PLUNGER LINKAGE AND SEAL FOR OPHTHALMIC MEDICAL DEVICE

Publication Classification

Abstract

A disposable injection device has a dispensing chamber housing and a plunger. The dispensing chamber housing has an inner surface and an outer surface. The inner surface partially defines a dispensing chamber for receiving a quantity of a substance. The plunger is engaged with the inner surface of the dispensing chamber housing, and is capable of sliding in the dispensing chamber housing, and is fluidly sealed to the inner surface of the dispensing chamber housing. The plunger has a plunger interface. The plunger interface mates with a mating surface on a mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.
Fig. 1 (Prior Art)
Fig. 7

Fig. 8
In response to an input, advancing a mechanical linkage interface until it contacts a plunger interface.

Further advancing the mechanical linkage interface to further advance the plunger to expel a substance from a dispensing chamber.

Retracting the mechanical linkage interface without substantially retracting the plunger to prevent reflux of the substance.

Fig. 19
Recognizing a connection between a disposable tip segment and a limited reuse assembly

Activating and controlling a temperature control device to alter the temperature of a substance contained in a dispensing chamber

Reading dosage information

In response to the dosage information, advancing a mechanical linkage to advance a plunger to expel the substance from the dispensing chamber

Retracting the mechanical linkage interface without substantially retracting the plunger to prevent reflux of the substance

Preventing reuse of the disposable tip segment

Recognizing the removal of the disposable tip segment from the limited reuse assembly

Fig. 20
PLUNGER LINKAGE AND SEAL FOR
OPHTHALMIC MEDICAL DEVICE

RELATED APPLICATIONS


BACKGROUND OF THE INVENTION

[0002] The present invention relates to a single-use medical device and more particularly to a two-piece ophthalmic drug delivery device with a disposable tip end containing an improved plunger linkage and seal.

[0003] Several diseases and conditions of the posterior segment of the eye threaten vision. Age related macular degeneration (ARMD), choroidal neovascularization (CNV), retinopathies (e.g., diabetic retinopathy, vitreoretinopathy), retinitis (e.g., cytomegalovirus (CMV) retinitis), uveitis, macular edema, glaucoma, and neuropathies are several examples.

[0004] These, and other diseases, can be treated by injecting a drug into the eye. Such injections are typically manually performed using a conventional syringe and needle. FIG. 1 is a perspective view of a prior art syringe used to inject drugs into the eye. In FIG. 1, the syringe includes a needle 105, a luer hub 110, a chamber 115, a plunger 120, a plunger shaft 125, and a thumb rest 130. As is commonly known, the drug to be injected is located in chamber 115. Pushing on the thumb rest 130 causes the plunger 120 to expel the drug through needle 105.

[0005] In using such a syringe, the surgeon is required to pierce the eye tissue with the needle, hold the syringe steady, and actuate the syringe plunger (with or without the help of a nurse) to inject the fluid into the eye. Fluid flow rates are uncontrolled. Reading the vernier is subject to parallax error which affects the precision and accuracy of the injected volume. Tissue damage may occur due to an “unsteady” injection. Reflux of the drug may also occur when the needle is removed from the eye.

[0006] An effort has been made to control the delivery of small amounts of liquids. A commercially available fluid dispenser is the ULTRAX™ positive displacement dispenser available from EFPI Inc. of Providence, R.I. The ULTRAX dispenser is typically used in the dispensing of small volumes of industrial adhesives. It utilizes a conventional syringe and a custom dispensing tip. The syringe plunger is actuated using an electrical stepper motor and an actuating fluid. With this type of dispenser, the volumes delivered are highly dependent on fluid viscosity, surface tension, and the specific dispensing tip. Parker Hannifin Corporation of Cleveland, Ohio distributes a small volume liquid dispenser for drug discovery applications made by Aurora Instruments LLC of San Diego, Calif. The Parker/Aurora dispenser utilizes a piezo-electric dispensing mechanism. While precise, this dispenser is expensive and requires an electrical signal to be delivered to the dispensing mechanism.

[0007] U.S. Pat. No. 6,290,690 discloses an ophthalmic system for injecting a viscous fluid (e.g. silicone oil) into the eye while simultaneously aspirating a second viscous fluid (e.g. perflourocarbon liquid) from the eye in a fluid/fluid exchange during surgery to repair a retinal detachment or tear. The system includes a conventional syringe with a plunger. One end of the syringe is fluidly coupled to a source of pneumatic pressure that provides a constant pneumatic pressure to actuate the plunger. The other end of the syringe is fluidly coupled to an infusion cannula via tubing to deliver the viscous fluid to be injected.

[0008] It would be desirable to have a portable hand piece for injecting a drug into the eye. Such a hand piece includes a limited re-use assembly attachable to and removable from a disposable tip segment. The disposable tip segment contains the drug, a needle for administering the drug, a plunger, and various other components. The limited re-use assembly includes a mechanism for driving the plunger to expel the drug from the disposable tip segment. The actuation of the plunger in the disposable tip segment is controlled by the limited re-use assembly. It would be desirable to have a plunger linkage and seal that maintains the sterility of the disposable tip segment and prevents reflux when the needle is removed from the eye after an injection.

SUMMARY OF THE INVENTION

[0009] In one embodiment consistent with the principles of the present invention, the present invention is a disposable injection device having a dispensing chamber housing and a plunger. The dispensing chamber housing has an inner surface and an outer surface. The inner surface partially defines a dispensing chamber for receiving a quantity of a substance. The plunger is engaged with the inner surface of the dispensing chamber housing, is capable of sliding in the dispensing chamber housing, and is fluidly sealed to the inner surface of the dispensing chamber housing. The plunger has a plunger interface. The plunger interface mates with a mating surface on a mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.

[0010] In another embodiment consistent with the principles of the present invention, the present invention is an ophthalmic injection system having a tip segment and a limited re-use assembly. The tip segment has a dispensing chamber housing and a plunger. The dispensing chamber housing has an inner surface and an outer surface. The inner surface partially defines a dispensing chamber for receiving a quantity of a substance. The plunger is engaged with the inner surface of the dispensing chamber housing, is capable of sliding in the dispensing chamber housing, and is fluidly sealed to the inner surface of the dispensing chamber housing. The plunger has a plunger interface. The limited re-use assembly has a power source, an actuator with a shaft, a controller for controlling the actuator, and a mechanical linkage interface. The mechanical linkage interface is coupled to the shaft and has a mating surface on an end. The plunger interface mates with the mating surface on the mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger
interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.

In another embodiment consistent with the principles of the present invention, the present invention is a dispensing mechanism for use in an ophthalmic drug delivery device. The dispensing mechanism has a dispensing chamber, a plunger, and a mechanical linkage interface. The dispensing chamber housing has an inner surface and an outer surface. The inner surface partially defines a dispensing chamber for receiving a quantity of a substance. The plunger is engaged with the inner surface of the dispensing chamber housing, is capable of sliding in the dispensing chamber housing, and is fluidly sealed to the inner surface of the dispensing chamber housing. The plunger has a plunger interface. The mechanical linkage interface has a mating surface on one end. The plunger interface mates with the mating surface on the mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are intended to provide further explanation of the invention as claimed. The following description, as well as the practice of the invention, set forth and suggest additional advantages and purposes of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying figures, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

FIG. 1 is a perspective view of a prior art syringe.

FIG. 2 is a view of an ophthalmic medical device including a disposable tip segment and a limited reuse assembly according to an embodiment of the present invention.

FIG. 3 is an embodiment of a limited reuse assembly according to the principles of the present invention.

FIG. 4 is an exploded cross section view of a disposable tip segment for an ophthalmic hand piece according to an embodiment of the present invention.

FIG. 5 is cross section view of a disposable tip segment and a limited reuse assembly according to an embodiment of the present invention.

FIGS. 6-16 are cross section views of various plunger and mechanical linkage interface designs according to the principles of the present invention.

FIGS. 17-18 are cross section views of two subassemblies according to the principles of the present invention.

FIGS. 19-20 are methods of operating an ophthalmic medical device according to the principles of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Reference is now made in detail to the exemplary embodiments of the invention, examples of which are illustrated in the accompanying figures. Wherever possible, the same reference numbers are used throughout the figures to refer to the same or like parts.

FIG. 2 depicts one view of an ophthalmic medical device including a disposable tip segment and a limited reuse assembly according to an embodiment of the present invention. In FIG. 2, the medical device includes a tip segment 205 and a limited reuse assembly 250. The tip segment 205 includes a needle 210, a housing 215, and an optional light 275. The limited reuse assembly 250 includes a housing 255, a switch 270, a lock mechanism 265, and a threaded portion 260.

Tip segment 205 is capable of being connected to and removed from limited reuse assembly 250. In this embodiment, tip segment 205 has a threaded portion on an interior surface of housing 215 that screws onto the threaded portion 260 of limited reuse assembly 250. In addition, lock mechanism 265 secures tip segment 215 to limited reuse assembly 250. Lock mechanism 265 may be in the form of a button, a sliding switch, or a cantilevered mechanism. Other mechanisms for connecting tip segment 205 to limited reuse assembly 250, such as those involving structural features that mate with each other, are commonly known in the art and are within the scope of the present invention.

Needle 210 is adapted to deliver a substance, such as a drug, into an eye. Needle 210 may be of any commonly known configuration. Preferably, needle 210 is designed such that its thermal characteristics are conducive to the particular drug delivery application. For example, when a heated drug is to be delivered, needle 210 may be relatively short (several millimeters) in length to facilitate proper delivery of the drug based on thermal characteristics.

Switch 270 is adapted to provide an input to the system. For example, switch 270 may be used to activate the system or to turn on a heater. Other switches, buttons, or user-directed control inputs are commonly known and may be employed with limited reuse assembly 250 and/or tip segment 205.

Optional light 275 is illuminated when tip segment 205 is ready to be used. Optional light 275 may protrude from housing 215, or it may be contained within housing 215, in which case, optional light 275 may be seen through a clear portion of housing 215. In other embodiments, optional light 275 may be replaced by an indicator, such as a liquid crystal display, segmented display, or other device that indicates a status or condition of disposable tip segment 205. For example, optional light 275 may also pulse on and off to indicate other states, such as, but not limited to a system error, fully charged battery, insufficiently charged battery or faulty connection between the tip segment 205 and limited use assembly 250. While shown on tip segment 205, optional light 275 or other indicator may be located on limited reuse assembly 250.

FIG. 3 is another embodiment of a limited reuse assembly according to the principles of the present invention. Limited reuse assembly 250 includes a button 310, a display 320, and a housing 330. Disposable tip segment 205
attaches to end 340 of limited reuse assembly 250. Button 310 is actuated to provide an input to the system. As with switch 270, button 310 may activate a heater or other temperature control device or initiate actuation of a plunger. Display 320 is a liquid crystal display, segmented display, or other device that indicates a status or condition of disposable tip segment 205 or limited reuse assembly 250.

In one embodiment of the present invention, the substance located in dispensing chamber 405 is a drug that is preloaded into the dispensing chamber. In such a case, disposable tip segment 205 is appropriate as a single use consumable product. Such a disposable product can be assembled at a factory with a dosage of a drug installed.

When a drug is preloaded into dispensing chamber 405, a set quantity of the drug can be preloaded. For example, 100 microliters of a drug can be loaded into dispensing chamber 405, and any quantity up to 100 microliters can be dispensed. Information about the amount of drug in dispensing chamber 205 and other dosage information can be stored in assembly 555. In such a case, the plunger 415 can be moved a precise distance to deliver a precise dosage of drug from the dispensing chamber 405 through the needle 210, and into an eye. This provides for flexibility of dosing and ease of assembly.

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In a limited reuse assembly 250, power source 310 provides power to actuator 515. An interface (not shown)

[0040] In limited reuse assembly 250, power source 310 provides power to actuator 515. An interface (not shown)
between power source 310 and actuator 515 serves as a conduit for providing power to actuator 515. Actuator 515 is connected to actuator shaft 510. When actuator 515 is a stepper motor, actuator shaft 510 is integral with actuator 515. Mechanical linkage interface 545 is connected to actuator shaft 510. In this configuration, as actuator 515 moves actuator shaft 510 upward toward needle 210, mechanical linkage interface 545 also moves upward toward needle 210.

[0041] Controller 305 is connected via interface 535 to limited reuse assembly interface connector 525. Limited reuse assembly interface connector 525 is located on a top surface of limited reuse assembly housing 255 adjacent to mechanical linkage interface 545. In this manner, both limited reuse assembly interface connector 525 and mechanical linkage interface 545 are adapted to be connected with tip interface connector 520 and plunger interface 420 respectively.

[0042] Controller 305 and actuator 515 are connected by an interface (not shown). This interface (not shown) allows controller 305 to control the operation of actuator 515. In addition, an interface (not shown) between power source 310 and controller 305 allows controller 305 to control operation of power source 310. In such a case, controller 305 may control the charging and the discharging of power source 310 when power source 310 is a rechargeable battery.

[0043] Controller 305 is typically an integrated circuit with power, input, and output pins capable of performing logic functions. In various embodiments, controller 305 is a targeted device controller. In such a case, controller 305 performs specific control functions targeted to a specific device or component, such as a temperature control device or a power supply. For example, a temperature control device controller has the basic functionality to control a temperature control device. In other embodiments, controller 305 is a microprocessor. In such a case, controller 305 is programmable so that it can function to control more than one component of the device. In other cases, controller 305 is not a programmable microprocessor, but instead is a special purpose controller configured to control different components that perform different functions. While depicted as one component in FIG. 5, controller 305 may be made of many different components or integrated circuits.

[0044] Tip segment 205 is adapted to mate with or attach to limited reuse assembly 250 as previously described. In the embodiment of FIG. 5, plunger interface 420 located on a bottom surface of plunger 415 is adapted to mate with mechanical linkage interface 545 located near a top surface of limited reuse assembly housing 255. In addition, tip interface connector 520 is adapted to connect with limited reuse assembly interface connector 525. When tip segment 205 is connected to limited reuse assembly 250 in this manner, actuator 515 and actuator shaft 510 are adapted to drive plunger 415 upward toward needle 210. In addition, an interface is formed between controller 305 and temperature control device 450. A signal can pass from controller 305 to temperature control device 450 through interface 535, limited reuse assembly interface connector 525, tip interface connector 520, and interface 530.

[0045] In operation, when tip segment 205 is connected to limited reuse assembly 250, controller 305 controls the operation of actuator 515. Actuator 515 is actuated and actuator shaft 510 is moved upward toward needle 210. In turn, mechanical linkage interface 545, which is mated with plunger interface 420, moves plunger 415 upward toward needle 210. A substance located in dispensing chamber 405 is then expelled through needle 210.

[0046] In addition, controller 305 controls the operation of temperature control device 450. Temperature control device 450 is adapted to heat and/or cool an outside surface of dispensing chamber housing 425. Since dispensing chamber housing 425 is at least partially thermally conductive, heating or cooling dispensing chamber housing 425 heats or cools a substance located in dispensing chamber 405. Temperature information can be transferred from thermal sensor 460 through interface 530, tip interface connector 520, limited reuse assembly interface connector 525, and interface 535 back to controller 305. This temperature information can be used to control the operation of temperature control device 450. When temperature control device 450 is a heater, controller 305 controls the amount of current that is sent to temperature control device 450. The more current sent to temperature control device 450, the hotter it gets. In such a manner, controller 305 can use a feed back loop utilizing information from thermal sensor 460 to control the operation of temperature control device 450. Any suitable type of control algorithm, such as a proportional integral derivative (PID) algorithm, can be used to control the operation of temperature control device 450.

[0047] FIGS. 6-16 are cross section views of various plunger and mechanical linkage interface designs according to the principles of the present invention. In FIGS. 6-16, a plunger 415 is disposed in dispensing chamber housing 425. Dispensing chamber 405 is adjacent to one face of plunger 415. Mechanical linkage interface 545 has a mating surface 605 on its distal end that mates with plunger interface 420. In the various designs depicted in FIGS. 6-16, plunger interface 420 and mating surface 605 of mechanical linkage interface 545 fit together without locking. As mechanical linkage interface 545 contacts plunger interface 420 and moves in a direction towards dispensing chamber 405, plunger 415 is moved in a direction towards dispensing chamber 415. In this manner, translation of mechanical linkage interface 545 results in translation of plunger 415 only in a direction towards dispensing chamber 405. As plunger 415 moves, a substance, for example, a drug, in dispensing chamber 405 is expelled through the needle (not shown). When mechanical linkage interface 545 is retracted or moved away from dispensing chamber 405, plunger 415 does not substantially move. In other words, plunger 415 can only be moved in one direction—towards dispensing chamber 405. This results in a smooth delivery of the substance without reflux. When the needle (not shown) is removed from the eye, the plunger remains substantially stationary thus preventing reflux.

[0048] In FIG. 6, plunger 415 includes an o-ring 615. O-ring 615 seals against an interior surface of dispensing chamber housing 425. In this manner, a sterile seal is maintained thus preventing contamination of the substance in dispensing chamber 405. Plunger 415 may be made of any suitable material, such as, for example, glass, stainless steel, or a polymer. O-ring 615 is typically made of rubber or a polymer. Mating surface 605 is substantially in the shape of half a sphere. Plunger interface 420 is configured to receive mating surface 605, and substantially align mechanical
linkage interface 545 with plunger 415. The embodiment of FIG. 7 is similar to that of FIG. 6 except FIG. 7 has two orings 705 and 710.

[0049] In the embodiment of FIG. 8, a ball joint is included on one end of mechanical linkage interface 545. The ball joint includes ball 805 which is rotatably coupled to a shaft 810. Shaft 810 is rigidly connected to an actuator shaft (not shown). Ball 805 is rigidly coupled to mechanical linkage interface 545. In this embodiment, mechanical linkage interface 545 can pivot with respect to actuator shaft 810. Ball 805 is free to rotate with respect to actuator shaft 810 resulting in the movement of mechanical linkage interface in an area defined by a cone. The ball joint allows greater freedom of movement and a better translation of force from mechanical linkage interface 545 to plunger 415 over a wider range of positions. The ball joint allows for a three dimensional movement of mechanical linkage interface 545, whereas the embodiment of FIG. 7, for example, does not. This can lead to improved coupling between mechanical linkage interface 545 and plunger 415.

[0050] In FIG. 9, surface 615 of mechanical linkage interface 545 has a lip that mates with a flat surface on plunger interface 420. The hemispherical mating surface 605 of mechanical linkage interface 545 mates with the bowl-like depression that comprises part of plunger interface 420. The configuration of FIG. 9 is yet another example of an embodiment of the present invention in which mating surface 605 of mechanical linkage interface 545 is designed to mate with plunger interface 420 so that force can be transferred effectively from mechanical linkage interface 545 to plunger 415. This configuration, like the other configurations depicted in FIGS. 6-16, properly aligns mechanical linkage interface 545 and plunger 415. This helps to prevent mechanical linkage interface 545 from binding or compressing plunger 415 against an interior surface of dispensing chamber housing 425.

[0051] The plunger 415 of FIG. 9 also includes an annular ridge 915 that forms a seal between plunger 415 and the interior surface of dispensing chamber housing 425. In FIG. 9, plunger 415 is made of a rubber or polymer material, and annular ridge 915 is integral with plunger 415. Annular ridge 915 functions like an o-ring 615 and reduces the seal contact surface.

[0052] In FIG. 10, plunger interface 420 is a flat surface. Likewise, mating surface 605 of mechanical linkage interface 545 is also a flat surface. Because of the location of dispensing chamber housing 425 with respect to plunger 415 (plunger 415 is disposed within dispensing chamber housing 425), it has been found that a pair of flat surfaces (embodied in plunger interface 420 and mating surface 605) provide proper alignment of mechanical linkage interface 545 and plunger 415. This pair of flat surfaces allows for effective transfer of motion from mechanical linkage interface 545 to plunger 415. In addition, mechanical linkage interface 545 has a disc-like end terminating at mating surface 605. The diameter of this disc is greater than the diameter of the remainder of mechanical linkage interface 545. Such a configuration decreases the amount of material needed to make mechanical linkage interface 545 and thus decreases weight.

[0053] In FIG. 11, plunger 415 utilizes o-ring 615 to seal itself against the interior surface of dispensing chamber housing 425. Plunger interface 420 mates with mating surface 605 on mechanical linkage interface 545. Mating surface 605 is substantially conical in shape with a rounded distal surface. The embodiment of FIG. 11 is an example of one of many different configurations that are within the scope of the present invention.

[0054] In the embodiment of FIG. 12, plunger interface and mating surface 605 of mechanical linkage interface 545 are each flat surfaces. Plunger 415 has two annular ridges 915, 920 that seal plunger 415 against the interior surface of dispensing chamber housing 425. Instead of o-rings or other sealing mechanisms, annular ridges 915, 920 perform the sealing function. Annular ridges 915, 920 are integral with plunger 415.

[0055] In FIG. 13, mechanical linkage interface 545 is tapered as shown. The end of mechanical linkage interface 545 that is closest to mating surface 605 has a smaller diameter than the end of mechanical linkage interface 545 that is furthest from mating surface 605. This taper can help in aligning mechanical linkage interface with the plunger 425.

[0056] In FIG. 14, plunger 415 is over molded onto a shaft 1405. Shaft 1405 is generally cylindrical in shape with a middle diameter that is less than a diameter on the distal and proximal ends of shaft 1405. Plunger interface 420 is a flat surface on the proximal end of shaft 1405. Mating surface 605 of mechanical linkage interface 545 is also a flat surface. Shaft 1415 is typically made of a rigid material such as stainless steel. Plunger 415 is made of a rubber or polymer material. In FIG. 15, plunger 415 has two annular ridges.

[0057] In FIG. 16, the distal end of shaft 1605 has a lip over which plunger 415 can be applied. Plunger 415 can be press fitted onto shaft 1605 and is retained in place by the lip on the distal end of shaft 1605. This allows for easier assembly. Instead of over molding plunger 415 onto a shaft, plunger 415 can be manufactured as a separate part and pushed onto the distal end of shaft 1605.

[0058] The various configurations of FIGS. 6-16 show examples of embodiments of the present invention. Other combinations of mechanical linkage interface 545 and plunger 415 are within the scope of the present invention. In addition, other surface shapes may be employed as mating surface 605 on mechanical linkage interface 545. Complementary surface shapes can comprise plunger interface 420.

[0059] FIGS. 17-18 are cross section views of two subassemblies according to the principles of the present invention. Each of these subassemblies depicts the path from the actuator 515 to the needle 210. FIG. 18 depicts a mechanical linkage interface 545 that is rigidly connected to actuator shaft 510, while FIG. 19 depicts a mechanical linkage assembly 545 with a ball joint 805.

[0060] In FIG. 17, actuator 515 has an actuator shaft 510 that is rigidly connected to mechanical linkage interface 545. Mechanical linkage interface mates with plunger interface 420. Plunger 415 is disposed within dispensing chamber housing 425 and is sealed against an inside surface of dispensing chamber housing 425. Dispensing chamber 405 is bounded by an interior surface of dispensing chamber housing 425 and the distal face of plunger 415. Temperature control device 450 at least partially surrounds dispensing chamber housing 425. Needle 210 is fluidly coupled to dispensing chamber 405.
In FIG. 18, actuator 515 has an actuator shaft 510 that is rigidly connected to shaft 810. Mechanical linkage interface 545 is rotatably connected to shaft 810 via ball joint 805. Mechanical linkage interface mates with plunger interface 420. Plunger 415 is disposed within dispensing chamber housing 425 and is sealed against an inside surface of dispensing chamber housing 425. Dispensing chamber 405 is bounded by an interior surface of dispensing chamber housing 425 and the distal face of plunger 415. Temperature control device 450 at least partially surrounds dispensing chamber housing 425. Needle 210 is fluidly coupled to dispensing chamber 405.

In FIGS. 17 and 18, actuator 515 drives actuator shaft 510 upward (in a direction towards needle 210). In turn, mechanical linkage interface 545 is also driven upward. When mechanical linkage interface 545 is at rest, plunger interface 420, plunger 420 is also moved upward. A substance contained in dispensing chamber 405 is expelled through needle 210. In this manner, motion and force is transferred from actuator shaft 510 to mechanical linkage interface 545 to plunger 415.

When dispensing chamber 405 contains a drug that is to be delivered into an eye, the various configurations of FIGS. 6-18 each eliminate reflux when the needle is removed from the eye. Motion of the plunger 415 is in a single direction (a direction that expels the drug in dispensing chamber 405). When mechanical linkage interface 545 is in a direction away from needle 210, for example, after the drug has been injected into the eye, the plunger 415 remains in place. Since plunger 415 is not rigidly connected to mechanical linkage interface 545, plunger 415 is not retracted as mechanical linkage interface 545 is retracted.

FIG. 19 is a method of operating an ophthalmic medical device according to the principles of the present invention. The method of FIG. 19 is one way in which the tip segment and limited reuse assembly may be operated. In 1910 the mechanical linkage interface is advanced until it contacts the plunger. In one embodiment of the present invention, the controller directs the actuator to move the shaft to which the mechanical linkage interface is attached. In 1920, the mechanical linkage interface is further advanced to advance the plunger to expel the substance that is contained in the dispensing chamber. In 1930, the mechanical linkage interface is retracted without retracting the plunger. This prevents reflux of the substance. Depending on the composition of the materials that are used, some friction force may be present between the mating surface of the mechanical linkage interface and the plunger interface. However, the mating surface of the mechanical linkage interface and plunger interface are designed to disengage very easily, substantially preventing the transfer of force or motion from the mechanical linkage interface to the plunger when the mechanical linkage interface is retracted.

FIG. 20 is a method of operating an ophthalmic medical device according to the principles of the present invention. The method of FIG. 20 is one way in which the tip segment and limited reuse assembly may be operated. In 2010, a connection is recognized between the disposable tip segment and the limited reuse assembly. In 2020, a temperature control device is activated to alter the temperature of a substance contained in the dispensing chamber. In one embodiment of the present invention, an input is received from the thermal sensor, and the input is used to control the temperature control device. In 2030, dosage information is read. In 2040, in response to the dosage information, the mechanical linkage interface is advanced to advance the plunger to expel the substance from the dispensing chamber. In 2050, the mechanical linkage interface is retracted without retracting the plunger to prevent reflux of the substance. In 2060, the disposable tip segment is prevented from being reused. In 2070, the removal of the disposable tip segment from the limited reuse assembly is recognized.

From the above, it may be appreciated that the present invention provides an improved system and methods for delivering precise volumes of a substance into an eye. The present invention provides a single use, disposable delivery device tip segment that is capable of delivering a precise dosage. The tip segment interfaces with a limited reuse assembly. The disposable tip segment has a plunger interface that mates with a mechanical linkage interface. The plunger interface and mechanical linkage interface are designed to prevent reflux of the substance when the needle is removed from the eye. The present invention is illustrated herein by example, and various modifications may be made by a person of ordinary skill in the art.

While the present invention is described in the context of a single-use drug delivery device, the present invention encompasses any single-use medical device that interfaces with a source of electric power. Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:
1. A disposable injection device comprising:
   a dispensing chamber housing having an inner surface and an outer surface, the inner surface partially defining a dispensing chamber for receiving a quantity of a substance; and
   a plunger engaged with the inner surface of the dispensing chamber housing, the plunger capable of sliding in the dispensing chamber housing, the plunger fluidly sealed to the inner surface of the dispensing chamber housing, the plunger having a plunger interface;

wherein the plunger interface mates with a mating surface on a mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.
2. The device of claim 1 further comprising:
   a housing at least partially enclosing the dispensing chamber housing and the plunger.
3. The device of claim 1 further comprising:
   a needle fluidly coupled to the dispensing chamber.
4. The device of claim 1 further comprising:
   a temperature control device in thermal contact with the dispensing chamber, the temperature control device for altering the temperature of the substance.
5. The device of claim 4 further comprising:
   a thermal sensor in thermal contact with the dispensing chamber.
6. The device of claim 1 wherein the substance is a drug for treating a condition of the eye.
7. The device of claim 1 wherein the plunger further comprises:
   an o-ring located around the plunger, the o-ring for fluidly sealing the plunger to the inner surface of the dispensing chamber housing.
8. The device of claim 7 wherein the plunger is made of a material selected from the group consisting of stainless steel, elastomer, and polymer.
9. The device of claim 1 wherein the plunger further comprises:
   an annular ring located around the plunger, the annular ring for fluidly sealing the plunger to the inner surface of the dispensing chamber housing.
10. The device of claim 1 wherein the plunger is over molded onto a rigid shaft, and the plunger interface is located on a proximal end of the shaft.
11. The device of claim 1 wherein the plunger is press-fitted onto a rigid shaft, and the plunger interface is located on a proximal end of the shaft.
12. The device of claim 1 wherein the plunger interface is substantially concave and the mating surface is substantially convex.
13. The device of claim 1 wherein the plunger interface is substantially convex and the mating surface is substantially concave.
14. The device of claim 1 wherein the plunger interface and the mating surface are both substantially flat.
15. The device of claim 1 further comprising:
   the mechanical linkage interface and an actuator for driving the mechanical linkage interface.
16. An ophthalmic injection system comprising:
   a tip segment and a limited reuse assembly;
   the tip segment comprising:
   a dispensing chamber housing having an inner surface and an outer surface, the inner surface partially defining a dispensing chamber for receiving a quantity of a substance; and
   a plunger engaged with the inner surface of the dispensing chamber housing, the plunger capable of sliding in the dispensing chamber housing, the plunger fluidly sealed to the inner surface of the dispensing chamber housing, the plunger having a plunger interface;
   the limited reuse assembly comprising:
   a power source;
   an actuator having a shaft;
   a controller for controlling the actuator; and
   a mechanical linkage interface coupled to the shaft, the mechanical linkage interface having a mating surface on an end;
   wherein the plunger interface mates with the mating surface on the mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.
17. The ophthalmic injection system of claim 16 wherein the tip segment further comprises:
   a needle fluidly coupled to the dispensing chamber.
18. The ophthalmic injection system of claim 16 wherein the tip segment further comprises:
   a temperature control device in thermal contact with the dispensing chamber, the temperature control device for altering the temperature of the substance.
19. The ophthalmic injection system of claim 18 wherein the tip segment further comprises:
   a thermal sensor in thermal contact with the dispensing chamber.
20. The ophthalmic injection system of claim 16 wherein the substance is a drug for treating a condition of the eye.
21. The ophthalmic injection system of claim 16 wherein the tip segment further comprises:
   an o-ring located around the plunger, the o-ring for fluidly sealing the plunger to the inner surface of the dispensing chamber housing.
22. The ophthalmic injection system of claim 21 wherein the plunger is made of a material selected from the group consisting of stainless steel, elastomer, and polymer.
23. The ophthalmic injection system of claim 16 wherein the tip segment further comprises:
   an annular ring located around the plunger, the annular ring for fluidly sealing the plunger to the inner surface of the dispensing chamber housing.
24. The ophthalmic injection system of claim 16 wherein the plunger is over molded onto a rigid shaft, and the plunger interface is located on a proximal end of the shaft.
25. The ophthalmic injection system of claim 16 wherein the plunger is press-fitted onto a rigid shaft, and the plunger interface is located on a proximal end of the shaft.
26. The ophthalmic injection system of claim 16 wherein the plunger interface is substantially concave and the mating surface is substantially convex.
27. The ophthalmic injection system of claim 16 wherein the plunger interface is substantially convex and the mating surface is substantially concave.
28. The ophthalmic injection system of claim 16 wherein the plunger interface and the mating surface are both substantially flat.
29. The ophthalmic injection system of claim 19 further comprising:
   an electrical interface for coupling the temperature control device to the limited reuse assembly.
30. The ophthalmic injection system of claim 16 wherein the controller operates the actuator such that the shaft is moved a calculated distance thereby displacing the plunger and causing a fixed amount of the substance to exit the dispensing chamber.
31. The ophthalmic injection system of claim 16 wherein the power source is a battery.

32. The ophthalmic injection system of claim 16 wherein the mechanical linkage interface is rigidly coupled to the shaft.

33. The ophthalmic injection system of claim 16 wherein the mechanical linkage interface is coupled to the shaft with a ball joint.

34. The ophthalmic injection system of claim 16 wherein the mechanical linkage interface is tapered near the end on which the mating surface is located.

35. A dispensing mechanism for use in an ophthalmic drug delivery device comprising:

a dispensing chamber housing having an inner surface and an outer surface, the inner surface partially defining a dispensing chamber for receiving a quantity of a substance;

a plunger engaged with the inner surface of the dispensing chamber housing, the plunger capable of sliding in the dispensing chamber housing, the plunger fluidly sealed to the inner surface of the dispensing chamber housing, the plunger having a plunger interface; and

a mechanical linkage interface having a mating surface on one end;

wherein the plunger interface mates with the mating surface on the mechanical linkage interface such that force is transferred from the mechanical linkage interface to the plunger along a first direction towards the plunger when the plunger interface is in contact with the mating surface of the mechanical linkage interface, and force is not substantially transferred from the mechanical linkage interface to the plunger along a second direction away from the plunger.

36. The dispensing mechanism of claim 35 further comprising:

a temperature control device in thermal contact with the dispensing chamber, the temperature control device for altering the temperature of the substance.

37. The dispensing mechanism of claim 35 further comprising:

an o-ring located around the plunger, the o-ring for fluidly sealing the plunger to the inner surface of the dispensing chamber housing.

38. The dispensing mechanism of claim 35 further comprising:

an annular ring located around the plunger, the annular ring for fluidly sealing the plunger to the inner surface of the dispensing chamber housing.

39. The dispensing mechanism of claim 35 wherein the plunger is over molded onto a rigid shaft, and the plunger interface is located on a proximal end of the shaft.

40. The dispensing mechanism of claim 35 wherein the plunger is press-fitted onto a rigid shaft, and the plunger interface is located on a proximal end of the shaft.

41. The dispensing mechanism of claim 35 wherein the plunger interface is substantially concave and the mating surface is substantially convex.

42. The dispensing mechanism of claim 35 wherein the plunger interface is substantially convex and the mating surface is substantially concave.

43. The dispensing mechanism of claim 35 wherein the plunger interface and the mating surface are both substantially flat.

44. The dispensing mechanism of claim 35 further comprising:

an actuator with a shaft, the shaft connected to the mechanical linkage interface.

45. The dispensing mechanism of claim 44 wherein the mechanical linkage interface is rigidly coupled to the shaft.

46. The dispensing mechanism of claim 44 wherein the mechanical linkage interface is coupled to the shaft with a ball joint.

47. The dispensing mechanism of claim 35 wherein the mechanical linkage interface is tapered near the end on which the mating surface is located.

48. The dispensing mechanism of claim 35 wherein the plunger interface and the mating surface permit transfer of motion only in a single direction.

49. The dispensing mechanism of claim 35 wherein when the mechanical linkage interface is retracted, the plunger remains in substantially the same position.

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