(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 3 562 532 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
06.10.2021 Bulletin 2021/40

(21) Application number: **17828940.1**

(22) Date of filing: **29.12.2017**

(51) Int Cl.:
A61M 5/20 (2006.01) ***A61M 5/315*** (2006.01)

(86) International application number:
PCT/EP2017/084856

(87) International publication number:
WO 2018/122394 (05.07.2018 Gazette 2018/27)

(54) **PLUNGER SUB-ASSEMBLY FOR A PREFILLED MEDICAMENT INJECTOR, A PREFILLED MEDICAMENT INJECTOR AND METHOD FOR ASSEMBLING A PREFILLED MEDICAL INJECTOR**

KOLBENBAUGRUPPE FÜR EINEN VORGEFÜLLTEN ARZNEIMITTELINJEKTOR, VORGEFÜLLTER ARZNEIMITTELINJEKTOR UND VERFAHREN ZUR MONTAGE EINES VORGEFÜLLTEN ARZNEIMITTELINJEKTORS

SOUS-ENSEMBLE PISTON POUR UN INJECTEUR DE MÉDICAMENT PRÉ-REMPLI, INJECTEUR DE MÉDICAMENT PRÉ-REMPLI ET PROCÉDÉ D’ASSEMBLAGE D’UN INJECTEUR MÉDICAL PRÉ-REMPLI

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

(30) Priority: **31.12.2016 EP 16207660**

(43) Date of publication of application:
06.11.2019 Bulletin 2019/45

(73) Proprietor: **Novo Nordisk A/S**
2880 Bagsværd (DK)

(72) Inventors:
- **EILAND, Jacob**
  2880 Bagsværd (DK)
- **HOLTEN-TINGLEFF, Frederik**
  2880 Bagsværd (DK)
- **BJERRUM, Peter**
  2880 Bagsværd (DK)
- **MØRKEBERG TORRY-SMITH, Jonas**
  2880 Bagsværd (DK)

(56) References cited:
EP-A2- 1 324 794
US-A- 5 695 472
US-A1- 2002 173 752
US-A1- 2013 023 831

EP 3 562 532 B1

Description

[0001] The present invention relates to an assembly of components for a medicament injector that allows for accurately dosing of a medicament from a cartridge. In particular, the present invention relates to a plunger sub-assembly for a prefilled medicament injector and a method of assembling such pre-filled medicament injector.

BACKGROUND

[0002] In relation to some diseases patients must inject a medicament on a regular basis such as once weekly, once daily or even a plurality of times each day. In order to help patients overcome fear of needles, fully automatic injection devices have been developed with the aim of making the use of the injection device as simple as possible. Auto-injectors typically include a container in the form of a cartridge or a syringe that is accommodated within a housing. Prefilled auto-injectors that are intended for single use have been developed to provide particularly simple and user-friendly devices. An example of such autoinjector is disclosed in WO 2016/075254 A1.

[0003] WO 2011/121061 discloses a piston rod assembly for a drug delivery device allowing for multiple dosing of a required dosage by respective dose setting and expelling operations. For the purpose of tolerance elimination the piston rod assembly comprises an adjusting member arranged between the piston and the piston rod. The adjusting member is threadedly engaged with the piston rod in order to axially displace the piston rod and the adjusting member relative to each other to ensure mutual abutment between the piston and the piston rod.

[0004] US 5,695,472 further discloses a modular fluid medication injection assembly. By disassembling the device, a user may prepare the device for the expelling of a first dose or prepare the device for expelling of subsequent doses. To enable use of different kinds of medication for the device, a user may manually adjust for variations in the length of a syringe of the device. Multiple components are used to enable variability of dose setting and the manual adjustment is not suitable to adjust for tolerance variations.

[0005] EP 1324794 A2 discloses a self-zeroing syringe wherein a plunger is movably disposed within a barrel and wherein a dosage selection ring is movably and rotatably disposed around the plunger and at least partly inside the circumference of the barrel. The ring and the plunger cooperatively engage each other by means that allow the ring and the plunger to be moved together. The ring moves until its flange dead-ends against the syringe barrel, preventing any forward movement of the ring or plunger.

[0006] The filling of medicament containers, such as septum-equipped cartridges, is impacted by the manufacturing of the container. For e.g. a glass cartridge, the dimensions of the cartridge combined with the filling technique typically results in minor inaccuracies of the total volume contained by the cartridge. Delivering a drug in a well-defined volume is essential for many therapies, e.g. treatment of diabetes.

[0007] For some medical applications prefilled medicament injectors that are intended for single use administration, such as pre-filled auto-injectors, do not meet the requirements having regard to dosage accuracy. Hence, in certain therapeutic areas there is a need for improved pre-filled medicament injectors.

SUMMARY

[0008] It is an object of the present invention to provide a medicament injector featuring improved dosage accuracy. It is a further object of the invention to provide a simplified and robust method of manufacturing such medicament injector. Finally, it is an object of the invention to provide an improved plunger assembly to be used in medicament injectors.

[0009] In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

[0010] In a first aspect, the present invention relates to a plunger sub-assembly for a pre-filled medicament injector for expelling a dose of a medicament, as defined in claim 1.

[0011] Due to the plunger sub-assembly includes a mechanism where axial length compensation of the plunger and the tolerance compensating element is performed by performing a relative rotational movement or rotational alignment between the tolerance compensating element and the plunger, and due to the plunger-assembly includes a stop surface to cooperate with the proximally facing rim surface of the container body, a particular simple way of obtaining tolerance compensation is obtained. Thereby, the accuracy of the amount of expelled dosages across different samples in a series of pre-filled medicament injectors can be obtained.

[0012] In accordance with the present invention, in large scale manufacturing, the tolerance compensation can be performed on the basis of simple measurements and simple tolerance compensation adjustments, which all can be carried out by automated means.

[0013] With the container in a pre-expelling state, a proximally facing surface of the piston assumes an axial start position relative to the proximally facing rim surface of the container body. The said axial start position can be easily determined or estimated and the plunger sub-assembly is adjusted so that, when built into a medicament injector, the expelling mechanism moves the plunger distally to perform an expelling movement for moving the piston of the container in an expelling stroke of high accuracy.

[0014] The tolerance compensating element may in some embodiments be formed as a collar arranged circumferentially relative to the plunger and having a distal annular surface that is configured for engaging the proximally facing rim surface of the container body. The collar may be formed to either partially of fully circumscribe the plunger.

[0015] The plurality of circumferentially disposed stop surfaces of the contour system may be formed to define a plurality of steps that are circumferentially arranged and axially offset relative to one another.

[0016] In some embodiments, instead of forming a stepped configuration, the plurality of circumferentially disposed stop surfaces of the contour system are provided as contiguously formed stop surfaces that together form at least one continuous rib extending helically around the central axis.

[0017] In a final assembly configuration of the plunger sub-assembly, such as prior to insertion of the plunger assembly into the housing of a medicament injector, or as delivered to the customer, the tolerance compensating element and the plunger are positioned rotationally locked relative to each other with rotational alignment of the counter stop surface with the selected one of the plurality of circumferentially disposed stop surfaces. Hence, when the plunger of the plunger-assembly has been moved fully distally relative to the container barrel, e.g. when the medicament injector has expelled the intended dose, said counter stop surface is in axially abutment with said selected one of the plurality of circumferentially disposed stop surfaces to thereby control the end position of the plunger relative to the container body.

[0018] In some embodiments, the plunger and the tolerance compensating element engage with each other by means of a tongue and groove system. The tongue and groove system may be formed to define at least one tongue and a plurality of axially extending grooves disposed in a coaxial configuration, i.e. where the at least one tongue is arranged on one of the plunger and the tolerance compensating element, and the a plurality of axially extending grooves are arranged on the other of the plunger and the tolerance compensating element. The tongue is positionable or positioned in a selective one of said plurality of axially extending grooves to rotationally align said counter stop surface with the selected one of the plurality of circumferentially disposed stop surfaces enabling an axially sliding movement of the plunger and the tolerance compensating element relative to each other while, when the plunger sub-assembly assumes a final assembled state, preventing relative rotational movement there between.

[0019] In other embodiments, wherein the plunger sub-assembly may comprise a base component that is mounted axially fixed relative to the container body, wherein the base component partially or fully encircles the plunger, and wherein the plunger and the base component are mounted non-rotatably relative to each other. In such assembly, the base component and the tolerance compensating element may be formed to engage with each other by means of a tongue and groove system, the tongue and groove system defining at least one tongue and a plurality of axially extending grooves disposed in a coaxial configuration, i.e. where the at least one tongue is arranged on one of the base component and the tolerance compensating element, and the a plurality of axially extending grooves are arranged on the other of the base component and the tolerance compensating element. The tongue is positionable or positioned in a selective one of said plurality of axially extending grooves to rotationally align said counter stop surface with the selected one of the plurality of circumferentially disposed stop surfaces to prevent relative rotation between the base component and the tolerance compensating element.

[0020] In some embodiments, the counter stop surface and additional corresponding counter stop surfaces are provided as a plurality of circumferentially disposed counter stop surfaces. These may be distributed regularly around the central axis. The respective ones of the plurality of circumferentially disposed counter stop surfaces are configured for simultaneously axially engaging a respective one of the plurality of circumferentially disposed stop surfaces.

[0021] The said system of cooperating grooves and tongue may be formed to comprise engaging surfaces being so configured that the tolerance compensating element and the plunger, or the base component, is selectively rotationally positionable relative to each other in incremental angular steps having a step size between 5 and 180 Deg., preferably between 10 and 30 Deg.

[0022] In some embodiments, the groove and tongue surfaces are so configured that the tolerance compensating element and the plunger are selectively rotationally positionable relative to each other in incremental angular steps having a step size of 180 Deg.

[0023] The plunger and the tolerance compensating element, when assuming a final assembly configuration, are prevented from rotating relative to each other by means of a rotational lock. Said lock may be formed by cooperating rigid geometries, or by a rotational detent mechanism.

[0024] In some embodiments, the groove and tongue surfaces comprise at least one resiliently biased tongue surface exclusively enabling rotational movement between the tolerance compensating element and the plunger, or the base component, upon exertion of torque exceeding a predetermined magnitude acting for relative rotation between the tolerance compensating element and the plunger.

[0025] In some embodiments, the container of the plunger sub-assembly defines a cartridge that comprises a septum that seals an expelling distal end of the container body, the septum being penetrable by a needle cannula to establish fluid communication with the interior of the container. In alternative embodiments, the container forms a syringe having a needle attached to the container body. In particular embodiments, the container body is provided as a tubular glass barrel.

[0026] In a second aspect, the present invention relates to a pre-filled medicament injector for expelling a dose of a medicament, comprising:

- a housing comprising first and second housing components,
- a plunger sub-assembly as defined in accordance with the first aspect, and
- an expelling mechanism comprising an actuator configured for, upon activation, exerting a distally directed force on the plunger for expelling the dose of the medicament,

wherein the plunger sub-assembly and the expelling mechanism are accommodated non-removably relative to the first and second housing components.

[0027] In some embodiments, the tolerance compensating element and the plunger are positioned relative to each other providing a permanent rotational alignment between the counter stop surface and a selected one of the circumferentially disposed stop surfaces, enabling said counter stop surface to axially abut said selected one of the circumferentially disposed stop surfaces to thereby control the end position of the plunger relative to the container.

[0028] In some embodiments, the tolerance compensating element is configured to remain in abutment with the proximally facing rim surface as the plunger moves distally expelling of the dose.

[0029] In alternative embodiments, the tolerance compensating element is configured to travel with the plunger as the plunger moves distally when the plunger drives the piston distally.

[0030] In some embodiments, the plunger is prevented from rotating relative to the housing of the device.

[0031] In some embodiments, the expelling mechanism may comprise an energy source, such as a prestressed spring, configured for providing said distally directed force on the plunger upon, e.g. upon activation of the expelling mechanism.

[0032] In particular embodiments, the pre-filled medicament injector is so configured that the expelling mechanism exclusively allows for a single activation for expelling a single dose of medicament from the container. As the container may be accommodated irreplaceably within the housing of the injector so that the container cannot be replaced, the pre-filled medicament injector is therefore to be discarded after a single administration.

[0033] In a third aspect, the invention relates to a method of assembling a pre-filled medicament injector in accordance with the second aspect described above. The method comprises the steps of:

a) providing the container,
b) determining the axial position (X_1) of a proximal face of the piston with respect to the proximally facing rim surface,
c) establishing a target axial end of dose position (X_2) of the proximal face of the piston with respect to the proximally facing rim surface for obtaining a predetermined target axial stroke (X_s) for the piston,
d) providing the plunger and the tolerance compensating element,
e) based on the target axial end of dose position (X_2) of the proximal face of the piston, determining a target axial end position for the distal end face of the plunger,
f) based on said target axial end position for the distal end face of the plunger, determining a target stop surface selected from the plurality of circumferentially disposed stop surfaces so that the axial end position of the distal end face of the plunger substantially corresponds to the target axial end of dose position (X_2) of the proximal face of the piston when said target stop surface axially abuts the counter stop surface,
g) based on the target stop surface, positioning the plunger and the tolerance compensating element with respect to each other so that the target stop surface rotationally aligns with the counter stop surface,
h) forming the plunger sub-assembly,
i) providing the expelling mechanism and the first and second housing components, and
j) permanently attaching the first and the second housing components to each other to form a housing, whereby the plunger sub-assembly and the expelling mechanism are accommodated non-removable relative to the housing.

[0034] In accordance with all the above aspects and embodiments of the invention, the tolerance compensating element or the group of tolerance compensating elements may be configured to compensate for a tolerance variations on the axial start position of the proximally facing surface of the piston relative to the proximally facing rim surface of the cartridge in the order of $\pm$0.5 mm, or, in further embodiments, in the order of $\pm$ 1.0 mm.

[0035] As used herein, the term "medicament" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a cannula or hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension.

BRIEF DESCRIPTION OF DRAWINGS

[0036] In the following the invention will be further described with reference to the drawings, wherein fig. 1a shows a cross sectional side view of an exemplary injection device which is applicable for use in connection with the present invention, wherein the device is in a state prior to triggering,

fig. 1b shows a cross sectional side view of the injection device of fig. 1a but in a state subsequent to triggering and wherein the device assumes an end of dose state, fig. 2 shows a cross sectional side view of a first embodiment of a plunger assembly according to the invention with the plunger assuming a start position,

fig. 3 shows a perspective view of a tolerance compensating element of the plunger assembly shown in fig. 2,

fig. 4 shows a cross sectional axial view in distal direction through the tolerance compensating element of the plunger assembly shown in fig. 2,

fig. 5 shows a view similar to the view of fig. 2 with additional information relating to the expellable amount of medicament from the cartridge,

fig. 6 shows a perspective view of the plunger assembly shown in fig. 2 with the plunger in the start position,

fig. 7 shows a cross sectional side view of a second embodiment of a plunger assembly according to the invention with the plunger assuming an end position,

fig. 8 shows a perspective view of a tolerance compensating element of the plunger assembly shown in fig. 7,

fig. 9 shows a cross sectional axial view in distal direction through the tolerance compensating element of the plunger assembly shown in fig. 7,

fig. 10 shows a perspective view of the plunger assembly shown in fig. 7 with the plunger in the end position,

fig. 11 shows a magnified view of the part of fig. 10 showing the tolerance compensating element, and

fig. 12 shows a cross sectional side view of a third, non-claimed, embodiment of a plunger assembly with the plunger assuming a start position.

[0037] Corresponding reference characters indicate corresponding parts throughout the several views. Although the drawings represent embodiments of the present invention, the drawings are not necessarily to scale, and certain features may be exaggerated or omitted in some of the drawings in order to better illustrate and explain the present invention.

DESCRIPTION

[0038] Figures 1a and 1b illustrate two operational states for an example injection device which is suitable for use in connection with the present invention. The injection device is shown in two different states of operation in order to explain functionality relating to the amount that will be expelled when the injection device is activated for dose expelling. The shown device is generally similar to the device disclosed in WO 2016/075254 A1 in connection with figs. 1c, 2c, 3c, 4a, 4b and 5c of said document. Fig 1a and 1b of the present disclosure correspond to fig. 1c respectively fig. 4b of the WO document. For a detailed description of the disclosed device reference is made to the WO document.

[0039] It is to be noted that the shown injection device forms a suitable but non-limiting example and that the principles of the present invention regarding adjusting the dosage amount can be used together with other types of injection devices. All the details of the shown injection device will not be described in detail herein since these details have already been described in the above WO document.

[0040] Figures 1a and 1b show an injection device 100 in the form of a single use prefilled autoinjector with a medicament containing cartridge 600 irreplaceably accommodated in a housing 200,210,220. The injection device 100 further includes an injection needle assembly 500 having a proximal needle end 520 and a distal needle end 510, a needle shield 350 and an expelling assembly or mechanism which primarily consist of an actuator in the form of a drive ram 310 and a compression spring 330 which provides a plunging force acting on a plunger in the form of ram spacer member 400. The expelling assembly is activatable by means of needle shield 350 so that pushing in of the needle shield 350 relative to the housing triggers the expelling assembly for initiating the expelling action.

[0041] In the shown embodiment, in the initial shielded state shown in figure 1a, the injection device assumes a state before triggering of the expelling assembly. In the shown embodiment, the container 600 forms a cartridge with a cylindrical body having a distally arranged outlet covered by a cartridge septum adapted to be pierced by the needle for establishing fluid communication with the cartridge interior. The body of the cartridge accommodates a slidably arranged piston 630. In the state where the needle has pierced cartridge septum, piston 630 is drivable towards the outlet in order to dispense medicament from the cartridge 600.

[0042] The ram spacer member 400 is formed with stop surfaces 401 positioned a predetermined distance from the distal end of ram spacer member 400 to cooperate with the rear end 611 of the body of cartridge 600 to thereby define a precise end of stroke position for the piston 630 inside cartridge 600. As the piston 630, during filling of the cartridge 600, can be positioned with respect to the rear end 611 of the cartridge 600 in accordance with the desired fill level of the cartridge, the exact volume of an expelled dose can be controlled by utilizing the stop surfaces 401 hitting the rear end 611 of cartridge 600 at completion of the expelling operation. In the shown embodiment, the ram spacer member 400 includes two longitudinally extending ribs positioned 180 deg. apart. Each longitudinally extending rib has a distal end surface which forms said stop surface 401. In the shown embodiment, the ram spacer member 400 is mounted rotationally fixed in the housing of the injection device 100.

[0043] Subsequent to triggering and injection, as shown in figure 1b, the injection device 100 assumes the end of dose state, but prior to removal of the device from the injection site. The expelling assembly has pushed the piston 630 of the cartridge distally, thereby causing the intended dose of the medicament in the cartridge to be expelled through the needle into the injection site. The stop surfaces 401 of ram spacer member 400 engage the rear end 611 of cartridge 600 thereby controlling the end position of ram spacer member 400 relative to the cartridge 600. Hence, the axial position of the proximal surface of piston 630 corresponds to the axial position of the distal face of the ram spacer member 400.

[0044] After the medicament has been injected, the needle shield 350 is again pushed forward with respect to the housing to shield the distal end of the needle. In the shown embodiment, this occurs as a consequence of the user manually retracting the housing of the injection device relative to the injection site. In the shown embodiment, the needle shield 350 is biased in the distal direction by means of a needle shield spring, and the needle shield thus moves automatically into the shielding state wherein the needle shield is permanently locked. The device is then ready to be disposed of.

[0045] The description above with respect to figures 1a and 1b has been provided to give background information on the use of an exemplary injection device applicable for use with the present invention. However, the injection device described is one of many different available injection devices that can be utilized with the principles according to the present invention.

[0046] In large scale manufacturing, for particular applications such as in connection with treatment with particular kinds of medicaments, the accuracy of the expelled dose from an injection device, such as the one described above, cannot be met with typical predefined tolerance levels. In particular, the initial axial position of the piston relative to the rear surface of the cartridge body may vary, such as in the order of ± 0.5 mm, or even ± 1.0 mm. In the following, different embodiments will be described which relate to principles that can be used to compensate for such tolerance variations. Utilizing these principles, the accuracy of expelling a single dose from a cartridge can be increased thereby providing an improved injection device.

[0047] Fig 2 shows a first embodiment of a plunger assembly 10.1 according to the invention. Plunger assembly 10.1 includes a cartridge 60, a plunger 40 and a tolerance compensating element 70. The plunger assembly 10.1 is intended to replace the ram spacer member 400 and the cartridge 600 in the above described injection device 100.

[0048] Cartridge 60 is similar to cartridge 600 referred to above. Cartridge 600 comprises a cylindrical body 61 within which a slideable piston 63 is arranged at a particular initial axial location with respect to a proximally facing rim surface 64 of body 61.

[0049] Plunger 40 performs the same function as ram spacer member 400 described above. Plunger 40 forms an elongated generally tubular element configured to be partially inserted axially into the body of the cartridge. In the shown embodiment, plunger 400 is formed with two radially opposed longitudinal extending ribs 45. Each of the longitudinal extending ribs 45 ends in a distally facing stop surface 46 which in this disclosure also will be referred to as "a counter stop surface". The distally facing stop surfaces 46 are positioned at a predefined axial distance from a distal end face 41 of plunger 40 in order to cooperate, via tolerance compensating element 70, with the proximally facing rim surface 64 of cartridge 60.

[0050] The tolerance compensating element 70 is better viewed in fig 3. In the first embodiment, the tolerance compensating element 70 is formed as a collar to be arranged circumferentially relative to the plunger 40 and with a distal annular face 74 dimensioned to engage and lie flush against the proximally facing surface 64 of cartridge 60. The proximal facing surface 76 of tolerance compensating element 70 is formed with a contour system comprising a plurality of circumferentially disposed stop surfaces 76.1-76.13 being arranged axially offset relative to each other. In the shown embodiment the contour system is formed with a plurality of steps that are circumferentially arranged and axially offset relative to one another. In the shown embodiment, two sets of contour systems are arranged opposing each other. In each contour system 13 individual steps are formed in a series of steps 76.1-76.13 covering an angle of 180 degrees. The 13 individual steps are thus repeated twice on the circumference so that each step at a particular axial position finds a counterpart separated by 180 degrees but arranged at the same axial level.

[0051] On the radially inwards facing surface of tolerance compensating element 70 a series of axially extending grooves 73 is arranged circumferentially to cooperate with one or more axially extending tongues 43 formed to protrude radially outwards from plunger 40. In an initial assembly configuration, before assembling the plunger 40 relative to the tolerance compensating element 70, a particular rotational orientation between the two components may be selected whereafter, when the plunger 40 is inserted into the tolerance compensating element 70, the two components becomes rotationally fixed relative to each other. The tongue and groove system 43/73 is formed so that the plunger 40 is freely axially slidable relative to the tolerance compensating element 70 even when the two components are rotationally fixed relative to each other. As an alternative to the shown rotational locking engagement, a rotational snap engagement may be provided forming a rotational detent mechanism which serves to enable rotational adjustment during assembly operations but to lock the two components to each other to prevent unintentional rotational movement after final assembly.

[0052] In a final assembly configuration, as shown in figs. 2 and 6, in accordance with the particular selected rotational position of the tolerance compensating element 70 relative to the plunger 40, the counter stop surfaces 46 and the selected ones of the circumferentially arranged radial steps 76.1-76.13 are rotationally aligned relative to each other, enabling said counter stop surfaces to axially abut respective selected ones of the circumferentially disposed steps to thereby control the end position of the plunger 40 relative to the proximally facing rim surface 64 of the container 60. In the shown example each of the counter stop surfaces 46 is aligned with a stop surface 76.7 on the tolerance compensating element 70.

[0053] Referring to fig. 5, during assembly operations of a particular plunger assembly 10.1, the initial axial position (X_1) of the piston 63 with respect to the proximally facing rim surface 64 of the cartridge body 61 may be determined by means of a measuring probe, by way of optical measurements, or by alternative suitable measuring methods. In accordance with the measured information, a particular rotational orientation may be selected between the plunger 40 and the tolerance compensating element 70. Said selection is performed, preferably in an automated manufacturing setup, to ensure that the axial stroke of the piston 63 relative to the cartridge body 61, as driven distally by the plunger 40 during a subsequent expelling procedure, is within a target axial stroke (X_s). When the desired amount has been expelled, i.e. with the piston 63 assuming the end of dose position, the piston is located at position (X_2) with respect to the proximally facing rim surface 64 of the cartridge body 61. Generally, when referring to the proximally facing rim surface 64 of the cartridge body 61, the distance X_2 equals X_1 + X_s. Generally, when the plunger sub-assembly is formed, e.g. when the medicament injector is assembled, the plunger will typically not assume a position where full engagement between the plunger and the piston is obtained. However, during expelling, after an initial movement of the plunger, the plunger reaches an axial position where it engages the piston and the final stroke of the plunger X_s generally corresponds to target axial stroke X_s of the piston.

[0054] The plunger assembly, in its final assembly configuration with the tolerance compensating element properly adjusted, can be assembled with the remaining components of an injection device. Preferably, the plunger assembly is received within housing components that are permanently attached relative to each other so as to render further adjustments impossible between the plunger and the tolerance compensating element. In the described manner, the tolerance variations of the individual components of the device, and the tolerance induced variations on the accuracy of the size of the expelled dose of medicament from the device, can be effectively eliminated.

[0055] It is to be noted that, in other alternative embodiments, the number of counter stop surfaces may be lower or higher than two. Similarly, instead of forming the contour system as two repeated series of steps, only a single or more than two series may be formed on the tolerance compensating element. The number of steps of each contour system may also be varied, such as incorporating only a limited number of axial positions, such as only two, three, four or more steps with a corresponding number of unique axial positions. In still other embodiments where the tolerance compensating element comprises one or more contour systems, a plurality of counter stop surfaces may be designed on the plunger as a separate contour system to cooperate with the contour system of the tolerance compensating element. It is to be noted that, even though the shown contour system comprises steps that are arranged along a helical path on the plunger, the contour system need not be arranged along a helical pat but could be formed along differently formed paths.

[0056] It is also to be noted that, in other alternative embodiments, the contour system may alternatively be formed onto the plunger whereas the counter stop surfaces may be provided on the tolerance compensating element. Further, instead of the tolerance compensating element being arranged to constantly engage the proximally facing rim surface of the container, the tolerance compensating element may be arranged to travel with the plunger as the plunger moves axially relative to the cartridge. In such system, the end position of the plunger is assumed when the distal face 74 of the tolerance compensating element hits the proximally facing rim surface 64.

[0057] Figs. 7-11 show a second embodiment of a plunger assembly 10.2 which is formed generally corresponding with the plunger assembly 10.1 of the first embodiment. However, instead of forming a rotational tongue and groove system between the plunger and the tolerance compensating element 70, the tolerance compensating element is, in an adjustable manner, rotationally aligned and subsequently locked relative to a housing component 21. Such housing component may be formed generally similar to housing component 210 of the injection device 100 shown in fig. 1a and 1b. To improve clarity the housing component 21 is omitted from view in figs. 9-11. For some embodiments, in a particular assembly state during manufacturing of a pre-filled medicament injector, the housing component 21 may form part of the plunger assembly 10.2.

[0058] As shown in figs. 8, 9 and 10, two tongues 75 are formed to protrude radially outwards from the outer surface of tolerance compensating element 70. Each tongue 73 is arranged to cooperate with a selected one of a plurality of axially extending grooves 23 formed circumferentially on a radially inwards facing surface in housing component 21. In an initial 75assembly configuration, before assembling tolerance compensating element 70 relative to the housing component 21, a particular rotational orientation between the two components may be selected. Hereafter, when the tolerance compensating element 70 is inserted into the housing component 21, the two components becomes rotationally fixed relative to each other.

[0059] The plunger assembly 10.2, in its final assembly configuration, can be subsequently assembled with the remaining components of an injection device to form a pre-filled injection device having superior dosage accuracy.

[0060] Finally, turning to fig. 12, a third, non-claimed, embodiment of a plunger assembly 10.3 is showed.

Plunger assembly 10.3 includes a plunger which forms two distally facing counter stop surfaces 46 configured to engage directly with the proximally facing rim surface 64 of the cartridge body 61. In this embodiment, the plunger connects to the piston 63 of the cartridge via a tolerance compensating element 80 connected to a distal end of the plunger 40. Tolerance compensating element 80 comprises a distally facing surface 81 configured for engaging directly with the distal surface of the piston 63. Tolerance compensating element 80 further comprises a proximally facing bore provided with a thread 88. The distal end of plunger 40 is formed with a corresponding external thread 48 that is in engagement with the thread 88 of tolerance compensating element 80.

[0061] By rotating the tolerance compensating element 80 and the plunger 40 relative to each other the effective axial distance between the distally facing surface 81 of tolerance compensating element 80 and the counter stop surfaces 46 can be selected in accordance with a measured axial position of the piston 63 relative to the proximally facing rim surface 64 of the cartridge body 61. The measurement may be performed by using the same means and methods as described above with respect to plunger assembly 10.1. The threaded engagement 88/48 is preferably formed as a self-locking threaded connection, meaning that the threaded engagement is configured to inhibit self-induced rotation when the plunger 40 exerts an axial force via the tolerance compensating element 80 onto the proximal face of the piston 63. Preferably, the friction between the threads 88 and 48 is designed with a magnitude so that rotation is exclusively performed when a suitable tool is exerting a torque between the plunger 40 and the tolerance compensating element 80.

[0062] The plunger assembly 10.3, in its final assembly configuration, just as with the plunger assemblies 10.1 and 10.2 described above, can be subsequently assembled with the remaining components of an injection device. Preferably, the plunger assembly 10.3 is received within housing components that are permanently attached relative to each other so as to render further adjustments impossible between the plunger and the tolerance compensating element. In the described manner, the tolerance variations of the individual components of the device, and the tolerance induced variations on the accuracy of the size of the expelled dose of medicament from the device, can be effectively eliminated.

[0063] Some preferred embodiments have been shown in the foregoing, but it should be stressed that the invention - which is defined by the appended claims - is not limited to these, but may be embodied in other ways within the subject matter defined in the following claims.

Claims

1. A plunger sub-assembly (40, 60, 70) for a pre-filled medicament injector for expelling a dose of a medicament, comprising:

   - a container (60) holding a medicament, the container (60) comprising a cylindrical container body (61) extending along a central axis between a medicament expelling distal end and a proximal end, wherein an axially slideable piston (63) is arranged within the container body (61) to seal the container proximally, and wherein the proximal end of the container body (61) comprises a proximally facing rim surface (64),
   - a plunger (40) arranged along the axis and configured for driving the piston (63) distally relative to the proximally facing rim surface (64), the plunger (40) being distally movable from a start position where the plunger (40) is not cooperating with the proximally facing rim surface (64) until an end position relative to the container (60) where the plunger (40) cooperates with the proximally facing rim surface (64) thereby preventing the plunger (40) from moving further distally, the piston (63) assuming an end of dose position relative to the proximally facing rim surface (64) when the plunger (40) assumes the end position, and
   - an adjustable blocking means associated with the plunger (40) and the container (60) to provide an axial blocking means for the plunger (40) in the end position,

   wherein the adjustable blocking means comprises a tolerance compensating element (70) configured to cooperate with the plunger (40) and to cooperate with the proximally facing rim surface (64), wherein the tolerance compensating element (70) is rotatable relative to the plunger (40) to adjust the piston end of dose position relative to the proximally facing rim surface (64), wherein the tolerance compensating element (70) is so configured that, when the plunger (40) assumes the end position, the plunger (40) engages directly with the piston (63), whereas the tolerance compensating element (70) directly engages both the plunger (40) and the proximally facing rim surface (64),

   characterized in that one of the plunger (40) and the tolerance compensating element (70) comprises a contour system comprising a plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) that are arranged axially offset relative to each other, and wherein the other of the plunger (40) and the tolerance compensating element (70) comprises a counter stop surface (46) arranged to axially engage a selective one of the plurality of circumferentially stop surfaces (76.1, 76.2, 76.7, 76.13), and wherein, when in an initial assembly configuration, the tolerance compensating element (70) and the plunger (40) are selectively positionable or positioned relative to each other to rotationally align the counter stop surface (46) with a selective one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) to thereby adjustably control the end position of the plunger (40) relative to the container (60), enabling the counter stop surface (46) to axially abut the selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13).

2. A plunger sub-assembly (40, 60, 70) as defined in claim 1, wherein, when the plunger (40) assumes the end position, a distally facing geometry (41) of the plunger (40) engages directly with the piston (63), whereas the tolerance compensating element (70) directly engages both the plunger (40) and the proximally facing rim surface (64), and wherein the tolerance compensating element (70) is formed as a collar arranged circumferentially relative to the plunger (40) and having a distal annular surface (74), the distal annular surface (74) configured for engaging the proximally facing rim surface (64).

3. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-2, wherein the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) of the contour system define a plurality of steps that are circumferentially arranged and axially offset relative to one another.

4. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-3, wherein, in a final assembly configuration, the tolerance compensating element (70) and the plunger (40) are positioned rotationally locked relative to each other with rotational alignment of the counter stop surface (46) with the selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13), causing said counter stop surface (46) to axially abut said selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.7, 76.13) to thereby control the end position of the plunger (40) relative to the container body (61).

5. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-4, wherein the plunger (40) and the tolerance compensating element (70) engage with each other by means of a tongue and groove system (43, 73), the tongue and groove system defining at least one tongue (43) and a plurality of axially extending grooves (73) disposed in a coaxial configuration, wherein the tongue (43) is positionable or positioned in a selective one of said plurality of axially extending grooves (73) to rotationally align said counter stop surface (46) with the selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) enabling an axially sliding movement of the plunger (40) and the tolerance compensating element (70) relative to each other while preventing relative rotational movement there between.

6. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-4,wherein the injector defines a base component (21) that is mounted axially fixed relative to the container body (61) and that partially or fully encircles the plunger (40), wherein the plunger (40) and the base component (21) are mounted non-rotatably relative to each other, wherein the base component (21) and the tolerance compensating element (70) engage with each other by means of a tongue and groove system (25, 75), the tongue and groove system defining at least one tongue (75) and a plurality of axially extending grooves (25) disposed in a coaxial configuration, and wherein the tongue (75) is positionable or positioned in a selective one of said plurality of axially extending grooves (25) to rotationally align said counter stop surface (46) with the selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) to prevent relative rotation between the base component (21) and the tolerance compensating element (70).

7. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-6, wherein said counter stop surface (46) and additional corresponding counter stop surfaces (46) are provided as a plurality of circumferentially disposed counter stop surfaces (46) distributed regularly around the central axis, wherein the respective ones of the plurality of circumferentially disposed counter stop surfaces (46) are configured for simultaneously axially engaging a respective one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13).

8. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 5-7, wherein the groove (73; 25) and tongue (43; 75) comprise engaging surfaces being so configured that the tolerance compensating element (70) and the plunger (40) is selectively rotationally positionable relative to each other in incremental angular steps having a step size between 5 and 1 Deg., preferably between 10 and 30 Deg.

9. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-8, wherein the plunger (40) and the tolerance compensating element (70), in a final assembly configuration, are prevented from rotating relative to each other by means of a rotational lock (43, 73; 25, 75).

10. A plunger sub-assembly (40, 60, 70) as defined in claim 9, wherein the rotational lock is formed by cooperating rigid geometries.

11. A plunger sub-assembly (40, 60, 70) as defined in claim 9, wherein the rotational lock is formed by a rotational detent mechanism.

12. A plunger sub-assembly (40, 60, 70) as defined in any of the claims 1-11, wherein the container (60) of the plunger sub-assembly defines a cartridge that comprises a septum that seals an expelling distal end of the container body (61), the septum being penetrable by a needle cannula to establish fluid communication with the interior of the container.

13. A pre-filled medicament injector for expelling a dose of a medicament, comprising:

- a housing comprising first and second housing components,
- a plunger sub-assembly (40, 60, 70) as defined in any of claims 1-12, and
- an expelling mechanism comprising an actuator configured for, upon activation, exerting a distally directed force on the plunger (40) for expelling the dose of the medicament,

wherein the plunger sub-assembly (40, 60, 70) and the expelling mechanism are accommodated non-removably relative to the first and second housing components.

14. A pre-filled medicament injector as defined in claim 13, wherein the tolerance compensating element (70) and the plunger (40) are positioned relative to each other providing a permanent rotational alignment between the counter stop surface (46) and a selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13), enabling said counter stop surface (46) to axially abut said selected one of the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) to thereby control the end position of the plunger (40) relative to the container (60).

15. A method of assembling a pre-filled medicament injector as defined in claim 14, comprising the steps of:

a) providing the container (60),
b) determining the axial position (X_1) of a proximal face of the piston (63) with respect to the proximally facing rim surface (64),
c) establishing a target axial end of dose position (X_2) of the proximal face of the piston (63) with respect to the proximally facing rim surface (64) for obtaining a predetermined target axial stroke (X_s) for the piston (63),
d) providing the plunger (40) and the tolerance compensating element (70),
e) based on the target axial end of dose position (X_2) of the proximal face of the piston (63), determining a target axial end position for the distal end face of the plunger (40),
f) based on said target axial end position for the distal end face of the plunger (40), determining a target stop surface selected from the plurality of circumferentially disposed stop surfaces (76.1, 76.2, 76.7, 76.13) so that the axial end position of the distal end face of the plunger (40) substantially corresponds to the target axial end of dose position (X_2) of the proximal face of the piston (63) when said target stop surface axially abuts the counter stop surface (46),
g) based on the target stop surface, positioning the plunger (40) and the tolerance compensating element (70) with respect to each other so that the target stop surface rotationally aligns with the counter stop surface (46),
h) forming the plunger sub-assembly (40, 60, 70),
i) providing the expelling mechanism and the first and second housing components, and
j) permanently attaching the first and the second housing components to each other to form a housing, whereby the plunger sub-assembly (40, 60, 70) and the expelling mechanism are accommodated non-removable relative to the housing.

Patentansprüche

1. Kolben-Unterbaugruppe (40, 60, 70) für einen vorgefüllten Medikamenteninjektor zum Ausstoßen einer Medikamentendosis, umfassend:

- einen ein Medikament enthaltenden Behälter (60), wobei der Behälter (60) einen zylindrischen Behälterkörper (61) aufweist, der sich entlang einer zentralen Achse zwischen einem das Medikament ausstoßenden distalen Ende und einem proximalen Ende erstreckt, wobei ein axial verschiebbarer Kolben (63) innerhalb des Behälterkörpers (61) zur proximalen Abdichtung des Behälters angeordnet ist, und wobei das proximale Ende des Behälterkörpers (61) eine proximal gegenüberliegende Randfläche (64) umfasst,
- einen entlang der Achse angeordneten und zum Antreiben des Kolbens (63) in distaler Richtung relativ zu der proximal gegenüberliegenden Randfläche (64) konfigurierten Kolben (40), wobei der Kolben (40) in distaler Richtung von einer Startposition, in der der Kolben (40) nicht mit der proximal gegenüberliegenden Randfläche (64) zusammenwirkt, bis zu einer Endposition relativ zu dem Behälter (60) bewegbar ist, in der der Kolben (40) mit der proximal gegenüberliegenden Randfläche (64) zusammen-

wirkt, wodurch verhindert wird, dass sich der Kolben (40) weiter in distaler Richtung bewegt, wobei der Kolben (63) eine Dosierende-Position relativ zu der proximal gegenüberliegenden Randfläche (64) einnimmt, wenn der Kolben (40) die Endposition einnimmt, und

- ein dem Kolben (40) und dem Behälter (60) zugeordnetes einstellbares Blockiermittel, um ein axiales Blockiermittel für den Kolben (40) in der Endposition vorzusehen,

wobei das einstellbare Blockiermittel ein Toleranzausgleichselement (70) aufweist, das zum Zusammenwirken mit dem Kolben (40) und zum Zusammenwirken mit der proximal gegenüberliegenden Randfläche (64) konfiguriert ist,

wobei das Toleranzausgleichselement (70) relativ zu dem Kolben (40) drehbar ist, um die Dosierende-Position des Kolbens relativ zu der proximal gegenüberliegenden Randfläche (64) einzustellen,

wobei das Toleranzausgleichselement (70) so konfiguriert ist, dass, wenn der Kolben (40) die Endposition einnimmt, der Kolben (40) direkt mit dem Kolben (63) in Eingriff steht, während das Toleranzausgleichselement (70) sowohl mit dem Kolben (40) als auch mit der proximal gegenüberliegenden Randfläche (64) direkt in Eingriff steht,

dadurch gekennzeichnet, dass einer von dem Kolben (40) und dem Toleranzausgleichselement (70) ein Kontursystem aufweist, das eine Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) umfasst, die relativ zueinander axial versetzt angeordnet sind, und wobei das andere Element, d. h. der Kolben (40) oder das Toleranzausgleichselement (70), eine Gegenanschlagfläche (46) aufweist, die so angeordnet ist, dass sie axial mit einer ausgewählten der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) in Eingriff kommt, und wobei in einer anfänglichen Montagekonfiguration das Toleranzausgleichselement (70) und der Kolben (40) selektiv relativ zueinander positionierbar oder positioniert sind, um die Gegenanschlagfläche (46) mit einer selektiven der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) drehend auszurichten, um dadurch die Endposition des Kolbens (40) relativ zum Behälter (60) einstellbar zu steuern, sodass die Gegenanschlagfläche (46) axial an der ausgewählten der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) anliegen kann.

2. Kolben-Unterbaugruppe (40, 60, 70) wie in Anspruch 1 definiert, wobei, wenn der Kolben (40) die Endposition einnimmt, eine distal gegenüberliegende Geometrie (41) des Kolbens (40) direkt mit dem Kolben (63) in Eingriff steht, während das Toleranzausgleichselement (70) sowohl mit dem Kolben (40) als auch mit der proximal gegenüberliegenden Randfläche (64) direkt in Eingriff steht, und wobei das Toleranzausgleichselement (70) als ein Kragen ausgebildet ist, der in Umfangsrichtung relativ zu dem Kolben (40) angeordnet ist und eine distale Ringfläche (74) aufweist, wobei die distale Ringfläche (74) zum Eingriff mit der proximal gegenüberliegenden Randfläche (64) konfiguriert ist.

3. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 3 definiert, wobei die Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) des Kontursystems eine Vielzahl von Stufen definieren, die in Umfangsrichtung angeordnet und axial zueinander versetzt sind.

4. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 3 definiert, wobei in einer endgültigen Montagekonfiguration das Toleranzausgleichselement (70) und der Kolben (40) relativ zueinander drehfest positioniert sind, wobei die Gegenanschlagfläche (46) mit der ausgewählten aus der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) drehend ausgerichtet ist, was bewirkt, dass die Gegenanschlagfläche (46) axial an der ausgewählten der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.7, 76.13) anliegt, um dadurch die Endposition des Kolbens (40) relativ zu dem Behälterkörper (61) zu steuern.

5. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 4 definiert, wobei der Kolben (40) und das Toleranzausgleichselement (70) mittels eines Feder- und Nutsystems (43, 73) miteinander in Eingriff stehen, wobei das Feder- und Nutsystem zumindest eine Feder (43) und eine Vielzahl von axial verlaufenden Nuten (73) definiert, die in einer koaxialen Konfiguration angeordnet sind, wobei die Feder (43) in einer ausgewählten der Vielzahl von sich axial erstreckenden Nuten (73) positionierbar oder positioniert ist, um die Gegenanschlagfläche (46) mit der ausgewählten der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) drehend auszurichten, was eine axiale Gleitbewegung des Kolbens (40) und des Toleranzausgleichselements (70) relativ zueinander ermöglicht, während eine relative Drehbewegung dazwischen verhindert wird.

6. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 4 definiert, wobei der Injektor eine Basiskomponente (21) definiert, die relativ zum

Behälterkörper (61) axial fest befestigt ist und den Kolben (40) teilweise oder vollständig umgibt, wobei der Kolben (40) und die Basiskomponente (21) relativ zueinander drehfest befestigt sind, wobei die Basiskomponente (21) und das Toleranzausgleichselement (70) mittels eines Feder- und Nutsystems (25, 75) ineinander eingreifen, wobei das Feder- und Nutsystem zumindest eine Feder (75) und eine Vielzahl von axial verlaufenden Nuten (25) definiert, die in einer koaxialen Konfiguration angeordnet sind, und wobei die Feder (75) in einer ausgewählten der Vielzahl von sich axial erstreckenden Nuten (25) positionierbar oder positioniert ist, um die Gegenanschlagfläche (46) mit der ausgewählten der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) drehend auszurichten, um eine relative Drehung zwischen dem Basisbauteil (21) und dem Toleranzausgleichselement (70) zu verhindern.

7. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 6 definiert, wobei die Gegenanschlagfläche (46) und zusätzliche entsprechende Gegenanschlagflächen (46) als eine Vielzahl von in Umfangsrichtung angeordneten Gegenanschlagflächen (46) vorgesehen sind, die regelmäßig um die Mittelachse herum verteilt sind, wobei die jeweiligen der Vielzahl von in Umfangsrichtung angeordneten Gegenanschlagflächen (46) so konfiguriert sind, dass sie gleichzeitig axial mit einer jeweiligen der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) in Eingriff kommen.

8. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 5 bis 7 definiert, wobei die Nut (73; 25) und die Feder (43; 75) Eingriffsflächen aufweisen, die so konfiguriert sind, dass das Toleranzausgleichselement (70) und der Kolben (40) selektiv drehend relativ zueinander in inkrementellen Winkelschritten mit einer Schrittgröße zwischen 5 und 1 Grad, bevorzugt zwischen 10 und 30 Grad, positionierbar sind.

9. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 8 definiert, wobei der Kolben (40) und das Toleranzausgleichselement (70) in einer endgültigen Montagekonfiguration mittels einer Drehverriegelung (43, 73; 25, 75) an einer Drehung relativ zueinander gehindert sind.

10. Kolben-Unterbaugruppe (40, 60, 70) wie in Anspruch 9 definiert, wobei die Drehverriegelung durch zusammenwirkende starre Geometrien ausgebildet ist.

11. Kolben-Unterbaugruppe (40, 60, 70) wie in Anspruch 9 definiert, wobei die Drehverriegelung durch einen Drehrastmechanismus ausgebildet ist.

12. Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 11 definiert, wobei der Behälter (60) der Kolben-Unterbaugruppe eine Patrone definiert, die ein Septum aufweist, das ein ausstoßendes distales Ende des Behälterkörpers (61) abdichtet, wobei das Septum von einer Nadelkanüle durchdringbar ist, um eine Fluidverbindung mit dem Inneren des Behälters herzustellen.

13. Vorgefüllter Medikamenteninjektor zum Ausstoßen einer Medikamentendosis, umfassend:

- ein Gehäuse, das erste und zweite Gehäusekomponenten aufweist,
- eine Kolben-Unterbaugruppe (40, 60, 70) wie in einem der Ansprüche 1 bis 12 definiert, und
- einen Ausstoßmechanismus, umfassend einen Aktuator, der bei Aktivierung, konfiguriert ist zum Ausüben einer distal gerichteten Kraft auf den Kolben (40) zum Ausstoßen der Medikamentendosis,

wobei die Kolben-Unterbaugruppe (40, 60, 70) und der Ausstoßmechanismus relativ zu der ersten und zweiten Gehäusekomponente nicht entfernbar aufgenommen sind.

14. Vorgefüllter Medikamenteninjektor wie in Anspruch 13 definiert, wobei das Toleranzausgleichselement (70) und der Kolben (40) relativ zueinander positioniert sind, wodurch eine dauerhafte Drehausrichtung zwischen der Gegenanschlagfläche (46) und einer ausgewählten aus der Vielzahl der in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) vorgesehen ist, wodurch die Gegenanschlagfläche (46) an der ausgewählten der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) axial anliegen kann, um dadurch die Endposition des Kolbens (40) relativ zu dem Behälter (60) zu steuern.

15. Verfahren zum Zusammenbau eines vorgefüllten Medikamenteninjektors wie in Anspruch 14 definiert, umfassend die Schritte:

a) Bereitstellen des Behälters (60),
b) Ermitteln der axialen Position (X1) einer proximalen Fläche des Kolbens (63) in Bezug auf die proximal gegenüberliegende Randfläche (64),
c) Festlegen einer axialen Dosierende-Position (X2) der proximalen Fläche des Kolbens (63) in Bezug auf die proximal gegenüberliegende Randfläche (64), um einen vorbestimmten axialen Soll-Hub (XS) für den Kolben (63) zu erhalten,

d) Bereitstellen des Kolbens (40) und des Toleranzausgleichselements (70),

e) basierend auf der axialen Soll-Dosierende-Position (X2) der proximalen Fläche des Kolbens (63), Ermitteln einer axialen Soll-Endposition für die distale Endfläche des Kolbens (40),

f) basierend auf der axialen Soll-Endposition für die distale Endfläche des Kolbens (40), Ermitteln einer Soll-Anschlagfläche, die aus der Vielzahl von in Umfangsrichtung angeordneten Anschlagflächen (76.1, 76.2, 76.7, 76.13) ausgewählt ist, sodass die axiale Endposition der distalen Endfläche des Kolbens (40) im Wesentlichen der axialen Soll-Dosierende-Position (X2) der proximalen Fläche des Kolbens (63) entspricht, wenn die Soll-Anschlagfläche axial an der Gegenanschlagfläche (46) anliegt,

g) basierend auf der Soll-Anschlagfläche, Positionieren des Kolbens (40) und des Toleranzausgleichselements (70) in Bezug zueinander, so dass die Soll-Anschlagfläche mit der Gegenanschlagfläche (46) drehend ausgerichtet ist,

h) Bilden der Kolben-Unterbaugruppe (40, 60, 70),

i) Bereitstellen des Ausstoßmechanismus und der ersten und zweiten Gehäusekomponente, und

j) dauerhaftes Befestigen der ersten und der zweiten Gehäusekomponente aneinander zur Ausbildung eines Gehäuses, wobei die Kolben-Unterbaugruppe (40, 60, 70) und der Ausstoßmechanismus relativ zu dem Gehäuse nicht entfernbar aufgenommen sind.

Revendications

1. Sous-ensemble de plongeur (40, 60, 70) pour un injecteur de médicament prérempli destiné à expulser une dose d'un médicament, comprenant :

- un récipient (60) contenant un médicament, le récipient (60) comprenant un corps de récipient cylindrique (61) s'étendant le long d'un axe central entre une extrémité distale d'expulsion de médicament et une extrémité proximale, dans lequel un piston coulissant axialement (63) est agencé au sein du corps de récipient (61) pour sceller le récipient de manière proximale, et dans lequel l'extrémité proximale du corps de récipient (61) comprend une surface de rebord orientée de manière proximale (64),
- un plongeur (40) agencé le long de l'axe et configuré pour entraîner le piston (63) de manière distale par rapport à la surface de rebord orientée de manière proximale (64), le plongeur (40) étant mobile de manière distale à partir d'une position de départ où le plongeur (40) ne coopère pas avec la surface de rebord orientée de manière proximale (64) jusqu'à une position de fin par rapport au contenant (60) où le plongeur (40) coopère avec la surface de rebord orientée de manière proximale (64) empêchant ainsi le plongeur (40) de se déplacer davantage de manière distale, le piston (63) prenant une position de fin de dose par rapport à la surface de rebord orientée de manière proximale (64) lorsque le plongeur (40) prend la position de fin, et
- un moyen de blocage réglable associé au plongeur (40) et au contenant (60) pour fournir un moyen de blocage axial du plongeur (40) dans la position de fin,

dans lequel le moyen de blocage réglable comprend un élément de compensation de tolérance (70) configuré pour coopérer avec le plongeur (40) et pour coopérer avec la surface de rebord orientée de manière proximale (64), dans lequel l'élément de compensation de tolérance (70) est rotatif par rapport au plongeur (40) pour régler l'extrémité de piston de la position de dose par rapport à la surface de rebord orientée de manière proximale (64),

dans lequel l'élément de compensation de tolérance (70) est configuré de telle sorte que, lorsque le plongeur (40) prend la position de fin,

le plongeur (40) vient directement en prise avec le piston (63), tandis que l'élément de compensation de tolérance (70) vient directement en prise à la fois avec le plongeur (40) et avec la surface de rebord orientée de manière proximale (64),

caractérisé en ce que l'un du plongeur (40) et de l'élément de compensation de tolérance (70) comprend un système de contour comprenant une pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) qui sont agencées de manière décalée axialement les unes par rapport aux autres, et dans lequel l'autre du plongeur (40) et de l'élément de compensation de tolérance (70) comprend une surface de contre-butée (46) agencée pour venir axialement en prise avec une surface sélective parmi la pluralité de surfaces de butée circonférentiellement (76.1, 76.2, 76.7, 76.13), et

dans lequel, une fois dans une configuration d'assemblage initiale, l'élément de compensation de tolérance (70) et le plongeur (40) sont positionnables ou positionnés de manière sélective l'un par rapport à l'autre pour aligner de manière rotative la surface de contre-butée (46) avec une surface sélective parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) pour commander ainsi de manière réglable la position de fin du plongeur (40) par rapport au récipient (60), permettant ainsi à la surface de contre-butée (46) de buter axialement contre la surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13).

2. Sous-ensemble de plongeur (40, 60, 70) selon la revendication 1, dans lequel, lorsque le plongeur (40) prend la position de fin, une géométrie orientée de manière distale (41) du plongeur (40) vient directement en prise avec le piston (63), tandis que l'élément de compensation de tolérance (70) vient directement en prise à la fois avec le plongeur (40) et avec la surface de rebord orientée de manière proximale (64), et dans lequel l'élément de compensation de tolérance (70) est formé comme un collier agencé circonférentiellement par rapport au plongeur (40) et ayant une surface annulaire distale (74), la surface annulaire distale (74) étant configurée pour venir en prise avec la surface de rebord orientée de manière proximale (64).

3. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 2, dans lequel la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) du système de contour définissent une pluralité de crans qui sont agencés circonférentiellement et décalés axialement les uns par rapport aux autres.

4. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 3, dans lequel, dans une configuration d'assemblage finale, l'élément de compensation de tolérance (70) et le plongeur (40) sont positionnés bloqués en rotation l'un par rapport à l'autre avec un alignement en rotation de la surface de contre-butée (46) avec la surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13), amenant ladite surface de contre-butée (46) à buter axialement contre ladite surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.7, 76.13) pour commander ainsi la position de fin du plongeur (40) par rapport au corps de récipient (61).

5. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 4, dans lequel le plongeur (40) et l'élément de compensation de tolérance (70) viennent en prise l'un avec l'autre au moyen d'un système à rainure et languette (43, 73), le système à rainure et languette définissant au moins une languette (43) et une pluralité de rainures s'étendant axialement (73) disposées dans une configuration coaxiale, dans lequel la languette (43) est positionnable ou positionnée dans une rainure sélective parmi ladite pluralité de rainures s'étendant axialement (73) pour aligner en rotation ladite surface de contre-butée (46) avec la surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) permettant ainsi un mouvement de coulissement axial du plongeur (40) et de l'élément de compensation de tolérance (70) l'un par rapport à l'autre tout en empêchant un mouvement de rotation relatif entre eux.

6. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 4, dans lequel l'injecteur définit un composant de base (21) qui est monté axialement fixe par rapport au corps de récipient (61) et qui encercle partiellement ou complètement le plongeur (40), dans lequel le plongeur (40) et le composant de base (21) sont montés de manière non rotative l'un par rapport à l'autre, dans lequel le composant de base (21) et l'élément de compensation de tolérance (70) viennent en prise l'un avec l'autre au moyen d'un système à rainure et languette (25, 75), le système à rainure et languette définissant au moins une languette (75) et une pluralité de rainures s'étendant axialement (25) disposées dans une configuration coaxiale, et dans lequel la languette (75) est positionnable ou positionnée dans une rainure sélective parmi ladite pluralité de rainures s'étendant axialement (25) pour aligner en rotation ladite surface de contre-butée (46) avec la surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) pour empêcher une rotation relative entre le composant de base (21) et l'élément de compensation de tolérance (70).

7. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 6, dans lequel ladite surface de contre-butée (46) et des surfaces de contre-butée correspondantes supplémentaires (46) sont fournies sous la forme d'une pluralité de surfaces de contre-butée disposées circonférentiellement (46) réparties régulièrement autour de l'axe central, dans lequel les surfaces respectives parmi la pluralité de surfaces de contre-butée disposées circonférentiellement (46) sont configurées pour venir simultanément en prise axialement avec une surface respective parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13).

8. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 5 à 7, dans lequel la rainure (73 ; 25) et la languette (43 ; 75) comprennent des surfaces de mise en prise configurées de telle sorte que l'élément de compensation de tolérance (70) et le plongeur (40) peuvent être positionnés sélectivement en rotation l'un par rapport à

l'autre par crans angulaires incrémentiels ayant une taille de cran entre 5 et 1 degrés, de préférence entre 10 et 30 degrés.

9. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 8, dans lequel le plongeur (40) et l'élément de compensation de tolérance (70), dans une configuration d'assemblage finale, sont empêchés de tourner l'un par rapport à l'autre au moyen d'un blocage de rotation (43, 73 ; 25, 75).

10. Sous-ensemble de plongeur (40, 60, 70) selon la revendication 9, dans lequel le blocage de rotation est formé par des géométries rigides coopérantes.

11. Sous-ensemble de plongeur (40, 60, 70) selon la revendication 9, dans lequel le blocage de rotation est formé par un mécanisme de verrou de rotation.

12. Sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 11, dans lequel le récipient (60) du sous-ensemble de plongeur définit une cartouche qui comprend un septum qui scelle une extrémité distale d'expulsion du corps de récipient (61), le septum pouvant être pénétré par une canule d'aiguille pour établir une communication fluidique avec l'intérieur du récipient.

13. Injecteur de médicament prérempli destiné à expulser une dose d'un médicament, comprenant :

- un boîtier comprenant des premier et second composants de boîtier,
- un sous-ensemble de plongeur (40, 60, 70) selon l'une quelconque des revendications 1 à 12, et
- un mécanisme d'expulsion comprenant un actionneur configuré pour, lors de l'activation, exercer une force dirigée de manière distale sur le plongeur (40) pour expulser la dose du médicament,

dans lequel le sous-ensemble de plongeur (40, 60, 70) et le mécanisme d'expulsion sont logés de manière non amovible par rapport aux premier et second composants de boîtier.

14. Injecteur de médicament prérempli selon la revendication 13, dans lequel l'élément de compensation de tolérance (70) et le plongeur (40) sont positionnés l'un par rapport à l'autre en fournissant un alignement rotatif permanent entre la surface de contre-butée (46) et une surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13), permettant ainsi à ladite surface de contre-butée (46) de buter axialement contre ladite surface sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) pour commander ainsi la position de fin du plongeur (40) par rapport au récipient (60).

15. Procédé d'assemblage d'un injecteur de médicament prérempli selon la revendication 14, comprenant les étapes de :

a) fourniture du récipient (60),
b) détermination de la position axiale (X1) d'une face proximale du piston (63) par rapport à la surface de rebord orientée de manière proximale (64),
c) établissement d'une extrémité axiale cible de position de dose (X2) de la face proximale du piston (63) par rapport à la surface de rebord orientée de manière proximale (64) pour obtenir une course axiale cible prédéterminée (XS) pour le piston (63),
d) fourniture du plongeur (40) et de l'élément de compensation de tolérance (70),
e) sur la base de l'extrémité axiale cible de la position de dose (X2) de la face proximale du piston (63), détermination d'une position de fin axiale cible pour la face d'extrémité distale du plongeur (40),
f) sur la base de ladite position de fin axiale cible pour la face d'extrémité distale du plongeur (40), détermination d'une surface d'arrêt cible sélectionnée parmi la pluralité de surfaces de butée disposées circonférentiellement (76.1, 76.2, 76.7, 76.13) de sorte que la position de fin axiale de la face d'extrémité distale du plongeur (40) correspond sensiblement à l'extrémité axiale cible de la position de dose (X2) de la face proximale du piston (63) lorsque ladite surface d'arrêt cible bute axialement contre la surface de contre-butée (46),
g) sur la base de la surface d'arrêt cible, positionnement du plongeur (40) et de l'élément de compensation de tolérance (70) l'un par rapport à l'autre de sorte que la surface d'arrêt cible s'aligne en rotation avec la surface de contre-butée (46),
h) formation du sous-ensemble de plongeur (40, 60, 70),
i) fourniture du mécanisme d'expulsion et des premier et second composants de boîtier, et
j) fixation de manière permanente du premier et du second composant de boîtier l'un à l'autre pour former un boîtier, où le sous-ensemble de plongeur (40, 60, 70) et le mécanisme d'expulsion sont logés de manière non amovible par rapport au boîtier.

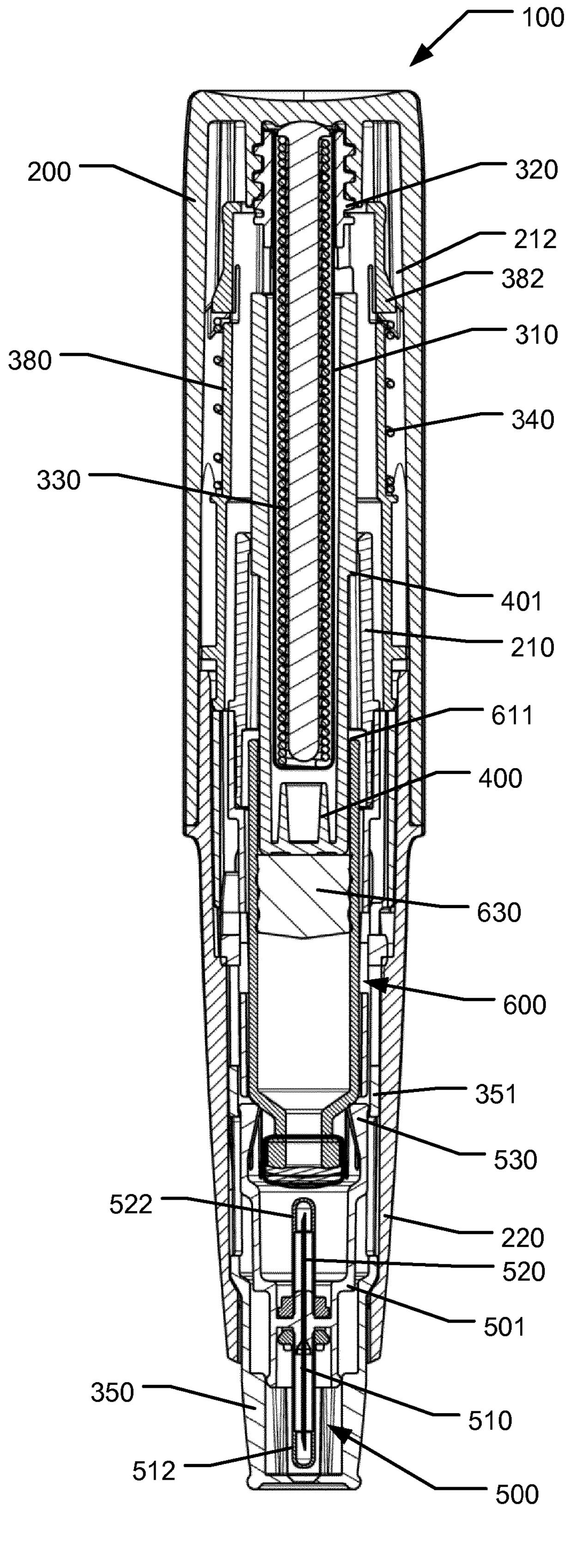
100
200
320
212
382
310
380
340
330
401
210
611
400
630
600
351
530
522
220
520
501
350
510
512
500

Fig. 1a

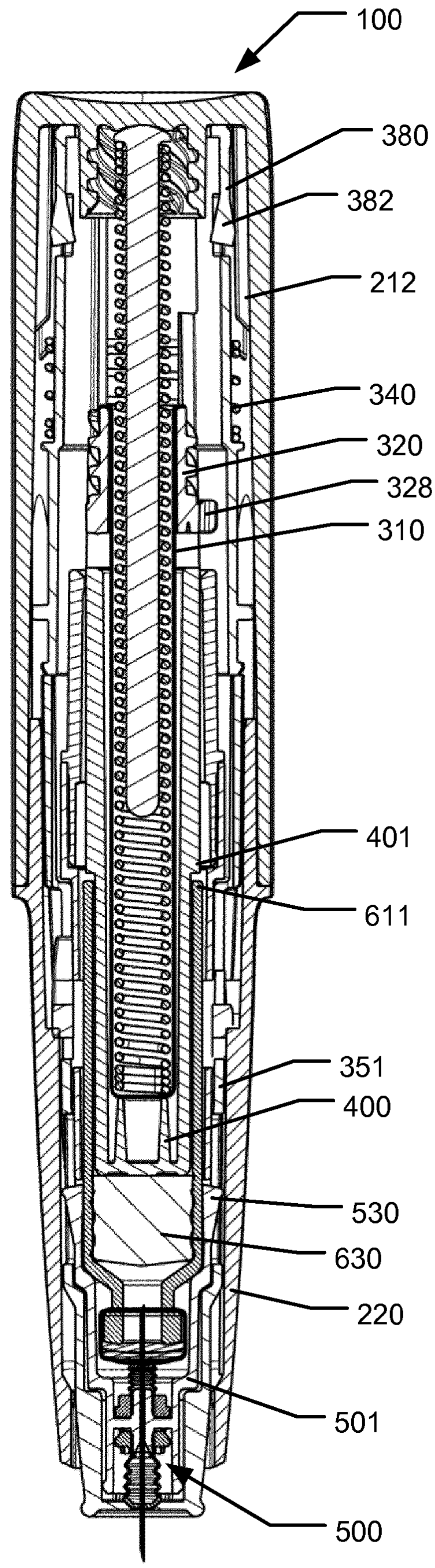
100
380
382
212
340
320
328
310
401
611
351
400
530
630
220
501
500

Fig. 1b

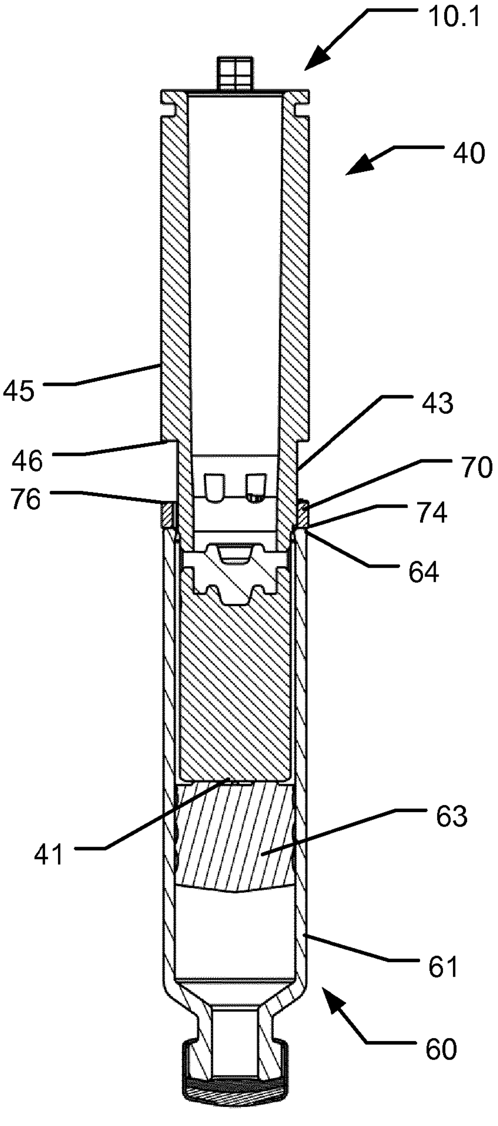

Fig. 2

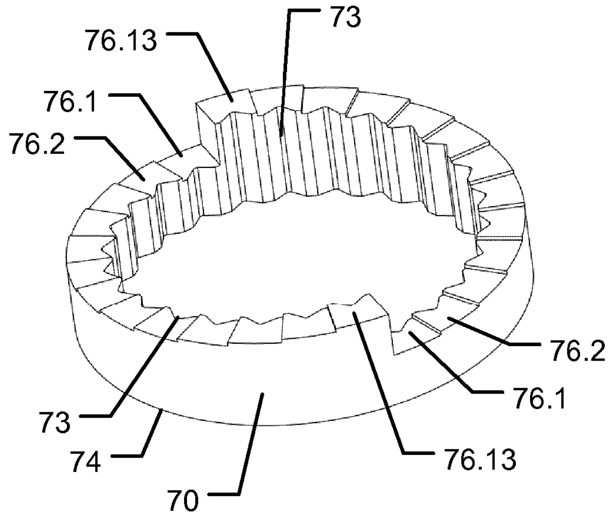

Fig. 3

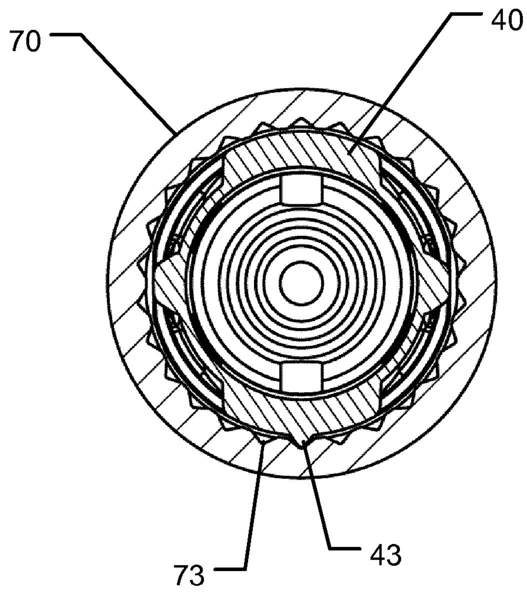

Fig. 4

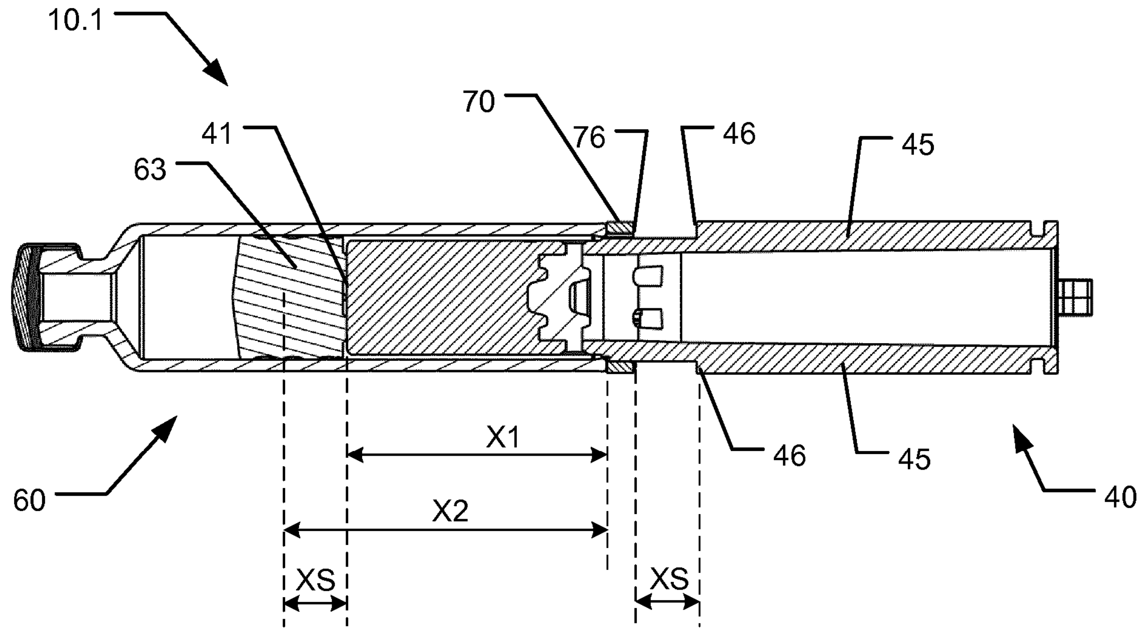

Fig. 5

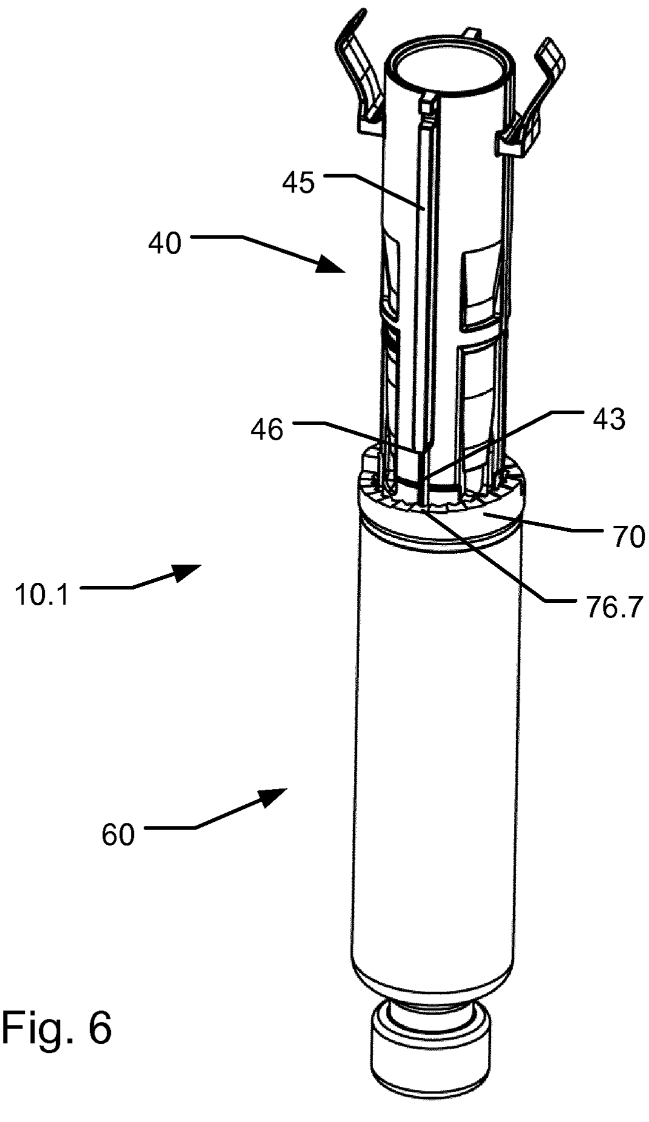

Fig. 6

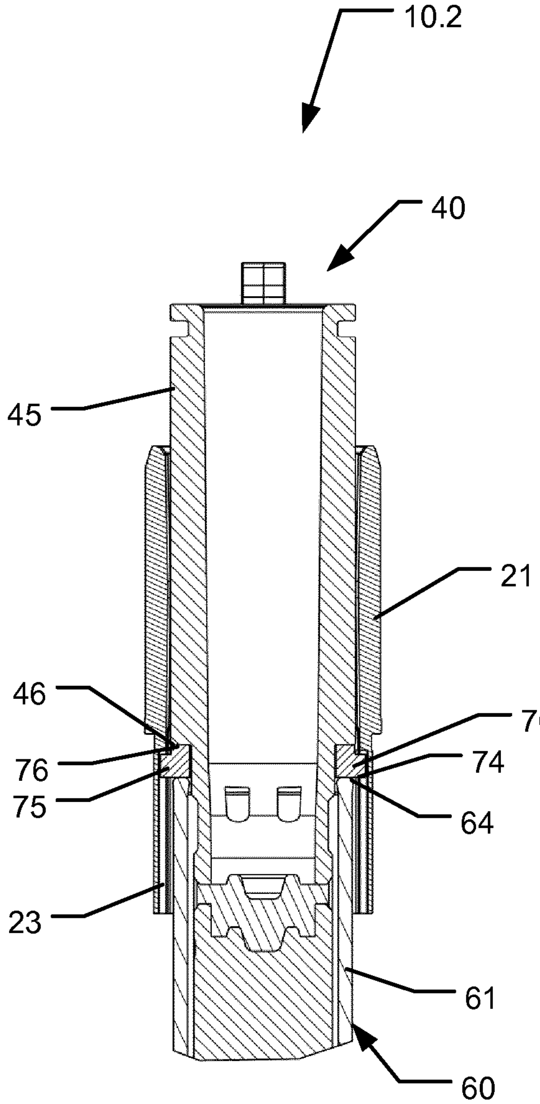

Fig. 7

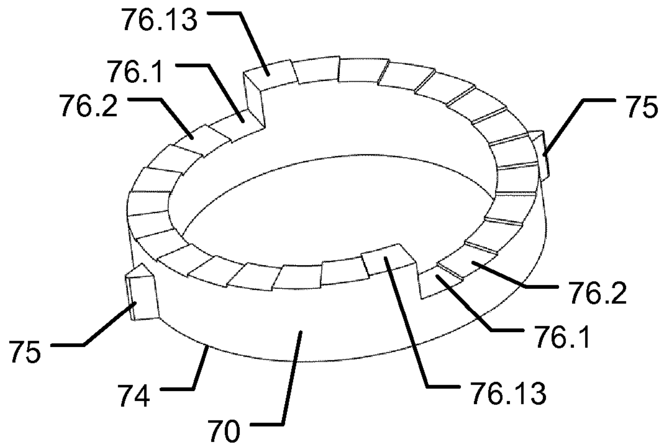

Fig. 8

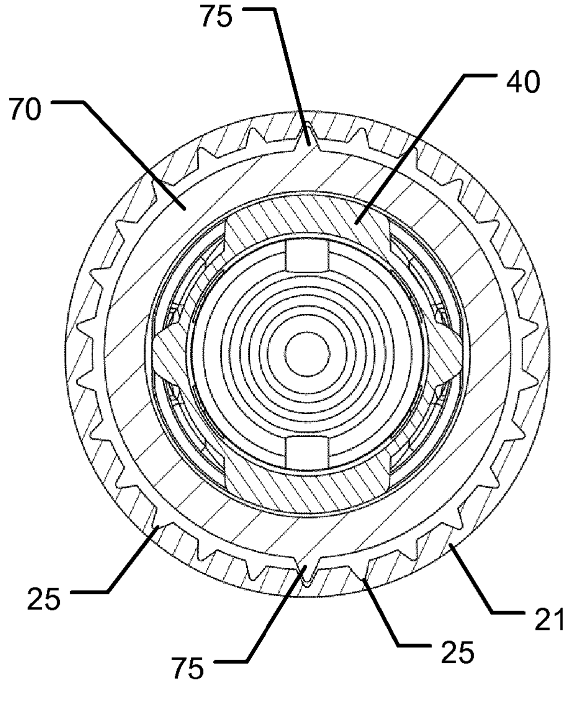

Fig. 9

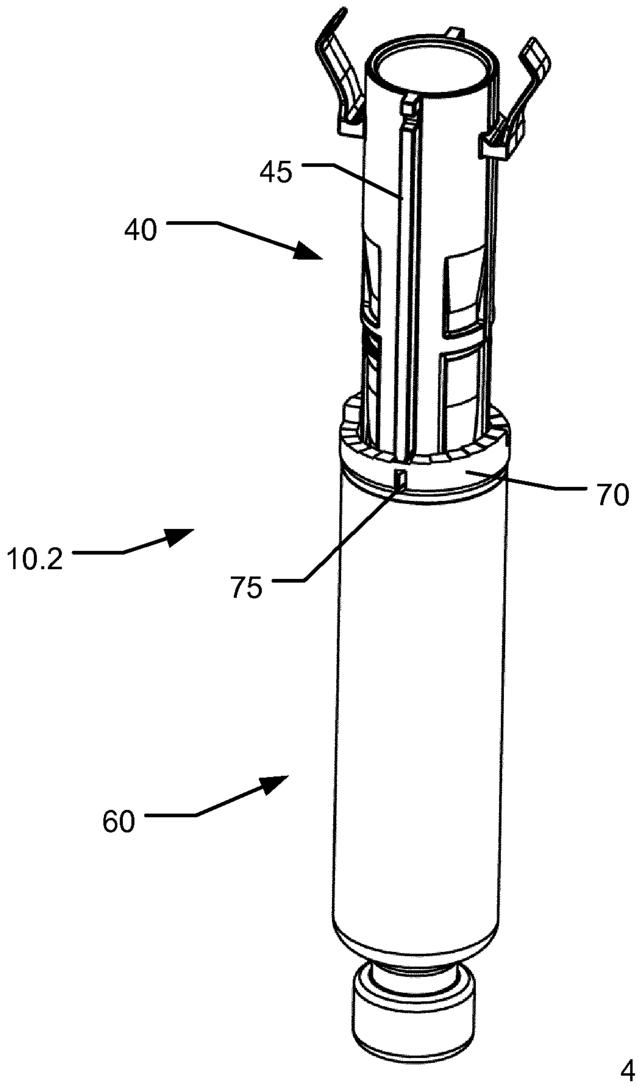

Fig. 10

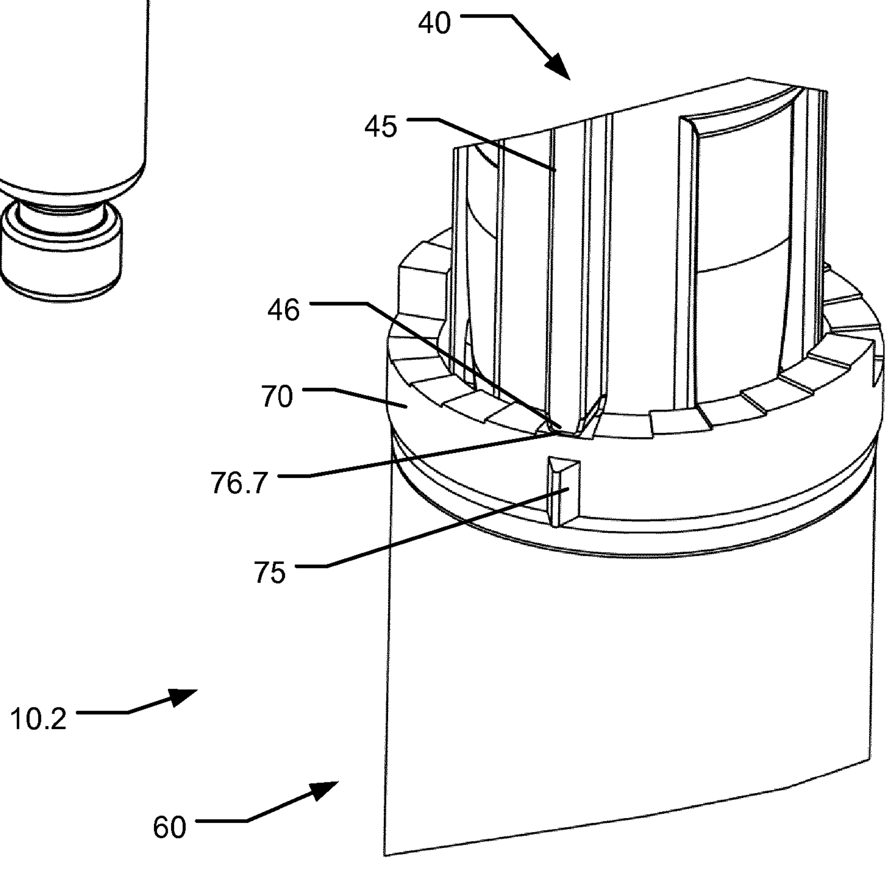

Fig. 11

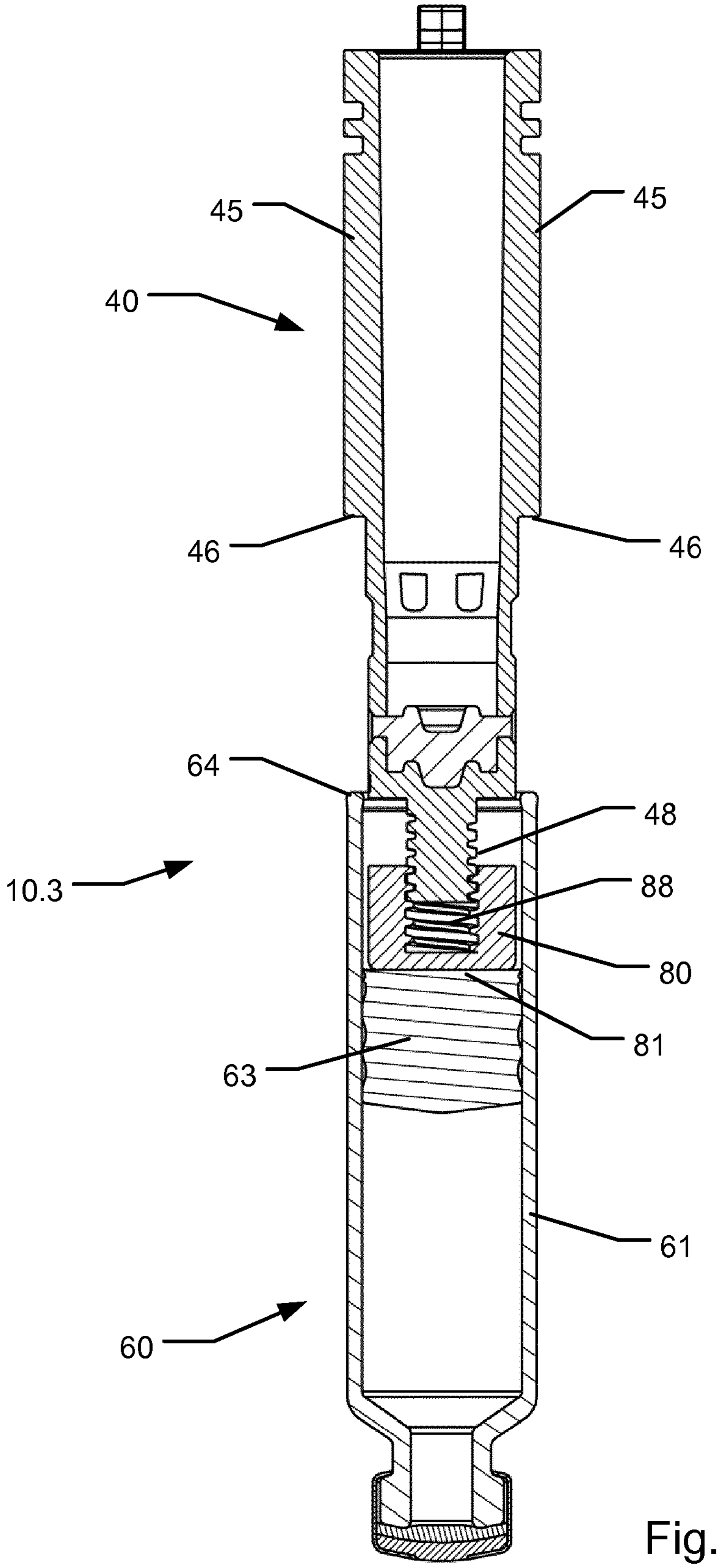

Fig. 12

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO 2016075254 A1 **[0002] [0038]**
- WO 2011121061 A **[0003]**
- US 5695472 A **[0004]**
- EP 1324794 A2 **[0005]**