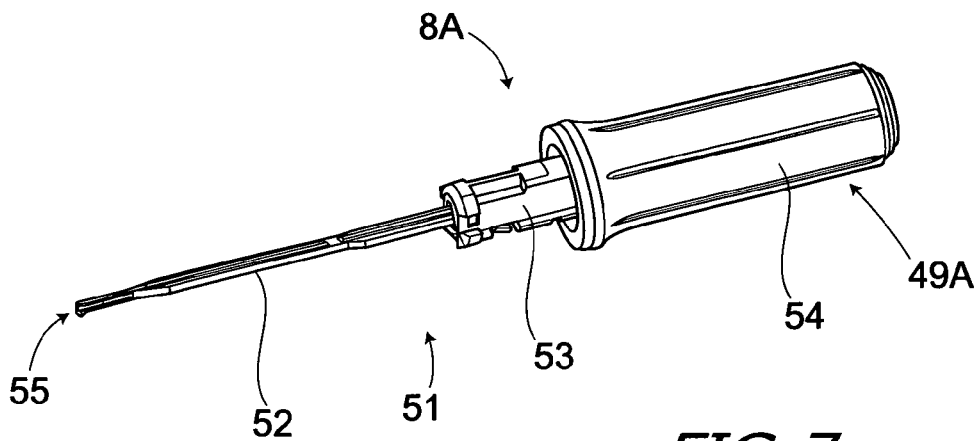
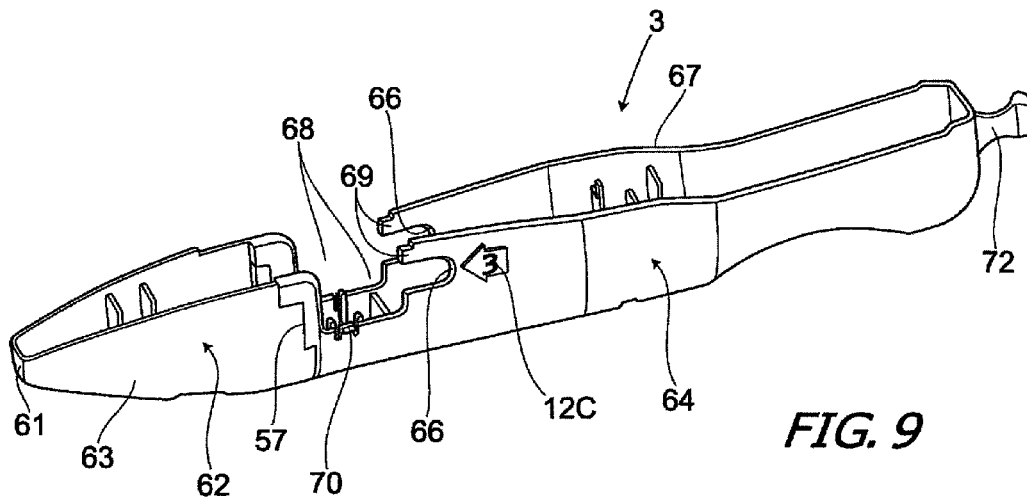
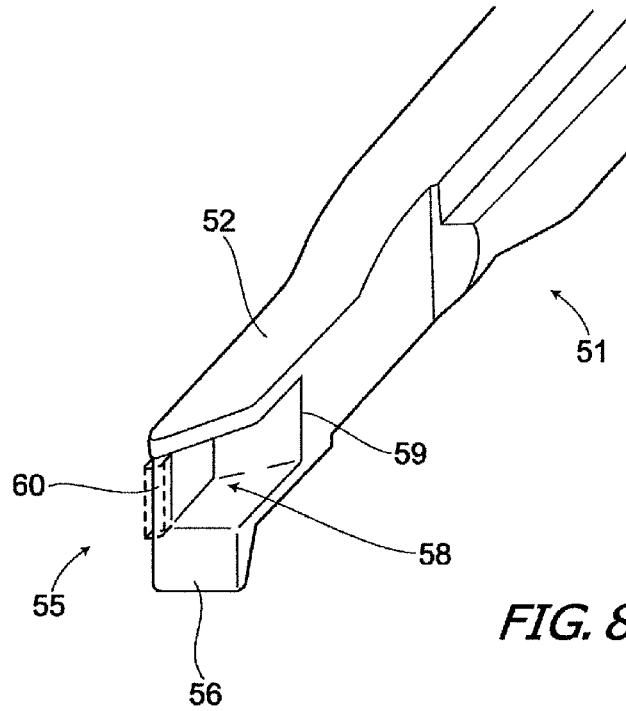


FIG. 7





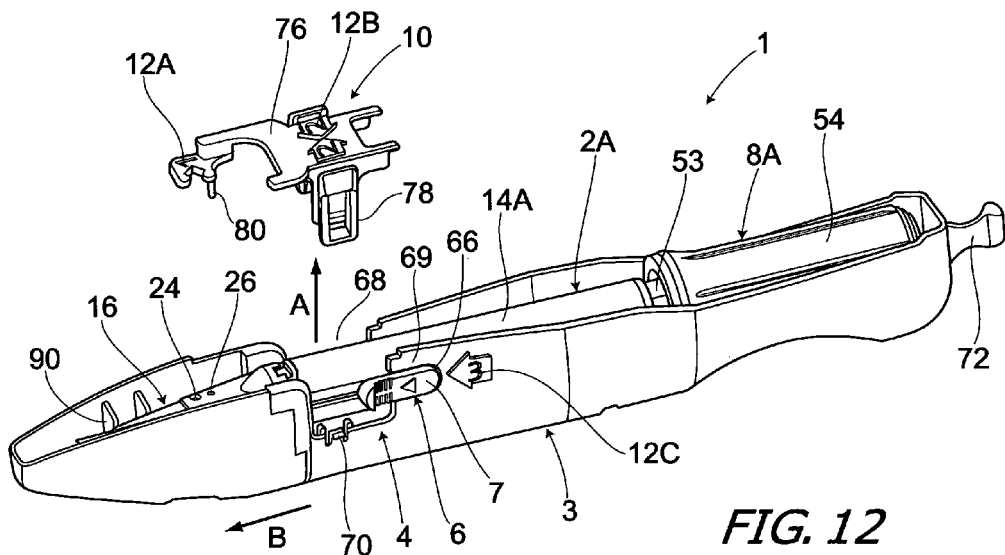


FIG. 12

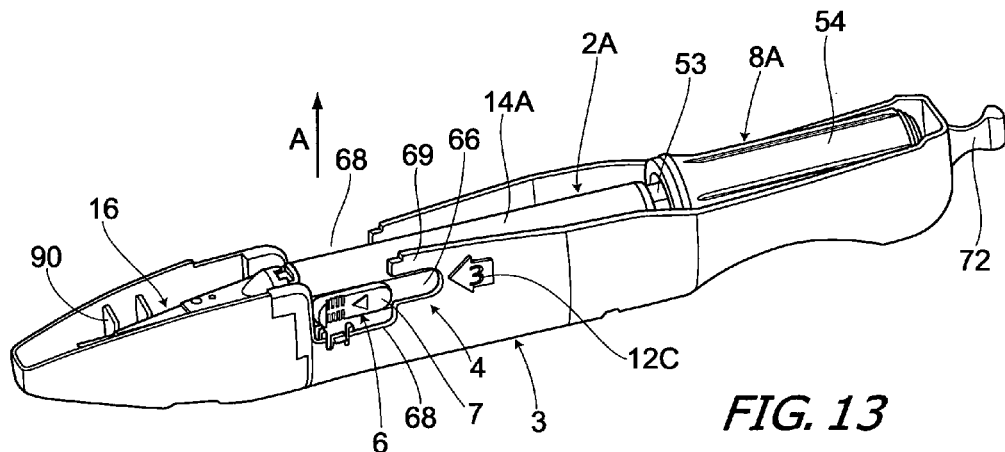
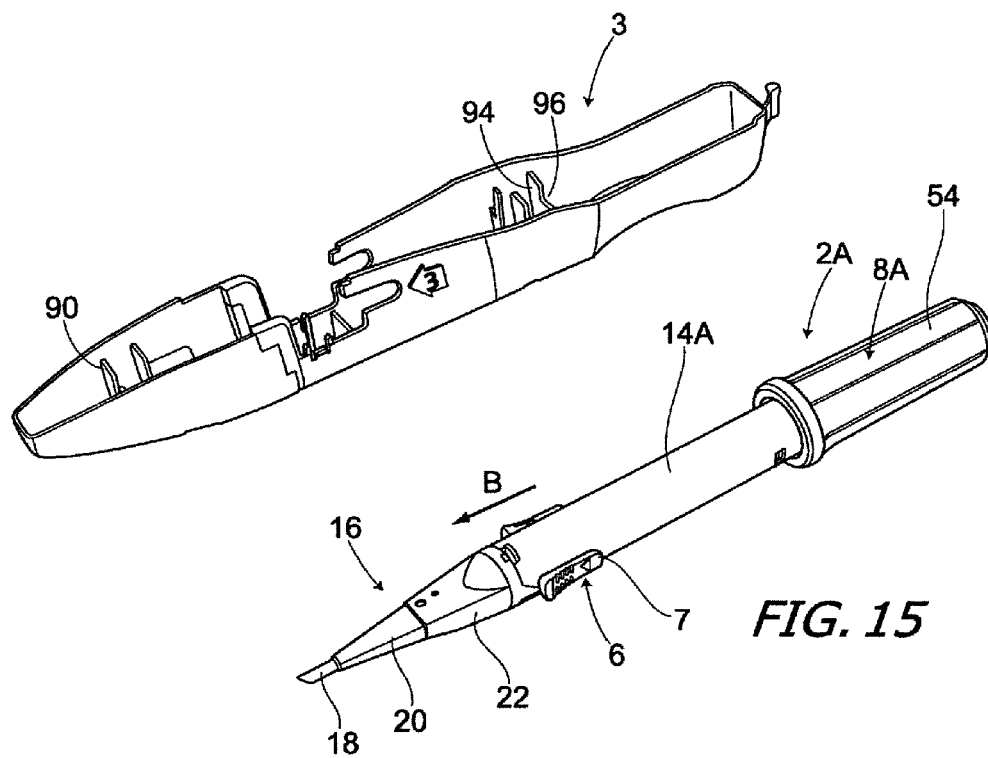
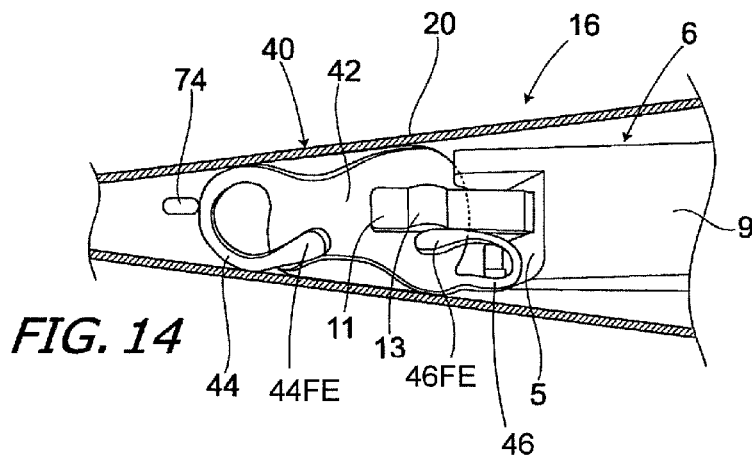
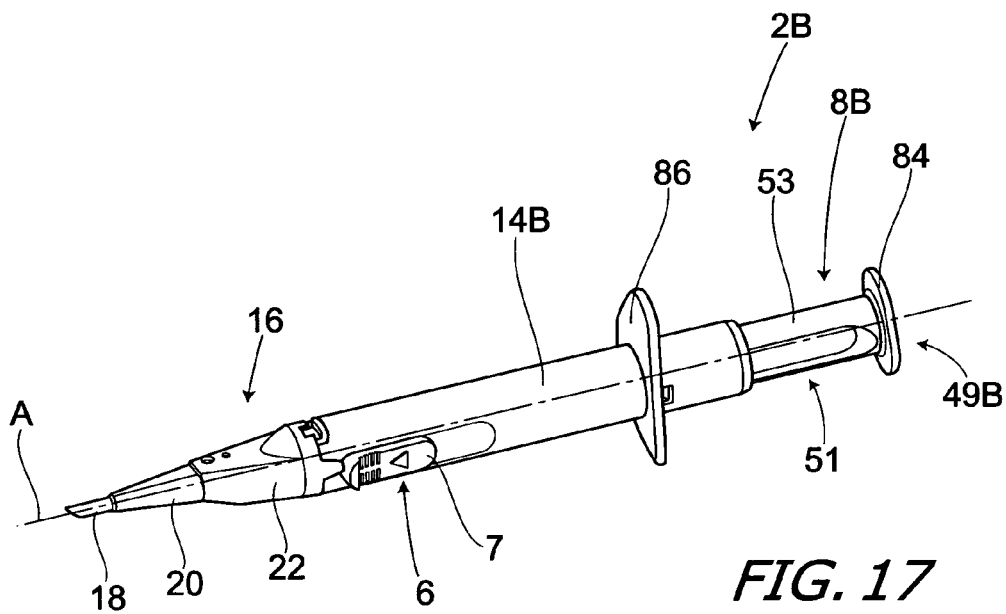
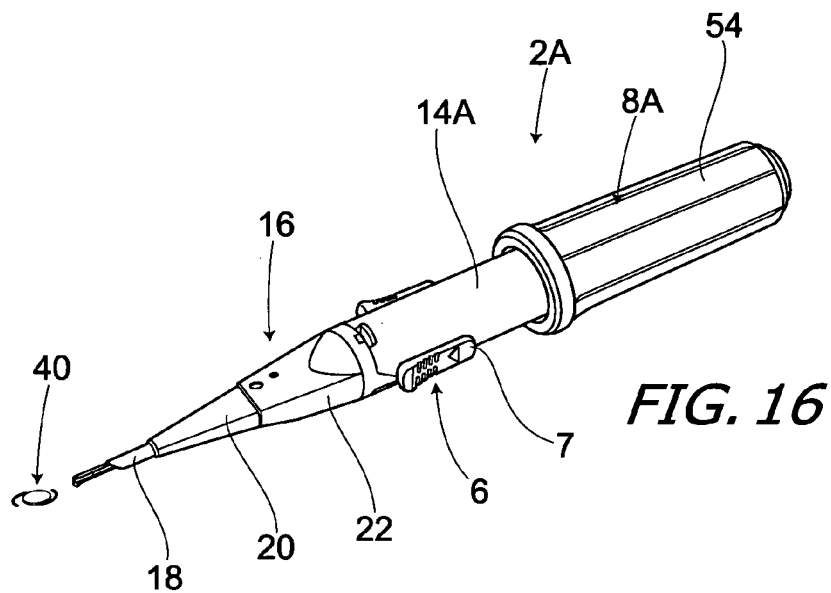


FIG. 13





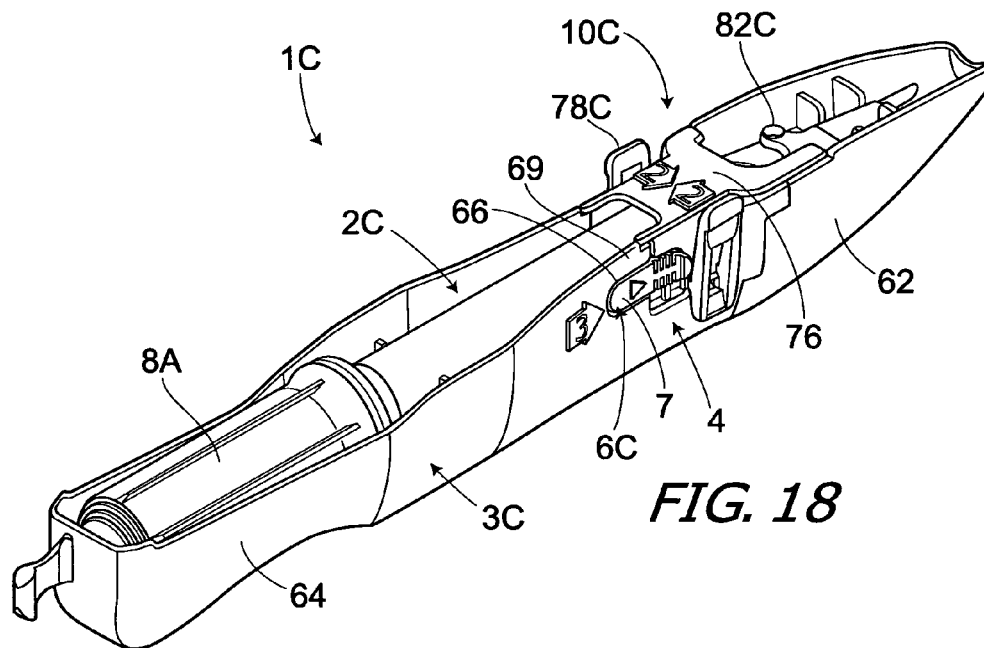


FIG. 18

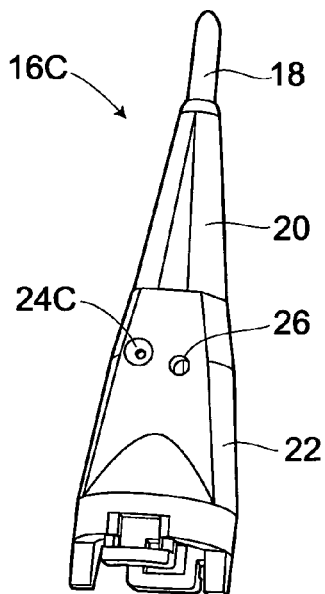


FIG. 19

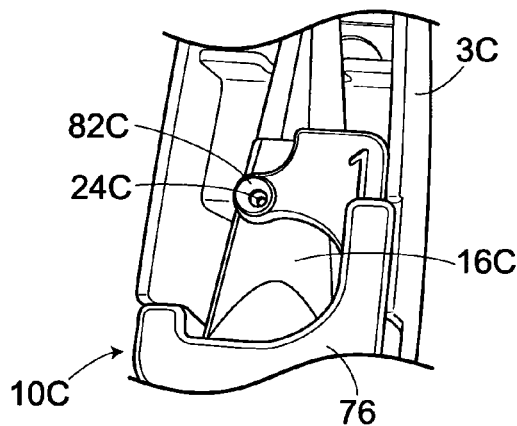


FIG. 20

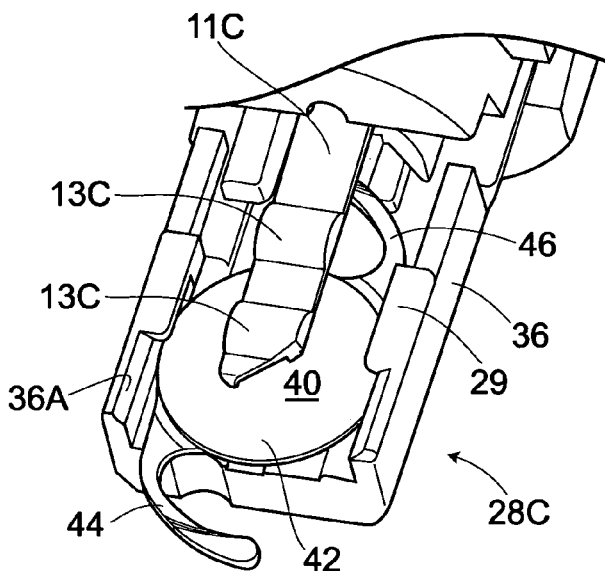


FIG. 21

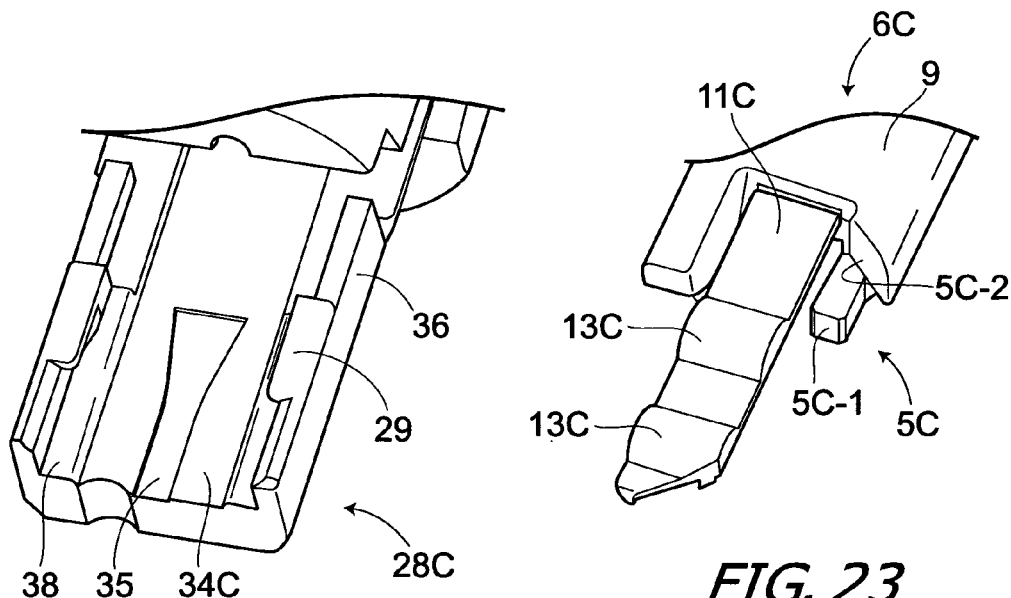
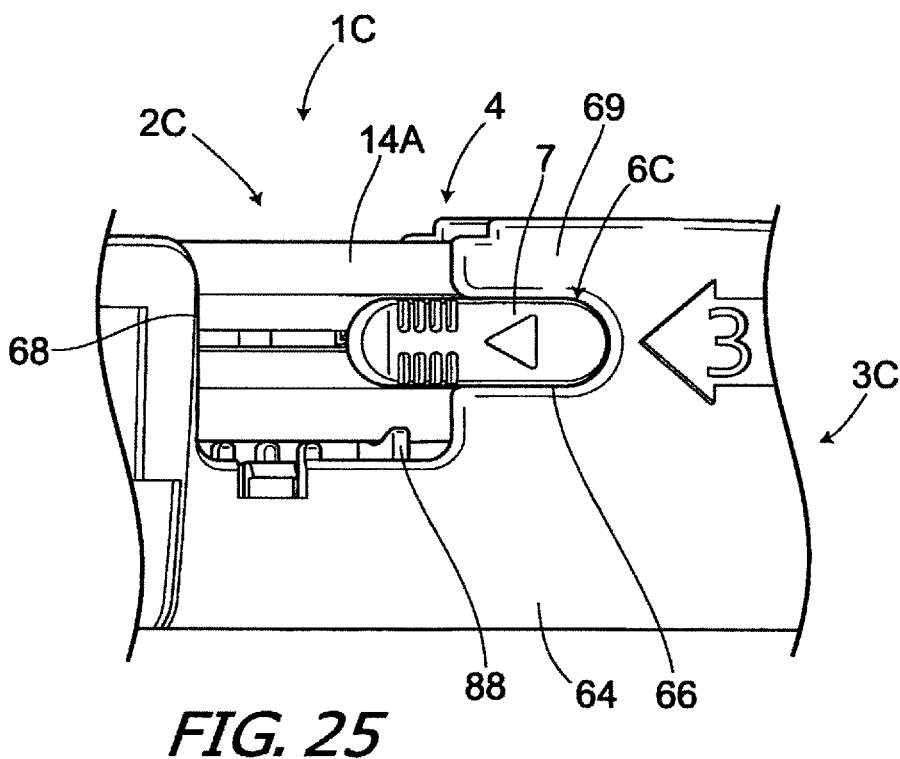
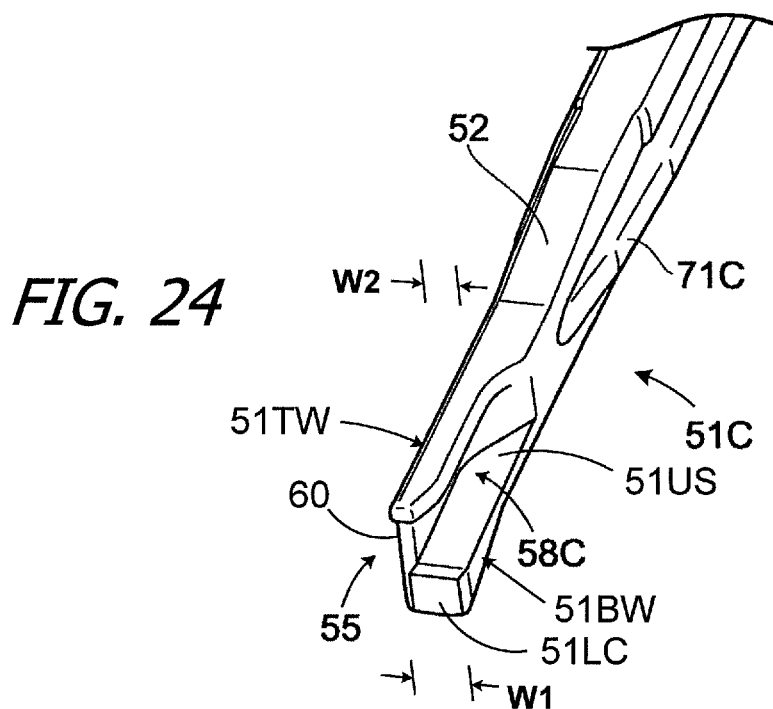
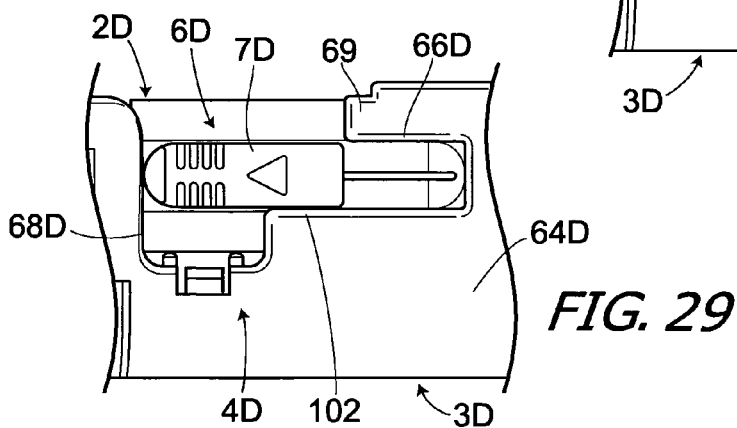
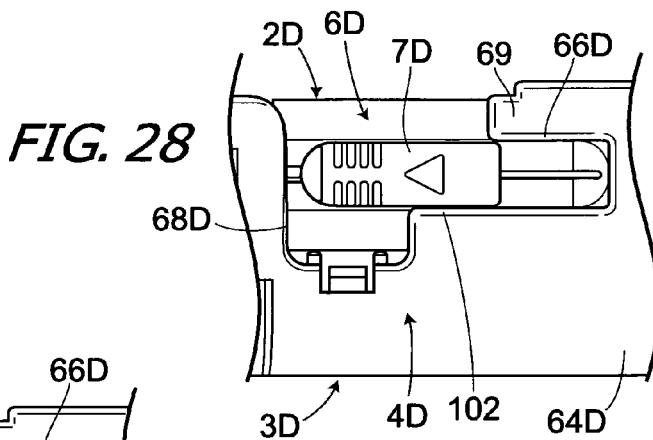
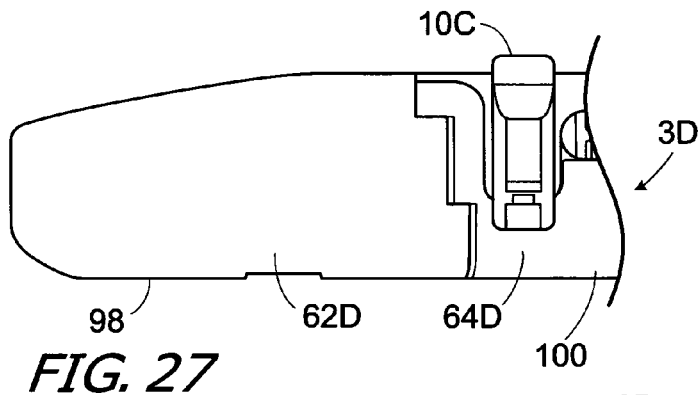
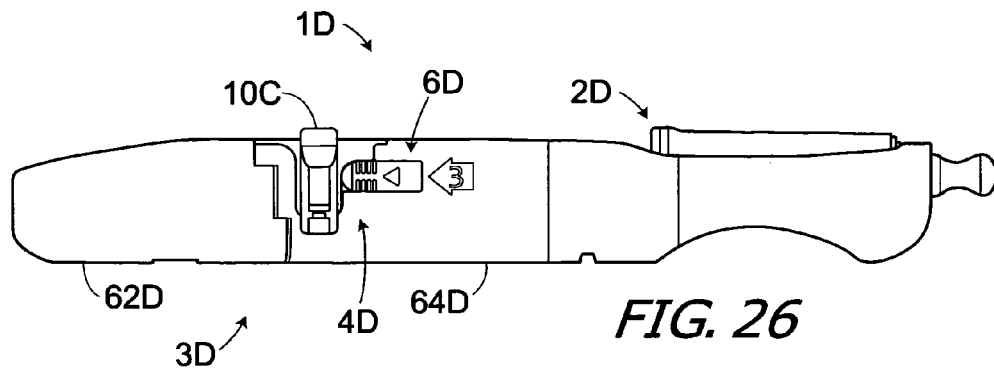


FIG. 22

FIG. 23







US 9,980,811 B2

1

**OCULAR IMPLANT INSERTION  
APPARATUS AND METHODS****CROSS-REFERENCE TO RELATED  
APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 15/071,880, filed Mar. 16, 2016, which is a continuation of U.S. application Ser. No. 14/145,846, filed Dec. 31, 2013, now U.S. Pat. No. 9,314,373, which is a continuation of U.S. application Ser. No. 13/699,708, now U.S. Pat. No. 8,647,382, which has a 35 U.S.C. § 371(c) date of May 11, 2013 and is a U.S. national phase application under 35 U.S.C. § 371 of International Patent Application No. PCT/JP2011/063747, filed Jun. 8, 2011, which claims priority to Japanese patent application No. 2010-132952, filed Jun. 10, 2010. The International Application was published in English on Dec. 15, 2011 as International Publication No. WO 2011/155636 A1. The content of each application is incorporated herein in its entirety.

**BACKGROUND OF THE INVENTIONS****1. Field of the Inventions**

The present inventions relate generally to apparatus and methods for inserting an ocular implant into an eye.

**2. Description of the Related Art**

There are a variety of instances where an ocular implant is inserted into the anterior chamber, posterior chamber, cornea, vitreous space and/or other portion of an eye. Exemplary ocular implants include, but are not limited to, lenses, capsular tension rings, ocular prosthesis and lamellar transplants. An intraocular lens (IOL), for example, may be inserted into an aphakic eye that has undergone a cataract surgery or may be inserted into a phakic eye during a refractive surgery. One type of lens is a foldable lens. Foldable lenses are formed from soft material such as a silicone elastomer, soft acrylic, or hydrogel and may be inserted into the eye through a small incision. Lens insertion apparatus, which may be used to push a foldable lens into an eye through a nozzle, generally include screw-type insertion apparatus and push-type insertion apparatus. In both cases, the lens insertion apparatus may include a plunger that is used to push a folded lens through the nozzle into the eye by way of an incision that is relatively small, e.g., an incision that is smaller than the diameter of an IOL optic.

Loading an ocular implant into an inserter can be a troublesome portion of the insertion procedure. The implant may be contaminated, damaged or improperly placed into the inserter by operator, e.g., a surgeon or assistant. Accordingly, in some instances, the insertion apparatus is preloaded, i.e., the insertion apparatus is shipped from the factory with the ocular implant (e.g., an IOL) stored therein. An operator using a preloaded inserter does not place the implant into the insertion apparatus, thereby eliminating the possibility of the aforementioned operator error associated with loading.

In addition to the basic functions of storing and inserting an IOL or other ocular implant, it may also be desirable for the insertion apparatus to minimize the physical load on the ocular implant during storage in order to ensure that the ocular implant returns to its unstressed state after being inserted into the eye. It may also be desirable to fold the IOL or other ocular implant into as small a state as possible in order to reduce the size of the incision and the likelihood of corneal astigmatism caused by the surgery or infection. Thus, the desired insertion apparatus must be able to fold the

2

unstressed ocular implant into a small state in a predetermined direction, and into a predetermined shape, in order to insure that the plunger can move the folded ocular implant through the nozzle without the insertion apparatus becoming clogged at or near the nozzle or the ocular implant being damaged. To that end, instead of using only a plunger to move the lens through the folding and insertion processes, some insertion apparatus have been configured to fold and move an IOL in stepwise fashion through the use of multiple IOL moving structures. Examples of such insertion apparatus are illustrated and described in PCT Pub. No. WO 2009/148091 (also published as US 2011/0082463) and Laid-open JP Pat. Pub. No. 2001-104347 (also published as US 2001/0007942).

The present inventor has, however, determined that insertion apparatus with multiple ocular implant moving structures are susceptible to improvement. For example, the present inventor has determined that such insertion apparatus are susceptible to erroneous operation, such as use of the moving structures in an incorrect sequence.

**SUMMARY**

An exemplary ocular implant insertion system includes a case and an ocular implant insertion apparatus including an ocular implant, a first movable structure that moves at least a portion of the ocular implant during movement thereof, and a second movable structure that moves the ocular implant through the nozzle. The ocular implant insertion apparatus is located at least partially within the case in pre-use state wherein the first and second movable structures have not folded and moved the ocular implant. The respective configurations of the case and the ocular implant insertion apparatus are such that the ocular implant insertion apparatus is not removable from the case when the ocular implant insertion apparatus is in the pre-use state and is removable after the first movable structure has moved at least a portion of the optical implant.

An exemplary method of using a system including a case and a preloaded ocular implant insertion apparatus locked to the case includes the steps of unlocking the insertion apparatus from the case by moving a first movable structure a distance sufficient to at least partial fold a stored ocular implant, removing the insertion apparatus from the case, and pushing the ocular implant from the insertion apparatus with a second movable structure.

There are a number of advantages associated with such systems and methods. For example, such systems and methods prevent the use of the first and second movable structures in an incorrect sequence.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Detailed description of exemplary embodiments of the inventions will be made with reference to the accompanying drawings.

FIG. 1 is a perspective view of an IOL insertion system, including an IOL insertion apparatus and an insertion apparatus case, in accordance with one embodiment of a present invention.

FIG. 2 is a perspective view of the exemplary IOL insertion apparatus illustrated in FIG. 1.

FIG. 3 is a perspective view of the insertion tube of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 4 is a perspective view of the main body of the exemplary IOL insertion apparatus illustrated in FIG. 2.

3

FIG. 5 is a perspective view of the lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 6 is a section view of the insertion tube and lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 7 is a perspective view of the plunger of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 8 is a perspective view of the distal portion of the plunger rod of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 9 is a perspective view of the exemplary insertion apparatus case illustrated in FIG. 1.

FIG. 10 is a partial section view of a portion of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 11 is a perspective view of the exemplary cover illustrated in FIG. 1.

FIG. 12 is a perspective view showing one aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 13 is a perspective view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 14 is a partial section view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 15 is a perspective view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 16 is a perspective view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 17 is a perspective view of another exemplary IOL insertion apparatus that may be combined with a case in the manner illustrated in FIG. 1 to form an IOL insertion system.

FIG. 18 is a perspective view of an IOL insertion system, including an IOL insertion apparatus and an insertion apparatus case, in accordance with one embodiment of a present invention.

FIG. 19 is a perspective view of the insertion tube of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 20 is a perspective view of a portion of the exemplary IOL insertion system illustrated in FIG. 18.

FIG. 21 is a perspective view of a portion of the slider and the lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 22 is a perspective view of the lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 23 is a perspective view of a portion of the slider of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 24 is a perspective view of a portion of the plunger rod of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 25 is a side view of a portion of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 26 is a perspective view of an IOL insertion system, including an IOL insertion apparatus and an insertion apparatus case, in accordance with one embodiment of a present invention.

FIG. 27 is a side view of a portion of the exemplary IOL insertion system illustrated in FIG. 26.

FIG. 28 is a side view of a portion of the exemplary IOL insertion system illustrated in FIG. 26.

4

FIG. 29 is a side view of a portion of the exemplary IOL insertion system illustrated in FIG. 26.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The following is a detailed description of the best presently known modes of carrying out the inventions. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the inventions. The present inventions are also applicable to a wide variety of ocular implants which, as used herein, refers to any structure, instrumentality or device that is placed into any ocular structure or region. Ophthalmic lenses, capsular tension rings, ocular prosthesis and lamellar transplants are examples of ocular implants. Although the exemplary implementations are described below in the context of an intraocular lens (IOL), the present inventions are also applicable other types of ocular implants, including those yet to be developed. For example, the present inventions are applicable to other types of ophthalmic lenses. Such lenses include, but are not limited to, intraocular contact lenses, phakic IOLs, and other lenses that may be inserted into the eye.

I. Overview

As illustrated in FIG. 1, the exemplary IOL insertion system 1 includes an IOL insertion apparatus 2A and a case 3 in which the IOL insertion apparatus 2A is stored during shipping and at other times prior to an insertion procedure. The IOL insertion apparatus 2A is a preloaded insertion apparatus and, to that end, an IOL 40 (FIG. 5) is placed within the insertion apparatus during the assembly process and the insertion apparatus is shipped and stored with the IOL located therein. The IOL insertion system 1 includes a lock mechanism 4 that prevents the IOL insertion apparatus 2A from being removed from the case 3 when in a locked state, and allows the IOL insertion apparatus to be removed from the case when in an unlocked state. As is discussed in greater detail below, the operation of the IOL insertion apparatus 2A itself is, generally speaking, a two-step process where the steps must be performed in the proper sequence. The first step involves folding a previously unstressed IOL into a particular configuration with a first device and the second step pushing the folded IOL through a tapered passage, where it is further folded, and then into the eye. The IOL insertion system 1 is configured such that the lock mechanism 4 will transition from the locked state to the unlocked state, thereby allowing the IOL insertion apparatus 2A to be removed from the case 3, when the first step is performed. In other words, the IOL insertion system 1 is configured such that the operator will not be able to remove the IOL insertion apparatus 2A from the case 3 unless the first step in the process has been performed. By requiring the first step to be performed prior to removal of the IOL insertion apparatus 2A from the case 3, the IOL insertion system 1 forces the operator to perform the steps in the correct order.

II. Exemplary IOL Insertion Apparatus

Turning to FIG. 2, the exemplary IOL insertion apparatus 2A includes a slider 6, a plunger 8A, a main body 14A and an insertion tube 16 that is mounted on the forward end of the main body. The main body 14A and insertion tube 16 together define the external housing of the insertion appa-

5

ratus 2A. The slider 6 and plunger 8A are movable relative to the external housing and relative to each other.

Operation of the IOL insertion apparatus 2A, where the IOL is pushed out of the apparatus and into the eye, is referred to herein as a “push-out” or “insertion” process. The slider 6, which has a pair of finger grips 7, performs the first step in the insertion process, i.e., folding a previously unstressed IOL into a particular configuration, and may therefore be referred to as one example of a first lens push-out mechanism. The exemplary slider 6 pushes the IOL 40 distally as it folds the IOL. In other implementations, the first “push-out” mechanism may perform the first step of the “push-out” process by simply folding an IOL without moving it distally. The exemplary plunger 8A performs the second step in the insertion process, i.e., pushing the folded IOL through a tapered lumen and then into the eye, and may therefore be referred to as one example of a second lens push-out mechanism. The IOL moves along a lens advancement axis A during the insertion process. Movement of the movable components of the insertion apparatus 2A and the IOL 40 towards the eye is referred to herein as movement in the forward (or “distal”) direction and movement away from the eye is referred to herein as movement in the rearward (or “proximal”) direction. Similarly, the end of a structure that faces the eye during use is referred to as the forward (or “distal”) end and the other end the structure is referred to as the rearward (or “proximal”) end. The slider 6 and plunger 8A are both movable in the forward and rearward directions relative to the main body 14A.

The exemplary insertion tube 16 includes a nozzle 18, a transition section 20 and a protector 22, with interior regions that are in communication with one another so that an IOL can pass therethrough. The insertion tube 16 is connected to the main body 14A by a connector arrangement 15 (FIG. 3) on the insertion tube and a corresponding connector arrangement 17 (FIG. 4) on the main body. The inner diameter of the transition section 20 tapers downwardly from the end adjacent to the protector 22 to the end adjacent the nozzle 18. The protector 22 has an injection port 24 for viscoelastic material and a first insertion hole 26 (discussed below).

Turning to FIG. 4, the exemplary main body 14A includes a tubular member 19, a lens placement section 28, a slider guide section 30 and a protrusion 32. The lens placement section 28 (described below with reference to FIG. 5) protrudes distally from the front end of the tubular member 19. The slider guide section 30 is configured to allow the slider 6 to move forwardly and rearwardly. The slider guide section 30 may be a pair of slits, formed in the tubular member 19, that are parallel to the lens advancement axis A. The slider guide section 30 also extends rearwardly from the distal end of the tubular member 19 to the central portion of the tubular member. The plunger 8A is threadedly connected to the main body 14A in the illustrated implementation. To that end, the exemplary main body 14A includes a male screw. The protrusion 32, which is transverse to the lens advancement axis A, defines a portion of the screw thread of the male screw and a portion of the outer surface of the tubular member 19 defines the root of the thread. Another protrusion (not shown) may be located on the tubular member 19 180 degrees offset from the tubular member 32.

As shown in FIG. 5, the IOL insertion apparatus 2A may be used to store an IOL 40 that has an optic 42 and a pair of supports 44 and 46 such as, for example, the illustrated pair of haptics. The exemplary lens placement section 28 includes a bottom surface 34, a pair of side walls 36 respectively located on opposite sides of the bottom surface and extending upwardly from the bottom surface, and a pair

6

of rails 38. The bottom surface 34 and the side walls 36 are parallel to the lens advancement axis A and the lens advancement axis A is located between the side walls. The side walls 36 each include, near the upper end, an inclined surface 36A. The rear portions of the side walls 36 include inward protrusions 48 that prevent the IOL 40 from moving in the rearward direction. The lens supporting surfaces of the rails 38 are oriented in a direction that is transverse to the lens advancement axis A and slope away from the axis A in the rearward to forward direction. As such, the stored IOL 40 is tilted relative to the lens advancement axis A, with the forward end of the IOL optic 42 closer to the bottom surface 34 than the rearward end. The lens supporting surfaces of the rails 38 are also located a sufficient distance above the bottom surface 34 to prevent the IOL optic 42 from coming into contact with the bottom surface (note FIG. 6).

It should be noted that references herein to “top,” “bottom,” “upward,” “downward” and the like are merely references to the illustrated orientation and/or the relationship of the components relative to one another in the illustrated orientation. For example, the side of the IOL 40 facing the bottom surface 34 is referred to “the downward side” and movement toward the bottom surface is referred to as movement in the “downward direction,” while the opposite side of the IOL 40 is referred to as the “the upward side” and movement away from the bottom surface 34 is referred to as movement in the “the upward direction.”

In addition to the grips 7, and referring to FIGS. 5 and 14, the exemplary slider 6 includes an elongate member 9, with a lens contact surface 5, that is carried within the main body 14A and is slidable relative thereto. The grips 7 are connected to elongate member 9. The lens contact surface 5, which is larger than the plunger distal end 55 (discussed below), is used to scoop up the proximal IOL support 46 during the initial folding of the IOL 40. A lens holder 11 is pivotably mounted on the distal end of elongate member 9 and includes a protrusion 13. The lens holder 11 controls the initial folding of the IOL 40 during the first step of the lens insertion process. More specifically, as the slider 6 moves distally, the protrusion 13 rides along the tapered inner surface of the transition section 20, which causes the lens holder 11 to pivot downwardly into contact with the IOL optic 42 to fold the IOL 40. The slider elongate member 9 also includes a slot 21 through which the plunger rod 51 (discussed below) passes during the second step of the insertion process. Additional discussion concerning the use of a lens holder to fold an IOL may be found in, for example, U.S. Pat. Pub. No. 2010/0185206.

Referring to FIG. 6, the protector 22 of exemplary insertion tube 16 includes protrusions 50, with inclined surfaces 50A, that extend downwardly and inwardly from both sides of the protector inner surface. The projections 50, which guide the insertion tube 16 onto the upper ends of the side walls 36 during assembly, are sized such that the inclined surfaces 50A extend beyond the side wall inclined surface 36A. This prevents the outer edge of the IOL optic 42 located in the lens placement section 28 from becoming wedged between the protrusions 50 and the side walls 36.

Turning to FIG. 7, the exemplary plunger 8A includes an operational member 49A and a rod 51 with a distal rod portion 52, a proximal rod portion 53, and a rod distal end 55. The distal rod portion 52, which is sized such that it can be inserted through the nozzle 18, may be connected to, or may be integral with, the proximal rod portion 53. The operational portion 49A includes a handle 54 that is generally cylindrical in shape. The proximal (or “rearward”) end of the handle 54 is rotatably journaled, or is otherwise

rotatably secured, to the proximal (or “rearward”) end of the proximal rod portion 53. The handle 54 is also hollow and configured to receive the proximal portion of the main body 14A. The inner surface of the handle 54 includes a female screw (not shown) with threads that operationally correspond to the threads on the male screw associated with the main body 14A (note protrusion 32 in FIG. 4). As such, after the plunger 8A has been moved distally from the position illustrated in FIG. 2 until the male thread defined in part by the protrusion 32 engages the female thread within the handle 54, further distal movement is accomplished by rotating the handle.

As illustrated for example in FIG. 8, the rod distal end 55 may have a lens contact portion 56 and a recess 58 in which the free end of the proximal IOL support 46 is located during the second step of the two-step process. The exemplary lens contact portion 56 is a planar surface that is perpendicular to the lens advancement axis A, and is provided on a lower portion of the rod distal end 55. The exemplary recess 58, which has an opening 59 on one lateral side and a wall 60 on the other lateral side, is located above the lens contact portion 56. The recess 58 may be formed by cutting (or otherwise removing) material from the rod distal portion 52, starting at the distal end 55, or by molding the rod in the illustrated configuration. The wall 60 engages the outer edge of the IOL optic 42 and prevents optic of the folded IOL 40 from entering the recess 58. The wall 60 also keeps the IOL support 46 within the recess 58. The distal end of the wall 60 may be in the same plane as the lens contact portion 56 (as shown) or may be located distally beyond the lens contact portion 56 (as shown in dashed lines).

With respect to operation of the exemplary IOL insertion apparatus 2A, and as alluded to above, the IOL 40 is initially pushed forwardly (or distally) and folded into a predetermined shape with the slider 6. The slider 6 also forms part of the lock mechanism 4 that locks the IOL insertion apparatus 2A to the case 3 and, as is discussed below, the initial forward movement of the slider, unlocks the lock mechanism. The folded IOL 40 is subsequently pushed by the plunger 8A forwardly (or distally) through the transition section 20 where it is further folded, then thorough the nozzle 18, and then into the eye. In other words, the exemplary IOL insertion apparatus 2A deforms an IOL that has been preloaded within the main body 14A and insertion tube 16 into a predetermined shape while moving the IOL in the forward direction, first by using the slider 6 and second by using the plunger 8A, and then discharges the folded IOL into the eye. The IOL 40 may be folded by operation of the slider 6 into the predetermined shape in which the optic 42 is curled up and around the lens advancement axis A, with an upper surface of the optic dented downwardly, and in which the free ends 44FE and 46FE of the supports 44 and 46 are tucked into the upper surface of the curled optic 42 (note FIG. 14).

### III. Exemplary Case

The case 3, which protects the IOL insertion apparatus 2A during shipping and storage, may be an elongated container with an open upper end. To that end, and referring to FIG. 9, the exemplary case 3 includes a pair of end walls 61, a pair of side walls 63 that each extend from one end wall to the other, and a bottom wall 65 (FIG. 10) at the bottom ends of the end and side walls. The top ends of the end walls 61 and side walls 63 define the open upper end 67 of the case 3. The front portion of the case 3 is identified by reference numeral 62 and the rear portion of the case is identified by referent

numeral 64. The front and rear portions 62 and 64 may be separable structures that are secured to one another during the assembly process (note joint 57) as is discussed below.

The case 3 also includes a portion of the lock mechanism 4 that locks the IOL insertion apparatus 2A to the case. In the illustrated embodiment, each of the side walls 63 includes a storage slot 66 and removal slot 68. The storage slots 66 are separated, in the upward direction, from the open upper end 67 of the case by projections 69. The removal slots 68 extend to and through the upper end 67 of the case 3, and each storage slot 66 extends to the adjacent removal slot. Engagement members 70, which are located at the lower end of each removal slot 68, may be detachably engaged with a cover 10 (FIG. 1) to secure the cover to the case 3. A handle 72 may be located on the rear end wall 61 and used to remove the IOL insertion system 1 from the sterile package in which it is stored. The slider grips 7 are respectively located within the storage slots 66 when the lock mechanism 4 is in a locked state (FIG. 1) and are located within the removal slots when the lock mechanism is in an unlocked state (FIG. 13). The width of the slider grips 7 (in the direction of axis A) is less than or equal to the width of the removal slots 68. The respective configurations of the IOL insertion apparatus 2A and case 3 are also such that the slider grips 7 can be located within the storage slots 66 when the slider 6 is in its retracted, storage location (FIG. 12) and can also be pushed distally beyond the storage slots 66 to the point at which the slider 6 has completed the initial folding of the IOL 40 (FIG. 13).

With respect to the locked state, the projections 69 prevent the slider grips 7 and, therefore, the IOL insertion apparatus 2A, from moving in the upward direction identified by arrow A in FIGS. 12 and 13. The projections 69 do not, on the other hand, prevent the slider grips 7 from moving upwardly when the slider grips are located within the removal slots 68.

The exemplary case 3 also includes structure that helps control the initial folding of the lens during the movement of the slider 6 moves from the position illustrated in FIG. 12 to the position illustrated in FIG. 13. To that end, and referring to FIG. 10, the front portion 62 of the exemplary case 3 includes a protrusion 74 that extends through a correspondingly sized and located insertion hole 75 on the bottom surface of the insertion tube 16. The exemplary protrusion 74 has an overall ellipsoidal shape that is elongate in a direction parallel to the lens advancement axis A, and has a rearward facing surface that is slanted upwardly in the lens advancement (i.e., proximal to distal) direction. The protrusion 74 is located within the path of the IOL 40 and used to deflect the distal IOL support 44, as is discussed below with reference to FIG. 14. The protrusion 74 is removed from the IOL path, by way of the insertion hole 75, when the IOL insertion apparatus 2A is removed from the case 3.

It should also be noted here that the front portion 62 of the exemplary case 3 may include one or more support walls 90 (two in the exemplary embodiment) with slots 92 in which the insertion tube 16 is supported (FIG. 10). The width of each slot 92 (in a direction perpendicular to the lens advancement axis A) is equal to the width of the portion of the insertion tube 16 that is located therein. Similarly, the rear portion 64 includes a wall 94 (FIG. 15) with a slot 96 that is smaller in width than, and located distally of, the distal end of the handle 54. As a result, the IOL insertion apparatus main body 14A, insertion tube 16 and handle 54 may not be moved forward (i.e., in the direction of arrow B in FIG. 12) when the insertion apparatus 2A is located within the case 3. Also, as discussed above, the insertion apparatus

2A may not be pulled out of the case 3 (i.e., in the direction of arrow A in FIGS. 12 and 13) when the slider grips 7 are within the storage slots 66.

The exemplary cover 10, which is shown in detail in FIG. 11, includes a flat main body 76 and a pair of clips (or other attachment devices) 78. The clips 78 are size and positioned such that they can be located in the removal slots 68, and are configured to interlock with the engagement members 70 on the case 3. The clips 78, which extend downwardly from and are perpendicular to the main body 76, are resiliently deflectable about the main body at the point at which the clips are attached to the main body. As a result, the cover 10 can be easily secured to and removed from the case 3 by pressing the top ends of the clips 78 toward one another.

A protrusion 80 (FIG. 10), which extends downwardly from the bottom surface of the main body 76, is located such that it will extend into the first insertion hole 26 on the insertion tube 16 when the IOL insertion apparatus 2A is located within the case 3 and the cover 10 is secured to the case. The protrusion 80 is located within the path of the IOL adjacent to the distal end of the IOL optic 42 and, therefore, prevents distal movement of the IOL 40 within the lens placement section 28 during shipping and other times prior to use. The protrusion 80 is removed from the IOL path when the cover 10 is removed from the case 3. The cover 10 also includes an injection port opening 82 that will be aligned with insertion tube injection port 24 when the IOL insertion apparatus 2A is located within the case 3 and the cover 10 is secured to the case.

The cover 10 may be attached to the case 3, with each of the clips 78 located with a portion of a removal slot 68 and secured to an engagement member 70, when the lock mechanism 4 is in the locked state illustrated in FIG. 1. The clips 78 are also positioned forward of the slider grips 7, thereby preventing the slider 6 from being moved forwardly to unlock the lock mechanism 4 and move the IOL 40, when the cover 10 is secured to the case 3.

#### IV. Assembly

The exemplary IOL insertion system 1 may be assembled from an IOL insertion apparatus 2A and case 3 in a variety of ways. One exemplary assembly methods begins with an IOL insertion apparatus 2A that is complete, but for the loading of the IOL 40 and the attachment of the insertion tube 16 to the main body 14A, and the front and rear portions 62 and 64 of the case 3 separated from one another. In the initial step of the exemplary assembly method, the slider 6 and plunger 8 are attached to the main body 14A and the slider 6 is moved to its forward position so that the grip will be located within the removal slots 68. The main body 14A is then attached to the rear portion 64 of the case 3, which is still separated from the front portion 62, and the slider 6 is moved to the rearward position with the grips 7 within the storage slots 66. The IOL 40 is then placed in the lens placement section 28, with the outer edge of the optic 42 on the rails 38, and the supports 44 and 46 located distally and proximally of the optic. The inward protrusions 48 (FIG. 5) prevent the IOL 40 from moving in the rearward direction. The insertion tube 16 may then be attached to the front end of the main body 14A such that the lens placement section 28 is covered by the protector 22.

Next, the cover 10 is inserted onto the case 3. The clips 78 move through the removal slots 68 until they clip onto the engagement members 70, thereby securing the cover 10 to the case 3. The cover protrusion 80 will now extend through the first insertion hole 26 and be positioned between the

forward support 44 and the optic 42 of the IOL 40. As a result, movement of the IOL 40 is held between the lens placement section inward protrusions 48 and the cover protrusion 80 with no physical load is applied thereto (FIG. 10). The proximal end of the case front portion 62 is then attached to the distal end of the rear portion 64 from underneath, thereby completing assembly of the exemplary IOL insertion system 1 (FIG. 1).

#### V. Operation and Instructive Indicia

Operation of the exemplary IOL insertion system 1 is discussed below with reference to FIGS. 1 and 12-16. The operational method may includes a number of step that are intended to be performed in a particular order. Some of the steps are associated with unlocking the lock mechanism 4 and removing the IOL insertion apparatus 2A from the case 3, some of the steps are associated with the operation of the IOL insertion apparatus itself, and at least one step is associated with both.

The exemplary IOL insertion system 1 may be provided with indicia that guides the operator through the initial steps in the proper sequence. More specifically, the exemplary IOL insertion system 1 includes markers 12A-12C. Each marker includes a number and, where appropriate, a directional indicator. Marker 12A is a "1" and is located on the cover 10 adjacent to the opening 82 for the injection port 24. Marker 12B, which is located on the cover 10 near the clips 78, includes a pair of inwardly facing arrows and each arrow has a "2" associated therewith. Marker 12C may be located on one or both sides of the case 3 adjacent to one or both of the storage slots 66. In the illustrated implementation, marker 12C consists of a forwardly facing arrow and a "3" adjacent to each of the storage slots 66 and, accordingly, each of the slider grips 7 when the IOL insertion system 1 is in its initial, pre-use state. As will be apparent from the discussion below, the markers 12A-12C reduce the likelihood of operator error by guiding the operator through the associated steps in the correct sequence.

The exemplary IOL insertion system 1 may be operated as follows. The IOL insertion system may be provided to the operator in a sterile bag and removed therefrom while holding the handle 72 (FIG. 1). A volume of viscoelastic material sufficient to fill the region around the IOL 40 may then be injected into the insertion tube 16 by way of injection port 24 (note marker 12A). The ends of the cover clips 78 adjacent to the main body 76 may then be pressed together (note marker 12B) to pivot the clips away from the engagement members 70, thereby disconnecting the cover 10 from the case 3. The cover 10 may then be removed from the case 3, as shown in FIG. 12. After the cover 10 has been removed from the case 3, the clips 78 will no longer prevent the slider grips 7 from being moved forwardly and the protrusion 80 will no longer prevent the IOL 40 from being moved forwardly. The lock mechanism 4 will, however, still be in the locked state.

As illustrated in FIG. 13, the next step is to move the slider 6 in the forward direction (note marker 12C) until the slider grips 7 have moved out of the storage slots 66 and, in the illustrated embodiment, have come into contact with a front ends of the removal slots 68. Such movement of the slider 6 causes the IOL 40 to move from the lens placement section 28 to the transition section 20, thereby causing the lateral sides of IOL optic 42 to fold upwardly as the lens holder 11 pushes the central portion of the IOL optic downwardly (FIG. 14). As the IOL 40 moves forwardly into the transition section 20, the protrusion 74 bends the distal

11

IOL support **44** such that the free end of the support is positioned on the upper surface of the folded IOL optic **42** (FIG. **14**). In particular, the slanted rearwardly facing surface of the protrusion **74** (FIG. **10**) scoops up the distal IOL support **44** as it is bent, thereby facilitating reliable positioning of the distal IOL support on the upper surface of the folded IOL optic **42**. The lens contact surface **5** of the slider **6** also scoops up the proximal IOL support **46** and pushes it forwardly such that the proximal IOL support **46** will also be positioned on the upper surface of the folded IOL optic **42**. With respect to the folding of the IOL optic **42**, the distal portion is folded to a greater extent than the proximal portion, with the lateral edges folded up and the center pushed down, due to the tapered shape of the interior of the transition section **20**. This completes the initial folding of the IOL **40**.

Movement of the slider **6** from the position illustrated in FIG. **12** to the position illustrated in FIGS. **13** and **14** also unlocks the lock mechanism **4** because the slider grips **7** are no longer within the storage slots **66** and, instead, are within the removal slots **68**. The IOL insertion apparatus **2A** may now be removed from the case **3** by simply lifting the apparatus in the direction identified by arrow A in FIG. **13**. In addition to freeing up the IOL insertion apparatus **2A** for use by the operator, removal of the IOL insertion apparatus from the case **3** also removes the protrusion **74**, which is part of the case and which facilitated reliable folding of the IOL **40** during movement of the slider **6**, from the path of the IOL. Thus, the protrusion **74** is located within the path of the IOL **40** when needed (i.e. during the initial folding of the IOL) and is automatically removed from the path when appropriate (i.e. prior to operation of the plunger **8A**).

Next, the operator pushes the plunger handle **54** forward in the direction of arrow B (FIG. **15**) until the threads associated with the inner surface of the handle engage the thread (note protrusion **32** in FIG. **5**) on the main body **14A**. The handle **54** may then be rotated to drive the plunger **8A**. Forward movement of the plunger rod **51** drives the IOL **40** into, and then through, the nozzle **18** and then into the eye (FIG. **16**). The IOL **40** is further folded from the state illustrated in FIGS. **14** and **15** as it moves into the nozzle **18**. The above-described initial state of the folded IOL **40**, i.e. the IOL optic **42** folded with the supports **44** and **46** resting on the upper surface thereof, facilitates the subsequent folding associated with movement of the plunger rod **51**.

It should be again emphasized here that the IOL insertion apparatus **2A** is secured to the case **3** by the lock mechanism **4** until the slider **6** has been moved forward, thereby unlocking the lock mechanism so that the IOL insertion apparatus can be removed from the case. By incorporating such movement of the slider **6** into the unlocking process, the present IOL insertion system **1** prevents the operator from erroneously pushing the IOL **40** with the plunger **8A** until after the IOL has undergone the initial folding associated with the slider **6**.

## VI. Other Exemplary Embodiments

The present inventions are not limited to the exemplary embodiments described above.

For example, in addition to screw-type IOL insertion apparatus such as that described above, the present inventions are applicable to push-type IOL insertion apparatus. One example of such a push-type IOL insertion apparatus is generally represented by reference numeral **2B** in FIG. **17**. The push-type IOL insertion apparatus **2B** is essentially identical to apparatus **2A** and similar elements are repre-

12

sented by similar reference numerals. Here, however, instead of a screw-type operational member, the plunger **8B** includes a push-type operational member **49B** that operates in a manner similar to a syringe. Operational member **49B** includes a disk-shaped member **84** on the proximal end of the proximal rod portion **53**, and a flange **86** on the outer surface of the main body **14B**. The plunger rod **51** is driven by resting one or more fingers on the flange **86** and pushing the disk-shaped member **84** with the thumb. The IOL insertion apparatus **2B** may be combined, for example, with the case **3** and cover **10** described above to form an IOL insertion system that requires operation of the slider **6** prior to removal of the IOL insertion apparatus from the case.

Another exemplary IOL insertion system, which is generally represented by reference numeral **1C** in FIG. **18**, includes an IOL insertion apparatus **2C** and a case **3C**. IOL insertion system **1C** is essentially identical to system **1** and similar elements are represented by similar reference numbers. For example, IOL insertion system **1C** includes a screw-type IOL insertion apparatus **2C**, a case **3C**, a lock mechanism **4** and a cover **10C**. In the interest of brevity, the discussion below focuses on the differences between the two systems.

As illustrated in FIG. **18**, the exemplary cover **10C** includes clips **78C** that extend above the main body **76** to a greater extent than do the clips **78** of the cover **10**. The additional length makes the clips **78C** easier to grip and the cover **10C** easier to remove.

Turning to FIGS. **19** and **20**, in the exemplary IOL insertion apparatus **2C**, the location of the injection port **24C** on the insertion tube **16C** decreases the likelihood that the cannula (not shown) delivering the viscoelastic material will come into contact with the IOL **40**. Additionally, the cover **10C** is provided with a frustoconical injection port opening **82C** that will be aligned with insertion tube injection port **24C** when the IOL insertion apparatus **2C** is located within the case **3C** and the cover is secured to the case. The frustoconical injection port opening **82C** guides the cannula into the injection port **24C**.

Referring to FIG. **21**, the exemplary IOL insertion apparatus **2C** includes a lens placement section **28C** with a pair of lens covers **29** that extend over the inward protrusions **48** (FIG. **5**) and portions of the IOL optic **42** and proximal support **46**. The lens covers **29** prevent upward movement of the IOL **40** prior to operation of the slider **6C** (e.g., during shipping or handling by the operator). As such, the lens covers **29** increase the likelihood that the IOL **40** will be properly positioned when the operator pushes the slider **6C** forward. Additionally, as shown in FIG. **22**, the lens placement section **28C** has a bottom surface **34C** with a groove **35** that guides the plunger rod **51C** (FIG. **24**) as it passes through the lens placement section, thereby increasing the likelihood that the plunger rod **51** will remain properly oriented.

With respect to the exemplary slider **6C**, and turning to FIG. **23**, the slider has a pivotable lens holder **11C** with a pair of protrusions **13C**. The dual protrusion arrangement causes the lens holder **11C** to engage the inner surface of the insertion tube **16C**, and begin the pivoting and associated IOL folding, at an earlier point in the movement of the slider **6C** than would be the case with the single protrusion embodiment illustrate in FIG. **14**. Such earlier folding of the IOL **40** helps insure that the edge of the IOL is positioned in the manner illustrated in FIG. **14** so that the proximal IOL support **46** can slide over the IOL optic **42**. With respect to deflection of the proximal IOL support **46**, the exemplary slider **6C** includes a lens contact assembly **5C** that has a



US 9,980,811 B2

13

support post 5C-1 and a vertical guide surface 5C-2 that tapers outwardly in the proximal to distal direction. The lens contact assembly 5C insures that the proximal IOL support 46 will deflect in the manner described above with reference to FIG. 14.

As illustrated example in FIG. 24, the exemplary plunger rod 51C has a rib 71C that extends distally to a point adjacent to the recess 58C. The rib 71C increases the rigidity of plunger rod 51C which, in turn, helps to maintain the alignment of the plunger rod 51C. The shape of the recess 58C, which is larger than recess 58, helps insure that the proximal support 46 will move out of the recess once in the eye. The plunger rod 51C also has a bottom wall 51BW with an upper surface 51US and a width W1, a lens contact surface 51LC that extends downwardly from the bottom wall upper surface, a top wall 51TW with a width W2 that is less than the bottom wall width, and a lateral wall 60.

Referring to FIG. 25, the exemplary case 3C includes a support member 88 that engages the bottom of the main body 14A when the IOL insertion apparatus 2C is stored within the case and the lock mechanism 4 is in the locked state (as shown). The support member 88, which may be a thin wall with a curved upper surface, prevents the main body 14A from bending in the downward direction as the user is pushing the slider 6C forwardly. Such bending could result in an undesirable level of friction between the case 3C and the slider grip 7.

Another exemplary IOL insertion system, which is generally represented by reference numeral 1D in FIG. 26, includes an IOL insertion apparatus 2D and a case 3D. IOL insertion system 1D is essentially identical to system 1C and similar elements are represented by similar reference numbers. For example, IOL insertion system 1D includes a screw-type IOL insertion apparatus 2D, a lock mechanism 4D, and a cover 10C. In the interest of brevity, the discussion below focuses on the differences between the two systems.

The present inventor has determined that there may be some instances where, during the first step of the two-step process, the operator will place the case on a table or other flat support surface, hold the front portion of the case with one hand and the push the slider forward the other hand. Referring first to the embodiment illustrated in FIG. 18, the front portion 62 of the case 6C includes a bottom surface that tapers upwardly. If the operator pushes the front portion 62 of the case 3C downwardly with too much force while firmly holding the slider grips 7, the front portion of the case may deflect, the case protrusion 74 may be completely or partially pulled out of the IOL path, and the IOL distal support 44 may not deflect properly. The front portion 62D of the exemplary case 3D illustrated in FIGS. 26 and 27 includes a flat bottom surface 98, which is aligned with the flat bottom surface 100 of the rear portion 64D, that prevents such bending.

The present inventor has also determined that there may be some instances where the operator attempts to pull the insertion apparatus out of the case, in a direction that is slightly angled from vertical, before the slider movement has been completed and the slider has engaged the distal wall of the removal slot. The curvature of the proximal ends of the slider grips may create a gap, between the curved proximal ends and the distal end of the storage slot protrusion (note grip 7 and protrusion 69 in FIG. 25) that invites these attempts. Turning to FIG. 28, the respective shapes of the slider grip 7D (not the flat proximal end), storage slot 66D and removal slot 68D (note extension 102) prevent the insertion apparatus 2D from being pulled out of the case 3D when the slider 6D is only in the almost fully forward

14

position illustrated in FIG. 28. The top corner of the slider grip 7D is in contact with the bottom corner of the protrusion 69. Only after the slider 6D is moved to the fully forward position illustrated in FIG. 29 will removal of the insertion apparatus 2D from the case 3D be possible.

Numerous other modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art. It is intended that the scope of the present inventions extends to all such modifications and/or additions.

We claim:

1. An intraocular lens insertion apparatus, comprising:
  - an outer body including a lens placement section and a nozzle and defining a lens movement direction;
  - an intraocular lens, having an optic with a diameter and haptics with respective free ends, stored in the lens placement section in such a manner that the optic diameter is perpendicular to the lens movement direction, one of the haptics is a proximal haptic and one of the haptics is a distal haptic; and
  - a plunger, at least a portion of which is carried within the outer body, that is movable relative to the outer body and which has a distal region that defines a longitudinal axis, the distal region including
    - a bottom wall having an upper surface and defining a width in a direction transverse to the longitudinal axis of the distal region,
    - a lens contact surface extending downwardly from the bottom wall upper surface,
    - a top wall defining a width in a direction transverse to the longitudinal axis of the distal region that is less than the width of the bottom wall, and
    - a lateral wall that extends from the bottom wall to the top wall in a direction perpendicular to the optic diameter that is perpendicular to the lens movement direction,
    - the top wall, bottom wall and lateral wall together defining a recess that is located above the bottom wall, that extends proximally from the lens contact surface, that has a first lateral side that is open, a second lateral side that is closed by the lateral wall, and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end is positioned over the optic.
2. An ocular implant insertion apparatus as claimed in claim 1, wherein
  - the plunger includes a slanted wall that defines the proximal end of the recess.
3. An ocular implant insertion apparatus as claimed in claim 2, wherein
  - the slanted wall is oriented at a non-perpendicular angle with respect to the longitudinal axis of the distal region.
4. An ocular implant insertion apparatus as claimed in claim 2, wherein
  - the slanted wall extends from the lateral wall to the first lateral side that is open.
5. An ocular implant insertion apparatus as claimed in claim 2, wherein
  - the width of the top wall at the open distal end of the recess is less than the width of the top wall at the proximal end of the recess.
6. An ocular implant insertion system as claimed in claim 1, further comprising:
  - a slider movable relative to the plunger from a pre-use slider position to a second slider position.

US 9,980,811 B2

15

7. An ocular implant insertion apparatus as claimed in claim 6, wherein the proximal haptic includes a free end; and movement of the slider from the pre-use slider position to the second slider position moves the free end of the proximal haptic over the optic.

8. An ocular implant insertion apparatus as claimed in claim 6, wherein the proximal haptic includes a free end; and movement of the slider from the pre-use slider position to the second slider position moves the free end of the distal haptic over the optic.

9. An ocular implant insertion apparatus as claimed in claim 1, wherein the plunger includes a rotatable handle.

10. An ocular implant insertion apparatus as claimed in claim 1, wherein the plunger includes a thumb rest.

11. An ocular implant insertion apparatus as claimed in claim 1, wherein the lens contact surface is planar.

12. An ocular implant insertion apparatus as claimed in claim 1, wherein

16

the lateral wall defines a lateral side of the distal region of the plunger.

13. An ocular implant insertion apparatus as claimed in claim 1, wherein the lateral wall defines a distal end; and the top wall defines a distal end that extends distally beyond the distal end of the lateral wall.

14. An ocular implant insertion apparatus as claimed in claim 1, further comprising: a tapered transition proximal of the nozzle.

15. An ocular implant insertion apparatus as claimed in claim 1, wherein the outer body comprises main body and an insertion tube mounted on the main body.

16. An ocular implant insertion apparatus as claimed in claim 15, wherein the insertion tube includes the nozzle.

17. An ocular implant insertion apparatus as claimed in claim 1, wherein the lateral wall extends distally beyond the lens contact surface.

\* \* \* \* \*

# **EXHIBIT 3**

(12) **United States Patent**  
**Kudo et al.**

(10) **Patent No.:** **US 9,655,718 B2**  
 (45) **Date of Patent:** **May 23, 2017**

(54) **INTRAOCULAR LENS INSERTION DEVICE**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 488 days.

(21) Appl. No.: **14/099,989**

(22) Filed: **Dec. 8, 2013**

(65) **Prior Publication Data**  
 US 2014/0194890 A1 Jul. 10, 2014

**Related U.S. Application Data**  
 (63) Continuation of application No. 13/143,322, filed as application No. PCT/JP2010/050029 on Jan. 5, 2010, now Pat. No. 8,603,103.

(30) **Foreign Application Priority Data**  
 Jan. 7, 2009 (JP) ..... 2009-001493

(51) **Int. Cl.**  
**A61F 2/16** (2006.01)

(52) **U.S. Cl.**  
 CPC ..... **A61F 2/167** (2013.01); **A61F 2/1672** (2013.01)

(58) **Field of Classification Search**  
 CPC ..... A61F 2/167; A61F 2/1662; A61F 2/1672; A61F 2/1675; A61F 2/1678; A61F 2/14; A61F 2/16  
 USPC ..... 606/107; 623/6.12  
 See application file for complete search history.

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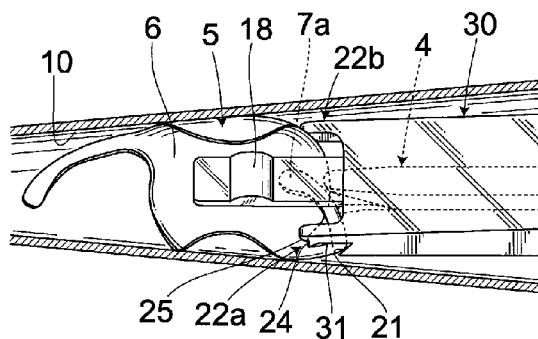
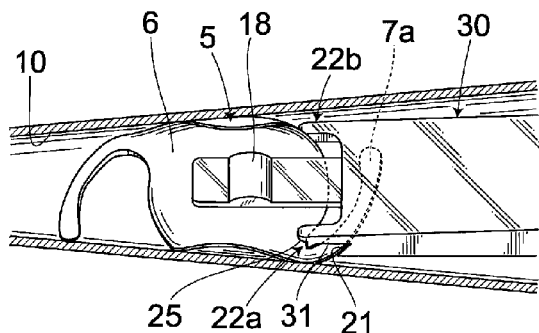
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(57) **ABSTRACT**

There is provided an intraocular lens insertion device capable of appropriately regulating the motion of a rear supporting portion during a process of moving an intraocular lens, and reducing the possibility of reoperation being required after the intraocular lens is inserted into an eye. An intraocular lens insertion device 1 comprises a main body 2, and a slider 3 and a plunger 4 that are attached to the main body 2. Further, the intraocular lens insertion device 1 is of a preset type in which an intraocular lens 5 is placed inside the main body 2 in advance. The slider 3 includes a first abutting portion 21 for pushing up a supporting portion 7 (rear supporting portion 7a) arranged on a rear side of an optical part 6 with respect to a lens advancement axis A, and second abutting portions 22a, 22b abutting against an outer edge of a rear portion of the optical part 6.

**16 Claims, 9 Drawing Sheets**



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Page 2

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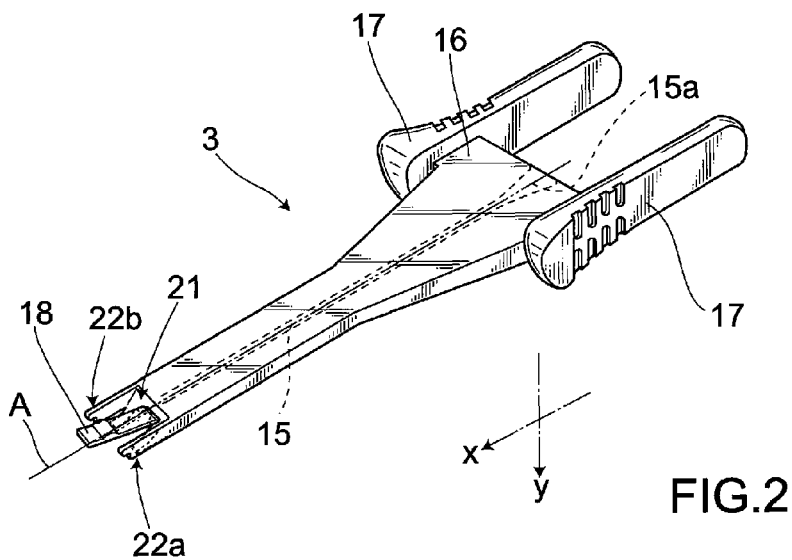
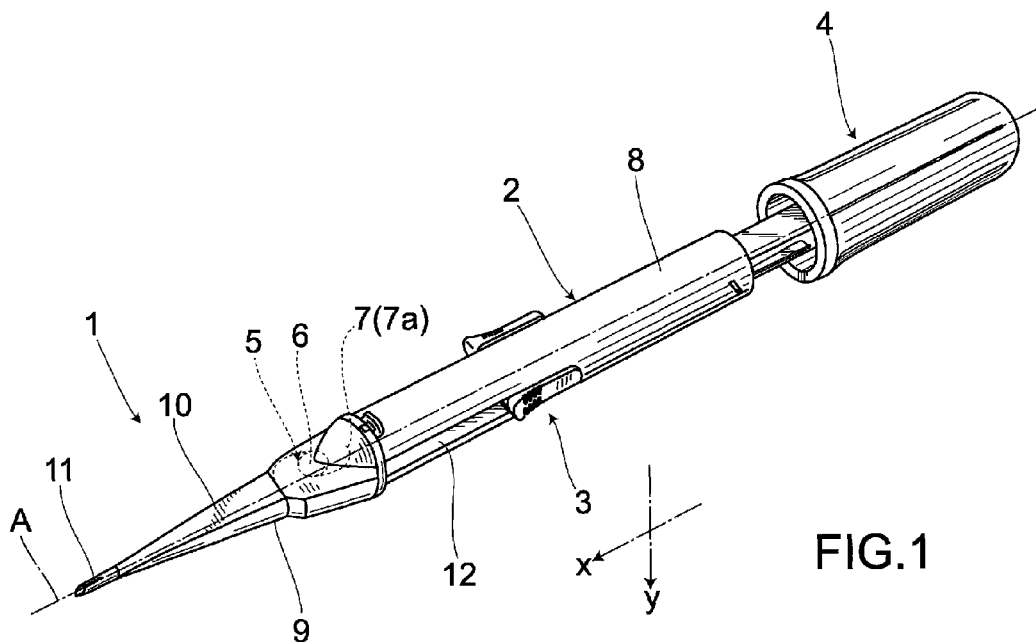
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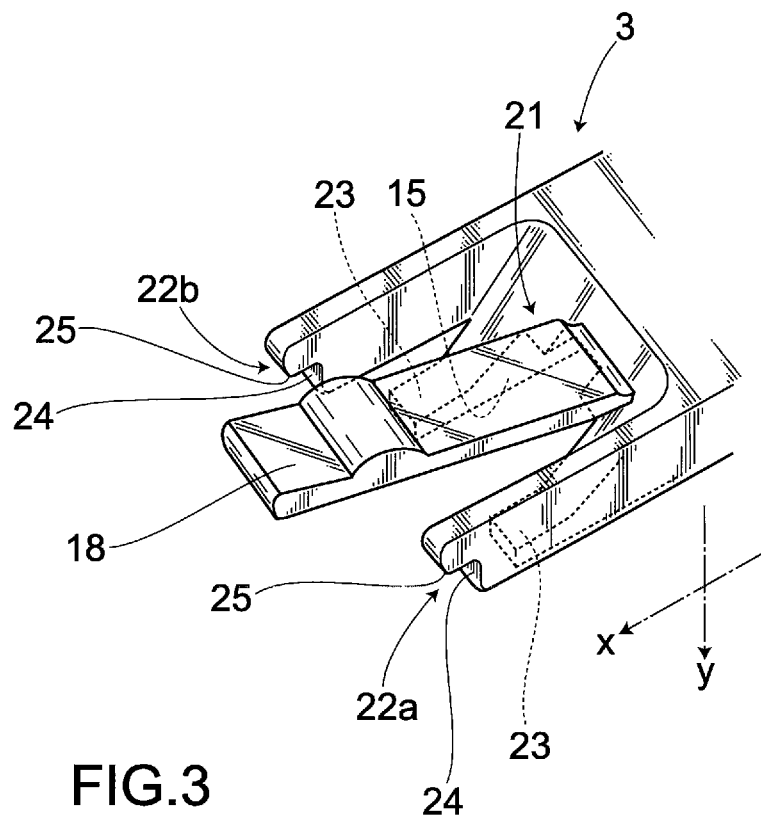
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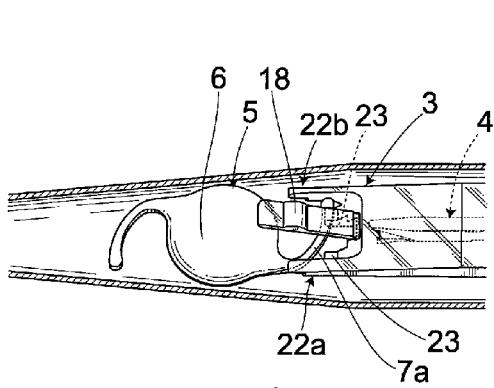


FIG. 4A

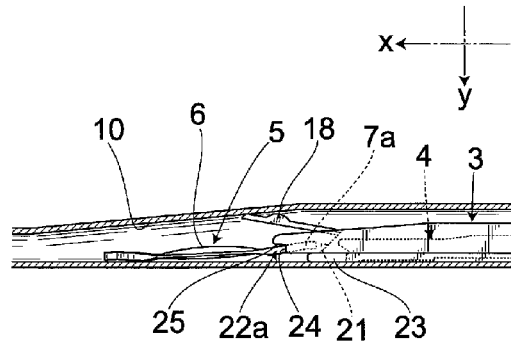


FIG. 4B

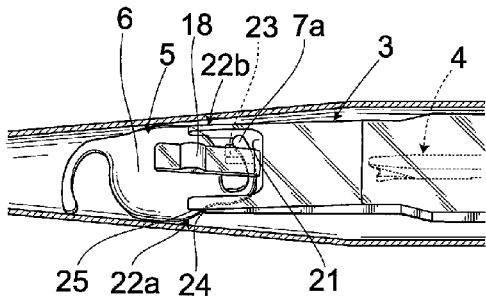


FIG. 5A

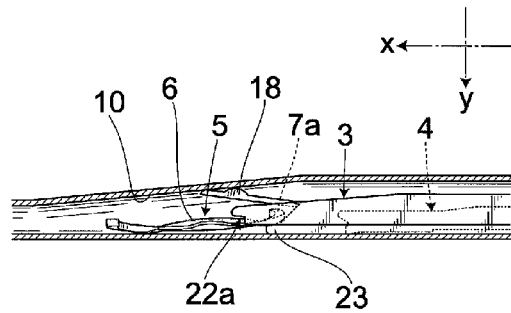


FIG. 5B

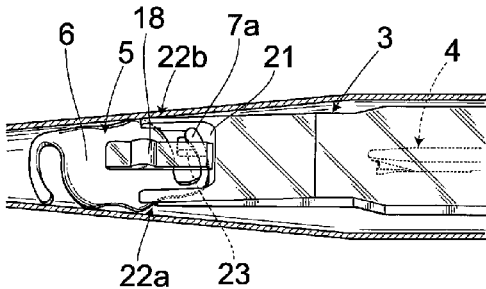


FIG. 6A

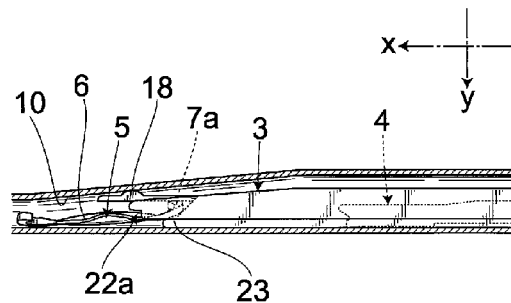


FIG. 6B

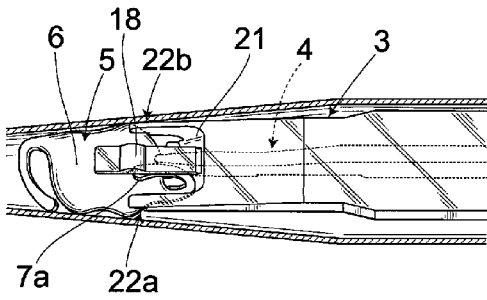


FIG. 7A

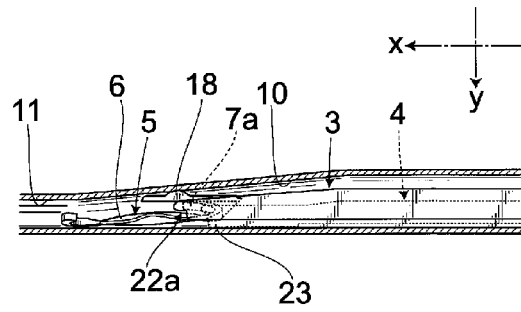


FIG. 7B

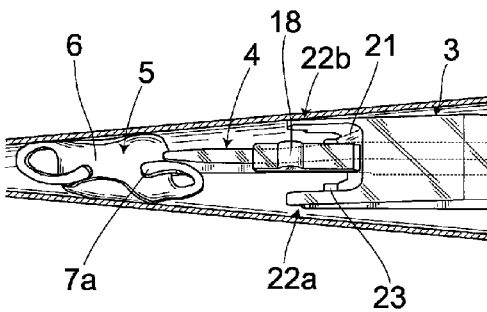


FIG. 8A

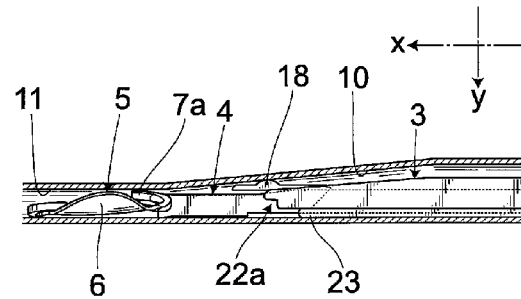


FIG. 8B

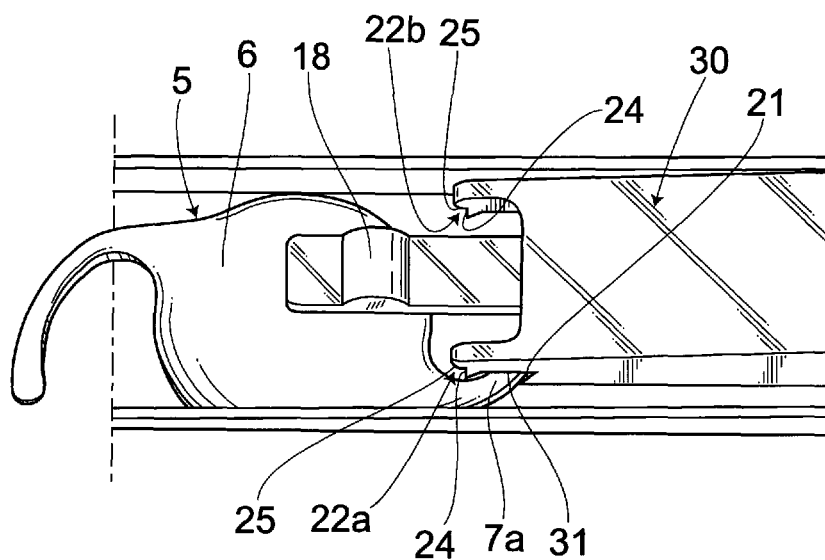


FIG.9

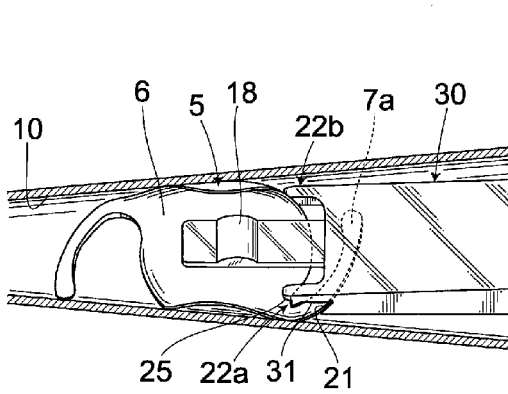


FIG. 10A

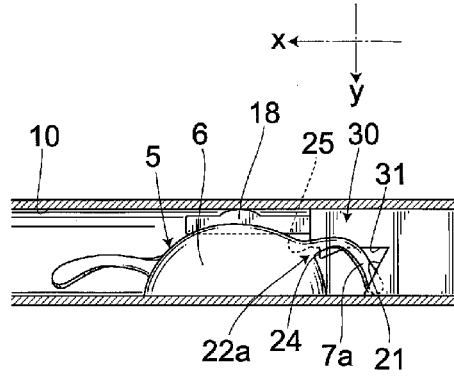


FIG. 10B

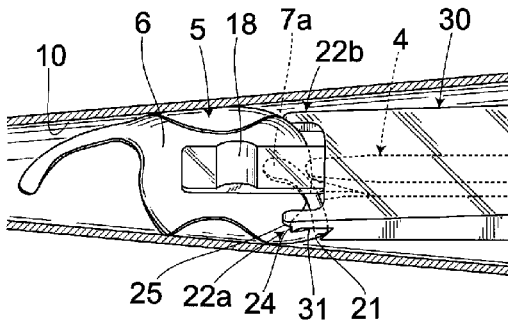


FIG. 11A

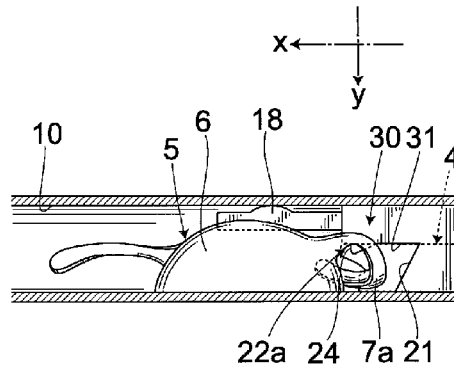


FIG. 11B

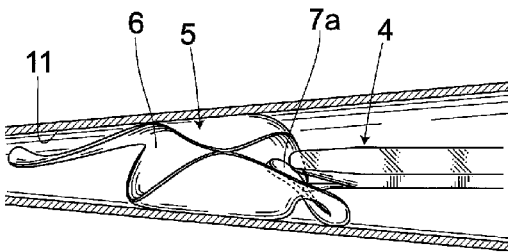


FIG. 12A

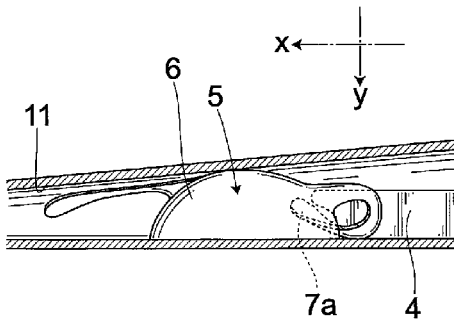
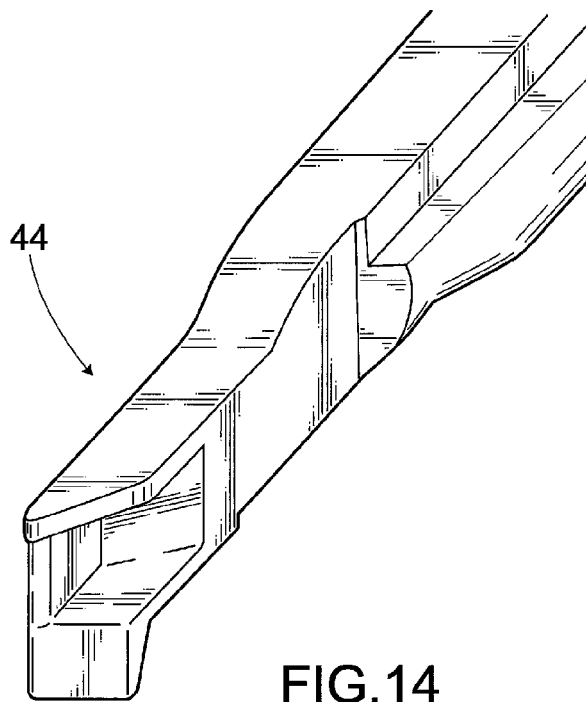
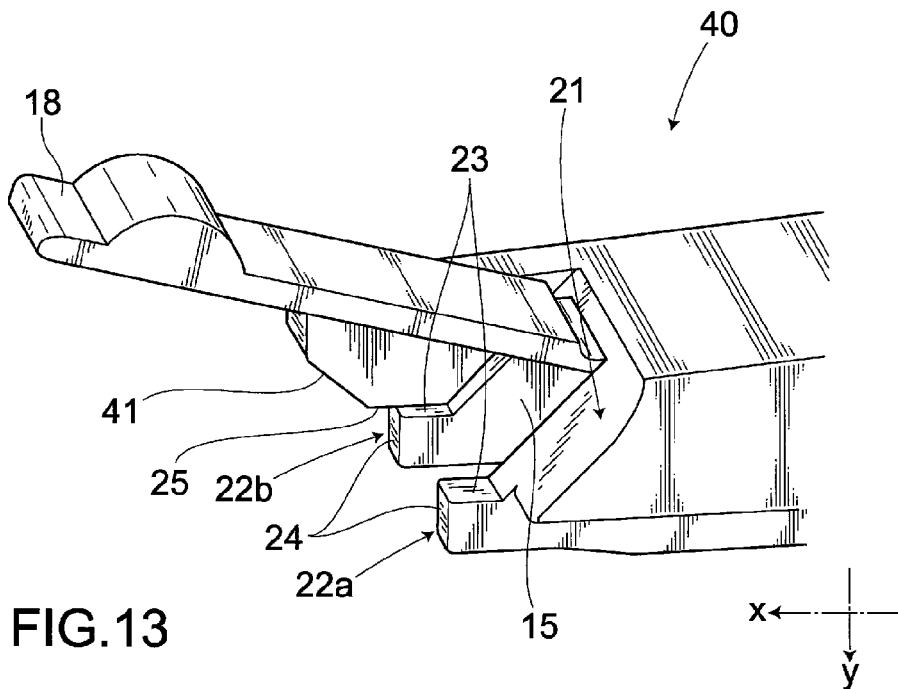


FIG. 12B



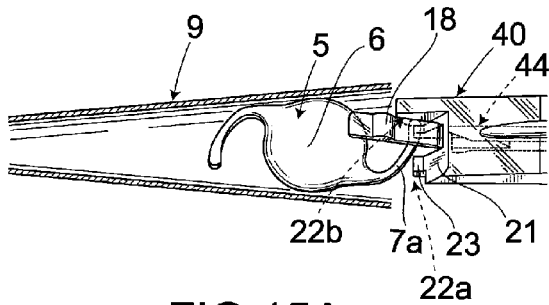


FIG. 15A

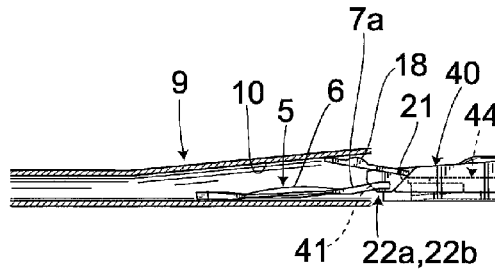


FIG. 15B

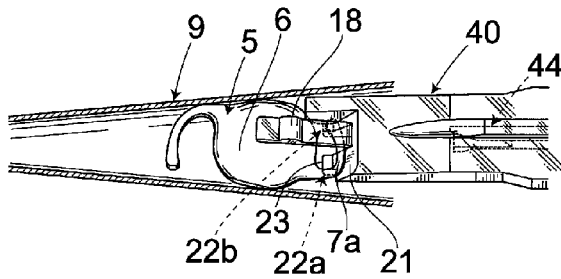


FIG. 16A

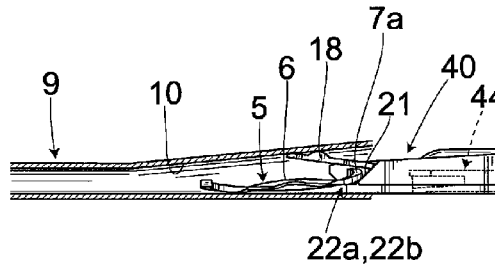


FIG. 16B

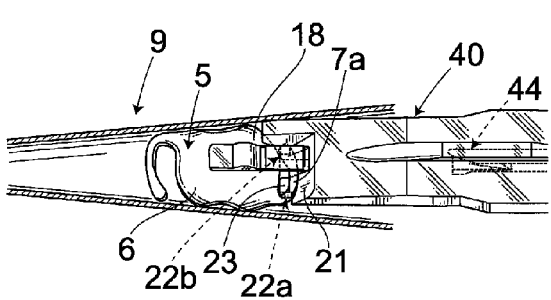


FIG. 17A

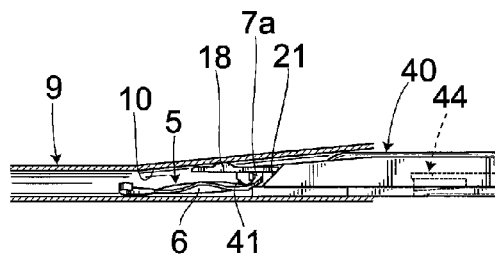


FIG. 17B

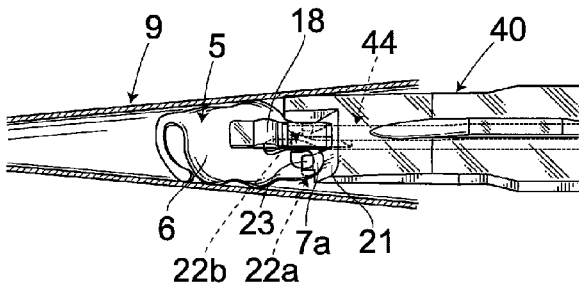


FIG. 18A

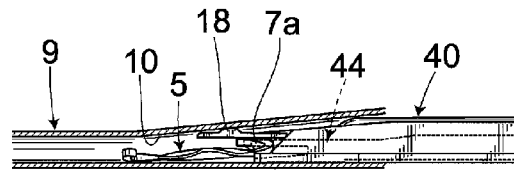


FIG. 18B

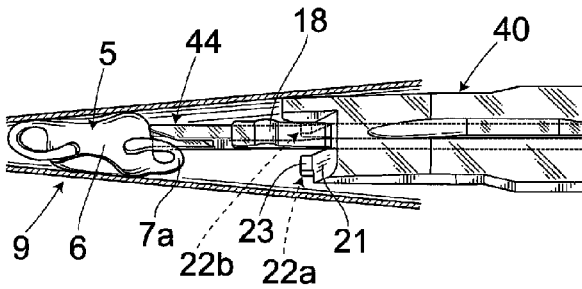


FIG. 19A

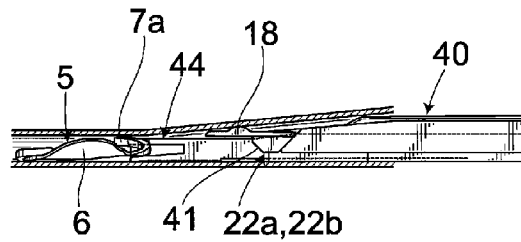


FIG. 19B



US 9,655,718 B2

1

**INTRAOCULAR LENS INSERTION DEVICE****CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 13/143,322, filed Jul. 5, 2011, now U.S. Pat. No. 8,603,103, which is a U.S. national phase application under 35 U.S.C. §371 of International Patent Application No. PCT/JP2010/050029 filed Jan. 5, 2010, which claims priority to Japanese patent application No. 2009-001493, filed Jan. 7, 2009. The International Application was published in Japanese on Jul. 15, 2010 as International Publication No. WO 2010/079780A1. The content of each application is incorporated herein in its entirety.

**TECHNICAL FIELD**

The present invention relates to an intraocular lens insertion device for inserting an intraocular lens into an eyeball as a substitute of a crystalline lens exenterated through cataract surgery.

**BACKGROUND ART**

Cataract surgery often involves removing an opacified crystalline lens through phacoemulsification (PEA), and implanting an intraocular lens after the crystalline lens has been removed. Intraocular lenses include hard intraocular lenses whose optical parts are made of hard materials such as PMMA or the like, and soft intraocular lenses whose optical parts are made of soft materials such as silicon elastomer, soft acrylic, hydrogel or the like.

When inserting a hard intraocular lens, there has to be formed on the cornea or the sclera an incision substantially as wide as the diameter of the optical part of the corresponding hard intraocular lens. In contrast, a soft intraocular lens can be inserted through an incision smaller than the diameter of the optical part thereof by allowing the corresponding optical part to be folded.

An intraocular lens is preferably inserted through a small incision in order to reduce the possibilities of corneal astigmatism and infection after the surgery. In this sense, soft intraocular lenses tend to be preferred nowadays. Types of soft intraocular lens include: a soft intraocular lens having an optical part made of a soft material and supporting portions made of a hard material such as PMMA or the like (the supporting portions of this type of intraocular lens are usually two thin filamentary members); a soft intraocular lens whose optical part and supporting portions are made of a same soft material (the supporting portions of this type are usually plate members); or a soft intraocular lens employing a plurality of thin strips as supporting portions, and the like.

Further, in order to insert an intraocular lens into an eye, there has also been used a dedicated intraocular lens insertion device having a structure for introducing the intraocular lens into the eye through an elongated tube. This type of intraocular lens insertion device allows an intraocular lens to be inserted through an incision smaller than 3 mm.

Furthermore, in recent years, there has been developed a type of intraocular lens insertion device which has an intraocular lens placed therein in advance and can be packaged and stored, in order to exclude the possibilities of bacteria contamination and errors in operation at the time of handling the intraocular lens (e.g., patent document 1).

However, this type of intraocular lens insertion device may cause a supporting portion (referred to as a rear

2

supporting portion, hereunder) arranged on a rear side with respect to a lens advancement axis to slip in between a plunger for pushing out the intraocular lens and a passage inner wall surface of the insertion device, or be tangled with the corresponding plunger, during a process of moving the intraocular lens. These problems are particularly noticeable with soft intraocular lenses employing thin filamentary members as supporting portions and intraocular lenses employing thin strips as supporting portions.

Further, this type of intraocular lens insertion device may cause the rear supporting portion to be stretched during the process of moving the intraocular lens. Accordingly, the corresponding rear supporting portion may then be left outside an eye ball at the time of performing insertion through a small incision on the eyeball, thereby requiring an additional operation for inserting such rear supporting portion into the eye ball after pushing out the intraocular lens with the plunger, and thus making the surgery troublesome.

In this sense, when using an intraocular lens insertion device to insert an intraocular lens into an eye, the motion of the rear supporting portion of the intraocular lens has to be appropriately regulated during the process of moving the intraocular lens.

In view of the aforementioned problems, there has been disclosed a device in which a clearance is formed on a front end side portion of a plunger, for allowing the rear supporting portion to be kept therein and thus preventing the same from being damaged (e.g., patent document 2). Further, there has been disclosed a device in which a rear supporting portion receiving passage for receiving the rear supporting portion is provided on a lower side portion of a plunger (e.g., patent document 3). Furthermore, there has also been disclosed a device in which the rear supporting portion is pushed up on a lump portion by means of a plunger, thereby allowing the corresponding haptic to be bended upward and eventually positioned higher than an IOL (e.g., patent document 4). Accordingly, all the devices disclosed in the aforementioned patent documents serve to reduce holding pressures applied to the rear supporting portions of intraocular lenses employing thin filaments or strips as supporting portions.

**REFERENCE**

- Patent document 1: WO2007/037223
- Patent document 2: Japanese Unexamined Patent Application Publication (Translation of PCT Application) No. 1999-506357
- Patent document 3: U.S. Pat. No. 6,733,507
- Patent document 4: Japanese Unexamined Patent Application Publication No. 2004-351196

**DISCLOSURE OF THE INVENTION****Problem to be Solved by the Invention**

However, according to the patent documents 2 and 3, the rear supporting portion received in the clearance formed on the front end side portion of the plunger and in the rear supporting portion receiving passage is stretched, thereby still incurring a problem in which the corresponding rear supporting portion may be left outside a small incision formed on an eye ball when inserting an intraocular lens therethrough. Particularly, with regard to intraocular lenses employing thin strips as supporting portions, reoperation is often troublesome because the corresponding supporting portions are composed of soft members that are thick in

US 9,655,718 B2

3

sizes. Further, according to the patent document 4, the supporting portion is pushed by a small plunger front end matched to a nozzle front end with a small aperture diameter, thus causing the rear supporting portion to be compressed into an unexpected shape when bending the supporting portion upward so as to position the same higher than an optical part or when allowing an intraocular lens to pass through a passage.

Here, in view of the aforementioned problems, it is an object of the present invention to provide an intraocular lens insertion device capable of appropriately regulating the motion of a rear supporting portion during a process of moving an intraocular lens, and reducing the possibility of reoperation being required after the intraocular lens has been inserted into an eye.

#### Means for Solving the Problem

The invention according to a first aspect of the present invention is an intraocular lens insertion device comprising: a lens placement section for placing an intraocular lens having an optical part and one or more supporting portions provided on an outer edge of the optical part; a transition section for deforming the intraocular lens; a nozzle section for releasing the intraocular lens; a slider for pushing out the intraocular lens placed in the lens placement section; and a plunger for releasing the intraocular lens pushed out by the slider from the nozzle section, in which the slider includes: a first abutting portion for pushing up a supporting portion disposed in a rear direction of a lens advancement axis; and one or more second abutting portions abutting against an outer edge of a rear portion of the intraocular lens.

According to the invention described in a second aspect of the present invention, the second abutting portions are provided outside the first abutting portion with respect to the lens advancement axis.

According to the invention described in a third aspect of the present invention, the first abutting portion slants downward in a lens advancement direction.

According to the invention described in a fourth aspect of the present invention, at least one of the second abutting portions includes: an x-direction abutting surface substantially perpendicular to a surface of the optical part; and a y-direction abutting surface substantially parallel with the surface of the optical part.

The invention according to a fifth aspect of the present invention comprises a guiding portion for guiding the outer edge of the optical part to the second abutting portions.

According to the invention described in a sixth aspect of the present invention, the second abutting portions are provided as a left-right pair centered about the lens advancement axis.

#### Effects of the Invention

According to the present invention, the first abutting portion provided on the slider serves to push up the supporting portion arranged on the rear side with respect to the lens advancement axis, thereby allowing the motion of the rear supporting portion to be appropriately regulated during the process of moving the intraocular lens, and thus reducing the possibility of reoperation being required after the intraocular lens is inserted into the eye.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view showing an overall structure of an intraocular lens insertion device of a first embodiment of the present invention.

4

FIG. 2 is a perspective view showing a structure of a slider of the first embodiment of the present invention.

FIG. 3 is a partially enlarged perspective view showing the structure of the slider of the first embodiment of the present invention.

FIGS. 4A and 4B are diagrams showing a usage state (1) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 4A is a cross sectional top view, and FIG. 4B is a longitudinal sectional view.

FIGS. 5A and 5B are diagrams showing a usage state (2) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 5A is a cross sectional top view, and FIG. 5B is a longitudinal sectional view.

FIGS. 6A and 6B are diagrams showing a usage state (3) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 6A is a cross sectional top view, and FIG. 6B is a longitudinal sectional view.

FIGS. 7A and 7B are diagrams showing a usage state (4) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 7A is a cross sectional top view, and FIG. 7B is a longitudinal sectional view.

FIGS. 8A and 8B are diagrams showing a usage state (5) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 8A is a cross sectional top view, and FIG. 8B is a longitudinal sectional view.

FIG. 9 is a partially enlarged perspective view showing a structure of a slider of a second embodiment of the present invention.

FIGS. 10A and 10B are diagrams showing a usage state (1) of an intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 10A is a cross sectional top view, and FIG. 10B is a longitudinal sectional view.

FIGS. 11A and 11B are diagrams showing a usage state (2) of the intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 11A is a cross sectional top view, and FIG. 11B is a longitudinal sectional view.

FIGS. 12A and 12B are diagrams showing a usage state (3) of the intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 12A is a cross sectional top view, and FIG. 12B is a longitudinal sectional view.

FIG. 13 is a partially enlarged perspective view showing a structure of a slider of a third embodiment of the present invention.

FIG. 14 is a partially enlarged perspective view showing a structure of a plunger of the third embodiment of the present invention.

FIGS. 15A and 15B are diagrams showing a usage state (1) of an intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 15A is a cross sectional top view, and FIG. 15B is a longitudinal sectional view.

FIGS. 16A and 16B are diagrams showing a usage state (2) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 16A is a cross sectional top view, and FIG. 16B is a longitudinal sectional view.

FIGS. 17A and 17B are diagrams showing a usage state (3) of the intraocular lens insertion device of the third

5

embodiment of the present invention, in which FIG. 17A is a cross sectional top view, and FIG. 17B is a longitudinal sectional view.

FIGS. 18A and 18B are diagrams showing a usage state (4) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 18A is a cross sectional top view, and FIG. 18B is a longitudinal sectional view.

FIGS. 19A and 19B are diagrams showing a usage state (5) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 19A is a cross sectional top view, and FIG. 19B is a longitudinal sectional view.

## BEST MODE FOR CARRYING OUT THE INVENTION

### 1. First Embodiment

#### (1) Basic Structure

An embodiment of the present invention is described hereunder in detail and with reference to the accompanying drawings.

An intraocular lens insertion device 1 shown in FIG. 1 comprises a main body 2, and a slider 3 and a plunger 4 that are attached to the main body 2. The intraocular lens insertion device 1 is of a preset type in which an intraocular lens 5 is placed inside the main body 2 in advance. Here, the intraocular lens 5 includes an optical part 6 and a pair of supporting portions 7 (or "haptics") provided on an outer edge of the optical part 6. As the supporting portions 7, there can be employed various types of members including, for example, members of a thin strip type.

In the following descriptions, an axis extending through the center of the intraocular lens 5 moving inside the main body 2 is referred to as a lens advancement axis A. Further, a direction to which the intraocular lens 5 moves is referred to as an "advancement direction x," and a downward direction is referred to as a "direction y."

The main body 2 is composed of a base end portion 8 and an insertion tube 9 connected to a front end of the base end portion 8 in the advancement direction x. Although not shown, a lens placement section made of a plate type member is formed on the front end of the base end portion 8 in the advancement direction x. The intraocular lens 5 is placed in the corresponding lens placement section. On side surfaces of the base end portion 8, there are provided slits 12 formed in parallel with the lens advancement axis A and extending to the front end of the base end portion 8. Further, the insertion tube 9 is integrally connected to the front end of the base end portion 8, thereby allowing the intraocular lens 5 placed in the lens placement section of the base end portion 8 to be disposed internally.

The insertion tube 9 comprises a transition section 10 and a nozzle section 11 that are successively disposed along the lens advancement axis A. The transition section 10 is formed into a tapered shape in which an inner wall of the transition section 10 tapers toward a front end thereof, such front end being further communicated with the nozzle section 11. The nozzle section 11 is so formed that an outer shape thereof can be inserted into an incision (not shown).

According to this intraocular lens insertion device 1, the intraocular lens 5 placed in the lens placement section is at first moved to the transition section 10 after being pushed out by the slider 3, thereby allowing the intraocular lens 5 to be reliably folded into a given shape. Next, the intraocular lens 5 is further moved to the nozzle section 11 after being

6

pushed out by the plunger 4, thereby causing the intraocular lens 5 to be folded even smaller, and thus allowing the intraocular lens 5 to be inserted into an eye from a front end of the nozzle section 11. Accordingly, the intraocular lens insertion device 1 allows the intraocular lens 5 to be moved in the advancement direction x in two stages involving successively the slider 3 and the plunger 4, thus causing the intraocular lens 5 to be folded into a given shape and releasing the same to the outside.

#### (2) Structure of Slider

Next, the slider 3 attached to the main body 2 is described. As shown in FIG. 2, the slider 3 serves to push out the intraocular lens 5 placed in the lens placement section to the transition section 10 without imposing a local load thereon, and fold the intraocular lens 5 into the given shape. The slider 3 includes a guiding groove 15, a wing portion 16, operation portions 17 and a lens pressing member 18.

The guiding groove 15 is so configured that the plunger 4 can be supported thereby along the lens advancement axis A. Specifically, the guiding groove 15 allows the plunger 4 to slide, and a front end of the plunger 4 to protrude from a front end of the slider 3. According to the present embodiment, the guiding groove 15 is longitudinally formed over an entire length of a surface of the slider 3 in a manner such that the guiding groove 15 is substantially located in the center of the surface of the slider 3. Accordingly, the guiding groove 15 serves as a groove parallel to the lens advancement axis A. A cross-sectional surface of the guiding groove 15 is substantially formed into a same shape as an outer shape of the plunger 4. A wedge guiding path 15a is formed on a base end of the guiding groove 15. In this way, the plunger 4 is allowed to be inserted into the guiding groove 15 formed on the slider 3, and slide within the guiding groove 15 in a longitudinal direction of the slider 3.

The wing portion 16 is inserted into the slits 12 provided on the main body 2, and serves to support the slider 3 along the lens advancement axis A. By inserting the wing portion 16 into the slits 12, the slider 3 is allowed to not only be held in a substantial center portion of the main body 2, but also move along the lens advancement axis A. In this sense, the plunger 4 can also be held in the center portion of the main body 2 and move along the lens advancement axis A, when inserted into the guiding groove 15 formed on the slider 3. The slider 3 can be easily moved by means of the operation portions 17.

The operation portions 17 are provided as a left-right pair centered about the lens advancement axis A. Further, the operation portions 17 are connected to side end portions of the wing portion 16, and protrude from each side of the base end portion 8.

The lens pressing member 18 serves to fold the intraocular lens 5 in a given direction by pressing a surface of the intraocular lens 5 only when the intraocular lens 5 is being pushed out. According to the present embodiment, the lens pressing member 18 serves to press a surface of the intraocular lens 5 to the direction y, thereby causing the intraocular lens 5 to be folded inside the nozzle section 11 with the foregoing surface being folded inwardly, such surface being a front surface when releasing the intraocular lens 5 into the eye. The lens pressing member 18 is made of a strip type member provided on the front end of the slider 3, and is capable of swinging freely to the direction y.

In addition to the structure described so far, the slider 3 of the present embodiment, as shown in FIG. 3, further includes a first abutting portion 21 for pushing up a supporting portion 7 arranged on a rear side with respect to the lens advancement axis A with respect to the optical part 6

(referred to as a rear supporting portion **7a**, hereunder), and second abutting portions **22a**, **22b** abutting against a rear outer edge of the optical part **6**.

The first abutting portion **21** has a slanting surface formed in the center of the front end of the slider **3** and slanting toward a direction between the advancement direction *x* and the direction *y*. The guiding groove **15** is opened in the center of the first abutting portion **21**, and a front end of the plunger **4** is thus allowed to protrude from the guiding groove **15** in the advancement direction *x*. Further, restriction portions **23** are formed on front ends of the first abutting portion **21**. The restriction portions **23** serve to prevent the rear supporting portion **7a** from entering in between the slider **3** and the main body **2** and thus being damaged, as the rear supporting portion **7a** deforms in the direction *y*. According to the present embodiment, the restriction portions **23** protrude from lower ends of the slanting surface to the advancement direction *x*.

The second abutting portions **22a**, **22b** are respectively provided on both sides of the first abutting portion **21**, and are configured to be able to abut against the outer edge of the optical part **6** of the intraocular lens **5**. According to the present embodiment, the second abutting portions **22a**, **22b** protrude from the front end of the slider **3** to the advancement direction *x*, and at least **22a** is allowed to abut against, along the lens advancement axis *A*, an outer edge of a section of the optical part **6**, such section of the optical part **6** being located outward from a connecting portion of the supporting portion **7** and the optical part **6**.

Further, the second abutting portions **22a**, **22b** have *x*-direction abutting surfaces **24** and *y*-direction abutting surfaces **25**. The *x*-direction abutting surfaces **24** are perpendicular to a surface of the optical part **6**, and are thus capable of pushing out the outer edge of the optical part **6**. The *y*-direction abutting surfaces **25** are parallel with the surface of the optical part **6**, and are thus able to restrict a surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded before the rear supporting portion **7a** has been sufficiently deformed.

As described above, according to the intraocular lens insertion device **1** of the present embodiment, the first abutting portion **21** and the second abutting portions **22a**, **22b** are provided on the slider **3** allowing the intraocular lens **5** to be in contact therewith through a contact area larger than that of the plunger **4**. Accordingly, the motion of the rear supporting portion **7a** can be appropriately regulated during the process of moving the intraocular lens **5**. Further, there can be reduced the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

### (3) Operation and Effect

According to the intraocular lens insertion device **1** having the aforementioned structure, the intraocular lens **5** is placed internally in a manner such that the optical part **6** thereof is arranged in parallel with the lens advancement axis *A* (FIGS. **4A** and **4B**). The slider **3** is at first moved to the advancement direction *x* in order to release the intraocular lens **5** internally placed in advance to the outside from the front end of the nozzle section **11**. In this way, the first abutting portion **21** formed on the front end of the slider **3** is caused to abut against the rear supporting portion **7a** (FIGS. **5A** and **5B**).

Since the first abutting portion **21** has the slanting surface, the rear supporting portion **7a** is pushed up therealong as the slider **3** is further moved to the advancement direction *x* (FIGS. **6A** and **6B**). At the same time, the *x*-direction abutting surfaces **24** of the second abutting portions **22a**, **22b** are caused to abut against as well as push out the optical part

**6**, thereby moving the intraocular lens **5** from the lens placement section to the transition section **10**. At that time, the outer edge of the optical part **6** is pushed by the inner wall of the transition section **10**. Further, the lens pressing member **18** is also pushed by the inner wall of the transition section **10**, and is thus caused to push down the surface of the optical part **6** to the direction *y*. In this way, the optical part **6** of the intraocular lens **5** is valley folded.

Next, as the plunger **4** is moved to the advancement direction *x*, the front end of such plunger **4** supported by the guiding groove **15** of the slider **3** is caused to abut against the outer edge of the optical part **6** (FIGS. **7A** and **7B**). The rear supporting portion **7a** pushed up by the first abutting portion **21** is thus caused to deform along the plunger **4** in a manner such that a front end of the rear supporting portion **7a** eventually points to the advancement direction *x*. In this way, the front end of the rear supporting portion **7a** deformed due to the first abutting portion **21**, is tucked into the surface of the valley-folded optical part **6**.

Here, the *y*-direction abutting surfaces **25** of the second abutting portions **22a**, **22b** are configured to restrict the surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded, thereby preventing the outer edge of the optical part **6** from interfering with the rear supporting portion **7a** during a deformation process of the rear supporting portion **7a**. Accordingly, the intraocular lens insertion device **1** allows the rear supporting portion **7a** to further reliably enter a space formed by the valley-folded surface of the optical part **6**, thereby making it possible to further reliably deform the intraocular lens **5** into the given shape.

Further, the restriction portions **23** provided on the first abutting portion **21** serve to prevent the rear supporting portion **7a** from deforming to the direction *y*. In this sense, the intraocular lens insertion device **1** allows the intraocular lens **5** to be further reliably deformed into the given shape.

Next, by further moving the plunger **4** to the advancement direction *x*, the intraocular lens **5** is moved from the transition section **10** to the nozzle section **11** (FIGS. **8A** and **8B**), followed by being released to the outside from the front end of the nozzle section **11** with the intraocular lens **5** itself being folded even smaller.

As described earlier, the intraocular lens insertion device **1** allows the rear supporting portion **7a** to be pushed up by the first abutting portion **21**, thereby making it possible to appropriately regulate the motion of the rear supporting portion **7a** during the process of moving the intraocular lens **5** and reduce the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

Further, since the first abutting portion **21** is provided on the slider **3**, the rear supporting portion **7a** is allowed to come into contact with the first abutting portion **21** through a large contact area. Accordingly, the intraocular lens insertion device **1** of the present embodiment allows the rear supporting portion **7a** to be further stably deformed, thereby making it possible to further appropriately regulate the rear supporting portion **7a**.

## 2. Second Embodiment

A second embodiment of the present invention is described hereunder with reference to the accompanying drawings. Here, the second embodiment differs from the first embodiment only in the structure of the front end portion of the slider **3**. Therefore, same symbols are used to describe

the same members as those in the first embodiment, and the descriptions of the corresponding members are thus omitted for the sake of convenience.

According to a slider **30** shown in FIG. **9**, at least **22a** of second abutting portions **22a**, **22b** is configured to abut against an outer edge of a section of the optical part **6** between the connecting portion of the rear supporting portion **7a** and the optical part **6**, and the lens advancement axis **A**. Further, this slider **30** has a cutout hole **31** formed on a side surface thereof, such cutout hole **31** allowing the rear supporting portion **7a** to be inserted therethrough inwardly from the outside.

According to the present embodiment having the aforementioned structure, the slider **30** is at first moved to the advancement direction **x** by gripping operation portions **17**. As a result, a first abutting portion **21** formed on a front end of the slider **30** is caused to abut against the rear supporting portion **7a**.

As the slider **30** is further moved to the advancement direction **x**, the rear supporting portion **7a** is pushed up with **x**-direction abutting surfaces **24** of the second abutting portion **22** abutting against and pushing out the optical part **6**, at the same time, thus allowing the intraocular lens **5** to be moved from a lens placement section to a transition section **10**. In this way, the optical part **6** is pushed by an inner wall of the transition section **10**, and a surface of the optical part **6** is pushed down to the direction **y** by means of a lens pressing member **18**, thus allowing the optical part **6** to be valley folded (FIGS. **10A** and **10B**).

Next, as a plunger **4** is moved to the advancement direction **x**, the front end of such plunger **4** supported by a guiding groove **15** of the slider **3** is caused to abut against the outer edge of the optical part **6** (FIGS. **11A** and **11B**). The supporting portion **7** pushed up by the first abutting portion **21** is thus caused to deform along the plunger **4** in a manner such that a front end of the supporting portion **7** eventually points to the advancement direction **x**. In this way, a front end of the supporting portion **7** deformed due to the first abutting portion **21**, is tucked into the surface of the valley-folded optical part **6**.

Next, by further moving the plunger **4** to the advancement direction **x**, the intraocular lens **5** is moved from the transition section **10** to a nozzle section **11** (FIGS. **12A** and **12B**), followed by being released to the outside from a front end of the nozzle section **11** with the intraocular lens **5** itself being folded even smaller.

Due to the aforementioned structure of the present embodiment, the present embodiment, as is the case in the first embodiment, allows the motion of the rear supporting portion **7a** to be appropriately regulated during the process of moving the intraocular lens **5**, and reduces the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

### 3. Third Embodiment

As shown in FIG. **13**, a slider **40** of the present embodiment includes a first abutting portion **21**, second abutting portions **22a**, **22b** and a guiding portion **41** for guiding the optical part **6** to the second abutting portion **22b**. The second abutting portion **22b** is provided on a location opposite to the connecting portion of the rear supporting portion **7a** and the optical part **6**, and is configured to be able to abut against the optical part **6** or the outer edge thereof. Further, the second abutting portion **22b** has an **x**-direction abutting surface **24**

and a **y**-direction abutting surface **25**. In contrast, the second abutting portion **22a** only has the **x**-direction abutting surface **24**.

Here, the **y**-direction abutting surface **25** of the second abutting portion **22b** may be arranged substantially on the same plane as restriction portions **23**, or beyond the restriction portions **23** in the direction **y**. According to the present embodiment, the **y**-direction abutting surface **25** is arranged on the same plane as the restriction portions **23**.

The guiding portion **41** has a slanting surface slanting toward a direction between the advancement direction **x** and an opposite direction of the direction **y**. A lower end of the guiding portion **41** is communicated with the **y**-direction abutting surface **25**. Here, a plunger having a shape shown in FIG. **14** can be used as a plunger **44**.

Next, there are described an operation and effect of the slider **40** having the aforementioned structure. The intraocular lens **5** is placed in a lens placement section (not shown) in a manner such that the optical part **6** thereof is arranged in parallel with the lens advancement axis **A** (FIGS. **15A** and **15B**). The slider **40** is at first moved to the advancement direction **x** in order to release such intraocular lens **5** to the outside from a front end of a nozzle section **11**. As a result, the first abutting portion **21** formed on a front end of the slider **40** is caused to abut against the rear supporting portion **7a** (FIGS. **16A** and **16B**).

Since the first abutting portion **21** has a slanting surface, the rear supporting portion **7a** is pushed up therealong as the slider **40** is further moved to the advancement direction **x** (FIGS. **17A** and **17B**). At the same time, the guiding portion **41** serves to push down a surface of the optical part **6** to the direction **y**, thereby guiding the corresponding optical part **6** to the second abutting portion **22b**. As a result, the **x**-direction abutting surface **24** of the second abutting portion **22b** and the **x**-direction abutting surface **24** of the second abutting portion **22a** are caused to abut against and then push out the optical part **6**, thus allowing the intraocular lens **5** to be moved from the lens placement section to a transition section **10**.

Here, the slider **40** allows the optical part **6** to be guided to the second abutting portion **22b** by means of the guiding portion **41**, thereby causing the second abutting portion **22b** to further reliably abut against the optical part **6**, and thus allowing the intraocular lens **5** to be further reliably pushed out.

In this way, the outer edge of the optical part **6** is pushed by an inner wall of the transition section **10**. Further, at that time, a lens pressing member **18** is also pushed by the inner wall of the transition section **10**, thus pushing down the surface of the optical part **6** to the direction **y**. As a result, the optical part **6** of the intraocular lens **5** is valley folded.

Next, as the plunger **44** is moved to the advancement direction **x**, the front end of such plunger **44** supported by a guiding groove **15** of the slider **40** is caused to abut against the outer edge of the optical part **6** (FIGS. **18A** and **18B**). The rear supporting portion **7a** pushed up by the first abutting portion **21** is thus caused to deform along the plunger **44** in a manner such that a front end of the rear supporting portion **7a** eventually points to the advancement direction **x**. In this way, the front end of the rear supporting portion **7a** deformed due to the first abutting portion **21**, is enclosed by the valley-folded surface of the optical part **6**.

Here, the **y**-direction abutting surface **25** of the second abutting portion **22b** is configured to restrict the surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded, thereby preventing the outer edge

**11**

of the optical part 6 from interfering with the rear supporting portion 7a during the deformation process of the rear supporting portion 7a.

Particularly, according to the present embodiment, since the y-direction abutting surface 25 is arranged on the same plane as the restriction portions 23, the outer edge of the optical part 6 is restricted from deforming to the opposite direction of the direction y, particularly, from deforming beyond the restriction portions 23 and the rear supporting portion 7a deformed due to the first abutting portion 21. In this sense, the slider 40 can further reliably prevent the outer edge of the optical part 6 from interfering with the rear supporting portion 7a, thereby allowing the intraocular lens 5 to be further reliably deformed into the given shape.

Next, by further moving the plunger 44 to the advancement direction x, the intraocular lens 5 is moved from a transition section 10 to a nozzle section 11 (FIGS. 19A and 19B), followed by being released to the outside from a front end of the nozzle section 11 with the intraocular lens 5 itself being folded even smaller.

Since the slider 40 of the present embodiment includes the first abutting portion 21 and the restriction portions 23, there can be achieved the same effects as those of the first embodiment.

4. Modified Embodiment

The present invention is not limited to the aforementioned embodiments. As a matter of fact, appropriate modifications are possible within the scope of the gist of the present invention. For example, in each one of the aforementioned embodiments, there are provided two second abutting portions in total. However, the present invention is not limited to this configuration. Particularly, the number of the second abutting portions can be one, three or more than three.

Further, in each one of the aforementioned embodiments, the second abutting portions 22 are provided as a symmetrical pair. However, the present invention is not limited to this configuration. The second abutting portions 22 can actually be provided in an asymmetrical manner. For example, one of the second abutting portions 22 may be formed longer than the other second abutting portion 22 in the advancement direction x, thereby making it possible to slightly rotate the intraocular lens 5 about an optical axis, and thus making it easier to regulate a supporting portion disposed forward.

DESCRIPTION OF SYMBOLS

- 1 intraocular lens insertion device q
- 2 main body
- 3 slider
- 4 plunger
- 5 intraocular lens
- 6 optical part
- 7 supporting portion
- 7a rear supporting portion
- 21 first abutting portion
- 22 second abutting portion
- x advancement direction
- y direction (downward direction)
- A lens advancement axis

The invention claimed is:

1. A method for use with an intraocular lens, including an optic, a forward haptic having an end and a rear haptic having an end, that is located within an insertion device defining a lens travelling axis and including a nozzle, a transition section and a plunger that moves forwardly toward

**12**

the nozzle and includes a forward region with a side wall and a bottom wall that together define a slot that extends rearwardly and is configured to receive a portion of the rear haptic, the method comprising the steps of:

pushing the end of the rear haptic upwardly and forwardly relative to the optic;

pushing the end of the rear haptic over the optic, while the portion of the optic over which the rear haptic passes remains unfolded, with the forward region of the plunger such that a portion of the rear haptic is bent and received in the slot that extends rearwardly;

folding the optic such that there is a space between folded portions of the optic; and

pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic.

2. A method as claimed in claim 1, wherein the insertion device includes a slider that is movable relative to the plunger; and

pushing the end of the rear haptic upwardly and forwardly comprises pushing the end of the rear haptic upwardly and forwardly relative to the optic with the slider.

3. A method as claimed in claim 1, wherein the insertion device includes a slider with an abutting portion that is slanted relative to the lens travelling axis and that is movable relative to the plunger; and

pushing the end of the rear haptic upwardly and forwardly comprises pushing the end of the rear haptic upwardly and forwardly relative to the optic with the abutting portion of the slider.

4. A method as claimed in claim 1, wherein folding the optic comprises folding the optic with the transition section.

5. A method as claimed in claim 1, wherein the insertion device includes a slider that is movable relative to the plunger; and folding the optic comprises pushing the optic into the transition section with the slider to fold the optic.

6. A method as claimed in claim 5, wherein the slider includes a pivotable lens pressing member; and folding the optic comprises pushing the optic into the transition section while the pivotable lens pressing member engages a portion of the optic to fold the optic.

7. A method as claimed in claim 1, wherein the insertion device includes a slider that is movable relative to the plunger, the slider having a first abutting portion that is slanted relative to the lens travelling axis and a pair of second abutting portions located on opposite sides of the lens travelling axis;

pushing the end of the rear haptic upwardly and forwardly comprises pushing the end of the rear haptic upwardly and forwardly relative to the optic with the first abutting portion of the slider before the second abutting portions contact the optic; and

folding the optic comprises pushing the optic into the transition section with the second abutting portions to fold the optic.

8. A method as claimed in claim 1, wherein pushing the intraocular lens through the nozzle comprises pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic and the end of the rear haptic faces in a lens travelling direction.

9. A method as claimed in claim 1, further comprising the step of:

US 9,655,718 B2

**13**

pushing the end of the forward haptic into the space between the folded portions of the optic.

**10.** A method as claimed in claim **1**, further comprising the step of:

prior to pushing the end of the rear haptic upwardly and forwardly relative to the optic, storing the lens in the insertion device with the optic parallel to the lens travelling axis and the rear haptic positioned at a different angle than the forward haptic relative to the lens travelling axis.

**11.** A method as claimed in claim **1**, wherein:

pushing the end of the rear haptic upwardly and forwardly comprises pushing the end of the rear haptic upwardly and forwardly relative to the optic while the end of the rear haptic is on a surface that is not parallel to the lens travelling axis.

**12.** A method performed by an insertion device, including a nozzle, a plunger that moves forwardly toward the nozzle and a transition section and defining a lens travelling axis, on an intraocular lens including an optic, a forward haptic having an end and a rear haptic having an end, the method comprising the steps of:

folding the optic with the insertion device such that there is a space between folded portions of the optic;  
moving the end of the rear haptic over the optic and into the space between the folded portions of the optic with the plunger;

**14**

moving the end of the forward haptic into the space between the folded portions of the optic with the insertion device; and

pushing the intraocular lens with the plunger through the nozzle with the ends of the forward and rear haptics in the space between the folded portions of the optic.

**13.** A method as claimed in claim **12**, wherein folding the optic comprises folding the optic with the transition section of the insertion device.

**14.** A method as claimed in claim **12**, wherein the insertion device includes a slider and the plunger is movable relative to the slider; and

moving the end of the rear haptic further includes pushing the end of the rear haptic upwardly and forwardly relative to the optic with the slider.

**15.** A method as claimed in claim **12**, wherein moving the end of the forward haptic comprises bending the end of the forward haptic into the space between the folded portions of the optic with an inner surface of the transition section as the intraocular lens moves toward the nozzle.

**16.** A method as claimed in claim **12**, further comprising the step of:

prior to folding the optic such that there is a space is between folded portions of the optic, pushing the end of the rear haptic with the insertion device upwardly and forwardly relative to the optic.

\* \* \* \* \*

# **EXHIBIT 4**



(12) **United States Patent**  
**Kudo et al.**

(10) **Patent No.:** **US 9,877,826 B2**  
 (45) **Date of Patent:** **\*Jan. 30, 2018**

(54) **INTRAOCULAR LENS INSERTION DEVICE**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/600,679**

(22) Filed: **May 19, 2017**

(65) **Prior Publication Data**

US 2017/0252149 A1 Sep. 7, 2017

**Related U.S. Application Data**

(63) Continuation of application No. 14/099,989, filed on Dec. 8, 2013, now Pat. No. 9,655,718, which is a (Continued)

(30) **Foreign Application Priority Data**

Jan. 7, 2009 (JP) ..... 2009-001493

(51) **Int. Cl.**  
**A61F 2/16** (2006.01)

(52) **U.S. Cl.**  
 CPC ..... **A61F 2/167** (2013.01); **A61F 2/1672** (2013.01)

(58) **Field of Classification Search**  
 CPC ..... A61F 2/167; A61F 2/1662; A61F 2/1672; A61F 2/1675; A61F 2/1678; A61F 2/14; A61F 2/16

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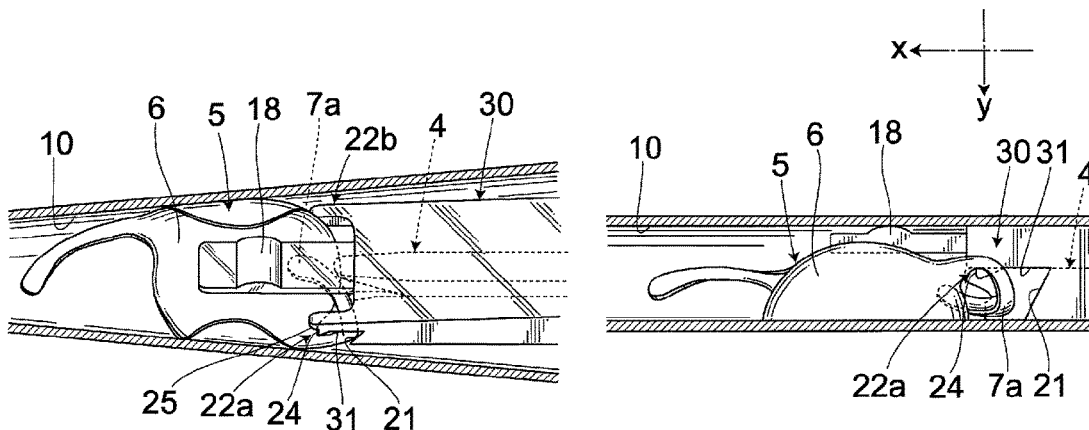
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(57) **ABSTRACT**

There is provided an intraocular lens insertion device capable of appropriately regulating the motion of a rear supporting portion during a process of moving an intraocular lens, and reducing the possibility of reoperation being required after the intraocular lens is inserted into an eye. An intraocular lens insertion device 1 comprises a main body 2, and a slider 3 and a plunger 4 that are attached to the main body 2. Further, the intraocular lens insertion device 1 is of a preset type in which an intraocular lens 5 is placed inside the main body 2 in advance. The slider 3 includes a first abutting portion 21 for pushing up a supporting portion 7 (rear supporting portion 7a) arranged on a rear side of an optical part 6 with respect to a lens advancement axis A, and second abutting portions 22a, 22b abutting against an outer edge of a rear portion of the optical part 6.

**16 Claims, 9 Drawing Sheets**



## US 9,877,826 B2

Page 2

**Related U.S. Application Data**

continuation of application No. 13/143,322, filed as application No. PCT/JP2010/050029 on Jan. 5, 2010, now Pat. No. 8,603,103.

(58) **Field of Classification Search**

USPC ..... 606/107; 623/6.12  
See application file for complete search history.

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Page 4

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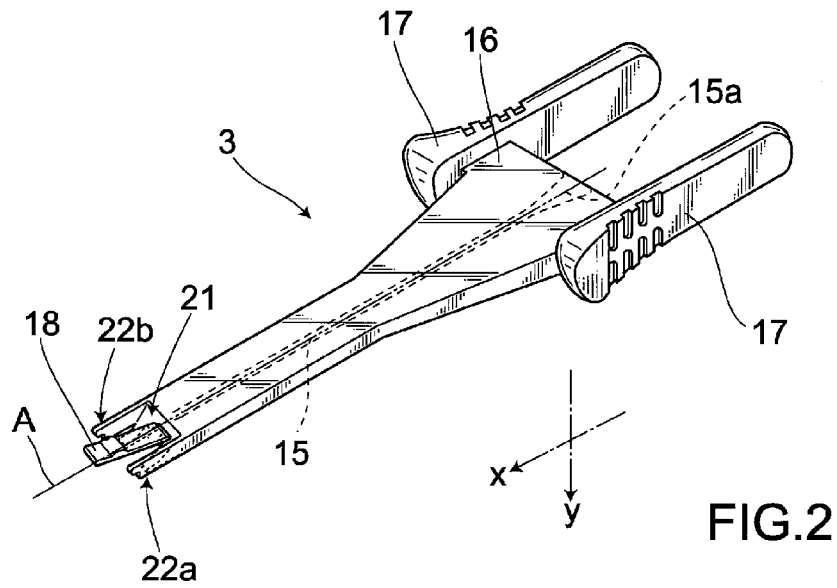
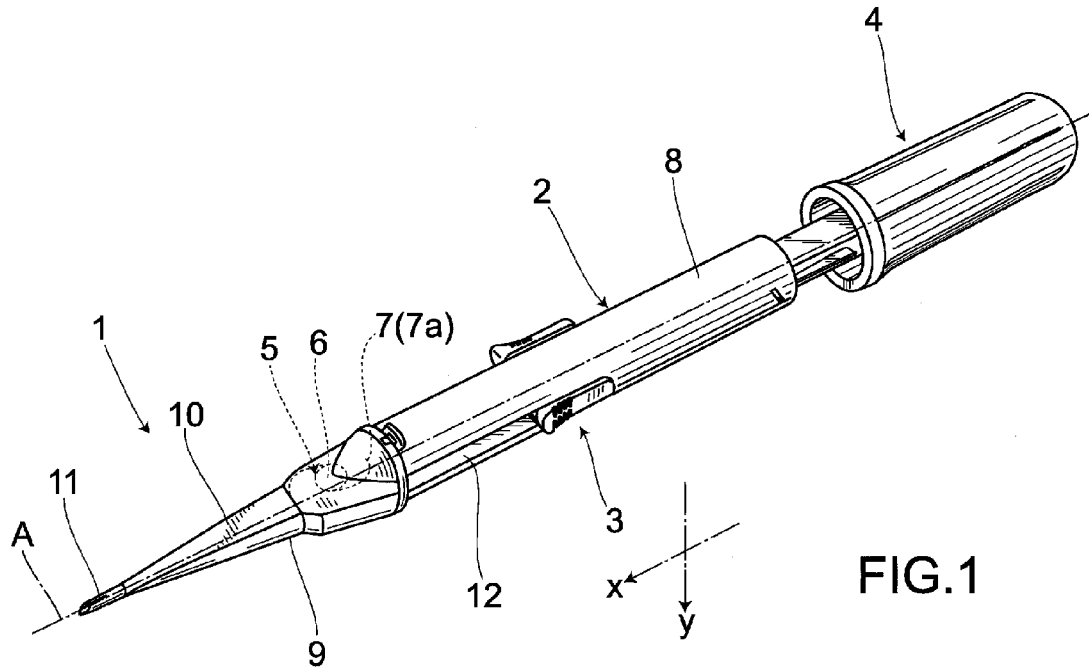
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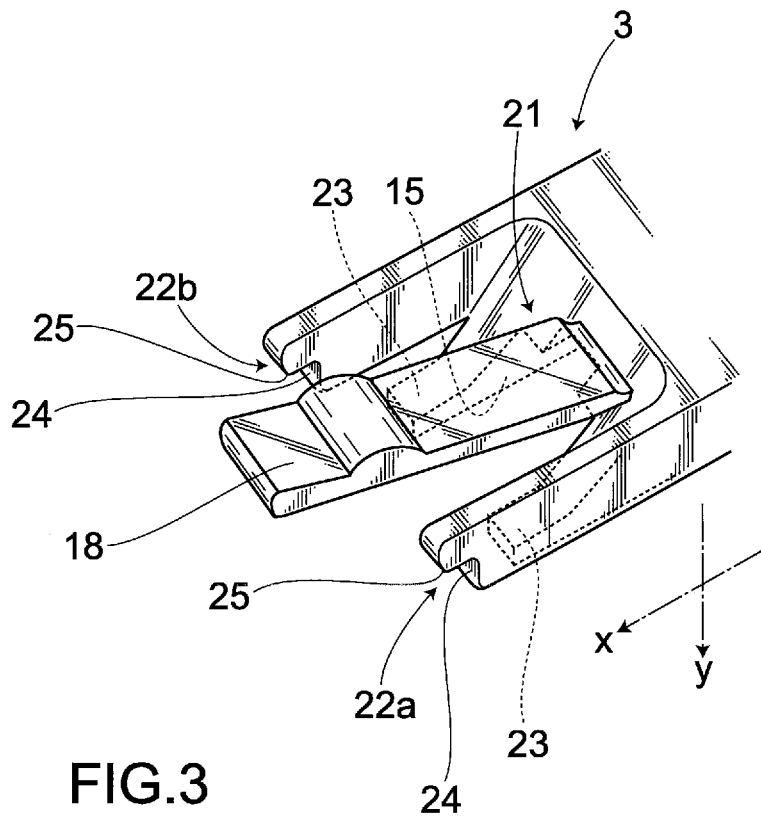
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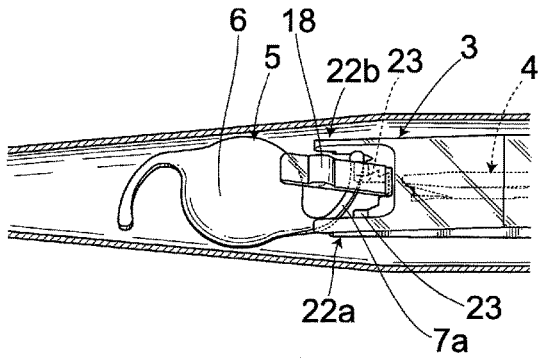


FIG. 4A

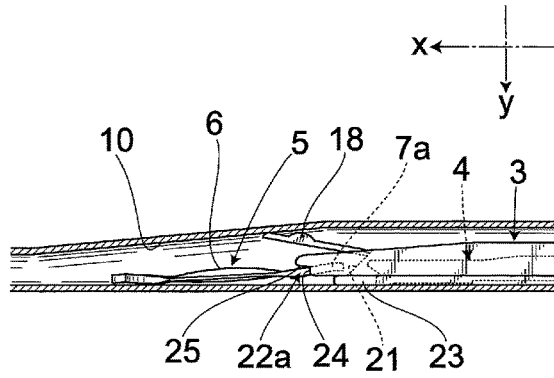


FIG. 4B

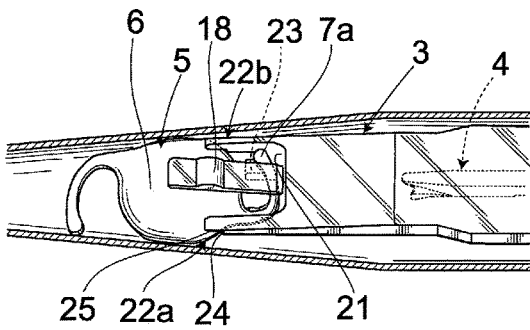


FIG. 5A

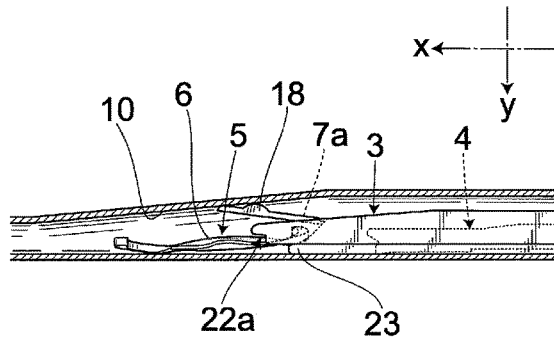


FIG. 5B

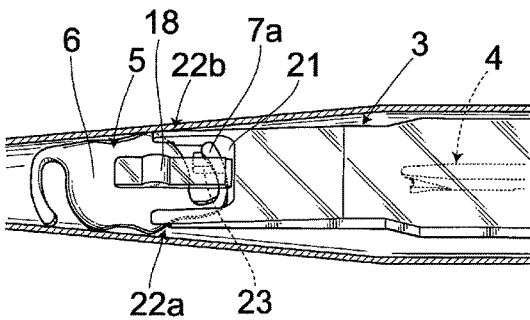


FIG. 6A

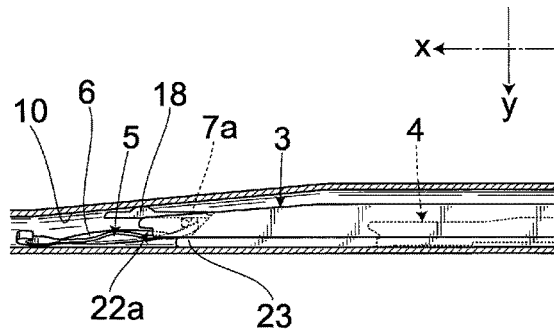


FIG. 6B

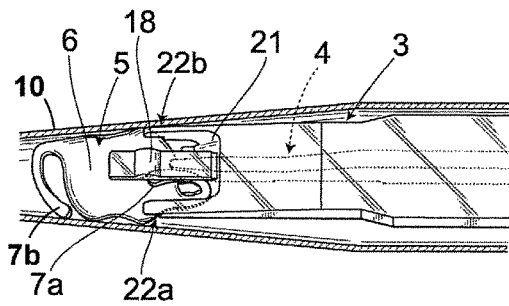


FIG. 7A

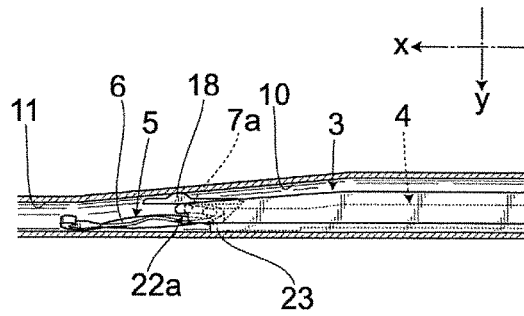


FIG. 7B

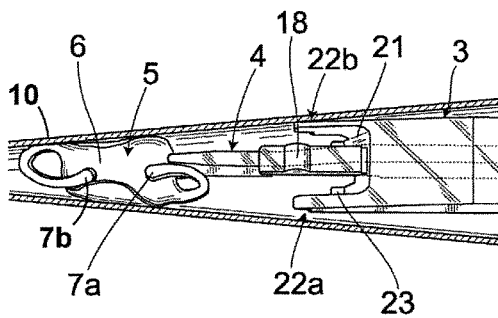


FIG. 8A

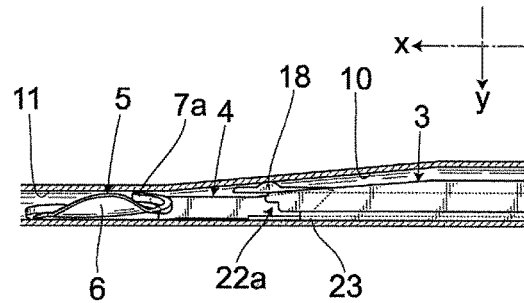


FIG. 8B



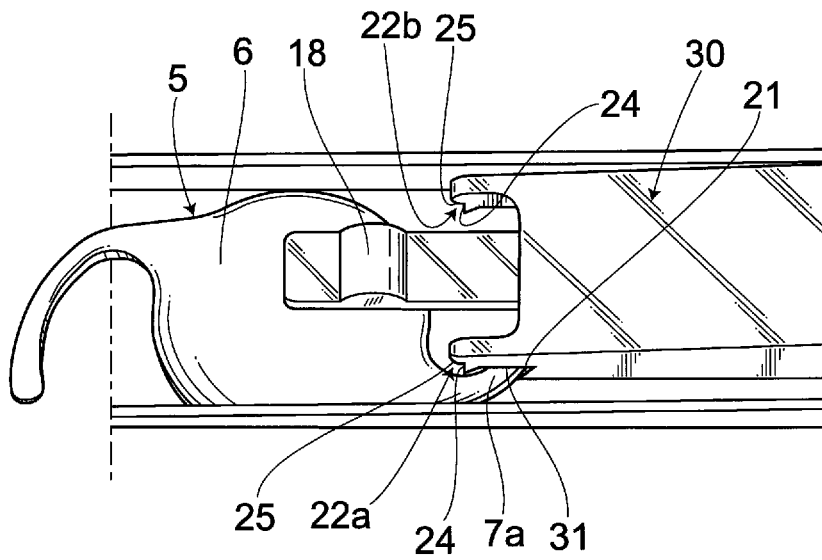


FIG.9

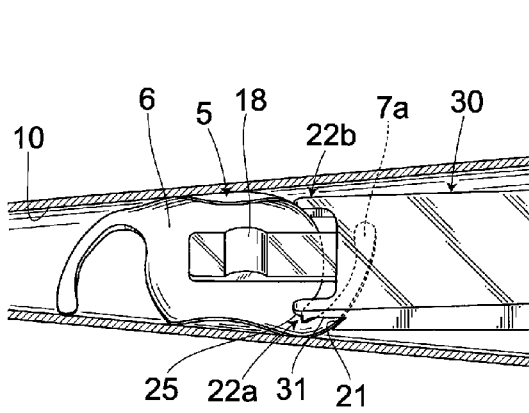


FIG. 10A

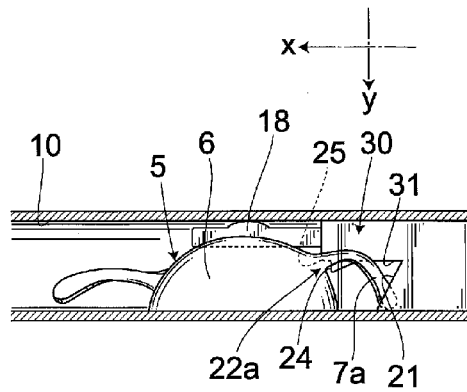


FIG. 10B

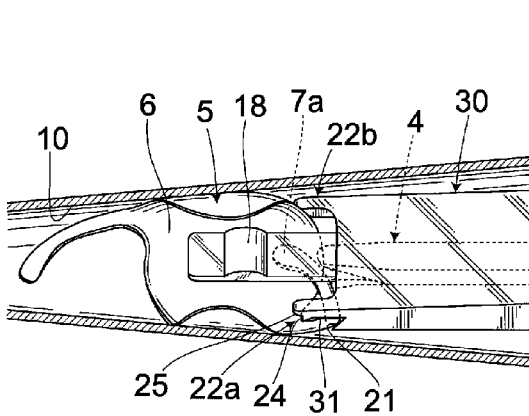


FIG. 11A

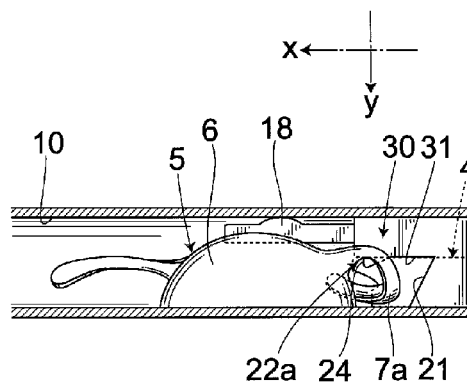


FIG. 11B

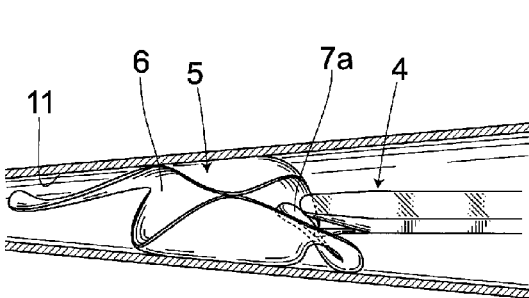


FIG. 12A

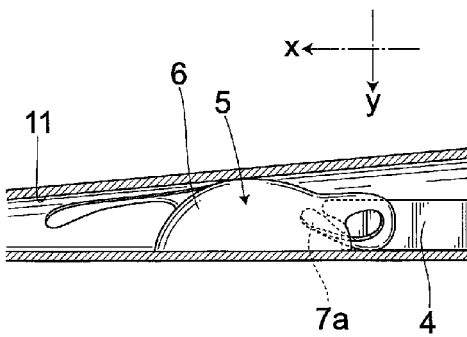
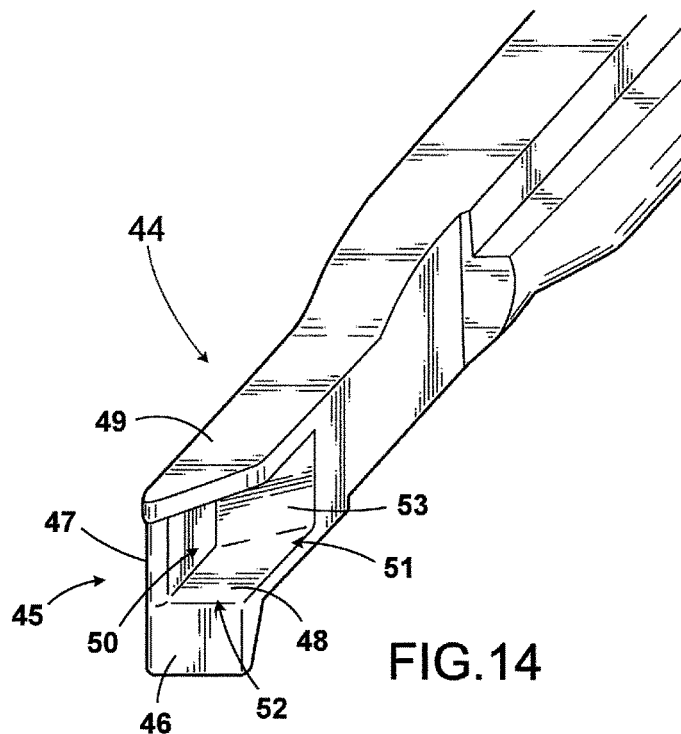
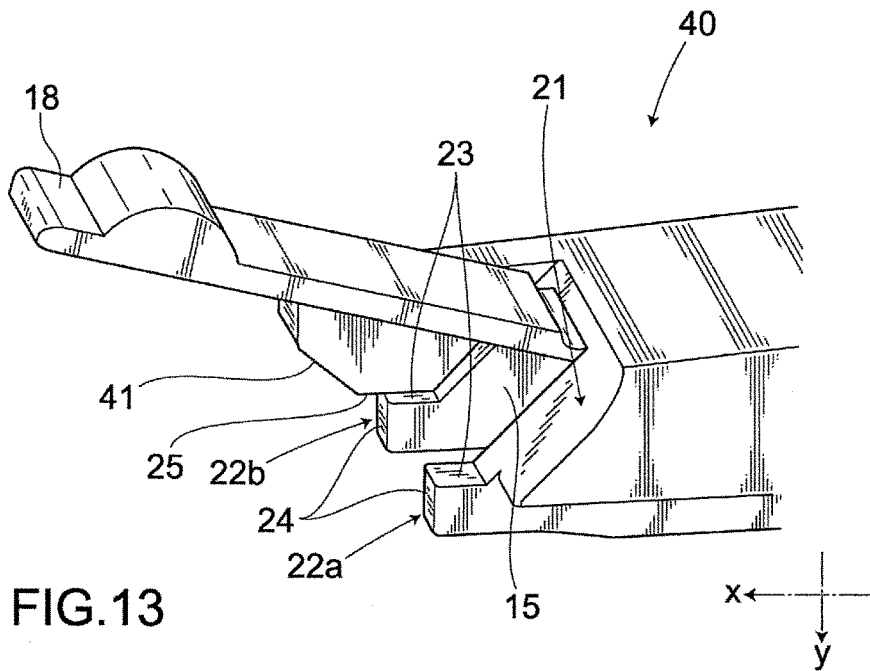


FIG. 12B



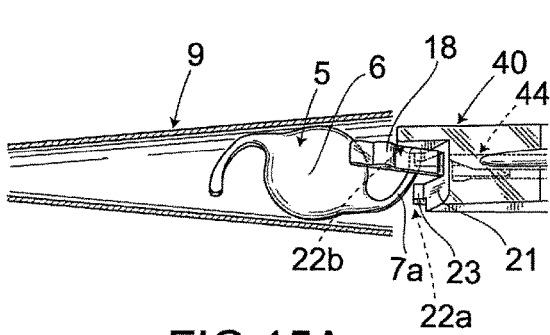


FIG. 15A

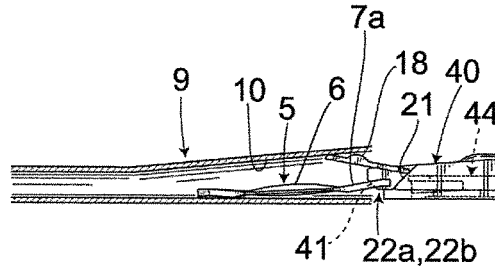


FIG. 15B

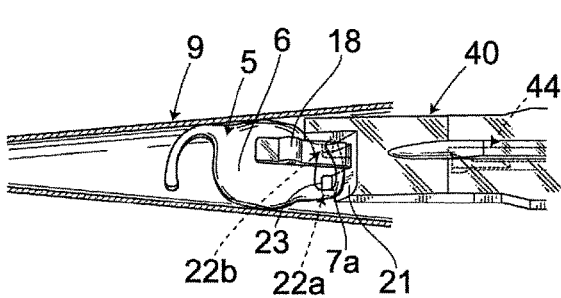


FIG. 16A

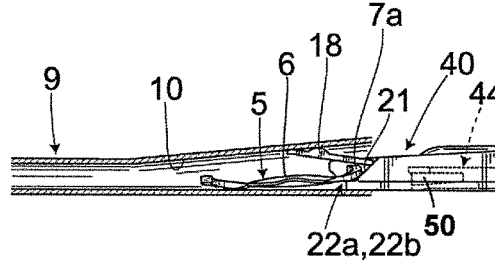


FIG. 16B

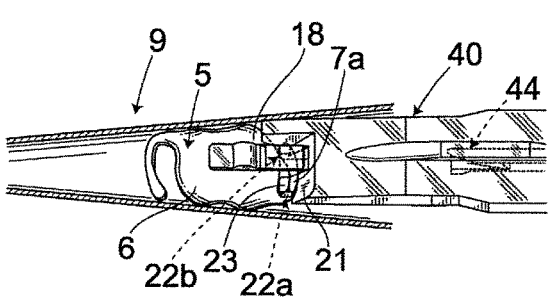


FIG. 17A

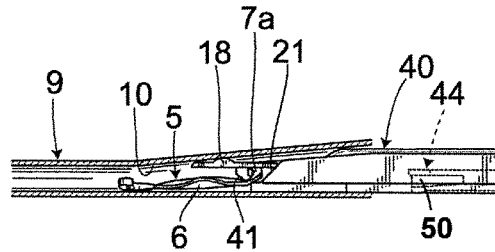


FIG. 17B

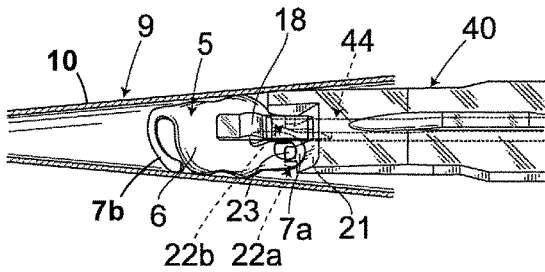


FIG. 18A

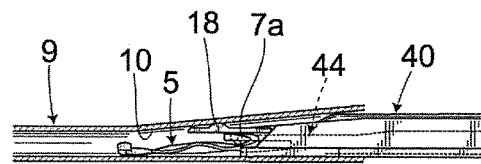


FIG. 18B

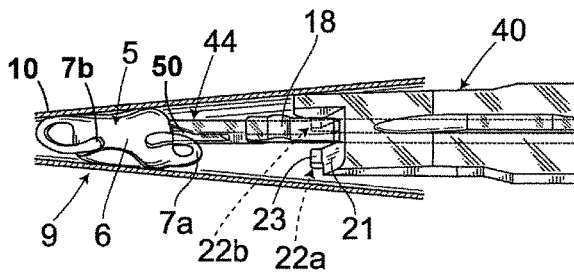


FIG. 19A

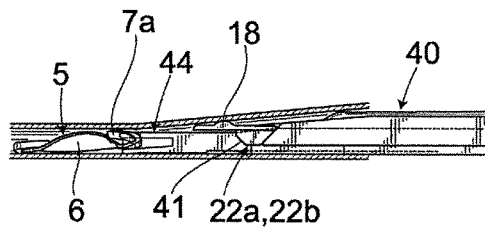


FIG. 19B

US 9,877,826 B2

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**INTRAOCULAR LENS INSERTION DEVICE****CROSS REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 14/099,989, filed Dec. 8, 2013, now U.S. Pat. No. 9,655,718, which is a continuation of U.S. application Ser. No. 13/143,322, filed Jul. 5, 2011, now U.S. Pat. No. 8,603,103, which is a U.S. national phase application under 35 U.S.C. §371 of International Patent Application No. PCT/JP2010/050029 filed Jan. 5, 2010, which claims priority to Japanese patent application No. 2009-001493, filed Jan. 7, 2009. The International Application was published in Japanese on Jul. 15, 2010 as International Publication No. WO 2010/079780A1. The content of each application is incorporated herein in its entirety.

**TECHNICAL FIELD**

The present invention relates to an intraocular lens insertion device for inserting an intraocular lens into an eyeball as a substitute of a crystalline lens exenterated through cataract surgery.

**BACKGROUND ART**

Cataract surgery often involves removing an opacified crystalline lens through phacoemulsification (PEA), and implanting an intraocular lens after the crystalline lens has been removed. Intraocular lenses include hard intraocular lenses whose optical parts are made of hard materials such as PMMA or the like, and soft intraocular lenses whose optical parts are made of soft materials such as silicon elastomer, soft acrylic, hydrogel or the like.

When inserting a hard intraocular lens, there has to be formed on the cornea or the sclera an incision substantially as wide as the diameter of the optical part of the corresponding hard intraocular lens. In contrast, a soft intraocular lens can be inserted through an incision smaller than the diameter of the optical part thereof by allowing the corresponding optical part to be folded.

An intraocular lens is preferably inserted through a small incision in order to reduce the possibilities of corneal astigmatism and infection after the surgery. In this sense, soft intraocular lenses tend to be preferred nowadays. Types of soft intraocular lens include: a soft intraocular lens having an optical part made of a soft material and supporting portions made of a hard material such as PMMA or the like (the supporting portions of this type of intraocular lens are usually two thin filamentary members); a soft intraocular lens whose optical part and supporting portions are made of a same soft material (the supporting portions of this type are usually plate members); or a soft intraocular lens employing a plurality of thin strips as supporting portions, and the like.

Further, in order to insert an intraocular lens into an eye, there has also been used a dedicated intraocular lens insertion device having a structure for introducing the intraocular lens into the eye through an elongated tube. This type of intraocular lens insertion device allows an intraocular lens to be inserted through an incision smaller than 3 mm.

Furthermore, in recent years, there has been developed a type of intraocular lens insertion device which has an intraocular lens placed therein in advance and can be packaged and stored, in order to exclude the possibilities of bacteria contamination and errors in operation at the time of handling the intraocular lens (e.g., patent document 1).

2

However, this type of intraocular lens insertion device may cause a supporting portion (referred to as a rear supporting portion, hereunder) arranged on a rear side with respect to a lens advancement axis to slip in between a plunger for pushing out the intraocular lens and a passage inner wall surface of the insertion device, or be tangled with the corresponding plunger, during a process of moving the intraocular lens. These problems are particularly noticeable with soft intraocular lenses employing thin filamentary members as supporting portions and intraocular lenses employing thin strips as supporting portions.

Further, this type of intraocular lens insertion device may cause the rear supporting portion to be stretched during the process of moving the intraocular lens. Accordingly, the corresponding rear supporting portion may then be left outside an eye ball at the time of performing insertion through a small incision on the eyeball, thereby requiring an additional operation for inserting such rear supporting portion into the eye ball after pushing out the intraocular lens with the plunger, and thus making the surgery troublesome.

In this sense, when using an intraocular lens insertion device to insert an intraocular lens into an eye, the motion of the rear supporting portion of the intraocular lens has to be appropriately regulated during the process of moving the intraocular lens.

In view of the aforementioned problems, there has been disclosed a device in which a clearance is formed on a front end side portion of a plunger, for allowing the rear supporting portion to be kept therein and thus preventing the same from being damaged (e.g., patent document 2). Further, there has been disclosed a device in which a rear supporting portion receiving passage for receiving the rear supporting portion is provided on a lower side portion of a plunger (e.g., patent document 3). Furthermore, there has also been disclosed a device in which the rear supporting portion is pushed up on a lump portion by means of a plunger, thereby allowing the corresponding haptic to be bended upward and eventually positioned higher than an IOL (e.g., patent document 4). Accordingly, all the devices disclosed in the aforementioned patent documents serve to reduce holding pressures applied to the rear supporting portions of intraocular lenses employing thin filaments or strips as supporting portions.

**REFERENCE**

Patent document 1: WO2007/037223  
 Patent document 2: Japanese Unexamined Patent Application Publication (Translation of PCT Application) No. 1999-506357  
 Patent document 3: U.S. Pat. No. 6,733,507  
 Patent document 4: Japanese Unexamined Patent Application Publication No. 2004-351196

**DISCLOSURE OF THE INVENTION****Problem to be Solved by the Invention**

However, according to the patent documents 2 and 3, the rear supporting portion received in the clearance formed on the front end side portion of the plunger and in the rear supporting portion receiving passage is stretched, thereby still incurring a problem in which the corresponding rear supporting portion may be left outside a small incision formed on an eye ball when inserting an intraocular lens therethrough. Particularly, with regard to intraocular lenses employing thin strips as supporting portions, reoperation is

often troublesome because the corresponding supporting portions are composed of soft members that are thick in sizes. Further, according to the patent document 4, the supporting portion is pushed by a small plunger front end matched to a nozzle front end with a small aperture diameter, thus causing the rear supporting portion to be compressed into an unexpected shape when bending the supporting portion upward so as to position the same higher than an optical part or when allowing an intraocular lens to pass through a passage.

Here, in view of the aforementioned problems, it is an object of the present invention to provide an intraocular lens insertion device capable of appropriately regulating the motion of a rear supporting portion during a process of moving an intraocular lens, and reducing the possibility of reoperation being required after the intraocular lens has been inserted into an eye.

#### Means for Solving the Problem

The invention according to a first aspect of the present invention is an intraocular lens insertion device comprising: a lens placement section for placing an intraocular lens having an optical part and one or more supporting portions provided on an outer edge of the optical part; a transition section for deforming the intraocular lens; a nozzle section for releasing the intraocular lens; a slider for pushing out the intraocular lens placed in the lens placement section; and a plunger for releasing the intraocular lens pushed out by the slider from the nozzle section, in which the slider includes: a first abutting portion for pushing up a supporting portion disposed in a rear direction of a lens advancement axis; and one or more second abutting portions abutting against an outer edge of a rear portion of the intraocular lens.

According to the invention described in a second aspect of the present invention, the second abutting portions are provided outside the first abutting portion with respect to the lens advancement axis.

According to the invention described in a third aspect of the present invention, the first abutting portion slants downward in a lens advancement direction.

According to the invention described in a fourth aspect of the present invention, at least one of the second abutting portions includes: an x-direction abutting surface substantially perpendicular to a surface of the optical part; and a y-direction abutting surface substantially parallel with the surface of the optical part.

The invention according to a fifth aspect of the present invention comprises a guiding portion for guiding the outer edge of the optical part to the second abutting portions.

According to the invention described in a sixth aspect of the present invention, the second abutting portions are provided as a left-right pair centered about the lens advancement axis.

#### Effects of the Invention

According to the present invention, the first abutting portion provided on the slider serves to push up the supporting portion arranged on the rear side with respect to the lens advancement axis, thereby allowing the motion of the rear supporting portion to be appropriately regulated during the process of moving the intraocular lens, and thus reducing the possibility of reoperation being required after the intraocular lens is inserted into the eye.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view showing an overall structure of an intraocular lens insertion device of a first embodiment of the present invention.

FIG. 2 is a perspective view showing a structure of a slider of the first embodiment of the present invention.

FIG. 3 is a partially enlarged perspective view showing the structure of the slider of the first embodiment of the present invention.

FIGS. 4A and 4B are diagrams showing a usage state (1) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 4A is a cross sectional top view, and FIG. 4B is a longitudinal sectional view.

FIGS. 5A and 5B are diagrams showing a usage state (2) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 5A is a cross sectional top view, and FIG. 5B is a longitudinal sectional view.

FIGS. 6A and 6B are diagrams showing a usage state (3) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 6A is a cross sectional top view, and FIG. 6B is a longitudinal sectional view.

FIGS. 7A and 7B are diagrams showing a usage state (4) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 7A is a cross sectional top view, and FIG. 7B is a longitudinal sectional view.

FIGS. 8A and 8B are diagrams showing a usage state (5) of the intraocular lens insertion device of the first embodiment of the present invention, in which FIG. 8A is a cross sectional top view, and FIG. 8B is a longitudinal sectional view.

FIG. 9 is a partially enlarged perspective view showing a structure of a slider of a second embodiment of the present invention.

FIGS. 10A and 10B are diagrams showing a usage state (1) of an intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 10A is a cross sectional top view, and FIG. 10B is a longitudinal sectional view.

FIGS. 11A and 11B are diagrams showing a usage state (2) of the intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 11A is a cross sectional top view, and FIG. 11B is a longitudinal sectional view.

FIGS. 12A and 12B are diagrams showing a usage state (3) of the intraocular lens insertion device of the second embodiment of the present invention, in which FIG. 12A is a cross sectional top view, and FIG. 12B is a longitudinal sectional view.

FIG. 13 is a partially enlarged perspective view showing a structure of a slider of a third embodiment of the present invention.

FIG. 14 is a partially enlarged perspective view showing a structure of a plunger of the third embodiment of the present invention.

FIGS. 15A and 15B are diagrams showing a usage state (1) of an intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 15A is a cross sectional top view, and FIG. 15B is a longitudinal sectional view.

FIGS. 16A and 16B are diagrams showing a usage state (2) of the intraocular lens insertion device of the third

5

embodiment of the present invention, in which FIG. 16A is a cross sectional top view, and FIG. 16B is a longitudinal sectional view.

FIGS. 17A and 17B are diagrams showing a usage state (3) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 17A is a cross sectional top view, and FIG. 17B is a longitudinal sectional view.

FIGS. 18A and 18B are diagrams showing a usage state (4) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 18A is a cross sectional top view, and FIG. 18B is a longitudinal sectional view.

FIGS. 19A and 19B are diagrams showing a usage state (5) of the intraocular lens insertion device of the third embodiment of the present invention, in which FIG. 19A is a cross sectional top view, and FIG. 19B is a longitudinal sectional view.

## BEST MODE FOR CARRYING OUT THE INVENTION

### 1. First Embodiment

#### (1) Basic Structure

An embodiment of the present invention is described hereunder in detail and with reference to the accompanying drawings.

An intraocular lens insertion device 1 shown in FIG. 1 comprises a main body 2, and a slider 3 and a plunger 4 that are attached to the main body 2. The intraocular lens insertion device 1 is of a preset type in which an intraocular lens 5 is placed inside the main body 2 in advance. Here, the intraocular lens 5 includes an optical part 6 and a pair of supporting portions 7 (or "haptics") provided on an outer edge of the optical part 6. As the supporting portions 7, there can be employed various types of members including, for example, members of a thin strip type.

In the following descriptions, an axis extending through the center of the intraocular lens 5 moving inside the main body 2 is referred to as a lens advancement axis A. Further, a direction to which the intraocular lens 5 moves is referred to as an "advancement direction x," and a downward direction is referred to as a "direction y."

The main body 2 is composed of a base end portion 8 and an insertion tube 9 connected to a front end of the base end portion 8 in the advancement direction x. Although not shown, a lens placement section made of a plate type member is formed on the front end of the base end portion 8 in the advancement direction x. The intraocular lens 5 is placed in the corresponding lens placement section. On side surfaces of the base end portion 8, there are provided slits 12 formed in parallel with the lens advancement axis A and extending to the front end of the base end portion 8. Further, the insertion tube 9 is integrally connected to the front end of the base end portion 8, thereby allowing the intraocular lens 5 placed in the lens placement section of the base end portion 8 to be disposed internally.

The insertion tube 9 comprises a transition section 10 and a nozzle section 11 that are successively disposed along the lens advancement axis A. The transition section 10 is formed into a tapered shape in which an inner wall of the transition section 10 tapers toward a front end thereof, such front end being further communicated with the nozzle section 11. The nozzle section 11 is so formed that an outer shape thereof can be inserted into an incision (not shown).

6

According to this intraocular lens insertion device 1, the intraocular lens 5 placed in the lens placement section is at first moved to the transition section 10 after being pushed out by the slider 3, thereby allowing the intraocular lens 5 to be reliably folded into a given shape. Next, the intraocular lens 5 is further moved to the nozzle section 11 after being pushed out by the plunger 4, thereby causing the intraocular lens 5 to be folded even smaller, and thus allowing the intraocular lens 5 to be inserted into an eye from a front end of the nozzle section 11. Accordingly, the intraocular lens insertion device 1 allows the intraocular lens 5 to be moved in the advancement direction x in two stages involving successively the slider 3 and the plunger 4, thus causing the intraocular lens 5 to be folded into a given shape and releasing the same to the outside.

#### (2) Structure of Slider

Next, the slider 3 attached to the main body 2 is described. As shown in FIG. 2, the slider 3 serves to push out the intraocular lens 5 placed in the lens placement section to the transition section 10 without imposing a local load thereon, and fold the intraocular lens 5 into the given shape. The slider 3 includes a guiding groove 15, a wing portion 16, operation portions 17 and a lens pressing member 18.

The guiding groove 15 is so configured that the plunger 4 can be supported thereby along the lens advancement axis A. Specifically, the guiding groove 15 allows the plunger 4 to slide, and a front end of the plunger 4 to protrude from a front end of the slider 3. According to the present embodiment, the guiding groove 15 is longitudinally formed over an entire length of a surface of the slider 3 in a manner such that the guiding groove 15 is substantially located in the center of the surface of the slider 3. Accordingly, the guiding groove 15 serves as a groove parallel to the lens advancement axis A. A cross-sectional surface of the guiding groove 15 is substantially formed into a same shape as an outer shape of the plunger 4. A wedge guiding path 15a is formed on a base end of the guiding groove 15. In this way, the plunger 4 is allowed to be inserted into the guiding groove 15 formed on the slider 3, and slide within the guiding groove 15 in a longitudinal direction of the slider 3.

The wing portion 16 is inserted into the slits 12 provided on the main body 2, and serves to support the slider 3 along the lens advancement axis A. By inserting the wing portion 16 into the slits 12, the slider 3 is allowed to not only be held in a substantial center portion of the main body 2, but also move along the lens advancement axis A. In this sense, the plunger 4 can also be held in the center portion of the main body 2 and move along the lens advancement axis A, when inserted into the guiding groove 15 formed on the slider 3. The slider 3 can be easily moved by means of the operation portions 17.

The operation portions 17 are provided as a left-right pair centered about the lens advancement axis A. Further, the operation portions 17 are connected to side end portions of the wing portion 16, and protrude from each side of the base end portion 8.

The lens pressing member 18 serves to fold the intraocular lens 5 in a given direction by pressing a surface of the intraocular lens 5 only when the intraocular lens 5 is being pushed out. According to the present embodiment, the lens pressing member 18 serves to press a surface of the intraocular lens 5 to the direction y, thereby causing the intraocular lens 5 to be folded inside the nozzle section 11 with the foregoing surface being folded inwardly, such surface being a front surface when releasing the intraocular lens 5 into the eye. The lens pressing member 18 is made of a strip type



member provided on the front end of the slider **3**, and is capable of swinging freely to the direction *y*.

In addition to the structure described so far, the slider **3** of the present embodiment, as shown in FIG. **3**, further includes a first abutting portion **21** for pushing up a supporting portion **7** arranged on a rear side with respect to the lens advancement axis *A* with respect to the optical part **6** (referred to as a rear supporting portion *7a*, hereunder), and second abutting portions **22a**, **22b** abutting against a rear outer edge of the optical part **6**.

The first abutting portion **21** has a slanting surface formed in the center of the front end of the slider **3** and slanting toward a direction between the advancement direction *x* and the direction *y*. The guiding groove **15** is opened in the center of the first abutting portion **21**, and a front end of the plunger **4** is thus allowed to protrude from the guiding groove **15** in the advancement direction *x*. Further, restriction portions **23** are formed on front ends of the first abutting portion **21**. The restriction portions **23** serve to prevent the rear supporting portion *7a* from entering in between the slider **3** and the main body **2** and thus being damaged, as the rear supporting portion *7a* deforms in the direction *y*. According to the present embodiment, the restriction portions **23** protrude from lower ends of the slanting surface to the advancement direction *x*.

The second abutting portions **22a**, **22b** are respectively provided on both sides of the first abutting portion **21**, and are configured to be able to abut against the outer edge of the optical part **6** of the intraocular lens **5**. According to the present embodiment, the second abutting portions **22a**, **22b** protrude from the front end of the slider **3** to the advancement direction *x*, and at least **22a** is allowed to abut against, along the lens advancement axis *A*, an outer edge of a section of the optical part **6**, such section of the optical part **6** being located outward from a connecting portion of the supporting portion **7** and the optical part **6**.

Further, the second abutting portions **22a**, **22b** have *x*-direction abutting surfaces **24** and *y*-direction abutting surfaces **25**. The *x*-direction abutting surfaces **24** are perpendicular to a surface of the optical part **6**, and are thus capable of pushing out the outer edge of the optical part **6**. The *y*-direction abutting surfaces **25** are parallel with the surface of the optical part **6**, and are thus able to restrict a surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded before the rear supporting portion *7a* has been sufficiently deformed.

As described above, according to the intraocular lens insertion device **1** of the present embodiment, the first abutting portion **21** and the second abutting portions **22a**, **22b** are provided on the slider **3** allowing the intraocular lens **5** to be in contact therewith through a contact area larger than that of the plunger **4**. Accordingly, the motion of the rear supporting portion *7a* can be appropriately regulated during the process of moving the intraocular lens **5**. Further, there can be reduced the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

### (3) Operation and Effect

According to the intraocular lens insertion device **1** having the aforementioned structure, the intraocular lens **5** is placed internally in a manner such that the optical part **6** thereof is arranged in parallel with the lens advancement axis *A* (FIGS. **4A** and **4B**). The slider **3** is at first moved to the advancement direction *x* in order to release the intraocular lens **5** internally placed in advance to the outside from the front end of the nozzle section **11**. In this way, the first

abutting portion **21** formed on the front end of the slider **3** is caused to abut against the rear supporting portion *7a* (FIGS. **5A** and **5B**).

Since the first abutting portion **21** has the slanting surface, the rear supporting portion *7a* is pushed up therealong as the slider **3** is further moved to the advancement direction *x* (FIGS. **6A** and **6B**). At the same time, the *x*-direction abutting surfaces **24** of the second abutting portions **22a**, **22b** are caused to abut against as well as push out the optical part **6**, thereby moving the intraocular lens **5** from the lens placement section to the transition section **10**. At that time, the outer edge of the optical part **6** is pushed by the inner wall of the transition section **10**. Further, the lens pressing member **18** is also pushed by the inner wall of the transition section **10**, and is thus caused to push down the surface of the optical part **6** to the direction *y*. In this way, the optical part **6** of the intraocular lens **5** is valley folded.

Next, as the plunger **4** is moved to the advancement direction *x*, the front end of such plunger **4** supported by the guiding groove **15** of the slider **3** is caused to abut against the outer edge of the optical part **6** (FIGS. **7A** and **7B**). The rear supporting portion *7a* pushed up by the first abutting portion **21** is thus caused to deform along the plunger **4** in a manner such that a front end of the rear supporting portion *7a* eventually points to the advancement direction *x*. In other words, the plunger **4** moves the front end (or "free end") of the rear supporting portion *7a* over the optical part **6**. In this way, the front end of the rear supporting portion *7a* deformed due to the first abutting portion **21**, is tucked into the surface of the valley-folded optical part **6** by the plunger **4**.

Here, the *y*-direction abutting surfaces **25** of the second abutting portions **22a**, **22b** are configured to restrict the surface of the optical part **6** in the vicinity of the outer edge thereof from being valley folded, thereby preventing the outer edge of the optical part **6** from interfering with the rear supporting portion *7a* during a deformation process of the rear supporting portion *7a*. Accordingly, the intraocular lens insertion device **1** allows the rear supporting portion *7a* to further reliably enter a space formed by the valley-folded surface of the optical part **6**, thereby making it possible to further reliably deform the intraocular lens **5** into the given shape. The inner surface of the transition section **10** deforms the free end of the forward supporting portion *7b* toward (and then over) the optical part **6** as the plunger is moved in the advancement direction *x*.

Further, the restriction portions **23** provided on the first abutting portion **21** serve to prevent the rear supporting portion *7a* from deforming to the direction *y*. In this sense, the intraocular lens insertion device **1** allows the intraocular lens **5** to be further reliably deformed into the given shape.

Next, by further moving the plunger **4** to the advancement direction *x*, the intraocular lens **5** is moved from the transition section **10** to the nozzle section **11** (FIGS. **8A** and **8B**) with the rear supporting portion *7a* and the forward supporting portion *7b* both over the optical part **6** and within the space between the folded portions of the optical part, followed by being released to the outside from the front end of the nozzle section **11** with the intraocular lens **5** itself being folded even smaller.

As described earlier, the intraocular lens insertion device **1** allows the rear supporting portion *7a* to be pushed up by the first abutting portion **21**, thereby making it possible to appropriately regulate the motion of the rear supporting portion *7a* during the process of moving the intraocular lens **5** and reduce the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

US 9,877,826 B2

9

Further, since the first abutting portion **21** is provided on the slider **3**, the rear supporting portion **7a** is allowed to come into contact with the first abutting portion **21** through a large contact area. Accordingly, the intraocular lens insertion device **1** of the present embodiment allows the rear supporting portion **7a** to be further stably deformed, thereby making it possible to further appropriately regulate the rear supporting portion **7a**.

## 2. Second Embodiment

A second embodiment of the present invention is described hereunder with reference to the accompanying drawings. Here, the second embodiment differs from the first embodiment only in the structure of the front end portion of the slider **3**. Therefore, same symbols are used to describe the same members as those in the first embodiment, and the descriptions of the corresponding members are thus omitted for the sake of convenience.

According to a slider **30** shown in FIG. **9**, at least **22a** of second abutting portions **22a**, **22b** is configured to abut against an outer edge of a section of the optical part **6** between the connecting portion of the rear supporting portion **7a** and the optical part **6**, and the lens advancement axis **A**. Further, this slider **30** has a cutout hole **31** formed on a side surface thereof, such cutout hole **31** allowing the rear supporting portion **7a** to be inserted therethrough inwardly from the outside.

According to the present embodiment having the aforementioned structure, the slider **30** is at first moved to the advancement direction **x** by gripping operation portions **17**. As a result, a first abutting portion **21** formed on a front end of the slider **30** is caused to abut against the rear supporting portion **7a**.

As the slider **30** is further moved to the advancement direction **x**, the rear supporting portion **7a** is pushed up with **x**-direction abutting surfaces **24** of the second abutting portion **22** abutting against and pushing out the optical part **6**, at the same time, thus allowing the intraocular lens **5** to be moved from a lens placement section to a transition section **10**. In this way, the optical part **6** is pushed by an inner wall of the transition section **10**, and a surface of the optical part **6** is pushed down to the direction **y** by means of a lens pressing member **18**, thus allowing the optical part **6** to be valley folded (FIGS. **10A** and **10B**).

Next, as a plunger **4** is moved to the advancement direction **x**, the front end of such plunger **4** supported by a guiding groove **15** of the slider **3** is caused to abut against the outer edge of the optical part **6** (FIGS. **11A** and **11B**). The supporting portion **7** pushed up by the first abutting portion **21** is thus caused to deform along the plunger **4** in a manner such that a front end of the supporting portion **7** eventually points to the advancement direction **x**. In this way, a front end of the supporting portion **7** deformed due to the first abutting portion **21**, is tucked into the surface of the valley-folded optical part **6**.

Next, by further moving the plunger **4** to the advancement direction **x**, the intraocular lens **5** is moved from the transition section **10** to a nozzle section **11** (FIGS. **12A** and **12B**), followed by being released to the outside from a front end of the nozzle section **11** with the intraocular lens **5** itself being folded even smaller.

Due to the aforementioned structure of the present embodiment, the present embodiment, as is the case in the first embodiment, allows the motion of the rear supporting portion **7a** to be appropriately regulated during the process

10

of moving the intraocular lens **5**, and reduces the possibility of reoperation being required after the intraocular lens **5** is inserted into the eye.

## 3. Third Embodiment

As shown in FIG. **13**, a slider **40** of the present embodiment includes a first abutting portion **21**, second abutting portions **22a**, **22b** and a guiding portion **41** for guiding the optical part **6** to the second abutting portion **22b**. The second abutting portion **22b** is provided on a location opposite to the connecting portion of the rear supporting portion **7a** and the optical part **6**, and is configured to be able to abut against the optical part **6** or the outer edge thereof. Further, the second abutting portion **22b** has an **x**-direction abutting surface **24** and a **y**-direction abutting surface **25**. In contrast, the second abutting portion **22a** only has the **x**-direction abutting surface **24**.

Here, the **y**-direction abutting surface **25** of the second abutting portion **22b** may be arranged substantially on the same plane as restriction portions **23**, or beyond the restriction portions **23** in the direction **y**. According to the present embodiment, the **y**-direction abutting surface **25** is arranged on the same plane as the restriction portions **23**.

The guiding portion **41** has a slanting surface slanting toward a direction between the advancement direction **x** and an opposite direction of the direction **y**. A lower end of the guiding portion **41** is communicated with the **y**-direction abutting surface **25**. Here, a plunger having a shape shown in FIG. **14** can be used as a plunger **44**. The plunger **44** includes a forward region **45** with a lens contact portion **46**, a side wall **47**, a bottom wall **48**, and a top wall **49**. An indentation **50** has a first lateral side **51** that is open, a second lateral side that is closed by the side wall **47**, and an open distal end **52**. The indentation **50** is located above, and extends proximally from, the lens contact portion **46**. The proximal end of the indentation **50** is defined by a slanted wall **53**.

Next, there are described an operation and effect of the slider **40** having the aforementioned structure. The intraocular lens **5** is placed in a lens placement section (not shown) in a manner such that the optical part **6** thereof is arranged in parallel with the lens advancement axis **A** (FIGS. **15A** and **15B**). The slider **40** is at first moved to the advancement direction **x** in order to release such intraocular lens **5** to the outside from a front end of a nozzle section **11**. As a result, the first abutting portion **21** formed on a front end of the slider **40** is caused to abut against the rear supporting portion **7a** (FIGS. **16A** and **16B**).

Since the first abutting portion **21** has a slanting surface, the rear supporting portion **7a** is pushed up therealong as the slider **40** is further moved to the advancement direction **x** (FIGS. **17A** and **17B**). At the same time, the guiding portion **41** serves to push down a surface of the optical part **6** to the direction **y**, thereby guiding the corresponding optical part **6** to the second abutting portion **22b**. As a result, the **x**-direction abutting surface **24** of the second abutting portion **22b** and the **x**-direction abutting surface **24** of the second abutting portion **22a** are caused to abut against and then push out the optical part **6**, thus allowing the intraocular lens **5** to be moved from the lens placement section to a transition section **10**.

Here, the slider **40** allows the optical part **6** to be guided to the second abutting portion **22b** by means of the guiding portion **41**, thereby causing the second abutting portion **22b**

11

to further reliably abut against the optical part 6, and thus allowing the intraocular lens 5 to be further reliably pushed out.

In this way, the outer edge of the optical part 6 is pushed by an inner wall of the transition section 10. Further, at that time, a lens pressing member 18 is also pushed by the inner wall of the transition section 10, thus pushing down the surface of the optical part 6 to the direction y. As a result, the optical part 6 of the intraocular lens 5 is valley folded.

Next, as the plunger 44 is moved to the advancement direction x, the front end of such plunger 44 supported by a guiding groove 15 of the slider 40 is caused to abut against the outer edge of the optical part 6 (FIGS. 18A and 18B). The rear supporting portion 7a pushed up by the first abutting portion 21 is thus caused to deform along the plunger 44 in a manner such that a front end of the rear supporting portion 7a eventually points to the advancement direction x and a part of the rear supporting portion 7a is in the indentation 50. In this way, the front end of the rear supporting portion 7a deformed due to the first abutting portion 21, is enclosed by the valley-folded surface of the optical part 6.

Here, the y-direction abutting surface 25 of the second abutting portion 22b is configured to restrict the surface of the optical part 6 in the vicinity of the outer edge thereof from being valley folded, thereby preventing the outer edge of the optical part 6 from interfering with the rear supporting portion 7a during the deformation process of the rear supporting portion 7a.

Particularly, according to the present embodiment, since the y-direction abutting surface 25 is arranged on the same plane as the restriction portions 23, the outer edge of the optical part 6 is restricted from deforming to the opposite direction of the direction y, particularly, from deforming beyond the restriction portions 23 and the rear supporting portion 7a deformed due to the first abutting portion 21. In this sense, the slider 40 can further reliably prevent the outer edge of the optical part 6 from interfering with the rear supporting portion 7a, thereby allowing the intraocular lens 5 to be further reliably deformed into the given shape. The inner surface of the transition section 10 deforms the end of the forward supporting portion 7b toward (and then over) the optical part 6 as the plunger is moved in the advancement direction x.

Next, by further moving the plunger 44 to the advancement direction x, the intraocular lens 5 is moved from a transition section 10 to a nozzle section 11 (FIGS. 19A and 19B) with the rear supporting portion 7a and the forward supporting portion 7b both over the optical part 6 and within the space between the folded portions of the optical part, followed by being released to the outside from a front end of the nozzle section 11 with the intraocular lens 5 itself being folded even smaller.

Since the slider 40 of the present embodiment includes the first abutting portion 21 and the restriction portions 23, there can be achieved the same effects as those of the first embodiment.

4. Modified Embodiment

The present invention is not limited to the aforementioned embodiments. As a matter of fact, appropriate modifications are possible within the scope of the gist of the present invention. For example, in each one of the aforementioned embodiments, there are provided two second abutting portions in total. However, the present invention is not limited

12

to this configuration. Particularly, the number of the second abutting portions can be one, three or more than three.

Further, in each one of the aforementioned embodiments, the second abutting portions 22 are provided as a symmetrical pair. However, the present invention is not limited to this configuration. The second abutting portions 22 can actually be provided in an asymmetrical manner. For example, one of the second abutting portions 22 may be formed longer than the other second abutting portion 22 in the advancement direction x, thereby making it possible to slightly rotate the intraocular lens 5 about an optical axis, and thus making it easier to regulate a supporting portion disposed forward.

DESCRIPTION OF SYMBOLS

- 1 intraocular lens insertion device
- 2 main body
- 3 slider
- 4 plunger
- 5 intraocular lens
- 6 optical part
- 7 supporting portion
- 7a rear supporting portion
- 21 first abutting portion
- 22 second abutting portion
- x advancement direction
- y direction (downward direction)
- A lens advancement axis

The invention claimed is:

1. A method performed by an intraocular lens insertion device on an intraocular lens, the intraocular lens including an optic, a forward haptic having an end and a rear haptic having an end, the insertion device including a nozzle, a transition section and a plunger having a forward region with a side wall and a bottom wall that together define an indentation and is configured to receive a portion of the rear haptic, the method comprising the steps of:

- pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic;
- pushing the rear haptic such that the end of the rear haptic passes over the optic, while the portion of the optic over which the rear haptic passes remains unfolded, with the forward region of the plunger in such a manner that the rear haptic is bent and a portion of the rear haptic is received in the indentation;
- folding a portion of the optic such that there is a space between folded portions of the optic; and
- pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic.

2. A method as claimed in claim 1, wherein folding a portion of the optic comprises folding a portion of the optic with the transition section such that there is a space between folded portions of the optic.

3. A method as claimed in claim 1, wherein pushing the intraocular lens through the nozzle comprises pushing the intraocular lens through the nozzle with the forward region of the plunger while the end of the rear haptic is in the space between the folded portions of the optic and the end of the rear haptic faces in a lens travelling direction.

4. A method as claimed in claim 1, further comprising the step of:  
bending the forward haptic such that the end of the forward haptic moves into the space between the folded portions of the optic.

13

5. A method as claimed in claim 1, wherein the intraocular lens insertion device defines a lens travelling axis; and  
the method further comprises the step of storing the lens in the insertion device with the optic parallel to the lens travelling axis and the rear haptic positioned at a different angle than the forward haptic relative to the lens travelling axis.

6. A method as claimed in claim 1, wherein the intraocular lens insertion device defines a lens travelling axis; and  
pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic comprises pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic while the end of the rear haptic is on a surface that is not parallel to the lens travelling axis.

7. A method as claimed in claim 1, wherein the insertion device includes a slider that is movable relative to the plunger; and  
pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic comprises pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic with the slider.

8. A method as claimed in claim 1, wherein the intraocular lens insertion device defines a lens travelling axis;  
the insertion device includes a slider with an abutting portion that is slanted relative to the lens travelling axis and that is movable relative to the plunger; and  
pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic comprises pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic with the abutting portion of the slider.

9. A method as claimed in claim 1, wherein the insertion device includes a slider that is movable relative to the plunger; and  
folding a portion of the optic comprises pushing a portion of the optic into the transition section with the slider.

10. A method as claimed in claim 9, wherein the slider includes a pivotable lens pressing member; and  
folding a portion of the optic comprises pushing a portion of the optic into the transition section while the pivotable lens pressing member engages the portion of the optic.

11. A method as claimed in claim 1, wherein the intraocular lens insertion device defines a lens travelling axis;  
the insertion device includes a slider that is movable relative to the plunger, the slider having a first abutting

14

portion that is slanted relative to the lens travelling axis and a pair of second abutting portions located on opposite sides of the lens travelling axis;  
pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic comprises pushing the rear haptic such that the end of the rear haptic moves upwardly and forwardly relative to the optic with the first abutting portion of the slider before the second abutting portions contact the optic; and  
folding a portion of the optic comprises pushing a portion of the optic into the transition section with the second abutting portions.

12. A method performed by an intraocular lens insertion device on an intraocular lens, the intraocular lens including an optic, a forward haptic having a free end and a rear haptic having a free end, the insertion device including a nozzle, a transition section and a plunger, the method comprising the steps of:  
moving the free end of the rear haptic, from a position rearward of the optic, over the optic and into a space between folded portions of the optic with the plunger;  
moving the free end of the forward haptic into the space between the folded portions of the optic with the transition section; and  
pushing the intraocular lens with the plunger through the nozzle with the free ends of the forward and rear haptics in the space between the folded portions of the optic.

13. A method as claimed in claim 12, wherein the optic is folded with the transition section of the insertion device.

14. A method as claimed in claim 13, further comprising the step of:  
prior to folding the optic, pushing the rear haptic such that the free end of the rear haptic moves upwardly and forwardly relative to the optic.

15. A method as claimed in claim 14, wherein the insertion device includes a slider, and the plunger is movable relative to the slider; and  
pushing the rear haptic such that the free end of the rear haptic moves upwardly and forwardly relative to the optic comprises pushing the rear haptic such that the free end of the rear haptic moves upwardly and forwardly relative to the optic with the slider.

16. A method as claimed in claim 13, wherein moving the free end of the forward haptic comprises bending the forward haptic into the space between the folded portions of the optic with an inner surface of the transition section as the intraocular lens moves toward the nozzle.

\* \* \* \* \*

# **EXHIBIT 5**

(12) **United States Patent**  
**Inoue**

(10) **Patent No.:** **US 9,907,647 B2**  
 (45) **Date of Patent:** **Mar. 6, 2018**

(54) **INTRAOCULAR LENS INSERTION DEVICE AND METHOD FOR CONTROLLING MOVEMENT OF THE INTRAOCULAR LENS**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/812,104**

(22) Filed: **Jul. 29, 2015**

(65) **Prior Publication Data**  
 US 2016/0113759 A1 Apr. 28, 2016

**Related U.S. Application Data**

(63) Continuation of application No. 12/667,510, filed as application No. PCT/JP2008/062382 on Jul. 9, 2008, now Pat. No. 9,114,006.

(30) **Foreign Application Priority Data**  
 Jul. 11, 2007 (JP) ..... 2007-182535

(51) **Int. Cl.**  
**A61F 2/16** (2006.01)

(52) **U.S. Cl.**  
 CPC ..... **A61F 2/167** (2013.01)

(58) **Field of Classification Search**  
 CPC ..... A61F 2/167; A61F 2/1662; A61F 2002/1681; A61F 2002/1682  
 See application file for complete search history.

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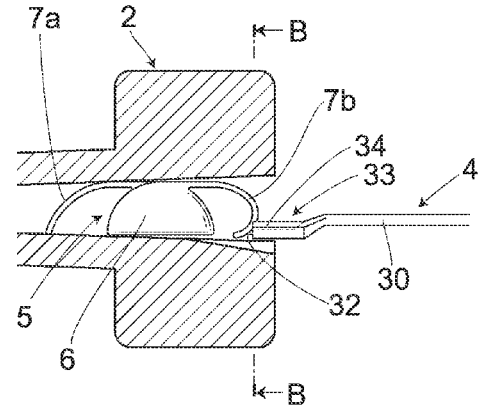
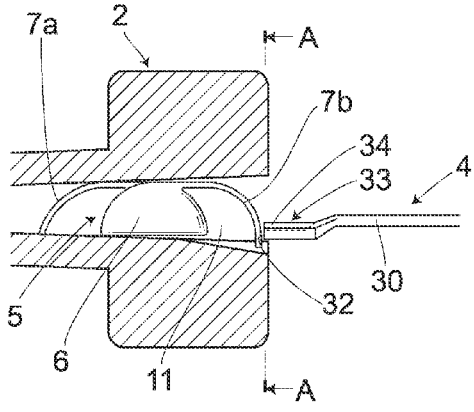
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(57) **ABSTRACT**

Provided is an intraocular lens insertion device capable of omitting a repeated operation after the intraocular lens is inserted into the eye. The intraocular lens insertion device (1) comprises a lens setting part (11) for mounting an intraocular lens (5) having an optic (6) and one or two or more supporting portions (7a and 7b) disposed at the outer edge of the optic (6), a plunger (4) for pushing out the intraocular lens (5) mounted in the lens setting part (11), and a nozzle (13) for releasing the intraocular lens (5) pushed out by the plunger (4). This plunger (4) includes a lens contact portion (32) for abutting against the outer edge of the optic (6), and a pushing portion (33) for pushing out the supporting portion (7b) arranged in the backward direction of a lens advancing axis (A).

**13 Claims, 6 Drawing Sheets**



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FIG.1

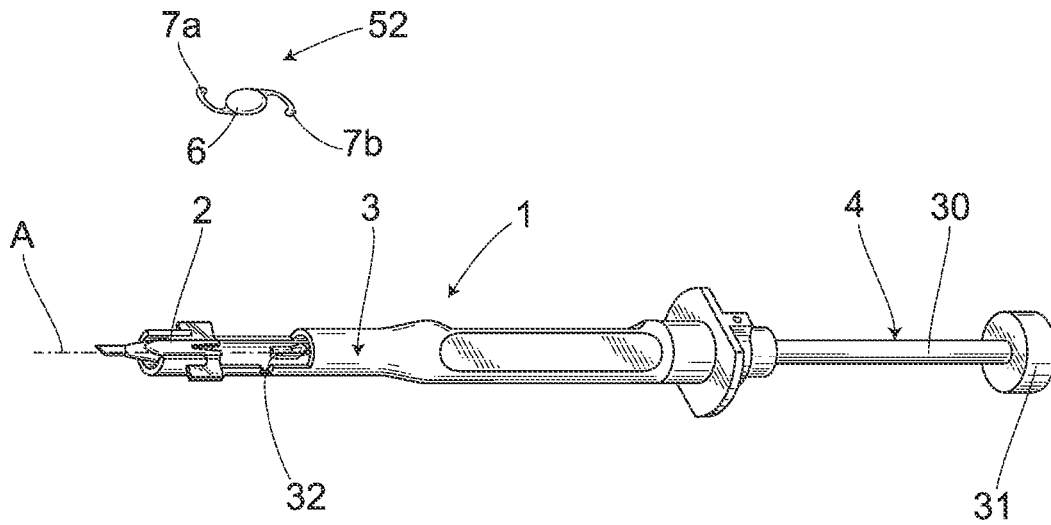


FIG.2

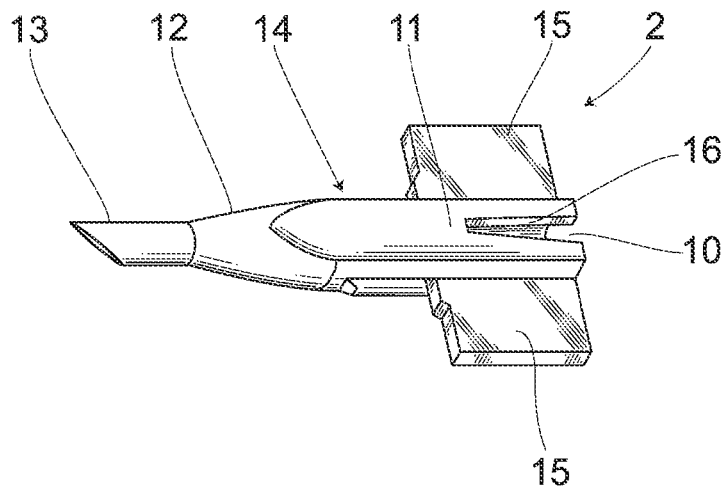


FIG.3

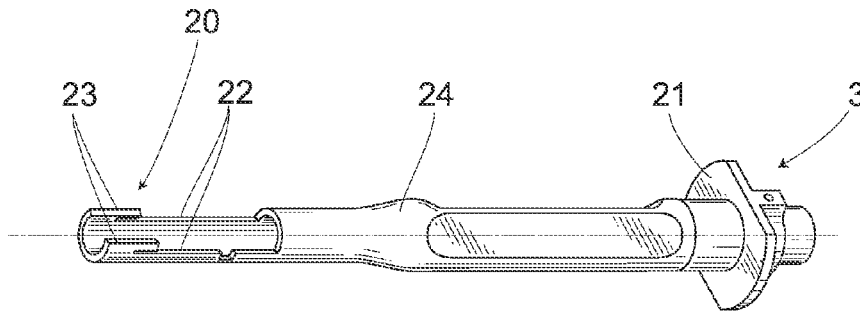
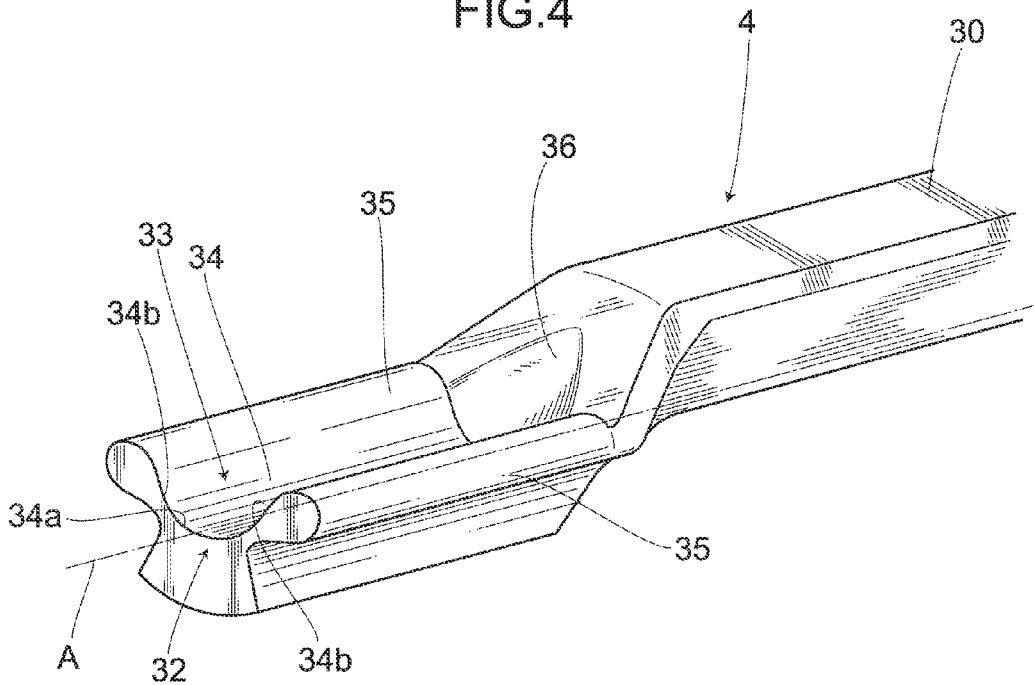
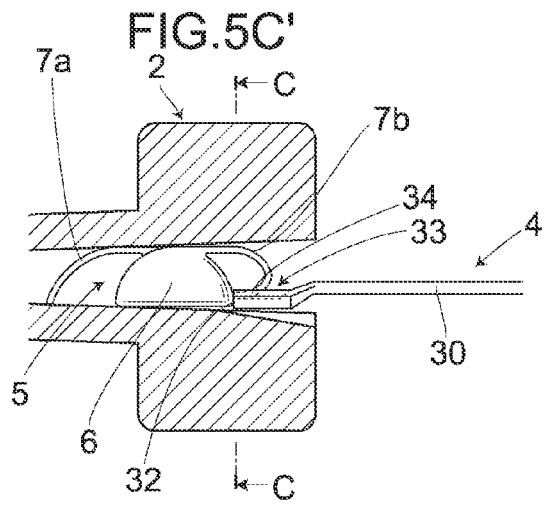
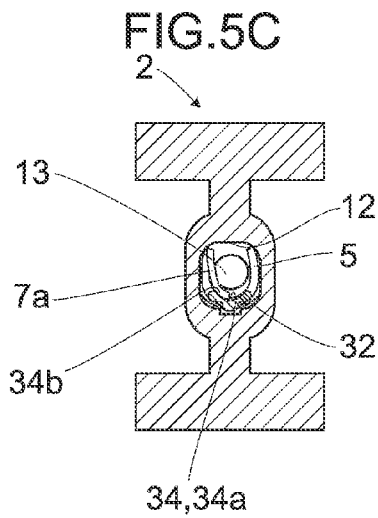
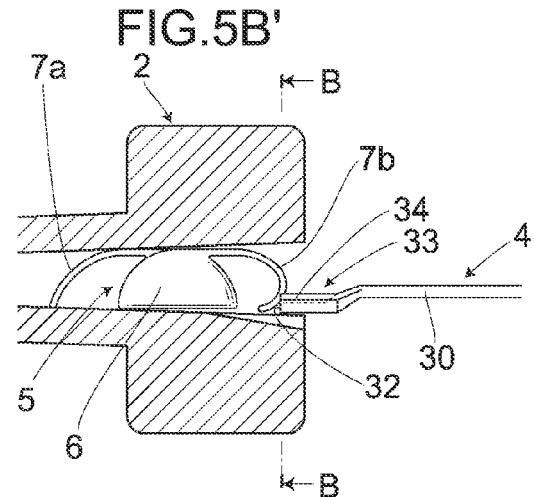
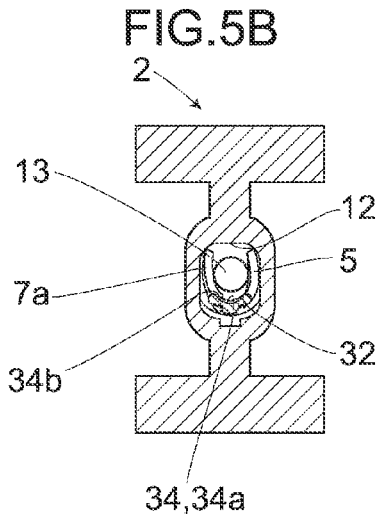
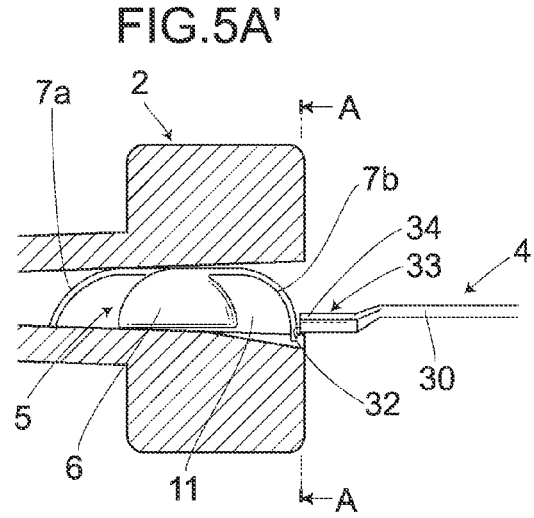
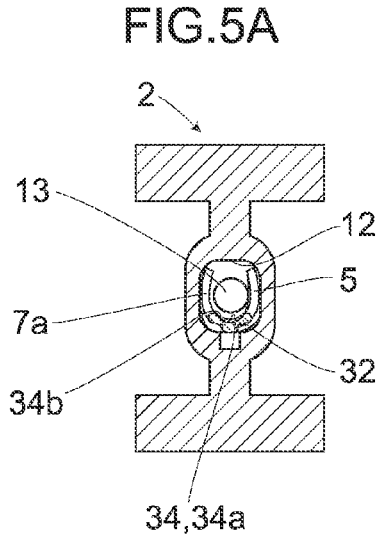


FIG.4





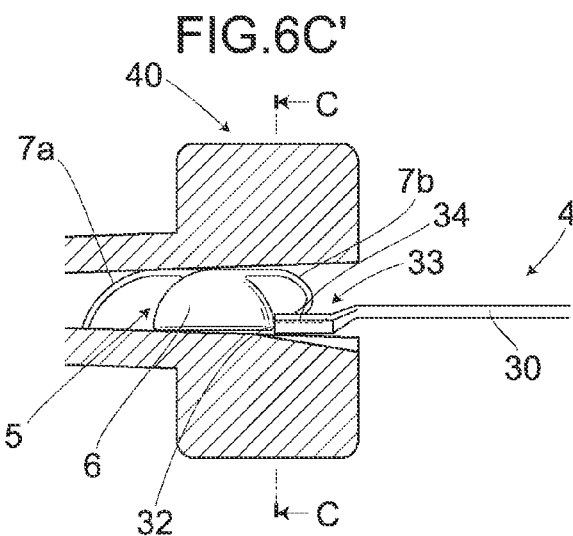
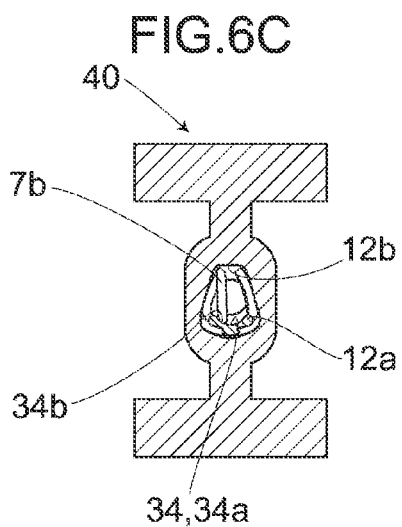
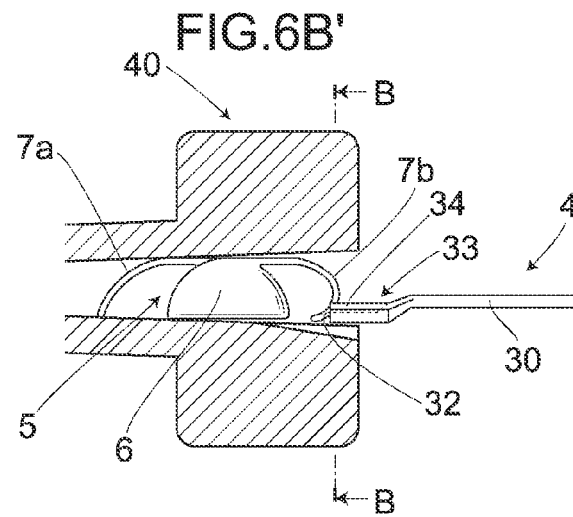
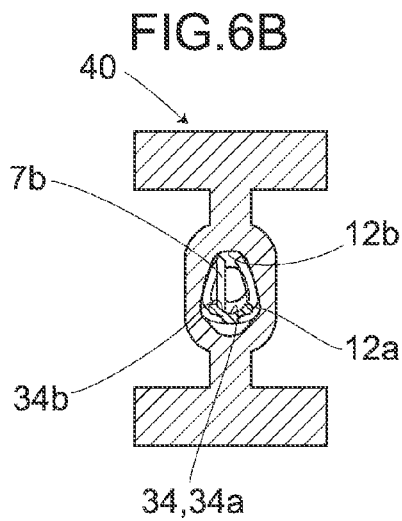
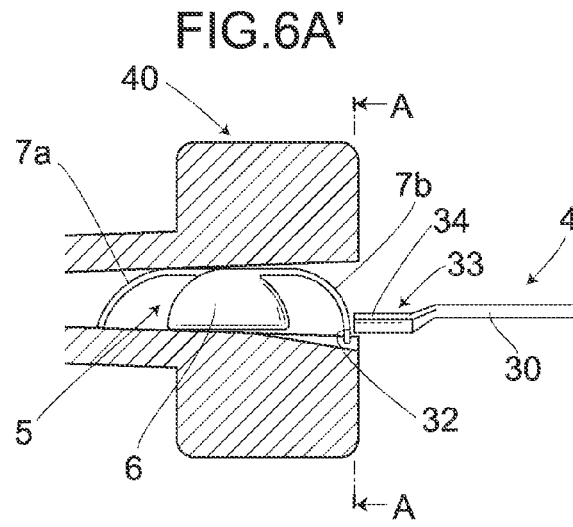
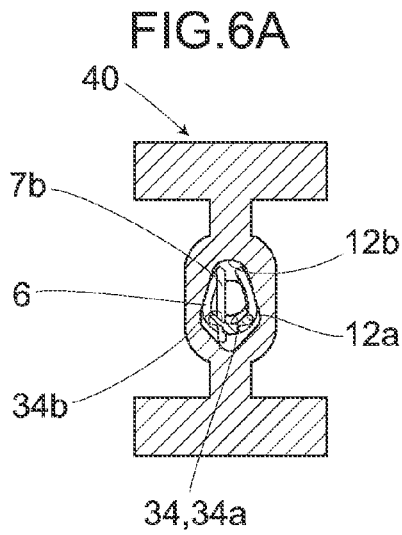


FIG. 7

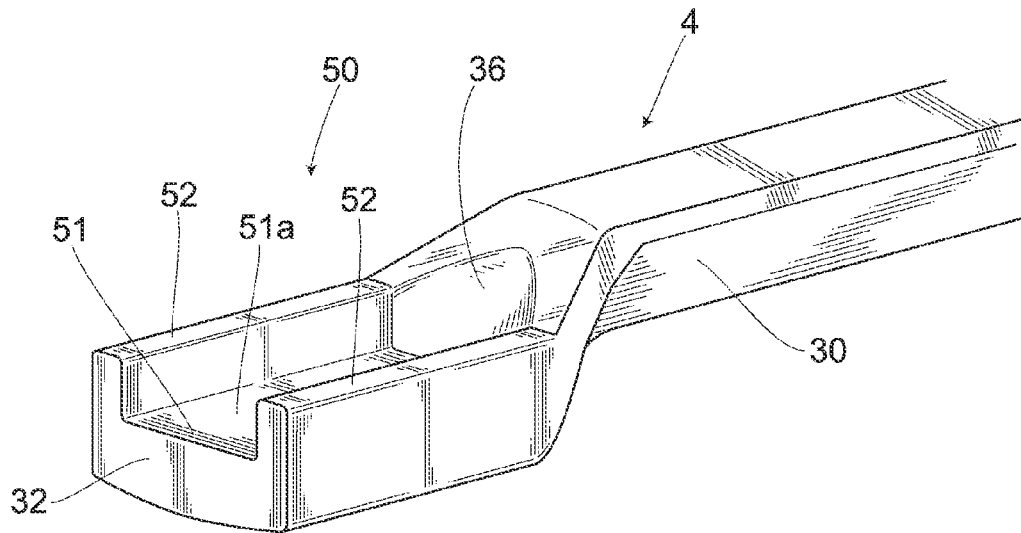
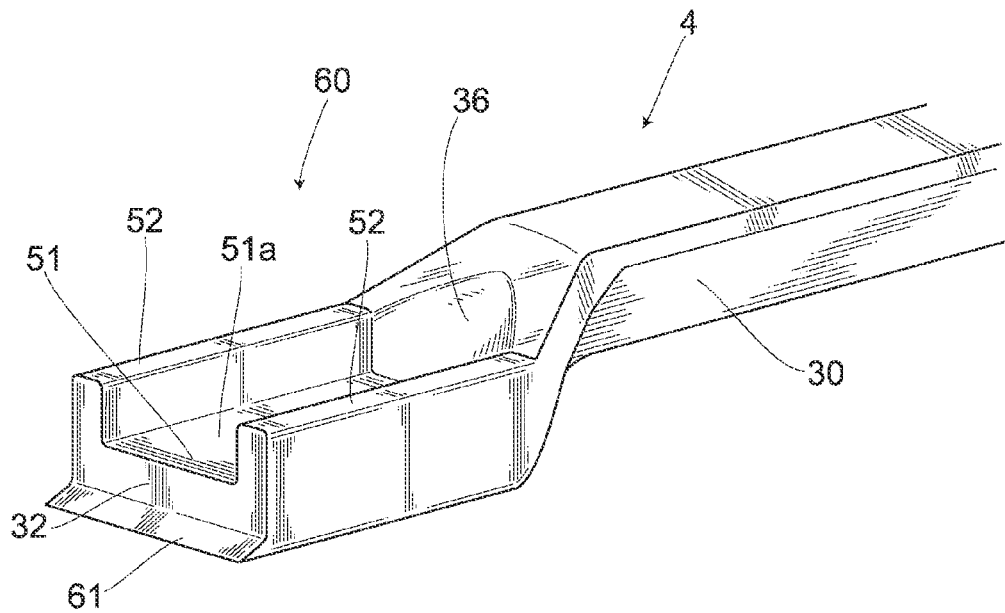
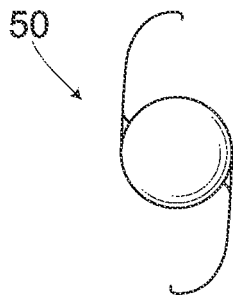


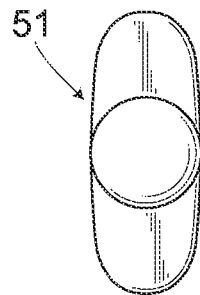
FIG. 8



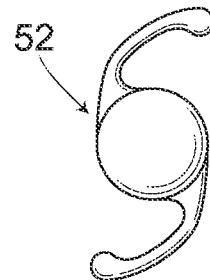
**FIG.9A**



**FIG.9B**



**FIG.9C**



US 9,907,647 B2

1

## INTRAOcular LENS INSERTION DEVICE AND METHOD FOR CONTROLLING MOVEMENT OF THE INTRAOcular LENS

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 12/667,510, filed Dec. 31, 2009, now U.S. Pat. No. 9,114,006, which was the U.S. national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/JP2008/062382, which has an International filing date of Jul. 9, 2008, and claims the benefit of Japanese Application No. 2007-182535, filed Jul. 11, 2007, each of which are incorporated by reference herein.

### TECHNICAL FIELD

The present invention relates to an intraocular lens insertion device and a method for controlling movement of the intraocular lens used to implant an intraocular lens into an eye in place of a crystalline lens removed in cataract surgery.

### BACKGROUND ART

In cataract surgery, there has been widely performed removal of opacified crystalline lenses by phacoemulsification and aspiration (PEA) followed by implantation of intraocular lenses into aphakic eyes. There are two types of intraocular lens: a hard intraocular lens whose optic is made of a hard material such as PMMA and a soft intraocular lens whose optic is made of a flexible material such as silicone elastomer, soft acrylic or hydrogel.

Upon use of a hard intraocular lens, the lens needs to be inserted through an incision having been cut in a cornea or sclera in a width approximately the same as the diameter of the optic of the lens. On the other hand, upon use of a soft intraocular lens, the lens can be inserted through an incision smaller than the diameter of the optic of the lens by folding the optic.

In order to reduce the risk of post-surgery corneal astigmatism or infection, insertion of a lens through a small incision is preferable. Consequently, soft intraocular lenses tend to be preferred now. There are three types of soft intraocular lens: Type 50 whose optic is made of a soft material and supporting portions are made of a hard material such as PMMA (generally, this type of intraocular lens has two thin filament-shaped supporting portions (FIG. 9A); Type 51 whose optic and supporting portions are made of the same soft material (generally, this type of intraocular lens has plate-like supporting portions (FIG. 9B); and Type 52 which has two or more thin plate-like supporting portions (FIG. 9C).

In addition, a dedicated intraocular lens insertion device having a mechanism to lead an intraocular lens to an eye through a slender tube is used in some cases in order to insert intraocular lenses into eyes. By using such an intraocular lens insertion device, an intraocular lens can be inserted through an incision opening smaller than 3 mm.

In recent years, in order to eliminate the possibility of bacterial contamination or operational error in handling intraocular lenses, an intraocular lens insertion device where an intraocular lens is set beforehand and which can be packaged and stored has been developed.

With such an intraocular lens insertion device, however, there was a problem that a supporting portion arranged in the backward direction of a lens advancing axis (hereinafter,

2

referred to as a trailing supporting portion) got caught in the gap between a plunger for pushing out the intraocular lens and an inner wall of a passage of the insertion device or entangled in the plunger in a process of movement of the intraocular lens. Such a problem is brought to the fore especially with a soft intraocular lens having thin filament-shaped supporting portions or a soft intraocular lens having thin plate-like supporting portions.

In such an intraocular lens insertion device, if the trailing supporting portion stretches in a process of movement of the intraocular lens, the trailing supporting portion is left outside of the eye when the lens is inserted through a small incision in the eye. Therefore, after the lens is pushed by the plunger, a repeated operation for inserting the trailing supporting portion into the eye is required, and it takes time and labor in surgery. In some cases, while the intraocular lens is moving inside the intraocular lens insertion device, the optic and the trailing supporting portion interfere with each other, resulting in damage or breakage of the optic or the trailing supporting portion.

Therefore, when an intraocular lens is inserted into an eye using the intraocular lens insertion device, the behavior of the trailing supporting portion of intraocular lens needs to be controlled appropriately in a process of movement of the intraocular lens.

In view of the foregoing problems, a lens insertion tool which has a side clearance provided at the distal end of a plunger for accommodating a trailing supporting portion to prevent damage to the trailing supporting portion has been disclosed (Patent Document 1, for example). A lens insertion tool provided with a relief channel for a trailing supporting portion at the lower side of a plunger has been also disclosed (Patent Document 2, for example). Furthermore, a lens insertion tool wherein a plunger pushes a trailing supporting portion up a ramp and bends haptics up and over IOL has been disclosed (Patent Document 3, for example). Thus, the above-mentioned Patent Documents can reduce getting caught of a trailing supporting portion of intraocular lens having thin filament-shaped or plate-like supporting portions. Patent Document 1: Japanese Translation of PCT International Application No. 11-506357  
Patent Document 2: U.S. Pat. No. 6,733,507  
Patent Document 3: Japanese Unexamined Patent Publication No. 2004-351196

### DISCLOSURE OF THE INVENTION

#### Problems to be Solved by the Invention

The above-mentioned Patent Documents 1 and 2, however, still have a problem that the trailing supporting portion relieved into a clearance at the distal end of plunger or a relief channel for a trailing supporting portion stretches and the trailing supporting portion is left outside of the incision when the intraocular lens is inserted through a small incision of the eye. Especially, an intraocular lens having thin plate-like supporting portions which are made of thick soft members has a problem that it takes time and labor to conduct a repeated operation. In the foregoing Patent Document 3, too, there are concerns that while an intraocular lens is moved further through the nozzle after the haptics are bent up and over IOL, the trailing supporting portion may be compressed into an unexpected shape, causing a breakage of the trailing supporting portion, a trouble during insertion, or a state of the folded trailing supporting portion accommodated in the intraocular lens not returning to a desired shape after insertion into an eye.



3

In view of the foregoing problems, an object of the present invention is to provide an intraocular lens insertion device and an intraocular lens movement control method which can appropriately control the behavior of a trailing supporting portion in a process of movement of the intraocular lens and can reduce the possibility of a repeated operation after insertion of the intraocular lens into an eye.

#### Means for Solving the Problems

The inventor of the present application conducted studies over and over again and found that the above-mentioned object could be achieved by folding an optic and supporting portions individually while minimizing the interference of the optic and the supporting portions during movement of the intraocular lens.

To achieve the above object, the invention according to claim 1 features an intraocular lens insertion device comprising: a lens setting part for setting an intraocular lens having an optic and one or two or more supporting portions disposed at the outer edge of the optic; a plunger for pushing out the intraocular lens set on the lens setting part; and a nozzle for releasing the intraocular lens pushed out by the plunger, the intraocular lens being set on the lens setting part with at least one of the supporting portions being arranged in the backward direction of a lens advancing axis, wherein the plunger includes a lens contact portion for abutting against the outer edge of the optic and a pushing portion for pushing out the supporting portion arranged in the backward direction of the lens advancing axis.

The invention according to claim 2 is characterized in that the pushing portion bends the supporting portion in the forward direction of the lens advancing axis.

The invention according to claim 3 is characterized in that the pushing portion bends the supporting portion in the forward direction of the lens advancing axis without interference of the optic and the supporting portion.

The invention according to claim 4 is characterized in that the pushing portion includes a guide extending in the direction of the lens advancing axis.

The invention according to claim 5 is characterized in that the pushing portion is a groove extending in the direction of the lens advancing axis.

The invention according to claim 6 is characterized in that the pushing portion includes a supporting portion abutting face for abutting against the deformed supporting portion.

The invention according to claim 7 features a method for controlling movement of an intraocular lens, comprising the steps of: setting an intraocular lens having an optic and one or two or more supporting portions disposed at the outer edge of the optic on a lens setting part with at least one of the supporting portions being arranged in the backward direction of a lens advancing axis; and moving the intraocular lens in the forward direction of the lens advancing axis, wherein the moving step includes the steps of: pushing out the supporting portion arranged in the backward direction of the lens advancing axis in the lens moving direction; and pushing out the outer edge of the optic in the forward direction of the lens advancing axis.

The invention according to claim 8 is characterized in that the step of pushing out of the supporting portion comprises a step of bending a tip of the supporting portion in the forward direction of the lens advancing axis.

#### Effect of the Invention

According to the intraocular lens insertion device set forth in claim 1 of the present invention, the pushing portion

4

provided on the plunger moves an intraocular lens forward with the supporting portion being caught, thereby preventing the supporting portion from stretching backward as the intraocular lens is moving forward. Therefore, with this intraocular lens insertion device, the supporting portions can be inserted together with the optic into an eye through an incision at one operation, thereby omitting a repeated operation after the intraocular lens was inserted into the eye.

According to the intraocular lens insertion device set forth in claim 2 of the present invention, the optic and the supporting portion arranged in the backward direction of the lens advancing axis are prevented from being damaged or broken while the intraocular lens is moving.

According to the intraocular lens insertion device set forth in claim 3 of the present invention, the intraocular lens is moved forward with a minimum of interference of the optic and the supporting portion arranged in the backward direction of the lens advancing axis, thereby preventing the optic and the trailing supporting portion from being damaged or broken while the intraocular lens is moving.

According to the intraocular lens insertion device set forth in claim 4 of the present invention, the supporting portion arranged in the backward direction of the lens advancing axis is prevented from dropping off in a process of movement of the intraocular lens, resulting in a more reliable control of the supporting portion.

According to the intraocular lens insertion device set forth in claim 5 of the present invention, the supporting portion arranged in the backward direction of the lens advancing axis is pushed out by the supporting portion abutting face and can be inserted into the eye, thereby ensuring that a repeated operation after insertion of the lens into the eye can be omitted.

According to the intraocular lens insertion device set forth in claim 6 of the present invention, the supporting portion can be caught with a simple configuration.

According to the intraocular lens movement control method set forth in claim 7 of the present invention, the pushing portion provided on the plunger moves the intraocular lens forward with the supporting portion being caught, thereby preventing the supporting portion from stretching as the intraocular lens moves forward. Therefore, the intraocular lens insertion device enables the supporting portions to be inserted together with the optic into an eye through an incision at one operation. Thus, the intraocular lens insertion device can omit a repeated operation after insertion of the intraocular lens into the eye.

According to the intraocular lens movement control method set forth in claim 8 of the present invention, the supporting portion can be more surely prevented from stretching backward as the intraocular lens moves forward.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows the overall configuration of an intraocular lens insertion device of the present invention.

FIG. 2 is a perspective view showing the configuration of a cartridge of the same as above.

FIG. 3 is a perspective view showing the configuration of a main body of the same as above.

FIG. 4 is a partial perspective view showing the configuration of a plunger of the same as above.

FIG. 5A' is a section view showing the intraocular lens insertion device illustrated in FIG. 1 with the plunger abutting against a supporting portion.

FIG. 5A is a section view taken along line A-A in FIG. 5A'.

US 9,907,647 B2

5

FIG. 5B' is a section view showing the intraocular lens insertion device illustrated in FIG. 1 with the plunger catching a supporting portion.

FIG. 5B is a section view taken along line B-B in FIG. 5B'.

FIG. 5C' is a section view showing the intraocular lens insertion device illustrated in FIG. 1 with the plunger abutting against an optic.

FIG. 5C is a section view taken along line C-C in FIG. 5C'.

FIG. 6A' is a section view showing another exemplary intraocular lens insertion device with the plunger abutting against a supporting portion.

FIG. 6A is a section view taken along line A-A in FIG. 6A'.

FIG. 6B' is a section view showing the intraocular lens insertion device illustrated in FIG. 6A' with the plunger catching a supporting portion.

FIG. 6B is a section view taken along line B-B in FIG. 6B'.

FIG. 6C' is a section view showing the intraocular lens insertion device illustrated in FIG. 6A' with the plunger abutting against an optic.

FIG. 6C is a section view taken along line C-C in FIG. 6C'.

FIG. 7 is a view showing a modified example of a plunger of the same as above.

FIG. 8 is a view showing another modified example of a plunger of the same as above.

FIG. 9A is a plan view of an intraocular lens having filament-shaped supporting portions.

FIG. 9B is a plan view of an intraocular lens having a plate-like supporting portion.

FIG. 9C is a plan view of an intraocular lens having thin plate-like supporting portions.

#### BEST MODE FOR CARRYING OUT THE INVENTION

Hereinafter, a preferred embodiment of the present invention will be described with reference to the accompanying drawings.

#### 1. Embodiment

##### (1) General Structure

An intraocular lens insertion device 1 shown in FIG. 1 has a cartridge 2, a main body 3 and a plunger 4. The cartridge 2 is installed to the main body 3 after an intraocular lens 5 is set on the cartridge. On the other hand, the plunger 4 is provided so that it can move in the forward and backward directions of the lens advancing axis A inside the main body 3. The intraocular lens insertion device 1 having such a configuration is generally configured to push out the intraocular lens 5 set in the cartridge 2 by using the plunger 4 and to release the intraocular lens 5 from the end of the cartridge 2 into an eye.

For reference's sake, an intraocular lens insertion device 1 may be made of various materials. For example, synthetic resin may be used for all portions of the tool, thereby allowing easy mass production; or metal such as titanium may be used. The intraocular lens 5 also has an optic 6 and a pair of thin plate-like supporting portions (sometimes referred to as "loop haptics") 7a,7b disposed at the outer edge of the optic 6.

6

Hereinafter, each configuration will be described in detail. In the description below, the forward direction of the lens advancing axis A is simply referred to as "forward" and the backward direction of the lens advancing axis A is simply referred to as "backward".

As shown in FIG. 2, the cartridge 2 comprises: a cartridge main body 14 having an insertion opening 10, a lens setting part 11, a transition part 12 and a nozzle 13 in the order along the lens advancing axis A; and wing portions 15,15 extending from both sides of the cartridge main body 14. At the insertion opening 10, an insertion groove 16 which was formed by notching in the direction of the lens advancing axis A is provided. In the forward direction of the lens advancing axis A of the insertion opening 10, a lens setting part 11 is provided. In the forward direction of the lens advancing axis A of the lens setting part 11, the transition part 12 is provided. The inner wall of the transition part 12 has a mortar shape tapering toward the distal end and communicates with a nozzle 13 at the distal end. With this configuration, the cartridge main body 14 is formed so that it can move from the lens setting part 11 to the transition part 12, and then, from the transition part 12 to the nozzle 13 when the intraocular lens 5 mounted on the lens setting part 11 through the insertion opening 10 is pushed by the plunger 4. The nozzle 13 is formed so that it has an outside diameter sized to be inserted into the incision opening (not shown). The bore of the cartridge 2 is formed so that it has an oval shape at the insertion opening 10, converging into a perfect circle toward the proximal end of the nozzle 13.

As shown in FIG. 3, the main body 3 comprises an attachment portion 20 for removably attaching the cartridge 2, a flange 21 for locking the fingers of the operator, and a tubular body 24 connecting the attachment portion 20 and the flange 21. The attachment portion 20 is provided at the distal end of the main body 3 formed into a semicircle shape and comprises guide passages 22,22 for guiding the wing portions 15,15 of the cartridge 2 and locking pieces 23,23 provided forward of the lens advancing axis A of the guide passages 22,22. The locking pieces 23,23 are configured so that it can lock the front ends of the wing portions 15,15 of the cartridge 2. The flange 21 is provided on the outer surface of the proximal end of the main body 3.

Next, a plunger 4 which is a characteristic component of the present invention will be described in detail. As shown in FIG. 1, the plunger 4 comprises a pushing rod 30 for pushing out the intraocular lens 5, a pressing portion 31 provided at the proximal end of the pushing rod 30 and a lens contact portion 32 provided at the distal end of the pushing rod 30. This plunger 4 is installed into the main body 3 in such a manner as to move forward or backward along the lens advancing axis A inside the main body 3. The plunger 4 installed into the main body 3 is configured so that the operator can push out the intraocular lens 5 by pushing the pressing portion 31 and bringing the lens contact portion 32 into contact with the intraocular lens 5 mounted on the lens setting part 11.

As shown in FIG. 4, the plunger has a lens contact portion 32 and a pushing portion 33 connected to the lens contact portion 32 at the distal end of the pushing rod 30.

The lens contact portion 32 is formed by a vertical plane relative to the lens advancing axis A. The pushing portion 33 catches the supporting portion (hereinafter referred to as the trailing supporting portion) 7b arranged in the backward direction of the lens advancing axis A and moves the trailing supporting portion 7b together with the optic 6 without separating from the optic 6. The pushing portion 33 is provided on one side of the lens contact portion 32 and

7

comprises a groove 34 extending in the backward direction from the distal end of the pushing rod 30, guides 35,35 provided on both sides of the groove 34 in parallel with the lens advancing axis A, and a supporting portion abutting face 36. In this embodiment, the groove 34 has a concave bottom face and connects to the guides 35,35 at the opening end of the side face 34b converging from the opening toward the bottom face 34a. These guides 35,35 are provided at both sides of the groove 34 and formed into a columnar shape, and their ends form part of the lens contact portion 32. The supporting portion abutting face 36 is provided so that a deformed trailing supporting portion 7b can abut against it. This supporting portion abutting face 36 is formed with a plane which slants backward as it goes upward from the surface of the groove 34, and blocks the backward end of the groove 34.

The plunger 4 having such a configuration is attached to the main body 3, as shown in FIG. 1, by inserting the lens contact portion 32, first, in the proximal end of the main body 3 and by positioning the lens contact portion 32 at the distal end of the main body 3 and the pressing portion 31 at the proximal end of the main body 3.

## (2) Operation and Effect

Next, the operation and effect of the above-mentioned intraocular lens insertion device 1 will be described with reference to the accompanying drawings. FIGS. 5A'-5C' are sectional views of the vicinity of the lens setting part 11 of the cartridge 2, and FIGS. 5A-5C are cross-sections of FIGS. 5A'-5C'.

First, the intraocular lens 5 folded into two by use of tweezers (not shown) is inserted through the insertion opening 10, and then the intraocular lens 5 is set on the lens setting part 11 of the cartridge 2 pre-filled with ophthalmic viscoelastic material. At this time, the intraocular lens 5 is set with a pair of supporting portions 7a,7b arranged in the forward and backward directions, respectively, relative to the optic 6 (FIGS. 5A and 5A'). The intraocular lens 5 is positioned with the folded optic 6 arranged on one side and the proximal ends of the supporting portions 7a,7b arranged on the other side, respectively. The tips of the supporting portions 7a,7b hang down on one side as they move in the forward and backward directions across the optic 6, respectively. Furthermore, the intraocular lens 5 which is folded into two comes into contact with the bore of the cartridge 2 formed into an oval shape, and accordingly, the supporting portions 7a,7b are arranged along the side wall of the bore.

Next, the cartridge 2 having the intraocular lens 5 mounted on the lens setting part 11 is attached to the attachment portion 20 of the main body 3 by sliding forward of the lens advancing axis A with the wing portions 15,15 mounted on the guide passages 22,22 and locking the front ends of the wing portions 15,15 with the locking pieces 23,23.

After the cartridge 2 is attached to the main body 3, the nozzle portion 13 is first inserted into an eye through the incision opening (not shown) by the operator.

On the other hand, the plunger 4 moves forward when the operator pushes the pressing portion 31. When the plunger 4 moves forward, the lens contact portion 32 provided at the distal end of the pushing rod 30 comes in contact with the tip of the trailing supporting portion 7b (FIGS. 5A and 5A'). At this time, the trailing supporting portion 7b is positioned along the bore of the cartridge 2 and comes in contact with the trailing supporting portion 7b at the distal end of the guides 35,35.

8

Furthermore, when the plunger 4 is pushed and the lens contact portion 32 moves forward, the trailing supporting portion 7b which is hanging down to one side is bent at its tip in the forward direction (FIGS. 5B and 5B'). At the same time, the trailing supporting portion 7b is guided into the central groove 34 by the side face 34b converging from the opening toward the bottom face 34a. In this way, the pushing portion 33 catches the trailing supporting portion 7b by supporting the tip of the trailing supporting portion 7b from one side by the groove 34.

The plunger 4, by which the trailing supporting portion 7b was caught at the pushing portion 33, is pushed further, and the lens contact portion 32 abuts against the outer edge of the intraocular lens 5 and moves the intraocular lens 5 forward (FIGS. 5C and 5C'). The intraocular lens 5 moving in the cartridge 2 is pushed inward by the inner wall of the transition part 12 and folded to a smaller size. In this way, the intraocular lens insertion device 1 releases the compactly folded intraocular lens 5 from the tip of the nozzle 13.

In the conventional intraocular lens insertion device 1, as the intraocular lens 5 moves forward, the trailing supporting portion 7b stretches backward. Therefore, by using the conventional intraocular lens insertion device 1, the trailing supporting portion 7b is left outside of the incision when the intraocular lens 5 is inserted through a small incision of an eye, and a repeated operation was needed to insert the trailing supporting portion 7b left outside of the incision into the incision.

In contrast, in the intraocular lens insertion device 1 according to this embodiment, the pushing portion 33 provided on the plunger 4 moves the intraocular lens 5 forward with the trailing supporting portion 7b being caught, thereby preventing the trailing supporting portion 7b from stretching backward as the intraocular lens 5 moves forward. Thus, the intraocular lens insertion device 1 allows the pushing portion 33 to move the intraocular lens 5 without separating the trailing supporting portion 7b from the optic 6 and enables the trailing supporting portion 7b and the optic 6 to be inserted into the eye through the incision at one operation. Therefore, the intraocular lens insertion device 1 can omit a repeated operation after the intraocular lens 5 was inserted into the eye.

In addition, the supporting portion abutting face 36 abuts against the trailing supporting portion 7b. By pushing out the trailing supporting portion 7b by the supporting portion abutting face 36, the trailing supporting portion 7b can be inserted into the eye. Thus, the intraocular lens insertion device 1 can omit a repeated operation more surely after the intraocular lens 5 was inserted into the eye.

As mentioned above, the plunger 4 is provided with a pushing portion 33 for pushing out the trailing supporting portion 7b, besides a lens contact portion 32, thereby folding the trailing supporting portion 7b and the optic 6, separately. Therefore, the intraocular lens insertion device 1 can move the intraocular lens 5 forward, keeping interference of the trailing supporting portion 7b and the optic 6 at a minimum level. Thus, the intraocular lens insertion device 1 can reduce interference of the optic 6 and the trailing supporting portion 7b during movement of the intraocular lens 5, thereby preventing the optic 6 and the trailing supporting portion 7b from being damaged or broken.

As mentioned above, in this embodiment, the guides 35,35 are formed into a columnar shape, and they can guide the trailing supporting portion 7b in contact with the distal ends of the guides 35,35 to the groove 34 without causing damage.

This pushing portion **33** is formed by the groove **34**, thereby catching the trailing supporting portion **7b** with such a simple structure. Also, the groove **34** has a concave bottom face and can guide the trailing supporting portion **7b** in contact with the guides **35,35** smoothly in the groove **34** in the center.

In addition, the bottom face of the groove **34** on the pushing portion **33** is formed by a concave face, thereby catching the trailing supporting portion **7b** guided to the groove **34** without causing damage.

Furthermore, as the pushing portion **33** is provided with the guides **35,35**, it can prevent the caught trailing supporting portion **7b** from falling off in the process of movement of the intraocular lens **5** and control the trailing supporting portion **7b** with more reliability.

## 2. Modified Example of Cartridge

The difference between the cartridge **40** shown in FIGS. **6A-6C'** and the above embodiment lies in only the bore shape. With regard to this cartridge **40**, when the side of the bore where the optic **6** of the intraocular lens **5** folded into two is placed is regarded as one side **12a**, the other side **12b** has a smaller width compared to the one side **12a**. FIGS. **6A'-6C'** are sectional views of the vicinity of the lens setting part **11** on the cartridge **40** and FIGS. **6A-6C** are cross-sections of FIGS. **6A'-6C'**.

In this modified example, when the operator pushes the pressing portion **31**, the plunger **4** moves forward and the lens contact portion **32** provided at the distal end of the pushing rod **30** abuts against the tip of the trailing supporting portion **7b** (FIGS. **6A** and **6A'**). The trailing supporting portion **7b** is pushed by the inner wall of the other side **12b** in the bore of the cartridge **40** having a smaller width compared with the one side **12a** which is the side of the optic **6** of the intraocular lens **5** placed on the cartridge and is placed in the vicinity of the center of the bore. As a result, the trailing supporting portion **7b** comes in contact with the center of the pushing portion **33**, that is, the groove **34**.

When the plunger **4** is pushed further and the lens contact portion **32** moves forward, the trailing supporting portion **7b** hanging down to the one side **12a** is bent in the forward direction at its tip (FIGS. **6B** and **6B'**). At the same time, the trailing supporting portion **7b** is guided into the groove **34** in the center by the side face **34b** converging from the opening toward the bottom face **34a**. In this way, the pushing portion **33** catches the trailing supporting portion **7b** by supporting the tip of the trailing supporting portion **7b** from the one side **12a** by the groove **34**.

When the plunger **4** which caught the trailing supporting portion **7b** at the pushing portion **33** is further pushed, the lens contact portion **32** abuts against the outer edge of the intraocular lens **5** and the intraocular lens **5** is moved forward (FIGS. **6C** and **6C'**). In this way, the cartridge **40** according to this modified example has a bore whose width of the other side **2b** is smaller than that of the one side **12a**, allowing the trailing supporting portion **7b** to be guided to the groove **34** in the center more easily than the above embodiment.

## 3. Modified Example of Plunger

The plunger **4** shown in FIG. **7** is different from the above embodiment in the structure of a pushing portion. More specifically, the pushing portion **50** according to this modified example is formed into a rectangular parallelepiped shape defined by a groove **51** and guides **52,52** integrally set

up on both sides of the groove **34**. The distal ends of the guides **52,52** form part of the lens contact portion **32**. The bottom face **51a** of the groove **51** is formed by a flat plane, and a pair of guides **52,52** formed on both sides of the groove **51** have a rectangular parallelepiped shape. The corners of these guides **52,52** are processed into round shape. Though this modified example has a simple shape compared to the above embodiment, it has an effect of omitting a repeated operation after the intraocular lens **5** is inserted into an eye.

In addition, the plunger **60** shown in FIG. **8** is provided with a scooping face **61** at the lens contact portion **32** on the pushing portion **50** shown in FIG. **7**. Providing such a scooping face **61** at the lens contact portion **32** can prevent the distal end of the plunger **4** from running on the optic **6** in the process of movement of the intraocular lens **5**. In this modified example, the same effect as the above embodiment can be obtained by providing the pushing portion **50**.

The present invention is not limited to the embodiment described above, and various modifications can be made thereto within the scope of the present invention. For example, in the above-mentioned embodiment, the transition part of the main body has a mortar shape tapering toward the distal end, and the intraocular lens **5** is folded into a small size by passing through the transition part. The present invention, however, is not limited to this embodiment, but applies to the main body having a simple cylindrical transition part.

According to the above-mentioned embodiment, the supporting portions are thin plates. The present invention, however, is not limited to this embodiment, but applies to an intraocular lens having thin filament-shaped supporting portions.

The invention claimed is:

1. A method of operating an insertion device including a main body, a nozzle, and a tapered transition portion proximal of the nozzle, the method comprising the steps of:
  - applying force to an intraocular lens, located within the main body and having an optic, a leading loop haptic with a fixed end at the optic and a free end, and a trailing loop haptic with a fixed end at the optic and a free end, with a plunger, including a distal portion with a lens contact surface and a slot that extends proximally from the lens contact surface, in such a manner that a portion of the trailing loop haptic is located within the slot while being bent toward the nozzle by the distal portion and the free end of the trailing loop haptic points toward the nozzle; and
  - pushing the intraocular lens into the nozzle with the plunger.
2. A method as claimed in claim 1, wherein the trailing loop haptic is in an unbent state prior to force being applied with the plunger.
3. A method as claimed in claim 1, wherein the main body and nozzle of the insertion device define a lens advancing axis; and the free end of the trailing loop haptic is located on the lens advancing axis when pointing toward the nozzle.
4. A method as claimed in claim 1, wherein the main body and nozzle of the insertion device define a lens advancing axis; and the distal portion with the lens contact surface and the slot has an outer surface that defines a non-circular shape in a cross-section that is perpendicular to the lens advancing axis.

US 9,907,647 B2

**11**

- 5. A method as claimed in claim 1, wherein the trailing and leading loop haptics comprise filament shaped loop haptics.
- 6. A method as claimed in claim 1, wherein the trailing and leading loop haptics comprise thin plate loop haptics.
- 7. A method as claimed in claim 1, wherein the distal portion of the plunger includes a scoop projecting from the lens contact surface.
- 8. A method as claimed in claim 1, further comprising the step of:
  - 10 folding the optic prior to applying force to the intraocular lens with a plunger.
- 9. A method as claimed in claim 8, wherein the main body and nozzle of the insertion device are part of a cartridge;
  - 15 the method further comprises the step of placing the intraocular lens with the folded optic into the cartridge prior to applying force to the intraocular lens with a plunger.
- 10. A method as claimed in claim 1, wherein the main body and nozzle of the insertion device define a lens advancing axis; and the slot comprises an elongate slot that is located on the lens advancing axis.
- 11. A method as claimed in claim 1, wherein at least a portion of the trailing haptic is bent into a U-shape when the trailing loop haptic is located within

**12**

- the slot and the free end of the trailing loop haptic points toward the nozzle.
- 12. A method of operating an insertion device including a main body and a nozzle, the method comprising the step of:
  - 5 applying force to an intraocular lens, located within the main body and having an optic, a leading loop haptic with a fixed end at the optic and a free end, and a trailing loop haptic with a fixed end at the optic and a free end, with a plunger, including a distal portion with a lens contact surface and an elongate slot that extends proximally from the lens contact surface, in such a manner that a portion of the trailing loop haptic is located within the elongate slot while being bent toward the nozzle by the distal portion and the free end of the trailing loop haptic points toward the nozzle prior to the lens contact surface contacting the optic.
- 13. A method as claimed in claim 12, further comprising
  - 20 the step of:
    - engaging the optic with the lens contact surface after the trailing loop haptic is located within the elongate slot and the free end of the trailing loop haptic points toward the nozzle.

\* \* \* \* \*

# **EXHIBIT 6**

(12) **United States Patent**  
**Kudo et al.**

(10) **Patent No.:** **US 10,039,668 B2**  
 (45) **Date of Patent:** **Aug. 7, 2018**

(54) **OCULAR IMPLANT INSERTION APPARATUS AND METHODS**

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/071,880**

(22) Filed: **Mar. 16, 2016**

(65) **Prior Publication Data**

US 2016/0193038 A1 Jul. 7, 2016

**Related U.S. Application Data**

(63) Continuation of application No. 14/145,846, filed on Dec. 31, 2013, now Pat. No. 9,314,373, which is a (Continued)

(30) **Foreign Application Priority Data**

Jun. 10, 2010 (JP) ..... 2010-132952

(51) **Int. Cl.**  
**A61F 2/16** (2006.01)  
**A61F 9/00** (2006.01)  
 (Continued)

(52) **U.S. Cl.**  
 CPC ..... **A61F 9/0017** (2013.01); **A61F 2/148** (2013.01); **A61F 2/167** (2013.01); **A61F 2/1667** (2013.01); **A61F 9/0008** (2013.01); **A61F 2/0095** (2013.01); **A61F 2/1678** (2013.01); **A61F 2/1691** (2013.01); **A61F 2002/1681** (2013.01)

(58) **Field of Classification Search**

CPC ..... A61F 2/148; A61F 9/0008; A61F 2/167; A61F 2/1662

See application file for complete search history.

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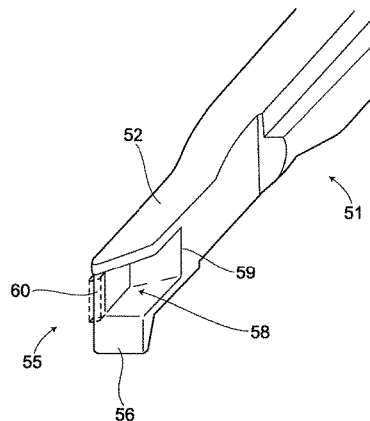
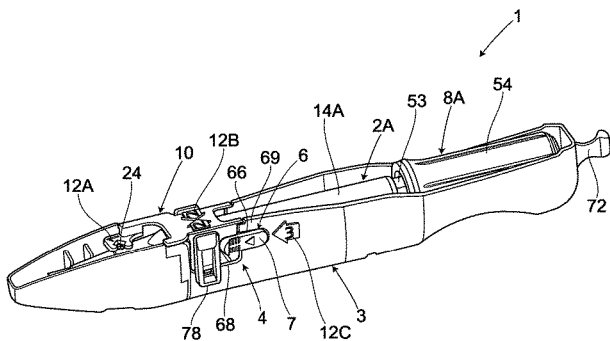
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(57) **ABSTRACT**

An exemplary ocular implant insertion system includes a case and a preloaded ocular implant insertion apparatus. The apparatus includes first and second movable structures that move the ocular implant in a predetermined sequence. The respective configurations of the case and the ocular implant insertion apparatus are such that the ocular implant insertion apparatus is not removable from the case when the ocular implant insertion apparatus is in the pre-use state and is removable after the first movable structure has moved at least a portion of the optical implant.

**17 Claims, 12 Drawing Sheets**



## US 10,039,668 B2

Page 2

**Related U.S. Application Data**

continuation of application No. 13/699,708, filed as application No. PCT/JP2011/063747 on Jun. 8, 2011, now Pat. No. 8,647,382.

(51) **Int. Cl.**

*A61F 2/14* (2006.01)  
*A61F 2/00* (2006.01)

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Page 4

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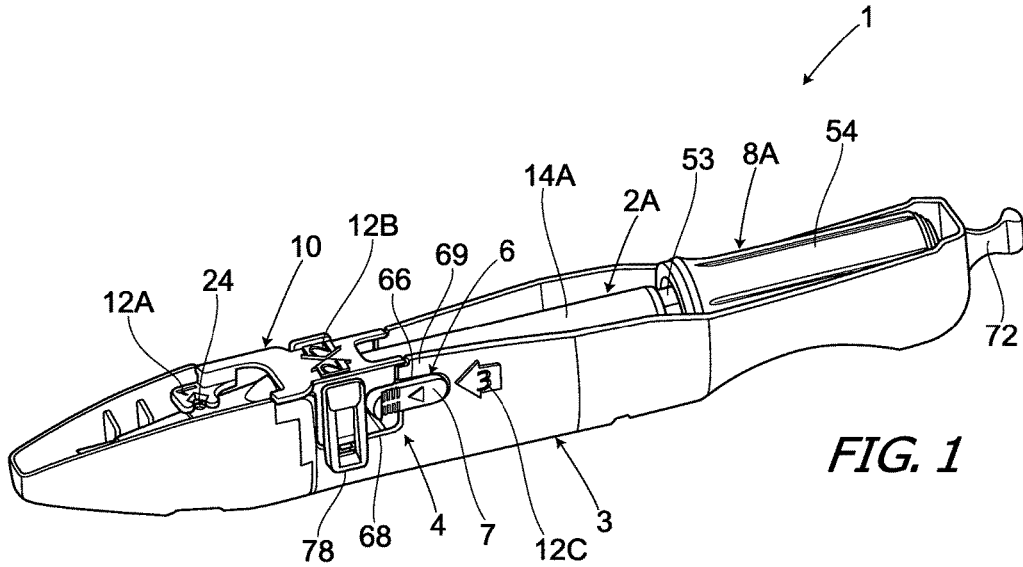


FIG. 1

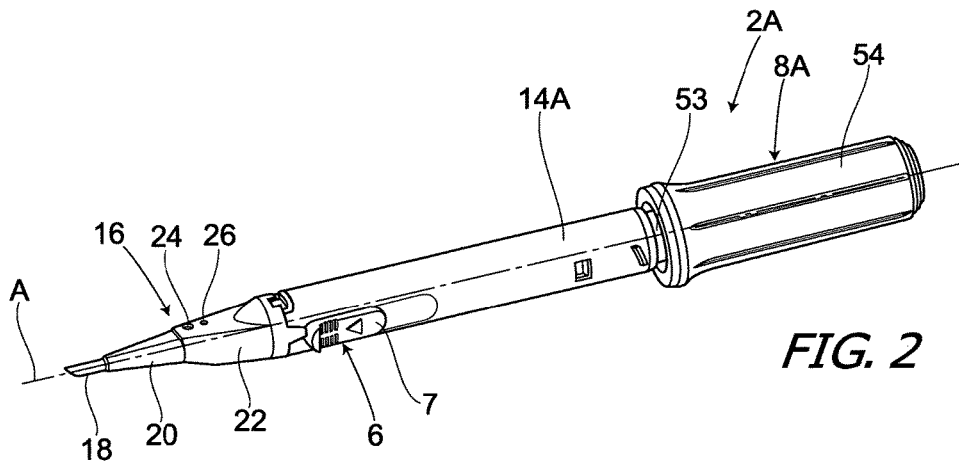


FIG. 2

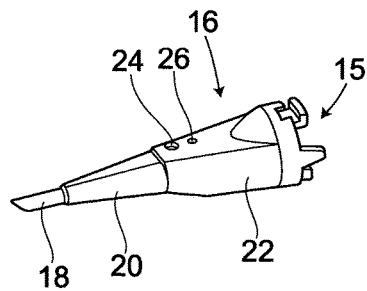
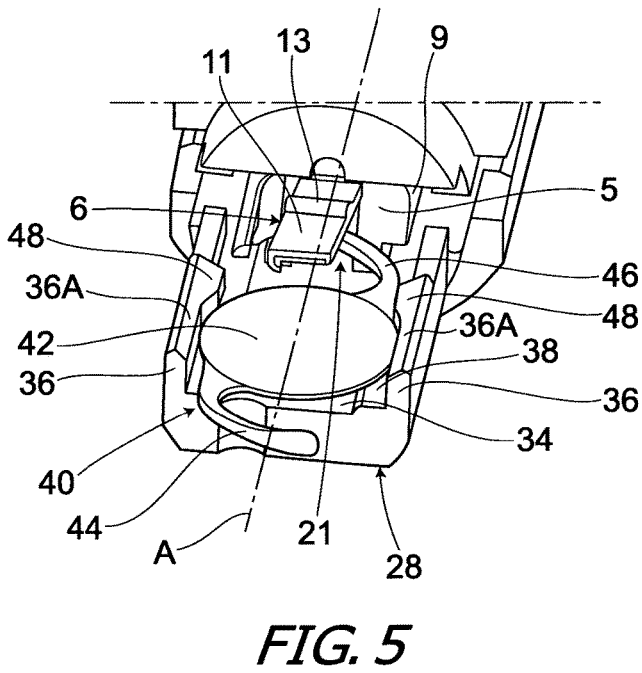
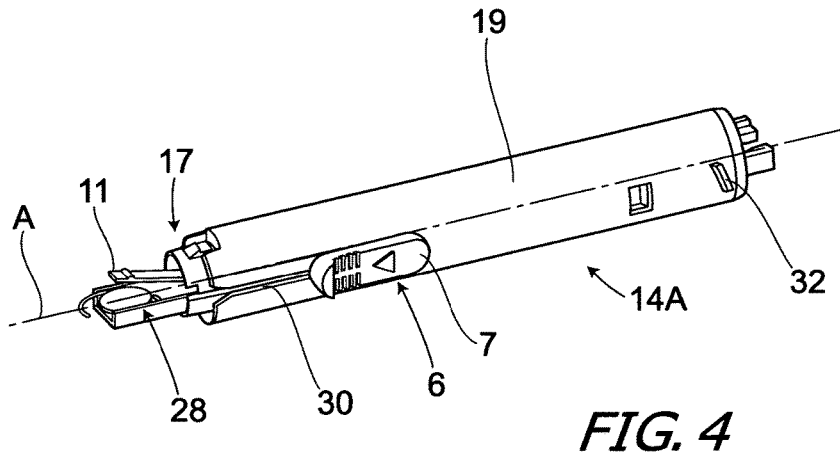


FIG. 3



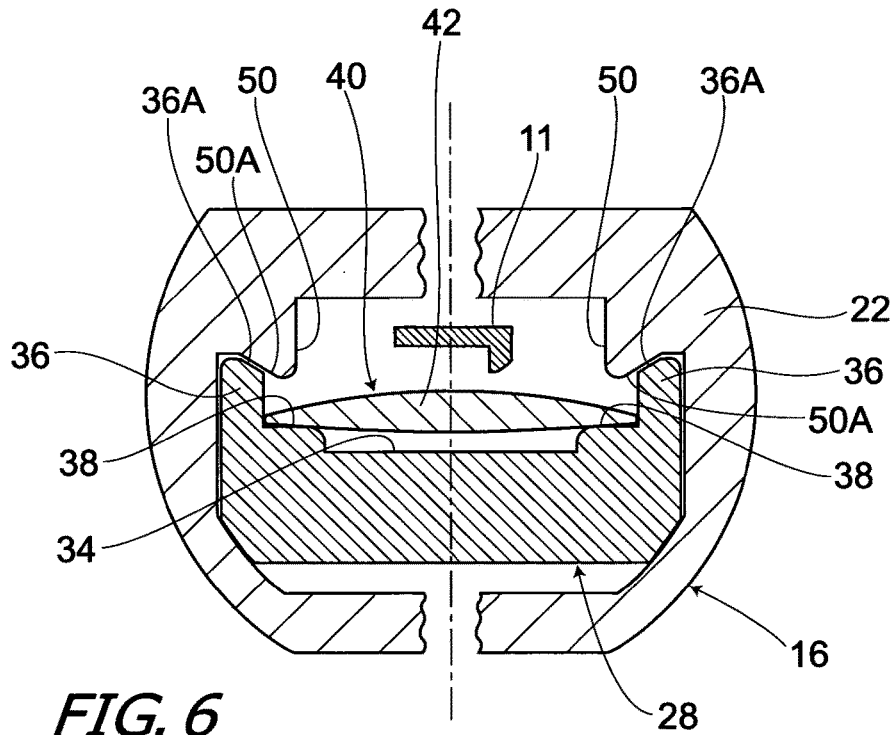


FIG. 6

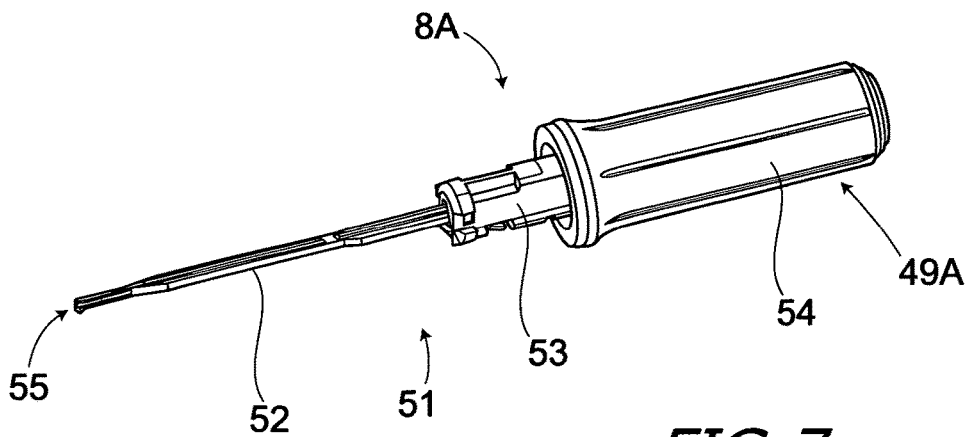
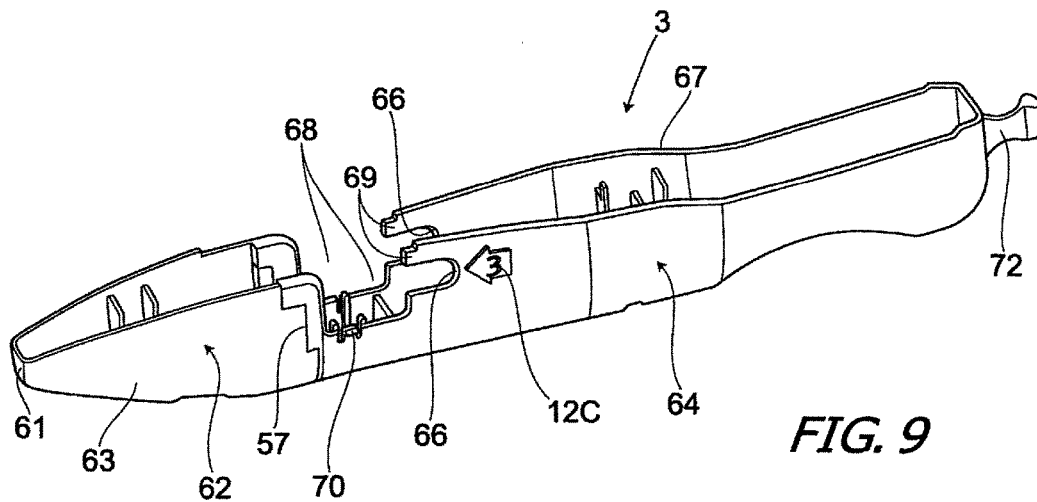
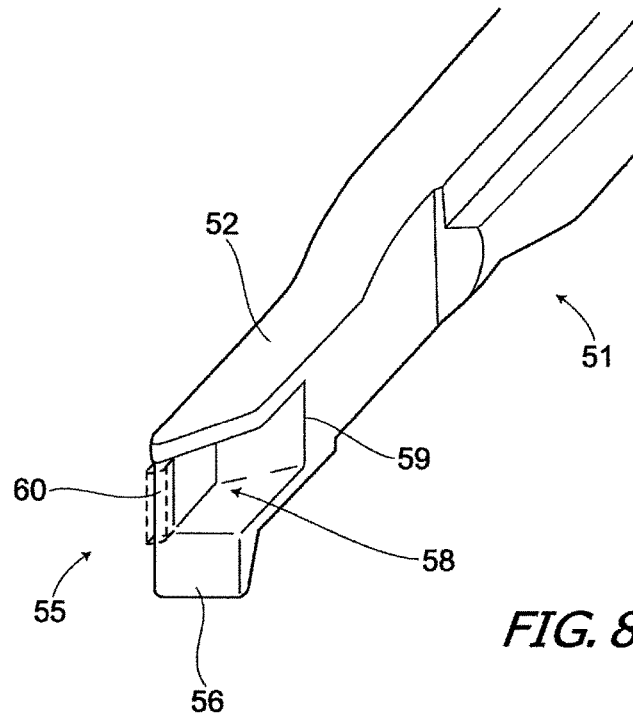
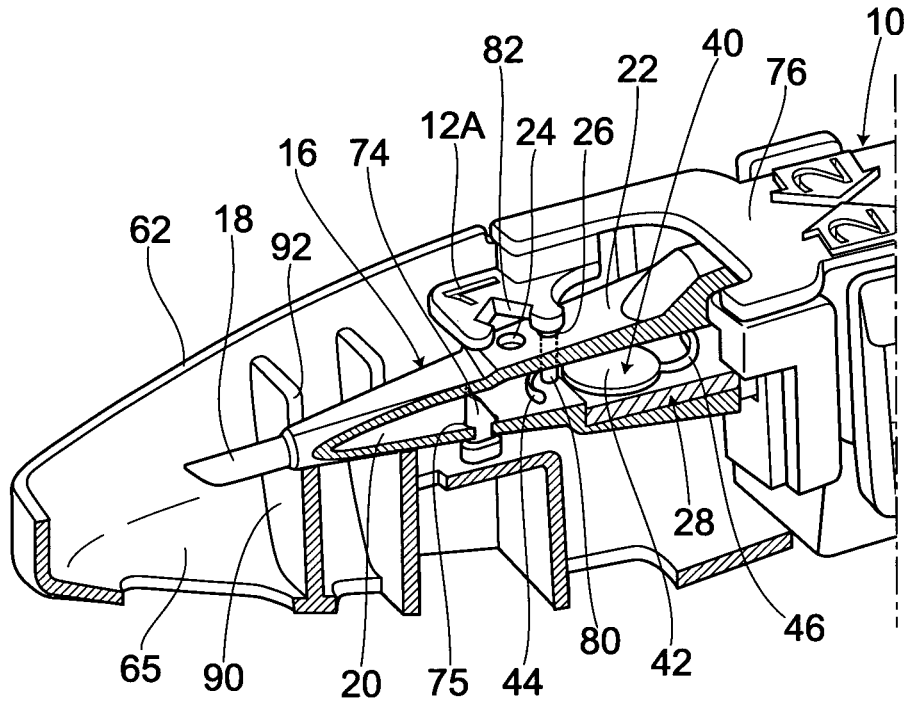
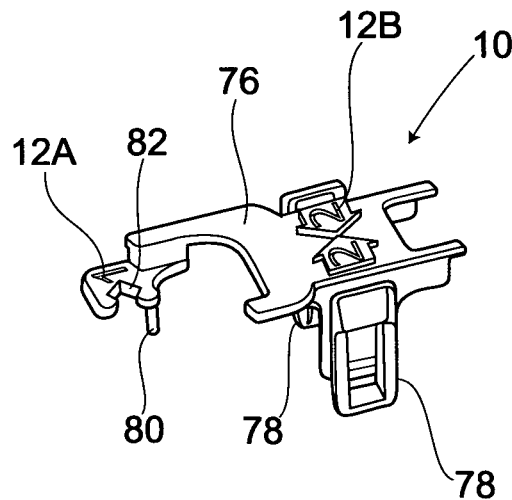


FIG. 7





**FIG. 10**



**FIG. 11**

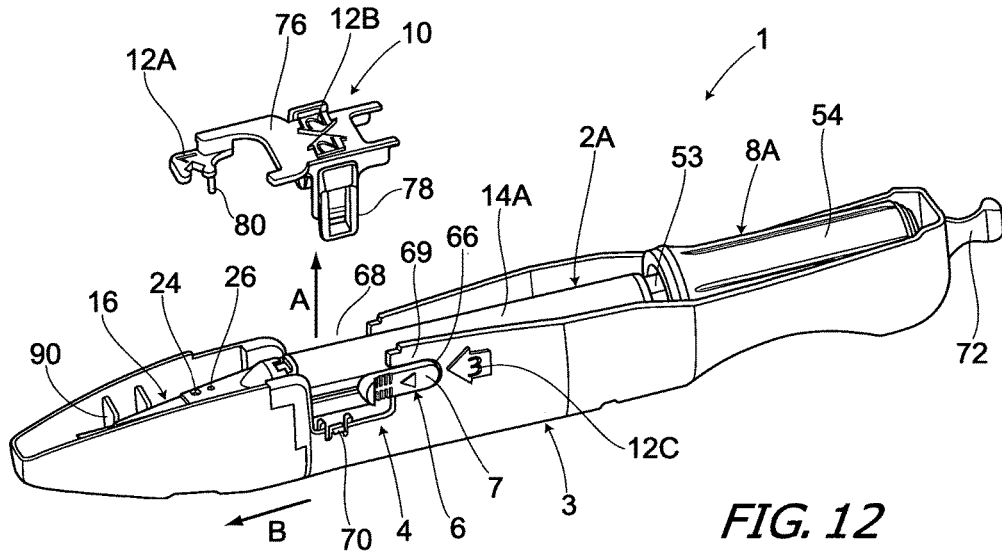


FIG. 12

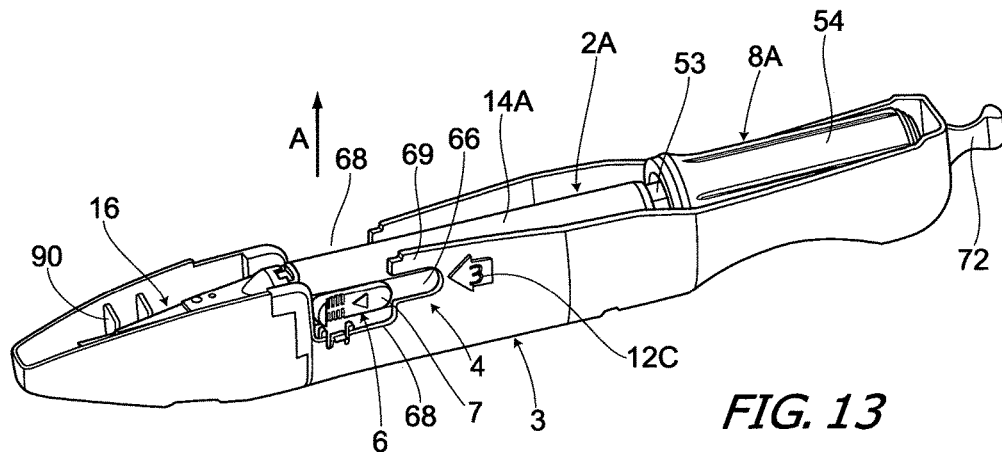
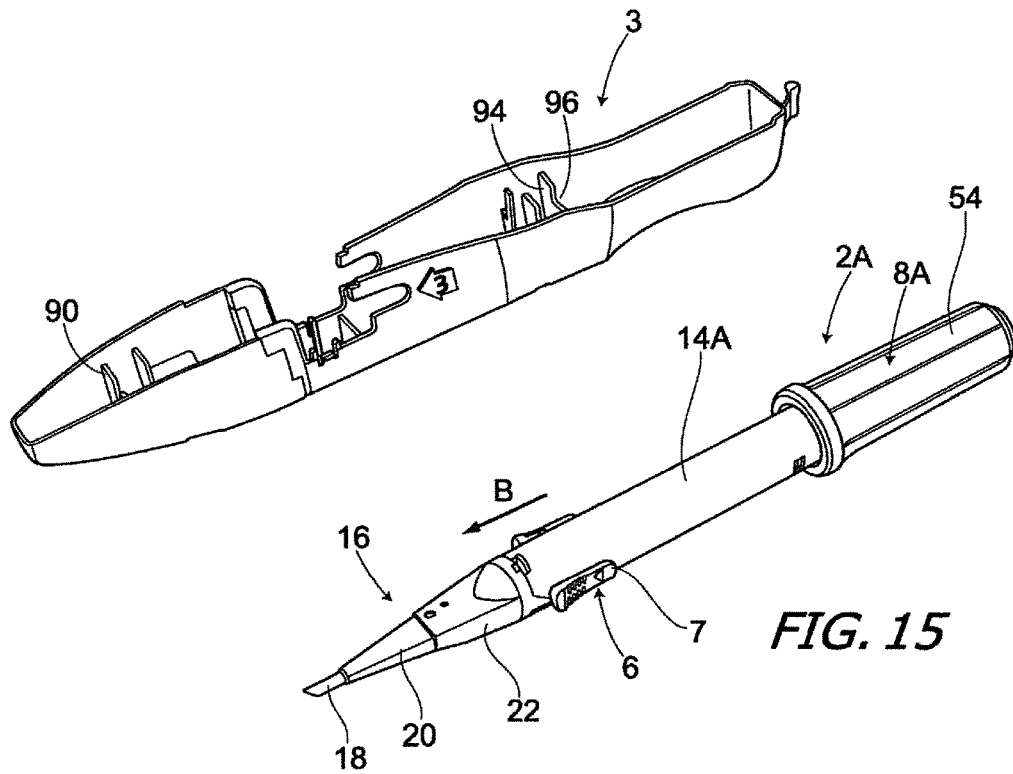
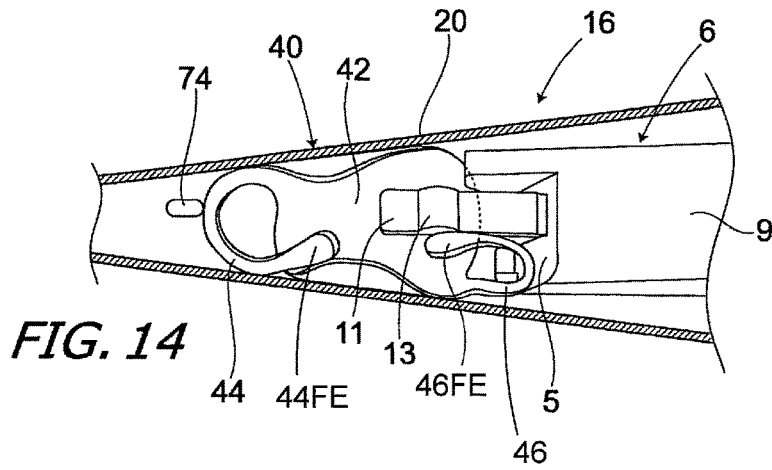


FIG. 13





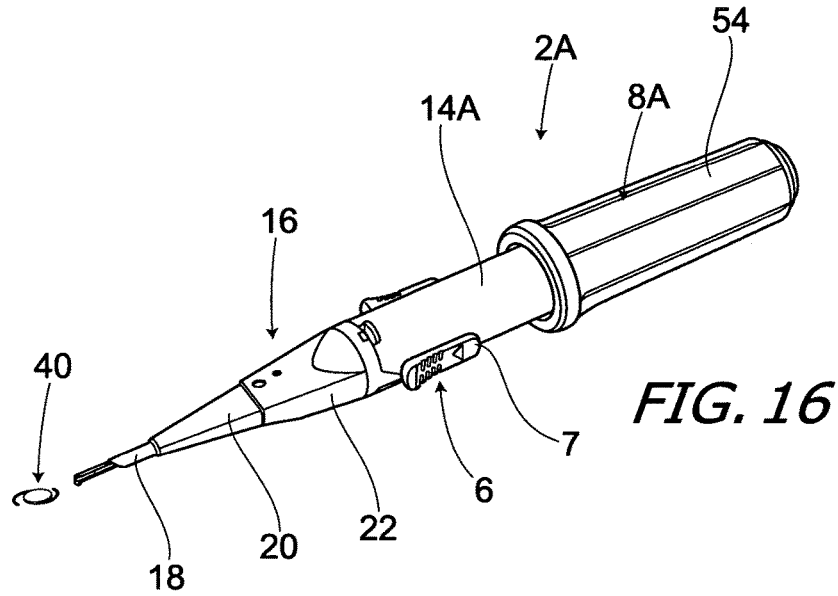


FIG. 16

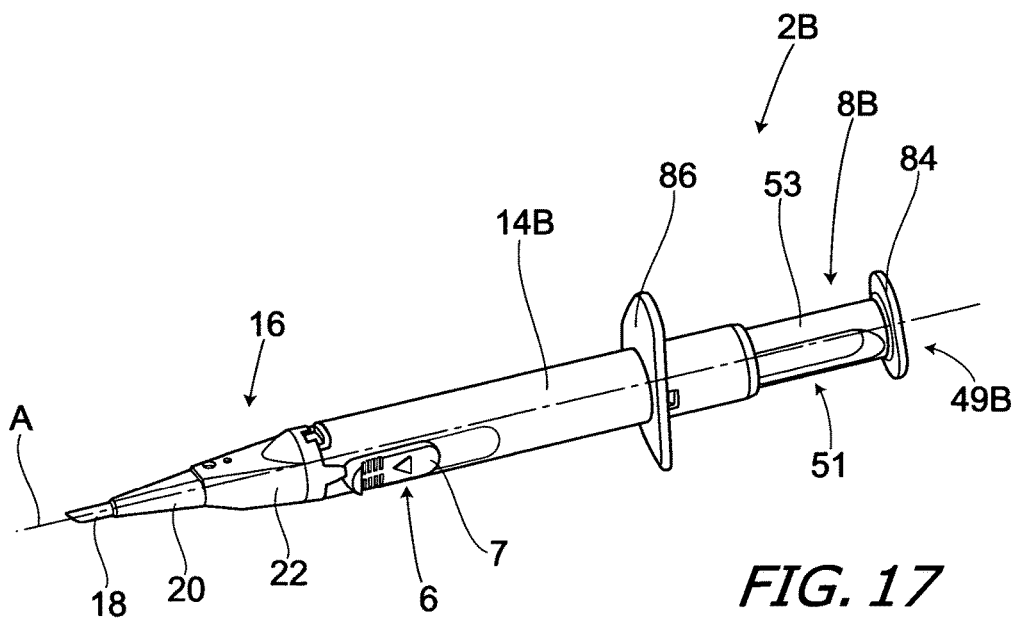
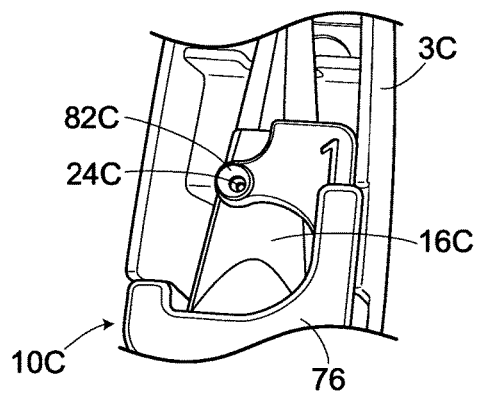
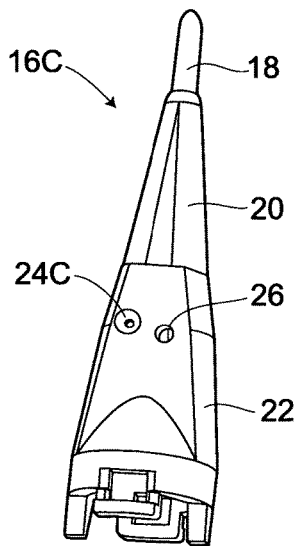
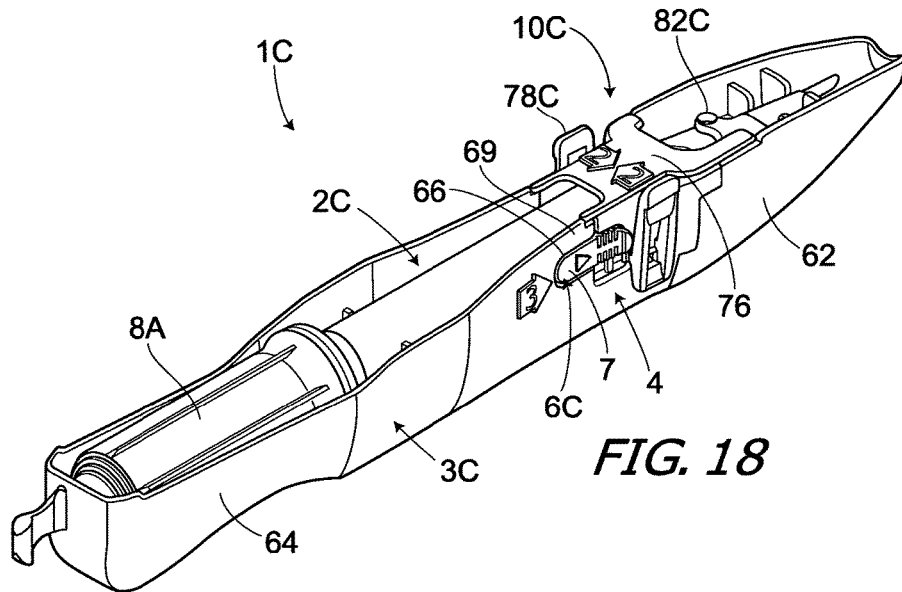
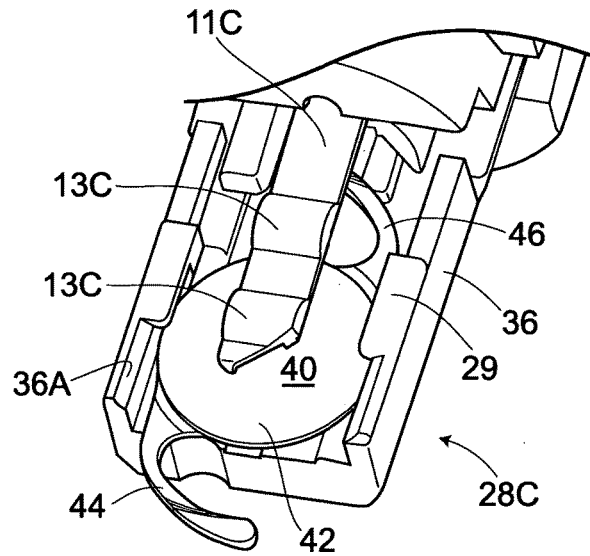
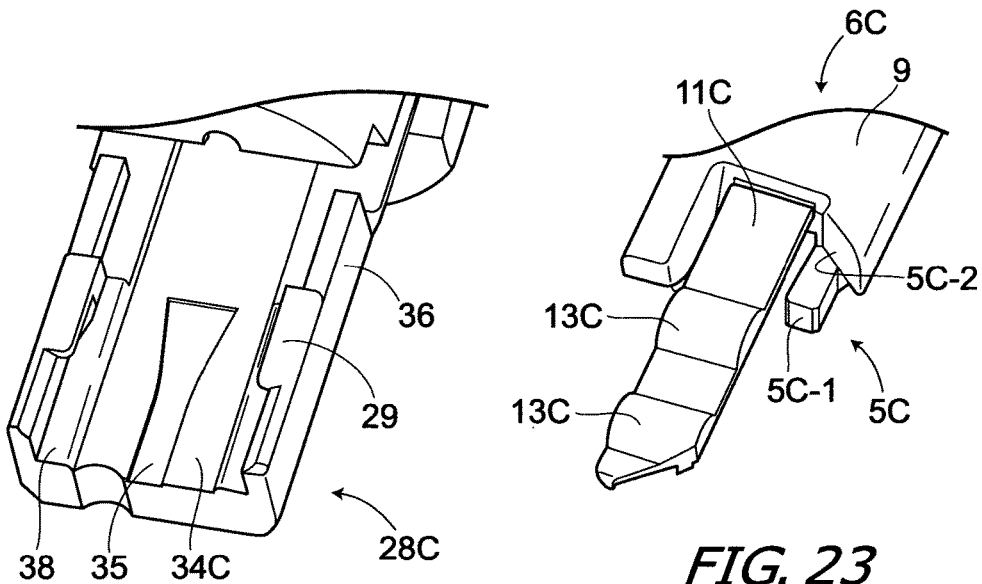


FIG. 17



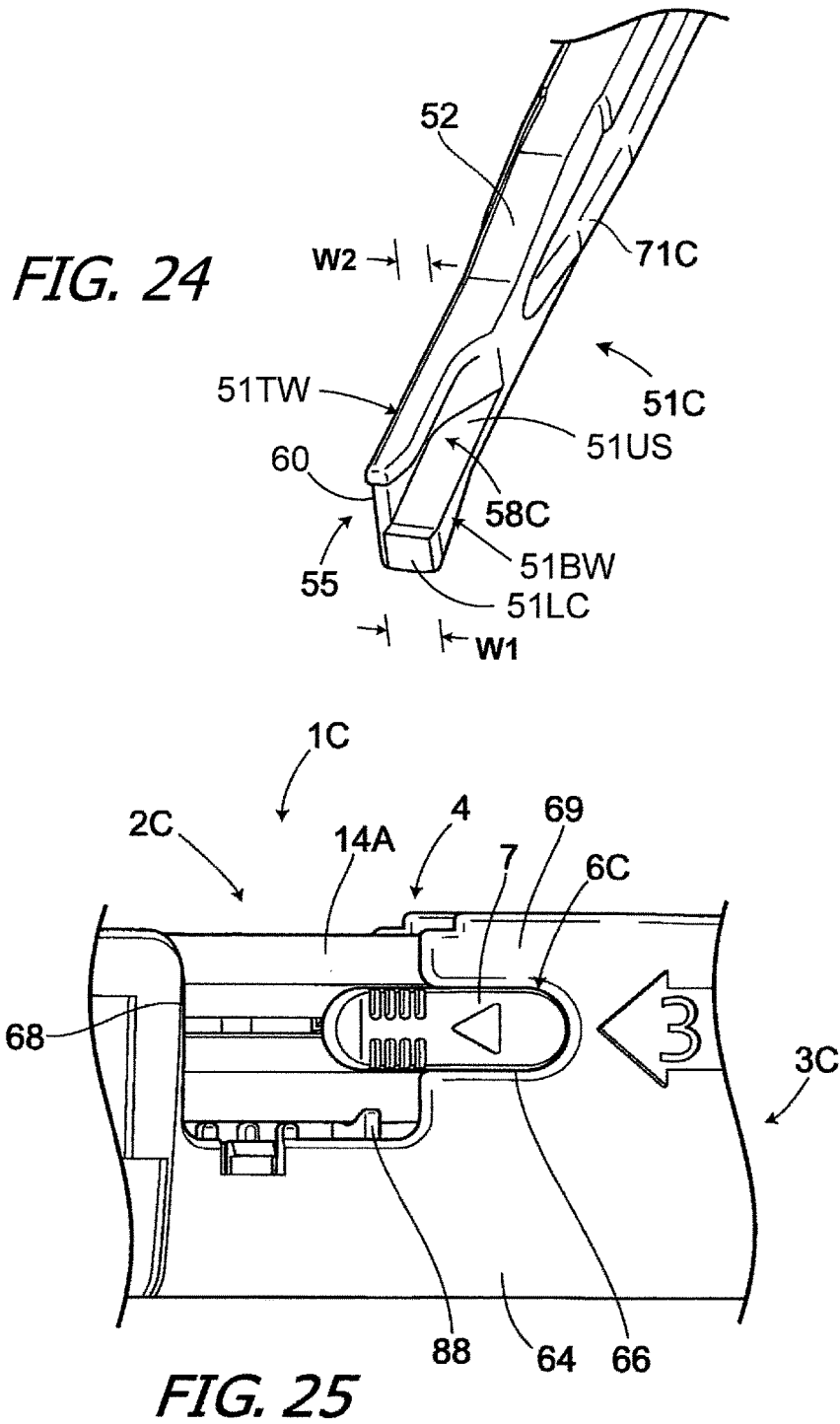


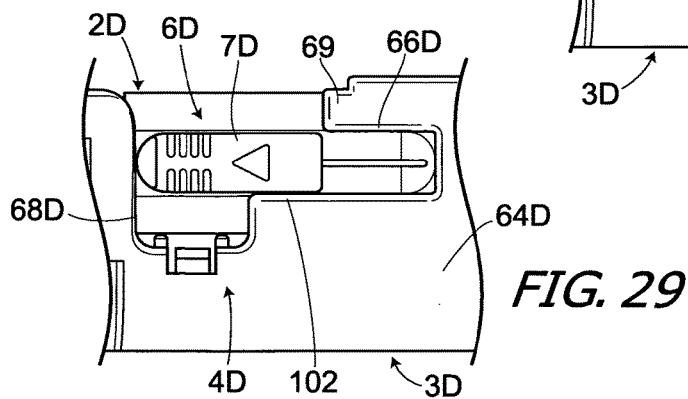
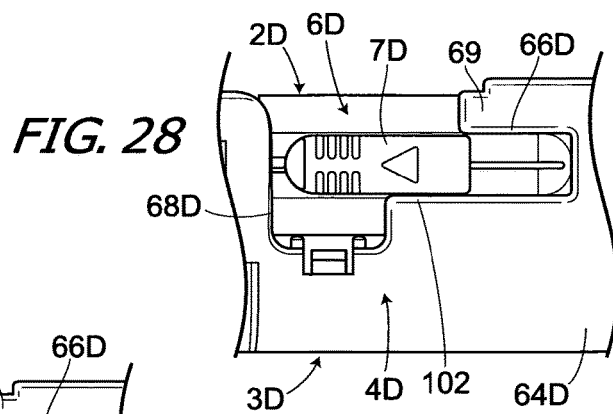
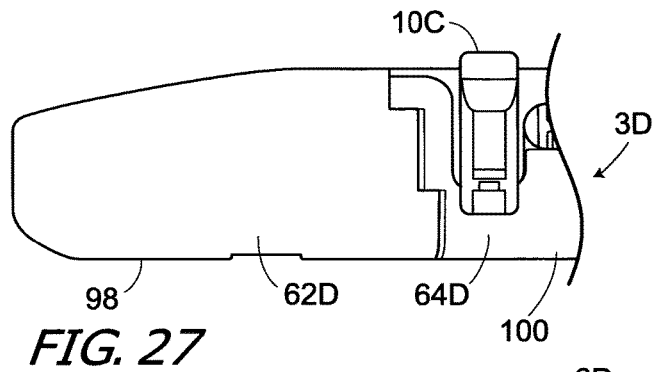
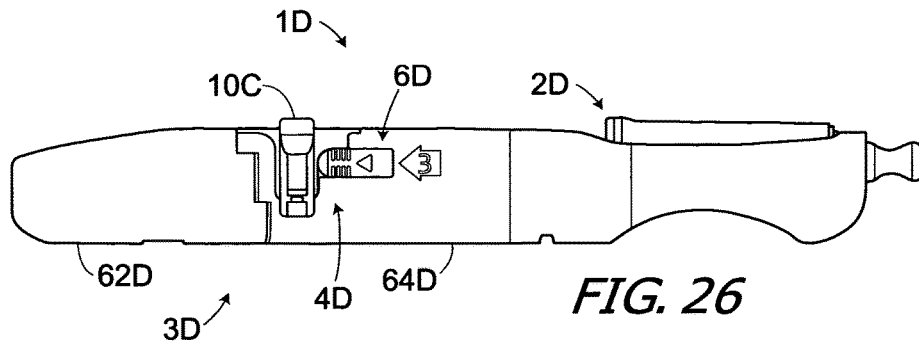
**FIG. 21**



**FIG. 22**

**FIG. 23**





US 10,039,668 B2

1

**OCULAR IMPLANT INSERTION  
APPARATUS AND METHODS****CROSS-REFERENCE TO RELATED  
APPLICATIONS**

This application is a continuation of U.S. application Ser. No. 14/145,846, filed Dec. 31, 2013, which is a continuation of U.S. application Ser. No. 13/699,708, now U.S. Pat. No. 8,647,382, which has a 35 U.S.C. § 371(c) date of May 11, 2013 and is a U.S. national phase application under 35 U.S.C. § 371 of International Patent Application No. PCT/JP2011/063747, filed Jun. 8, 2011, which claims priority to Japanese patent application No. 2010-132952, filed Jun. 10, 2010. The International Application was published in English on Dec. 15, 2011 as International Publication No. WO 2011/155636 A1. The content of each application is incorporated herein in its entirety.

**BACKGROUND OF THE INVENTIONS****1. Field of the Inventions**

The present inventions relate generally to apparatus and methods for inserting an ocular implant into an eye.

**2. Description of the Related Art**

There are a variety of instances where an ocular implant is inserted into the anterior chamber, posterior chamber, cornea, vitreous space and/or other portion of an eye. Exemplary ocular implants include, but are not limited to, lenses, capsular tension rings, ocular prosthesis and lamellar transplants. An intraocular lens (IOL), for example, may be inserted into an a phakic eye that has undergone a cataract surgery or may be inserted into a phakic eye during a refractive surgery. One type of lens is a foldable lens. Foldable lenses are formed from soft material such as a silicone elastomer, soft acrylic, or hydrogel and may be inserted into the eye through a small incision. Lens insertion apparatus, which may be used to push a foldable lens into an eye through a nozzle, generally include screw-type insertion apparatus and push-type insertion apparatus. In both cases, the lens insertion apparatus may include a plunger that is used to push a folded lens through the nozzle into the eye by way of an incision that is relatively small, e.g., an incision that is smaller than the diameter of an IOL optic.

Loading an ocular implant into an inserter can be a troublesome portion of the insertion procedure. The implant may be contaminated, damaged or improperly placed into the inserter by operator, e.g., a surgeon or assistant. Accordingly, in some instances, the insertion apparatus is preloaded, i.e., the insertion apparatus is shipped from the factory with the ocular implant (e.g., an IOL) stored therein. An operator using a preloaded inserter does not place the implant into the insertion apparatus, thereby eliminating the possibility of the aforementioned operator error associated with loading.

In addition to the basic functions of storing and inserting an IOL or other ocular implant, it may also be desirable for the insertion apparatus to minimize the physical load on the ocular implant during storage in order to ensure that the ocular implant returns to its unstressed state after being inserted into the eye. It may also be desirable to fold the IOL or other ocular implant into as small a state as possible in order to reduce the size of the incision and the likelihood of corneal astigmatism caused by the surgery or infection.

2

Thus, the desired insertion apparatus must be able to fold the unstressed ocular implant into a small state in a predetermined direction, and into a predetermined shape, in order to insure that the plunger can move the folded ocular implant through the nozzle without the insertion apparatus becoming clogged at or near the nozzle or the ocular implant being damaged. To that end, instead of using only a plunger to move the lens through the folding and insertion processes, some insertion apparatus have been configured to fold and move an IOL in stepwise fashion through the use of multiple IOL moving structures. Examples of such insertion apparatus are illustrated and described in PCT Pub. No. WO 2009/148091 (also published as US 2011/0082463) and Laid-open JP Pat. Pub. No. 2001-104347 (also published as US 2001/0007942).

The present inventor has, however, determined that insertion apparatus with multiple ocular implant moving structures are susceptible to improvement. For example, the present inventor has determined that such insertion apparatus are susceptible to erroneous operation, such as use of the moving structures in an incorrect sequence.

**SUMMARY**

An exemplary ocular implant insertion system includes a case and an ocular implant insertion apparatus including an ocular implant, a first movable structure that moves at least a portion of the ocular implant during movement thereof, and a second movable structure that moves the ocular implant through the nozzle. The ocular implant insertion apparatus is located at least partially within the case in pre-use state wherein the first and second movable structures have not folded and moved the ocular implant. The respective configurations of the case and the ocular implant insertion apparatus are such that the ocular implant insertion apparatus is not removable from the case when the ocular implant insertion apparatus is in the pre-use state and is removable after the first movable structure has moved at least a portion of the optical implant.

An exemplary method of using a system including a case and a preloaded ocular implant insertion apparatus locked to the case includes the steps of unlocking the insertion apparatus from the case by moving a first movable structure a distance sufficient to at least partial fold a stored ocular implant, removing the insertion apparatus from the case, and pushing the ocular implant from the insertion apparatus with a second movable structure.

There are a number of advantages associated with such systems and methods. For example, such systems and methods prevent the use of the first and second movable structures in an incorrect sequence.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Detailed description of exemplary embodiments of the inventions will be made with reference to the accompanying drawings.

FIG. 1 is a perspective view of an IOL insertion system, including an IOL insertion apparatus and an insertion apparatus case, in accordance with one embodiment of a present invention.

FIG. 2 is a perspective view of the exemplary IOL insertion apparatus illustrated in FIG. 1.

FIG. 3 is a perspective view of the insertion tube of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 4 is a perspective view of the main body of the exemplary IOL insertion apparatus illustrated in FIG. 2.

US 10,039,668 B2

3

FIG. 5 is a perspective view of the lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 6 is a section view of the insertion tube and lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 7 is a perspective view of the plunger of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 8 is a perspective view of the distal portion of the plunger rod of the exemplary IOL insertion apparatus illustrated in FIG. 2.

FIG. 9 is a perspective view of the exemplary insertion apparatus case illustrated in FIG. 1.

FIG. 10 is a partial section view of a portion of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 11 is a perspective view of the exemplary cover illustrated in FIG. 1.

FIG. 12 is a perspective view showing one aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 13 is a perspective view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 14 is a partial section view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 15 is a perspective view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 16 is a perspective view showing another aspect of the operation of the exemplary IOL insertion system illustrated in FIG. 1.

FIG. 17 is a perspective view of another exemplary IOL insertion apparatus that may be combined with a case in the manner illustrated in FIG. 1 to form an IOL insertion system.

FIG. 18 is a perspective view of an IOL insertion system, including an IOL insertion apparatus and an insertion apparatus case, in accordance with one embodiment of a present invention.

FIG. 19 is a perspective view of the insertion tube of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 20 is a perspective view of a portion of the exemplary IOL insertion system illustrated in FIG. 18.

FIG. 21 is a perspective view of a portion of the slider and the lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 22 is a perspective view of the lens placement section of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 23 is a perspective view of a portion of the slider of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 24 is a perspective view of a portion of the plunger rod of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 25 is a side view of a portion of the exemplary IOL insertion apparatus illustrated in FIG. 18.

FIG. 26 is a perspective view of an IOL insertion system, including an IOL insertion apparatus and an insertion apparatus case, in accordance with one embodiment of a present invention.

FIG. 27 is a side view of a portion of the exemplary IOL insertion system illustrated in FIG. 26.

FIG. 28 is a side view of a portion of the exemplary IOL insertion system illustrated in FIG. 26.

4

FIG. 29 is a side view of a portion of the exemplary IOL insertion system illustrated in FIG. 26.

#### DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The following is a detailed description of the best presently known modes of carrying out the inventions. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the inventions. The present inventions are also applicable to a wide variety of ocular implants which, as used herein, refers to any structure, instrumentality or device that is placed into any ocular structure or region. Ophthalmic lenses, capsular tension rings, ocular prosthesis and lamellar transplants are examples of ocular implants. Although the exemplary implementations are described below in the context of an intraocular lens (IOL), the present inventions are also applicable other types of ocular implants, including those yet to be developed. For example, the present inventions are applicable to other types of ophthalmic lenses. Such lenses include, but are not limited to, intraocular contact lenses, phakic IOLs, and other lenses that may be inserted into the eye.

#### I. Overview

As illustrated in FIG. 1, the exemplary IOL insertion system 1 includes an IOL insertion apparatus 2A and a case 3 in which the IOL insertion apparatus 2A is stored during shipping and at other times prior to an insertion procedure. The IOL insertion apparatus 2A is a preloaded insertion apparatus and, to that end, an IOL 40 (FIG. 5) is placed within the insertion apparatus during the assembly process and the insertion apparatus is shipped and stored with the IOL located therein. The IOL insertion system 1 includes a lock mechanism 4 that prevents the IOL insertion apparatus 2A from being removed from the case 3 when in a locked state, and allows the IOL insertion apparatus to be removed from the case when in an unlocked state. As is discussed in greater detail below, the operation of the IOL insertion apparatus 2A itself is, generally speaking, a two-step process where the steps must be performed in the proper sequence. The first step involves folding a previously unstressed IOL into a particular configuration with a first device and the second step pushing the folded IOL through a tapered passage, where it is further folded, and then into the eye. The IOL insertion system 1 is configured such that the lock mechanism 4 will transition from the locked state to the unlocked state, thereby allowing the IOL insertion apparatus 2A to be removed from the case 3, when the first step is performed. In other words, the IOL insertion system 1 is configured such that the operator will not be able to remove the IOL insertion apparatus 2A from the case 3 unless the first step in the process has been performed. By requiring the first step to be performed prior to removal of the IOL insertion apparatus 2A from the case 3, the IOL insertion system 1 forces the operator to perform the steps in the correct order.

#### II. Exemplary IOL Insertion Apparatus

Turning to FIG. 2, the exemplary IOL insertion apparatus 2A includes a slider 6, a plunger 8A, a main body 14A and an insertion tube 16 that is mounted on the forward end of the main body. The main body 14A and insertion tube 16 together define the external housing of the insertion appa-



US 10,039,668 B2

5

ratus 2A. The slider 6 and plunger 8A are movable relative to the external housing and relative to each other.

Operation of the IOL insertion apparatus 2A, where the IOL is pushed out of the apparatus and into the eye, is referred to herein as a “push-out” or “insertion” process. The slider 6, which has a pair of finger grips 7, performs the first step in the insertion process, i.e., folding a previously unstressed IOL into a particular configuration, and may therefore be referred to as one example of a first lens push-out mechanism. The exemplary slider 6 pushes the IOL 40 distally as it folds the IOL. In other implementations, the first “push-out” mechanism may perform the first step of the “push-out” process by simply folding an IOL without moving it distally. The exemplary plunger 8A performs the second step in the insertion process, i.e., pushing the folded IOL through a tapered lumen and then into the eye, and may therefore be referred to as one example of a second lens push-out mechanism. The IOL moves along a lens advancement axis A during the insertion process. Movement of the movable components of the insertion apparatus 2A and the IOL 40 towards the eye is referred to herein as movement in the forward (or “distal”) direction and movement away from the eye is referred to herein as movement in the rearward (or “proximal”) direction. Similarly, the end of a structure that faces the eye during use is referred to as the forward (or “distal”) end and the other end the structure is referred to as the rearward (or “proximal”) end. The slider 6 and plunger 8A are both movable in the forward and rearward directions relative to the main body 14A.

The exemplary insertion tube 16 includes a nozzle 18, a transition section 20 and a protector 22, with interior regions that are in communication with one another so that an IOL can pass therethrough. The insertion tube 16 is connected to the main body 14A by a connector arrangement 15 (FIG. 3) on the insertion tube and a corresponding connector arrangement 17 (FIG. 4) on the main body. The inner diameter of the transition section 20 tapers downwardly from the end adjacent to the protector 22 to the end adjacent the nozzle 18. The protector 22 has an injection port 24 for viscoelastic material and a first insertion hole 26 (discussed below).

Turning to FIG. 4, the exemplary main body 14A includes a tubular member 19, a lens placement section 28, a slider guide section 30 and a protrusion 32. The lens placement section 28 (described below with reference to FIG. 5) protrudes distally from the front end of the tubular member 19. The slider guide section 30 is configured to allow the slider 6 to move forwardly and rearwardly. The slider guide section 30 may be a pair of slits, formed in the tubular member 19, that are parallel to the lens advancement axis A. The slider guide section 30 also extends rearwardly from the distal end of the tubular member 19 to the central portion of the tubular member. The plunger 8A is threadedly connected to the main body 14A in the illustrated implementation. To that end, the exemplary main body 14A includes a male screw. The protrusion 32, which is transverse to the lens advancement axis A, defines a portion of the screw thread of the male screw and a portion of the outer surface of the tubular member 19 defines the root of the thread. Another protrusion (not shown) may be located on the tubular member 19 180 degrees offset from the tubular member 32.

As shown in FIG. 5, the IOL insertion apparatus 2A may be used to store an IOL 40 that has an optic 42 and a pair of supports 44 and 46 such as, for example, the illustrated pair of haptics. The exemplary lens placement section 28 includes a bottom surface 34, a pair of side walls 36 respectively located on opposite sides of the bottom surface and extending upwardly from the bottom surface, and a pair

6

of rails 38. The bottom surface 34 and the side walls 36 are parallel to the lens advancement axis A and the lens advancement axis A is located between the side walls. The side walls 36 each include, near the upper end, an inclined surface 36A. The rear portions of the side walls 36 include inward protrusions 48 that prevent the IOL 40 from moving in the rearward direction. The lens supporting surfaces of the rails 38 are oriented in a direction that is transverse to the lens advancement axis A and slope away from the axis A in the rearward to forward direction. As such, the stored IOL 40 is tilted relative to the lens advancement axis A, with the forward end of the IOL optic 42 closer to the bottom surface 34 than the rearward end. The lens supporting surfaces of the rails 38 are also located a sufficient distance above the bottom surface 34 to prevent the IOL optic 42 from coming into contact with the bottom surface (note FIG. 6).

It should be noted that references herein to “top,” “bottom,” “upward,” “downward” and the like are merely references to the illustrated orientation and/or the relationship of the components relative to one another in the illustrated orientation. For example, the side of the IOL 40 facing the bottom surface 34 is referred to “the downward side” and movement toward the bottom surface is referred to as movement in the “downward direction,” while the opposite side of the IOL 40 is referred to as the “the upward side” and movement away from the bottom surface 34 is referred to as movement in the “the upward direction.”

In addition to the grips 7, and referring to FIGS. 5 and 14, the exemplary slider 6 includes an elongate member 9, with a lens contact surface 5, that is carried within the main body 14A and is slidable relative thereto. The grips 7 are connected to elongate member 9. The lens contact surface 5, which is larger than the plunger distal end 55 (discussed below), is used to scoop up the proximal IOL support 46 during the initial folding of the IOL 40. A lens holder 11 is pivotably mounted on the distal end of elongate member 9 and includes a protrusion 13. The lens holder 11 controls the initial folding of the IOL 40 during the first step of the lens insertion process. More specifically, as the slider 6 moves distally, the protrusion 13 rides along the tapered inner surface of the transition section 20, which causes the lens holder 11 to pivot downwardly into contact with the IOL optic 42 to fold the IOL 40. The slider elongate member 9 also includes a slot 21 through which the plunger rod 51 (discussed below) passes during the second step of the insertion process. Additional discussion concerning the use of a lens holder to fold an IOL may be found in, for example, U.S. Pat. Pub. No. 2010/0185206.

Referring to FIG. 6, the protector 22 of exemplary insertion tube 16 includes protrusions 50, with inclined surfaces 50A, that extend downwardly and inwardly from both sides of the protector inner surface. The projections 50, which guide the insertion tube 16 onto the upper ends of the side walls 36 during assembly, are sized such that the inclined surfaces 50A extend beyond the side wall inclined surface 36A. This prevents the outer edge of the IOL optic 42 located in the lens placement section 28 from becoming wedged between the protrusions 50 and the side walls 36.

Turning to FIG. 7, the exemplary plunger 8A includes an operational member 49A and a rod 51 with a distal rod portion 52, a proximal rod portion 53, and a rod distal end 55. The distal rod portion 52, which is sized such that it can be inserted through the nozzle 18, may be connected to, or may be integral with, the proximal rod portion 53. The operational portion 49A includes a handle 54 that is generally cylindrical in shape. The proximal (or “rearward”) end of the handle 54 is rotatably journaled, or is otherwise

rotatably secured, to the proximal (or “rearward”) end of the proximal rod portion 53. The handle 54 is also hollow and configured to receive the proximal portion of the main body 14A. The inner surface of the handle 54 includes a female screw (not shown) with threads that operationally correspond to the threads on the male screw associated with the main body 14A (note protrusion 32 in FIG. 4). As such, after the plunger 8A has been moved distally from the position illustrated in FIG. 2 until the male thread defined in part by the protrusion 32 engages the female thread within the handle 54, further distal movement is accomplished by rotating the handle.

As illustrated for example in FIG. 8, the rod distal end 55 may have a lens contact portion 56 and a recess 58 in which the free end of the proximal IOL support 46 is located during the second step of the two-step process. The exemplary lens contact portion 56 is a planar surface that is perpendicular to the lens advancement axis A, and is provided on a lower portion of the rod distal end 55. The exemplary recess 58, which has an opening 59 on one lateral side and a wall 60 on the other lateral side, is located above the lens contact portion 56. The recess 58 may be formed by cutting (or otherwise removing) material from the rod distal portion 52, starting at the distal end 55, or by molding the rod in the illustrated configuration. The wall 60 engages the outer edge of the IOL optic 42 and prevents optic of the folded IOL 40 from entering the recess 58. The wall 60 also keeps the IOL support 46 within the recess 58. The distal end of the wall 60 may be in the same plane as the lens contact portion 56 (as shown) or may be located distally beyond the lens contact portion 56 (as shown in dashed lines).

With respect to operation of the exemplary IOL insertion apparatus 2A, and as alluded to above, the IOL 40 is initially pushed forwardly (or distally) and folded into a predetermined shape with the slider 6. The slider 6 also forms part of the lock mechanism 4 that locks the IOL insertion apparatus 2A to the case 3 and, as is discussed below, the initial forward movement of the slider, unlocks the lock mechanism. The folded IOL 40 is subsequently pushed by the plunger 8A forwardly (or distally) through the transition section 20 where it is further folded, then thorough the nozzle 18, and then into the eye. In other words, the exemplary IOL insertion apparatus 2A deforms an IOL that has been preloaded within the main body 14A and insertion tube 16 into a predetermined shape while moving the IOL in the forward direction, first by using the slider 6 and second by using the plunger 8A, and then discharges the folded IOL into the eye. The IOL 40 may be folded by operation of the slider 6 into the predetermined shape in which the optic 42 is curled up and around the lens advancement axis A, with an upper surface of the optic dented downwardly, and in which the free ends 44FE and 46FE of the supports 44 and 46 are tucked into the upper surface of the curled optic 42 (note FIG. 14).

### III. Exemplary Case

The case 3, which protects the IOL insertion apparatus 2A during shipping and storage, may be an elongated container with an open upper end. To that end, and referring to FIG. 9, the exemplary case 3 includes a pair of end walls 61, a pair of side walls 63 that each extend from one end wall to the other, and a bottom wall 65 (FIG. 10) at the bottom ends of the end and side walls. The top ends of the end walls 61 and side walls 63 define the open upper end 67 of the case 3. The front portion of the case 3 is identified by reference numeral 62 and the rear portion of the case is identified by referent

numeral 64. The front and rear portions 62 and 64 may be separable structures that are secured to one another during the assembly process (note joint 57) as is discussed below.

The case 3 also includes a portion of the lock mechanism 4 that locks the IOL insertion apparatus 2A to the case. In the illustrated embodiment, each of the side walls 63 includes a storage slot 66 and removal slot 68. The storage slots 66 are separated, in the upward direction, from the open upper end 67 of the case by projections 69. The removal slots 68 extend to and through the upper end 67 of the case 3, and each storage slot 66 extends to the adjacent removal slot. Engagement members 70, which are located at the lower end of each removal slot 68, may be detachably engaged with a cover 10 (FIG. 1) to secure the cover to the case 3. A handle 72 may be located on the rear end wall 61 and used to remove the IOL insertion system 1 from the sterile package in which it is stored. The slider grips 7 are respectively located within the storage slots 66 when the lock mechanism 4 is in a locked state (FIG. 1) and are located within the removal slots when the lock mechanism is in an unlocked state (FIG. 13). The width of the slider grips 7 (in the direction of axis A) is less than or equal to the width of the removal slots 68. The respective configurations of the IOL insertion apparatus 2A and case 3 are also such that the slider grips 7 can be located within the storage slots 66 when the slider 6 is in its retracted, storage location (FIG. 12) and can also be pushed distally beyond the storage slots 66 to the point at which the slider 6 has completed the initial folding of the IOL 40 (FIG. 13).

With respect to the locked state, the projections 69 prevent the slider grips 7 and, therefore, the IOL insertion apparatus 2A, from moving in the upward direction identified by arrow A in FIGS. 12 and 13. The projections 69 do not, on the other hand, prevent the slider grips 7 from moving upwardly when the slider grips are located within the removal slots 68.

The exemplary case 3 also includes structure that helps control the initial folding of the lens during the movement of the slider 6 moves from the position illustrated in FIG. 12 to the position illustrated in FIG. 13. To that end, and referring to FIG. 10, the front portion 62 of the exemplary case 3 includes a protrusion 74 that extends through a correspondingly sized and located insertion hole 75 on the bottom surface of the insertion tube 16. The exemplary protrusion 74 has an overall ellipsoidal shape that is elongate in a direction parallel to the lens advancement axis A, and has a rearward facing surface that is slanted upwardly in the lens advancement (i.e., proximal to distal) direction. The protrusion 74 is located within the path of the IOL 40 and used to deflect the distal IOL support 44, as is discussed below with reference to FIG. 14. The protrusion 74 is removed from the IOL path, by way of the insertion hole 75, when the IOL insertion apparatus 2A is removed from the case 3.

It should also be noted here that the front portion 62 of the exemplary case 3 may include one or more support walls 90 (two in the exemplary embodiment) with slots 92 in which the insertion tube 16 is supported (FIG. 10). The width of each slot 92 (in a direction perpendicular to the lens advancement axis A) is equal to the width of the portion of the insertion tube 16 that is located therein. Similarly, the rear portion 64 includes a wall 94 (FIG. 15) with a slot 96 that is smaller in width than, and located distally of, the distal end of the handle 54. As a result, the IOL insertion apparatus main body 14A, insertion tube 16 and handle 54 may not be moved forward (i.e., in the direction of arrow B in FIG. 12) when the insertion apparatus 2A is located within the case 3. Also, as discussed above, the insertion apparatus

2A may not be pulled out of the case 3 (i.e., in the direction of arrow A in FIGS. 12 and 13) when the slider grips 7 are within the storage slots 66.

The exemplary cover 10, which is shown in detail in FIG. 11, includes a flat main body 76 and a pair of clips (or other attachment devices) 78. The clips 78 are size and positioned such that they can be located in the removal slots 68, and are configured to interlock with the engagement members 70 on the case 3. The clips 78, which extend downwardly from and are perpendicular to the main body 76, are resiliently deflectable about the main body at the point at which the clips are attached to the main body. As a result, the cover 10 can be easily secured to and removed from the case 3 by pressing the top ends of the clips 78 toward one another.

A protrusion 80 (FIG. 10), which extends downwardly from the bottom surface of the main body 76, is located such that it will extend into the first insertion hole 26 on the insertion tube 16 when the IOL insertion apparatus 2A is located within the case 3 and the cover 10 is secured to the case. The protrusion 80 is located within the path of the IOL adjacent to the distal end of the IOL optic 42 and, therefore, prevents distal movement of the IOL 40 within the lens placement section 28 during shipping and other times prior to use. The protrusion 80 is removed from the IOL path when the cover 10 is removed from the case 3. The cover 10 also includes an injection port opening 82 that will be aligned with insertion tube injection port 24 when the IOL insertion apparatus 2A is located within the case 3 and the cover 10 is secured to the case.

The cover 10 may be attached to the case 3, with each of the clips 78 located with a portion of a removal slot 68 and secured to an engagement member 70, when the lock mechanism 4 is in the locked state illustrated in FIG. 1. The clips 78 are also positioned forward of the slider grips 7, thereby preventing the slider 6 from being moved forwardly to unlock the lock mechanism 4 and move the IOL 40, when the cover 10 is secured to the case 3.

#### IV. Assembly

The exemplary IOL insertion system 1 may be assembled from an IOL insertion apparatus 2A and case 3 in a variety of ways. One exemplary assembly methods begins with an IOL insertion apparatus 2A that is complete, but for the loading of the IOL 40 and the attachment of the insertion tube 16 to the main body 14A, and the front and rear portions 62 and 64 of the case 3 separated from one another. In the initial step of the exemplary assembly method, the slider 6 and plunger 8 are attached to the main body 14A and the slider 6 is moved to its forward position so that the grip will be located within the removal slots 68. The main body 14A is then attached to the rear portion 64 of the case 3, which is still separated from the front portion 62, and the slider 6 is moved to the rearward position with the grips 7 within the storage slots 66. The IOL 40 is then placed in the lens placement section 28, with the outer edge of the optic 42 on the rails 38, and the supports 44 and 46 located distally and proximally of the optic. The inward protrusions 48 (FIG. 5) prevent the IOL 40 from moving in the rearward direction. The insertion tube 16 may then be attached to the front end of the main body 14A such that the lens placement section 28 is covered by the protector 22.

Next, the cover 10 is inserted onto the case 3. The clips 78 move through the removal slots 68 until they clip onto the engagement members 70, thereby securing the cover 10 to the case 3. The cover protrusion 80 will now extend through the first insertion hole 26 and be positioned between the

forward support 44 and the optic 42 of the IOL 40. As a result, movement of the IOL 40 is held between the lens placement section inward protrusions 48 and the cover protrusion 80 with no physical load is applied thereto (FIG. 10). The proximal end of the case front portion 62 is then attached to the distal end of the rear portion 64 from underneath, thereby completing assembly of the exemplary IOL insertion system 1 (FIG. 1).

#### V. Operation and Instructive Indicia

Operation of the exemplary IOL insertion system 1 is discussed below with reference to FIGS. 1 and 12-16. The operational method may includes a number of step that are intended to be performed in a particular order. Some of the steps are associated with unlocking the lock mechanism 4 and removing the IOL insertion apparatus 2A from the case 3, some of the steps are associated with the operation of the IOL insertion apparatus itself, and at least one step is associated with both.

The exemplary IOL insertion system 1 may be provided with indicia that guides the operator through the initial steps in the proper sequence. More specifically, the exemplary IOL insertion system 1 includes markers 12A-12C. Each marker includes a number and, where appropriate, a directional indicator. Marker 12A is a "1" and is located on the cover 10 adjacent to the opening 82 for the injection port 24. Marker 12B, which is located on the cover 10 near the clips 78, includes a pair of inwardly facing arrows and each arrow has a "2" associated therewith. Marker 12C may be located on one or both sides of the case 3 adjacent to one or both of the storage slots 66. In the illustrated implementation, marker 12C consists of a forwardly facing arrow and a "3" adjacent to each of the storage slots 66 and, accordingly, each of the slider grips 7 when the IOL insertion system 1 is in its initial, pre-use state. As will be apparent from the discussion below, the markers 12A-12C reduce the likelihood of operator error by guiding the operator through the associated steps in the correct sequence.

The exemplary IOL insertion system 1 may be operated as follows. The IOL insertion system may be provided to the operator in a sterile bag and removed therefrom while holding the handle 72 (FIG. 1). A volume of viscoelastic material sufficient to fill the region around the IOL 40 may then be injected into the insertion tube 16 by way of injection port 24 (note marker 12A). The ends of the cover clips 78 adjacent to the main body 76 may then be pressed together (note marker 12B) to pivot the clips away from the engagement members 70, thereby disconnecting the cover 10 from the case 3. The cover 10 may then be removed from the case 3, as shown in FIG. 12. After the cover 10 has been removed from the case 3, the clips 78 will no longer prevent the slider grips 7 from being moved forwardly and the protrusion 80 will no longer prevent the IOL 40 from being moved forwardly. The lock mechanism 4 will, however, still be in the locked state.

As illustrated in FIG. 13, the next step is to move the slider 6 in the forward direction (note marker 12C) until the slider grips 7 have moved out of the storage slots 66 and, in the illustrated embodiment, have come into contact with a front ends of the removal slots 68. Such movement of the slider 6 causes the IOL 40 to move from the lens placement section 28 to the transition section 20, thereby causing the lateral sides of IOL optic 42 to fold upwardly as the lens holder 11 pushes the central portion of the IOL optic downwardly (FIG. 14). As the IOL 40 moves forwardly into the transition section 20, the protrusion 74 bends the distal

11

IOL support **44** such that the free end of the support is positioned on the upper surface of the folded IOL optic **42** (FIG. **14**). In particular, the slanted rearwardly facing surface of the protrusion **74** (FIG. **10**) scoops up the distal IOL support **44** as it is bent, thereby facilitating reliable positioning of the distal IOL support on the upper surface of the folded IOL optic **42**. The lens contact surface **5** of the slider **6** also scoops up the proximal IOL support **46** and pushes it forwardly such that the proximal IOL support **46** will also be positioned on the upper surface of the folded IOL optic **42**. With respect to the folding of the IOL optic **42**, the distal portion is folded to a greater extent than the proximal portion, with the lateral edges folded up and the center pushed down, due to the tapered shape of the interior of the transition section **20**. This completes the initial folding of the IOL **40**.

Movement of the slider **6** from the position illustrated in FIG. **12** to the position illustrated in FIGS. **13** and **14** also unlocks the lock mechanism **4** because the slider grips **7** are no longer within the storage slots **66** and, instead, are within the removal slots **68**. The IOL insertion apparatus **2A** may now be removed from the case **3** by simply lifting the apparatus in the direction identified by arrow **A** in FIG. **13**. In addition to freeing up the IOL insertion apparatus **2A** for use by the operator, removal of the IOL insertion apparatus from the case **3** also removes the protrusion **74**, which is part of the case and which facilitated reliable folding of the IOL **40** during movement of the slider **6**, from the path of the IOL. Thus, the protrusion **74** is located within the path of the IOL **40** when needed (i.e. during the initial folding of the IOL) and is automatically removed from the path when appropriate (i.e. prior to operation of the plunger **8A**).

Next, the operator pushes the plunger handle **54** forward in the direction of arrow **B** (FIG. **15**) until the threads associated with the inner surface of the handle engage the thread (note protrusion **32** in FIG. **5**) on the main body **14A**. The handle **54** may then be rotated to drive the plunger **8A**. Forward movement of the plunger rod **51** drives the IOL **40** into, and then through, the nozzle **18** and then into the eye (FIG. **16**). The IOL **40** is further folded from the state illustrated in FIGS. **14** and **15** as it moves into the nozzle **18**. The above-described initial state of the folded IOL **40**, i.e. the IOL optic **42** folded with the supports **44** and **46** resting on the upper surface thereof, facilitates the subsequent folding associated with movement of the plunger rod **51**.

It should be again emphasized here that the IOL insertion apparatus **2A** is secured to the case **3** by the lock mechanism **4** until the slider **6** has been moved forward, thereby unlocking the lock mechanism so that the IOL insertion apparatus can be removed from the case. By incorporating such movement of the slider **6** into the unlocking process, the present IOL insertion system **1** prevents the operator from erroneously pushing the IOL **40** with the plunger **8A** until after the IOL has undergone the initial folding associated with the slider **6**.

## VI. Other Exemplary Embodiments

The present inventions are not limited to the exemplary embodiments described above.

For example, in addition to screw-type IOL insertion apparatus such as that described above, the present inventions are applicable to push-type IOL insertion apparatus. One example of such a push-type IOL insertion apparatus is generally represented by reference numeral **2B** in FIG. **17**. The push-type IOL insertion apparatus **2B** is essentially identical to apparatus **2A** and similar elements are repre-

12

sented by similar reference numerals. Here, however, instead of a screw-type operational member, the plunger **8B** includes a push-type operational member **49B** that operates in a manner similar to a syringe. Operational member **49B** includes a disk-shaped member **84** on the proximal end of the proximal rod portion **53**, and a flange **86** on the outer surface of the main body **14B**. The plunger rod **51** is driven by resting one or more fingers on the flange **86** and pushing the disk-shaped member **84** with the thumb. The IOL insertion apparatus **2B** may be combined, for example, with the case **3** and cover **10** described above to form an IOL insertion system that requires operation of the slider **6** prior to removal of the IOL insertion apparatus from the case.

Another exemplary IOL insertion system, which is generally represented by reference numeral **1C** in FIG. **18**, includes an IOL insertion apparatus **2C** and a case **3C**. IOL insertion system **1C** is essentially identical to system **1** and similar elements are represented by similar reference numbers. For example, IOL insertion system **1C** includes a screw-type IOL insertion apparatus **2C**, a case **3C**, a lock mechanism **4** and a cover **10C**. In the interest of brevity, the discussion below focuses on the differences between the two systems.

As illustrated in FIG. **18**, the exemplary cover **10C** includes clips **78C** that extend above the main body **76** to a greater extent than do the clips **78** of the cover **10**. The additional length makes the clips **78C** easier to grip and the cover **10C** easier to remove.

Turning to FIGS. **19** and **20**, in the exemplary IOL insertion apparatus **2C**, the location of the injection port **24C** on the insertion tube **16C** decreases the likelihood that the cannula (not shown) delivering the viscoelastic material will come into contact with the IOL **40**. Additionally, the cover **10C** is provided with a frustoconical injection port opening **82C** that will be aligned with insertion tube injection port **24C** when the IOL insertion apparatus **2C** is located within the case **3C** and the cover is secured to the case. The frustoconical injection port opening **82C** guides the cannula into the injection port **24C**.

Referring to FIG. **21**, the exemplary IOL insertion apparatus **2C** includes a lens placement section **28C** with a pair of lens covers **29** that extend over the inward protrusions **48** (FIG. **5**) and portions of the IOL optic **42** and proximal support **46**. The lens covers **29** prevent upward movement of the IOL **40** prior to operation of the slider **6C** (e.g., during shipping or handling by the operator). As such, the lens covers **29** increase the likelihood that the IOL **40** will be properly positioned when the operator pushes the slider **6C** forward. Additionally, as shown in FIG. **22**, the lens placement section **28C** has a bottom surface **34C** with a groove **35** that guides the plunger rod **51C** (FIG. **24**) as it passes through the lens placement section, thereby increasing the likelihood that the plunger rod **51** will remain properly oriented.

With respect to the exemplary slider **6C**, and turning to FIG. **23**, the slider has a pivotable lens holder **11C** with a pair of protrusions **13C**. The dual protrusion arrangement causes the lens holder **11C** to engage the inner surface of the insertion tube **16C**, and begin the pivoting and associated IOL folding, at an earlier point in the movement of the slider **6C** than would be the case with the single protrusion embodiment illustrate in FIG. **14**. Such earlier folding of the IOL **40** helps insure that the edge of the IOL is positioned in the manner illustrated in FIG. **14** so that the proximal IOL support **46** can slide over the IOL optic **42**. With respect to deflection of the proximal IOL support **46**, the exemplary slider **6C** includes a lens contact assembly **5C** that has a

US 10,039,668 B2

13

support post 5C-1 and a vertical guide surface 5C-2 that tapers outwardly in the proximal to distal direction. The lens contact assembly 5C insures that the proximal IOL support 46 will deflect in the manner described above with reference to FIG. 14.

As illustrated example in FIG. 24, the exemplary plunger rod 51C has a rib 71C that extends distally to a point adjacent to the recess 58C. The rib 71C increases the rigidity of plunger rod 51C which, in turn, helps to maintain the alignment of the plunger rod 51C. The shape of the recess 58C, which is larger than recess 58, helps insure that the proximal support 46 will move out of the recess once in the eye. The plunger rod 51C also has a bottom wall 51BW with an upper surface 51US and a width W1, a lens contact surface 51LC that extends downwardly from the bottom wall upper surface, a top wall 51TW with a width W2 that is less than the bottom wall width, and a lateral wall 60.

Referring to FIG. 25, the exemplary case 3C includes a support member 88 that engages the bottom of the main body 14A when the IOL insertion apparatus 2C is stored within the case and the lock mechanism 4 is in the locked state (as shown). The support member 88, which may be a thin wall with a curved upper surface, prevents the main body 14A from bending in the downward direction as the user is pushing the slider 6C forwardly. Such bending could result in an undesirable level of friction between the case 3C and the slider grip 7.

Another exemplary IOL insertion system, which is generally represented by reference numeral 1D in FIG. 26, includes an IOL insertion apparatus 2D and a case 3D. IOL insertion system 1D is essentially identical to system 1C and similar elements are represented by similar reference numbers. For example, IOL insertion system 1D includes a screw-type IOL insertion apparatus 2D, a lock mechanism 4D, and a cover 10C. In the interest of brevity, the discussion below focuses on the differences between the two systems.

The present inventor has determined that there may be some instances where, during the first step of the two-step process, the operator will place the case on a table or other flat support surface, hold the front portion of the case with one hand and the push the slider forward the other hand. Referring first to the embodiment illustrated in FIG. 18, the front portion 62 of the case 6C includes a bottom surface that tapers upwardly. If the operator pushes the front portion 62 of the case 3C downwardly with too much force while firmly holding the slider grips 7, the front portion of the case may deflect, the case protrusion 74 may be completely or partially pulled out of the IOL path, and the IOL distal support 44 may not deflect properly. The front portion 62D of the exemplary case 3D illustrated in FIGS. 26 and 27 includes a flat bottom surface 98, which is aligned with the flat bottom surface 100 of the rear portion 64D, that prevents such bending.

The present inventor has also determined that there may be some instances where the operator attempts to pull the insertion apparatus out of the case, in a direction that is slightly angled from vertical, before the slider movement has been completed and the slider has engaged the distal wall of the removal slot. The curvature of the proximal ends of the slider grips may create a gap, between the curved proximal ends and the distal end of the storage slot protrusion (note grip 7 and protrusion 69 in FIG. 25) that invites these attempts. Turning to FIG. 28, the respective shapes of the slider grip 7D (not the flat proximal end), storage slot 66D and removal slot 68D (note extension 102) prevent the insertion apparatus 2D from being pulled out of the case 3D when the slider 6D is only in the almost fully forward

14

position illustrated in FIG. 28. The top corner of the slider grip 7D is in contact with the bottom corner of the protrusion 69. Only after the slider 6D is moved to the fully forward position illustrated in FIG. 29 will removal of the insertion apparatus 2D from the case 3D be possible.

Numerous other modifications and/or additions to the above-described preferred embodiments would be readily apparent to one skilled in the art. It is intended that the scope of the present inventions extends to all such modifications and/or additions.

We claim:

1. An intraocular lens insertion apparatus, comprising:
  - a plunger, at least a portion of which is carried within the outer body, that is movable relative to the outer body and which has a distal region that defines a longitudinal axis, the distal region including
    - a bottom wall having an upper surface and defining a width in a direction transverse to the longitudinal axis of the distal region,
    - a lens contact surface extending downwardly from the bottom wall upper surface,
    - a top wall defining a width in a direction transverse to the longitudinal axis of the distal region that is less than the width of the bottom wall, and
    - a lateral wall that extends from the bottom wall to the top wall in a direction perpendicular to the spacing direction that is perpendicular to the lens movement direction,
  - the top wall, bottom wall and lateral wall together defining a recess that is located above the bottom wall, that extends proximally from the lens contact surface, that has a first lateral side that is open, a second lateral side that is closed by the lateral wall, and an open distal end, and that is configured to hold a portion of the proximal haptic when the proximal haptic is bent such that the free end is positioned over the optic.
2. An ocular implant insertion apparatus as claimed in claim 1, wherein
  - the plunger includes a slanted wall that defines the proximal end of the recess.
3. An ocular implant insertion apparatus as claimed in claim 2, wherein
  - the slanted wall is oriented at a non-perpendicular angle with respect to the longitudinal axis of the distal region.
4. An ocular implant insertion apparatus as claimed in claim 2, wherein
  - the slanted wall extends from the lateral wall to the first lateral side that is open.
5. An ocular implant insertion apparatus as claimed in claim 2, wherein
  - the width of the top wall at the open distal end of the recess is less than the width of the top wall at the proximal end of the recess.

US 10,039,668 B2

15

6. An ocular implant insertion system as claimed in claim 1, further comprising:

a slider movable relative to the plunger from a pre-use slider position to a second slider position.

7. An ocular implant insertion apparatus as claimed in claim 6, wherein

the proximal haptic includes a free end; and movement of the slider from the pre-use slider position to the second slider position moves the free end of the proximal haptic over the optic.

8. An ocular implant insertion apparatus as claimed in claim 6, wherein

the proximal haptic includes a free end; and movement of the slider from the pre-use slider position to the second slider position moves the free end of the distal haptic over the optic.

9. An ocular implant insertion apparatus as claimed in claim 1, wherein

the plunger includes a rotatable handle.

10. An ocular implant insertion apparatus as claimed in claim 1, wherein

the plunger includes a thumb rest.

11. An ocular implant insertion apparatus as claimed in claim 1, wherein

the lens contact surface is planar.

16

12. An ocular implant insertion apparatus as claimed in claim 1, wherein

the lateral wall defines a lateral side of the distal region of the plunger.

13. An ocular implant insertion apparatus as claimed in claim 1, wherein

the lateral wall defines a distal end; and the top wall defines a distal end that extends distally beyond the distal end of the lateral wall.

14. An ocular implant insertion apparatus as claimed in claim 1, further comprising:

a tapered transition proximal of the nozzle.

15. An ocular implant insertion apparatus as claimed in claim 1, wherein

the outer body comprises main body and an insertion tube mounted on the main body.

16. An ocular implant insertion apparatus as claimed in claim 15, wherein

the insertion tube includes the nozzle.

17. An ocular implant insertion apparatus as claimed in claim 1, wherein

the lateral wall extends distally beyond the lens contact surface.

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