(19) DANMARK

(10) **DK/EP 2913075 T3**

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: ***A 61 M 5/315 (2006.01)***

(45) Oversættelsen bekendtgjort den: **2017-08-28**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2017-05-03**

(86) Europæisk ansøgning nr.: **15151119.3**

(86) Europæisk indleveringsdag: **2010-03-29**

(87) Den europæiske ansøgnings publiceringsdag: **2015-09-02**

(30) Prioritet: **2009-10-30 PL 38942709**

(62) Stamansøgningsnr: **10713161.7**

(84) Designerede stater: **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 SE SI SK SM TR**

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(54) Benævnelse: **AUTOMATISK APPLIKATOR TIL FLYDENDE FARMACEUTISKE MIDLER**

(56) Fremdragne publikationer:
EP-A2- 0 338 806
WO-A1-99/38554
WO-A1-2009/039851

DESCRIPTION

The field of the invention

[0001] The present invention concerns an automatic applicator for liquid pharmaceutical preparations, particularly for insulin, more particularly for multiple injection application of set doses of a medicine from an exchangeable container, for example for the self-application of insulin by diabetes patients.

The state of art

[0002] The European patent EP 0 338 806 B1 (Holman and Marchall) which discloses the closest prior art, teaches a syringe comprising a body, a dose-setting device in the form of a rotary cap or ring mounted on the body and capable of being moved to a selected set position where a latch is arranged to retain the setting device in that set position, the movement of the setting device being accompanied by straining of a spring, which, when the latch is released, provides the force for expelling the set dose, characterised by means arranged to release the latch, which causes the return of the setting device to an original position to drive a plunger through a one-way clutch to expel the set dose; and by a quick pitch screw thread arrangement capable of transforming rotation of the setting device into linear movement of the plunger.

[0003] Also Polish patent application P 341 395 teaches a syringe for distribution of set doses of a medicine from a cartridge containing the amount of the medicine sufficient to prepare several treatment doses, comprising a housing, a piston rod having noncircular cross-section and an external screw thread, a piston rod drive arrangement comprising two elements, i.e. piston rod leaders and a nut with an internal screw thread corresponding to the piston rod external screw thread, as well as a dose-setting mechanism comprising non-self-blocking screw thread connection, along which an injection push-button is unscrewed from the nearer housing end, causing rotation of the dose-setting element. This syringe is characterised in that between the nut and the piston rod leaders there is unidirectional coupling enabling the rotation of both these parts in one direction but not in the opposite direction, wherein the allowed rotation is the only one, by means of which the piston rod is moved in the circumferential direction in the syringe. The coupling is designed in such way that the initial resistance, sufficient to resist the torque exerted on the coupling by setting a dose, has to be overcome to allow rotation. The marks indicating the size of the selected dose could be placed under the housing.

[0004] The main disadvantage of the known devices is lack of the provision of application of the precisely controlled and set dose of a medicine.

[0005] The above discussed syringe for manual application of a medicine requires from a patient the manual adjustment of the pressure force on the injection push-button, which defines the speed of the injection. This causes additional stress and discomfort at application. An additional disadvantage is a complex arrangement to transform the linear displacement of the injection push-button into the linear displacement of the piston rod by means of the rotary movement of the nut. Other disadvantages of a syringe for an application of a medicine using a tensioned spring comprise the failure prone construction of the trigger device, which does not ensure reliable nut blocking, and the lack of an external guiding means for the tensioned spring. This negatively affects maintaining the control and the precision of the application of the set dose of a medicine.

[0006] Besides, known devices do not ensure adequate protection against damaging the clutch or the driving arrangement due to excessive rotation of the dose-setting element. Also, forces of friction opposing the action of the plunger are too large. The arrangements for dose indication in known devices are too complex and the scale usually placed on the external surface of the housing can be easily effaced.

Aims of the invention

[0007] The main aim of the present invention concerning an automatic applicator particularly for insulin, more particularly for multiple injection application of set doses of a medicine from an exchangeable container, is to ensure a capability for the precisely controlled application of the set dose of a medicine, preserving an automatic application of the medicine without any stress, providing external guidance for the tensioned spring and providing adequate protection against damaging the clutch or the driving arrangement due to excessive rotation of the dose-setting element.

[0008] The second aim of the invention is to ensure the reduction of forces of friction opposing the action of the plunger and provide reliable nut blocking by means of a reliable construction of a trigger device, preserving an automatic application of the medicine.

[0009] The third aim of the present invention concerning an automatic applicator is to ensure an indicator device having the scale marks placed not on the external surface of the housing, which prevents effacing them during the operating of the applicator by its user.

The summary of the invention

[0010] The main goal of the present invention has been achieved by an automatic applicator for liquid pharmaceutical preparations, comprising a body housing, having a plunger, driven via a double action clutch unit, by a tensioning spring situated in the body housing, wherein the said tensioning spring is a twisted spring, the said tensioning spring tensioned by a rotary

hand-dose-setting ring via the same double action clutch unit, wherein the said driving unit is activated by a trigger unit and a dose is indicated by an indicating arrangement via an inspection window. According to the present invention the said automatic applicator is characterised in claim 1 in that the double action clutch unit comprises a coupling sleeve that is rigidly connected to the rotary hand-dose-setting ring and radially coupled with a body of a ratchet barrel that is rigidly connected to the tensioning spring that is connected to a spring block that is rigidly connected to the body housing and secured against rotation.

[0011] The said automatic applicator comprises at least one block key placed in the upper part of the ratchet barrel, collaborating with at least one key placed in the internal part of the cylindrical body housing.

[0012] Preferably, when the coupling sleeve is rotated clockwise for increasing a dose, a resilient arm of a pawl of the ratchet barrel is displaced on slide edges of a ratchet tooth ring, from one blocking edge of the ratchet tooth ring to the neighbor edge depending on an angle of rotation.

[0013] Preferably, when the coupling sleeve is rotated by turning the rotary hand-dose setting ring clockwise for increasing a dose, the ratchet barrel is rotated together with the coupling sleeve and the resilient arm of the pawl is displaced radially, alternatively inside and outside.

[0014] The pawl can be separately meshed with the ratchet tooth ring via a hook.

[0015] Preferably, the body of the ratchet barrel is rigidly connected to a tensioning spring holder which enables transfer of the rotation of the rotary hand-dose-setting ring to the tensioning spring holder.

[0016] The driving unit can be released by pressing the trigger unit and can continue to operate while the trigger unit is pressed by being driven by force from the tensioning spring to unscrew the plunger by acting on a thread of the plunger.

[0017] After the trigger unit is released, it can be urged to return to the initial position by a spring placed directly under the trigger unit.

[0018] The tensioning spring can be mounted, from the side of the needle, in the tensioning spring holder having the form of a protective sleeve rigidly connected to the body of the ratchet barrel.

[0019] The plunger can comprise at least one longitudinal groove enabling linear displacement of the plunger in a plunger block guide by means of at least one key.

[0020] The novel construction of the automatic applicator enables the precisely controlled application of the set dose of a medicine, preserving an automatic application of the medicine without any stress, providing external guidance for the tensioned spring and providing

adequate protection against damaging the clutch or the driving arrangement due to excessive rotation of the dose-setting element.

[0021] Advantageously the automatic applicator comprises two block keys placed directly on the circumferential surface of the ratchet barrel, collaborating with two keys on the internal part of the cylindrical surface of the cylindrically shaped body housing, placed above a viewing window.

[0022] The second goal of the present invention has been achieved by an automatic applicator variant wherein the integrated driving unit, suitable for immobilising, driving, leading linearly and blocking rotation of the plunger, comprises a plunger block guide and a driving nut, whereas the plunger block guide is blocked in a toothed ring of the seat element, urged to it by means of the container housing of the exchangeable insulin container, and in the said integrated driving unit a nut is bearingly mounted in a seat element, advantageously by means of a ball bearing.

[0023] Owing to such construction, there is provided reliable driving nut blocking, minimally affecting the positioning of the nut and simultaneously preventing any its rotation or influencing the position of the plunger during dose setting, as well as ensured the reduction of forces of friction opposing the action of the plunger.

[0024] Further, advantageously the driving tensioning spring is a twisted spring and the second spring is placed directly under the trigger unit.

[0025] The third goal of the present invention has been achieved by an automatic applicator variant, in which the indicating arrangement comprises a scale deposited linearly on a cylindrical part of the ratchet barrel under the block keys and an inspection window situated in the cylindrically shaped body housing. Owing to such construction, the scale is appropriately displaced during dose setting and is well visible in the inspection window.

Description of the drawings

[0026] The present invention has been presented in detail, in the advantageous example of its embodiment, in the drawings, where

Fig. 1 presents the longitudinal section of the automatic applicator, without an exchangeable container and its casing,

Fig. 2 presents the cross-section B-B of the ratchet mechanism of the automatic applicator with the pawls meshed with the toothed ring of the nut,

Fig. 3 presents the cross-section C-C of the automatic applicator from the Fig.1, in the place, in which the trigger mechanism meshes with the toothed ring of the nut,

Fig. 4 presents the cross-section D-D of the automatic applicator from the Fig.1, showing the system blocking the rotation of the scale, which defines the working range of the automatic applicator,

Fig. 5 presents pictorially the cross-section E-E of the automatic applicator from the Fig.1, showing the positioning of the elements of the arrangement blocking the plunger against rotation,

Fig. 6 presents the front axonometric view of the automatic applicator from the Fig.1, with parts of the housings removed, showing the advantageous mutual positioning of the elements of the internal mechanisms of the automatic applicator, and

Fig. 7 presents the exploded front axonometric view of the automatic applicator from the Fig.1.

The embodiment of the invention

[0027] As shown in the figures 1, 6 and 7, an automatic applicator for liquid pharmaceutical preparations, particularly for insulin, more particularly for multiple injection application of set doses of a medicine from an exchangeable container, comprises a body housing 1, connected to a housing 2 of an exchangeable container with a medicine (not shown in the drawings). The insulin is expelled by a plunger 12, linearly displaced by means of a driving unit, suitable for immobilising, driving, leading linearly and blocking rotation of the plunger 12, driven via a double action clutch unit by a tensioning spring 15, wherein the driving tensioning spring 15 is a twisted spring situated in the body housing 1, tensioned by a rotary hand-dose-setting ring 3 also via a double clutch unit, wherein the driving unit is activated by a trigger unit 13 and a displaceable indicating cylinder is situated on a tensioning spring 15 holder and a scale 5.7 with the scale visible in an inspection window 1.1 deposited on a ratchet barrel 5.

[0028] The automatic applicator for liquid pharmaceutical preparations, particularly for insulin, more particularly for multiple injection application of set doses of a medicine from an exchangeable container, operates as follows.

[0029] In order to replace the insulin container you should unscrew the container housing 2, which is connected to the body housing 1 (Fig.1) by turning it anti-clockwise. After unscrewing the container housing 2, a plunger block guide 11 and a seat element 9 become automatically disengaged owing to the action of a disengaging spring 10 by means of moving the plunger block guide 11 coaxially in the direction of plunger 12. This enables hand backing of the plunger 12 by using the force in the axial direction to push it into the body housing 1. A plunger ending 12.1 is independently rotated on the plunger 12. The coupling between the plunger 12 and a nut 7 is by a quick thread, so while being pushed into the housing 1 the plunger 12 screws itself into the nut 7. The plunger should be pushed until it almost completely hides in the housing 1, which allows a new container with insulin to be inserted.

[0030] The nut 7 is coupled to the plunger 12 by a thread having pitch enabling application of the appropriate dose of insulin. Further, the nut 7 is bearingly mounted in the seat element 9, advantageously by means of a ball bearing 8.

[0031] Then you should remove the needle (not shown) mounted on the housing 2 by turning it anti-clockwise, remove the empty container by withdrawing it from the container housing 2 and install a new container.

[0032] To install a new container you should insert it into the container housing 2, which you should place in the body housing 1 by turning it clockwise. Next you should fix a new needle and cover it with a protecting cap.

[0033] The dose-setting is carried out by turning the rotary hand-dose-setting ring 3 (Fig.1) clockwise. The currently set dose can be seen on the cylindrical part of the ratchet barrel 5 by means of an inspection window 1.1 situated in the body housing 1, which together with the scale 5.7 deposited linearly under the block keys 5.6 comprises an indicating arrangement. The cylinder of the ratchet barrel 5 is scaled by every four units and the turning of the rotary hand-dose-setting ring 3 is accompanied by a characteristic clicking at every two units, corresponding to 0.02 ml of insulin. The dose-setting can be realised up to two units, wherein the scale 5.7 visible through the inspection window 1.1, stops at any value or between the given dose values, which is easy to check as two consecutive doses are then seen in the inspection window 1.1, and a red line indicator shows the position between them.

[0034] The rotary hand-dose-setting ring 3 is rigidly connected to a coupling sleeve 6. When a dose is to be increased, the coupling sleeve 6 (Fig.2) is rotated clockwise (looking in the direction of the needle) wherein the resilient arm of a pawl 5.3 is displaced on the slide edges 7.5 of the ratchet tooth ring 7.1 of the stationary driving nut 7, from one blocking edge of the ratchet tooth ring 7.1 to the neighbour edge(s) depending on the angle of rotation. The ratchet barrel 5 is driven by the coupling sleeve 6 by means of a steering recess 6.1 made in the inner wall of the coupling sleeve 6 meshed with a key 5.4 situated in the inner wall of the ratchet barrel 5. Therefore, when the coupling sleeve 6 is rotated, the ratchet barrel 5 is rotated together with it. During the rotation in the clockwise direction, the resilient arm of the pawl 5.3 is displaced radially, alternatively inside and outside.

[0035] The ratchet barrel 5 is rigidly connected to the twisted spring 15, which in turn is connected to a spring block 4. The spring block 4 is rigidly connected to the body housing 1 and secured against rotation.

[0036] During the dose setting the nut 7 is immobilised by the trigger unit 13 by means of the rectangular grooves 7.7 (Fig.3) situated on the circumference of the nut 7, collaborating with a key 13.1 of the trigger unit 13.

[0037] The operational range of the automatic applicator is defined by two block keys 5.6

(Fig.4) placed directly on the circumferential surface of the ratchet barrel 5, collaborating with two keys 1.3 on the internal part of the cylindrical surface of the body housing 1 placed above the inspection window 1.1. The keys are situated on the opposite sides and simultaneously slightly displaced axially. Such arrangement enables realising one incomplete rotation of the dose setting elements.

[0038] After setting the dose you can actuate the dosing of insulin by pressing the trigger unit 13 in the direction of the needle. The trigger unit 13 should be pressed throughout the whole time of the insulin application. The range of the trigger displacement is defined by the displacement of the key 13.1 in the corresponding groove 1.2 in the body housing 1. After pressing the trigger unit 13 the nut 7 is released by the disengagement of the ring with the rectangular grooves 7.7 and the key 13.1 of the trigger unit 13. The mechanism starts rotating, driven by the force from the twisted spring 15. The nut 7 causes the unscrewing of the plunger 12 on the thread 12.1 of the plunger 12, The rotation of the plunger 12 is blocked by a key 11.1 of the plunger block guide 11 and a recess 12.2 made in the plunger 12 (Fig.5). The plunger 12 acts directly on the piston of the insulin container, placed in the container housing 2. It causes the injection of insulin from the needle mounted on the container housing 2. This action is accompanied by the reverse movement of the whole mechanism to its initial position, i.e. the twisted spring 15 unwinds, and the ratchet barrel 5 with the scale 5.7 returns to the position "0".

[0039] After completing the dose-setting you can release the trigger unit 13. The trigger unit 13 will then automatically return to its initial position urged by a spring 14, which is placed directly under the trigger unit 13, and will again block the nut 7.

[0040] The double action clutch unit best seen in the Fig. 2, which presents the cross-section B-B of the ratchet mechanism of the automatic applicator with the pawls meshed with the toothed ring of the nut comprises the coupling sleeve 6 radially coupled with the body of the ratchet barrel 5 and coupled with the pawls 5.3 having hooks separately meshed with the ratchet tooth ring 7.1 of the driving nut 7.

[0041] The coupling sleeve 6 is rigidly connected to the rotary hand-dose-setting ring 3 and the body of the ratchet barrel 5 is rigidly connected to the twisted spring 15 holder, in the form of a protective sleeve, which enables transfer of the rotation of the rotary hand-dose-setting ring 3 to the twisted spring 15 holder.

[0042] The twisted spring 15 (Fig.1 and Fig.6) is mounted, form the side of the needle, in the twisted spring 15 holder, in the form of a protective sleeve rigidly connected to the body of the ratchet barrel 5.

[0043] The integrated driving unit (Fig.5), suitable for immobilising, driving, leading linearly and blocking rotation of the plunger 12 comprises the plunger block guide 11 and the driving nut 7. The construction of the integrated driving unit enables hand backing of the plunger 12 by pushing it into the driving nut 7 in such way that it minimally protrudes from the housing, allows

a new container, eg. with insulin, to be inserted.

[0044] The nut 7 (as mentioned above) is coupled to the plunger 12 by a thread having pitch enabling application of the appropriate dose of insulin. Additionally, the plunger 12 comprises at least one longtitudal groove enabling linear displacement of the plunger 12 in the plunger block guide 11 by means of at least one key.

[0045] The trigger unit (Fig.3) constitutes the trigger 13 with the key 13.1 slidingly displaced in the groove 1.2 situated in the body housing 1 in order to block the ring with the rectangular grooves 7.7 of the driving nut 7.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- EP0338806B1 [0002]
- PLP341395 [0003]

P A T E N T K R A V

1. Automatisk applikator til flydende farmaceutiske midler, hvilken applikator omfatter et huslegeme (1), der har et stempel (12), som er egnet til at fortrænge medicinen og er lineært forskudt ved hjælp af en integreret drivenhed ved hjælp af en spændefjeder anbragt i huslegemet (1), hvilken drivenhed drives via en dobbeltvirkende koblingsenhed, hvor spændefjederen (15) er en snoet fjeder, hvor spændefjederen spændes ved en roterende hånddoseringsindstillingsring (3) via den samme dobbeltvirkende koblingsenhed, hvor drivenheden er aktiveret ved at trykke på en udløserenhed (13), og en dosis er indikeret ved et indikationsarrangement via et inspektionsvindue (1.1), k e n d e t e g n e t ved, at den dobbeltvirkende koblingsenhed omfatter en koblingsmuffe (6), der er stift forbundet til den roterende hånddoseringsindstillingsring (3) og radialt koblet til et legeme af en skraldetromle (6), som er stift forbundet til spændefjederen (15), der er forbundet til en fjederblok (4), som er stift forbundet til huslegemet (1) og sikret mod rotation.

2. Automatisk applikator ifølge krav 1, hvor legemet af skraldetromlen (5) er stift forbundet til en holder til spændefjederen (15), hvilken forbindelse muliggør overførsel af rotationen fra den roterende hånddosseringsindstillingsring (3) til holderen af spændefjederen (15).

3. Automatisk applikator ifølge et hvilket som helst af de foregående krav, hvor drivenheden bliver frigjort ved at trykke på en udløserenhed (13) og fortsætter med at være i drift, mens udløserenheden (13) bliver trykket ned ved at blive drevet af en kraft fra spændefjederen (15), hvilket skruer stemplet (12) ud ved at påvirke et gevind (12.1) af stemplet (12).

4. Automatisk applikator ifølge et hvilket som helst af de foregående krav, hvor spændefjederen (15) er monteret i holderen til spændefjederen (15) fra siden af nålen, hvilken holder har form som en beskyttende muffe, der er stift forbundet til legemet af skraldetromlen (5).

DRAWINGS

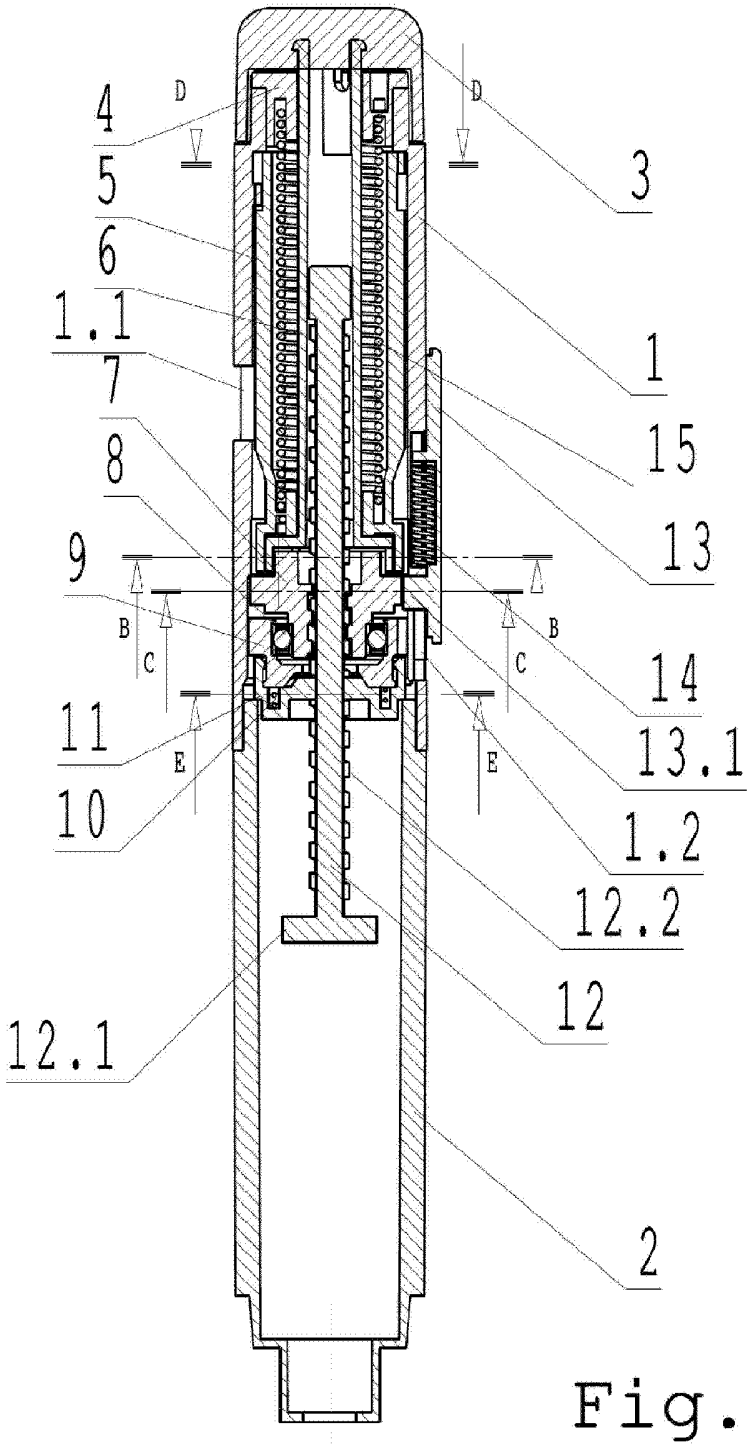

Fig.1

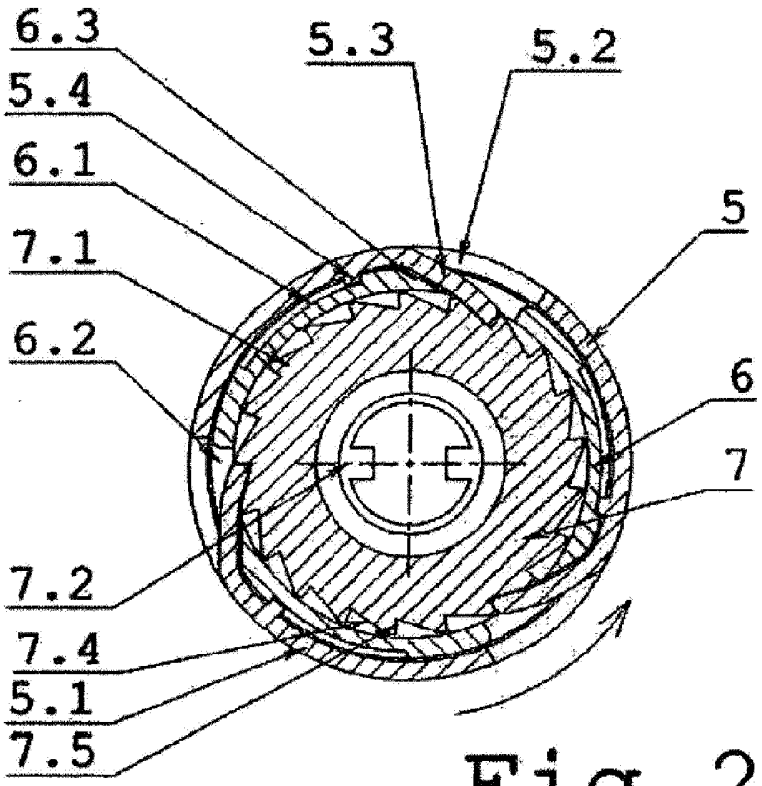

Fig.2

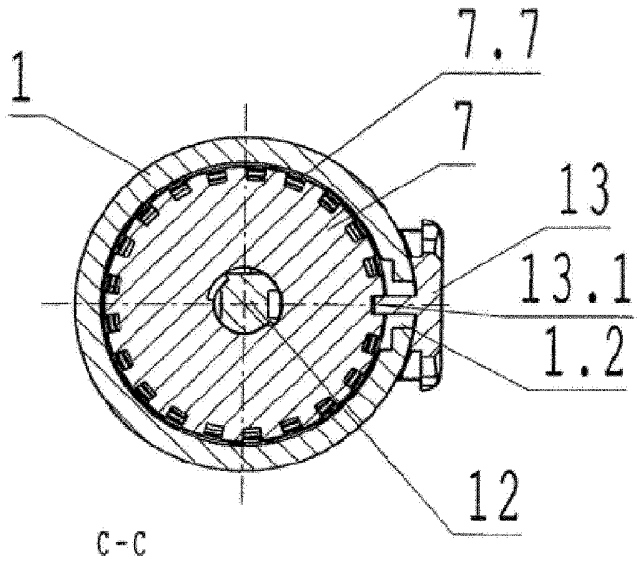

Fig.3

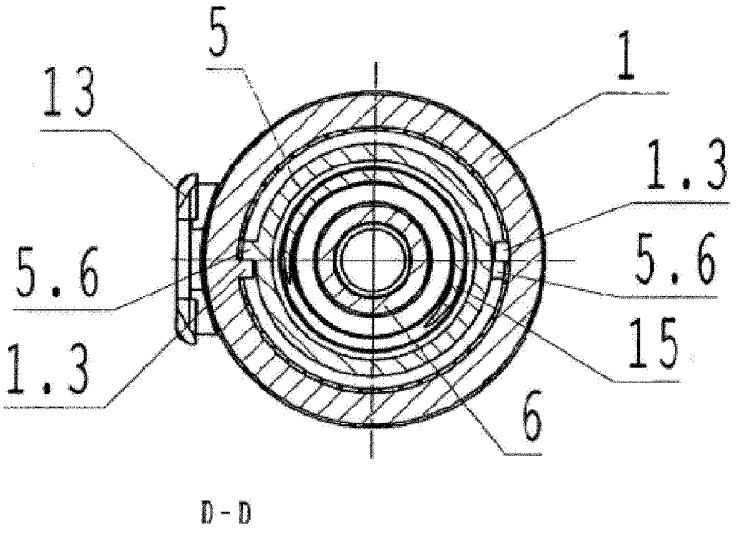

Fig.4

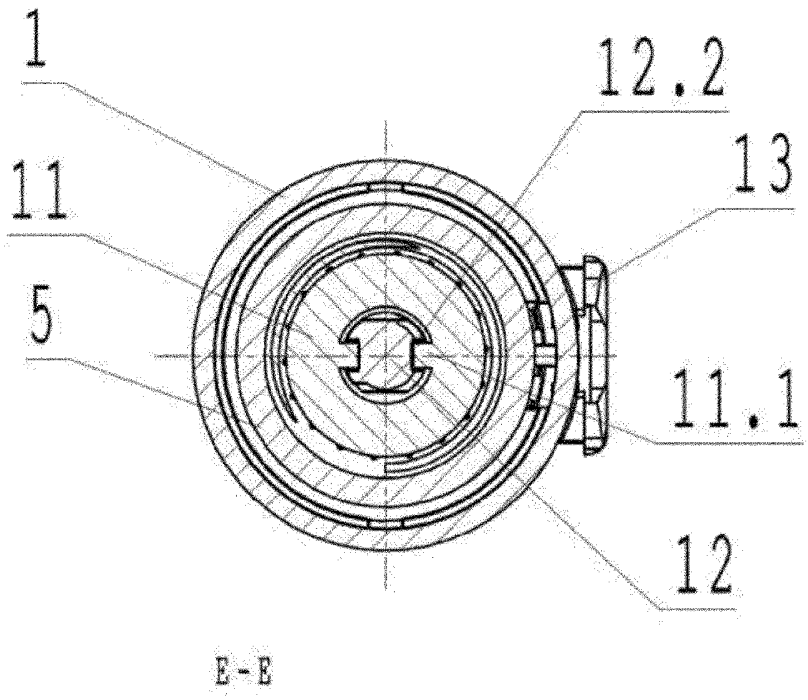

Fig.5

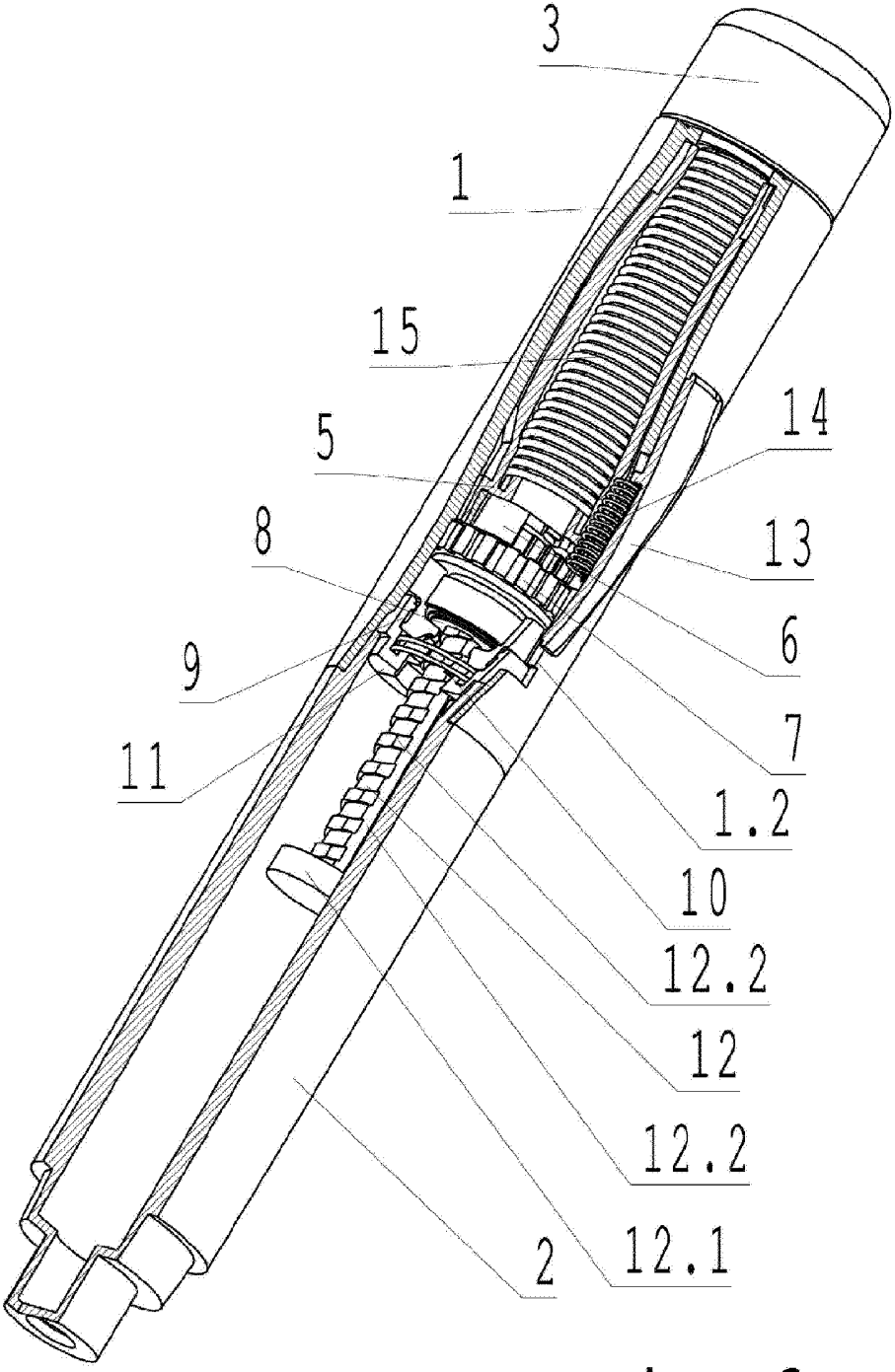

Fig.6

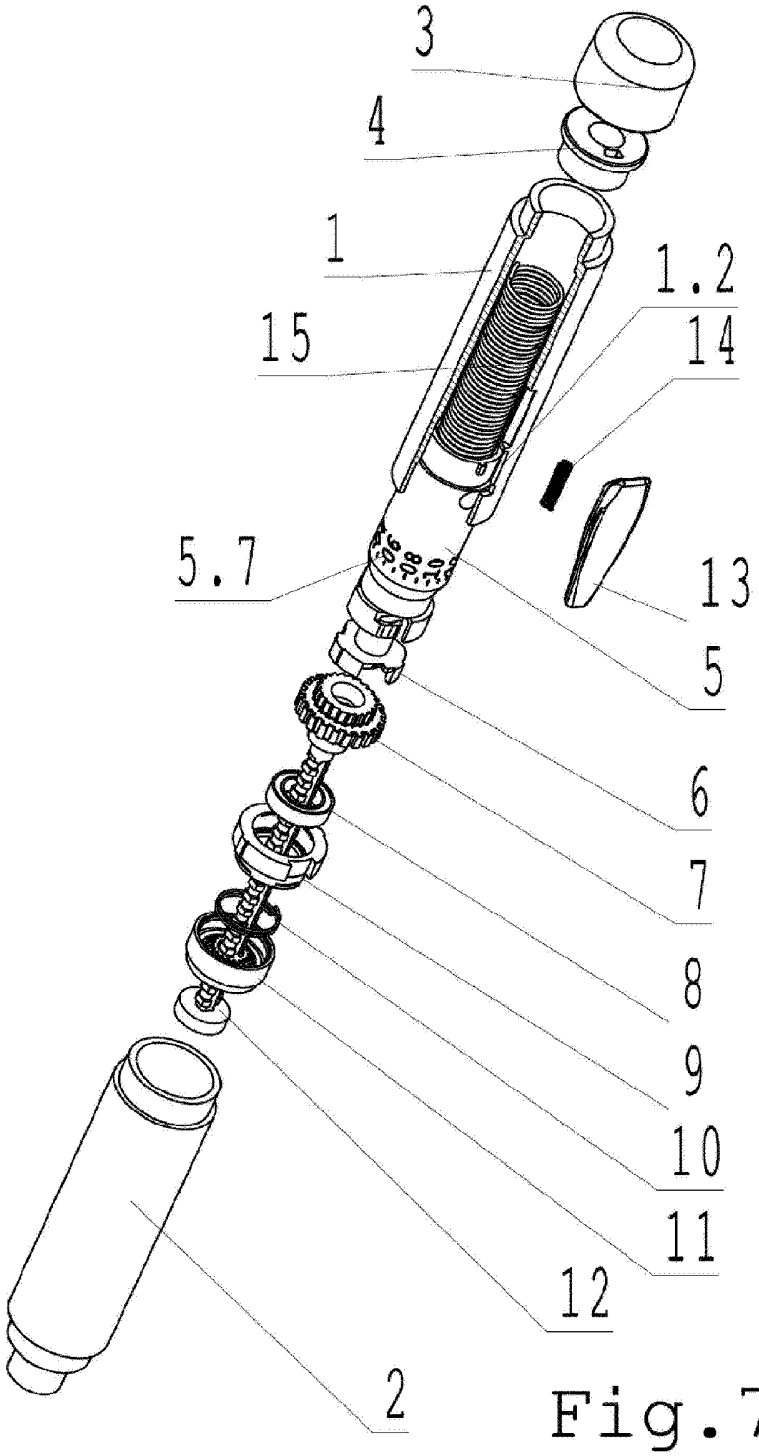

Fig.7