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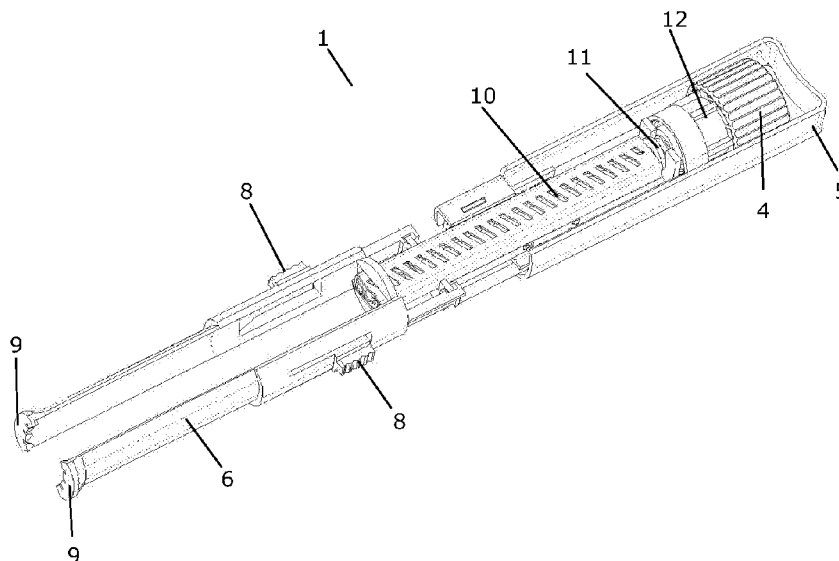
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(54) Title: AN INJECTION DEVICE AND A METHOD OF CHANGING A CARTRIDGE IN THE DEVICE



(57) Abstract: A refillable injection device (1) having a dose setting mechanism with a dose setting member (4) and a dose rod (11). The dose setting member and the dose rod engage during normal operation of the injection device, and they do not engage during change of cartridge. The dose setting member and the dose rod need to be moved into engagement when a new cartridge is inserted in the injection device. Thereby there is a risk that stress is build-up in the piston rod. In order to prevent this, the cartridge holder is operatively connected to the dose rod in such a manner that when a cartridge is being inserted in the cartridge holder, the dose rod is caused to move along with the piston rod in an axial direction, at least while the dose setting member and the dose rod are moved into engagement.

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## AN INJECTION DEVICE AND A METHOD OF CHANGING A CARTRIDGE IN THE DEVICE

## FIELD OF THE INVENTION

The present invention relates to an injection device in which it is possible to exchange an empty cartridge with a new cartridge containing a liquid drug to be injected into a person.

5 Such an injection device is also known as a refillable injection device. More particularly, the present invention relates to an injection device with a dose setting mechanism comprising a dose rod. The injection device of the present invention is particularly suitable for repetitive self-injection, e.g. of insulin or growth hormone. The injection device may preferably be in the form of a so-called injection pen. The present invention further relates to a method of  
10 changing a cartridge in such an injection device.

## BACKGROUND OF THE INVENTION

When changing the cartridge of a refillable injection device it is desirable to let the piston of the new cartridge push the piston rod of the injection device back into the injection device. Thereby it is ensured that the piston rod contacts the piston when the cartridge is positioned  
15 correctly, and the injection device is therefore ready for use. Thereby the need for very large air shots before taking the injection device into use is avoided.

However, in prior art refillable injection devices having a dose rod, the piston rod is pushed, pulled or rotated back manually, thereby introducing the problem that it can not be ensured that the piston rod contacts the piston, and very large air shots are therefore necessary in  
20 order to ensure correct use of the injection device.

In order to ensure proper operation of the injection device during setting of a desired dose, the dose rod and a dose setting member must be rotationally locked when the cartridge is positioned correctly. This is usually obtained by letting the dose rod and the dose setting member engage, e.g. by means of mating sets of teeth positioned on the dose rod and the  
25 dose setting member, respectively. This may cause stress to be introduced in the piston rod, and this tension may have the consequence that liquid drug will be expelled from the injection device when a needle is subsequently attached to the new cartridge.

In WO 02/092153 an attempt to solve the above mentioned problem is disclosed. Thus, WO 02/092153 discloses a medication injector apparatus, such as an injection pen. The injection  
30 pen includes a resettable cartridge plunger drive assembly including an axially floating nut, a cartridge plunger engaging screw, and a drive clutch movable with the nut and which when rotated causes the screw to screw through the nut. When a cartridge assembly is mounted to

the pen base, the floating nut and drive clutch are shifted proximally such that the drive clutch is in torque transmitting engagement with a rotatable drive member of the pen, such that rotation of that drive member results in drive screw advancement through the nut in the distal direction. When the cartridge assembly is not mounted to the pen base, the floating nut and drive clutch are biased distally to disengage the drive clutch from torque transmitting engagement with the rotatable drive member and to thereby allow the drive screw to be reset proximally through the nut to a position more retracted within the pen base. Thereby drooling of the pen is limited.

The injection device of WO 02/092153 is not of the kind having a dose setting mechanism comprising a dose rod, and the mechanism disclosed therein is not suitable for use in such an injection device.

#### SUMMARY OF THE INVENTION

It is, thus, an object of the invention to provide an injection device of the kind having a dose setting mechanism comprising a dose rod, and in which the above mentioned problems of introducing stress in the piston rod are avoided, or at least minimised.

According to a first aspect of the invention, the above and other objects are fulfilled by providing an injection device comprising:

- a dose setting mechanism operable to set a desired dose, the dose setting mechanism comprising a dose setting member and a dose rod, the dose setting mechanism being adapted to be in a first position in which the dose setting member and the dose rod engage, and a second position in which the dose setting member and the dose rod do not engage, the dose setting mechanism being in the first position during normal operation of the injection device, and in the second position during cartridge change,
- a piston rod adapted to cooperate with a piston in a cartridge in order to expel a dose of liquid from the cartridge,
- an injection mechanism operable to cause the piston rod and the piston to expel a previously set dose of liquid from the cartridge, and
- a cartridge holder for releasably holding a cartridge,

wherein the cartridge holder is operatively connected to the dose rod in such a manner that when a cartridge is being inserted in the cartridge holder, the dose rod is caused to move along with the piston rod in an at least substantially axial direction, at least while the dose setting mechanism is moved from the second position to the first position.

- 5 The injection device is preferably of the kind having an elongated shape, i.e. a so-called injection pen.

The dose setting mechanism comprises a dose setting member and a dose rod. The dose setting member is a part of the dose setting mechanism which is actually operated by the user during setting of a desired dose, e.g. by dialling the dose setting member or pulling it in  
10 a direction away from a housing enclosing the injection device. The dose setting member may, thus, be or comprise a dose knob, such as a rotatable dose knob. The dose setting member is preferably positioned at or near a proximal end of the injection device, i.e. opposite the end where an injection needle would normally be positioned.

The dose rod is an elongated part extending along a longitudinal direction of the injection  
15 device. When the dose setting member is operated to set a desired dose, the dose rod is caused to move along with the dose setting member, preferably in a rotational movement. The dose rod thereby causes the injection mechanism to be moved to a position where it is ready for causing injection of the set dose. This may, e.g., be done by moving an injection  
20 button in a proximal direction, as will be further explained below. The dose rod preferably extends from the dose setting member to a position at or near a proximal end of the cartridge holder.

During normal operation of the injection device, the dose setting mechanism is adapted to be in a first position in which the dose setting member and the dose rod engage. Thereby it is ensured that when a user operates the dose setting member, the desired dose is actually set.  
25 When the cartridge is being changed, on the other hand, the dose setting mechanism is in a second position in which the dose setting member and the dose rod do not engage. Thus, during cartridge change the dose setting member and the dose rod are allowed to move independently, preferably in a rotational manner. Accordingly, when a new cartridge is being inserted, the dose setting mechanism will need to be moved from the second position to the  
30 first position during this operation, i.e. the dose setting member and the dose rod need to be moved into engagement. As mentioned above, the dose rod will be prevented from performing a rotational movement relatively to the dose setting member during this operation. This will be described further below.

- The injection mechanism preferably comprises an injection button which is moved in a proximal direction during setting of a desired dose. When the set dose is subsequently injected, the user pushes the injection button in a distal direction, i.e. in a direction opposite the direction in which it was moved during setting of the dose. The injection button is, in this case, connected to the piston in such a manner that moving the injection button in the distal direction causes the piston rod to also be moved in the distal direction, possibly with a suitable gearing. Since the piston rod cooperates with the piston of the cartridge, preferably by abutting the piston, the piston is moved a corresponding distance, and the set dose is thereby expelled from the cartridge.
- 10 The cartridge holder is releasably holding a cartridge. This should be interpreted to mean that it is possible to remove the cartridge from the cartridge holder, e.g. when the cartridge is empty, and replace it by another cartridge. Thus, the injection device is of the refillable kind. However, during normal operation of the injection device, the cartridge holder should be positioned in such a manner that it is not possible to remove the cartridge. Furthermore, the
- 15 cartridge holder is preferably movable relatively to the remaining parts of the injection device during change of cartridge. In this embodiment the cartridge holder, holding the cartridge, is at least partly removed from the injection device, the cartridge is replaced by a new cartridge, and the cartridge holder, holding the new cartridge, is inserted into the injection device.
- 20 The cartridge holder is operatively connected to the dose rod. This has the consequence that when a new cartridge is being inserted in the injection device by means of the cartridge holder, the dose rod is caused to move along with the piston rod in an at least substantially axial direction while the dose rod and the dose setting member are moved into engagement. As mentioned above, the piston rod is pushed in a proximal direction by the piston of the new
- 25 cartridge during insertion of the cartridge. By causing the dose rod to move along with the piston rod while the dose rod and the dose setting member are moved into engagement, and the dose rod is therefore prevented from rotating relatively to the dose setting member, the piston rod is allowed to continue its axial movement. Thereby a build-up of stress in the piston rod is prevented, and when an injection needle is subsequently inserted in the
- 30 cartridge, no drug will be expelled due to such a stress. This is very advantageous.
- This may advantageously be obtained in the following manner. When the new cartridge is being inserted in the injection device, the piston of the cartridge pushes the piston rod back. During this movement a nut will cause the dose rod to perform a rotational movement. When the cartridge is almost in position, the cartridge holder pushes a carrier which is also
- 35 connected to the nut. Thereby the nut is also pushed back. Accordingly, the dose rod and the nut will be moved back in an axial direction with the same velocity, and the nut will therefore

no longer cause a rotational movement of the dose rod. Thereby the dose rod and the dose setting member may be moved into engagement without the risk of introducing stress in the piston rod.

5 The first position of the dose setting mechanism may be defined by engagement of a set of teeth positioned on the dose setting member and a mating set of teeth positioned on the dose rod. In this case the dose rod will be prevented from rotating relatively to the dose setting member as soon as the mating teeth start to move into engagement. From this point until the teeth have been moved fully into engagement, the dose rod is moved along with the piston rod as described above.

10 The cartridge holder may comprise a cartridge holding member comprising a set of jaws adapted to clamp a distal end of a cartridge. In this embodiment the cartridge is held by the cartridge holder by means of the set of jaws. The set of jaws is preferably movable in such a manner, that during normal operation of the injection device they firmly clamp the cartridge, thereby securing it with respect to the remaining parts of the injection device. During  
15 cartridge change, on the other hand, the jaws may be moved to a position in which they release the grip on the cartridge, thereby allowing one cartridge to be removed from and another to be positioned in the cartridge holder. The injection device in this case preferably comprises a releasable locking mechanism which locks the jaws in the clamping position during normal operation of the injection device, and which may be operated to release the  
20 grip when it is desired to replace the cartridge.

Alternatively, the cartridge holder may comprise a frame member adapted to carry the cartridge, and the cartridge may be moved along with and by means of the frame member during cartridge change. According to this embodiment the cartridge holder is preferably in the form of a 'drawer' in which the cartridge may be positioned. When a cartridge is removed  
25 from the injection device the complete frame member is pulled at least partly out of the injection device. The cartridge is removed, a new cartridge is positioned in the frame member, and the complete frame member, holding the new cartridge, is repositioned in the injection device.

30 The injection device may further comprise a biasing mechanism causing the dose setting mechanism to be in the second position when no cartridge is positioned in the cartridge holder, and when the cartridge holder is open. Thereby the dose setting member and the dose rod will automatically be moved out of engagement when the cartridge is being replaced. The biasing mechanism may advantageously comprise a spring member.

According to a second aspect of the invention, the above and other objects are fulfilled by providing a method of changing a cartridge in an injection device, the injection device comprising a dose setting mechanism operable to set a desired dose, the dose setting mechanism comprising a dose setting member and a dose rod, the dose setting member  
5 being adapted to be in a first position in which the dose setting member and the dose rod engage, and a second position in which the dose setting member and the dose rod do not engage, the injection device further comprising a cartridge holder being operatively connected to the dose rod, the method comprising the steps of:

- 10 - moving the cartridge holder holding an empty cartridge in such a manner that the empty cartridge is accessible, and in such a manner that the dose setting mechanism is caused to move from the first position to the second position,
- removing the empty cartridge from the cartridge holder,
- inserting a new cartridge into the cartridge holder,
- 15 - moving the cartridge holder holding the new cartridge in such a manner that a piston rod of the injecting device is moved along with a piston of the new cartridge, and
- moving the dose setting mechanism from the second position to the first position while causing the dose rod to move along with the piston rod in an at least substantially axial direction.

20 It should be noted that a person skilled in the art would readily recognise that any feature which has been described in combination with the first aspect could also be combined with the second aspect, and vice versa.

The method according to the second aspect of the invention is, thus, performed using an injection device according to the first aspect of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

25 The invention will now be described in further details with reference to the accompanying drawings in which

Fig. 1 is a perspective view of an injection device according to an embodiment of the invention, the injection device being in a position in which it is ready for operation,

Fig. 2 is a perspective view of the injection device of Fig. 1, in which an old cartridge is about to be removed,

Fig. 3 shows selected parts of the injection device of Figs. 1 and 2 in a position where it is ready for normal operation,

- 5 Fig. 4 shows selected parts of the injection device of Figs. 1-3 during insertion of a new cartridge,

Fig. 5 shows the injection device of Fig. 4 with an additional part removed, and

Fig. 6 is an exploded view of selected parts of the injection device of Figs. 1-5.

#### DETAILED DESCRIPTION OF THE DRAWINGS

- 10 Fig. 1 is a perspective view of an injection device 1 according to an embodiment of the invention. The injection device 1 comprises a housing 2 with a display 3 mounted thereon. The display 3 may show the amount of drug left in a cartridge, a set dose, etc. The injection device 1 further comprises a dose setting member 4 being rotationally operable to set a desired dose, and an injection button 5 being operable to cause a set dose to be expelled  
15 from the injection device 1. Furthermore, the injection device 1 comprises a cartridge holder 6 for releasably holding a cartridge 7. The cartridge holder 6 may be released by means of release buttons 8. In Fig. 1 the injection device 1 is in a position in which it is ready for setting a dose, i.e. a cartridge 7 is positioned in the cartridge holder 6, and the cartridge holder 6 has not been released.

- 20 Fig. 2 is a perspective view of the injection device 1 of Fig. 1. In Fig. 2 the cartridge 7 is being exchanged. Thus, the release buttons 8 have been pushed in order to release the cartridge holder 6. Thereby a set of jaws 9 of the cartridge holder 6 has been moved out of the housing 2, and the jaws 9 are no longer gripping the cartridge 7 firmly. Accordingly, the cartridge 7 can be removed from the injection device 1. In Fig. 2 the cartridge 7 has been  
25 pulled partly out. A piston rod 10 is visible.

- Fig. 3 shows selected parts of the injection device 1 of Figs. 1 and 2. For clarity only the parts which are essential for explaining the change of cartridge are shown, the remaining parts being omitted. Fig. 3 corresponds to Fig. 1 in that it shows the injection device 1 in a position where it is ready for use. The jaws 9 of the cartridge holder 6 are in a position where they  
30 are adapted to clamp a cartridge firmly. The piston rod 10 is positioned as close to the dose setting member 4 as possible, indicating that the cartridge (not shown) is full, i.e. it has just

been inserted in the injection device 1. In Fig. 3 a dose rod 11 is further visible. The dose rod 11 and the dose setting member 4 engage at a position which is hidden by member 12. This will be explained below with reference to Fig. 5.

Fig. 4 shows selected parts of the injection device 1 of Figs. 1-3. Fig. 4 corresponds to Fig. 2  
5 in that it shows the injection device 1 during a cartridge change. The jaws 9 of the cartridge holder 6 are positioned further apart than is the case in Fig. 3, thereby indicating that they have been released by means of the release buttons 8, and that they are therefore no longer firmly gripping a cartridge. The piston rod 10 is shown in a position which is relatively far from the dose setting member 4, thereby indicating that a cartridge has been emptied. In  
10 Fig. 4 the dose rod 11 is more clearly visible than in Fig. 3.

Fig. 5 shows the injection device 1 of Fig. 4 with the only exception that member 12 has been removed. Thereby it is possible to see that the dose setting member 4 is provided with a first set of teeth 13, and the dose rod 11 is provided with a second set of teeth 14. The second set of teeth 14 is adapted to slide into the first set of teeth 13, thereby causing the dose  
15 setting member 4 and the dose rod 11 to engage. As soon as the teeth 13, 14 start to engage, the dose rod 11 can no longer rotate relatively to dose setting member 4.

When a new cartridge is being inserted into the injection device 1, it is positioned between the jaws 9 and moved into the injection device 1. During this movement the piston of the cartridge will push the piston rod 10 backwards from the position shown in Fig. 5, and the  
20 dose rod 11 will rotate. When the cartridge is almost in position, it will press against the cartridge holder 6 which is thereby moved into the injection device 1. The cartridge holder 6 thereby presses against a carrier 15 which, via a nut (16, not shown in Fig. 5), prevents further rotation of the dose rod 11. The teeth 13, 14 are then moved into engagement by means of an axial movement of the dose rod 11. Thereby it is ensured that no stress is build-  
25 up in the piston rod 10.

Fig. 6 is an exploded view of selected parts of the injection device 1 of Figs. 1-5.

## CLAIMS

1. An injection device comprising:

- 5           – a dose setting mechanism operable to set a desired dose, the dose setting mechanism comprising a dose setting member and a dose rod, the dose setting mechanism being adapted to be in a first position in which the dose setting member and the dose rod engage, and a second position in which the dose setting member and the dose rod do not engage, the dose setting mechanism being in the first position during normal operation of the injection device, and in the second position during cartridge change,
- 10          – a piston rod adapted to cooperate with a piston in a cartridge in order to expel a dose of liquid from the cartridge,
- an injection mechanism operable to cause the piston rod and the piston to expel a previously set dose of liquid from the cartridge, and
- a cartridge holder for releasably holding a cartridge,

15          wherein the cartridge holder is operatively connected to the dose rod in such a manner that when a cartridge is being inserted in the cartridge holder, the dose rod is caused to move along with the piston rod in an at least substantially axial direction, at least while the dose setting mechanism is moved from the second position to the first position.

20          2. An injection device according to claim 1, wherein the first position of the dose setting mechanism is defined by engagement of a set of teeth positioned on the dose setting member and a mating set of teeth positioned on the dose rod.

3. An injection device according to claim 1 or 2, wherein the cartridge holder comprises a cartridge holding member comprising a set of jaws adapted to clamp a distal end of a cartridge.

25          4. An injection device according to claim 1 or 2, wherein the cartridge holder comprises a frame member adapted to carry the cartridge, wherein the cartridge is moved along with and by means of the frame member during cartridge change.

5. An injection device according to any of the preceding claims, further comprising a biasing mechanism causing the dose setting mechanism to be in the second position when no cartridge is positioned in the cartridge holder.

6. A method of changing a cartridge in an injection device, the injection device comprising a  
5 dose setting mechanism operable to set a desired dose, the dose setting mechanism comprising a dose setting member and a dose rod, the dose setting member being adapted to be in a first position in which the dose setting member and the dose rod engage, and a second position in which the dose setting member and the dose rod do not engage, the  
10 injection device further comprising a cartridge holder being operatively connected to the dose rod, the method comprising the steps of:

- moving the cartridge holder holding an empty cartridge in such a manner that the empty cartridge is accessible, and in such a manner that the dose setting mechanism is caused to move from the first position to the second position,
- removing the empty cartridge from the cartridge holder,
- 15 - inserting a new cartridge into the cartridge holder,
- moving the cartridge holder holding the new cartridge in such a manner that a piston rod of the injecting device is moved along with a piston of the new cartridge, and
- moving the dose setting mechanism from the second position to the first position while causing the dose rod to move along with the piston rod in an at least  
20 substantially axial direction.

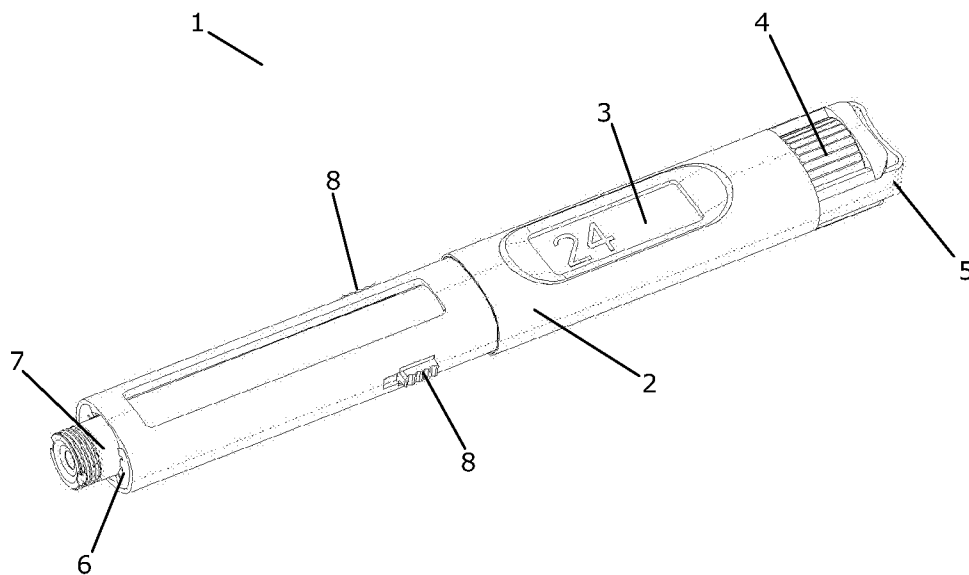


Fig. 1

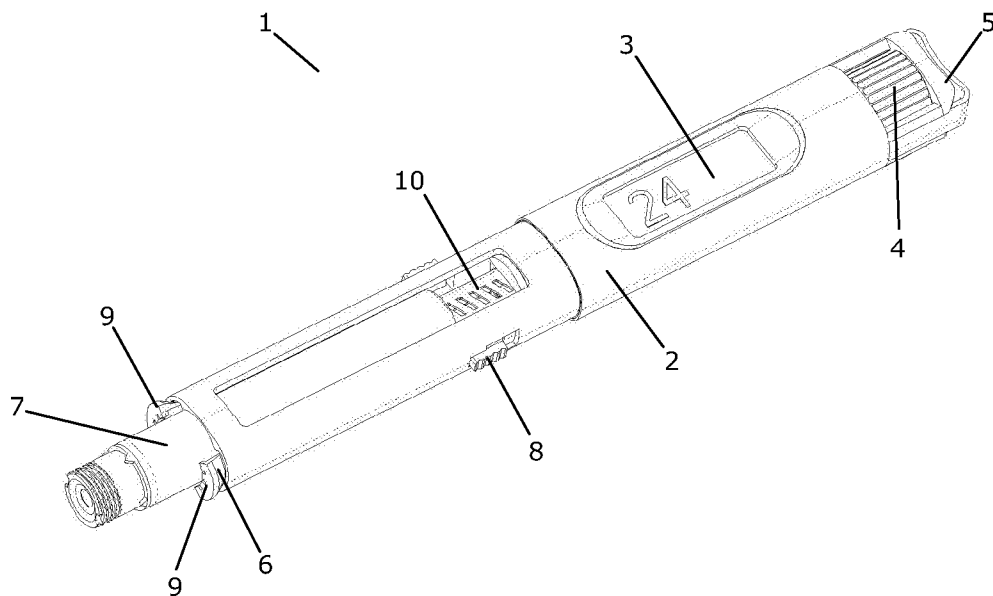


Fig. 2

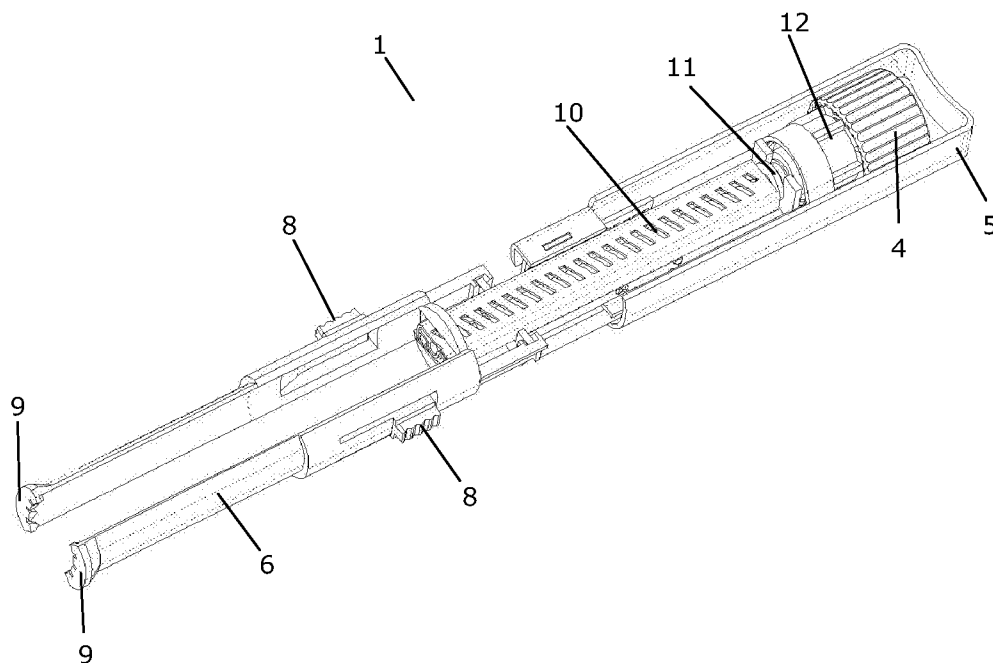


Fig. 3

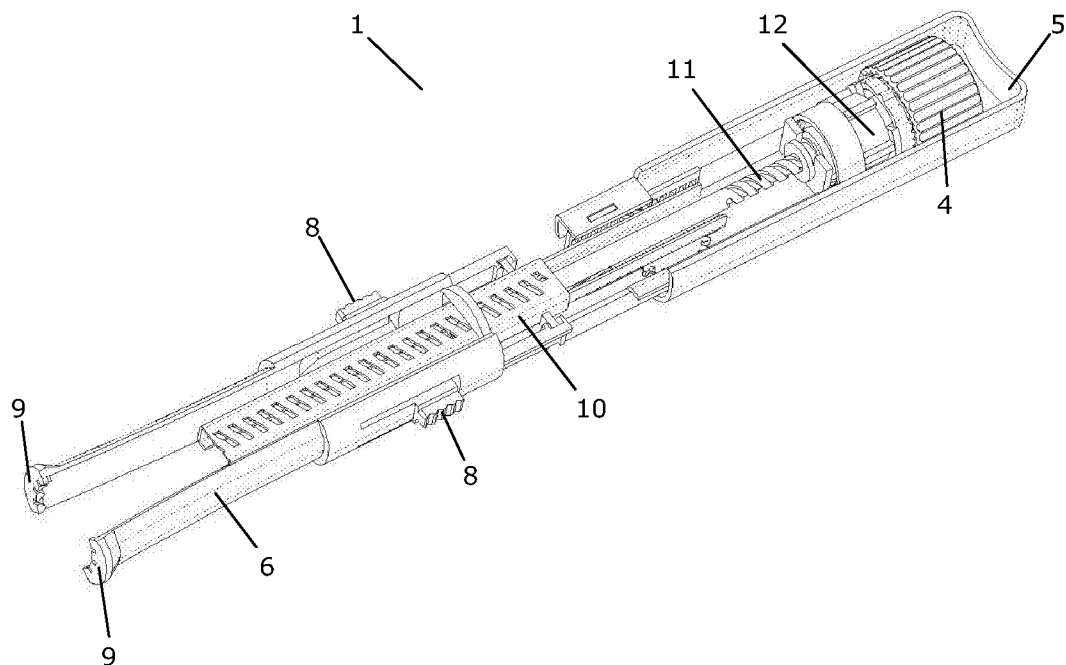


Fig. 4

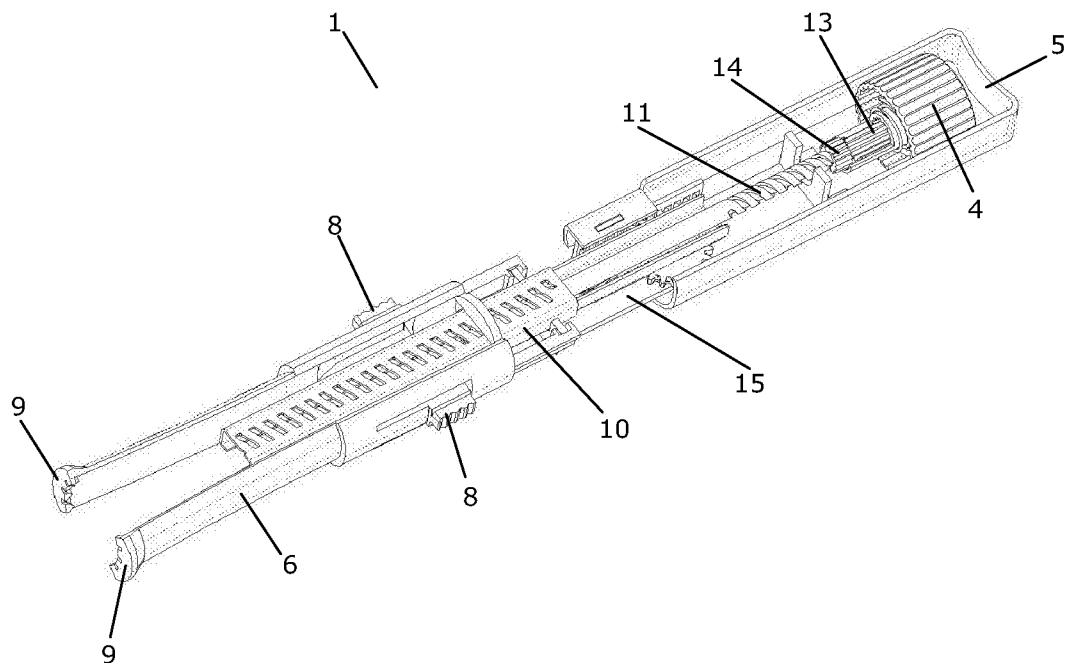


Fig. 5

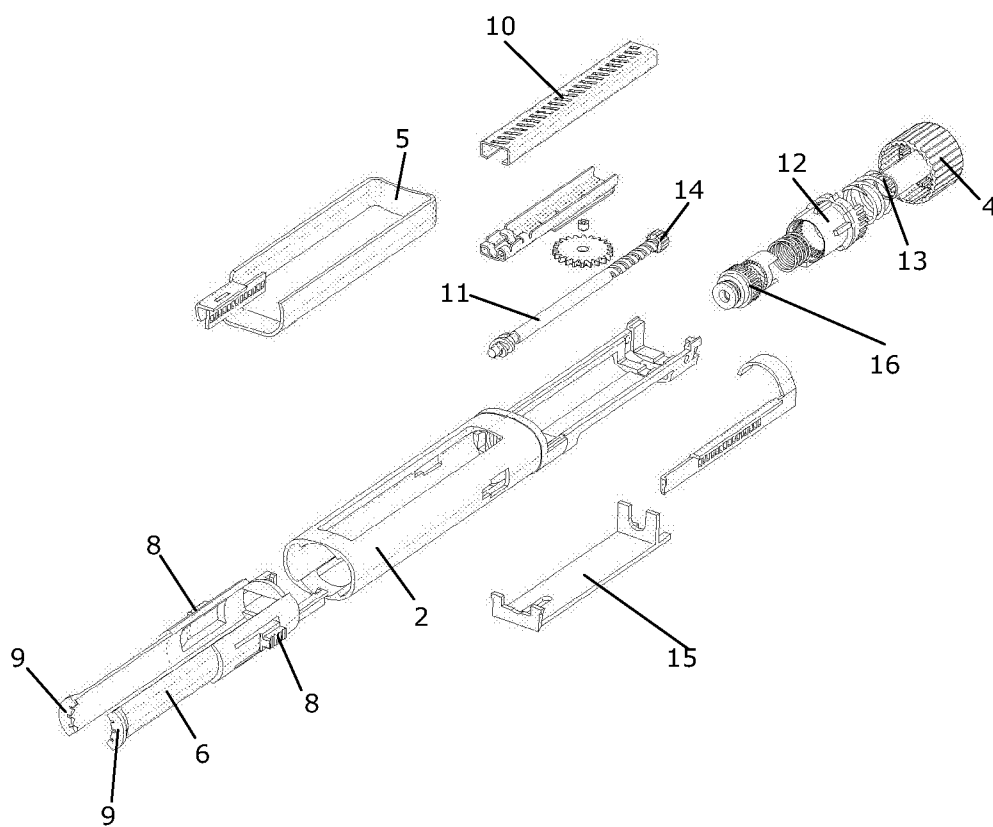


Fig. 6

# INTERNATIONAL SEARCH REPORT

International application No  
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**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61M5/315 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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A	US 4 498 904 A (TURNER ET AL) 12 February 1985 (1985-02-12) abstract figures 9-14 column 9, line 33 - column 11, line 5	1-6
A	EP 1 541 185 A (NOVO NORDISK A/S) 15 June 2005 (2005-06-15) abstract	1-6
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Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

Date of mailing of the international search report

24 May 2007

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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/EP2007/051757

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96/07443 A (OWEN MUMFORD LIMITED; MARSHALL, JEREMY; CROSSMAN, DAVID, DANVERS) 14 March 1996 (1996-03-14) abstract  -----	1-6

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Information on patent family members

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