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WO 2013/119591 A1 WO 2010/146358 A1
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(54) Title of the Invention: **Improved syringe for autoinjector device**
Abstract Title: **Syringe for Autoinjector Device**

(57) A syringe 10 for use in an autoinjector, the syringe comprising a barrel 12 having a front outlet 12a, an open rear end 12b, and a tubular body 12c extending between the front outlet and open rear end. The tubular body has an internal diameter D1 and defines a volume for containing medicament, and the open rear end has a diameter D2 substantially equal to or greater than the internal diameter of the tubular body. The syringe further comprises a polymeric elongate plunger rod 16 having a stopper 18 at a forward end and a resilient outer layer 20 along the length of the elongate plunger rod. The elongate plunger rod is disposable within the barrel such that the stopper seals against the inside of the tubular body and is slidable therein by axial translation of the plunger rod in the barrel. The resilient outer layer can be sleeve, coating or overmoulded layer that may comprise of an elastomeric material such as silicone. The resilient layer acts to strengthen the rod and can minimize the risk of the plunger rod deforming and contacting the tubular body under a high load from a driving member.

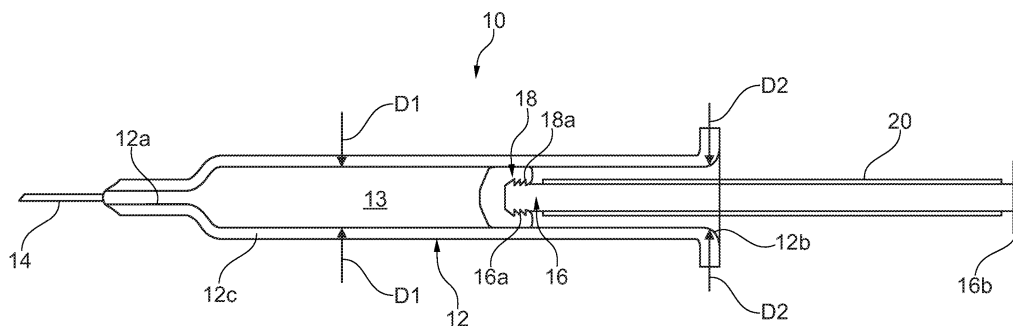


Fig. 1

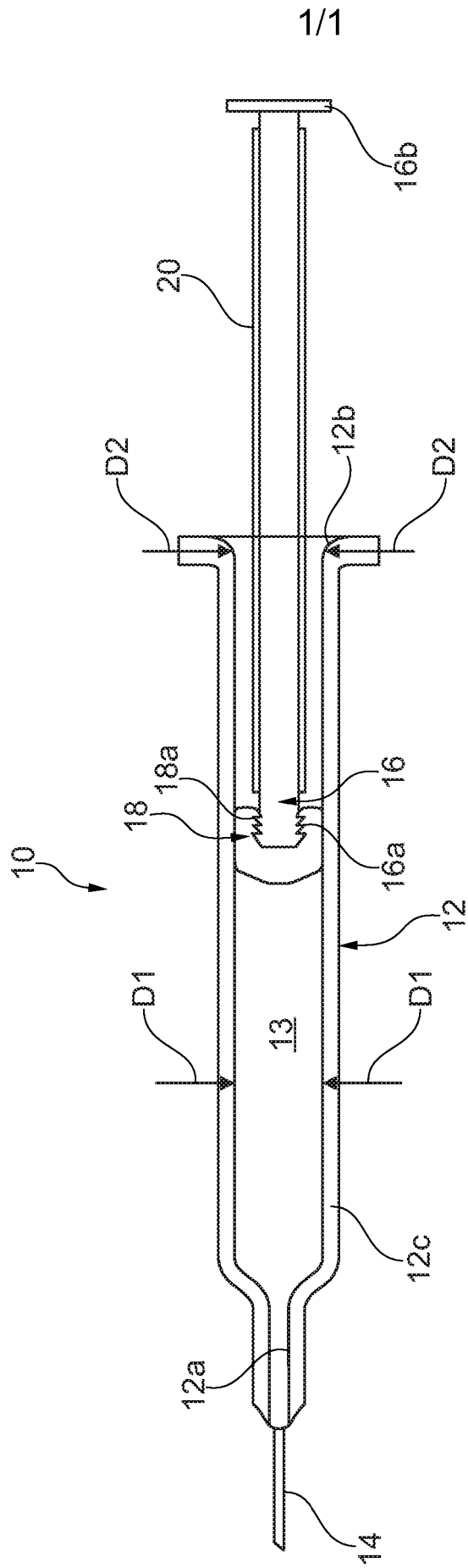


Fig. 1

Improved Syringe for Autoinjector Device

5 [0001] This invention relates to an improved syringe, and in particular to an improved syringe for use in an autoinjector device that improves the reliability and safety of the autoinjector device.

BACKGROUND

10 [0002] Syringes are known and offer a convenient means of delivering a dose of medicament. Syringes may be hand operated, where a user applies a direct force to a plunger rod, to expel medicament. Alternatively, and increasingly common, syringes may form part of an autoinjector device where a driving means acts on a plunger rod of the syringe to expel medicament from the syringe and into a delivery site (e.g. via a needle).

15 [0003] Syringes used in autoinjectors are often so-called "standard syringes" that prevalent in the industry and are both proven to be generally safe and reliable. However, when syringes are subject to the forces imparted by components of an autoinjector device, there is the potential risk of damage and possible breakage. Such damage or breakage may lead to a partially or fully incomplete dose of medicament being delivered to a patient and this may have serious, or possibly fatal, consequences.

20 [0004] It is therefore an object of certain embodiments of the present invention to provide an improved syringe that is suitable for use in an autoinjector device wherein the risk of damage or breakage is reduced in comparison with prior art devices.

BRIEF SUMMARY OF THE DISCLOSURE

25 [0005] In accordance with a first aspect of the present invention there is provided a syringe for use in an autoinjector, the syringe comprising:

a barrel having a front outlet, an open rear end, and a tubular body extending between the front outlet and open rear end, wherein the tubular body has an internal diameter and defines a volume for containing medicament, and the open rear end has a diameter substantially equal to or greater than the internal diameter of the tubular body; and

30 a polymeric elongate plunger rod having a stopper at a forward end and a resilient outer layer along the length of the elongate plunger rod, the elongate plunger rod being disposable within the barrel such that the stopper seals against the inside of the tubular body of the barrel and is slidable therein by axial translation of the plunger rod in the barrel.

35 [0006] In one embodiment, said resilient outer layer comprises a sleeve surrounding the circumference of the elongate plunger rod.

[0007] In an alternative embodiment, said resilient outer layer comprises a coating surrounding the circumference of the elongate plunger rod. Alternatively, said resilient outer layer may comprise an overmoulded layer.

5 **[0008]** In any embodiment, said resilient outer layer may comprise an elastomeric material, and optionally comprises silicone.

[0009] The resilient outer layer may extend along at least 50% of the length of the elongate plunger rod, extend along at least 75% of the length of the elongate plunger rod, or extend along at least 90% of the length of the elongate plunger rod.

10 **[0010]** In one embodiment, the elongate plunger rod has a radially outwardly projecting flange at a rear end.

[0011] In accordance with a second aspect of the present invention, there is provided an autoinjector device, including:

- a syringe according to the first aspect of the present invention; and
- a driving member for moving the plunger rod axially forwardly in the barrel.

15 **[0012]** In accordance with a third aspect of the present invention, there is provided an autoinjector device, including:

- a housing for receiving a syringe;
- a polymeric elongate plunger rod for insertion into a barrel of a received syringe and for connection to a stopper disposed in the barrel, the elongate plunger rod having a resilient
- 20 outer layer along the length of the elongate plunger rod; and
- a driving member for moving the plunger rod axially forwardly in the barrel.

[0013] Said resilient outer layer may comprise a sleeve surrounding the circumference of the elongate plunger rod.

25 **[0014]** Said resilient outer layer may comprise a coating surrounding the circumference of the elongate plunger rod.

[0015] Said resilient outer layer may comprise an overmoulded layer.

[0016] Said resilient outer layer may comprise an elastomeric material.

[0017] Said elastomeric material may comprise silicone.

30 **[0018]** In certain embodiments, said resilient outer layer may extend along at least 50%, at least 75% or at least 90% of the length of the elongate plunger rod.

[0019] The elongate plunger rod may have a radially outwardly projecting flange at a rear end.

[0020] The autoinjector device may further comprise a syringe received in the housing, wherein the syringe comprises a barrel having a front outlet, an open rear end, a tubular body

extending between the front outlet and the open rear end, and a stopper disposed in the barrel, wherein the elongate plunger rod is disposed in the barrel and is connected to the stopper in the syringe.

5 **BRIEF DESCRIPTION OF THE DRAWINGS**

[0021] Embodiments of the invention are further described hereinafter with reference to the accompanying drawings, in which:

Figure 1 is a cross-sectional view of a syringe in accordance with an embodiment of the present invention.

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DETAILED DESCRIPTION

[0022] Figure 1 shows a syringe 10 according to an embodiment of the present invention. The syringe 10 includes a barrel 12 having a front outlet 12a, an open rear end 12b and a tubular body 12c extending therebetween. The tubular body 12c has a generally constant cross section in an axial direction and has an internal diameter D1.

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[0023] An elongate plunger rod 16 is disposed in the barrel 12 and is axially moveable therein. In the non-limiting example shown in Figure 1, the plunger rod 16 has a screw thread 16a at a front end that engages with a corresponding screw thread 18a of a stopper 18. In alternative embodiments, the stopper 18 may be connected to the plunger rod 16 by different means other than a screw thread 16a. For example, the stopper 18 may be connected to the plunger rod 16 by a ball and socket joint or a snap fit joint. The stopper 18 is sized and configured to seal against the inside of the tubular body 12c when disposed in the barrel 12. Axial translation of the plunger rod 16 results in axial translation of the stopper 18 in the tubular body 12c.

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[0024] A chamber 13 is defined in the barrel 12 between the stopper 18 and the front outlet 12a, where the chamber 13 may contain a medicament. Due to the sealing between the stopper 18 and the tubular body 12c, forward axial translation of the stopper 18 causes pressurization of the chamber 13 so that any medicament contained therein is expelled from the barrel via front outlet 12a.

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[0025] The open rear end 12b of the barrel 12 has a diameter D2 that is either substantially equal to or greater than the internal diameter D1 of the tubular body 12c. This is required to permit assembly of the plunger rod 16 with stopper 18 into the barrel 12. As a result of this arrangement, there is an annular space around the plunger rod 16, between the plunger rod 16 and the barrel 12. In reality, the open rear end 12b may include radially inward deformations of the order of 1 mm due to the manufacturing process. However, even with such irregularities, the open rear end 12b of the barrel 12 may still be considered to have a diameter D2 that is

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substantially equal to the internal diameter D1 of the tubular body 12c in accordance with the present invention. When assembling such a syringe 10, the stopper 18 may deform to pass the minor deformations at the open rear end 12b and enter the tubular body 12c.

5 **[0026]** The syringe 10 is suitable for use in an autoinjector device where a driving member acts on the plunger rod 16 to translate the stopper 18 axially forward in the barrel 12 to expel a medicament contained in the chamber 13. The axially forward force may be provided in the autoinjector by a spring or other suitable power source. In the non-limiting embodiment shown in Figure 1, the rear end of the plunger rod 16 includes a radially extending flange 16b which may facilitate better engagement of the driving member with the plunger rod 16. In alternative
10 embodiments within the scope of the present invention, the finger flange 16b may not be present.

[0027] To ensure the plunger rod 16 is suitable for use in an autoinjector device in which a (sometimes large) force is applied to the plunger rod 16 by a driving member, the plunger rod 16 of the present invention is constructed from a polymeric material that is preferably suitably
15 strong enough to transmit axial load from the driving member to the stopper 18 and ultimately pressurize the chamber 13. As noted above, in some autoinjector devices, the force provided by the driving member is particularly large. For example, a large driving force may be used to minimize the risk that the whole dose of medicament is not delivered, or to expel a particularly viscous medicament in a defined time. However, the large driving force acting on the plunger
20 rod 16 may result in radial deformation or displacement of the plunger rod 16 which may consequently cause the plunger rod 16 to contact the barrel 12. In a substantially full syringe (i.e. when the starting position of the stopper 18 is close to the rear open end 12b of the barrel 12), any contact between the plunger rod 16 and the barrel 12 is likely to occur around the rear open end 12b of the barrel 12 where a shoulder of the barrel 12 is formed. In other situations
25 where the starting position of the stopper 18 is further forward (e.g. a half full delivery), the plunger rod 16 is liable to bending and there is the risk that a radially deformed part of the plunger rod 16 (e.g. an antinode) will strike the inner surface of the tubular body 12c. To minimize the risk of this contact resulting in the breakage of the barrel 12, the plunger rod 16 according to the present invention is provided with a resilient outer layer 20 along its length.
30 The resilient outer layer cushions any force between the plunger rod 16 and the barrel 12 and increases the time that any force applied by the plunger rod 16 acts on the barrel 12, thereby increasing the impulse, I (since, for a force, F , applied over time interval, Δt , $I = F\Delta t$). Thus, the cushioning effect created by the presence of the resilient outer layer 20 minimizes the risk of breakage of the barrel 12 during movement of the plunger rod 16 therein.

35 **[0028]** In tests conducted by the applicant, it was found that significantly fewer breakages occurred during actuation of a large number of autoinjectors when the resilient outer layer 20

was present compared to test conducted where the resilient outer layer was not present.

[0029] The resilient outer layer 20 may be a sleeve that surrounds plunger rod 16 or may alternatively be a coating applied to the plunger rod 16. In the case where the resilient outer layer 20 is a sleeve, the sleeve may be formed tightly around the plunger rod 16 so that axial movement of the sleeve relative to the plunger rod 16 is limited. In alternative embodiments, the sleeve may be otherwise fixed to the plunger rod 16 so as to prevent or limit axial movement of the sleeve relative to the plunger rod 16. In any embodiment, the resilient outer layer 20 may be formed from any suitably resilient material that provides an adequate cushioning effect. In one example, the resilient outer layer 20 is made of an elastomeric material. In certain embodiments, the resilient outer layer 20 may be made of a material incorporating or consisting of silicone.

[0030] The impact between the plunger rod 16 and the barrel 12 may occur at any time when the driving member is acting on the plunger rod 16. In preferable embodiments, therefore, the resilient outer layer 20 is provided along substantially all of the exposed length of the plunger rod 16, i.e. between the stopper and the rear end of the plunger rod (or radially extending flange 16b, if present). However, depending on the specific application, or for devices where impact was known to most likely occur at a particular stage of the axial movement of the plunger rod 16 in the barrel 12, the resilient outer layer 20 may extend along at least 50%, 75% or 90% of the exposed length of the plunger rod 16. In these embodiments, the resilient outer layer 20 may extend along the front 50%, 75% or 90% of the exposed length of the plunger rod 16, the rear 50%, 75% or 90% of the exposed length of the plunger rod 16, or an intermediate 50%, 75% or 90% of the exposed length of the plunger rod 16. Larger coverage by the resilient outer layer 20 is preferable as this minimizes breakage most effectively by providing protection in the event of unpredictable deformation or deflection of the plunger rod 16.

[0031] In accordance with certain embodiments of the present invention, there may be provided an autoinjector device that includes a housing configured to receive a syringe. The autoinjector device may include a plunger rod in accordance with that described above such that a syringe (without a plunger rod) may be installed in the autoinjector device and the plunger rod of the autoinjector device may be used to expel medicament from the syringe. In other embodiments, the autoinjector device may be provided with a syringe and plunger rod installed.

[0032] Throughout the description and claims of this specification, the words “comprise” and “contain” and variations of them mean “including but not limited to”, and they are not intended to (and do not) exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires

otherwise.

[0033] Features, integers, characteristics, compounds, chemical moieties or groups described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive. The invention is not restricted to the details of any foregoing embodiments. The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

[0034] The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

CLAIMS

1. A syringe for use in an autoinjector, the syringe comprising:
a barrel having a front outlet, an open rear end, and a tubular body extending between
5 the front outlet and open rear end, wherein the tubular body has an internal diameter and
defines a volume for containing medicament, and the open rear end has a diameter
substantially equal to or greater than the internal diameter of the tubular body; and
a polymeric elongate plunger rod having a stopper at a forward end and a resilient outer
10 layer along the length of the elongate plunger rod, the elongate plunger rod being disposable
within the barrel such that the stopper seals against the inside of the tubular body of the barrel
and is slidable therein by axial translation of the plunger rod in the barrel.
2. A syringe according to claim 1, wherein said resilient outer layer comprises a sleeve
15 surrounding the circumference of the elongate plunger rod.
3. A syringe according to claim 1, wherein said resilient outer layer comprises a coating
surrounding the circumference of the elongate plunger rod.
4. A syringe according to claim 1, wherein said resilient outer layer comprises an overmoulded
20 layer.
5. A syringe according to any preceding claim, wherein said resilient outer layer comprises an
elastomeric material.
- 25 6. A syringe according to claim 5, wherein said elastomeric material comprises silicone.
7. A syringe according to claim any preceding claim, wherein said resilient outer layer extends
along at least 50% of the length of the elongate plunger rod.
- 30 8. A syringe according to claim 7, wherein said resilient outer layer extends along at least 75%
of the length of the elongate plunger rod.
9. A syringe according to claim 8, wherein said resilient outer layer extends along at least 90%
of the length of the elongate plunger rod.
- 35 10. A syringe according to any preceding claim, wherein the elongate plunger rod has a radially
outwardly projecting flange at a rear end.

11. An autoinjector device, including:
 - a syringe according to any preceding claim; and
 - a driving member for moving the plunger rod axially forwardly in the barrel.
12. An autoinjector device, including:
 - 5 a housing for receiving a syringe;
 - a polymeric elongate plunger rod for insertion into a barrel of a received syringe and for connection to a stopper disposed in the barrel, the elongate plunger rod having a resilient outer layer along the length of the elongate plunger rod; and
 - a driving member for moving the plunger rod axially forwardly in the barrel.
- 10 13. An autoinjector device according to claim 12, wherein said resilient outer layer comprises a sleeve surrounding the circumference of the elongate plunger rod.
14. An autoinjector device according to claim 12, wherein said resilient outer layer comprises a
15 coating surrounding the circumference of the elongate plunger rod.
15. An autoinjector device according to claim 12, wherein said resilient outer layer comprised an overmoulded layer.
- 20 16. An autoinjector device according to any of claims 12 to 15, wherein said resilient outer layer comprises an elastomeric material.
17. An autoinjector device according to claim 16, wherein said elastomeric material comprises
25 silicone.
18. An autoinjector device according to any of claims 12 to 17, wherein said resilient outer layer extends along at least 50% of the length of the elongate plunger rod.
19. An autoinjector device according to claim 18, wherein said resilient outer layer extends
30 along at least 75% of the length of the elongate plunger rod.
20. An autoinjector device according to claim 19, wherein said resilient outer layer extends along at least 90% of the length of the elongate plunger rod.
- 35 21. An autoinjector device according to any of claims 12 to 20, wherein the elongate plunger rod has a radially outwardly projecting flange at a rear end.

22. An autoinjector device according to any of claims 12 to 21, further comprising a syringe received in the housing, wherein the syringe comprises a barrel having a front outlet, an open rear end, a tubular body extending between the front outlet and the open rear end, and a stopper disposed in the barrel, wherein the elongate plunger rod is disposed in the barrel and is connected to the stopper in the syringe.
23. A syringe for use in an autoinjector as hereinbefore described with reference to the accompanying drawing.
24. An autoinjector device as hereinbefore described with reference to the accompanying drawing.



Application No: GB1401677.8

Examiner: Mr Michael Bate

Claims searched: 1-24

Date of search: 12 August 2014

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1, 2, 4, 7-13, 15 and 18-22	WO2010/146358 A1 (MCLOUGHLIN) See whole document, particularly figures 15-19.
X	1, 2, 4, 7-13, 15 and 18-22	WO2013/119591 A1 (ADLON) See in particular figures 2-8.
X	1, 2, 4, 7-13, 15 and 18-22	US6413237 B1 (CAIZZA I) See figures 1-5.
X	1, 2, 4, 7-13, 15 and 18-22	US6409701 B1 (CAIZZA II) See figures 1-4.
X	1, 2, 4, 7-13, 15 and 18-22	US2001/0053886 A1 (CAIZZA III) See figures 1-4.
X	1, 2, 4, 7-13, 15 and 18-22	WO2006/020953 A1 (SCHILLER) See figures 1-3.
X	1, 2, 5-13 and 16-22	CN2824966 Y (ZHENJUN) See figure 1 and accompanying description.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^X :

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Worldwide search of patent documents classified in the following areas of the IPC

A61M

The following online and other databases have been used in the preparation of this search report



EPODOC, WPI, TXTE

International Classification:

Subclass	Subgroup	Valid From
A61M	0005/315	01/01/2006