Medication delivery device

The present invention relates to a medication delivery device, a use and a method of manufacturing or assembling the device. The invention refers particularly to dosing mechanisms suitable for use in medication delivery devices, in particular in pen-type injectors, preferably having dose setting means and a drive device enabling the administration of a medicinal product from a multi-dose medication cartridge. In particular, the present invention relates to such medication delivery devices where a user may set a dose of medication to be delivered from a multi-dose cartridge and where the multi-dose medication cartridge can be replaced when the medication has been fully dispensed.

The present invention further relates to an actuation means for a medication delivery device, and particularly to an actuation means being designed to bring a guiding means of the medication delivery device into a guiding position.

Such medication delivery devices have application where regular injections by persons without formal medical training occur, i.e., patients. This is increasingly common amongst those having diabetes where self-treatment enables such persons to conduct effective management of their diabetes.

These circumstances set a number of requirements for medication delivery devices of this kind. The device must be robust in construction, yet easy to use in terms of the manipulation of the parts, understanding by a user of its operation and the delivery of the required dose of medicament. Dose setting must be easy and unambiguous. In the case of those with diabetes, many users will be physically infirm and may also have impaired vision requiring the dosing mechanism to have a drive device which requires a low dispensing force and the medication delivery device to have an easy to read dose setting display.

As a result of environmental and economical reasons this kind of medication delivery device has been developed to allow only a part of the device to be discarded after all

the medicament has been delivered, usually the medication cartridge only. This provides the additional requirement for such a medication delivery device that the resetting of the drive mechanism, when a new cartridge is attached to or inserted into the medication delivery device, needs to be easy and unambiguous without the need for the user to touch any component of the drive mechanism directly, thereby reducing the possibility of damage to the drive mechanism through e.g. contamination.

A further requirement of such reusable devices is that when a new cartridge is attached there should be no movement of the bung in the cartridge and thus no pressurisation of the contents of the cartridge prior to dose setting and dose delivery. If this occurs, the accuracy of the device could be affected.

User operated medication delivery devices are well known within the medical field.

WO 2004/078239 A1 discloses a drive mechanism for a drug delivery device with a housing having a helical thread, a dose dial sleeve having a helical thread engaged with the helical thread of the housing, a drive sleeve releasably connected to the dose dial sleeve and a clutch means located between the dose dial sleeve and the drive sleeve. When the dose dial sleeve and the drive sleeve are coupled via the clutch means, both are allowed to rotate with respect to the housing. When the dose dial sleeve and the drive sleeve are decoupled, rotation of the dose dial sleeve with respect to the housing is allowed whilst rotation of the drive sleeve with respect to the housing is not allowed, whereby axial movement of the drive sleeve is allowed so that a force is transferred in the longitudinal direction to a piston rod for medication delivery. This document neither describes the replacement of the cartridge, nor a resetting of the drive mechanism.

The following prior art documents address the reusability of such devices using a disposable and replaceable medicament cartridge that is attachable to/detachable from a reusable (resettable) drive mechanism.

In EP 0 554 996 B1 discloses an injection device comprising a housing and means for mounting a fluid containing cartridge containing an internal piston to the housing. A lead screw is movably mounted within the housing and a dose setting means is provided for selecting the amount of fluid to be delivered by the device. This device provides a solution for changing the cartridge and resetting the dosing mechanism of the reusable injection device. The new cartridge is inserted into the housing which is then screwed into place while the piston of the cartridge pushes the lead screw into the device which may have the disadvantage of applying pressure to the piston at the end of the screwing.

US 5,827,232 teaches a medication delivery pen, comprising a disposable medication containing cartridge assembly. The cartridge assembly comprises a cartridge with a pierceably sealed distal end and a plunger in sliding fluid tight engagement therein to dispense medication from the cartridge when the plunger slides in a distal direction. Furthermore, the medication delivery pen comprises a reusable pen body assembly which has a housing, a lead screw disposed in the housing and a driver means for moving the lead screw distally in the pen body assembly selected amounts. Whilst this device provides a solution for resetting a medication delivery pen drive mechanism it does require the user to align the cartridge holder with slots at the distal end of the piston rod which may be difficult for users with impaired eyesight and/or impaired dexterity.

WO 1997/010864 A1 describes a medication delivery pen comprising a cartridge holder assembly for holding a cartridge having a plunger, the cartridge holder assembly having a plurality of threads at a proximal end. A pen body assembly comprises a plurality of threads at a distal end for threading with the threads in the cartridge holder assembly. A lead screw extends form the distal end for engaging the plunger in the cartridge. Means for driving the lead screw into the cartridge are provided to move the plunger in the distal direction. Furthermore, means for disengaging the driving means from the lead screw are provided to permit the lead screw to automatically and easily retract into the pen body when the pen body assembly approaches and is being threaded to the cartridge holder assembly.

However, the disclosed solution for mounting a new cartridge holder assembly to the reusable pen body assembly may have the disadvantage of applying pressure to the plunger at the end of the assembling.

Embodiments of the present invention seek to avoid the disadvantages of the known medication delivery devices, particularly to provide a flexible reset mechanism for use in a medication delivery device by means of which the medication delivery device can be reset for re-use when the medication cartridge is replaced.

The dosing mechanism for a medication delivery device according to embodiments of the present invention seek to provide a valuable technical alternative for known dosing mechanisms. The dosing mechanism according to embodiments of the present invention e.g. has the advantage that the piston rod is driven back into the device body when a new cartridge is attached, without the user having to touch any part of the dosing mechanism and without any movement of the cartridge bung. The dosing mechanism according to embodiments of the present invention further provides the advantage of an easy replacement of the medication cartridge almost without application of pressure on the bung of the cartridge during resetting of the device and therefore without pressurization of the medication within the cartridge before the first setting and dispensing of a dose.

According to an aspect of the present invention, a medication delivery device is provided, comprising:

- a housing having a proximal and a distal end,
- a medication receptacle designed to be engaged with the distal end of the housing by engagement of first engagement means with second engagement means and
- a dosing mechanism including
  - a piston rod which is moveable in a distal direction for medication delivery and
  - a drive device for moving the piston rod (17) in the distal direction for medication delivery;

  characterized in that

the medication receptacle comprises an actuation means for bringing a guiding means in a guiding position in which the guiding means guides the piston rod for medication delivery,

wherein the first engagement means and the second engagement means are moveable into engagement by a movement of the medication receptacle which ends in a rotational movement without axial movement of the medication receptacle with respect to the housing, the actuation means thereby bringing the guiding means in the guiding position.

The guiding means is brought into the guiding position during the rotational movement of the medication receptacle while the medication receptacle does not move axially with respect to the housing.

The medication delivery device can be designed such that, by the rotational movement of the actuation means, the actuation means is directly or indirectly interacting with the guiding means for bringing the same in the guiding position and thereby in an operational state for medication delivery in which the guiding means is prevented from rotating with respect to the housing.

Preferably the medication delivery device according to embodiments of the present invention is designed such that, when the guiding means is in the guiding position, the piston rod can be moved axially in the distal direction with respect to the housing by the drive device of the dosing mechanism for medication delivery and the piston rod is prevented from axial movement in the proximal direction with respect to the housing. Most preferably the medication delivery device according to embodiments of the present invention is designed such that, when the guiding means is in the guiding position, the piston rod can be moved axially in the distal direction and rotated in one direction with respect to the housing by the drive device of the dosing mechanism for medication delivery and the piston rod is prevented from axial movement in the proximal direction with respect to the housing.

According to a preferred embodiment of the present invention the medication delivery device is designed such that when the guiding means is in the guiding position, the guiding means is prevented from rotation with respect to the housing, more preferably the guiding means is prevented from any movement (translational as well as rotational movement) with respect to the housing. Preferably, the guiding means is mounted within the housing such that it is prevented from axial movement with respect to the housing at any time and it is additionally prevented from rotation only in the guiding position. Most preferably, the guiding means is mounted within the housing such that it is retained for rotational movement and for limited axial movement with respect to the housing when it is not in the guiding position and it is prevented from axial movement and from rotation with respect to the housing in the guiding position.

Additionally or alternatively, the medication delivery device can be designed such that when the guiding means is not in the guiding position, the piston rod is free to move axially in the proximal direction with respect to the housing (preferably while rotating in the other direction). Most preferably, the medication delivery device is designed such that when the guiding means is not in the guiding position, the piston rod is free to be wound back in the proximal direction with respect to the housing e.g. for resetting the piston rod when a new medication receptacle (e.g. a new cartridge or a cartridge holder with a new cartridge) is mounted on the distal end of the housing of the device.

In a preferred embodiment of the present invention the first and second engagement means are designed such that for moving the medication receptacle and the housing into engagement the actuation means are first rotated and moved axially with respect to the housing and are thereafter rotated without being moved axially, thereby bringing the guiding means in the guiding position. When the first and second engagement means are moved out of engagement (and thus when the medication receptacle is disengaged from the housing), the guiding means preferably moves out of the guiding position into another position in which it no longer guides the piston rod.

Further, in the medication delivery device according to embodiments of the present invention

- the drive device can comprise a drive sleeve and

- the piston rod can comprise two threaded sections, wherein a first threaded section is provided for threaded engagement with the guiding means and a second threaded section is provided for threaded engagement with the drive sleeve and wherein the pitch direction of the second threaded section is opposedly directed to the pitch direction of the first threaded section.

In this embodiment, the medication delivery device can be designed such that the drive sleeve is engaged with the piston rod and when the drive sleeve drives the piston rod in distal direction for medication delivery, the drive sleeve is moved axially and is prevented from rotation with respect to the housing during medication delivery, thereby causing axial movement and rotation of the piston rod.

Further, the dosing mechanism of the medication delivery device according to embodiments of the present invention can comprise:

- a dose dial sleeve having a helical thread engaged with a helical thread of the housing, the drive sleeve being releasably coupled with the dose dial sleeve and
- a clutch means located between the dose dial sleeve and the drive sleeve,

wherein,

a) when the dose dial sleeve and the drive sleeve are coupled (by means of the clutch means), both are allowed to rotate with respect to the housing, and

b) when the dose dial sleeve and the drive sleeve are de-coupled, rotation of the dose dial sleeve with respect to the housing is allowed, whilst rotation of the drive sleeve with respect to the housing is not allowed and axial movement of the drive sleeve is allowed in the distal direction thereby transferring a force in the distal direction to the piston rod.

In all of the embodiments of the present invention, the guiding means is preferably a nut means which is threadedly engaged with the piston rod. According to a preferred embodiment of the present invention the guiding means is a nut means which is threadedly engaged with the piston rod and which is engaged with a locking means in the guiding position.

The locking means and the guiding means can comprise face teeth which interlock when the locking means and the guiding means are engaged in the guiding position.

In all above mentioned embodiments, the medication delivery device can comprise a locking means which is non-rotatable with respect to the housing and which is engageable with the guiding means, thereby locking the guiding means for preventing rotation of the guiding means with respect to the housing. Preferably, the locking means is splined to the housing or to an insert of the housing, thereby being allowed to move axially but being prevented from rotating with respect to the housing. Preferably, the locking means is allowed to move axially only for a limited axial movement with respect to the housing.

When the guiding means is engaged with the locking means in the guiding position, the piston rod is preferably prevented from rotation in one rotational direction and from axial movement in the proximal direction with respect to the housing but is allowed to rotate in the other rotational direction and move axially in the distal direction with respect to the housing for medication delivery.

The guiding means or the locking means of the medication delivery device according to embodiments of the present invention can comprise a shape which interacts with the shape of the actuation means for driving the locking means and the guiding means into engagement by the rotational movement (without axial movement) of the actuation means with respect to the housing.

Particularly, at least one inclined surface can be arranged on the actuation means and at least one correspondingly inclined surface can be arranged on the guiding means or on the locking means, wherein the inclined surfaces are formed such that for interaction of the actuation means and the guiding means or of the actuation means and the locking means the inclined surfaces can glide along each other.

Preferably, the actuation means comprises at least one protrusion with the inclined surface fixedly or moveably arranged on the actuation means or at least one ramp with an inclined surface for interacting with the guiding means or the locking means by the rotational movement of the actuation means in one direction with respect to the housing, thereby driving the guiding means and the locking means into engagement.

Further, the medication delivery device is preferably designed such that the locking means disengages from the guiding means under the force of a biasing means when the medication receptacle is disengaged from the distal end of the housing. The biasing means is preferably a spring which forces the guiding means and the locking means apart when the medication receptacle is separated from the housing of the medication delivery device. Most preferably the biasing means moves the locking means axially away from the guiding means when the medication receptacle is disengaged from the distal end of the housing, thereby disengaging the locking means and the guiding means.

Additionally or alternatively, the medication delivery device can be designed such that when the medication receptacle is disengaged from the housing, the locking means is disengaged from the guiding means, whereby the guiding means is free to rotate with respect to the housing. When the locking means and the guiding means are disengaged in this embodiment, the guiding means is no longer in the guiding position. According to a preferred embodiment of the present invention the piston rod is free to move proximally when the locking means is disengaged from the guiding means.

Preferably, the medication receptacle is a cartridge holder which is designed to receive a cartridge filled with medication. The medication receptacle is designed to be engaged with a distal end of the housing. Alternatively the medication receptacle can e.g. be a cartridge having first engagement means for engaging second engagement means of the housing.

According to a preferred embodiment of the present invention the medication receptacle or an insert of the medication receptacle comprises the first engagement

means and the housing or an insert of the housing comprises the second engagement means.

The first engagement means can e.g. be a thread of the medication receptacle (preferably an external thread) and the second engagement means an engaging element of the housing or of an insert of the housing for engagement with the thread of the medication receptacle, wherein the distal end of the thread of the medication receptacle merges into an annular groove such that the medication receptacle is engaged with the housing by first rotating and moving proximally with respect to the housing and then only rotating with respect to the housing. The pure rotation at the end of the engaging movement is caused by the engaging element moving along the annular groove which does not have a pitch (i.e. the lead of which is zero). Preferably the annular groove is only a part annular groove which runs around a part (e.g. 1/6) of the perimeter of an essentially tubular end of the medication receptacle.

Alternatively, the distal end of the housing can e.g. be provided with an insert comprising the second engagement means and designed to engage with the first engagement means at the proximal end of the medication receptacle, the insert being secured against rotation but being free to move axially with respect to the housing (limited axial movement), wherein distal axial movement of the insert is limited by a retaining means. Particularly, the insert of the housing can comprise an inner thread as a second engagement means for engaging a first engagement means which is an outer thread at the proximal end of the medication receptacle, the medication receptacle comprising the actuation means and being rotated and moved axially with respect to the insert and the housing in a first step for engaging the medication receptacle with the housing and the medication receptacle being rotated while axial movement of the medication receptacle is prevented with respect to the housing in a second step for engaging the medication receptacle with the housing, the insert being moved in the distal direction by the rotation of the medication receptacle during the second step. The insert can be moved in the distal direction e.g. until the insert abuts the retaining means or until the inner thread of the insert ends.

According to a preferred embodiment of the present invention the insert is a movable sleeve with an internal thread and the retaining member is a retaining ring which limits the distal axial movement of the sleeve. The retaining ring is attached to the distal end of the housing such that it is prevented from rotation and from axial movement with respect to the housing. Furthermore, a spring member is provided to move the sleeve against a proximal axial stop means (e.g. an annular rib) within the housing when the medication receptacle is not engaged with the housing of the device. The spring member preferably abuts the proximal side of the retaining ring on one side and the distal side of the moveable sleeve on the other side. The sleeve is engaged with the housing such that it is allowed to move linearly and restrained from rotation. When the housing and the medication receptacle are moved into engagement, an external thread on the proximal end of the medication receptacle engages the internal thread of the sleeve. Therefore the medication receptacle is screwed into distal end of the housing, until the proximal edge or shoulder of the medication receptacle abuts the distal side of the retaining ring. This abutment prevents a further linear proximal movement of the medication receptacle. However, a further rotation of the medication receptacle is allowed, thereby causing the sleeve to move linearly in the distal direction against the force of the spring means until the sleeve abuts the proximal side of the retaining ring. This abutment ends the engaging movement of the housing and the medication receptacle. The pure rotation of the medication receptacle at the end of the engaging movement is used to bring a guiding means into its guiding position in which it guides the piston rod for medication delivery.

According to a preferred embodiment of the present invention the medication receptacle (or an insert of the medication receptacle) and the housing (or an insert of the housing) can additionally be provided with snap-in features by means of which the medication receptacle and the housing are held in engagement during normal use of the medication delivery device, especially during medication delivery. Furthermore the snap-in features can provide an audible and/or tactile feedback to the user, when the medication receptacle is safely attached to the housing.

The medication delivery device can be a pen-type device and/or an injector-type device. The medication delivery device can comprise a needle or be a needle-free device.

The term "medication delivery device" according to embodiments of the present invention shall mean a single-dose or multi-dose, disposable or re-useable device designed to dispense a dose of a medicinal product, preferably multiple selected doses, e.g. of insulin, growth hormones, low molecular weight heparins, and their analogues and/or derivatives etc. Said device may be of any shape, e.g. compact or pen-type. Dose delivery may be provided through a mechanical (optionally manual) dosing mechanism or electrical dosing mechanism or electro-mechanical dosing mechanism or stored energy dosing mechanism, such as a spring, etc. Dose selection may be provided through a manual mechanism or electronic mechanism or electro-mechanical mechanism. Additionally, said device may contain components designed to monitor physiological properties such as blood glucose levels, etc. Furthermore, the said device may comprise a needle or may be needle-free. Preferably, the term "medication delivery device" shall mean a re-useable multi-dose pen-type device having mechanical and manual dose selection and dose delivery mechanisms, which is designed for regular use by persons without formal medical training such as patients. Preferably, the medication delivery device is of the injector-type.

The term "medication receptacle" in the context of embodiments of the present invention shall preferably mean a cartridge containing a medication or a cartridge assembly, most preferably a cartridge holder for receiving a cartridge containing a medication. Furthermore, the terms "medication receptacle" and "cartridge" and "cartridge assembly" are exchangeable in the context of embodiments of the present invention. This means that by using the term "medication receptacle", any meaning of the terms "cartridge" or "cartridge assembly" is included, and vice versa.

The term "cartridge holder" according to embodiments of the present invention shall mean any component and/or components designed to house a medicament cartridge containing a medication to be delivered by the medication delivery device. Said cartridge holder

may be of any shape, e.g. cylindrical and/or tubular. In general, the cartridge holder may be unitary or a multipart component of a cylindrical tubular or non-tubular shape. It may be made of any suitable material known by a person skilled in the art, e.g. of a transparent material. Further the cartridge holder or an insert of the cartridge holder is preferably provided with engagement means, e.g. helical threads or part threads or bayonet or the like, on an external and/or internal surface of the distal end and/or proximal end of the cartridge holder or the insert designed for engagement with corresponding engagement means located on an exterior and/or interior surface of a housing, an insert of the housing and/or a needle assembly. In a preferred embodiment the cartridge holder is of a unitary tubular design having an external thread located at its proximal end.

The term "housing" according to embodiments of the present invention shall preferably mean any exterior housing ("housing", "body", "shell") or interior housing ("insert", "inner body") having an engaging means, such as a helical thread, spline or any other suitable means known by a person skilled in the art. The housing may be designed to enable the safe, correct, and comfortable handling of the medication delivery device or any of its mechanisms. Usually, it is designed to engage with any of the inner components of the medication delivery device (e.g., the dosing mechanism, cartridge, plunger, piston rod), to house, fix, guide, and/or protect by limiting the exposure to contaminants, such as liquid, dust, dirt etc. In general, the housing may be unitary or a multipart component of tubular or non-tubular shape. The exterior housing may also serve to house a cartridge from which a number of doses of a medicinal product may be dispensed.

The term "guiding means" according to embodiments of the present invention shall preferably mean any component designed to guide the piston rod of the medication delivery device when the guiding means is in the guiding position. For this guiding function of the guiding means it preferably comprises a shape for interacting with a corresponding shape of the piston rod, e.g. an inner thread for engaging an outer thread of the piston rod or a non circular opening for holding a piston rod with a corresponding non-circular form or a piston rod with a section having the corresponding non-circular form.

The term "guiding position" according to embodiments of the present invention shall preferably mean a position or state of the guiding means in which the guiding means guides the piston rod and directly or indirectly prevents a movement of the piston rod in the proximal direction. The guiding means is preferably in the guiding position when the medication delivery device is used for dose setting and medication delivery. The guiding means can take up another position or state which is not the guiding position in which a resetting of the medication delivery device by proximal movement of the piston rod is allowed.

The term "nut means" according to embodiments of the present invention shall preferably mean any component designed to be threadedly engaged with a piston rod, preferably to act as a guide for the piston rod. Further, the term "nut means" according to embodiments of the present invention shall mean any component with a threaded circular opening that may be a single or multiple part component. According to a preferred embodiment of the present invention, the guiding means is a nut means. In a further more specific embodiment the nut means is free to rotate with respect to the housing when not engaged with a locking means of the medication delivery device. According to one embodiment of the present invention, the nut means is free to rotate with respect to the housing and is secured against linear axial movement with respect to the housing when not engaged with a locking means of the medication delivery device, but is secured against rotation and linear axial movement with respect to the housing when engaged with the locking means. Most preferably, the nut means is free to rotate and retained for limited linear axial movement with respect to the housing when not engaged with a locking means of the medication delivery device, but is secured against rotation and linear axial movement with respect to the housing when engaged with the locking means. In an even more specific embodiment the nut means has a textured surface, for example a set of face teeth (saw teeth, dog teeth, crown teeth, or the like) or any other suitable frictional face, preferably to engage a textured surface of another component of the device, most preferably of a locking means.

The term "locking means" according to embodiments of the present invention shall preferably mean any component that is engaged with the housing or with an insert of the housing such that

it is prevented from rotational movement with respect to the housing, most preferably such that it is allowed to move longitudinally but is prevented from rotational movement with respect to the housing. In a preferred embodiment the locking means has a textured surface, for example a set of face teeth (saw teeth, dog teeth, crown teeth, or the like) or any other suitable frictional face. In a more preferred embodiment a non-rotatable locking means is designed to engage with the guiding means, thereby preventing rotation of the guiding means with respect to the housing. In a more specific preferred embodiment of instant invention, a textured surface of the non-rotatable locking means engages with a textured surface of a guiding means (preferably a nut means) in a guiding position to prevent the guiding means from rotating as long as a medication receptacle (preferably a cartridge holder) is engaged with the housing.

The term "actuation means" according to embodiments of the present invention shall preferably mean any component of the medication delivery device and/or part of a component of the medication delivery device designed to move any other component(s) of the medication delivery device into and/or out of engagement with another component of the medication delivery device and/or components of the medication delivery device and/or to maintain any component(s) of the medication delivery device in engagement. Preferably the actuation means is a means to actuate a locking means in order to move the locking means into engagement with the guiding means. In a preferred embodiment of instant invention, the actuation means shall form an integral part of the proximal end of the medication receptacle, e.g. the cartridge holder of the medication delivery device.

The term "stop means" according to embodiments of the present invention shall mean any feature(s) and/or component(s) of the medication delivery device designed to prevent axial and/or rotational movement of any component and/or components at least in one direction. In a preferred embodiment of instant invention, the term "stop means" shall mean any feature perpendicular to the distal-proximal axis of the medication delivery device (particularly any planar surface feature perpendicular to the distal-proximal axis of the medication delivery device) designed to prevent axial movement of a component in one direction when this component abuts the perpendicular feature. According to

another preferred embodiment of the present invention the term "stop means" shall mean any feature which provides a radial or rotational stop designed to prevent rotational movement of a component in one rotational direction when an abutment element of the component abuts the radial or rotational stop feature.

In still a further preferred embodiment of instant invention, the term "stop means" shall mean a component ("end stop") of the dosing mechanism which prevents the setting of a dose which exceeds the amount of medication left in the medication receptacle. Preferably the end stop is a component which is secured against rotation but allowed to move axially with respect to a housing and which shall prevent at least one component of the dosing mechanism from rotational and/or axial movement when a final dose has been delivered, thereby preventing the setting of a dose which exceeds the amount of medication left in the cartridge. Furthermore, the "end stop" shall preferably have a helical thread on an exterior surface designed to engage with an interior helical thread of a dose dial sleeve of the dosing mechanism or of an insert of a dose dial sleeve of the dosing mechanism. Preferably the lead of an external helical thread of the said dose dial sleeve for threaded engagement with the housing shall be greater than the lead of the internal helical thread of the dose dial sleeve for threaded engagement of the said end stop.

The term "engaging" according to embodiments of the present invention shall mean the interlocking of two or more components of the dosing mechanism/medication delivery device, by means of e.g. a spline, thread, or meshed teeth connection, preferably the interlocking of threads of components ("threadedly engaged").

The term "engagement means" according to embodiments of the present invention shall preferably mean any means known to those skilled in the art which can be used to engage two or more components of a medication delivery device, e.g. full or part threads, grooves, engaging elements which mesh with threads and/or grooves or the means which form a bayonet lock.

The term "disengaging" according to embodiments of the present invention shall mean the unlocking of two or more components of the dosing mechanism/medication delivery device. According to one example the term "disengaging" according to embodiments of the present invention shall mean the unlocking of two or more components of the dosing mechanism/medication delivery device under the force of a biasing means. Two components can also be disengaged by the force of a user of the device, e.g. by a patient unscrewing the medication receptacle from the housing.

The term "biasing means" according to embodiments of the present invention shall preferably mean any component that is provided for exerting a force on a component and/or components to ensure that the component and/or components are forced together (e.g. into engagement) or forced apart (e.g. out of engagement). Preferably the biasing means may be manufactured from any suitable flexible energy storage material known by a person skilled in the art (e.g. metal, rubber or plastics) and may take any suitable form, e.g., a spring. In a more preferred embodiment the biasing means is a spring component e.g. located between the guiding means and the locking means. In another preferred embodiment the biasing means is a spring component located between a nut means and a locking means and located in the housing.

The term "distal end" according to embodiments of the present invention shall mean the end of the device or a component of the device which is closest to the dispensing end of the device. Preferably a needle assembly is provided at the distal end of the medication delivery device of the present invention the needle of which can be inserted into the skin of a patient for medication delivery.

The term "proximal end" according to embodiments of the present invention shall mean the end of the device or a component of the device which is furthest away from the dispensing end of the device. Preferably a button is provided at the proximal end of the medication delivery device of embodiments of the present invention which is pushed for dose delivery.

The term "dosing mechanism" according to embodiments of the present invention shall mean any component and/or components and/or assembly designed to allow a user to select

and/or set a dose to be dispensed and/or to provide and/or to transmit a force necessary to dispense a dose of a medication. Said dosing mechanism may be composed of mechanical and/or electro-mechanical and/or electronic components. Additionally, the dosing mechanism may be housed by and/or engaged with the device housing or may be an independent assembly. The dosing mechanism of embodiments of the present invention comprises a piston rod and a drive device for moving the piston rod in the distal direction for medication delivery. Preferably, the dosing mechanism of embodiments of the present invention comprises a drive sleeve and a dose dial sleeve. More preferably, the dosing mechanism of embodiments of the present invention comprises a drive sleeve, a dose dial sleeve, a clutch means, a dose dial grip and a button means.

The term "piston rod" according to embodiments of the present invention shall mean a component adapted to operate through/within the housing, designed to translate axial movement (preferably towards the distal end) through/within the medication delivery device, preferably from a drive sleeve to the piston of the cartridge, for the purpose of discharging/dispensing a medication from the cartridge, preferably an injectable product. Said piston rod may be flexible or not. It may be a simple rod, a lead-screw, a part of a rack and pinion system, a part of a worm gear system, or the like. The "piston rod" shall further mean a component having a circular or non-circular cross-section. It may be made of any suitable material known by a person skilled in the art.

In a preferred embodiment, the piston rod comprises at least one, more preferably two, external and/or internal helical threads (threaded sections). In another preferred embodiment of the piston rod according to instant invention, a first helical thread (first threaded section) is located at a distal end and a second helical thread (second threaded section) is located at a proximal end of the said piston rod, whereby the said threads of the threaded sections may have the same or, preferably, opposite dispositions. In another preferred embodiment the piston rod of instant invention comprises at least two threaded sections with threads having the same leads and the same pitches at the distal and the proximal end. In yet another preferred embodiment of instant invention the lead and the pitch of the second helical thread of the piston rod shall be greater than the lead and the pitch of the first helical thread. More preferred,

the ratio of the leads of the helical threads of the said first and the second helical threads is in the range of 1:1,01 to 1:20, even more preferred in the range of 1:1,1 to 1:10, most preferred 1:2,3. Preferably, one of the said threads (thread of the second threaded section) is designed to engage with the drive sleeve. Preferably another of the said threads (thread of the first threaded section) is designed to engage with the guiding means, more preferably with a nut means. According to a most preferred embodiment of the present invention, a first external threaded section of the piston rod with a thread having a smaller lead is designed to engage with an internal thread of a nut means and a second external threaded section of the piston rod with a thread having a larger lead is designed to engage with an internal thread of a drive sleeve. In a further preferred embodiment of instant invention, the piston rod is provided with a stop means designed to limit the proximal axial movement of an end stop. The stop means may e.g. be the start of one of the external threads of the piston rod.

The term "dose dial sleeve" according to embodiments of the present invention shall preferably mean a component of the medication delivery device which is directly or indirectly used to select/dial a dose of medication to be delivered. Additionally or alternatively the dose dial sleeve is designed to indicate a selected dose of a dispensable product (medication). This may be achieved by use of markings, symbols, numerals, etc., e.g. printed on the external surface of a sleeve or an odometer, or the like. In a preferred embodiment of the present invention, the dose dial sleeve is an essentially tubular component of essentially circular cross-section having either:

- both an internal and external thread, or
- an internal thread, or
- an external thread.

Preferably, the dose dial sleeve comprises an external thread for engaging an internal thread of the housing or of an insert of the housing. Preferably, the dose dial sleeve according to embodiments of the present invention comprises an external helical thread having a lead, which is similar to, preferably the same as the lead of an internal helical thread of the drive sleeve. In a more specific embodiment of instant invention, the dose dial sleeve is provided with a plurality of radially extending members adapted to abut a corresponding plurality of radial stops provided within the housing or an insert of the

housing. These radial stop means are preferably provided for stopping a further winding of the dose dial sleeve out of the housing when a dose is set and/or for stopping the further winding of the dose dial sleeve into the housing when a dose has been dispensed.

The term "drive device" according to embodiments of the present invention shall preferably mean any component and/or components and/or assembly designed to transmit a force to the piston rod for dispensing a dose of a medication. Said drive device may be composed of mechanical and/or electro-mechanical and/or electronic components. The drive device may be housed by and/or engaged with the housing or may be an independent assembly. Preferably, the drive device of embodiments of the present invention comprises a drive sleeve. More preferably, the drive device of embodiments of the present invention comprises a drive sleeve, a clutch means and a button means.

The term "drive sleeve" according to embodiments of the present invention shall preferably mean any component for directly or indirectly driving the piston rod in a distal direction for medication delivery, most preferably for driving the piston rod directly. According to a preferred embodiment of the present invention, the drive sleeve is an essentially tubular component of essentially circular cross-section. In a preferred embodiment the drive sleeve is engaged with the piston rod. Preferably the drive sleeve comprises an internal thread for engaging an external thread of the piston rod. The drive sleeve is further preferably releasably coupled to the dose dial sleeve, most preferably by a clutch means.

The term "thread" or "helical thread" according to embodiments of the present invention shall preferably mean a full or part thread, e.g., a cylindrical spiral rib/groove, located on the internal and/or external surface of a component of the medication delivery device, having an essentially triangular or square or rounded section designed to allow continuous free rotational and axial movement between components. Optionally, a thread may be further designed to prevent rotational or axial movement of certain components in one direction by being non-overhaulable.

The term "lead" according to embodiments of the present invention shall preferably mean the axial distance a nut would advance in one complete revolution; preferably "lead" shall mean the axial distance through which a component having a helical thread, i.e. dose dial sleeve, drive sleeve, piston rod, etc., of the dosing mechanism travels during one rotation. Therefore the lead is a function of the pitch of the thread of the relevant component.

The term "pitch" according to embodiments of the present invention shall preferably mean the distance between consecutive contours on a helical thread, measured parallel to the axis of the helical thread.

One embodiment of the present invention provides a medication delivery device according to instant invention for dispensing a medicinal product preferably for dispensing a pharmaceutical formulation (e.g. solution, suspension etc.) comprising an active compound selected from the group consisting of insulin, growth hormone, low molecular weight heparin, their analogues and their derivatives.

Embodiments of the present invention further refer to a method of manufacturing or assembling a medication delivery device according to one of the above-mentioned embodiments. This method preferably comprises the step of moving a medication receptacle into engagement with the distal end of the housing of the device by engaging first engagement means with second engagement means. The first engagement means and the second engagement means are engaged by a movement of the medication receptacle which ends in a rotational movement without axial movement of the medication receptacle with respect to the housing. This rotational movement without axial movement of the medication receptacle with respect to the housing causes an actuation means of the medication receptacle to bring a guiding means in a guiding position in which the guiding means guides the piston rod of the medication delivery device for medication delivery.

According to embodiments of the present invention, the use of a medication delivery device according to one of the above-mentioned embodiments of a medication delivery device for dispensing a medicinal product is also provided. The use preferably comprises the dispensing of a

pharmaceutical formulation (e.g. a liquid medication like a solution, a suspension etc.) comprising an active compound selected from the group consisting of insulin, growth hormone, low molecular weight heparin, their analogues, and their derivatives.

Without any limitation, the instant invention will be explained in greater detail below with reference to the drawings in which:

- figures 1a to 1c show a cross-sectional view of an embodiment of a medication delivery device according to the invention in three different states;
- figures 2a to 2c show schematically an embodiment of the actuation means interacting with locking means in three different states according to one embodiment of the present invention;
- figure 3 shows a cross-sectional enlarged view of a middle part of the embodiment according to figures 1a to 1c showing the actuation means and the guiding means of the medication delivery device,
- figure 4 shows schematically a different embodiment of the medication delivery device according to the present invention with a different arrangement of actuation means, locking means and guiding means and
- figure 5 shows another embodiment of a medication delivery device according to the invention.

Referring first to Figures 1a to 1c, there is shown a medication delivery device in accordance with the present invention in three different positions.

The medication delivery device 1 comprises a cartridge holder 2 and a (exterior) housing 3. Preferably the housing 3 is lacquered. The distal end of the housing 3 is provided with an insert 3A which is immovably attached to the housing. The insert 3A is provided with second engagement means 4 for engaging first engagement means 5

of the cartridge holder 2. In the illustrated embodiment the insert 3A of the housing 3 is provided with a series of part threads formed on an interior surface of the insert 3A. The proximal end of the cartridge holder 2 is provided with first engagement means 5 for engaging the second engagement means 4 of the insert 3A. In the illustrated embodiment the cartridge holder 2 is provided with a thread, the distal end of which merges into a (part) annular groove (not shown) formed on an exterior surface of the cartridge holder 2. The cartridge holder 2 is secured within the distal end of the housing 3 by the engagement of the second engagement means 4 of the insert 3A of the housing 3 with the first engagement means 5 of the cartridge holder 2. In the shown preferred embodiment of present invention, the proximal end of the cartridge holder 2 is further provided with an actuation means 70 designed to activate and lock a guiding means (nut means 11) in a guiding position (described below and shown in figure 3).

A cartridge 6 from which a number of doses of a medicinal product may be dispensed is provided in the cartridge holder 2. A piston 7 is retained in the cartridge 6.

A removable cap (not shown) can be releasably retained over the distal end of the cartridge holder 2. Preferably the cap comprises a clip which is snapped onto the cap.

The distal end of the cartridge holder 2 is provided with suitable engaging means 8, such as a helical thread, bayonet or the like, for engagement with a suitable needle assembly (not shown) to enable medicament to be dispensed from the cartridge 6 and injected.

The medication delivery device 1 according to figures 1a to 1c comprises a dosing mechanism which includes a piston rod 17. The piston rod 17 is of generally circular cross-section. A pressure foot 18 is located at the distal end of the piston rod 17. The pressure foot 18 is preferably made of two separate parts which are snapped together around a distal end portion of the piston rod 17. The pressure foot 18 is disposed to abut the proximal face of the piston 7. The piston rod 17 is moveable in a distal direction by means of a drive device, thereby pushing the piston 7 to move axially

within the cartridge 6 in the distal direction for medication delivery. A first thread 15 is formed at the distal end of the piston rod 17. A second thread 16 is formed at the proximal end of the piston rod 17. The first thread 15 and the second thread 16 are oppositely disposed. Preferably at least one of the first and second threads 15, 16 is a multi-start thread, most preferably both are two-start threads.

The drive device comprises a drive sleeve 19 which extends about the piston rod 17. The drive sleeve 19 is generally cylindrical. The drive sleeve 19 is provided at a distal end with a radially extending flange 20. A helical groove (thread) 21 extends along the internal surface of the drive sleeve 19. The second thread 16 of the piston rod 17 is adapted to work within the helical groove 21 of the drive sleeve 19.

A shoulder 22A and an extension 22B are formed at the proximal end of the drive sleeve 19. The extension 22B has reduced inner and outer diameters in comparison to the remainder of the drive sleeve 19. A proximal end of the extension 22B is provided with a radially outwardly directed flange 23.

A clutch 24 is disposed about the drive sleeve 19, between the drive sleeve 19 and an end stop 28 (described below). The clutch 24 is located adjacent the proximal end of the drive sleeve 19. The clutch 24 is generally cylindrical and is provided at the distal end with a series of circumferentially directed saw teeth 29. Each saw tooth comprises a longitudinally directed surface and an inclined surface. Towards the proximal end of the clutch 24 there is located a radially inwardly directed flange 30. The flange 30 of the clutch 24 is disposed between the shoulder 22A of the drive sleeve 19 and the radially outwardly directed flange 23 of the extension 22B. The proximal end of the clutch 24 is provided with a plurality of saw teeth 31. The clutch 24 is keyed to the drive sleeve 19 by way of splines (not shown) to prevent rotation between the clutch 24 and the drive sleeve 19. The clutch 24 is provided with a plurality of flexible arms 32 (not shown) that engage a plurality of splines on an interior surface of a dose dial sleeve 27 (described below).

A clutch plate 25 and a biasing means 26 are located between the distal end of the clutch 24 and the proximal face of the radially extending flange 20 of the drive sleeve 19. In the illustrated embodiment, the biasing means 26 is a spring. The proximal face of the clutch plate 25 is provided with a series of circumferentially directed saw teeth 33. The clutch plate 25 is secured against rotation with respect to the housing 3. The saw teeth 33 of the clutch plate 25 interact with the saw teeth 29 at the distal end of the clutch 24 during dose setting (described below).

An end stop 28 is disposed about the drive sleeve 19, between the drive sleeve 19 and the dose dial sleeve 27. The end stop 28 is secured against rotation with respect to the housing 3 and is free to move axially with respect to the housing 3. At the distal end of the end stop 28 a radially extending flange 34 is provided designed to engage with spline features (not shown) on an interior surface of the housing 3. In the illustrated embodiment, the external surface of the end stop 28 is provided with a helical groove (thread) that extends the full length of the end stop 28. The helical groove (thread) is engaged with a threaded insert 53 of the dose dial sleeve 27. An interior surface of the end stop 28 is provided with a number of spline features (not shown). The clutch plate 25 is engaged with these spline features and thereby secured against rotation with respect to the housing 3

A dose dial sleeve 27 is provided between the clutch 24 and the housing 3. A helical groove (thread) 41 is provided about an outer surface of the dose dial sleeve 27. The housing 3 is provided with a helical rib (thread) 42, adapted to be seated in the helical groove (thread) 41 of the dose dial sleeve 27. In the illustrated embodiment, the helical rib (thread) 42 is formed on an interior surface of an insert 43. The threaded insert 43 is secured against rotation and axial movement with respect to the housing 3.The helical rib 42 extends for a single sweep of the inner surface of the insert 43. A proximal end of the dose dial sleeve 27 is provided with an inwardly directed flange in the form of a number of radially extending members 45.

The housing 3 is further provided with a window 40 (not shown) through which a part of the outer surface of the dose dial sleeve 27 may be seen. A visual indication of the

dose that may be dialed is provided on the outer surface of the dose dial sleeve 27. The window 40 conveniently only allows a visual indication of the dose currently dialed to be viewed. The window can be designed such that it allows an enlarged visual indication of the dose currently dialled to be viewed by acting as a magnifying lens. Preferably the window 40 is filled with a transparent polymer. Most preferably the window 40 is part of an insert of the housing 3 which is made by two component injection moulding, wherein a section with a dark polymer surrounds a section with a transparent polymer. The insert is immovably fixed to the housing.

The threaded insert 43 of the housing 3 is provided with a series of radial stop features 55, 56 (not shown). A distal end of the dose dial sleeve 27 is provided with a plurality of stop features 44 (not shown) which abut the stop features 56 of the insert 43 to prevent the dose dial sleeve 27 from being wound out of the housing 3 any further when a maximum dose has been set.

A dose dial grip 46 is disposed about an outer surface of the proximal end of the dose dial sleeve 27. An outer diameter of the dose dial grip 46 preferably corresponds to the outer diameter of the housing 3. The dose dial grip 46 is secured to the dose dial sleeve 27 to prevent movement therebetween. The dose dial grip 46 is provided with central opening 47. An annular recess 48, located in the proximal end of the dose dial grip 46, extends around the opening 47.

A button 49 is provided at the proximal end of the medication delivery device 1. In the illustrated embodiment of instant invention, the button 49 is of generally 'T' section, with a stem 50. The button 49 is free to rotate with respect to the housing 3. Preferably the button 49 contains a washer (not shown) made of a friction reducing material (e.g. a friction modified polymer material) in order to reduce the friction between the button and dose dial grip 46 during dose delivery. The stem 50 of the button 49 extends through the central opening 47 in the dose dial grip 46 and through the inner diameter of the extension 22B of the drive sleeve 19. The stem 50 of the button 49 is retained for limited axial movement in the drive sleeve 19 and the clutch 24. In the illustrated embodiment, a head 51 of the button 49 is generally circular. A skirt 52 depends from

a periphery of the head 51. The skirt 52 is adapted to be seated in the annular recess 48 of the dose dial grip 46.

An internal surface at the distal end of the dose dial sleeve 27 is provided with a helical thread (not shown). In the illustrated embodiment, the helical thread of the dose dial sleeve 27 is provided on an internal surface of the threaded insert 53. The insert 53 is retained within the dose dial sleeve 27 by means of an end cap 54 secured to the distal end of the dose dial sleeve 27. The end cap 54 is secured against both rotational and axial movement with respect to the dose dial sleeve 27. The helical groove (thread) of the end stop 28 is engaged with the threaded insert 53 of the dose dial sleeve 27.

The medication delivery device 1 further comprises nut means 11 which is a guiding means and which has a series of face teeth 12 on a distal surface and a threaded circular opening 13. The first thread 15 of the piston rod 17 extends through and is threadedly engaged with the threaded circular opening 13 of the nut means 11. The nut means 11 is prevented from axial movement in the distal and/or proximal direction with respect to the housing 3, e.g. in the proximal direction by means of a web 57 within the housing 3. The web 57 can be a separate component or can be formed as part of the housing 3. In the devices shown in figures 1a to 1c the nut means 11 is in a guiding position in which the nut means 11 is prevented from rotation with respect to the housing 3 by means of a locking means 9 and therefore guides the piston rod 17 during dose delivery.

In the illustrated embodiment, the medication delivery device 1 is further provided with a locking means 9. The locking means 9 is secured against rotational movement with respect to the housing 3, but the locking means 9 is free for limited axial movement with respect to the housing 3 when the housing 3 is engaged with or disengaged from the cartridge holder 2. The locking means 9 is provided on a proximal surface with a series of face teeth 10 for engaging the face teeth 12 of the nut means 11. A biasing means 14, in the form of a spring, is provided between the proximal face of the locking means 9 and a web 57 within the housing.

In the shown embodiments according to figures 1a to 1c the cartridge holder 2 (medication receptacle) comprises actuation means 70 with ramps 71, the inclined surfaces of the ramps 71 interacting with inclined surfaces 72 of the locking means 9 when the cartridge holder 2 is being connected with the housing 3 (described later with respect to figures 2a to 2c and 3). By this interaction the locking means 9 is moved into engagement with the nut means 11. The actuation means 70 thereby brings the nut means 11 in the guiding position. This interaction will be described in detail below.

Operation of the medication delivery device 1 in accordance with the present invention will now be described.

To dial a dose a user rotates the dose dial grip 46, thereby rotating the dose dial sleeve 27. During dose dialling the clutch 24 is engaged with the dose dial sleeve 27 via the saw teeth 31 at the proximal end of the clutch 24. As the clutch 24 is engaged with the rotating dose dial sleeve 27, the clutch 24 and the drive sleeve 19 rotate with the dose dial sleeve 27 because of the splined engagement of the clutch 24 and the drive sleeve 19.

Audible and tactile feedback of the dose being dialled is provided by the clutch plate 25 and the clutch 24. This feedback is provided by the saw teeth 29 of the clutch 24 gliding over the saw teeth 33 of the clutch plate 25 during the rotational movement of the clutch 24 with respect to the housing 3. During dose dialling, the clutch plate 25 is pushed axially towards the proximal end of the device by the biasing means 26, thus ensuring that the saw teeth 29 and 33 of clutch plate 25 and clutch 24 maintain contact. As the clutch plate 25 is secured against rotation by spline features on the interior surface of the end stop 28, which is secured against rotation with respect to the housing, the clutch 24 rotates relative to the clutch plate 25 during dose setting. Due to the profile of the saw teeth 29 and 33, preferably triangular, the saw teeth 29 of the clutch 24 are able to glide over the saw teeth 33 of the clutch plate 25 as the clutch 24 rotates. Preferably, the ratio of the angular spacing of the saw teeth 29 of the clutch 24

and the saw teeth 33 of the clutch plate 25 is such that each tooth pitch corresponds to a conventional unit dose, or the like.

The dose dial sleeve 27 is wound out of the housing 3 (rotational movement and axial movement in the proximal direction) when a larger dose is set because of its engagement with (insert 43 of) the housing 3 via the threads 41, 42. The helical groove 41 of the dose dial sleeve 27 and the internal thread 21 of the drive sleeve 19 have the same lead. This allows the dose dial sleeve 27 to extend from the housing 3 and the drive sleeve 19 to climb along the second thread 16 of the piston rod 17 at the same rate.

At the limit of travel, a radial stop (not shown) on the dose dial sleeve 27 engages with a stop feature 56 provided on the insert 43 of the housing 3 to prevent further movement. During dose setting rotation of the piston rod 17 is prevented due to the opposing directions of the first and second threads 15, 16 on the piston rod 17, the first thread 15 being engaged with the nut means 11 and the second thread 16 being engaged with the drive sleeve 19.

The end stop 28 which is prevented from rotating with respect to the housing 3, preferably by means of spline features (not shown), moves axially towards the proximal end of the housing 3 when the dose dial sleeve 27 rotates and moves in the proximal direction during dose setting. When a dose is set that can maximally be dispensed from the cartridge 6, the radially extending flange 34 abuts a radial stop means 60 formed on the piston rod 17, preventing the end stop 28 from further proximal axial movement and both the dose dial sleeve 27 and the drive sleeve 19 from rotating further in the direction for setting a larger dose.

Should a user inadvertently dial beyond the desired dosage, the medication delivery device allows the dosage to be dialed down without dispense of medicinal product from the cartridge 6. The dose dial grip 46 is counter rotated for this purpose. This causes the system to act in reverse. The reverse rotation of the clutch 24 causes the saw teeth 29 and 33 of the clutch 24 and the clutch plate 25 to ride over one another to

create the clicks corresponding to dialled dose reduction. Preferably the saw teeth 29 and 33 are so disposed that the circumferential extent of each saw tooth corresponds to a unit dose.

Figure 1a shows the medication delivery device in a state before a first dose has been set. Figure 1b shows the medication delivery device 1 according to figure 1a in a state in which a dose has been set. The dose dial sleeve 27 is extending proximally from the housing 3.

When the desired dose has been dialled, the user may then dispense this dose by depressing the button 49. This displaces the clutch 24 axially towards the distal end of the device with respect to the dose dial sleeve 27, thereby decoupling the clutch 24 from the dose dial sleeve 27. However, the clutch 24 remains keyed in rotation to the drive sleeve 19. Therefore the decoupling of the clutch 24 results in a decoupling of the dose dial sleeve 27 and the drive sleeve 19 The dose dial sleeve 27 and associated dose dial grip 46 are free to rotate, guided by the helical rib 42 of the insert 43 located in the helical groove 41 of the dose dial sleeve 27. During dose delivery the dose dial sleeve 27 is wound back into the housing 3 in the distal direction.

The pressure of the user on the button 49 further results in an axial movement of the clutch 24 in the distal direction without rotation with respect to the housing 3. The axial movement of the clutch 24 moves the clutch plate 25 distally against the force of the biasing means 26 until the clutch plate 25 abuts a shoulder on the drive sleeve 19 and the clutch 24 and clutch plate 25 are engaged such that relative rotation between the clutch 24 and the clutch plate 25 is prevented, thus preventing rotation of the clutch 24 and the drive sleeve 19 with respect to the housing 3 during dose delivery. As the clutch plate 25 is splined to the end stop 28 to prevent rotation of the clutch plate 25 with respect to the housing 3, the clutch plate 25 and the clutch 24 travel together distally but do not rotate.

The axial movement of the clutch 24 causes the drive sleeve 19 to move axially in the distal direction. The distal longitudinal axial movement of the drive sleeve 19 further

causes (by means of the internal thread 21 of the drive sleeve 19 and the second thread 16 of the piston rod 17) the piston rod 17 to rotate and thus to wind through the opening 13 in the nut means 11, thereby to advance the piston 17 in the cartridge 6.

Once the dialled dose has been dispensed, the dose dial sleeve 27 is prevented from further rotation by a plurality of rotational stop features (not shown) extending from the dose dial grip 46 engaging with stop features 55 located on the insert 43 of the housing 3. In the illustrated embodiment, the rotational stop features extend axially from the dose dial grip 46 and have an inclined end surface. The zero position is determined by the abutment of one of the axially extending edges of the rotational stop features (not shown) with a corresponding stop 55 on the insert 43.

The rotational movement of the dose dial sleeve 27 during dose delivery causes the end stop 28 to move axially in a distal direction back to its initial position within the housing 3.

Figure 1c shows the medication delivery device according to figures 1a and 1b after a dose has been dispensed. The piston rod 17 and the piston 7 in the cartridge 6 have been advanced in the distal direction. The dose dial sleeve 27 and the end stop 28 are in their original position with respect to the housing 3.

When the final dose has been dispensed, the spent cartridge 6 may be removed and disposed of. To remove the cartridge 6, the cartridge holder 2 is disengaged from the housing 3 by disengaging the first and second engagement means 5, 4. Once the cartridge holder 2 is disengaged from the housing 3, the spent cartridge 6 can be removed from the cartridge holder 2 and a new cartridge 6 can be placed in the cartridge holder 2.

Disengagement of the cartridge holder 2 from the housing 3, causes the locking means 9, under the force of the biasing means 14, to disengage from the nut means 11. The nut means 11 is not in the guiding position anymore. This allows the nut means 11 to

rotate freely and therefore the piston rod 6 to be wound back up in the proximal direction.

In order to attach the cartridge holder 2 containing the new cartridge 6 on the housing 3, the piston rod 17 has to be moved axially in the proximal direction. This proximal movement may be caused by the piston 7 of the cartridge 6 abutting the end of the piston rod 17 and being moved proximally with respect to the housing 3 when the cartridge holder 2 with the cartridge 6 is moved towards the housing 3 by the user. Alternatively the user may push the piston rod 17 in the proximal direction by means of a finger and then attach the cartridge holder 2 with cartridge 6 to the housing 3. As the nut means 11 (which is threadedly engaged with the piston rod 17) is free to rotate with respect to the housing 3 the piston rod 17 is free to rotate and translate proximally until the locking means 9 and the nut means 11 engage. The pushing back of the piston rod 17 by means of the piston 7 of the new cartridge 6 which is pushed against the pressure foot 18 of the piston rod 17 has the advantage, that the pressure foot 18 of the piston rod 17 already abuts the piston 7 of the cartridge 6 when the device is reset. Therefore, the priming movement of the piston rod 17 (to remove air from the cartridge 6) can be very small and the loss of medication due to priming thus be kept to a minimum.

The cartridge holder 2 containing the new cartridge 6 is engaged with the housing 3 by moving the first and second engagement means 5, 4 into engagement. As the cartridge holder 2 is moved into engagement with the housing 3, the cartridge holder 2 first rotates and moves axially in a proximal direction, because the second engagement means 4 of the insert 3A of the housing 3 moves along the threaded section of the first engagement means 5 of the cartridge holder 2 until the second engagement means 4 reaches the annular groove section of the first engagement means 5. The further movement of the second engagement means 4 in this annular groove causes the cartridge holder 2 to rotate without moving axially with respect to the housing 3. The first and second engagement means 5, 4 are therefore moveable into engagement by a movement of the cartridge holder 2 which ends in a rotational movement without axial movement of the actuation means 70 with respect to the

housing 3. This further rotation of the cartridge holder 2 (without axial movement) causes the ramps 71 of the actuation means 70 to glide along the inclined surfaces 72 of the locking means 9. The locking means 9 is thereby moved axially in the proximal direction against the force of the biasing means 14 until the face teeth 10 of the locking means 9 are engaged with the face teeth 12 of the nut means 11, thereby bringing the nut means 11 (guiding means) in the guiding position. In this position the nut means 11 is secured against axial movement and against rotation. In this guiding position the piston rod 17 is prevented from rotation in one rotational direction and from axial movement in the proximal direction with respect to the housing 3 but is allowed to rotate in the other rotational direction and move axially in the distal direction with respect to the housing 3 for medication delivery.

The pure rotational movement of the cartridge holder 2 and the actuation means 70 which moves the locking means 9 into engagement with the nut means 11 ends when snap-in features (not shown) of the cartridge holder 2 and the insert 3A of the housing 3 engage. In this position the actuation means 70 holds the nut means 11 in the guiding position.

The rotational movement (without axial movement) of the cartridge holder 2 with respect to the housing 3 which moves the locking means 9 into engagement with the nut means 11 has the advantage of not building up any pressure on the piston 7 of the cartridge 6 before the medication delivery device 1 is used.

Thus the dosing mechanism of the medication delivery device 1 according to the present invention is reset into a zero (or no dose delivered) position as indicated in Figure 1a.

Figures 2a to 2c show schematically an embodiment of an actuation means interacting with locking means in three different states according to one embodiment of the present invention.

Figure 2a shows a locking means 9 and an actuation means 70 before an interaction takes place therebetween. In the shown embodiment the actuation means 70 is e.g. part of a medication receptacle (e.g. a cartridge holder 2) of the medication delivery device. In the shown embodiment the component of the medication delivery device comprising the actuation means 70 further comprises first engagement means 5 for engaging with second engagement means 4 which are preferably part of the housing of the medication delivery device or of an insert of the housing. The first and second engagement means 5, 4 are designed such that for moving the two components which comprise the engagement means 5, 4 (preferably the housing and the medication receptacle) into engagement, the two components are first rotated and moved axially with respect to each other (first step) and then only rotated without being moved axially with respect to each other (second step). The interaction between the actuation means 70 and the locking means 9 only takes place in this second step, when the two components (e.g. the medication receptacle and the housing) and therefore the actuation means 70 and the locking means 9 only rotate with respect to each other. The locking means 9 is preferably not rotatable with respect to the housing of the medication delivery device.

Figure 2a shows the actuation means 70 and the locking means 9 during the first step, when both rotation (arrow 35) and axial movement (arrow 36) therebetween take place. During this step the second engagement means 4 moves along a first section of the first engagement means 5 which is represented by a thread 37. The distal end of the thread 37 merges into a second section of the first engagement means 5 which is represented by a part of annular groove 38. In the schematic drawing this annular groove 38 looks like a straight section because the drawing represents a view onto the outer surface of essentially cylindrical components.

The second engagement means 4 is at least one engaging element which engages with the thread 37 and the annular groove 38. The shown engaging element has the shape of a parallelogram.

In the shown embodiment the locking means 9 and the actuation means 70 have special shapes for interacting. The actuation means comprises ramps 71 with inclined surfaces for interacting with correspondingly inclined surfaces 39 of the locking means 9 which form triangular recesses 58.

In figure 2a the combined axial movement 36 and rotation 35 of the actuation means 70 with respect to the locking means 9 results in the actuation means 70 approaching the locking means 9 until the actuation means 70 abuts the locking means 9 in a position in which the ramps 71 are joined with the triangular recesses 58 of the locking means 9 as shown in figure 2b. In this position the second engagement means 4 has reached the point in which the thread 37 of the first engagement means 5 merges into the annular groove 38 of the first engagement means 5. The combined axial movement 36 and rotation 35 of the actuation means 70 with respect to the locking means 9 (first engagement step) now switches over into a rotation 35 only of the actuation means 70 with respect to the locking means 9 (second engagement step).

During this rotation the inclined surfaces of the ramps 71 and the recesses 58 glide along each other. This interaction of the actuation means 70 and the locking means 9 during the rotational movement without axial movement drives the locking means 9 (which is non-rotatable with respect to the (not shown) housing) axially in the proximal direction (arrow 59) as shown in figure 2c. By this axial movement of the locking means 9 (preferably against the force of a not shown biasing means) the locking means 9 is driven into engagement with a (not shown) guiding means (e.g. a nut means), thereby bringing the guiding means in a guiding position in which it guides the piston rod during medication delivery with the medication delivery device. The engagement of the locking means 9 and the guiding means can be established e.g. by interlocking of face teeth of the locking means 9 and the guiding means.

Figure 3 shows a cross-sectional enlarged view of a middle part of the embodiment according to figures 1a to 1c showing the actuation means, the locking means and the guiding means of the medication delivery device.

The cartridge holder 2 of the medication delivery device is attached to the housing 3 of the medication delivery device by first engagement means 5 being engaged with second engagement means 4 (not shown). The cartridge holder 2 comprises the first engagement means 5 and the insert 3A of the housing 3 comprises the second engagement means 4. A two-part pressure foot 18 is mounted on the distal end of the piston rod 17 and abuts the piston 7 of the medication cartridge 6.

According to this embodiment the cartridge holder 2 comprises actuation means 70 which comprise ramps 71 with inclined surfaces for interacting with correspondingly inclined surfaces 72 of locking means 9. The locking means 9 is engaged with a nut means 11 which is a guiding means in the guiding position for guiding the piston rod 17. The tips of the ramps 71 of the actuation means 70 are pushed against the distal surface of the locking means 9, thereby holding the nut means 11 in the guiding position. Face teeth 10 of the locking means 9 are engaged with face teeth 12 of the nut means 11. By this engagement of the nut means 11 with the locking means 9 rotation of the nut means 11 with respect to the housing 3 is prevented. The nut means 11 is in threaded engagement with the first thread 15 of the piston rod 17. By means of this threaded engagement and of the engagement of the (oppositely disposed) second thread 16 of the piston rod 17 with the (not shown) drive sleeve, movement of the piston rod 17 in the proximal direction is prevented as long as the nut element 11 is in the guiding position. A biasing means 14 is provided to push the nut means 11 and the locking means 9 apart when the cartridge holder 2 is disconnected from the housing 3.

Figure 4 shows schematically a different embodiment of the medication delivery device according to the present invention with a different arrangement of actuation means and guiding means.

The actuation means 70 comprises ramps 71 and the medication receptacle 2 comprises first engagement means 5 with threaded sections 37 and an annular groove 38. The guiding means 11 has inclined surfaces 39 for interaction with the ramps 71 of the actuation means 70. When the inclined surfaces of the ramps 71 and the guiding means 11 abut and glide along one another during rotational movement of the

actuation means 70 with respect to the housing 3 in the second engagement step, the guiding means 11 is pushed against a locking means 9, face teeth 12 of the guiding means 11 thereby engaging with face teeth 10 of the locking means 9. The locking means 9 of this embodiment is not necessarily a separate component. It can also be part of the housing 3.

Figure 5 shows another embodiment of a medication delivery device according to the invention.

The medication delivery device 1 according to figure 5 comprises a cartridge holder 2 and a (exterior) housing 3. The distal end of the housing 3 is provided with an insert 3B designed to engage with the proximal end of the cartridge holder 2. The insert 3B is secured against rotation with respect to the housing 3 but is free to move axially with respect to the housing 3. The extent of axial movement of the insert 3B is limited by a retaining means 63 which is engaged with the housing 3 and secured against both axial and rotational movement with respect to the housing 3.

An inner surface of the insert 3B is provided with second engagement means 4. The second engagement means 4 could be any suitable means known by a person skilled in the art, such as a bayonet, helical thread, or the like. Preferably, the second engagement means 4 is a helical thread and corresponds to the first engagement means 5 at the proximal end of the cartridge holder 2, which is preferably also a helical thread.

In the shown embodiment of present invention, the proximal end of the cartridge holder 2 is further provided with an actuation means (not shown) designed to activate and lock a guiding means (not shown) in a guiding position.

A biasing means 64 is provided between the proximal face of the retaining means 63 and the distal face of the insert 3B. The biasing means 64 may be manufactured from any suitable flexible material known to a person skilled in the art, such as stainless steel, rubber, or the like, and may be in any suitable form, such as a spring, spacer, or

the like. In the illustrated embodiment of instant invention, the biasing means 64 is a wave spring. The biasing means 64 is designed to ensure that the insert 3B does not abut the retaining means 63 when the cartridge holder 2 is not engaged with the housing 3.

The further components of this medication delivery device will not be described in detail, but are preferably similar to the components as described with reference to figures 1a to 1c.

Operation of the drug delivery device in accordance with the present invention will now be described.

The dialling of a dose and the dispensing of a dose can e.g. work in a similar way as described with reference to figures 1a to 1c.

When the final dose dispensed position is reached, the spent cartridge 6 may be removed and disposed of. To remove the cartridge 6, the cartridge holder 2 is disengaged from the housing 3, preferably the cartridge holder 2 is unscrewed from the housing 3, Once the cartridge holder 2 is disengaged from the housing 3, the spent cartridge 6 can be removed from the cartridge holder 2 and a new cartridge 6 can be placed in the cartridge holder 2.

Disengagement of the cartridge holder 2 from the housing 3, causes the (not shown) guiding means of the device to be moved out of its guiding position, e.g. by a locking means under the force of a biasing means disengaging from the guiding means. This for example allows the guiding means to rotate freely and thus the piston rod 17 to be moved in the proximal direction for resetting the device.

With the cartridge holder 2 removed, the insert 3B is free to move axially in a proximal direction away from the distal end of the housing 3 (away from the retaining means 63) for a limited distance by virtue of the force exerted by the biasing means 64.

In order to attach the cartridge holder 2 on the housing 3 the piston rod is moved axially in the proximal direction with respect to the housing 3. This proximal movement is caused by the piston of the new cartridge abutting the end of the piston rod and being moved proximally with respect to the housing 3 when the cartridge holder 2 with the cartridge is moved towards the housing 3. As the guiding means is not yet in the guiding position the piston rod is free to translate proximally until the guiding means is in the guiding position, e.g. until locking means and the guiding means engage. The pushing back of the piston rod by means of the piston of the new cartridge 6 which is pushed against the pressure foot 18 of the piston rod 17 has the advantage, that the pressure foot 18 of the piston rod 17 already abuts the piston 7 of the cartridge 6 when the device is reset. Therefore, the priming movement of the piston rod 17 (to remove air from the cartridge 6) can be very small and the loss of medication due to priming thus be kept to a minimum.

The cartridge holder 2 containing the new cartridge 6 is then engaged with the housing 3, preferably threadedly engaged. As the cartridge holder 2 is moved into engagement with the housing 3, the first engagement means 5 located at the proximal end of the cartridge holder 2 engages with the second engagement means of the insert 3B. The cartridge holder 2 is allowed to rotate and move axially in a proximal direction (first engagement step) until stop means 65 (e.g. an annular outer rim) located on the cartridge holder 2 abuts the retaining means 63 The stop means 65 prevent further axial movement of the cartridge holder 2 but allow the cartridge holder 2 to rotate (second engagement step). As the cartridge holder 2 rotates further, the insert 3B is moved axially, against the force of the biasing means 64, towards the distal end of the housing 3 and therefore towards the retaining means 63.

This pure rotation of the cartridge holder 2 additionally causes the activation means to bring the guiding means into the guiding position (not shown), e.g. by a locking means being moved axially in a proximal direction against the force of a biasing means until the face teeth of the locking means are engaged with face teeth of the guiding means

Thus the drive mechanism is reset into a zero (or no dose delivered) position

The rotational movement (without axial movement) of the cartridge holder 2 which brings the guiding means in the guiding position has the advantage of not building up any pressure on the piston of the cartridge before the medication delivery device 1 is used for the first time after inserting a new cartridge.

Reference Numbers

1	medication delivery device
2	cartridge holder
3	housing
3A	insert of the housing
3B	insert of the housing
4	second engagement means
5	first engagement means
6	cartridge
7	piston
8	engaging means
9	locking means
10	face teeth of locking means
11	guiding means / nut means
12	face teeth of nut means
13	opening of nut means
14	biasing means
15	first thread of piston rod
16	second thread of piston rod
17	piston rod
18	pressure foot
19	drive sleeve
20	flange of drive sleeve
21	internal thread of drive sleeve
22A	shoulder
22B	extension
23	flange
24	clutch
25	clutch plate
26	biasing means
27	dose dial sleeve
28	end stop
29	saw teeth at distal end of clutch
30	flange of clutch
31	saw teeth at proximal end of clutch
32	flexible arms
33	saw teeth of clutch plate
34	flange at distal end of end stop
35	rotation
36	axial movement
37	thread
38	annular groove
39	inclined surfaces
40	window
41	outer helical thread of dose dial sleeve
43	thread of insert of the housing
44	stop features on dose dial sleeve
45	radially extending members
46	dose dial grip
47	central opening of dose dial grip
48	annular recess of dose dial grip
49	button
50	stem of button
51	head of button
52	skirt of button
53	threaded insert of dose dial sleeve
54	end cap

55 stop features on insert 43
56 stop features on insert 43
57 web
58 recesses
59 proximal direction
60 radial stop means on piston rod
63 retaining means
64 biasing means
65 stop means
70 actuation means
71 ramps
72 inclined surfaces

Claims

1. A medication delivery device comprising:

- a housing having a proximal and a distal end,
- a medication receptacle designed to be engaged with the distal end of the housing by engagement of first engagement means with second engagement means and
- a dosing mechanism including
- a piston rod which is moveable in a distal direction for medication delivery and
- a drive device for moving the piston rod in the distal direction for medication delivery;

characterized in that

- the medication receptacle comprises an actuation means for bringing a guiding means in a guiding position in which the guiding means guides the piston rod for medication delivery, wherein the first engagement means and the second engagement means are moveable into engagement by a movement of the medication receptacle which ends in a rotational movement without axial movement of the medication receptacle with respect to the housing, the actuation means thereby bringing the guiding means in the guiding position.

2. The medication delivery device according to claim 1, characterized in that in the guiding position the guiding means is prevented from rotation with respect to the housing.

3. The medication delivery device according to any of claims 1 or 2, characterized in that, when the guiding means is in the guiding position the piston rod can be moved axially in the distal direction with respect to the housing by the drive device and the piston rod is prevented from axial movement in the proximal direction with respect to the housing.

4. The medication delivery device according to one of claims 1 to 3, characterized in that when the guiding means is not in the guiding position, the piston rod is free move axially in the proximal direction with respect to the housing.

5. The medication delivery device according to any of claims 1 to 4, characterized in that the first and second engagement means are designed such that for moving the medication receptacle and the housing into engagement the actuation means are first rotated and moved axially with respect to the housing and are thereafter rotated without being moved axially, thereby bringing the guiding means in the guiding position.

6 The medication delivery device according to one of claims 1 to 5, characterized in that the guiding means is a nut means threadedly engaged with the piston rod.

7. The medication delivery device according to any of claims 1 to 6, characterized in that

- the drive device comprises a drive sleeve and
- the piston rod comprises two threaded sections, wherein a first threaded section is provided for threaded engagement with the guiding means and a second threaded section is provided for threaded engagement with the drive sleeve and wherein the pitch direction of the second threaded section is oppositely directed to the pitch direction of the first threaded section.

8 The medication delivery device according to claim 7, characterized in that the drive sleeve is engaged with the piston rod for driving the piston rod in the distal direction during medication delivery, the drive sleeve being moved axially and being prevented from rotation with regard to the housing during medication delivery, thereby causing axial movement and rotation of the piston rod.

9. The medication delivery device according to claims 7 or 8, characterized in that the dosing mechanism comprises:

- a dose dial sleeve having a helical thread engaged with a helical thread of the housing, the drive sleeve being releasably coupled with the dose dial sleeve and
- a clutch means located between the dose dial sleeve and the drive sleeve,

wherein,

a) when the dose dial sleeve and the drive sleeve are coupled, both are allowed to rotate with respect to the housing, and

b) when the dose dial sleeve and the drive sleeve are de-coupled, rotation of the dose dial sleeve with respect to the housing is allowed, whilst rotation of the drive sleeve with respect to the housing is not allowed and axial movement of the drive sleeve is allowed in the distal direction thereby transferring a force in the distal direction to the piston rod.

10. The medication delivery device according to any of claims 1 to 9, characterized in that the medication delivery device comprises a locking means which is non-rotatable with respect to the housing and which is engageable with the guiding means, thereby locking the guiding means for preventing rotation of the guiding means with respect to the housing.

11. The medication delivery device according to claim 10, characterized in that when the guiding means is engaged with the locking means in the guiding position, the piston rod is prevented from rotation and axial movement in the proximal direction with respect to the housing but is allowed to rotate and move axially in the distal direction with respect to the housing for medication delivery.

12. The medication delivery device according to claims 10 or 11, characterized in that the guiding means or the locking means comprises a shape which interacts with the shape of the actuation means for driving the locking means and the guiding means into engagement by the rotational movement of the actuation means.

13. The medication delivery device according to any of claims 10 to 12, characterized in that at least one inclined surface is arranged on the actuation means and at least one correspondingly inclined surface is arranged on the guiding means or on the locking means, the inclined surfaces being formed such that for interaction of the actuation means and the guiding means or of the actuation means and the locking means the inclined surfaces glide along each other.

14 The medication delivery device according to claim 13, characterized in that the actuation means comprises at least one protrusion with the inclined surface fixedly or moveably arranged on the actuation means or at least one ramp with an inclined surface for interacting with the guiding means or the locking means by a rotational movement of the actuation means in one direction, thereby driving the guiding means and the locking means into engagement.

15. The medication delivery device according to one of claims 10 to 14, characterized in that the guiding means is a nut means which is threadedly engaged with the piston rod and which is engaged with the locking means in the guiding position.

16. The medication delivery device according to any of claims 10 to 15, characterized in that locking means and the guiding means comprise face teeth which interlock when the locking means and the guiding means are engaged in the guiding position.

17. The medication delivery device according to any of claims 10 to 16, characterized in that the locking means and the guiding means disengage under the force of a biasing means when the medication receptacle is disengaged from the housing.

18 The medication delivery device according to any of claims 10 to 17, characterized in that when the medication receptacle is disengaged from the

housing, the locking means and the guiding means are disengaged, whereby the guiding means is free to rotate with respect to the housing.

19. The medication delivery device according to one of claims 1 to 18, characterized in that the medication receptacle is a cartridge holder which is designed to receive a cartridge filled with medication.

20. The medication delivery device according to one of claims 1 to 19, characterized in that the medication receptacle or an insert of the medication receptacle comprises the first engagement means and that the housing or an insert of the housing comprises the second engagement means.

21. The medication delivery device according to one of claims 1 to 20, characterized in that the first engagement means is a thread of the medication receptacle and the second engagement means is an engaging element of the housing or of an insert of the housing for engagement with the thread of the medication receptacle, wherein the distal end of the thread of the medication receptacle merges into a annular groove such that the medication receptacle is engaged with the housing by first rotating and moving proximally with respect to the housing and then only rotating with respect to the housing.

22. The medication delivery device according to one of claims 1 to 20, characterized in that the distal end of the housing is provided with an insert comprising the second engagement means designed to engage with the first engagement means at the proximal end of the medication receptacle, the insert being secured against rotation but being free to move axially with respect to the housing, wherein distal axial movement of the insert is limited by a retaining means.

23. The medication delivery device according to claim 22, characterized in that the insert of the housing comprises an inner thread as a second engagement means for engaging a first engagement means which is an outer thread at the proximal end of the medication receptacle, the medication receptacle comprising the actuation means and being rotated and moved axially with

respect to the insert and the housing in a first step for engaging the medication receptacle with the housing and the medication receptacle being rotated while axial movement of the medication receptacle is prevented with respect to the housing in a second step for engaging the medication receptacle with the housing, the insert being moved in the distal direction by the rotation of the medication receptacle during the second step.

24. The medication delivery device according to one of claims 1 to 23, characterized in that the medication receptacle and the housing are provided with snap-in features by means of which the medication receptacle and the housing are held in engagement during medication delivery.

25. The medication delivery device according to any of claims 1 to 24 which is a pen-type device.

26. The medication delivery device according to any of claims 1 to 25 which is an injector-type device.

27. The medication delivery device according to one of claims 1 to 26, characterized in that medication delivery device comprises a needle.

28. The medication delivery device according to one of claims 1 to 27, the device comprising a medicinal product.

29. The medication delivery device according to the preceding claim, the device comprising a pharmaceutical formulation comprising an active compound selected from the group consisting of insulin, growth hormone, low molecular weight heparin, their analogues, and their derivatives.

30. The method of manufacturing or assembling a medication delivery device, as defined in any of claims 1 to 29.