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# Injection device


## Abstract

The present invention relates to an injection device that includes a housing having an axis, and a needle sleeve that is axially movably within the housing. Axial movement of the needle sleeve into the housing is configured to actuate an injection process. The needle sleeve includes a first part that is slidably mounted to the housing, and a second part that protrudes from the housing and is rotationally coupled to the first part. The needle sleeve includes a locking mechanism that is configured to prevent axial movement of the needle sleeve into the housing until the second part of the needle sleeve has been rotated relative to the first part of the needle sleeve.



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## Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS (1) The present application is a continuation application of U.S. patent application Ser. No. 16/768,288, filed on May 29, 2020, which is the national stage entry of International Patent Application No. PCT/EP2018/083182, filed on Nov. 30, 2018, and claims priority to Application No. EP 17306676.2, filed on Dec. 1, 2017, the disclosures of which are incorporated herein by reference.

TECHNICAL FIELD
(1) The present disclosure relates to an injection device for a medicament.
BACKGROUND

(2) Cartridge injection devices, for example cartridge auto-injectors, typically have a sealed cartridge that contains a medicament and a needle that is initially separated from the cartridge. Before use of the injection device the cartridge and needle are combined so that the needle pierces the cartridge. A plunger can then be moved into the cartridge to dispense medicament through the needle for injection into the tissue of a user.

SUMMARY

(3) According to an aspect of the disclosure, an injection device includes: a housing having an axis, and a needle sleeve that is axially movably within the housing, wherein axial movement of the needle sleeve into the housing is configured to actuate an injection process. The needle sleeve comprises: a first part slidably mounted to the housing, a second part that protrudes from the housing and is rotatably coupled to the first part such that the second part can be rotated relative to the first part about the axis, and a locking mechanism arranged to prevent axial movement of the needle sleeve into the housing until the second part of the needle sleeve has been rotated relative to the first part of the needle sleeve.

(4) The locking mechanism may comprise a slot and an engaging member, wherein the engaging member may be disposed in the slot, and wherein the slot may be arranged to prevent axial movement of the needle sleeve until the second part of the needle sleeve has been rotated relative to the first part about the axis.

(5) The second part of the needle sleeve may comprise one of the slot and the engaging member, and the housing may comprise the other of the slot and the engaging member.

(6) The slot may comprise a radially extending portion and an axially extending portion, and rotation of the needle sleeve relative to the first part may move the engaging member from the radially extending portion into the axially extending portion such that the needle sleeve can move axially into the housing.

(7) The second part of the needle sleeve may be rotatable between a first position in which the locking mechanism prevents the needle sleeve from moving axially into the housing, and a second position in which the locking mechanism permits the needle sleeve to move axially into the housing.

(8) The injection device may further comprise a reservoir for a medicament and a spring-loaded mechanism for dispensing medicament from the reservoir, and further comprising a catch arranged to hold the spring-loaded mechanism before use of the injection device, and wherein movement of the needle sleeve into the housing may release the catch to actuate the injection process.

(9) In some examples, the locking mechanism comprises a slot and a protrusion, and wherein rotation of the second part of the needle sleeve brings the slot and the protrusion into alignment to permit axial movement of the needle sleeve into the housing.

(10) The slot may be formed in one of the housing and the second part of the needle sleeve, and the protrusion may be formed in the other of the housing and the second part of the needle sleeve. In one example, the slot is formed in the housing and the protrusion is formed on the second part of the needle sleeve. In another example, the slot is formed in the second part of the needle sleeve and the protrusion is formed on the housing.

(11) The protrusion may be adapted to snap into the slot when the slot and protrusion are aligned with each other to prevent further rotation of the needle sleeve. The snap may also create a sound to inform the user that the rotation is complete.

(12) The second part of the needle sleeve may comprise a circumferentially extending slot, and the first part of the needle sleeve may comprise a catch that engages the circumferentially extending slot to couple the second part to the first part and permit rotational movement of the second part relative to the second part as the catch moves within the circumferentially extending slot.

(13) In some examples, the injection device may further comprise a member arranged to prevent rotation of the first part of the needle sleeve relative to the housing. For example, the member may extend from the housing and engage an axially extending slot or groove in the first part of the

needle sleeve, or the member may extend from the first part of the needle sleeve and engage an axially extending slot in the housing.
(14) In various examples, one of the first part of the needle sleeve and the housing comprises an axially extending slot, and the other of the first part of the needle sleeve and the housing comprises a protrusion that engages the axially extending slot to prevent rotation of the first part of the needle sleeve relative to the housing.
(15) The second part of the needle sleeve may comprise an axially extending slot or a protrusion, and wherein the axially extending slot or the protrusion of the second part may be aligned with the protrusion or axially extending slot, respectively, of the housing after the second part of the needle sleeve has been rotated. In this way, the axially extending slot and protrusion that allows the first part of the needle sleeve to move axially and prevents rotation of the first part of the needle sleeve also serves to prevent axial movement of the second part of the needle sleeve (and therefore the entire needle sleeve) until the second part of the needle sleeve has been rotated.
(16) The injection device may further comprise a needle unit having a needle, and a cartridge having a reservoir for a medicament. Prior to use of the injection device the reservoir may be sealed from the needle, and rotation of the second part of the needle sleeve may be configured to move the needle unit such that the needle is placed in fluid communication with the reservoir.
(17) Therefore, actuation of the injection process by axial movement of the needle sleeve is prevented at least until the second part of the needle sleeve has been rotated to engage the needle unit and cartridge.
(18) The second part of the needle sleeve may comprise an engaging member arranged to move the needle unit in an axial direction when the second part of the needle sleeve is rotated.
(19) In some examples, the engaging member may comprise a helical guide arranged to engage a protrusion on the needle unit and move the needle unit as the second part of the needle sleeve is rotated.
(20) The engaging member may be arranged to disengage from the needle unit after the second part has been rotated. In this way, the needle sleeve is decoupled from the needle unit and is able to move axially independently of the needle unit to actuate the injection process.
(21) The injection device may further comprise a piston disposed in the cartridge and a piston drive mechanism arranged to drive the piston to dispense medicament via the needle. Axial movement of the needle sleeve into the housing may be adapted to actuate the piston drive mechanism.
(22) The cartridge may comprise a medicament in the reservoir.
(23) According to another aspect of the disclosure, a method of using an injection device that includes a housing and a needle sleeve is provided. The method includes: rotating a part of the needle sleeve relative to the housing to unlock the needle sleeve, and moving the needle sleeve into the housing to actuate an injection process.
(24) These and other aspects of the disclosure will be apparent from and elucidated with reference to the embodiments described hereinafter.

## Description

BRIEF DESCRIPTION OF THE FIGURES
(1) Embodiments of the invention are described, by way of example only, with reference to the accompanying drawings, in which:
(2) FIG. **1**A is a schematic side view of an injection device that embodies the invention, and a removable cap;
(3) FIG. **1**B is a schematic side view of the injection device of FIG. **1**A, with the cap removed from the housing;
(4) FIG. **2** is a cross-sectional view of an injection device;

(5) FIG. **3** is a cross-sectional view of a needle sleeve;
(6) FIG. **4** is a cross-sectional view of a needle sleeve;
(7) FIGS. **5**A to **5**C show a needle unit for use with the injection device;
(8) FIGS. **6**A to **6**C show steps of operation of the injection device;
(9) FIG. **7**A shows an alternative needle sleeve for the injection device; and,
(10) FIG. **7**B shows an alternative needle unit for the injection device.

DETAILED DESCRIPTION

(11) A drug delivery device, as described herein, may be configured to inject a medicament into a patient. For example, delivery could be sub-cutaneous, intra-muscular, or intravenous. Such a device could be operated by a patient or care-giver, such as a nurse or physician, and can include various types of safety syringe, pen-injector, or auto-injector. The device can include a cartridge-based system that requires piercing a sealed ampule before use. Volumes of medicament delivered with these various devices can range from about 0.5 ml to about 2 ml. Yet another device can include a large volume device ("LVD") or patch pump, configured to adhere to a patient's skin for a period of time (e.g., about 5, 15, 30, 60, or 120 minutes) to deliver a "large" volume of medicament (typically about 2 ml to about 10 ml).

(12) In combination with a specific medicament, the presently described devices may also be customized in order to operate within required specifications. For example, the device may be customized to inject a medicament within a certain time period (e.g., about 3 to about 20 seconds for auto-injectors, and about 10 minutes to about 60 minutes for an LVD). Other specifications can include a low or minimal level of discomfort, or to certain conditions related to human factors, shelf-life, expiry, biocompatibility, environmental considerations, etc. Such variations can arise due to various factors, such as, for example, a drug ranging in viscosity from about 3 cP to about 50 cP. Consequently, a drug delivery device will often include a hollow needle ranging from about 25 to about 31 Gauge in size. Common sizes are 27 and 29 Gauge.

(13) The delivery devices described herein can also include one or more automated functions. For example, one or more of combining the needle and cartridge, needle insertion, medicament injection, and needle retraction can be automated. Energy for one or more automation steps can be provided by one or more energy sources. Energy sources can include for example, mechanical, pneumatic, chemical, or electrical energy. Mechanical energy sources can include for example springs, levers, elastomers, or other mechanical mechanisms to store or release energy. One or more energy sources can be combined into a single device. Devices can further include gears, valves, or other mechanisms to convert energy into movement of one or more components of a device.

(14) The one or more automated functions of an auto-injector may each be activated via an activation mechanism. Such an activation mechanism can include an actuator, for example, one or more of a button, a lever, a needle sleeve, or other activation component. Activation of an automated function may be a one-step or multi-step process. That is, a user may need to activate one or more activation components in order to cause the automated function. For example, in a one-step process, a user may depress a needle sleeve against their body in order to cause injection of a medicament. Other devices may require a multi-step activation of an automated function. For example, a user may be required to depress a button and retract a needle shield in order to cause an injection.

(15) In addition, activation of one automated function may activate one or more subsequent automated functions, thereby forming an activation sequence. For example, activation of a first automated function may activate at least two of combining the needle and cartridge, needle insertion, medicament injection, and needle retraction. Some devices may also require a specific sequence of steps to cause the one or more automated functions to occur. Other devices may operate with a sequence of independent steps.

(16) Some delivery devices can include one or more functions of a safety syringe, pen-injector, or

auto-injector. For example, a delivery device could include a mechanical energy source configured to automatically inject a medicament (as typically found in an auto-injector) and a dose setting mechanism (as typically found in a pen-injector).

(17) According to some embodiments of the present disclosure, an example of a drug delivery device **10** is shown in FIGS. **1**A and **1**B. Device **10**, as described above, is configured to inject a medicament into a patient's body. Device **10** includes a housing **11** which typically contains a cartridge that defines a reservoir containing the medicament to be injected, and the components required to facilitate one or more steps of the delivery process.

(18) The device **10** can also include a cap **12** that can be detachably mounted to the housing **11**. Typically, a user must remove cap **12** from housing **11** before device **10** can be operated.

(19) As shown, housing **11** is substantially cylindrical and has a substantially constant diameter along the longitudinal axis A-A. The housing **11** has a distal region D and a proximal region P. The term “distal” refers to a location that is relatively closer to a site of injection, and the term “proximal” refers to a location that is relatively further away from the injection site.

(20) Device **10** can also include a needle sleeve **19** coupled to housing **11** to permit movement of sleeve **19** relative to housing **11**. For example, sleeve **19** can move in a longitudinal direction parallel to longitudinal axis A-A. Specifically, movement of sleeve **19** in a proximal direction can permit a needle **17** to extend from distal region D of housing **11**.

(21) Insertion of needle **17** can occur via several mechanisms. For example, needle **17** may be fixed relative to housing **11** and initially be located within an extended needle sleeve **19**. Proximal movement of sleeve **19** by placing a distal end of sleeve **19** against a patient's body and moving housing **11** in a distal direction will uncover the distal end of needle **17**. Such relative movement allows the distal end of needle **17** to extend into the patient's body. Such insertion is termed “manual” insertion as needle **17** is manually inserted via the patient's manual movement of housing **11** relative to sleeve **19**.

(22) Another form of insertion is “automated”, whereby needle **17** moves relative to housing **11**. Such insertion can be triggered by movement of sleeve **19** or by another form of activation, such as, for example, a button **13**. As shown in FIGS. **1**A and **1**B, button **13** is located at a proximal end of housing **11**. However, in other embodiments, button **13** could be located on a side of housing **11**.

(23) Other manual or automated features can include drug injection or needle retraction, or both. Injection is the process by which a bung or piston **14** is moved from a proximal location to a more distal location within the reservoir of the cartridge **18** in order to force a medicament from the cartridge **18** through needle **17**. In some embodiments, a drive spring (not shown) is under compression before device **10** is activated. A proximal end of the drive spring can be fixed within proximal region P of housing **11**, and a distal end of the drive spring can be configured to apply a compressive force to a proximal surface of piston **14**. Following activation, at least part of the energy stored in the drive spring can be applied to the proximal surface of piston **14**. This compressive force can act on piston **14** to move it in a distal direction. Such distal movement acts to compress the liquid medicament within the cartridge **18**, forcing it out of needle **17**.

(24) Following injection, needle **17** can be retracted within sleeve **19** or housing **11**. Retraction can occur when sleeve **19** moves distally as a user removes device **10** from a patient's body. This can occur as needle **17** remains fixedly located relative to housing **11**. Once a distal end of sleeve **19** has moved past a distal end of needle **17**, and needle **17** is covered, sleeve **19** can be locked. Such locking can include locking any proximal movement of sleeve **19** relative to housing **11**.

(25) Another form of needle retraction can occur if needle **17** is moved relative to housing **11**. Such movement can occur if the cartridge **18** within housing **11** is moved in a proximal direction relative to housing **11**. This proximal movement can be achieved by using a retraction spring (not shown), located in distal region D. A compressed retraction spring, when activated, can supply sufficient force to the cartridge **18** to move it in a proximal direction. Following sufficient retraction, any relative movement between needle **17** and housing **11** can be locked with a locking mechanism. In

addition, button **13** or other components of device **10** can be locked as required.
(26) FIG. **2** illustrates an example injection device **20** having a housing **21**, a cartridge **22**, a needle unit **23**, and a needle sleeve **26**. The injection device **20** further includes a piston **24** and a piston drive mechanism **25**.
(27) The cartridge **22** defines a reservoir **28** that contains a medicament and is mounted within the housing **21**. A distal end D of the cartridge **22** is sealed by an end cap **29**. A cartridge mounting portion **30** of the housing **21** supports the cartridge **22**. As illustrated, a part of the cartridge mounting portion **30** is tubular and surrounds the distal end of the cartridge **22**. This tubular part of the cartridge mounting portion **30** has an external surface disposed within the housing **21**.
(28) As shown in FIG. **2**, in an initial condition the proximal end of needle **31** of the needle unit **23** is spaced from the end cap **29** at the distal end of the cartridge **22**. Before or during use of the injection device **20** the needle unit **23** is moved into engagement with the distal end of the cartridge **22** such that the proximal end of needle **31** pierces the end cap **29** of the cartridge **22**. In this way, medicament can be expelled from the reservoir **28** via the needle **31**, as explained further hereinafter.
(29) In the initial condition, illustrated in FIG. **2**, the piston **24** is positioned at a proximal end of the reservoir **28** in the cartridge **22**, and the piston drive mechanism **25** is disposed in the proximal end of the housing **21**. The piston drive mechanism **25** comprises a spring **32**, a plunger **33**, and a catch **34**. The spring **32** is arranged to urge the plunger **33** against the piston **24** and into the reservoir **28** to expel medicament from the reservoir **28** during use. In the initial condition before use, as illustrated, the spring **32** is held in a compressed state by a catch **34**. Specifically, the catch **34** holds the plunger **33**, which holds the spring **32** in a compressed state such that no force is applied to the piston **24**. In this state, the piston drive mechanism **25** is pre-loaded.
(30) As explained further hereinafter, the injection device **20** is actuated by an actuator, in this example the needle sleeve **26** that is rotationally and slidably movable within the housing **21** and protrudes from the distal end of the housing **21**. In this way, during use, the needle sleeve **26** is placed against the user's skin and the injection device **20** is pushed towards the user's skin while holding the housing **21**, this moves the needle sleeve **26** in a proximal direction, into the housing **21**.
(31) The needle sleeve **26** acts to release the catch **34** once the needle sleeve **26** has moved into the housing **21** in a proximal direction. Once the catch **34** is released, the spring **32** urges the plunger **33** against the piston **24** and into the reservoir **28**.
(32) As illustrated in FIG. **2**, the catch **34** may include a tubular element **35** that surrounds the plunger **33** and spring **32**. The tubular element **35** includes protrusions **36** that engage recesses **37** in the plunger **33**, such that in the position illustrated in FIG. **2** the plunger **33** is prevented from moving in a distal direction by the protrusions **36** and the recesses **37**.
(33) As the needle sleeve **26** is moved proximally into the housing **21**, an end of the needle sleeve **26** engages the tubular element **35**, causing the tubular element **35** to rotate about the axis A of the injection device **20**. This rotation causes the protrusions **36** to disengage from the recesses **37**, thereby releasing the plunger **33**, which then moves under the force of the spring **32** into the reservoir **28**.
(34) In one example, the end of the needle sleeve **26** that engages the tubular element **35** may comprise a chamfer (i.e. angled edge) that engages a protrusion on the tubular element **35** to cause the rotation. In other examples, the tubular element **35** may comprise a chamfer (i.e. angled edge) that is engaged by a protrusion on the needle sleeve **26** to cause the rotation.
(35) In other examples, the catch **34** may comprise arms that include the protrusions that engage the plunger **33**. In this case, the needle sleeve **26** might deflect the arms by lifting them to disengage the protrusions from the recesses, thereby releasing the plunger **33**.
(36) A biasing member, for example a spring **42**, may be arranged to act between the housing **21** and the needle sleeve **26** to urge the needle sleeve **26** in a distal direction so that it protrudes from

the distal end of the housing **21**.
(37) In other examples, movement of the needle sleeve **26** into the housing **21** can actuate the injection process in other ways. For example, movement of the needle sleeve **26** into the housing **21** may move an intermediate component to release the catch **34**. In other examples, movement of the needle sleeve **26** into the housing **21** may close or open an electronic switch which in turn releases the plunger **33**. In still more examples, the plunger **33** may be electronically or pneumatically actuated by an actuator during the injection process, and in such examples movement of the needle sleeve **26** into the housing **21** may activate such an actuator. Therefore, it will be appreciated that movement of the needle sleeve **26** into the housing **21** can actuate the injection process (i.e. movement of the plunger **33** into the reservoir **28**) in various ways.
(38) Before or during use, the needle unit **23** is combined with the cartridge **22** before the catch **34** is released. As explained below, rotating a part of the needle sleeve **26** about the axis A causes one of the needle unit **23** or the cartridge **22** to move axially within the housing **21** so that the needle **31** is placed in fluid communication with the reservoir **28**. A subsequent movement of the needle sleeve **26** in a proximal direction releases the catch **34** so that plunger **33** begins delivery of the medicament via the needle **31**. In various examples described hereinafter, a part of the needle sleeve **26** must be rotated to engage the needle unit **23** and cartridge **22** before the needle sleeve **26** can move axially into the housing **21** to actuate the piston drive mechanism **25**.
(39) FIG. **3** illustrates the distal end of the needle sleeve **26** of the injection device **20**. As shown, the needle sleeve **26** has a first part **38** and a second part **39**. The second part **39** of the needle sleeve **26** is rotationally coupled to the end of the first part **38**. As shown, the second part **39** includes a slot **40** and the first part **38** includes a catch **41** that is received in the slot **40**.
(40) In the example of FIG. **3**, the slot **40** is only slightly larger than the catch **41**. In an initial position, the catch **41** is not aligned with the slot **40** and is in a deflected state acting against the inside of the second part **39** of the needle sleeve **36**. Rotation of the second part **39** of the needle sleeve **26** about the axis A moves the catch **41** into alignment with the slot **40** so that the catch **41** snaps into the slot **40** to prevent further rotation.
(41) In the example of FIG. **4**, the slot **40** extends circumferentially about the needle sleeve **26**. The slot **40** thereby allows the second part **39** to rotate relative to the first part **38** about axis A as the catch **41** moves within the slot **40**. The extent of rotation is limited by the length of the slot **40**. In an initial position the catch **41** is at a first end of the slot **40**, and rotation of the second part **39** of the needle sleeve **26** moves the catch **41** to an opposite end of the slot **40**.
(42) In the examples of FIGS. **3** and **4**, there are two slots **40** arranged on opposite sides of the needle sleeve **26**. However, it will be appreciated that only one slot **40** may be provided, or more than two slots **40** may be provided, and the first part **39** will have a corresponding number of catches **41**.
(43) As also illustrated in FIG. **4**, in some examples the second part **39** of the needle sleeve **26** includes an axially extending slot **43**. The axially extending slot **43** moves as the second part **39** of the needle sleeve **26** is rotated. Rotation of the second part **39** of the needle sleeve **26** moves the axially extending slot **43** into alignment with a protrusion (not illustrated) on the housing. In this way, the axially extending slot **43** and protrusion act as a locking mechanism because the protrusion will prevent axial movement of the needle sleeve **26** into the housing **21** until the second part **39** of the needle sleeve **26** has been rotated to align the axially extending slot **43** with the protrusion.
(44) Also shown in FIGS. **3** and **4**, the second part **39** of the needle sleeve **26** also includes an engaging member, in this example a helical guide **44** arranged on an internal surface of the second part **39** of the needle sleeve **26**, extending partially about the internal circumference of the needle sleeve **26**. In examples, the needle sleeve **26** may comprise one or more helical guides **44**, for example two helical guides **44**, or three helical guides **44**.
(45) The helical guide **44** acts to move the needle unit **23** into engagement with the cartridge **22** as

the second part **39** of the needle sleeve **26** is rotated.
(46) FIGS. **5**A to **5**C illustrate a needle unit **23** that may be used with the needle sleeve **26** described with reference to FIGS. **3** and **4**. As shown in FIG. **5**A, the needle unit **23** includes a needle body **45** to which a needle **31** is attached. The needle body **45** includes a recess **46**. The recess **46** is adapted to be positioned over the cartridge mounting portion **30** (see FIG. **2**) of the housing **21** (see FIG. **2**) when the needle unit **23** is combined with the cartridge **22** (see FIG. **2**) during use of the injection device **20**.
(47) As shown in FIG. **5**A, and referring to FIG. **2**, the needle body **45** includes a groove **47** arranged to cooperate with a rail (not illustrated) on the cartridge mounting portion **30** of the housing **21**. The groove **47** is located on the internal surface of the needle body **45**, in the recess **46**. The cooperation of the rail and the groove **47** prevents rotation of the needle unit **23** relative to the housing **21** and cartridge **22**, and guides the needle unit **23** in an axial direction when the helical guide **44** of the second part **39** of the needle sleeve **26** pushes the needle unit **23** onto the cartridge **22**, as explained hereinafter.
(48) As shown in FIGS. **5**B and **5**C, the outer surface of the needle body **45** includes protrusions **48**. In this example, the external surface of the needle body **45** includes two protrusions **48**, but it will be appreciated that one protrusion **48** is provided for each helical guide **44** on the second part **39** of the needle sleeve **37**. The protrusions **48** are generally circular, but may be other shapes. The protrusions **48** are equally spaced around the circumference of the needle body **45**.
(49) Referring to FIGS. **2** to **5**C, the protrusions **48** on the needle body **45** are arranged to engage with the helical guides **44** on the second part **39** of the needle sleeve **26** such that rotation of the second part **39** of the needle sleeve **26** causes axial movement of the needle unit **23** towards the cartridge **22**. In this way, during use of the injection device **20**, the user rotates the second part **39** of the needle sleeve **26** to engage the needle unit **23** with the cartridge **22** and place the needle **31** in fluid communication with the reservoir **28** before the injection process is started.
(50) FIGS. **6**A to **6**C illustrate the process of combining of the needle unit **23** and cartridge **22**.
(51) As shown in FIG. **6**A, and referring also to FIGS. **3** to **5**C, in this initial position the needle unit **23** is spaced from the cartridge **22**. The needle sleeve **26** is in an extended position and covers the needle **31**. In particular, the second part **39** of the needle sleeve **26** protrudes from a distal end of the housing **21**. In this position, the needle unit **23** is held in place by a combination of the engagement between the protrusions **48** and helical guides **44**, the engagement between a proximal end of the needle body **45** and the cartridge mounting portion **30** of the housing **21**, and engagement between the rail (not illustrated) and groove **47**.
(52) As the second part **39** of the needle sleeve **26** is rotated the engagement between the helical guides **44** on the second part **39** of the needle sleeve **26** and the protrusions **48** on the needle unit **23** drive the needle unit **23** in an axial direction towards the cartridge **22**. The rail and groove **47** prevent rotation of the needle unit **23** and guide the needle unit **23** onto the cartridge mounting portion **30**.
(53) As shown in FIG. **6**A, the proximal end of the needle body **45** includes catches **49** that initially have to be deflected to allow the needle body **45** to move over the cartridge mounting portion **30** of the housing **21**. In the initial position, shown in FIG. **6**A, engagement between the catches **49** and the cartridge mounting portion **30** help to hold the needle unit **23** in position within the injection device **20**.
(54) FIG. **6**B shows the injection device **20** after the second part **39** of the needle sleeve **26** has been rotated to move the needle unit **23** into engagement with the cartridge **22**. As shown, the catches **49** on the proximal end of the needle body **45** have engaged with recesses **50** on the cartridge mounting portion **30**, so that the needle unit **23** is secured in place on the cartridge mounting portion **30**. Also, a proximal end of the needle **31** has pierced the end cap **29** of the cartridge **22**, so that the needle **31** is in fluid communication with the reservoir **28**. The needle sleeve **26** remains in an extended position due to the action of the spring **42**.

(55) Due to the rotation of the second part **39** of the needle sleeve **26** the helical members **44** have disengaged from the protrusions (**48**, see FIGS. **5**A to **5**C), so that the needle sleeve **26** is able to move axially independently of the needle unit **23**.
(56) Furthermore, as explained previously with reference to FIGS. **3** to **5**C, rotation of the second part **39** of the needle sleeve **26** moves the catches **41** into engagement with the slots **40** (FIG. **3**), or moves the catches **41** along the slots **40** (FIG. **4**). Rotation of the second part **39** of the needle sleeve **26** has also brought the axially extending slot **43** into line with the protrusion on the housing **21**, so that the needle sleeve **26** is not able to move axially into the housing **21**.
(57) FIG. **6**C shows the injection device **20** after the injection device **20** has been pressed against the user's skin to start the injection process. As illustrated, the needle sleeve **26** has moved proximally into the housing **21**, exposing the needle **31** so that the needle **31** can pierce the user's skin. Also, as explained previously, proximal movement of the needle sleeve **26** into the housing **21** releases the catch (**34**, see FIG. **2**) of the piston drive mechanism (**25**, see FIG. **2**) to release the plunger (**33**, see FIG. **2**), and the spring (**32**, see FIG. **2**) then drives the piston (**24**, see FIG. **2**) into the cartridge **22** to dispense medicament from the reservoir **28** via the needle **31**.
(58) After use, the spring **42** urges the needle sleeve **26** back to an extended position to re-cover the needle **31**.
(59) FIGS. **7**A and **7**B illustrate an alternative example injection device **20**. In particular FIG. **7**A illustrates an alternative second part **39** of the needle sleeve **26** and FIG. **7**B illustrates the needle unit **23** for use with the alternative second part **39**. The second part **39** of the needle sleeve **26** of FIG. **7**A and needle unit **23** of FIG. **7**B can be used with the injection device **20** of FIG. **2**, but in this example, the needle unit **23** is rotationally mounted within the housing **21** and there is no rail and groove **47** as described with reference to previous examples.
(60) Referring to FIGS. **2**, **7**A and **7**B, the needle unit **23** has a needle body **51** having a recess **52**, and an internal thread in the recess **52**. The internal thread is arranged to engage with an external thread on the cartridge mounting portion **30** of the housing **21**, or with an external thread on the cartridge **22**. In an initial position the thread is aligned or partially started, such that on rotation of the needle unit **23** (explained below) the thread moves the needle unit **23** axially into engaged with the cartridge **22**. In this way, the thread acts to guide the needle unit **23** into engagement with the cartridge **22** when the second part **39** of the needle sleeve **26** is rotated.
(61) The internal surface of the needle sleeve **26** includes a groove **53**, preferably two grooves **53**. The external surface of the needle body **51** includes a protrusion **54**, preferably two protrusions **54**, that engage with the grooves **53** of the second part **39** of the needle sleeve **26**. In this way, rotating the second part **39** of the needle sleeve **26** in the housing **21** causes rotation of the needle unit **23** within the housing **21**, and the thread moves the needle unit **23** axially into engagement with the cartridge **22** so that the needle **31** is placed in fluid communication with the reservoir **28**.
(62) As shown in FIG. **7**B, the needle unit **23** may also include end stops **55** that engage a part of the cartridge mounting portion **30** after the needle unit **23** has been rotated onto the cartridge mounting portion **30** by the thread. Additionally or alternatively, recesses **56** may be provided to engage with catches on the cartridge mounting portion **30**, to secure the needle unit **23** on the cartridge mounting portion **30**.
(63) The threaded connection between the needle unit **23** and cartridge mounting portion **30** may have a high pitch, so that comparatively less rotation is needed to achieve the desired axial movement. For example, the rotation may be between 30 and 120 degrees, or about 90 degrees. However, the rotation may be greater than 120 degrees, for example 180 degrees.
(64) In various examples, the threaded connection may comprise an external thread on the cartridge mounting portion **30** and an internal thread on the needle unit **23**, or alternatively one of the internal and external threads may be replaced by a protrusion arranged to engage the other thread, so that on rotation of the needle sleeve **23** the protrusion follows the path of the thread and moves the needle unit **23** into engagement with the cartridge **22**.

(65) The terms “drug” or “medicament” are used synonymously herein and describe a pharmaceutical formulation containing one or more active pharmaceutical ingredients or pharmaceutically acceptable salts or solvates thereof, and optionally a pharmaceutically acceptable carrier. An active pharmaceutical ingredient (“API”), in the broadest terms, is a chemical structure that has a biological effect on humans or animals. In pharmacology, a drug or medicament is used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being. A drug or medicament may be used for a limited duration, or on a regular basis for chronic disorders.

(66) As described below, a drug or medicament can include at least one API, or combinations thereof, in various types of formulations, for the treatment of one or more diseases. Examples of API may include small molecules having a molecular weight of 500 Da or less; polypeptides, peptides and proteins (e.g., hormones, growth factors, antibodies, antibody fragments, and enzymes); carbohydrates and polysaccharides; and nucleic acids, double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (siRNA), ribozymes, genes, and oligonucleotides. Nucleic acids may be incorporated into molecular delivery systems such as vectors, plasmids, or liposomes. Mixtures of one or more drugs are also contemplated.

(67) The drug or medicament may be contained in a primary package or “drug container” adapted for use with a drug delivery device. The drug container may be, e.g., a cartridge, syringe, reservoir, or other solid or flexible vessel configured to provide a suitable chamber for storage (e.g., short- or long-term storage) of one or more drugs. For example, in some instances, the chamber may be designed to store a drug for at least one day (e.g., 1 to at least 30 days). In some instances, the chamber may be designed to store a drug for about 1 month to about 2 years. Storage may occur at room temperature (e.g., about 20° C.), or refrigerated temperatures (e.g., from about −4° C. to about 4° C.). In some instances, the drug container may be or may include a dual-chamber cartridge configured to store two or more components of the pharmaceutical formulation to-be-administered (e.g., an API and a diluent, or two different drugs) separately, one in each chamber. In such instances, the two chambers of the dual-chamber cartridge may be configured to allow mixing between the two or more components prior to and/or during dispensing into the human or animal body. For example, the two chambers may be configured such that they are in fluid communication with each other (e.g., by way of a conduit between the two chambers) and allow mixing of the two components when desired by a user prior to dispensing. Alternatively or in addition, the two chambers may be configured to allow mixing as the components are being dispensed into the human or animal body.

(68) The drugs or medicaments contained in the drug delivery devices as described herein can be used for the treatment and/or prophylaxis of many different types of medical disorders. Examples of disorders include, e.g., diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism. Further examples of disorders are acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis. Examples of APIs and drugs are those as described in handbooks such as Rote Liste 2014, for example, without limitation, main groups 12 (anti-diabetic drugs) or 86 (oncology drugs), and Merck Index, 15th edition.

(69) Examples of APIs for the treatment and/or prophylaxis of type 1 or type 2 diabetes mellitus or complications associated with type 1 or type 2 diabetes mellitus include an insulin, e.g., human insulin, or a human insulin analogue or derivative, a glucagon-like peptide (GLP-1), GLP-1 analogues or GLP-1 receptor agonists, or an analogue or derivative thereof, a dipeptidyl peptidase-4 (DPP4) inhibitor, or a pharmaceutically acceptable salt or solvate thereof, or any mixture thereof. As used herein, the terms “analogue” and “derivative” refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring

peptide, for example that of human insulin, by deleting and/or exchanging at least one amino acid residue occurring in the naturally occurring peptide and/or by adding at least one amino acid residue. The added and/or exchanged amino acid residue can either be codable amino acid residues or other naturally occurring residues or purely synthetic amino acid residues. Insulin analogues are also referred to as “insulin receptor ligands”. In particular, the term “derivative” refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, in which one or more organic substituent (e.g. a fatty acid) is bound to one or more of the amino acids. Optionally, one or more amino acids occurring in the naturally occurring peptide may have been deleted and/or replaced by other amino acids, including non-codeable amino acids, or amino acids, including non-codeable, have been added to the naturally occurring peptide. Examples of insulin analogues are Gly(A21), Arg(B31), Arg(B32) human insulin (insulin glargine); Lys(B3), Glu(B29) human insulin (insulin glulisine); Lys(B28), Pro(B29) human insulin (insulin lispro); Asp(B28) human insulin (insulin aspart); human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala(B26) human insulin; Des(B28-B30) human insulin; Des(B27) human insulin and Des(B30) human insulin.

(70) Examples of insulin derivatives are, for example, B29-N-myristoyl-des(B30) human insulin, Lys(B29) (N-tetradecanoyl)-des(B30) human insulin (insulin detemir, Levemir®); B29-N-palmitoyl-des(B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl-ThrB29LysB30 human insulin; B29-N—(N-palmitoyl-gamma-glutamyl)-des(B30) human insulin, B29-N-omega-carboxypentadecanoyl-gamma-L-glutamyl-des(B30) human insulin (insulin degludec, Tresiba®); B29-N—(N-lithocholyl-gamma-glutamyl)-des(B30) human insulin; B29-N-(w-carboxyheptadecanoyl)-des(B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.

(71) Examples of GLP-1, GLP-1 analogues and GLP-1 receptor agonists are, for example, Lixisenatide (Lyxumia®), Exenatide (Exendin-4, Byetta®, Bydureon®, a 39 amino acid peptide which is produced by the salivary glands of the Gila monster), Liraglutide (Victoza®), Semaglutide, Taspoglutide, Albiglutide (Syncria®), Dulaglutide (Trulicity®), rExendin-4, CJC-1134-PC, PB-1023, TTP-054, Langlenatide/HM-11260C, CM-3, GLP-1 Eligen, ORMD-0901, NN-9924, NN-9926, NN-9927, Nodexen, Viador-GLP-1, CVX-096, ZYOG-1, ZYD-1, GSK-2374697, DA-3091, MAR-701, MAR709, ZP-2929, ZP-3022, TT-401, BHM-034. MOD-6030, CAM-2036, DA-15864, ARI-2651, ARI-2255, Exenatide-XTEN and Glucagon-Xten. An examples of an oligonucleotide is, for example: mipomersen sodium (Kynamro®), a cholesterol-reducing antisense therapeutic for the treatment of familial hypercholesterolemia. Examples of DPP4 inhibitors are Vildagliptin, Sitagliptin, Denagliptin, Saxagliptin, Berberine. Examples of hormones include hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, and Goserelin.

(72) Examples of polysaccharides include a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra-low molecular weight heparin or a derivative thereof, or a sulphated polysaccharide, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium. An example of a hyaluronic acid derivative is Hylan G-F 20 (Synvisc®), a sodium hyaluronate.

(73) The term “antibody”, as used herein, refers to an immunoglobulin molecule or an antigen-binding portion thereof. Examples of antigen-binding portions of immunoglobulin molecules include F(ab) and F(ab′)2 fragments, which retain the ability to bind antigen. The antibody can be

polyclonal, monoclonal, recombinant, chimeric, de-immunized or humanized, fully human, non-human, (e.g., murine), or single chain antibody. In some embodiments, the antibody has effector function and can fix complement. In some embodiments, the antibody has reduced or no ability to bind an Fc receptor. For example, the antibody can be an isotype or subtype, an antibody fragment or mutant, which does not support binding to an Fc receptor, e.g., it has a mutagenized or deleted Fc receptor binding region. The term antibody also includes an antigen-binding molecule based on tetravalent bispecific tandem immunoglobulins (TBTI) and/or a dual variable region antibody-like binding protein having cross-over binding region orientation (CODV).

(74) The terms “fragment” or “antibody fragment” refer to a polypeptide derived from an antibody polypeptide molecule (e.g., an antibody heavy and/or light chain polypeptide) that does not comprise a full-length antibody polypeptide, but that still comprises at least a portion of a full-length antibody polypeptide that is capable of binding to an antigen. Antibody fragments can comprise a cleaved portion of a full length antibody polypeptide, although the term is not limited to such cleaved fragments. Antibody fragments that are useful in the present invention include, for example, Fab fragments, F(ab′)2 fragments, scFv (single-chain Fv) fragments, linear antibodies, monospecific or multispecific antibody fragments such as bispecific, trispecific, tetraspecific and multispecific antibodies (e.g., diabodies, triabodies, tetrabodies), monovalent or multivalent antibody fragments such as bivalent, trivalent, tetravalent and multivalent antibodies, minibodies, chelating recombinant antibodies, tribodies or bibodies, intrabodies, nanobodies, small modular immunopharmaceuticals (SMIP), binding-domain immunoglobulin fusion proteins, camelized antibodies, and VHH containing antibodies. Additional examples of antigen-binding antibody fragments are known in the art.

(75) The terms “Complementarity-determining region” or “CDR” refer to short polypeptide sequences within the variable region of both heavy and light chain polypeptides that are primarily responsible for mediating specific antigen recognition. The term “framework region” refers to amino acid sequences within the variable region of both heavy and light chain polypeptides that are not CDR sequences, and are primarily responsible for maintaining correct positioning of the CDR sequences to permit antigen binding. Although the framework regions themselves typically do not directly participate in antigen binding, as is known in the art, certain residues within the framework regions of certain antibodies can directly participate in antigen binding or can affect the ability of one or more amino acids in CDRs to interact with antigen. Examples of antibodies are anti PCSK-9 mAb (e.g., Alirocumab), anti IL-6 mAb (e.g., Sarilumab), and anti IL-4 mAb (e.g., Dupilumab).

(76) Pharmaceutically acceptable salts of any API described herein are also contemplated for use in a drug or medicament in a drug delivery device. Pharmaceutically acceptable salts are for example acid addition salts and basic salts.

(77) Those of skill in the art will understand that modifications (additions and/or removals) of various components of the APIs, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope and spirit of the present invention, which encompass such modifications and any and all equivalents thereof.

## Claims

1. A method of using an injection device, the injection device comprising a housing having an axis, a needle sleeve, and a needle, the method comprising: rotating a part of the needle sleeve about the axis to move the part of the needle sleeve from a locked position in which the part of the needle sleeve is prevented from moving axially into the housing, to an unlocked position in which the needle sleeve is permitted to move axially into the housing; pressing the part of the needle sleeve against an injection site to move the needle sleeve axially into the housing to actuate an injection process, wherein the injection process automatically dispenses a medicament via the needle; wherein the injection device is an auto-injector, and wherein the needle sleeve comprises a first part

and a second part, wherein the second part is rotatably coupled to the first part such that the second part can be rotated relative to the first part about the axis, and wherein rotating the part of the needle sleeve comprises rotating the second part of the needle sleeve relative to the housing and relative to the first part of the needle sleeve.
2. The method of claim 1, wherein the needle sleeve covers the needle prior to rotating the part of the needle sleeve, and wherein moving the needle sleeve axially into the housing exposes the needle to allow the needle to pierce a user's skin.
3. The method of claim 1, wherein rotating the part of the needle sleeve about the axis comprises gripping the part of the needle sleeve and rotating the part of the needle sleeve relative to the housing.
4. The method of claim 1, further comprising removing the needle sleeve from the injection site, wherein the needle sleeve moves distally as the needle sleeve is removed from the injection site to cover the needle.
5. The method of claim 1, wherein the injection device further comprises a cartridge comprising a reservoir, and wherein the medicament is in the reservoir.
6. The method of claim 5, wherein moving the needle sleeve axially into the housing causes a plunger to move into the reservoir for dispensing the medicament.
7. The method of claim 5, wherein the injection device further comprises a piston disposed in the cartridge and a piston drive mechanism configured to drive the piston, wherein moving the needle sleeve axially into the housing actuates the piston drive mechanism for dispensing the medicament.
8. The method of claim 1, wherein the injection device further comprises a needle unit comprising the needle, and a cartridge comprising a reservoir containing the medicament, and wherein, prior to use of the injection device, the reservoir is sealed from the needle.
9. The method of claim 8, wherein rotating the part of the needle sleeve moves the needle unit to place the needle in fluid communication with the reservoir.
10. The method of claim 9, wherein the part of the needle sleeve comprises an engaging member which moves the needle unit in an axial direction when the part of the needle sleeve is rotated.
11. The method of claim 10, wherein the engaging member disengages from the needle unit after the part has been rotated.
12. The method of claim 1, wherein the housing comprises a proximal end and a distal end, wherein the needle sleeve is provided at the distal end of the housing, and wherein the second part is distal to the first part.
13. The method of claim 1, comprising removing a cap from the injection device prior to rotating the part of the needle sleeve about the axis.
14. A method of using an injection device, the injection device comprising a housing, a needle sleeve, and a needle, the method comprising: gripping a part of the needle sleeve and rotating the part of the needle sleeve which is gripped, relative to the housing of the injection device to move the part of the needle sleeve from a locked position in which the part of the needle sleeve is prevented from moving axially into the housing, to an unlocked position in which the part of the needle sleeve is permitted to move axially into the housing; and moving the needle sleeve axially into the housing, while the part of the needle sleeve is in the unlocked position, to actuate an injection process, wherein the injection process automatically dispenses a medicament via the needle; wherein the injection device is an auto-injector, and wherein the needle sleeve comprises a first part and a second part, wherein the second part is rotatably coupled to the first part such that the second part can be rotated relative to the first part about the axis, and wherein rotating the part of the needle sleeve comprises rotating the second part of the needle sleeve relative to the housing and relative to the first part of the needle sleeve.
15. The method of claim 14, wherein the needle sleeve covers the needle prior to rotating the part of the needle sleeve, and wherein moving the needle sleeve axially into the housing exposes the needle to allow the needle to pierce a user's skin.

16. The method of claim 14, further comprising pressing the part of the needle sleeve against an injection site to move the needle sleeve axially into the housing.
17. The method of claim 16, further comprising removing the needle sleeve from the injection site, wherein the needle sleeve moves distally as the needle sleeve is removed from the injection site to cover the needle.
18. The method of claim 14, wherein the injection device further comprises a cartridge comprising a reservoir, and wherein the medicament is in the reservoir.
19. The method of claim 18, wherein moving the needle sleeve axially into the housing causes a plunger to move into the reservoir for dispensing the medicament.
20. The method of claim 14, wherein the injection device further comprises a needle unit comprising the needle, and a cartridge comprising a reservoir containing the medicament, and wherein, prior to use of the injection device, the reservoir is sealed from the needle.
21. The method of claim 20, wherein rotating the part of the needle sleeve moves the needle unit to place the needle in fluid communication with the reservoir.
22. The method of claim 14, wherein the needle sleeve comprises a first part and a second part, and wherein gripping the part of the needle sleeve and rotating the part of the needle sleeve comprises gripping the second part of the needle sleeve and rotating the second part of the needle sleeve relative to the housing and relative to the first part of the needle sleeve.
23. A method of using an injection device, the injection device comprising a housing having an axis, a needle unit comprising a needle, a needle sleeve, and a cartridge comprising a reservoir containing medicament, wherein, prior to use of the injection device, the reservoir is sealed from the needle, the method comprising: rotating a part of the needle sleeve about the axis to move the part of the needle sleeve from a locked position in which the part of the needle sleeve is prevented from moving axially into the housing, to an unlocked position in which the part of the needle sleeve is permitted to move axially into the housing; pressing the part of the needle sleeve against an injection site to move the needle sleeve axially into the housing to actuate an injection process, wherein the injection process automatically dispenses a medicament via the needle; wherein the injection device is an auto-injector, and wherein the needle sleeve comprises a first part and a second part, wherein the second part is rotatably coupled to the first part such that the second part can be rotated relative to the first part about the axis, and wherein rotating the part of the needle sleeve comprises rotating the second part of the needle sleeve relative to the housing and relative to the first part of the needle sleeve.
24. The method of claim 23, wherein rotating the part of the needle sleeve moves the needle unit to place the needle in fluid communication with the reservoir.
25. A method of using an injection device, the injection device comprising a housing, a needle sleeve comprising a first part and a second part, and a needle, the method comprising: rotating the second part of the needle sleeve relative to the housing to move the second part of the needle sleeve from a locked position in which the first and second parts of the needle sleeve are prevented from moving axially into the housing, to an unlocked position in which the first and second parts of the needle sleeve are permitted to move axially into the housing; and then moving the needle sleeve axially into the housing to actuate an injection process that automatically dispenses a medicament via the needle, wherein rotating the second part of the needle sleeve relative to the housing comprises gripping the second part of the needle sleeve and rotating the second part of the needle sleeve relative to the housing.
26. The method of claim 25, further comprising pressing the second part of the needle sleeve against an injection site to move the needle sleeve axially into the housing.
27. The method of claim 25, wherein rotating the second part of the needle sleeve comprises rotating the second part of the needle sleeve relative to the first part of the needle sleeve.