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(54) **INTRAOCULAR LENS DELIVERY SYSTEM WITH A DISPOSABLE PLUNGER SEGMENT AND METHOD OF USE THEREFOR**

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(57) **ABSTRACT**

The present invention is directed to an intraocular lens delivery system with a multi-segment plunger. More particularly, the present invention relates to an intraocular lens delivery device that includes a disposable plunger tip segment that can be attached and removed from a reusable plunger base segment.

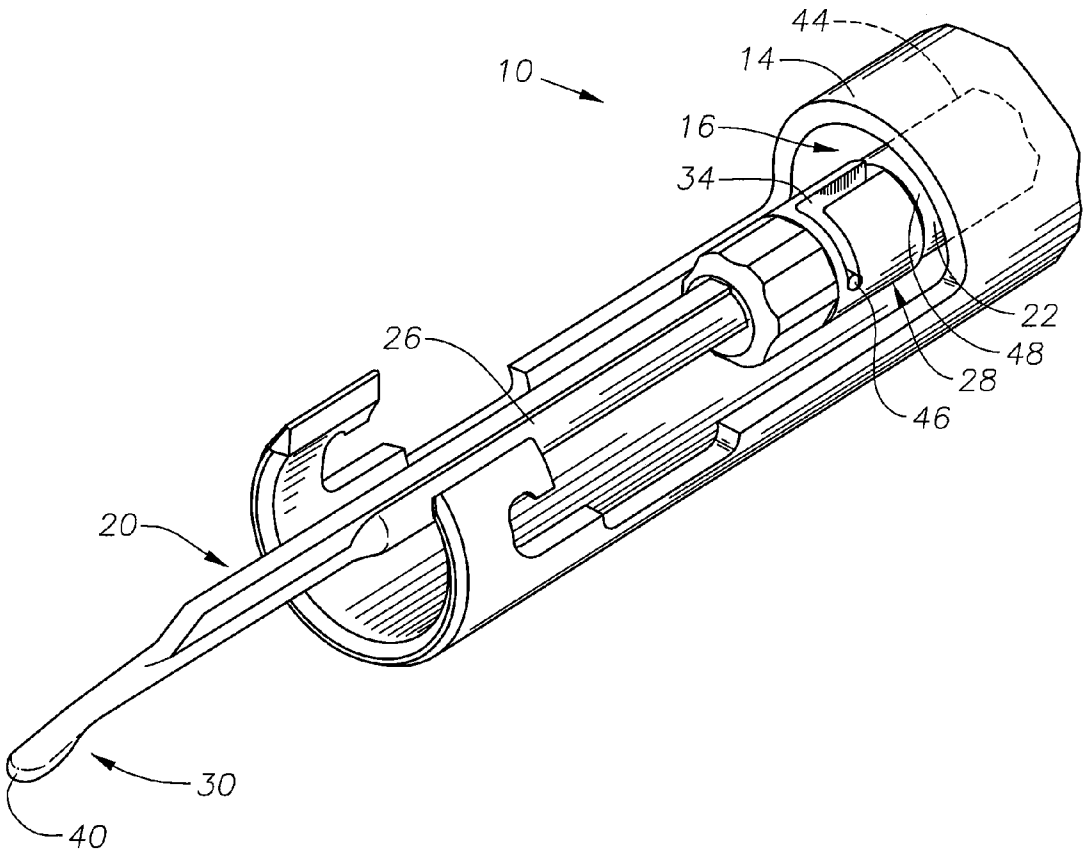


Fig. 1

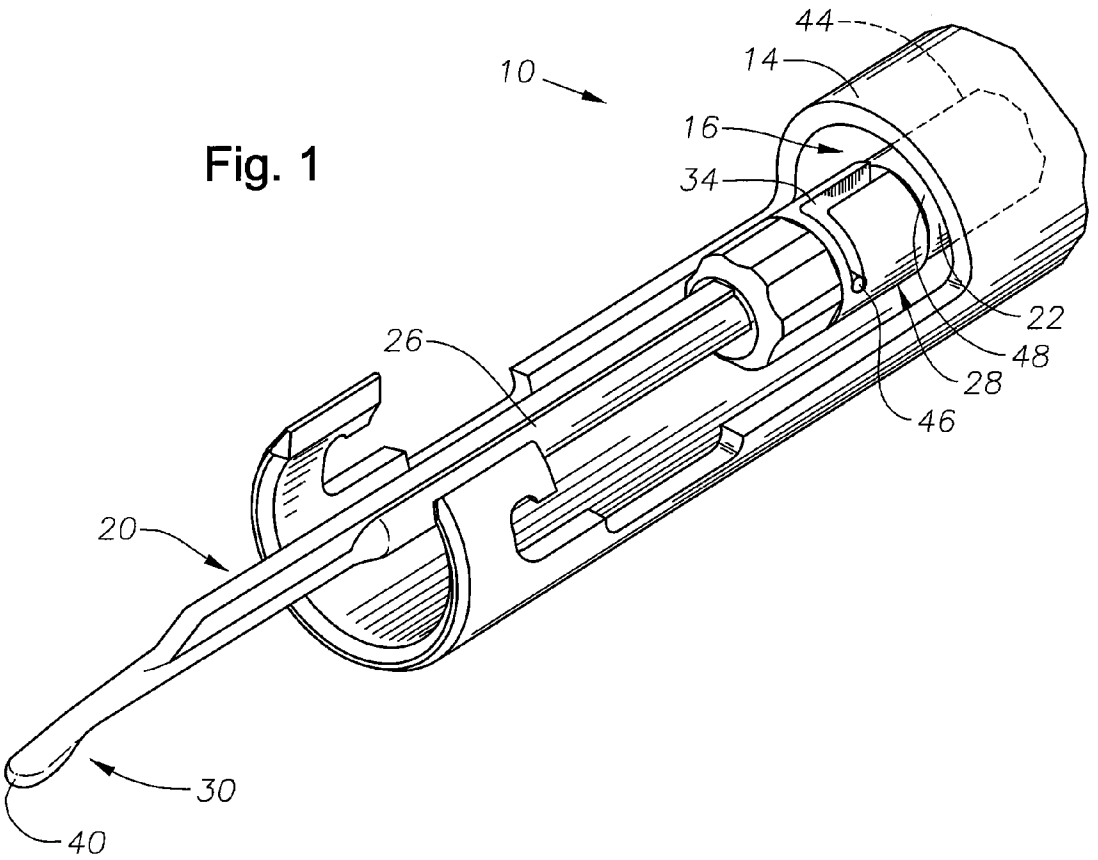


Fig. 2

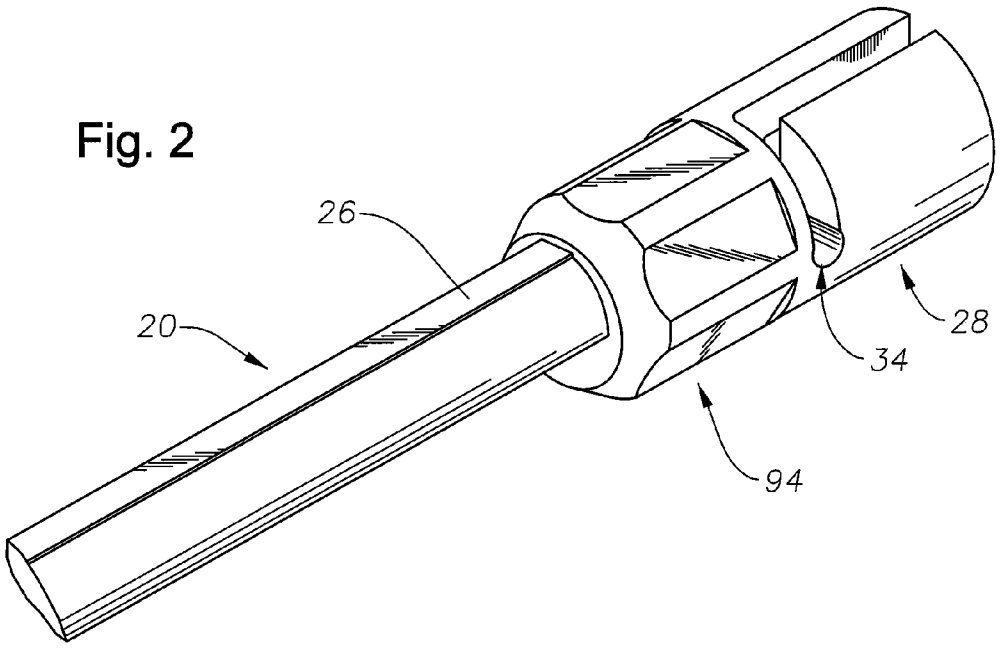


Fig. 3

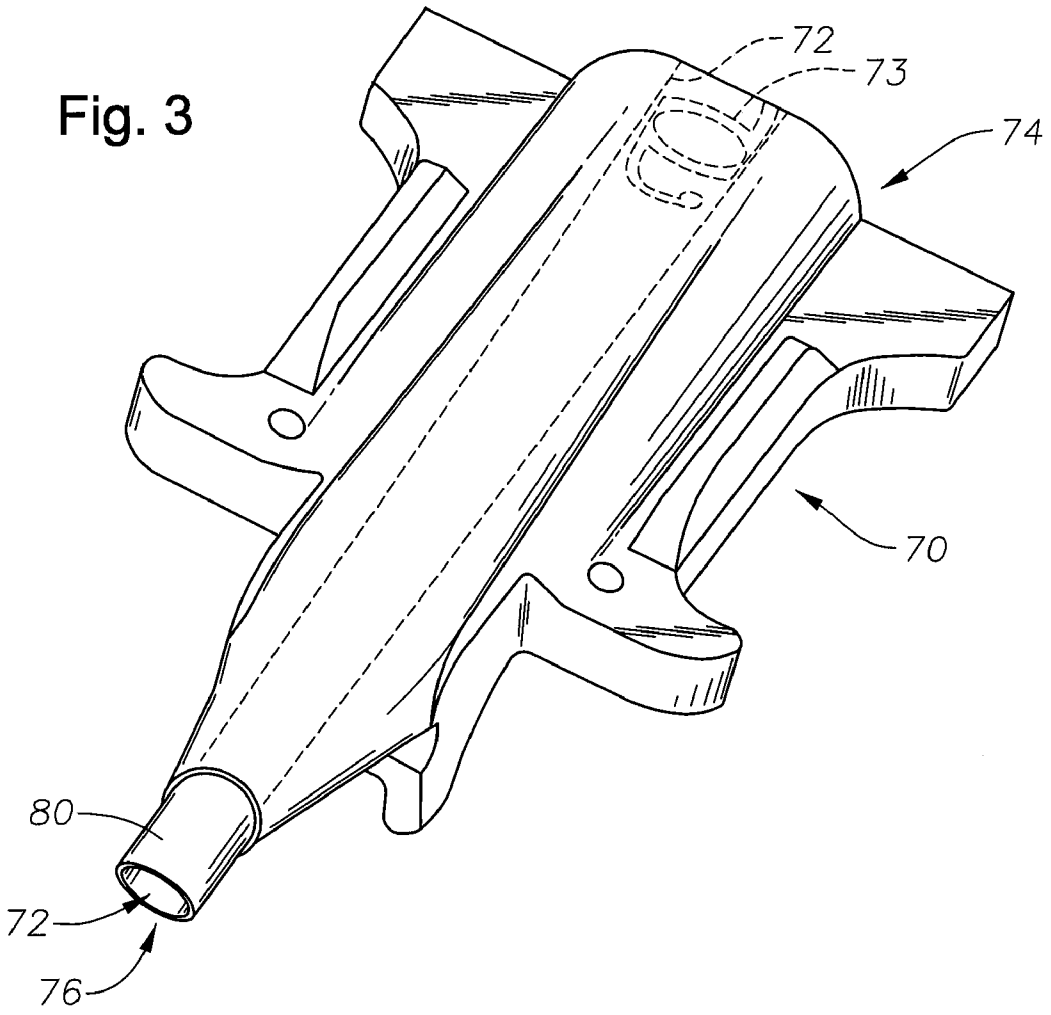
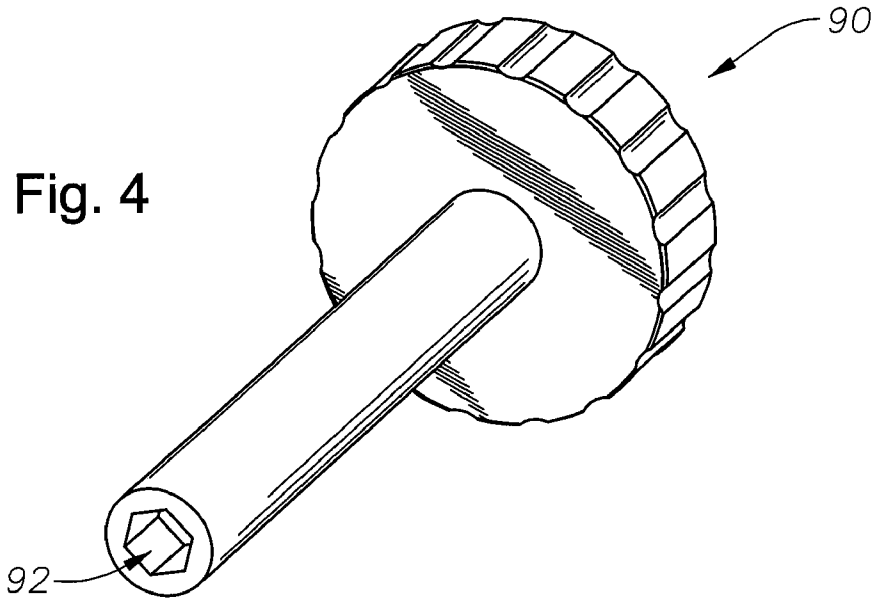


Fig. 4



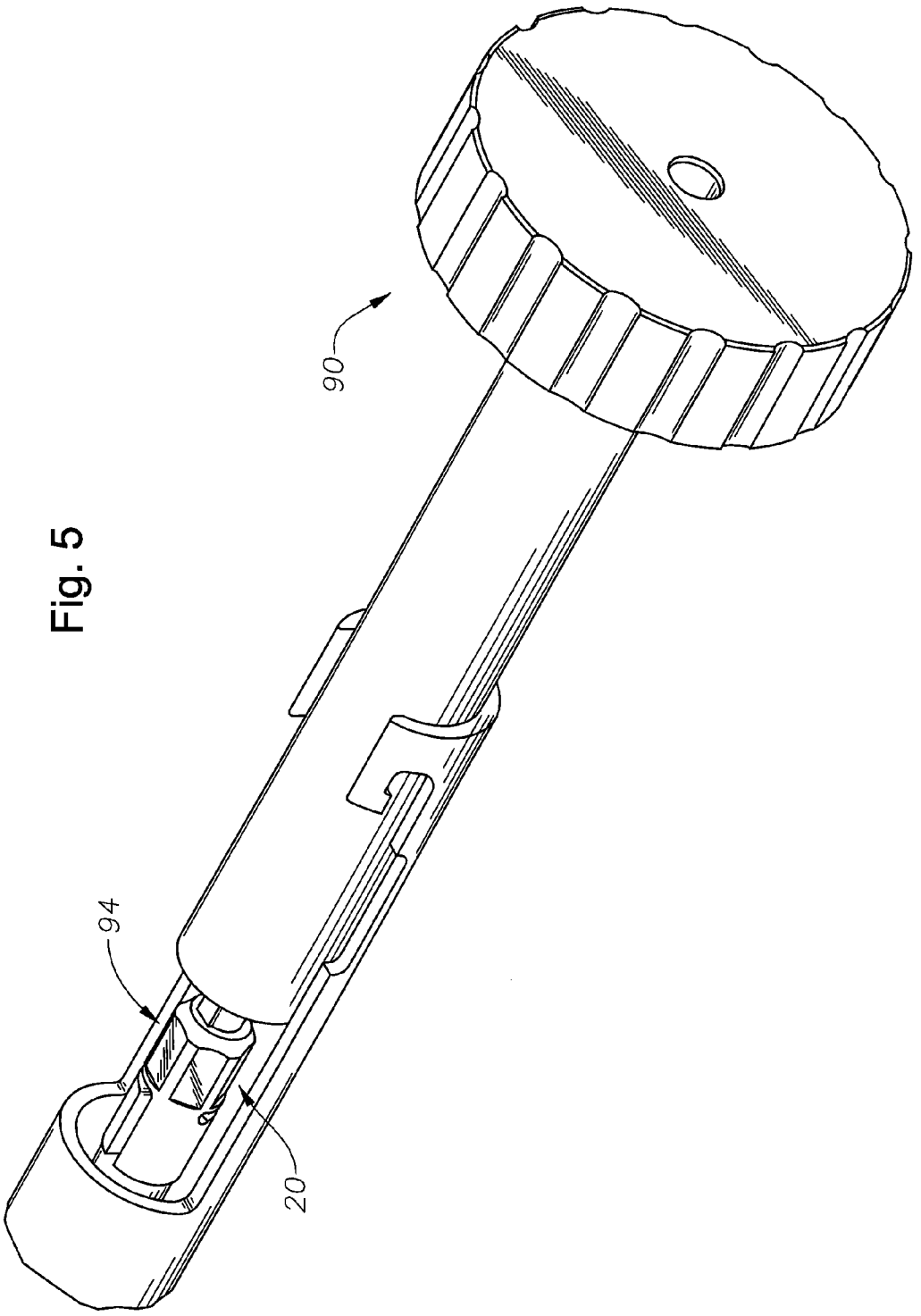


Fig. 5

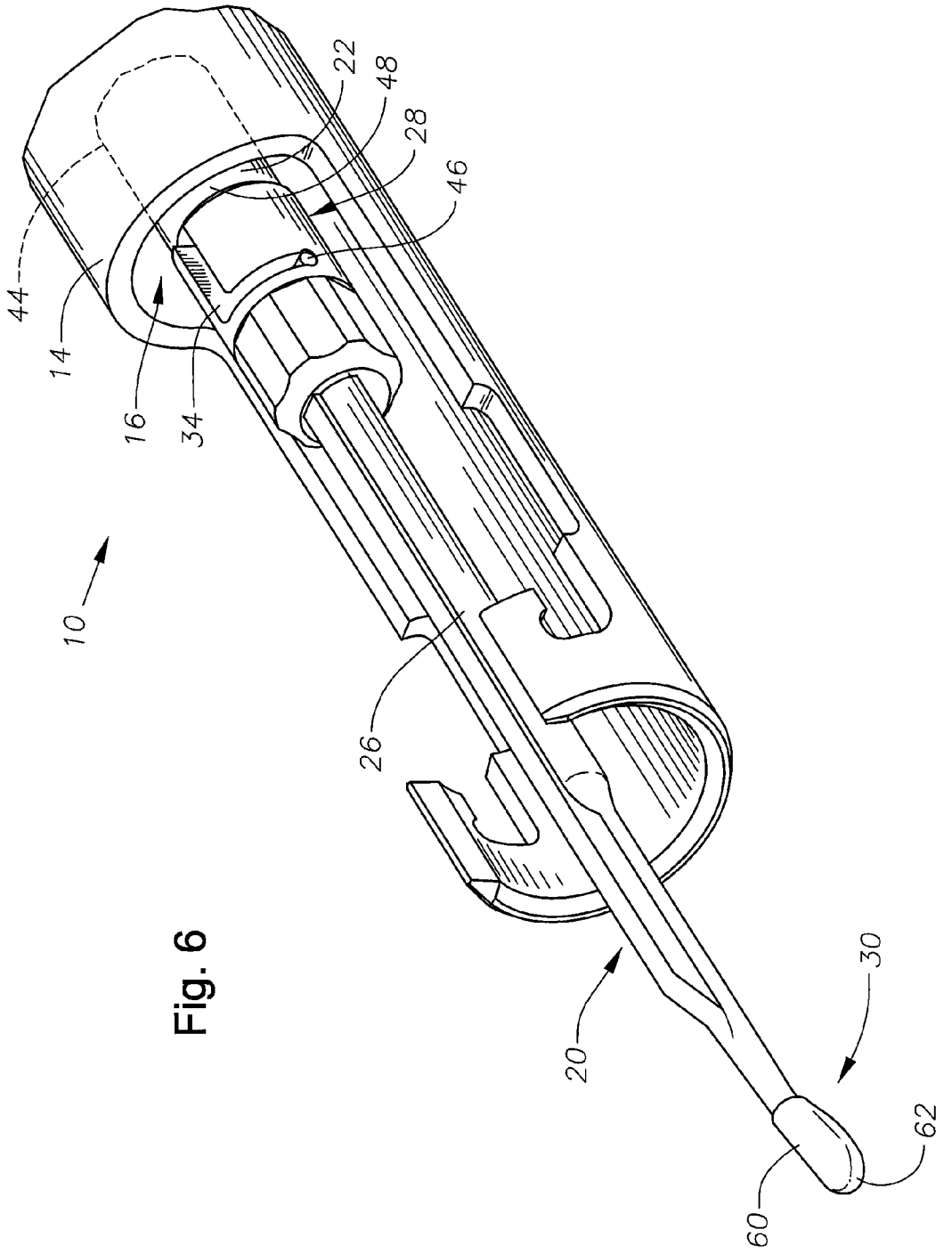


Fig. 6

INTRAOCULAR LENS DELIVERY SYSTEM WITH A DISPOSABLE PLUNGER SEGMENT AND METHOD OF USE THEREFOR

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority under 35 U.S.C. §119 to U.S. Provisional Patent Application Ser. No. 61/182,270, filed May 29, 2009, the entire contents of which are incorporated herein by reference.

TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates to an intraocular lens delivery system with a multi-segment plunger. More particularly, the present invention relates to an is intraocular lens delivery system that includes a plunger comprised of a disposable plunger tip segment that can be attached and removed from a reusable plunger base segment.

BACKGROUND OF THE INVENTION

[0003] The human eye functions to provide vision by transmitting and refracting light through a clear outer portion called the cornea, and further focusing the image by way of a lens onto the retina at the back of the eye. The quality of the focused image depends on many factors including the size, shape and length of the eye, and the shape and transparency of the cornea and lens.

[0004] When trauma, age, disease or other malady cause an individual's natural crystalline lens to become less transparent, vision deteriorates because of the diminished light which can be transmitted to the retina. This deficiency in the lens of the eye is often referred to as a cataract. The treatment for this condition is surgical removal of the natural crystalline lens and implantation of an intraocular lens (IOL).

[0005] While early IOLs were made from hard plastic, such as polymethylmethacrylate (PMMA), soft, foldable IOLs made from silicone, soft acrylics and hydrogels have become increasingly popular because of the ability to fold or roll these soft lenses and insert them through a smaller incision. Several methods of rolling or folding the lenses are used. One popular method is an injector cartridge that folds the lenses and provides a relatively small diameter lumen through which the lens may be pushed into the eye, usually by a plunger.

[0006] One commonly used injector cartridge design is illustrated in U.S. Pat. No. 4,681,102 (Bartell), and includes a split, longitudinally hinged cartridge. Other designs are illustrated in U.S. Pat. Nos. 5,494,484 and 5,499,987 (Feingold) and U.S. Pat. Nos. 5,616,148 and 5,620,450 (Eagles, et al.), the entire contents of which are incorporated herein by reference for all purposes. Still other cartridges are described in U.S. Pat. No. 5,275,604 (Rheinish, et al.), U.S. Pat. No. 5,653,715 (Reich, et al.) and U.S. Pat. No. 5,947,876 (Van Noy, et al.), the entire contents of which are incorporated herein by reference for all purposes.

[0007] The cartridge is typically preloaded with an IOL and then used as part of a delivery system to deliver the IOL to an eye of a mammal (e.g., a human). The delivery system will typically include a hand-piece that includes a plunger within a housing. The delivery cartridge is attached to the hand-piece (e.g., to the housing of the hand-piece) and then the tip of the cartridge can be inserted into an eye of a mammal. The plunger can then advance the IOL along the lumen of the cartridge and into the eye. After IOL delivery, the cartridge is typically removed from the hand-piece so that the hand-piece can be reused with a different cartridge. This system, while generally desirable, has some drawbacks.

[0008] As one exemplary drawback, the plunger of the hand-piece or the entire hand-piece must typically be sterilized (e.g., by autoclaving) after delivery of an IOL. Such sterilization is typically required because the tip of the plunger often enters the eye during insertion of the IOL and it can retain biological matter after removal from the eye. The sterilization process can require significant amounts of time and can limit the number of IOL deliveries that can be accomplished in a given time span.

[0009] As another exemplary drawback, the plunger of the hand-piece is typically sized to accommodate the size of a lumen of a particular cartridge. If it becomes desirable to use a new cartridge having a different size lumen, an entirely new plunger or entirely new hand-piece must typically be employed to accommodate that cartridge.

[0010] As yet another exemplary drawback, recent trends in IOL delivery systems have made the use of soft tip plungers quite desirable, however, the reusable plungers associated with these types of delivery system are often formed of metal or some other autoclavable material and providing such materials with a soft tip can be problematic.

[0011] It would be quite desirable to provide a plunger for an intraocular lens delivery system where that plunger overcomes one or more of the aforementioned drawbacks and/or additional drawbacks associated with conventional IOL delivery systems.

SUMMARY OF THE INVENTION

[0012] Accordingly, the present invention is directed to an improved plunger for is use in IOL delivery and an IOL delivery system having such a plunger. The delivery system will typically include an elongated housing having a length and a plunger having a disposable tip segment and a reusable base segment. The reusable segment of the plunger is typically disposed within the housing and movable along the length of the housing. The reusable segment typically includes a fastening mechanism at a distal end thereof. When included, the fastening mechanism of the reusable segment is typically a projection or a cavity. The disposable segment typically includes an elongated body, a fastening mechanism at a proximate end of the elongated body and a pushing surface at a distal end of the elongated body. The fastening mechanism of the disposable segment, that that of the reusable segment is typically a projection or cavity. The projection or cavity of the fastening mechanism of the reusable segment mates with the projection or cavity of the disposable segment of the fastening mechanism of the disposable segment to releasably, but securely and rigidly, fasten the disposable segment to the reusable segment. The elongated body and fastening projection or cavity of the disposable segment are integrally molded of a single polymeric material. The single polymeric material preferably has a flexural modulus of at least 3500 MPa.

[0013] In preferred embodiment of the invention the system can include either or both of the following characteristics: an opening at a distal end of the cartridge having a maximum internal diameter that is less than 4 millimeters; and/or a soft push tip that is overmolded onto the elongated body at the distal end thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. **1** is a perspective view of an exemplary hand-piece and plunger of an exemplary IOL delivery system according to an aspect of the present invention.

[0015] FIG. **2** is a magnified perspective view of an exemplary proximate end of an exemplary disposable plunger segment of the IOL delivery system of FIG. **1**.

[0016] FIG. **3** is a perspective view of an exemplary preloaded IOL cartridge of an IOL delivery system in accordance with an aspect of the present invention.

[0017] FIG. **4** is a perspective view of an exemplary tool for manipulating a disposable plunger segment in accordance with an aspect of the present invention.

[0018] FIG. **5** is an illustration of the exemplary tool of FIG. **4** being used to manipulate the disposable plunger segment of FIGS. **1** and **2**.

[0019] FIG. **6** is a perspective view of the hand-pieced of FIG. **1** wherein the plunger has been provided with an exemplary soft tip in accordance with an aspect of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The present invention is predicated upon the provision of a disposable segment for a plunger of an intraocular lens (IOL) delivery system. Advantageously, the disposable segment of the plunger can enter the eye of a mammal during insertion of an IOL and can then be disposed of after such insertion rather than requiring sterilization. The disposable segment of the plunger is particularly desirable for use with an IOL delivery system that employs a single handpiece in conjunction with multiple cartridges. The cartridges can also be disposable such that all portions of the IOL delivery system that potentially contact the eye can be disposed of subsequent to delivery of an IOL. In such an embodiment, multiple disposable segments can, if needed or desired, be shaped or sized to correspond to the multiple different cartridges.

[0021] FIGS. **1-2** illustrate an exemplary hand-piece **10** of an exemplary IOL delivery system in accordance with the present invention. The hand-piece **10** includes a housing **14** and a plunger **16** disposed within the housing **14**. The plunger **16** includes a disposable plunger tip segment **20** and a reusable plunger base segment **22**.

[0022] The disposable segment **20** has an elongated body **26** with a proximate end **28** opposite a distal end **30**. A fastening mechanism **34** is located at the proximate end **28** of the elongated body **26** and a pushing surface **40** is located at the distal end **30** of the elongated body **26**.

[0023] The reusable segment **22** has an elongated body **44** with a fastening mechanism **46** located at a distal end **48** of the elongated body **44**. In the embodiment shown, the fastening mechanism **46** of the reusable segment **22** is a projection that mates with or is received by the fastening mechanism **34** of the disposable segment **20**, which is a cavity. However, it is contemplated that this system may be reversed such that the fastening mechanism of the disposable segment, which would be a projection, would mate with or be received by the fastening mechanism of the reusable segment, which would be a cavity. **34**. As still another alternative, each of the fastening mechanisms could include a projection and a cavity such that the projection of each fastening mechanism mates with or is received in the cavity the other fastening mechanism.

[0024] In the embodiment illustrated, the fastening mechanisms **34**, **46** cooperatively form a twist lock connector. It will be understood that various different fastening systems may be employed as long as the system releasably, but securely and rigidly, attaches the disposable segment **20** to the reusable segment **22**.

[0025] The housing **14** and the reusable segment **22** of the handpiece **10** can be formed of a variety of materials and the materials for each component may be the same or different. The materials of the housing **14** and the reusable segment **22** should be durable and rigid. Such materials can include, without limitation, metals, ceramics and high strength plastics. It is generally preferable that the material[s] of the housing **14** and reusable segment **22** be easy to clean, autoclavable (i.e., have a melting temperature greater than 100° C.) or both. In a preferred embodiment, the housing **14** and the reusable segment **22** are formed of the same material and that material is a metal, most preferably stainless steel or titanium.

[0026] The disposable segment **20**, including the elongated body **26** and the fastening mechanism **34** are formed of one or more molded polymeric materials, but preferably a singular integrated molded polymeric material. The pushing surface may also be formed of the molded polymeric material, however, the pushing surface may alternatively be provided by a soft tip material, which is further described herein. The molded polymeric material[s] of the disposable segment may be filled or unfilled and may include various additives such as plasticizers, toughners, etc. The molded polymeric material is preferably injection molded or compression molded to its desired shape. In a preferred embodiment, the moldable material is a rigid plastic material, which may be a thermoset material, but is preferably a thermoplastic material. The rigid plastic material preferably exhibits one or more desirable mechanical properties. In particular, the rigid plastic material preferably has a flexural modulus of at least 3500 megapascal (MPa), more typically at least 10,000 MPa, even more typically at least 30,000 MPa and even possibly at least 50,000 MPa. Flexural modulus of these materials can be determined in accordance with ASTM D790. It is also preferable that the rigid plastic material be formed of a biologically compatible material.

[0027] Examplary preferred rigid plastic materials for the disposable segment include, without limitation, polystyrene, acrylonitrile butadiene styrene, polycarbonate, polyamide, polyimide, polyetherimide, polyarylamide, polyetheretherketone, polybutylene terephthalate, polypropylene, polysulphone, liquid crystal polymer, combinations thereof or the like.

[0028] Advantageously, multiple disposable segments according to the present invention can be rapidly and inexpensively molded (e.g., injection molded). In turn, it becomes much more reasonable in terms of cost and other efficiencies to use a new disposable segment for each IOL insertion procedure.

[0029] As an additional advantage, these disposable segments can be more easily provided with soft tips. In particular, a relatively soft material may be overmolded or otherwise located at the distal end of the disposable segment. Preferably, the soft tip material is adhered or otherwise non-detachably attached to the material of the rest of the disposable segment. Such adhesion can be a natural adhesion between the materials (e.g., natural adhesion occurring during overmolding) or an adhesive can located between the materials. FIG. **7** illustrates such a soft tip **60**, which also provides a pushing surface **62** for pushing an IOL. The soft tip material will typically exhibit an elongation at break of at least 100%, more typically at least 200% and even possibly at least 400%. The elongation at break of the soft tip material is typically no greater than 1500% and even more typically no greater than 780%. Such elongation at break can be measure in accordance with ASTM

D-638. The soft tip materials will also typically have an elastic modulus of from about 100 psi to about 300 psi at an elongation of 100% and/or an elastic modulus of from about 210 psi to about 540 psi at an elongation of 300%. Such soft tips and soft tip materials are particularly desirable for pushing an IOL through a narrow lumen since the tip can deform to accommodate the lumen.

[0030] The soft tip can be formed of a variety of materials such as silicone, elastomer, combinations thereof or the like. In a preferred embodiment, the soft tip material is an elastomeric material, which may be thermoset or thermoplastic. The soft tip material should also be biologically compatible. Exemplary potential materials include, without limitation, styrenic block copolymers, polyolefin blends (TPOs), elastomeric alloys, thermoplastic polyurethanes (TPUs), thermoplastic copolyesters and thermoplastic polyamides.

[0031] With reference to FIG. **3**, there is illustrated an exemplary cartridge **70** in accordance with the present invention. The cartridge **70** has a lumen **72** extending down its length (L) and the lumen **72** is pre-loaded with an IOL **73**. The cartridge **70** and lumen **72** extend from a proximate end **74** of the cartridge **70** to a distal end **76** of the cartridge **70**. The cartridge **70** includes a tip **80** at its distal end **76** and the lumen **72** extends along the tip **80**. The tip **80** is defined herein to include any portion of the cartridge **70** that is inserted within an eye during insertion of an IOL within that eye. Preferably, the maximum diameter of lumen **72**, taken perpendicular to the length (L), within the tip **80** is no greater than 7 millimeters (mm), more typically no greater than 5 mm and even possibly no greater than 4 mm.

[0032] The cartridge **70** may be formed of multiple different materials. In a preferred embodiment, the cartridge **70** is formed of a polymeric material and more preferably, a polypropylene material. The cartridge **70** may also be disposable. Examples of cartridges that could be used in conjunction with the present invention are described in U.S. Pat. Nos. 6,398,789, 6,143,001, 6,083,231, and 5,947,976 all of which are incorporated herein by reference for all purposes.

[0033] The plunger of the present invention is used to assist in the delivery of an IOL into an eye. The disposable segment of the plunger is releasably, but securely and rigidly, attached to the reusable segment of the plunger. Then, the plunger is advanced along the length of the housing, the cartridge or both for moving the IOL into the eye. Thereafter, the disposable segment of the plunger is removed from the reusable segment and is then preferably properly disposed of.

[0034] In the particular embodiment illustrated in FIGS. **1-5**, the fastening mechanisms **34**, **46** of the disposable segment **20** and the reusable segment **22** are mated or, more particularly, twist locked. The cartridge **70** is then attached to the housing **14** to align the IOL **73** with the plunger **16**. The tip **80** of the cartridge **70** is then inserted into an incision in the eye. The plunger **16** is advanced along the length of the housing **14** and the length of the cartridge **70** to push the IOL **73** along the lumen **72** until it is released out of the tip **80** into the eye. The cartridge tip **80** is then removed from the incision followed by removal of the cartridge **70** from the housing **14** and removal of the disposable segment **20** from the reusable segment **22**. The disposable segment **20** can then be properly disposed of.

[0035] A tool may be provided, for example as part of a kit with any combination of the handpiece, the disposable segment and the cartridge, to assist in attaching and detaching the disposable segment from the reusable segment. Preferably, such tool is formed of the same or a similar material as the disposable segment and is itself disposable. In such an embodiment, the tool can be used to assist in attaching and detaching the disposable segment from the reusable segment and can then be properly disposed of in the same fashion as the disposable segment.

[0036] With reference to FIGS. **4** and **5**, an exemplary tool **90** is illustrated. As can be seen, the tool **90** includes a shaped cavity **92** (e.g., a hex shape cavity) corresponding to a hex shaped portion **94** (e.g., shown as the proximate end) of the disposable segment **20**. The hex shaped portion is received in the cavity **92** and the tool **90** can then twist the disposable segment **20** to attach or detach that segment **20** from the reusable segment **22**.

[0037] The plunger **16** can be advanced during IOL delivery through manual pushing of the plunger **16** or through the used of twistable threaded mechanisms. Plungers have been advanced using these techniques in products such as the MONARCH® system, which is commercially available from Alcon Laboratories, Inc., Fort Worth, Tex.

[0038] Through use of the system of the present invention, a first disposable plunger segment and, in particular embodiments, a first tool and/or a first cartridge can be used in conjunction with a hand-piece as described above for delivery of a first IOL. Then, the first disposable plunger segment, the first tool and/or the first cartridge can be replaced with a second disposable plunger, a second tool and/or a second disposable cartridge, which can be used with the same handpiece that was used in conjunction with the first segment, tool and/or cartridge to deliver a second IOL.

[0039] Advantageously, the disposable segment of the plunger does not have to be sterilized after implantation of an IOL. Moreover, soft tips can be more effectively attached to the disposable segments for those embodiments where soft tips are desirable (e.g., in circumstances where the diameter of the cartridge opening is small). It is also contemplated that multiple different sized disposable segments may be used with a single hand-piece to deliver IOLs using cartridges having differently sized lumens. Advantageously, the segments can be specifically sized to correspond to the differently sized lumens.

[0040] The entire contents of all cited references in this disclosure are specifically incorporated herein by reference. Further, when an amount, concentration, or other value or parameter is given as either a range, preferred range, or a list of upper preferable values and lower preferable values, this is to be understood as specifically disclosing all ranges formed from any pair of any upper range limit or preferred value and any lower range limit or preferred value, regardless of whether ranges are separately disclosed. Where a range of numerical values is recited herein, unless otherwise stated, the range is intended to include the endpoints thereof, and all integers and fractions within the range. It is not intended that the scope of the invention be limited to the specific values recited when defining a range.

[0041] Other embodiments of the present invention will be apparent to those skilled in the art from consideration of the present specification and practice of the present invention disclosed herein. It is intended that the present specification and examples be considered as exemplary only with a true scope and spirit of the invention being indicated by the following claims and equivalents thereof.

We claim:

1. A disposable plunger tip segment for an intraocular lens delivery system, the disposable segment comprising:

an elongated body having a proximate end and a distal end;

a fastening mechanism, which is a projection, a cavity or both, at the proximate end of the elongated body; and

a pushing surface at the distal end of the elongated body;

wherein:

i. the elongated body and fastening projection or cavity are integrally molded of single polymeric material;

ii. the fastening mechanism is configured to releasably, but securely and rigidly, attach the disposable segment to a reusable plunger segment of the intraocular lens delivery system; and

iii. the single polymeric material has a flexural modulus of at least 3500 MPa.

2. A disposable segment as in claim **1** wherein the fastening mechanism is a cavity that lockably receives a projection extending from the reusable segment.

3. A disposable segment as in claim **2** wherein the pushing surface is provided by a soft push tip that is overmolded onto the elongated body at the distal end thereof.

4. A disposable segment as in claim **3** wherein the soft push tip is formed of a material having an elongation at break of at least 200%.

5. A disposable segment as in claim **1** wherein the single polymeric material is a thermoplastic material and has a flexural modulus of at least 30,000 MPa.

6. A disposable segment as in claim **1** wherein the disposable segment forms a kit in conjunction with a disposable tool that is used to attach and detach the disposable segment from the reusable segment and/or a cartridge that is attachable and detachable from the handpiece.

7. An intraocular delivery system, the system comprising:

an elongated housing having a length;

a plunger having a disposable tip segment and a reusable base segment wherein:

i. the reusable segment of the plunger is disposed within the housing and movable along the length of the housing;

ii. the reusable segment includes a fastening mechanism at a distal end thereof;

iii. the fastening mechanism of the reusable segment is a projection or a cavity;

iv. the disposable segment includes an elongated body, a fastening mechanism at a proximate end of the elongated body and a pushing surface at a distal end of the elongated body;

v. the fastening mechanism of the disposable segment is a projection or cavity;

vi. the projection or cavity of the fastening mechanism of the reusable segment mates with the projection or cavity of the disposable segment of the fastening mechanism of the disposable segment to releasably, but securely and rigidly, fasten the disposable segment to the reusable segment;

vii. the elongated body and fastening projection or cavity of the disposable segment are integrally molded of a single polymeric material; and

viii. the single polymeric material has a flexural modulus of at least 3500 MPa.

8. A system as in claim **7** further comprising a cartridge fastened to the housing wherein the cartridge includes an opening at a distal end of the cartridge and the opening has a maximum internal diameter that is less than 4 millimeters.

9. A system as in claim **7** wherein the fastening mechanism is a cavity that lockably receives a projection extending from the reusable segment.

10. A system as in claim **7** wherein the pushing surface is provided by a soft push tip that is overmolded onto the elongated body at the distal end thereof.

11. A system as in claim **10** wherein the soft push tip is formed of a material having an elongation at break of at least 200%.

12. A system as in claim **7** wherein the single polymeric material is a thermoplastic material and has a flexural modulus of at least 30,000 MPa.

13. A system as in claim **7** wherein the disposable segment forms a kit in conjunction with a disposable tool that is used to attach and detach the disposable segment from the reusable segment and/or a cartridge that is attachable and detachable from the handpiece.

14. A method of using the system of claim **7**, the method including:

advancing the plunger to move an intraocular lens into any eye of a mammal;

releasing the disposable segment from the reusable segment after location of the intraocular lens within the eye of the mammal;

disposing of the disposable segment.

15. A method as in claim **14** wherein the disposable segment is an original segment and further comprising:

attaching second disposable segment to the reusable segment.

16. A method as in claim **15** wherein second disposable segment is sized and/or shape to correspond to a different cartridge than the original disposable segment.

* * * * *