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APPARATUSES AND METHODS FOR INJECTING MEDICAMENTS

Abstract

The disclosure relates to injectors that are configured to inject and deliver medicaments and other fluids from a syringe into a target site.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION [0001] This application is a divisional application of U.S. patent application Ser. No. 17/361,912, filed Jun. 29, 2021, which is a continuation application of U.S. patent application Ser. No. 17/212,226, filed Mar. 25, 2021, now U.S. Pat. No. 11,065,392, which claims the benefit of priority to U.S. Provisional Patent Application No. 62/994,448, filed on Mar. 25, 2020, the entire disclosure of each of which is expressly incorporated herein by reference in its entirety.

FIELD

[0002] The invention relates to injectors for medicaments and other fluids. Specifically, to injectors configured to inject a medicament and other fluids from a syringe.

BACKGROUND

[0003] Many methods are used to inject medicaments and other fluids into a target site. These include syringes, auto-injectors, and drug pumps. The medicament can be injected at a variety of depths. For example, the medicament can be injected into the epidermis, the dermis, the subcutaneous region, or into the muscles (intramuscular). Medicament or other fluids can also be delivered intravenously, intraosseusly, and/or to other parts of the body such as into the eye. Some of these devices are specifically intended for at home use by a patient. These devices can be used to deliver a variety of medicaments. For example, the injectors can be used for the delivery of epinephrine to patients who are at risk of anaphylaxis. Such devices include the ANAPEN™ injector sold by Lincoln Medical Ltd. of the United Kingdom and the EPIPEN® injector sold by Mylan Inc. of Pennsylvania.

[0004] Many injectors use powerful springs to drive a plunger rod into a pre-filled syringe and inject the medicament into the tissue while pushing the injector into the side of the leg or other body location. Some of these injectors have the advantage of visually shielding the needle before and/or after use, thereby benefiting patients who have a fear of needles. Present injectors can contain more than twenty-six parts, including electronics and even speakers, and may be complicated to assemble due to the amount and complexity of the parts, which contributes to high prices for the user. The additional parts also increase the chance of failure of these complex devices.

SUMMARY

[0005] In one or more embodiments, an injector includes an outer tubular sleeve defining a longitudinal axis. In one or more embodiments, the injector includes a cam disposed within the outer sleeve. In one or more embodiments, the injector includes an inner sleeve disposed partially within the outer sleeve and a first end of the inner sleeve is configured to engage with the cam. In one or more embodiments, the injector includes a syringe comprising a barrel, a needle mounted to an end of the barrel, a plunger, and a seal slidably mounted in the barrel. In some embodiments, the plunger is engaged with the outer sleeve in a fixed spatial relationship such that the plunger and outer sleeve translate as a unit throughout operation of the injector. In some embodiments, the outer sleeve is disposed and configured for axial translation relative to the inner sleeve from a first configuration. In some embodiments, the inner sleeve is configured to extend from the outer sleeve a first distance to a second configuration in which the inner sleeve extends from the outer sleeve a second distance that is less than the first distance. In some embodiments, the inner sleeve is further configured to extend from the outer sleeve a to a third configuration in which the inner sleeve extends from the outer sleeve a third distance that is greater than the second distance and the cam

rotates from a first position to a second position thereby restricting the inner sleeve from axially translating with respect to the outer sleeve.
[0006] In one or more embodiments, a medicament delivery system includes an injector. In some embodiments, the injector includes an outer tubular sleeve defining a longitudinal axis. In some embodiments, the injector includes a cam disposed within the outer sleeve. In some embodiments, the injector includes an inner sleeve disposed partially within the outer sleeve and a first end of the inner sleeve is configured to engage with the cam. In some embodiments, the injector includes a syringe comprising a barrel, a needle mounted to an end of the barrel, a plunger, and a seal slidably mounted in the barrel. In some embodiments, the plunger is engaged with the outer sleeve in a fixed spatial relationship such that the plunger and outer sleeve translate as a unit throughout operation of the injector. In some embodiments, the outer sleeve is disposed and configured for axial translation relative to the inner sleeve from a first configuration. In some embodiments, the inner sleeve is configured to extend from the outer sleeve a first distance to a second configuration in which the inner sleeve extends from the outer sleeve a second distance that is less than the first distance. In some embodiments, the inner sleeve is further configured to extend from the outer sleeve a to a third configuration in which the inner sleeve extends from the outer sleeve a third distance that is greater than the second distance and the cam rotates from a first position to a second position thereby restricting the inner sleeve from axially translating with respect to the outer sleeve. In one or more embodiments, the medicament delivery system includes an adapter configured to couple to a second end of the inner sleeve.
[0007] A variety of additional aspects will be set forth in the description that follows. The aspects can relate to individual features and to combination of features. It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the broad inventive concepts upon which the embodiments disclosed herein are based.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0008] The features of the devices and methods provided herein will be more fully disclosed in, or rendered obvious by, the following detailed description of the preferred embodiment of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts.
[0009] FIG. **1** is a side view of an injector according to one embodiment described herein.
[0010] FIG. **2** is a side cross-sectional view of the injector of FIG. **1**.
[0011] FIG. **3** is an exploded side view of the injector of FIG. **1**.
[0012] FIG. **4** is an exploded side view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1**.
[0013] FIG. **5**A is a perspective view of the cam of the injector of FIG. **1**.
[0014] FIG. **5**B is an end view of the cam of FIG. **5**A.
[0015] FIG. **6** is a perspective view of the inner sleeve of the injector of FIG. **1**.
[0016] FIG. **7** is a detail perspective view of an end of the inner sleeve of FIG. **6**.
[0017] FIG. **8** is a cross-sectional perspective view of the inner sleeve of FIG. **6**.
[0018] FIG. **9** is an end view of the inner sleeve of FIG. **6**.
[0019] FIG. **10** is a perspective view of the outer sleeve of the injector of FIG. **1**.
[0020] FIG. **11** is a cross-sectional perspective view of the outer sleeve of FIG. **10**.
[0021] FIGS. **12**A and **12**B are side and side cross-sectional views, respectively, of the injector of FIG. **1** after removal of the cap.
[0022] FIGS. **13**A and **13**B are side and side cross-sectional views, respectively, of the injector of

FIG. **1** after extending the needle of syringe from the inner sleeve of the injector to insert the needle in a target site.
[0023] FIGS. **14**A and **14**B are side and side cross-sectional views, respectively, of the injector of FIG. **1** after delivery of the medicament.
[0024] FIGS. **15**A and **15**B are side and side cross-sectional views, respectively, of the injector of FIG. **1** after the inner sleeve extends over the needle of the syringe.
[0025] FIG. **16**A is an end view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1** prior to injection of medicament.
[0026] FIG. **16**B is an end view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1** after completion of injection of the medicament.
[0027] FIG. **16**C is an end view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1** after extension and lockout of the inner sleeve.
[0028] FIG. **17**A is a cross-sectional perspective view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1** prior to injection of medicament.
[0029] FIG. **17**B is a cross-sectional perspective view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1** after completion of injection of the medicament.
[0030] FIG. **17**C is a cross-sectional perspective view of the outer sleeve, inner sleeve, and cam of the injector of FIG. **1** after extension and lockout of the inner sleeve.
[0031] FIG. **18**A is a perspective view of the cap of the injector of FIG. **1**.
[0032] FIG. **18**B is a side cross-sectional view of the cap of FIG. **18**A.
[0033] FIG. **19** is a perspective view of the needle cover engagement member of the injector of FIG. **1**.
[0034] FIG. **20** is a perspective view of the plunger of the injector of FIG. **1**.
[0035] FIG. **21** is a perspective view of an alternative embodiment of the plunger of the injector of FIG. **1**.
[0036] FIG. **22** is a perspective view of a Luer adapter configured for use with the injector of FIG. **1**, according to one embodiment described herein.
[0037] FIG. **23** is a side cross-sectional view of the Luer adapter of FIG. **22**.
[0038] FIG. **24** is a detail side cross sectional view of the tip of the Luer adapter of FIG. **22**.
[0039] FIG. **25** is a detail cross-sectional perspective view of the Luer adapter of FIG. **22** attached to the injector of FIG. **1**.
[0040] FIG. **26** is a detail cross-sectional perspective view of the Luer adapter of FIG. **22** attached to the adapter of FIG. **1** after extension of the needle of the syringe.
[0041] FIG. **27** is a perspective view of a nasal spray adapter configured for use with the injector of FIG. **1**, according to one embodiment described herein.
[0042] FIG. **28** is a side cross-sectional view of the nasal spray adapter of FIG. **27**.
[0043] FIG. **29** is a detail side cross sectional view of the tip of the nasal spray adapter of FIG. **27**.
[0044] FIG. **30** is a detail side cross-sectional view of the nasal spray adapter of FIG. **27** attached to the injector of FIG. **1**.
[0045] FIG. **31** is a side view of the syringe of the injector of FIG. **1**.
[0046] FIG. **32** is a side cross-sectional view of the syringe of FIG. **31**.
[0047] FIG. **33** is a cross-sectional perspective view of the outer sleeve and the inner sleeve of the adapter of FIG. **1**.
[0048] FIG. **34** is a perspective view of cam and the inner sleeve of the injector of FIG. **1** showing the engagement of the cam elements of the cam with the cam teeth of the inner sleeve.
[0049] FIG. **35** is an exploded view of an atomizing insert of the nasal spray adapter of FIG. **27**.
[0050] FIG. **36** is a perspective view of the inner member of the atomizing insert of FIG. **35**.
[0051] FIG. **37** is a perspective view of an alternative embodiment of the inner sleeve of the injector of FIG. **1**.
[0052] FIG. **38** is a perspective view of an alternative embodiment of the plunger of the injector of

FIG. **1**.
[0053] FIG. **39** is a side view of the plunger of the injector of FIG. **38**.
DETAILED DESCRIPTION
[0054] This description of preferred embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written description of this invention. The drawing figures are not necessarily to scale and certain features of the invention may be shown exaggerated in scale or in somewhat schematic form in the interest of clarity and conciseness. In the description, relative terms such as “horizontal,” “vertical,” “up,” “down,” “top,” and “bottom” as well as derivatives thereof (e.g., “horizontally,” “downwardly,” “upwardly,” etc.) should be construed to refer to the orientation as then described or as shown in the drawing figure under discussion. These relative terms are for convenience of description and normally are not intended to require a particular orientation. Terms including “inwardly” versus “outwardly,” “longitudinal” versus “lateral” and the like are to be interpreted relative to one another or relative to an axis of elongation, or an axis or center of rotation, as appropriate. Terms concerning attachments, coupling and the like, such as “connected” and “interconnected,” refer to a relationship wherein structures are secured or attached to one another either directly or indirectly through intervening structures, as well as both movable or rigid attachments or relationships, unless expressly described otherwise. The term “operatively or operably connected” is such an attachment, coupling or connection that allows the pertinent structures to operate as intended by virtue of that relationship. In the claims, means-plus-function clauses, if used, are intended to cover the structures described, suggested, or rendered obvious by the written description or drawings for performing the recited function, including not only structural equivalents but also equivalent structures. The terms “medicament” or “drug” as used herein refers to any substance for delivery to a target. For example, these terms include anticoagulants, vaccines, biologics, and any injectable fluid.
[0055] The present disclosure describes an injector for injecting medicament into a target site. The injector provides for easy use by a medical professional, caregiver, or self-administration by patient and is configured for reliable use after being stored for long periods of time. In addition, because the injector utilizes a low number of parts, it is inexpensive and easy to manufacture. The injectors described herein can be used to deliver, for example, epinephrine, ketamine, atropine, diazepam, or naloxone.
[0056] FIG. **1** shows a side view of an injector **100** according to one embodiment, and FIG. **2** shows a side cross-sectional view of the injector **100**. FIG. **3** shows an exploded view of the injector **100**. The injector **100** includes a plunger **102**, a biasing member **104**, a syringe **106**, a cam **108**, an inner sleeve **110**, an outer sleeve **112**, a needle cover engagement member **114**, and a cap **116**. As shown in FIG. **2**, the syringe **106** is disposed in a chamber defined by the inner sleeve **110**, the outer sleeve **112**, and the cap **116**. As described in further detail herein, when a user desires to inject the medicament contained in the syringe **106**, the user removes the cap **116** and selectively deploys the needle of the syringe **106** to inject the medicament.
[0057] FIG. **4** shows an exploded view of the cam **108**, the inner sleeve **110**, and the outer sleeve **112**. As described in further detail herein, the cam **108**, the inner sleeve **110**, and the outer sleeve **112** work together to: (i) cover the needle of the syringe prior to insertion of the needle in the injection site; (ii) provide audible (e.g., a “click”) and/or tactile feedback upon completion of injection of the medicament; and (iii) cover the needle of the syringe after completion of injection to prevent inadvertent needle stick injuries.
[0058] As shown in FIG. **2**, the cam **108** is disposed within the outer sleeve **112** and is configured for axial translation within the outer sleeve **112**. As described in more detail herein, the cam **108** is also configured to rotate within the outer sleeve **112** during use of the injector **100**. FIG. **5**A shows a perspective view of the cam **108** and FIG. **5**B shows an end view of the cam **108**. The cam **108** includes a cylindrical body **120** and a ring **122** extending from the cylindrical body **120** and having

a larger outer diameter than the cylindrical body **120**—for example, at one end of the cylindrical body **120**. The cam **108** further includes a plurality of protrusions **124** extending radially outward from the ring **122** that define a first set of recesses **125-1** and a second set of recesses **125-2** such that the first and the second sets of recesses are alternately and circumferentially disposed around the cam **108** between the plurality of protrusions **124**. The protrusions **124** are circumferentially spaced around the ring **122**. The protrusions **124** are configured to guide translation and rotation of the cam **108** within the outer sleeve **112** during use, as described herein. The cam **108** further includes cam elements **126** extending from the outside of the cylindrical body **120**—for example, adjacent to the ring **122**. The cam elements **126** each include a cam face **128**. The cam faces **128** are angled relative to the circumference of the cylindrical body **120** such that engagement with corresponding faces on the inner sleeve **110** imparts a circumferential force on the cam **108** that causes the cam **108** to rotate at desired times during operation of the injector **100**, as described in detail herein. The cylindrical body **120** defines an aperture **130** to allow for the passage of the plunger **102**.

[0059] FIG. **6** shows a perspective view of the inner sleeve **110**, and FIG. **37** shows a perspective view of an alternative inner sleeve **110**. FIG. **7** shows a detailed perspective view of an end of the inner sleeve **110**. FIG. **8** shows a cross-sectional perspective view of the inner sleeve **110**. FIG. **9** shows an end view of the inner sleeve **110**. The inner sleeve **110** includes a cylindrical body **134** extending from a first end **136** to a second end **138**. The inner sleeve **110** further includes a ring **140** extending from the cylindrical body **134** and having a larger outer diameter than the cylindrical body **134** and a plurality of projections **142** extending radially outward from the ring **140**—for example, at the first end **136** of the cylindrical body **134**. As described in further detail herein, the projections **142** are configured to restrict rotation of the inner sleeve **110** in the outer sleeve **112** during operation of the injector **100**. The inner sleeve **110** further includes a plurality of cam teeth **144** extending from the first end **136** of the cylindrical body **134**. The cam teeth **144** each include an angled face **146** (i.e., angled relative to the circumference of the cylindrical body **134**) configured to engage a cam face **128** of the cam elements **126** of the cam **108** during operation of the injector **100** to cause rotation of the cam **108**, as described in detail herein. As shown in FIGS. **8** and **9**, the inner sleeve **110** further includes a plurality of ribs **148** extending radially inward from the cylindrical body **134** and extending longitudinally along the cylindrical body **134**. The ribs **148** locate and retain the syringe **106** in position when it is disposed within the cylindrical body **134** of the inner sleeve **110**. The inner sleeve **110** further includes a window **150** extending through the inner sleeve **110** that allows a user to view the contents of the syringe **106** before injection (e.g., after removal of the cap **116**). It is noted that the inner sleeve **110** illustrated in FIG. **37** includes one or more of the same or similar features as the inner sleeve **110** illustrated in FIG. **6**, and the inner sleeve **110** of FIG. **37** is provided to show that inner sleeve **110** may include any number of cam teeth **144**, such as six cam teeth, to correspond to the number of cam elements **126** of cam **108**.

[0060] The inner sleeve **110** further includes ridges **152** extending from the cylindrical body **134** at the second end **138** of the cylindrical body **134**. The ridges **152** each extend partially around the circumference of the inner sleeve **110** and include faces that are disposed at an acute angle with respect to a circumference of the cylindrical body **134**. As described in further detail herein, the ridges **152** allow for the connection of adapters to the injector **100** by engaging with threads of the adapters.

[0061] The inner sleeve **110** further includes a rib **154** extending from a front face **156** of the inner sleeve **110** and extending circumferentially around an aperture **158** through the front face **156**. The aperture **158** is configured to allow the passage of the needle of the syringe **106** therethrough during operation of the injector. As described in further detail herein, the rib **154** is configured to engage a diaphragm of an adapter coupled to the injector **100** to seal the inner sleeve **110** to the adapter.

[0062] FIG. **10** shows a perspective view of the outer sleeve **112**, and FIG. **11** shows a cross-

sectional perspective view of the outer sleeve **112**. The outer sleeve **112** includes a cylindrical body **160** for housing the inner sleeve **110**, the cam **108**, and the syringe **106**. The cylindrical body **160** extends from a first end **162** to a second end **164**. The outer sleeve **112** includes a plurality of first ribs **166** and a plurality of second ribs **168** each extending inward from the cylindrical body **160**. The first ribs **166** extend from the second end **164** and toward the first end **162**, however, the first ribs **166** do not extend all the way to the first end **162**. As described further herein, this allows the cam **108** to rotate within the outer sleeve **112** at a specific stage of operation of the injector **100**, specifically at completion of injection of the medicament. The second ribs **168** are spaced apart from the second end **164**. As described in further detail herein, this allows the cam **108** to rotate within the outer sleeve **112** at a specific stage of operation of the injector **100**, specifically after removal of the injector **100** from the injection site and extension of the inner sleeve **110**. In various embodiments, the first **166** and second **168** ribs extend parallel to the longitudinal axis A of the injector **100** (shown in FIG. **3**). The first ribs **166** define a shoulder **170** configured to engage the ring **140** on the inner sleeve **110**, when the inner sleeve **110** is extended, to locate the inner sleeve **110**.

[0063] The outer sleeve **112** further includes fingers **172** extending from the second end **164** of the cylindrical body **160**. A groove **174** is defined in the outside of the fingers **172**. The groove **174** is configured to receive a bead on the cap **116** to couple the cap **116** to the outer sleeve **112**, as described in more detail herein. The outer sleeve **112** also includes ramped projections **176** configured to engage the cap **116** when the cap **116** is in place on the injector **100**. The ramped projections **176** may extend outward from the cylindrical body **160** and along the outside of one or more of the fingers **172**. The ramped projections **176** may have surfaces that are inclined relative to the longitudinal axis of the outer sleeve **112**. As described in more detail herein, the inclined faces cause the cap **116** to be pushed outward, away from the first end **162** of the outer sleeve **112** when the cap **116** is twisted relative to the outer sleeve **112**. The fingers **172** can flex inward (toward the longitudinal axis A) during installation and removal of the cap **116**.

[0064] The outer sleeve **112** has apertures **178** at the first end **162** configured to receive teeth of the plunger **102** to couple the plunger **102** to the outer sleeve **112**, as described herein. The outer sleeve **112** also has ramps **180** at the first end **162** to provide a lead in for the teeth of the plunger **102**.

[0065] FIGS. **18**A and **18**B show perspective and cross-sectional side views, respectively, of the cap **116**. The cap **116** can include features that allow a user to grasp the cap **116** and remove it from the injector **100**. The cap **116** includes a bead **182** extending circumferentially around the inside of the cap **116** to engage the groove **174** in the outer sleeve **112**. The cap **116** defines recesses **184** extending into the end of the cap **116** and configured to receive the ramped projections **176** of the outer sleeve **112**. When the cap is twisted by a user, the sides of the recesses **184** contact the ramped projections **176**. This contact imparts an axial force on the cap **116** that pushes the cap **116** axially, way from the outer sleeve **112** to assist the user in removing the cap **116** from the injector **100**. The cap **116** has a boss **186** at its bottom end. The boss **186** includes a groove **187** that is configured to receive a portion of the needle cover engagement member **114**.

[0066] As shown in FIG. **19**, the needle cover engagement member **114** includes a cylindrical body **188** and teeth **190** extending inward from the cylindrical body **188**. The teeth **190** are configured to engage the needle cover of the syringe **106**. The teeth **190** can be formed by pressing portions of the cylindrical body **188** inward, toward the center of the cylindrical body **188**. The needle cover engagement member **114** further includes feet **192** to engage the cap **116** to couple the needle cover engagement member **114** to the cap **116**. Specifically, the feet **192** engage the groove **187** in the cap **116**. Hence, the removal of the cap **116** also removes the needle cover from the syringe **106**.

[0067] FIG. **31** shows a side view of the syringe **106** and FIG. **32** shows a side cross-sectional view of the syringe **106**. The syringe **106** may be pre-filled with a medicament and includes a barrel **194**, a needle **196**, a needle cover **198**, and a plunger seal **200**. The barrel **194** can be a glass barrel, such as those constructed from straight cane glass. Alternatively, the barrel **194** can be constructed of a

polymeric material. The barrel **194** can be coated with a material to reduce chemical interactions between the barrel **194** and the medicament. The needle **196** is mounted at the distal end of the barrel **194** and defines a lumen through which medicament can be delivered from the barrel **194** to the target site. The needle **196** can be attached to the barrel **194** using any appropriate method, such as staking and adhesives. The plunger seal **200** is disposed within the barrel **194** and is configured for axial translation within the barrel **194**. The plunger seal **200** can be constructed of an elastomeric material and provide a seal against the inner wall of the barrel **194** to maintain the sterility of the medicament prior to use.

[0068] FIG. **20** shows a perspective view of the plunger **102**. The plunger **102** includes a cap portion **202** and a plunger rod **204** extending from the cap portion **202**. The plunger rod **204** can include a threaded portion **205** at the end opposite the cap portion **202** for engaging the plunger seal **200** of the syringe **106**. During assembly of the injector **100**, the plunger rod **204** is inserted through aperture **130** in the cam **108** and through the aperture **158** in the inner sleeve **110** so that the plunger rod **204** can engage the plunger seal **200** of the syringe **106**. The plunger **102** can further include one or more arms **206** extending from the cap portion **202** for engaging the apertures **178** in the outer sleeve **112** to lock the plunger **102** to the outer sleeve **112**, as shown in FIG. **2**, for example. Each arm **206** can include an outwardly extending tooth **208** for engaging the aperture **178**. During assembly, each tooth **208** contacts a respective one of the ramps **180** on the outer sleeve **112** and the arm **206** flexes radially inward. When the tooth **208** reaches the aperture **178** the arm **206** flexes back toward its natural position such that the tooth **208** engages the aperture **178**. With the teeth **208** engaged with the apertures **178**, the plunger **102** is locked to the outer sleeve **112** such that they translate together during use, as described herein. As illustrated, for example, in FIGS. **20** and **21**, the plunger **102** can further include a clip **210** extending from the cap portion **202** that can be used to clip the injector **100** to a belt or other item for ease of transportation and retrieval of the injector **100**. In another example, as illustrated in FIGS. **38** and **39**, the plunger **102** can alternatively include an alligator clip **211** that can be used to clip the injector **100** to a belt or other item for ease of transportation and retrieval of the injector **100**. In some cases, the alligator clip **211** may be molded into a portion of the injector **100**. For example, an end **213** of the alligator clip **211** may be molded into the outer sleeve **112** of the injector, thereby securing the alligator clip **211** to the injector **100**. In some other cases, the alligator clip **211** may be removably coupled to the injector **100**. For example, the end **213** of the alligator clip **211** may include a ring-like structure that when placed on the outer sleeve **112** expands over the outer sleeve **112** and snaps around the surface of the outer sleeve **112** to fasten to the injector **100**. In such cases, the alligator clip **211** may be a separate component from the plunger **102**.

[0069] In some embodiments, as shown in FIG. **21**, the cap **116** of the plunger **102** includes an indicator **212** that corresponds to the type of medicament contained in the syringe **106**. For example, the indicator **212** can be in the shape of a circle, an oval, a hexagon, a trapezoid, a heart, a star, or any other appropriate or desired shape.

[0070] The biasing member **104** can be, for example, a helical coil spring. However, it should be understood that the biasing member **104** can take on other forms. For example, the biasing member **104** can be a compressible, elastomeric component.

[0071] The operation of the injector **100** will now be described. FIGS. **1** and **2** show side and side cross-sectional views, respectively, of the injector **100** in an initial configuration, which may be the configuration in which the injector **100** is provided to users. In this initial configuration, the cap **116** is in place on the injector **100** and is coupled to the outer sleeve **112**. Specifically, the ramped projections **176** on the outer sleeve **112** are disposed in the recesses **184** on the cap **116** and the bead **182** on the cap **116** is disposed in the groove **174** in the outer sleeve **112**. In addition, the teeth **190** of the needle cover engagement member **114** are engaged with the needle cover **198** of the syringe **106**. When the user is ready to use the injector **100**, the user can twist and/or pull the cap **116** with respect to the outer sleeve **112** to remove the cap **116** from the injector **100**. Removal of

the cap **116** also removes the needle cover **198** due to the engagement of the teeth **190** with the needle cover **198**.

[0072] FIGS. **12**A and **12**B show side and side cross-sectional views, respectively, of the injector **100** after removal of the cap **116**. As can be seen in these figures, the inner sleeve **110** is extended, as a result of the force applied by the biasing member **104**, such that the inner sleeve **110** shields the needle **196** of the syringe **106**. As shown in FIG. **12**B, the biasing member **104** is positioned such that one end of the biasing member **104** is in contact with the cap portion **202** of the plunger **102** and the opposite end of the biasing member **104** is in contact with the cam **108**. With the injector **100** in the configuration shown in FIGS. **12**A and **12**B, the biasing member **104** may be fully extended or nearly fully extended. As a result, the biasing member **104** is not imparting a large force on the inner sleeve **110** or the other components of the injector **100**. This allows the injector **100** to be stored for long durations without fear that components will be damaged or become permanently deformed as a result of being exposed to high forces during storage. This may provide an advantage over prior art devices that include springs or other biasing members that are in a compressed or loaded state during storage. The ring **140** of the inner sleeve **110** is in contact with the shoulder **170** of the outer sleeve **112** to prevent the inner sleeve **110** from falling out of the outer sleeve **112**.

[0073] FIG. **16**A shows an end view of the outer sleeve **112**, the inner sleeve **110**, and the cam **108** when the injector **100** is in the configuration shown in FIGS. **12**A and **12**B, and FIG. **17**A shows a cross-sectional perspective view of the same components in this configuration, at a first operational stage. The other components of the injector **100** are not shown for illustrative purposes. As shown in FIG. **34**, the cam teeth **144** of the inner sleeve **110** are in contact with the cam elements **126** of the cam **108**. Any appropriate number of cam teeth **144** and cam elements **126** can be used. For example, in one embodiment, the inner sleeve **110** includes seven cam teeth **144** (as shown in, for example, FIG. **7**) and the cam **108** includes seven cam elements **126** (as shown in, for example, FIG. **5**A). In another example, in another embodiment, the inner sleeve **110** includes six cam teeth **144** (as shown in, for example, FIG. **37**) and the cam **108** includes six cam elements **126** that correspond to the six cam teeth **144**. The angle that the interfacing surfaces (cam faces **128** and angled faces **146**) make with the longitudinal axis A can be chosen to provide the desired circumferential force on the cam **108**. For example, in one embodiment, these interfacing surfaces each define a helix angle of about **30** degrees with respect to the longitudinal axis A.

[0074] As shown in FIG. **33**, the projections **142** of the inner sleeve **110** are disposed on opposite sides of respective first ribs **166** of the outer sleeve **112**, with this engagement preventing rotation of the inner sleeve **110** with respect to the outer sleeve **112** during use of the injector **100**. For example, projections **142-1** and **142-2** are positioned on opposite sides of first rib **166-1**. Each protrusion **124** of the cam **108** is positioned between a first rib **166** and a second rib **168** of the outer sleeve **112**. For example, as shown in FIGS. **16**A and **17**A, the protrusion **124-1** is positioned between first rib **166-1** and second rib **168-1**. The inner sleeve **110** can include more projections **142** than the cam **108** has protrusions **124**. As a result, the inner sleeve **110** can include a projection **142** on each side of each first rib **166** while the cam **108** has a protrusion **124** on only a single side of each first rib **166**.

[0075] When the user wishes to inject the medicament contained in the syringe **106**, the user brings the second end **138** of the inner sleeve **110** into contact with the injection site (i.e., the patient's tissue). With the inner sleeve **110** in contact with the injection site, applying pressure on the plunger **102** causes the outer sleeve **112** to translate toward the injection site and over the inner sleeve **110**, thereby compressing the biasing member **104**. As the outer sleeve **112** travels forward, the projections **142** of the inner sleeve **110** and the protrusions **124** of the cam **108** engage and slide along the first ribs **166** and the second ribs **168**.

[0076] As the plunger **102** and the outer sleeve **112** translate forward, the syringe **106** is also moved forward as a result of the pressure applied by the plunger **102** on the plunger seal **200**. The forward

movement of the syringe **106** causes the needle **196** to extend through the aperture **158** at the end of the inner sleeve **110**, as shown in FIGS. **13**A and **13**B, and be inserted into the injection site (i.e., the patient's tissue). The biasing member **104** is not shown in FIGS. **13** and **14** for clarity, but it should be understood that the biasing member **104** would be present and compressed in these configurations. The syringe **106** moves forward until the flange **194***a* at the end of the barrel **194** contacts the end of the ribs **148** in the inner sleeve **110**. With the flange **194***a* in contact with the ribs **148**, further translation of the syringe barrel **194** with respect to the inner sleeve **110** is prevented and continued depression of the plunger **102** causes translation of the plunger seal **200** within the barrel **194** and injection of the medicament stored within the barrel **194**. This position is shown in FIGS. **14**A and **14**B. The length of the ribs **148** (i.e., the distance from the end of the ribs **148** to the front face of the inner sleeve **110**) can be chosen to provide the desired insertion depth of the needle **196**. Because the contact of the flange **194***a* of the syringe barrel **194** with the ribs **148** controls the extent of the needle **196** that extends from the inner sleeve **110**, changing the length of the ribs **148** may change the depth of insertion. Changing the length of the ribs **148** may also be used to customize the injector **100** for use with different syringes **106** or needles **196**. This controlled depth of insertion provides advantages in controlling the depth of insertion to ensure the medicament is injected in the proper location (e.g., intramuscular injections).

[0077] When the end of the injection is reached (i.e., when the desired amount of medicament in the syringe **106** has been injected), the protrusions **124** of the cam **108** reach the end of the first ribs **166**. Once the protrusions **124** clear the first ribs **166**, the contact of the cam faces **128** of the cam elements **126** and the angled faces **146** of the projections **142** on the inner sleeve **110** causes the cam **108** to rotate. As can be seen by comparing the position of protrusion **124-1** in FIGS. **16**A and **16**B and in FIGS. **17**A and **17**B, the cam **108** has rotated counterclockwise. Rotation of the cam **108** causes each protrusion **124** to contact a respective one of the second ribs **168** (e.g., protrusion **124-1** contacts second rib **168-2**). This contact can provide audible (e.g., a “click”) and/or tactile feedback to the user that injection is complete (e.g., a clicking sound). The length of the first ribs **166** can be chosen to achieve the desired stroke of the plunger rod **205**—and, thereby, the plunger seal **200**—within the syringe barrel **194**. This ensures the proper amount of medicament is delivered prior to the audible or tactile indication that delivery is complete. The length of the first ribs **166** can be customized based on the length of the syringe barrel **194**. This may allow the injector **100** to be configured for different syringe sizes without modifying each of the components of the injector **100**. For example, the plunger **102**, the cam **108**, the inner sleeve **110**, and the cap **116** can be used with an outer sleeve **112** that has first ribs **166** customized to fit a particular syringe. This may reduce tooling costs and simplify and reduce the amount of inventory that a manufacturer must carry.

[0078] After completion of the injection, the user can begin to remove the injector **100** from the injection site. As the user does so, the inner sleeve **110** and cam **108**, under the urging of the biasing member **104**, travel back toward the second end **164** of the outer sleeve **112** to the position shown in FIGS. **15**A and **15**B. When the protrusions **124** of the cam **108** reach the end of the second ribs **168**, the contact of the cam faces **128** of the cam elements **126** and the angled faces **146** of the cam teeth **144** again causes rotation of the cam **108**. In this case, the cam **108** rotates such that the cam elements **126** move toward, and may come in contact with, the vertical faces **147** (shown in FIG. **7**) of the cam teeth **144**. When the cam **108** comes to a stop, each protrusion **124** of the cam **108** is aligned and engaged in contact with the end of a respective one of the second ribs **168**. For example, as shown in FIGS. **16**C and **17**C, protrusion **124-1** is aligned with and in contact with the end of second rib **168-2**. In this position, at a second operational stage, the cam **108** and inner sleeve **110** cannot translate axially within the outer sleeve **112**. Thus, the inner sleeve **110** and the outer sleeve **112** are locked in their positions. As a result, the inner sleeve **110** cannot be retracted and the needle **196** cannot again be exposed from the end of the inner sleeve **110**. This prevents inadvertent needle stick injuries that can occur with prior art injectors.

[0079] In another aspect, as shown in FIGS. **22-26**, a Luer adapter **300** to be used with the injector **100** is provided. The Luer adapter **300** allows the medicament in the syringe **106** to be provided to a patient via, for example, an intravenous line. The Luer adapter **300** includes a body **302** having a cylindrical portion **304** and a tip **306** at one end of the cylindrical portion **304**. The cylindrical portion **304** defines a cavity **308** that is open at the end of the cylindrical body **302** that is opposite the tip **306**. The cavity **308** is configured to at least partially receive the injector **100**. The adapter **300** includes an interior wall **310** defining threads to engage the ridges **152** at the end of the inner sleeve **110** to couple the adapter **300** to the inner sleeve-for example, by way of a ¼ turn thread engagement.
[0080] At the end of the tip **306**, the adapter **300** includes a Luer connector **314**. The Luer connector **314** can be a male Luer connector for connection to a female Luer fitment of a tubing set. Alternatively, the Luer connector **314** can be a female Luer connector for connection to a male Luer fitment. The connection of the adapter **300** with the tubing set may, for example, use locking or slipping type Luer connections, such as those sold under the names LUER-LOK™ and LUER-SLIP™ by Becton Dickinson.
[0081] The adapter further includes a diaphragm **316** positioned within the tip **306**. The diaphragm **316** includes a frustoconical portion **318** and a flange **320**. The flange **320** is configured to be positioned between a shoulder of the adapter **300** and the inner sleeve **110**. The diaphragm **316** can be sealed by ribs on the inner sleeve (e.g., rib **154**) and the shoulder of the adapter **300**. During use, the frustoconical portion **318** of the diaphragm **316** is pierced by the needle **196** of the syringe **106**. The diaphragm **316** can be constructed from, for example, an elastomeric material. The diaphragm **316** is configured to ensure that the medicament is delivered though the Luer connector **314** and does not leak from the injector **100** or the Luer adapter **300**.
[0082] The connector **314** and the diaphragm **316** together define a channel **322** within which the needle **196** is at least partially disposed while the medicament is injected, as shown in FIG. **26**.
[0083] The adapter **300** can further include finger flanges **324** extending outward from the cylindrical portion **304**. To deliver the medicament from the syringe **106**, the user can grasp the injector **100** with the user's fingers around the finger flanges **324** and with the cap portion **202** of the plunger **102** resting against the user's palm. The user can then squeeze to cause dispensing of the medicament. After dispensing the medicament, the user can release to allow the inner sleeve **110** to slide outward with respect to the inner sleeve **110**, as described above, such that the needle **196** is retracted from the diaphragm **316**. With the position of the inner sleeve **110** locked, the user can then remove the adapter **300** from the injector **100** and dispose of both the injector **100** and the Luer adapter **300**.
[0084] FIG. **25** shows the adapter **300** coupled to the injector **100**. As shown, the second end **138** of the inner sleeve **110** is engaged with the diaphragm **316** and the needle **196** is disposed in the inner sleeve **110**. FIG. **26** shows the injector **100** and the adapter **300** after depression of the plunger **102** and the outer sleeve **112** to extend the needle **196** and pierce the frustoconical portion **318** of the diaphragm **316** such that it is disposed in the channel **322**. With the needle **196** in this position, depression of the plunger **102** causes the medicament to be dispensed through tubing coupled to the Luer connector **314**.
[0085] In another embodiment, a nasal spray adapter **400** is provided for use with the injector **100**. The nasal spray adapter **400** allows the medicament in the syringe **106** to be provided to a patient via nasal delivery. The nasal spray adapter **400** includes a body **402** having a cylindrical portion **404** and a tip **406** at one end of the cylindrical portion **404**. The cylindrical portion **404** defines a cavity **408** configured to partially receive the injector **100**. The adapter **400** includes an interior wall **410** defining threads to engage the ridges **152** at the end of the inner sleeve **110** to couple the adapter **400** to the inner sleeve—for example, by way of a ¼ turn thread engagement.
[0086] At the end of the tip **406**, the adapter **400** includes an aperture **412** to allow medicament to be expelled into a user's nasal passages via a spray. The adapter **400** further includes a diaphragm

416 positioned within the tip **406**. The diaphragm **416** includes a frustoconical portion **418** and a flange **420**. The flange **420** is configured to be positioned between a shoulder of the adapter **400** and the second end **138** of the inner sleeve **110**. The diaphragm **416** can be sealed by ribs on the inner sleeve **110** (e.g., rib **154**) and the adapter **400**. During use, the frustoconical portion **418** of the diaphragm **416** is pierced by the needle **196** of the syringe **106**, as shown in FIG. **30**, so that the medicament can be expelled through the aperture **412**. The diaphragm **416** can be constructed from, for example, an elastomeric material. The diaphragm **416** is configured to ensure that the medicament is delivered though the aperture **412** and does not leak from the injector **100** or the adapter **400**.

[0087] Further, as shown in FIG. **28** an atomizing insert **414** can be positioned in the tip **406** adjacent to the aperture **412**. The atomizing insert **414** may convert the medicament into fine particles or droplets for delivery to the patient via the aperture **412**. The atomizing insert **414** is shown in more detail in the cross-sectional views of FIGS. **29** and **30** and in FIGS. **35** and **36**. As shown in FIGS. **29** and **30**, the atomizing insert **414** is positioned in the tip **406** between the diaphragm **416** and the aperture **412**. FIG. **36** shows an exploded view of the atomizing insert **414**. The atomizing insert **414** may include an inner member **430** and an outer member **432**. The outer member **432** defines an inner passage **436** within which the inner member **430** is disposed. FIG. **36** shows a perspective view of the inner member **430**. The inner member **430** may be substantially cylindrical and include one or more channels **438** extending longitudinally along the length of the inner member **430**. The channels **438** allow for the flow of medicament between the inner member **430** and the outer member **432** toward the aperture **412**. The inner member **430** may further include tracks **440** formed in the distal face **442** of the inner member. Each track **440** extends from a respective channel **438** toward a center of the inner member **430**. The tracks **440** may meet at the center of the distal face **442** adjacent to the aperture **412**. The tracks **440** may follow curved paths such that they impart a swirling motion on the medicament traveling toward the aperture **412**.

[0088] The adapter **400** can further include finger flanges **424** extending outward from the cylindrical portion **404**. To deliver the medicament from the syringe **106**, the user can grasp the injector **100** with the user's fingers around the finger flanges **424** and with the cap portion **202** of the plunger **102** resting against the user's palm. The user can then squeeze to cause dispensing of the medicament. After dispensing the medicament, the user can release to allow the inner sleeve **110** to slide outward with respect to the inner sleeve **110**, as described above, such that the needle **196** is retracted from the diaphragm **416**. With the position of the inner sleeve **110** locked, the user can then remove the adapter **400** from the injector **100** and dispose of both the injector **100** and the nasal spray adapter **400**.

[0089] The nasal spray adapter **400** allows for the medicament to be delivered intranasally, which avoids the need for an insertion of a needle into the patient, which may be preferable for some patients, specifically, those with a fear of needles or those with missing limbs or who lack adequate peripheral circulation. By delivering the medicament across the mucosal membrane, and to the patient's blood stream, the injector with nasal spray adapter **400** delivers an effective dose of delivery. This can be particularly useful for medicaments used to treat opioid overdoses, such as Naloxone.

[0090] In various embodiments, a kit is provided. The kit includes the injector **100**, the Luer adapter **300**, and the nasal spray adapter **400**. By providing the nasal spray adapter **400** and the Luer adapter **300**, the medicament can be delivered either via the spray nozzle to the mucosal membranes, intravenously using the Luer adapter **300**, or via the needle intramuscularly, subcutaneously, intraosseously, or at any other appropriate depth. This provides the user or patient with the option at time of delivery, allowing them to choose the method of delivery which is more comfortable or most effective for them.

[0091] In another embodiment, a method of operating an injector is provided. The method includes removing a cap from the injector. The method includes placing an end of an inner sleeve against the

target location. With the injector in place, a force is applied to an outer sleeve. Applying the force to the outer sleeve (i) causes axial translation of the outer sleeve and a syringe relative to the inner sleeve, (ii) causes a needle of a syringe to extend out from the distal end of the inner sleeve and into the target location, and (iii) causes the flange on the syringe barrel to contact a rib on the inner sleeve. Subsequently, a continued force is applied to the outer sleeve and plunger. Applying the continued force to the outer sleeve causes translation of a plunger rod and a seal within the syringe to cause delivery of the medicament. After delivery of the medicament, the injector is removed from the target location. A biasing member applies a force on the inner sleeve to cause the inner sleeve to translate in the distal direction with respect to the outer sleeve to cover the needle of the syringe such that the inner sleeve is locked in place with respect to the outer sleeve.

[0092] In another embodiment, a method of using an injector and a nasal spray adapter to deliver a medicament intranasally is provided. A cap of the injector is first removed. The nasal spray adapter is engaged with the injector. A tip of the nasal spray adapter is placed within or adjacent to a nostril of the patient. An outer sleeve of the injector is translated toward the tip of the nasal spray adapter to expel the medicament through the tip of the nasal spray adapter and to the patient.

[0093] In another embodiment, a method of using an injector to deliver a medicament intravenously is provided. A cap of the injector is first removed. A Luer adapter is connected to the injector. The Luer adapter is coupled to a tubing set. An outer sleeve of the injector is translated toward the Luer fitment to deliver the medicament through the Luer connector, through the tubing set, and to the patient.

[0094] While the foregoing description and drawings represent preferred or exemplary embodiments of the present invention, it will be understood that various additions, modifications and substitutions may be made therein without departing from the spirit and scope and range of equivalents of the embodiments described herein. In particular, it will be clear to those skilled in the art that the present invention may be embodied in other forms, structures, arrangements, proportions, sizes, and with other elements, materials, and components, without departing from the spirit or essential characteristics thereof. In addition, numerous variations in the methods/processes described herein may be made without departing from the spirit of the invention. One skilled in the art will further appreciate that the invention may be used with many modifications of structure, arrangement, proportions, sizes, materials, and components and otherwise, used in the practice of the invention, which are particularly adapted to specific environments and operative requirements without departing from the principles of the present invention.

Claims

1. A medicament delivery kit, comprising: an injector comprising a syringe comprising a needle configured to extend through an insertion end of the injector to deliver the medicament, via the needle, intramuscularly, subcutaneously, or intraosseoussly; a Luer adapter configured to couple to the insertion end of the injector to deliver medicament intravenously; and a nasal spray adapter configured to couple to the insertion end of the injector to deliver the medicament intranasally.

2. The medicament delivery kit of claim 1, wherein the injector further comprises: an outer sleeve comprising a first set of ribs and a second set of ribs protruding radially inward from an inner surface of the outer sleeve; a cam configured for axial translation with and disposed within the outer sleeve and comprising a first set of recesses and a second set of recesses such that the first and the second sets of recesses are alternately and circumferentially disposed around the cam between a plurality of protrusions extending radially outward from the cam; an inner sleeve partially disposed within the outer sleeve, a first end of the inner sleeve being configured to engage with the cam to engage the first set of ribs with the first set of recesses that corresponds to a first operational stage or the second set of ribs with the second set of recesses that corresponds to a second operational stage.

3. The medicament delivery kit of claim 2, wherein: the second end portion of the syringe is configured to extend through a second end of the inner sleeve in the first operational stage; and the second end portion of the syringe is restricted from extending beyond the second end of the inner sleeve in the second operational stage.
4. The medicament delivery kit of claim 2, wherein the injector further comprising a biasing member positioned between the first end of the outer sleeve and the first end of the inner sleeve.
5. The medicament delivery kit of claim 2, wherein the syringe comprises a barrel, a needle mounted to an end of the barrel, a plunger, and a seal slidably mounted in the barrel, the plunger being disposed on the first end portion of the syringe and the needle being disposed on the second end portion of the syringe; and wherein the inner sleeve comprises a plurality of ribs that extend radially inwards from an inner surface of the inner sleeve, and are configured to contact a portion of the barrel and restrict the needle from axially translating a distance beyond the second end of the inner sleeve.
6. The medicament delivery kit of claim 1, wherein the injector comprises a ridge extending from an outer surface thereof, the ridge configured to engage with the adapters to secure the adapters to the injector.
7. The medicament delivery kit of claim 6, wherein a body of each adapter comprises a cavity sized to receive the insertion end of the injector, an interior wall of the cavity being threaded and configured to engage with the ridge of the injector.
8. The medicament delivery kit of claim 1, wherein the Luer adapter comprises: a body having a cylindrical portion and a tip at one end of the cylindrical portion; the cylindrical portion defining a cavity that is open at an end of the cylindrical body that is opposite the tip, the cavity being configured to at least partially receive the injector; the tip of the body including a Luer connector.
9. The medicament delivery kit of claim 8, wherein the Luer connector is a male Luer connector for connection to a female Luer fitment of a tubing set.
10. The medicament delivery kit of claim 8, wherein the Luer connector is a female Luer connector for connection to a male Luer fitment.
11. The medicament delivery kit of claim 8, wherein the Luer adapter comprises a diaphragm positioned to be pierced by the needle of the syringe when the Luer adapter is connected to the injector and arranged to promote the medicament being delivered through the Luer connector without leaking from the injector or Luer adapter.
12. The medicament delivery kit of claim 11, wherein the diaphragm is formed from an elastomeric material.
13. The medicament delivery kit of claim 11, wherein the Luer connector and diaphragm together define a channel within which the needle is at least partially disposed while the medicament is being dispensed.
14. The medicament delivery kit of claim 8, wherein the Luer adapter includes finger flanges extending outward from the cylindrical portion for use in causing dispensing of the medicament.
15. The medicament delivery kit of claim 1, wherein the nasal spray adapter comprises: a body having a cylindrical portion and a tip at one end of the cylindrical portion; the cylindrical portion defining a cavity that is open at an end of the cylindrical body that is opposite the tip, the cavity being configured to at least partially receive the injector; the tip of the body including an aperture to allow the medicament to be expelled into a nasal passage via a spray.
16. The medicament delivery kit of claim 15, wherein the nasal spray adapter comprises a diaphragm positioned to be pierced by the needle of the syringe when the nasal spray adapter is connected to the injector and arranged to promote the medicament being delivered through the aperture without leaking from the injector or Luer adapter.
17. The medicament delivery kit of claim 16, wherein the diaphragm is formed from an elastomeric material.
18. The medicament delivery kit of claim 15, wherein the nasal spray adapter comprises an

atomizing insert positioned in the tip adjacent to the aperture.

19. The medicament delivery kit of claim 15, wherein the nasal spray adapter includes finger flanges extending outward from the cylindrical portion for use in causing dispensing of the medicament.

20. A medicament delivery kit, comprising: an injector comprising a syringe comprising a needle configured to extend through an insertion end of the injector to deliver the medicament, via the needle, intramuscularly, subcutaneously, or intraosseoussly; and at least one adapter configured to couple to the insertion end of the injector to deliver medicament intravenously or intranasally.