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(54) **Title:** IMPROVED INJECTION DEVICE

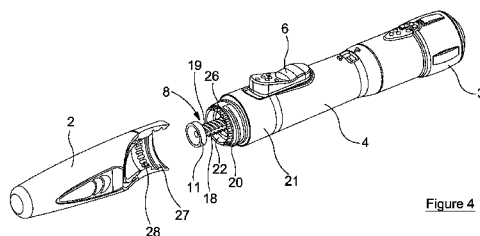


Figure 4

(57) **Abstract:** An injection device comprising a main housing (4) defining a first screw thread (20) and a plunger comprising a leadscrew (19) and a cap (11) rotatably attached to the leadscrew such that, in use, the cap engages a bung of a cartridge containing medicament. A drive gear is mounted within the housing for rotating around the leadscrew to drive the plunger axially through the housing when the leadscrew is locked against rotation with respect to the housing. A cartridge housing (2) is also provided for holding a cartridge containing medicament. This housing defines a second screw thread (27) for engagement with said first screw thread in order to secure the cartridge housing to the main housing. The device further comprises a locking mechanism (26,28) which is actuated when the cartridge housing is secured to the main housing and which locks the leadscrew against rotation with respect to the housing. Cooperating features are provided for allowing the leadscrew to rotate relative to the cartridge housing during attachment of the cartridge housing to the main housing whilst allowing relative rotation of the engaged first and second screw threads to cause rotation of the leadscrew relative to the housing and hence axial movement of the leadscrew into the housing.

WO 2011/114122 A1

IMPROVED INJECTION DEVICE

5 The present invention relates to an improved injection device, and more particularly to an injection device which provides for automatic medication delivery and for variable dose setting.

10 WO2007063342 describes a generally pen-like syringe as shown in Figure 1 and which is suitable for use with a cartridge containing a medicament. The cartridge is held within a cartridge housing and is adapted to receive a needle (not shown) which pierces a rubber septum sealing a proximal end (with respect to a user's skin) of the cartridge. A cap 1 is provided for covering the cartridge housing 2 and cartridge, and any attached needle. The syringe incorporates a dose metering device provided by a dose knob 3 which is rotatable with respect to the main housing 4 to a position related to the dose of medication to be injected. Rotation of the cap stores energy in a torsion spring 5, which is prevented from unwinding by cooperating ratchet teeth. The user disengages the ratchet teeth by means of a sliding trigger 6 coupled to the outside of the main housing 4, resulting in the unwinding of the spring. This in turn causes rotation of a drive gear 7 which is coupled to a plunger 8 via a quick pitch screw thread 9. During firing, the plunger is prevented from rotating by splines 10 fixed relative to the main housing 4 and which interact with recesses along the axial direction of the plunger, such that rotation of the gear results in axial movement of the plunger 8 through the main housing. As illustrated schematically in Figure 2, a cap 11 rotatably mounted on the end of the plunger 8 acts on a "bung" 12 of the cartridge 13, driving medicament 14 from the cartridge, through an attached needle, as the plunger moves in the direction of arrow A.

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30 A user, who may be an end user or patient or a device assembler, receives the device with the plunger 8 in a given position with respect to the housing. Whatever this starting position of the plunger, it will probably need to be moved axially with respect to the housing 4 in order to align the cap 11 of the plunger with the bung 12 when the cartridge and cartridge housing are attached to the housing. This also applies when a user wishes to replace a used cartridge with a new cartridge. Adjustment of the

plunger position is facilitated by screwing the plunger into, or out of, the housing. A clutch mechanism is provided for this purpose.

5 A problem with the prior art device of Figure 1 and of other similar devices, is that the components of the clutch mechanism are engaged by relative movement over a finite axial distance, e.g. 5mm. Over most of the course of this movement, the plunger is prevented from rotating relative to the housing, and therefore from moving axially with respect to the housing. However, during engagement of the clutch, the cartridge housing continues to be screwed onto the housing and to move towards the housing.
10 This exerts a potentially large force on the cartridge bung, in turn exerting a force on the inside of the septum 15, because the cartridge is closed and a pressure will be built up in the medicament. This may lead the septum to burst, or at the very least cause medicament to be unnecessarily driven out of the cartridge when a needle is being attached.

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WO 2009/049885 describes an injection device with reset of the piston rod caused by cartridge exchange. EP0688571 and EP0450905 also describe injection devices.

20 According to an aspect of the present invention there is provided an injection device comprising a main housing defining a first screw thread and a plunger comprising a leadscrew and a cap rotatably attached to the leadscrew such that, in use, the cap engages a bung of a cartridge containing medicament. A drive gear is mounted within the housing and the drive gear engages with a screw thread on said leadscrew such that rotation of the drive gear around the leadscrew drives the plunger axially through
25 the housing when the leadscrew is locked against rotation with respect to the housing. A cartridge housing is also provided for holding a cartridge containing medicament. This housing defines a second screw thread for engagement with said first screw thread in order to secure the cartridge housing to the main housing. The device further comprises a locking mechanism which is actuated when the cartridge housing is
30 secured to the main housing and which locks the leadscrew against rotation with respect to the housing. Cooperating features are provided for allowing the leadscrew to rotate relative to the cartridge housing during attachment of the cartridge housing to the main housing whilst allowing relative rotation of the engaged first and second screw threads to cause rotation of the leadscrew relative to the housing and hence axial

movement of the leadscrew into the housing. The pitch of the thread provided on the leadscrew is substantially the same as the pitch of said first and second screw threads. This pitch arrangement, together with the cooperating features, enables the leadscrew and cartridge housing to move substantially at the same axial speed when attaching
5 the cartridge housing to the main housing.

Embodiments of the present invention may allow the injection device to be assembled without exerting undesirable pressure on the cartridge before firing the injection device.

10 The locking mechanism may comprise a clutch collar engaged with said leadscrew so as to rotate with the leadscrew but to be axially moveable relative to the leadscrew. Said cooperating features may comprise one or more axially extending features defined on the clutch collar and one or more axially extending features defined on the
15 cartridge housing, these features mating during attachment of the cartridge housing to the main housing so as to cause the clutch collar and the leadscrew to rotate with the cartridge housing. These features on the clutch collar and the cartridge housing are splines.

A resilient coupling may be provided between said clutch collar and said main housing
20 and which exerts a force on the clutch collar so as to push the clutch collar away from the main housing.

The injection device may comprise a bush coupling the clutch collar to the leadscrew such that the bush and the clutch collar rotate together but can move axially with
25 respect to one another. The bush may comprise one or more splines, with the leadscrew defining one or more axially extending slots, each said slot receiving a spline of the bush.

30 For a better understanding of the present invention and in order to show how the same may be carried into effect reference will now be made by way of example to the accompanying drawings in which:

Figure 1 shows a horizontal cross-section through a prior art injector pen and a detail of the same horizontal cross-section;

Figure 2 is a perspective view of a plunger of the device of Figure 1, interacting with a medicament containing cartridge;

Figure 3 shows a partial cut-away view of an improved injector pen;

Figure 4 shows a further partial cut-away view of the injector pen of Figure 3;

5 Figure 5 is a perspective view of a clutch assembly of the injector pen of Figure 3 and 4;

Figure 6 shows a horizontal cross-section through part of the improved injector pen; and

Figure 7 shows an exploded view of the improved injector pen.

10

A known injection device has been described with reference to Figures 1 and 2. In order to address certain short comings of that and other known devices, certain improvements will now be described with references to Figures 3 to 7. Features of this device are listed in the table presented below, together with respective reference
15 numerals as used in the Figures.

15

Figures 3 to 7 show an injection device having a main housing 4 which contains a dose setting mechanism and a firing mechanism, which mechanisms are substantially as described in WO2007063342. Features common to the prior art and the improved
20 device are identified with like reference numerals. In particular, a dose knob 3 is provided at a proximal end of the device and which is rotatable with respect to the main housing 4. Rotation of the cap stores energy in a torsion spring 5, which is prevented from unwinding by cooperating ratchet teeth 16 formed on a drive gear 7 and a sliding trigger 6. The user disengages the ratchet teeth 16 by means of the sliding trigger 6,
25 which is coupled to the outside of the main housing, resulting in the unwinding of the spring. This in turn causes rotation of a drive gear 7 which is coupled to a plunger 8 via a quick pitch screw thread. During firing, the plunger 8 is prevented from rotating by splines 17 interacting with recesses 18 along the axial direction of the plunger, such that rotation of the drive gear 7 results in axial movement of the plunger through the
30 main housing 4.

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The plunger 8 comprises a leadscrew 19 and a cap 11 and protrudes from the main housing 4 to a variable extent. The leadscrew 19 has a screw thread 9 provided along the length of its outer surface. Recesses 18 are formed along the length of the

leadscrew 19. The screw thread 9 provided on the leadscrew 19 engages with a complimentary screw thread formed on an inner surface of the drive gear 7.

5 A screw thread 20 is provided around an external surface of a main housing collar 21, which snap fits onto the main housing. The pitch of this screw thread 20 is substantially the same as the pitch of the screw thread 9 provided on the leadscrew 19.

10 A clutch assembly 22 consists of a locking bush 23, a clutch collar 24 and a spring 25. The clutch assembly 22 is telescopically located within the main housing 4, such that a part of the locking bush protrudes from the main housing. The spring 25 biases the locking bush 23 in an extended state relative to the clutch collar 24. A further spring 29 acts between the trigger slide 6 and the locking bush 23, biasing the whole clutch assembly in an extended state relative to the main housing in the absence of any external force. Splines 17 are provided on the inside of the clutch assembly 22 to
15 engage with the recesses 18 along the length of the leadscrew 19. Spline teeth 26 are provided on the outside of the clutch assembly 22 at a distal end thereof.

A cartridge housing 2 is provided for receiving a disposable medication filled cartridge 13 (as illustrated in Figure 2). The cartridge has a movable rubber bung 12 towards
20 the distal end of the cartridge, with the proximal end containing a septum 15 being arranged to receive a disposable needle. The septum 15 is self-sealing to allow it to close when a needle is removed. An internal screw thread 27 is provided at the distal end of the cartridge housing. Spline teeth 28 are provided on the inside of the cartridge housing 2 adjacent to the internal screw thread 27 of the cartridge housing 2. The
25 section of the cartridge housing with the internal thread 27 has a larger internal diameter than the section of the cartridge housing with the spline teeth 28 and is located closer to the distal end of the cartridge housing.

30 In the absence of a cartridge housing and cartridge, a user can rotate the leadscrew 19 by hand to adjust the distance it protrudes from the main housing 4. The leadscrew 19 can also be pushed into the housing by applying a force on the cap 11 of the plunger in axial direction (the cap rotates relative to the leadscrew). Typically, a user will wind out the leadscrew to a point beyond where it needs to be in order to engage a bung of a cartridge to be attached. The attachment process then continues as described

hereinbelow. Whilst it is possible to position the cap 11 closer to the housing than is required to engage the bung, and then fire the device until engagement is achieved, this is undesirable as, prior to attachment of a needle, the impact may overstress the septum or result in an excessive first dose. Even if a needle is attached prior to pre-firing the device, this procedure will result in additional user steps and waste of medicament as a result of that firing.

Assume that the leadscrew has indeed been wound out beyond where it needs to be to engage the bung and that a user now inserts a cartridge into the cartridge housing, and places the distal end of the cartridge housing over the cap 11 of the plunger. Assume also that the plunger is presently extended from the housing such that the cap 11 engages the bung 12 before the screw threads on the cartridge housing and the main housing collar 21 contact one another. When the user exerts sufficient force, the plunger will be pushed into the main housing, with the leadscrew rotating as it travels. After the plunger 8 has been pushed far enough into the main housing 4 for the screw threads 20 and 27 of the cartridge housing and main housing collar to engage, the user begins screwing the cartridge housing onto the clutch collar. The cartridge housing will continue to apply a force on the plunger during this phase of the attachment process.

After about one turn of the cartridge housing, the spline teeth 28 of the cartridge housing engage with the spline teeth 26 of the clutch collar. The spring 25 inside the clutch assembly allows for smooth engaging of the spline teeth of the clutch collar with the cartridge housing. When the spline teeth of the cartridge housing and the clutch collar engage, they will lock the rotation of the cartridge housing 2 and the clutch assembly 22 together, while accommodating varying compression of the cartridge housing and the main housing. Since splines 17 are provided on the inside of the clutch assembly to engage with the recesses 18 along the length of the leadscrew, the leadscrew must rotate together with the clutch assembly and hence with the cartridge housing. The cartridge housing 2 is arranged to be rotated another turn or so until it is screwed tight onto the main housing. During this last attachment phase, the leadscrew rotates with the cartridge housing. Since the pitch of the screw thread of the cartridge housing is the same as the pitch of the screw thread of the leadscrew, the cartridge housing and the plunger will not only rotate together, but they will also move together in the axial direction. This synchronisation of motions prevents the cap 11 from exerting

any significant force on the bung 12 within the cartridge. This in turn prevents any significant force being applied to the septum 13 and the risk of the septum rupturing is greatly reduced.

- 5 It will be appreciated by the person of skill in the art that various modifications may be made to the above described embodiment without departing from the scope of the present invention.

Table with parts

Reference numeral	Description
1	Cap
2	Cartridge housing
3	Dose knob
4	Main housing
5	Torsion spring
6	Trigger
7	Drive gear
8	Plunger
9	Thread of plunger
10	Splines of prior art
11	Plunger cap
12	Bung
13	Cartridge
14	Medicament
15	Septum
16	Ratchet teeth
17	Splines of improved injector
18	Recesses
19	Leadscrew
20	Screw thread
21	Main housing collar
22	Clutch assembly
23	Locking bush
24	Clutch collar
25	Spring
26	Spline teeth of clutch
27	Screw thread of cartridge housing
28	Cartridge housing spline teeth
29	Spring

CLAIMS:

1. An injection device comprising:
- 5 a main housing defining a first screw thread;
- a plunger comprising a leadscrew and a cap rotatably attached to the leadscrew such that, in use, the cap engages a bung of a cartridge containing medicament;
- 10 a drive gear within the housing and engaging with a screw thread on said leadscrew such that rotation of the drive gear around the leadscrew drives the plunger axially through the housing when the leadscrew is locked against rotation with respect to the housing;
- a cartridge housing for holding a cartridge containing medicament and defining a second screw thread for engagement with said first screw thread in order to secure the cartridge housing to the main housing;
- 15 a locking mechanism, actuated when the cartridge housing is secured to the main housing, for locking the leadscrew against rotation with respect to the housing;
- cooperating features for allowing the leadscrew to rotate relative to the cartridge housing during attachment of the cartridge housing to the main housing whilst
- 20 allowing relative rotation of the engaged first and second screw threads to cause rotation of the leadscrew relative to the housing and hence axial movement of the leadscrew into the housing, wherein the pitch of the thread provided on the leadscrew is substantially the same as the pitch of said first and second screw threads.
- 25
2. A device according to claim 1, wherein said locking mechanism comprises a clutch collar engaged with said leadscrew so as to rotate with the leadscrew but to be axially moveable relative to the leadscrew, said cooperating features comprising one or more axially extending features defined on the clutch collar and one or more axially
- 30 extending features defined on the cartridge housing, these features mating during attachment of the cartridge housing to the main housing so as to cause the clutch collar and the leadscrew to rotate with the cartridge housing.

3. A device according to claim 2, wherein said features on the clutch collar and the cartridge housing are splines.
4. A device according to claim 2 or 3 and comprising a resilient coupling between said clutch collar and said main housing, the coupling exerting a force on the clutch collar which tends to push the clutch collar away from the main housing.
5. A device according to any one of claims 2 to 4 and comprising a bush coupling the clutch collar to the leadscrew such that the bush and the clutch collar rotate together but can move axially with respect to one another, the bush comprising one or more splines and the leadscrew defining one or more axially extending slots, each said slot receiving a spline of the bush.

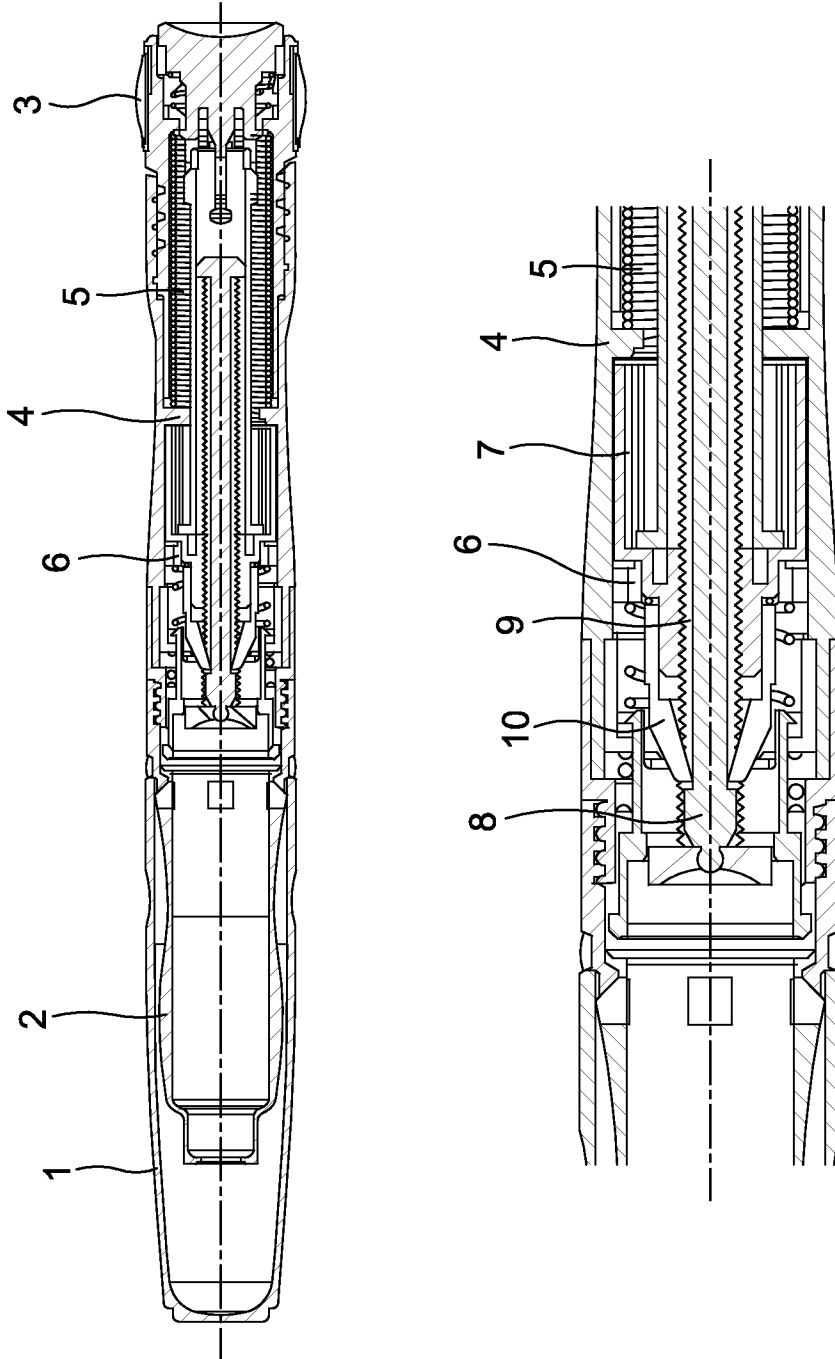


Figure 1

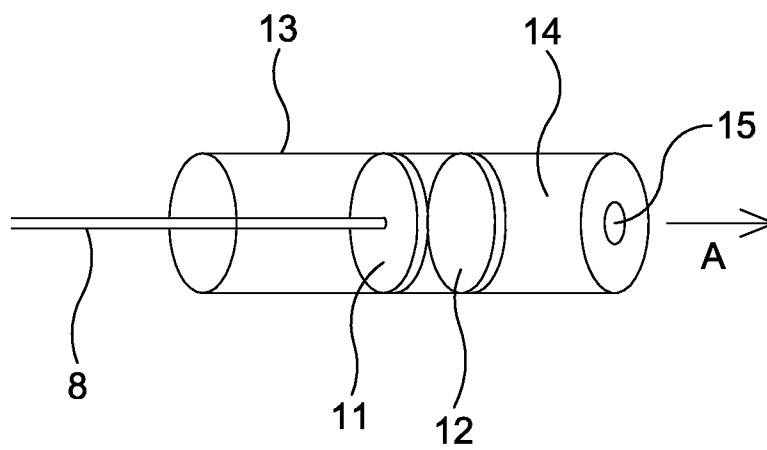


Figure 2

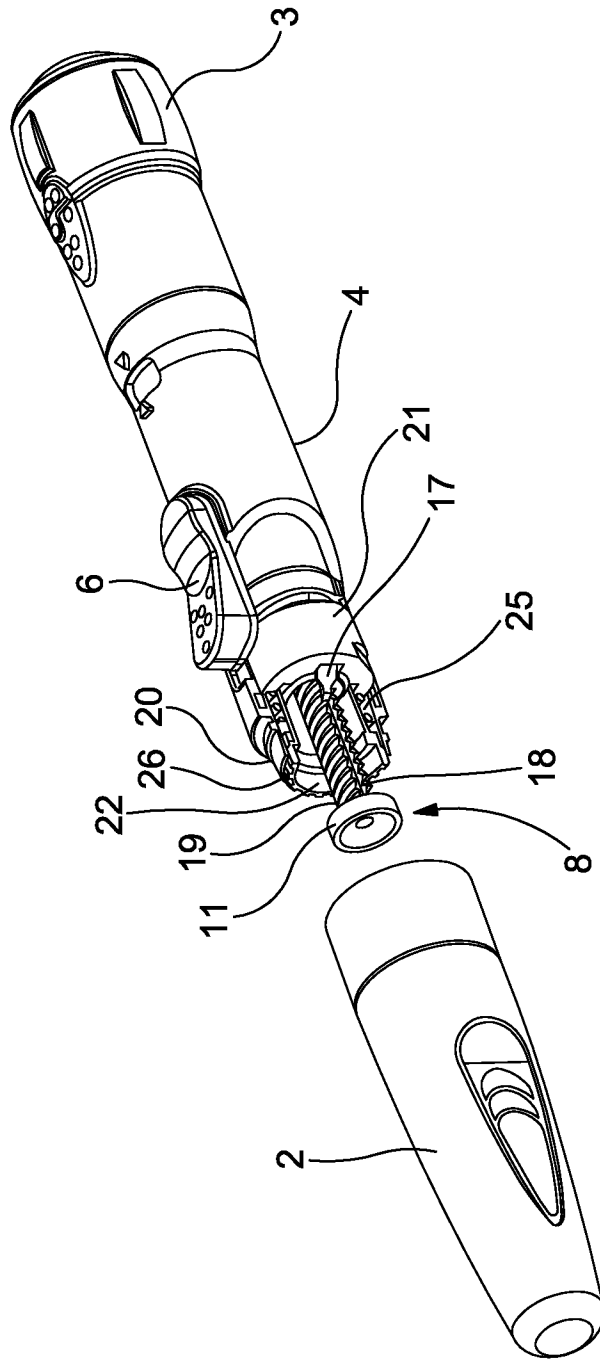


Figure 3

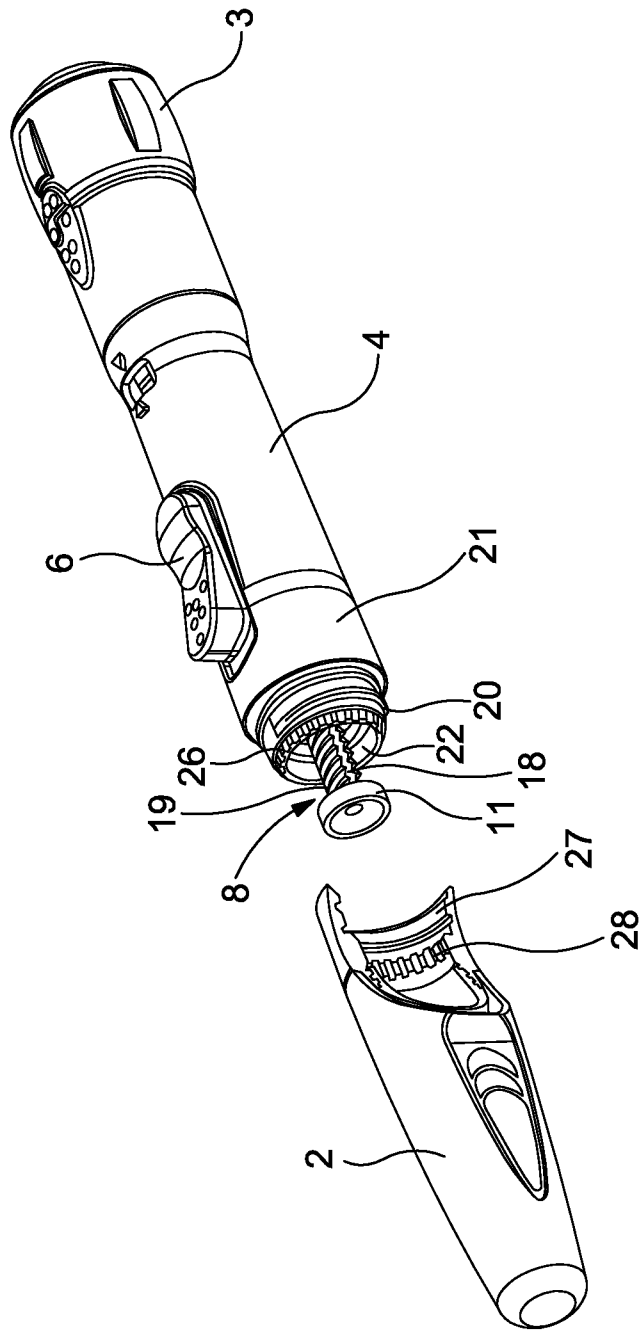


Figure 4

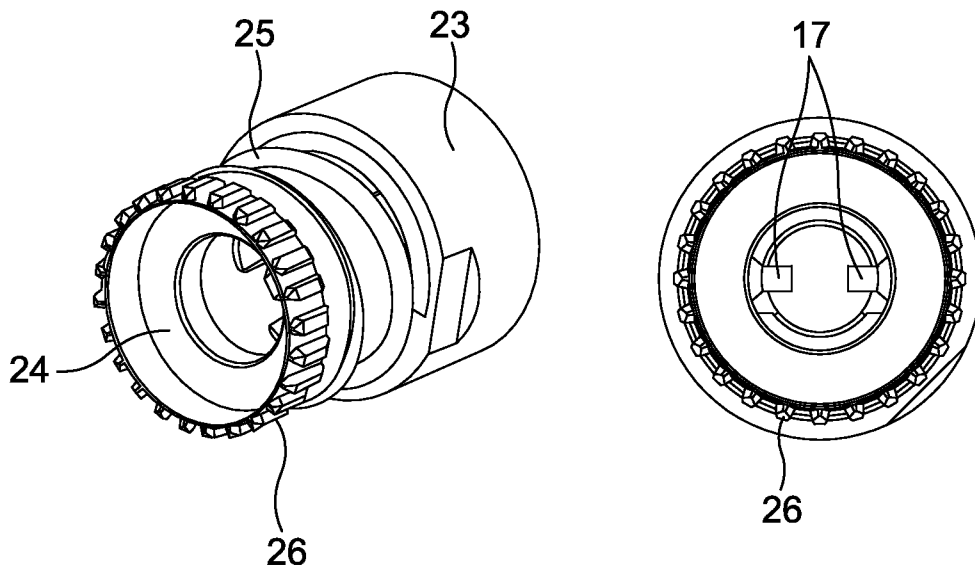


Figure 5

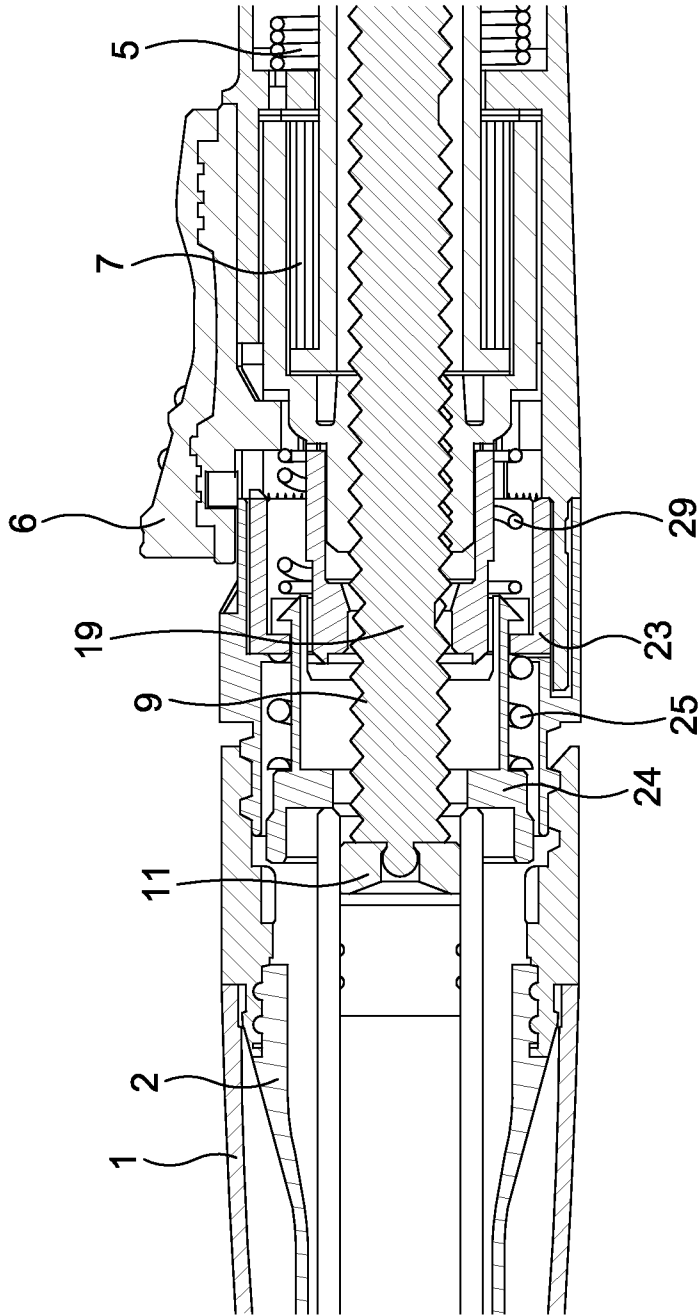


Figure 6

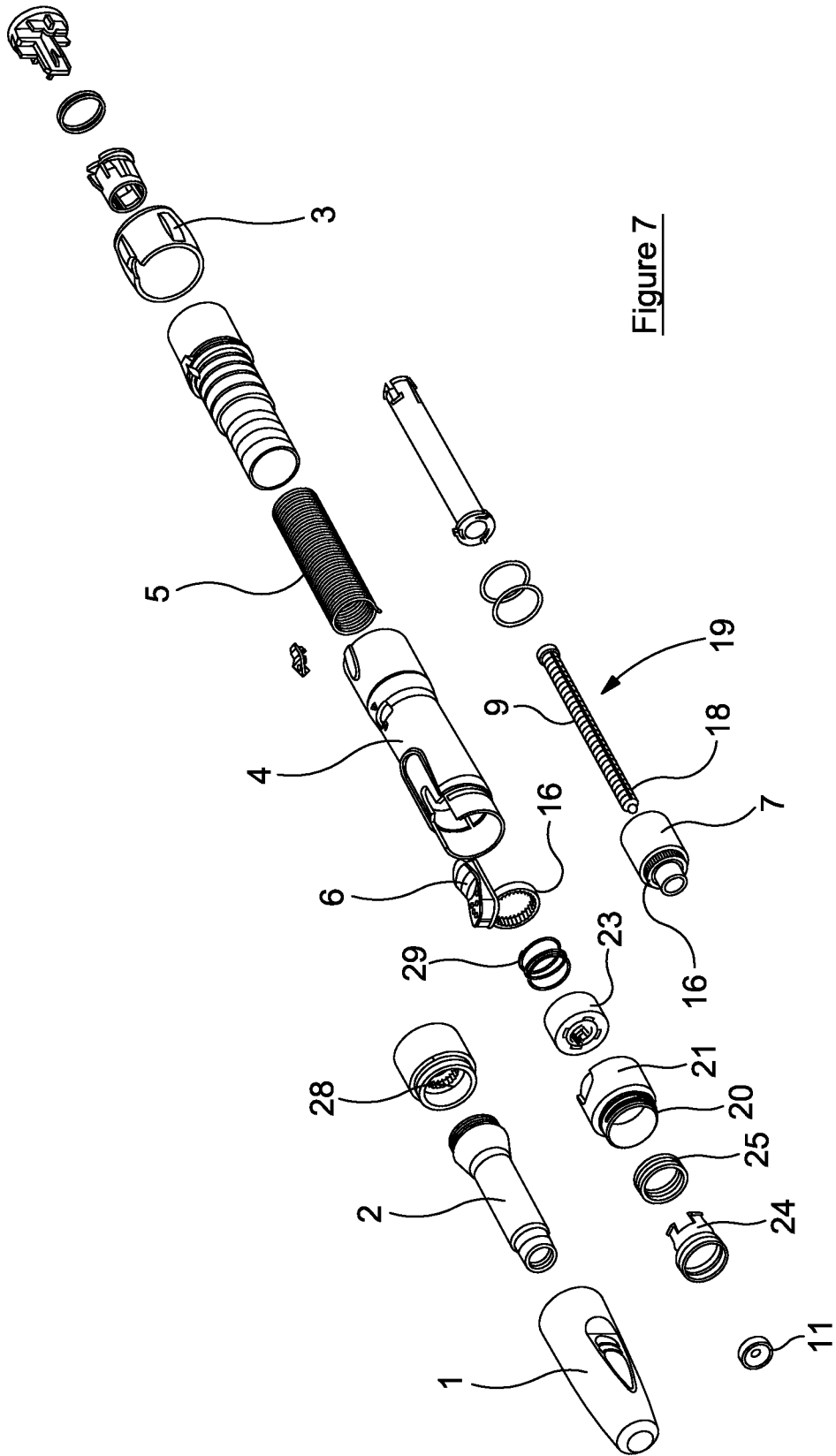


Figure 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2011/050316

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61M5/315 A61M5/24
 ADD.

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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Y	page 4, line 18 - page 5, line 4 page 10, lines 5,6 page 11, line 5 - page 13, line 11 figures 2-4	4,5
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X	----- EP 0 688 571 A1 (BECTON DICKINSON CO [US]) 27 December 1995 (1995-12-27) page 8, line 14 - page 9, line 51; figures 1-9	1-3
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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

15 April 2011

Date of mailing of the international search report

28/04/2011

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2011/050316

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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