(19)





(11) **EP 2 822 618 B1**

(12)

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication and mention of the grant of the patent:10.01.2024 Bulletin 2024/02
- (21) Application number: 13757994.2
- (22) Date of filing: 05.03.2013

- (52) Cooperative Patent Classification (CPC):
 A61M 5/2033; A61M 5/50; A61M 2005/2013; A61M 2005/2073; A61M 2005/3267
- (86) International application number: PCT/US2013/029085
- (87) International publication number: WO 2013/134244 (12.09.2013 Gazette 2013/37)

(54) PREFILLED SYRINGE WITH BREAKAWAY FORCE FEATURE

VORGEFÜLLTE SPRITZE MIT LOSBRECHKRAFTFUNKTION AMPOULE-SERINGUE À CARACTÉRISTIQUE DE FORCE DE RUPTURE

- (84) Designated Contracting States: AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
- (30) Priority: 06.03.2012 US 201261607339 P
- (43) Date of publication of application: 14.01.2015 Bulletin 2015/03
- (73) Proprietor: Antares Pharma, Inc. Ewing, NJ 08628 (US)
- (72) Inventors:
 LANNAN, James, W. Brooklyn Center, MN 55429 (US)

- SUND, Julius, C.
 Plymouth, MN 55447 (US)
- (74) Representative: Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
- WO-A1-94/11041

 WO-A1-03/095003
 WO-A1-94/11041

 WO-A1-03/095003
 WO-A1-2010/136078

 US-A- 6 102 896
 US-A1- 2011 144 594

 US-A1- 2011 144 594
 US-A1- 2012 004 608

 US-A1- 2012 004 608
 US-B1- 6 391 003

2 822 618 B1 Ч

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

BACKGROUND OF THE INVENTION

- ⁵ **[0001]** The present invention relates to a jet injector and in some arrangements a needle-assisted jet injector that uses a low jet injection pressure and has a lock ring that provides breakaway force resistance. US 2011/144594 A1 discloses an injector having an end cap. A rear end of latches provided on retractable guard interacts with a cap to prevent the guard from being retracted. From US 6 102 896 A, an injector is known, which has a configuration, that when a guard is pressed into the skin, a protrusion breaks away.
- 10 [0002] Certain jet injection devices have needle guards that must be retracted prior to insertion of the needle and triggering of the jet injection. A certain amount of force is normally required to trigger the jet injection. To assure sufficient needle guard travel for needle insertion and triggering, it is at times desirable to require a breakaway force prior to significant needle guard retraction to assure that insertion of the needle and triggering of triggering force is overcome. The present invention addresses this problem. Further relevant prior art is described in US 2011/144594 A1, US
- ¹⁵ 2012/004608 A1, US 6 102 896 A, WO 03/095003 A1.

SUMMARY OF THE INVENTION

- [0003] In particular, an injector is provided having the features defined in claim 1. Further preferred embodiments are defined in the dependent claims. In the following there are described some arrangements. However the scope of protection is defined by the claims. There may be described some arrangements which are not in accordance with the present invention, but they are however helpful for understanding the present invention. In one arrangement, the jet injector includes a prefilled syringe having a container portion defining a fluid chamber containing a medicament; an injectionassisting needle disposed at the distal end of the chamber, having an injecting tip configured for piercing an insertion
- ²⁵ location, and defining a fluid pathway in fluid communication with the chamber for injecting the fluid from the chamber into an injection site; a plunger movable within the fluid chamber; a housing that houses the prefilled syringe and is configured for allowing insertion of the needle at the injection location to an insertion point that is at a penetration depth below the surface, the housing including: a retractable guard that is movable between a protecting position in which the needle is disposed within the guard and an injecting position in which the tip of the needle is exposed for insertion to
- ³⁰ the insertion point, and an interference component adjacent to the retractable guard that interferes with the movement of the retractable guard when the retractable component is moved at least partially from the protecting position toward the injecting position; a syringe support supportively mounting the prefilled syringe in the housing; an energy source configured for biasing the plunger with a force selected to produce an injecting pressure on the medicament in the fluid chamber to jet inject the medicament from the fluid chamber through the needle to the injection site.
- ³⁵ **[0004]** In certainarrangements, the energy source and prefilled syringe are configured such that the injecting pressure remains between about 5.52 bar (80 p.s.i.) and about 68.95 bar (1,000 p.s.i.) during injection of the medicament. In one arrangement, the energy source and prefilled syringe are configured such that the injecting pressure remains below about 34.47 bar (500 p.s.i.) and above about 6.21 bar (90 p.s.i.) during the injection of the medicament. In another arrangement, the energy source and prefilled syringe are configured to produce the injecting pressure that remains at
- 40 least at about 6.89 bar (100 p.s.i.) during the injection of the medicament. In one arrangement, the energy source and prefilled syringe are configured such that the injecting pressure remains up to about 24.13 bar (350 p.s.i.) during the injection of the medicament.

[0005] In certain arrangements, the prefilled syringe has a distal portion in which the injection-assisting needle is located, and a proximal portion opposite the distal portion; and the syringe support axially supports the proximal portion

of the pre-filled syringe during the jet injection of the medicament, such that the distal portion of the prefilled syringe is substantially unsupported in an axial direction. In one arrangement, the container portion of the pre-filled syringe is made of blown glass. In another arrangement, the injection-assisting needle is adhered to the glass.
 [0006] In certain arrangement, the interference component is a ring having at least one abutment arm extending distally

from a proximal end dimensioned to fit within the housing, the abutment arm having at least one tapered portion. In one arrangement, the at least one abutment arm has an engagement portion axially adjacent to the at least one tapered portion that is configured to cause resistance to the movement of the retractable guard when the retractable guard is moved at least partially from the protecting position toward the injecting position.

[0007] In one arrangement, the energy source comprises a spring. In one arrangement, the jet injector further includes a ram that is biased by the spring against the plunger to produce the injecting pressure, wherein the ram comprises a bell portion on which the spring is seated, and the bell portion defines a hollow interior configured for receiving the prefilled syringe when the device is fired, such that the spring surrounds the prefilled syringe.

[0008] In some arrangements, the jet injector further includes a trigger mechanism operably associated with the energy source for activating the energy source to jet inject the medicament, wherein the trigger mechanism is configured for

activating the energy source after the retractable guard is retracted from the protecting position. In one arrangement, the retractable guard is operably associated with the trigger mechanism to cause the trigger mechanism to activate the energy source when the guard is retracted to the injecting position.

[0009] In certain arrangements, the housing is configured for allowing insertion of the needle to the penetration depth, which is between about 0.5 mm and about 5 mm below the surface at the insertion location.

[0010] In certain arrangements, the housing is configured for allowing insertion of the needle to the penetration depth, which is between about 11 mm and about 13 mm below the surface at the insertion location.

[0011] In certain arrangements, the chamber contains about between 0.02 mL and about 4 mL of the medicament.

[0012] In certain arrangements, the penetration depth and injecting pressure are sufficient to substantially prevent backflow of the injected medicament.

[0013] In other arrangements, the jet injector further includes a syringe cushion associated with the syringe support and prefilled syringe to compensate for shape irregularities of the pre-filled syringe.

[0014] In certain arrangements, the invention relates to a lock ring for a jet injector. In other arrangements, the lock ring includes at least one abutment arm extending distally from a proximal end of a body dimensioned to fit within in a

¹⁵ housing of the jet injector, the abutment arm having at least one tapered portion and at least one engagement portion axially adjacent to the at least one tapered portion, the engagement portion being configured to cause resistance to the movement of a retractable guard of the jet injector; and at least one flap radially adjacent to the at least one abutment arm extending distally from the proximal end of the body.

20 BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0015] The foregoing summary, as well as the following detailed description of arrangements, will be better understood when read in conjunction with the appended drawings of arrangements.

[0016] In the drawings:

25

5

10

FIG. 1 is a side view of an arrangement of a jet injector, showing the injector prior to injection;

- FIG. 2 is a cross-sectional view of the jet injector of FIG. 1 thereof taken along plane II-II;
- FIG. 3 is a perspective view of a prefilled syringe for use in the jet injector of FIG. 1;
- FIG. 4 is a perspective view of a syringe cushion of the jet injector of FIG. 1;
- FIG. 5 is a cross-sectional view of the jet injector of FIG. 1, showing the injector at the start of the jet injection;
 FIG. 6 is a graph showing the pressure present in the polluted chamber over time that contains medicament in an arrangement during jet injection;

FIG. 7 is a side view of another arrangement of an injector that is configured for using a narrow diameter prefilled syringe;

- FIG. 8 is a cross-sectional view of the jet injector of FIG. 1; taken along plane VIII-VIII;
 FIG. 9 is a cross-sectional view of another arrangement of an injector using a needle for intramuscular jet-injection;
 FIG. 10A is a side view of an interference component of a jet injector in accordance with an exemplary arrangement;
 FIG. 10B is a perspective view of an interference component of a jet injector in accordance with an exemplary arrangement;
 a perspective view of an interference component of a jet injector in accordance with an exemplary arrangement;
- ⁴⁰ FIG. 11 is a graph showing the breakaway force over time of an jet injector in accordance with an exemplary arrangement.

DETAILED DESCRIPTION OF THE INVENTION

- ⁴⁵ **[0017]** With reference to the accompanying drawings, various arrangements of the present invention are described more fully below. Some but not all arrangements of the present invention are shown. Indeed, various arrangements of the invention may be embodied in many different forms and should not be construed as limited to the arrangements expressly described. Like numbers refer to like elements throughout. The singular forms "a," "an," and "the" include the singular and plural unless the context clearly dictates otherwise.
- 50 [0018] Referring to FIGS. 1 and 2, an arrangement of an injector 10 has a housing 12 configured for allowing a user to handle the injector 10. The housing 12 includes an outer housing member 14 that substantially houses most of the components shown in FIG. 2. A syringe support member 16 is housed within and mounted with the housing 12. The syringe support member 16 is configured to hold and position a prefilled syringe 18, which is shown in FIG. 3. In one arrangement, the syringe support member 16 is substantially fixed to the housing 12, such as by snaps, an adhesive,
- ⁵⁵ a weld, or another known attachment. The prefilled syringe **18** has a container portion **20** that defines in its interior a fluid chamber **22**, which is prefilled with medicament to be injected. At the distal end of the prefilled syringe **18** is an injection-assisting needle **24**. Needle **24** has an injecting tip **26** configured as known in the art to penetrate the tissue of a patient, in certain arrangements, the skin of the patient. A needle bore extends through the needle **24**, as known in

the art. The bore is in fluid communication with the medicament in the fluid chamber **22** and is open at the needle tip 26 to inject the medicament.

[0019] At a proximal side of the fluid chamber 22, opposite from the needle 24, is a plunger 28 that seals the medicament in the fluid chamber 22. In certain arrangements, a syringe wall 30 comprises a tubular portion, in some arrangements

- ⁵ closed at a distal end and open at a proximal end, to define the fluid chamber 22. Plunger 28 is slideably received in the tubular portion. The prefilled syringe 20 is configured such that when the plunger 28 is displaced in a distal direction, the volume of the fluid chamber 22 is decreased, forcing the medicament out therefrom and through the bore of the needle 24.
- [0020] At the distal end of the fluid chamber 22 is a needle hub portion 32 to which the needle is mounted. In one arrangement, a syringe flange 34 extends radially from the proximal end of the syringe wall 30.
- [0021] In one arrangement, the syringe 18 has a syringe body 36 that includes the flange 34, wall 30 and hub portion 32. In one arrangement, syringe body 36 that includes flange 34, wall 30, and hub portion 32 is of unitary construction. A preferred material for the syringe body 36 is glass, but other materials can be used in other arrangements. A suitable prefilled syringe is the BD Hypak[™], which is available in various sizes and volumes and is sold prefilled with medicament.
- ¹⁵ The glass of the syringe body **36** is adhered to the needle **24**. Typical medicaments and medicament categories include epinephrine, atropine, sumatriptan, antibiotics, antidepressants, and anticoagulants. Using a prefilled syringe **18** facilitates handling of the medicament when the injector **10** is assembled, and there is an extensive body of knowledge of how the medicaments keep and behave in a prefilled syringe.
- [0022] A syringe cushion 38, which is shown in detail in FIG. 4, is in certain arrangements made of an elastomeric material or other resilient material. A flange 40 of the syringe cushion 38 extends radially and is disposed and serves as an interface between the distal side of the syringe support member 16 and the syringe flange 34. Elevated portions, such as nubs 42 extend proximately from the cushion flange 40 and are configured and dimensioned to abut the syringe flange 34.
- [0023] Prefilled syringes that are manufactured by a blown glass process can have significant dimensional tolerances and unevenness, particularly in the glass body **36.** The cushion **38** can serve to accommodate the shape irregularities and to properly position and locate the prefilled syringe **18** within the syringe support **16.** Typically, the axial thickness of glass blown syringe flanges on a 1 mL prefilled syringe is within about ±0.5 mm. For a BD Hypak[™] 1 mL standard prefilled syringe, the thickness of the syringe flange **34** is 2 mm+0.5 mm or -0.4 mm, and in a 1 mL long configuration BD Hypak[™] syringe, the flange axial thickness is about 1.65 mm±0.25 mm. Other dimensional variations that occur in
- 30 typical glass prefilled syringes are in the internal and external diameters of the tubular wall **30**. These variations can be accommodated by the resilient sleeve portion **44** of the syringe cushion **38**, which extends axially around the interior of the syringe support **16**. In one arrangement, the syringe cushion **38** is received in the interior of the syringe support **16** and receives the syringe body **36**, in certain arrangements fitting snugly therein.
 [0024] In one arrangement, the sleeve portion **44** has radially inwardly extending protrusions **46** with a surface area
- ³⁵ and configuration selected to allow the insertion of the prefilled syringe **18** therein during assembly, but providing sufficient friction to maintain the syringe **18** in place and to provide cushioning and shock absorption during the firing of the injector **10**. Outward protrusions **48** are also provided on the sleeve portion **44**, which can be received in corresponding recesses of the syringe support **16** to prevent axial rotation therebetween. Recessed areas **50** can be provided on the interior and exterior of the syringe cushion **38** opposite corresponding protrusions **48** on the opposite radial side of the sleeve portion.
- 40 44 if an increased wall thickness of the sleeve portion 44 is not desired. In an alternative arrangement one or both of the flange 40 and sleeve 44 of the syringe cushion 38 are substantially smooth, substantially without any protrusions. In one arrangement, the material and configuration of the syringe cushion 38 is also sufficient to entirely support the prefilled syringe 20 to withstand a firing force applied axially in a distal direction on the plunger 28. Thus, the entire support for the prefilled 20 can be provided on the syringe flange 34, while the distal end of the syringe 18 may itself be

⁴⁵ substantially unsupported in an axial direction. This can help withstand the shock on the glass body 36 of the prefilled syringe 20 produced by the elevated pressures within the fluid chamber 22.
[0025] To radially position the distal end of the prefilled syringe 18, the syringe support 16 in certain arrangements has a narrowed bore portion 51 that is in certain arrangements configured to abut the outside of the syringe wall 30. This is especially beneficial when the needle 24 is inserted into the patient's skin. The narrowed bore portion 51 can be

- ⁵⁰ made of a resilient material, such as an elastomer, or it can be made unitarily with the rest of the syringe support 16, in certain arrangements of a plastic material.
 [0026] Referring to FIG. 2, in one arrangement, a trigger mechanism 52 is also housed within housing 12. The trigger mechanism 52 includes an inner housing 54 that can be attached to the outer housing 14, such as by snaps, an adhesive, a weld, or other known attachment. Trigger protrusions 56 extend inwardly from the proximal end of the inner housing
- 55 54 and are resiliently biased outwardly. Trigger protrusions 56 are received in a recess 58 of ram 60 in blocking association therewith to prevent distal movement of the ram 60 prior to the firing of the device. The ram 60 is urged towards the distal end of the injector 10 by an energy source, which in certain arrangements is a compression spring 52, although other suitable energy sources can alternative be used such as elastomer or compressed-gas springs. In one arrangement,

the compression spring is a coil spring.

[0027] A trigger member of the trigger mechanism 52, such as a latch housing 64, is provided exterior to the inner housing to retain the trigger protrusions 56 in the blocking association in the recess 58 to prevent premature firing of the injector 10. The latch housing 64 is slideable inside the outer housing 14 with respect to the inner housing 54, in certain arrangements in an evial direction, and the latch housing 64 is provided the inner housing 54.

- ⁵ arrangements in an axial direction, and the latch housing **64** in certain arrangements surrounds the inner housing **54**. [0028] The housing **12** has a needle guard **66** that is moveable with respect to the outer housing **14**. The needle guard **66** is shown in FIGS. 1 and 2 in a protecting position, in which the needle **24** is disposed within the guard **66**. The needle guard **66** is retractable, in one arrangement into the outer housing **14**, in a proximal direction to an injecting position, in which the needle **24** is exposed as shown in FIG. 5 for insertion into a patient. ¹⁰ In one arrangement, the proximal movement of the guard is prevented substantially at the injecting position.
- In one arrangement, the proximal movement of the guard is prevented substantially at the injecting position.
 [0029] In one arrangement, an interference component 134 interferes with the movement of the needle guard when the needle guard is moved at least partially from the protecting position toward the injecting position.
 [0030] In one arrangement, the housing 12 has an interference component 134, e.g., a lock ring, adjacent to the needle guard 66, the interference component 134 interferes with the movement of the needle guard when the needle guard is
- ¹⁵ moved at least partially from the protecting position toward the injecting position. Interference component prevents movement of the needle guard until the breakaway force **146** is exceeded. The interference component **134** is shown in FIGS. 10A and 10B. In one arrangement, the interference component **134** is included as part of a ring having at least one abutment arm **136** extending distally from a proximal end **138** dimensioned to fit within the housing **14**, the abutment arm **136** having at least one tapered portion **140**. The abutment arm **136** has an engagement portion **142** axially adjacent
- to the at least one tapered portion 140 that is configured to cause resistance to the movement of the needle guard 66 when the needle guard 66 is moved at least partially from the protecting position toward the injecting position. While interference component 134 may have more than one abutment arm 136 and correspondingly more than one engagement portion 142, certain arrangements include only one abutment arm 136 having an engagement portion 142. The interference component includes at least one flap 144 radially adjacent to the at least one abutment arm 136 extending distally from the proximal end 138 of the interference component 134.
- distally from the proximal end 138 of the interference component 134.
 [0031] The interference component 134 may also be coupled to the housing 12, incorporated in a sleeve separate from the housing 12, or include a latch.

[0032] Referring to FIG. 11, breakaway force **146** is needed to overcome the resistance on the needle guard **66** caused by the engagement portion **142** when the needle guard **66** is moved at least partially from the protecting position toward

- 30 the injecting position. Referring to Fig. 11, breakaway force **146** is the resistance to retraction that is exerted on the needle guard **66** when an initial attempt to retract the needle guard **66** occurs. Breakaway force **146** is a distinct force from the triggering force **148** that is needed to cause jet injection of the medicament and is a greater force than that provided by the spring **62** that biases the needle guard **66** in the extended position. Breakaway force **146** is sometimes also a greater force than what occurs due to the friction of the needle guard **66** retracting motion sliding on other mating
- ³⁵ components in the device. In one arrangement the breakaway force **146** is controlled and only occurs as a single event. [0033] Referring to FIG. 2, the needle guard **66** is associated with the latch housing **64** such that when the guard **66** is displaced distally it slides the latch housing **64** also in a distal direction to release the trigger protrusions **56** from the recess **58**. In one arrangement, the latch housing **64** has a latching portion **68** that abuts the inner housing **54** in an association to bias and maintain the trigger protrusions **58** positioned in the blocking association with the ram **60** prior
- to the firing of the device 10. When the latch is slid proximately by the retracting of the guard 66 to the injecting position, the latching portion 68 slides beyond the portion of inner housing 54 that is contacts to flex the trigger protrusions 56 into the recess 58 of the ram 60, allowing the trigger protrusions 56 to move radially outwardly from the recess 58 and therefore from the blocking association. When this happens, spring 62 biases the ram 60 against plunger 28 to fire the jet injector 10. In certain arrangements, latch housing 64 defines trigger openings 70 adjacent to latching portions 68,

which is configured to receive a portion of the inner housing 54, such as the surface disposed radially outwardly from the trigger protrusions 56.
 [0034] In certain arrangements, the guard 66 is resiliently biased distally towards the protecting position by compression

coil spring 72. Also, the needle guard 66 has an axial opening 74 to allow the needle 24 pass there through, and which may be sized according to the type of injector desired. The construction of the present arrangement allows a user to

- ⁵⁰ push the distal end of the injector **10** against the patient's skin, pushing the needle **24** into the skin at an insertion location, substantially at the same speed as the injector is pushed. Once the needle **24** is fully inserted to an insertion point at a penetration depth, the trigger mechanism **56** fires the jet injection to an injection site. [0035] Referring to FIG. 5, in one arrangement, the prefilled syringe **18** and its needle **24** are not shuttled forward
- automatically into the patient's skin, such as by the firing energy source during the injection firing. The user preferably gently pushes the entire device forward to insert the needle **24**, in certain arrangements retracting a guard against the skin in the process. In one arrangement, the prefilled syringe **18** is substantially stationary within the housing **12**, and, in one arrangement, is substantially fixed thereto. In this manner, the present invention provides for a gentler treatment of the syringe during injection that enables the use of a sufficiently powerful spring **62** or other energy source to produce

a jet injection without the risk of damaging the relatively fragile and complex shapes of the prefilled syringe, also allowing, for example, the injection of high viscosity solutions, where the risk of breaking a syringe, such as at the flange, is elevated in prior art injectors that shuttle the syringe forward in the housing and into the patient. Residual stresses are also often present in the glass bodies of prefilled syringes, and this configuration reduces the additional stresses imposed

- thereon during use, further protecting the syringe. Also, misalignments in the prefilled syringe are also rendered operationally less significant due to the gentle insertion of the needle that is possible with this configuration.
 [0036] In one arrangement, the injecting position of the guard 66 is such that a predetermined length of the end of needle 24 is exposed from the guard 66. In some arrangements, such as where the opening 74 is of a sufficiently large diameter, the skin of the patient maybe allowed to extend into the opening 74 when the device 10 is pressed there
- ¹⁰ against, and a needle that does not protrude beyond the distal end of the guard **66** can be used while still penetrating the skin to a certain depth. In most arrangements, the distance **76** by which the needle tip **26** extends past the distal end of the guard **66** will be fairly close to the depth of the insertion of the needle. [0037] In one arrangement, such as for subcutaneous injection, the guard **66** is configured to allow insertion of the
- needle 24 to a penetration depth in the skin that is up to about 5 mm below the skin surface. In another arrangement, the penetration depth is less than about 4 mm, and in one arrangement is less than about 3 mm. In one arrangement, the insertion depth is at least about 0.5 mm and, in other arrangements, at least about 1 mm. In another arrangement, the distance 76 by which the needle extends past the guard 66 or the distal surface of the guard 66 that contacts the skin is up to about 5 mm, in one arrangement, up to about 4 mm, and in another arrangement up to about 3 mm. In certain arrangements, extension distance 76 is at least about 0.5 mm, in one arrangement at least about 1 mm, and in
- another arrangement at least about 2 mm. In one arrangement, tip 26 extends by a distance 76 of around 2.5 mm beyond the portion of the guard 66 that contacts the skin in the injecting position.
 [0038] In another arrangement, such as for intramuscular injection, the injector is configured to allow the needle 24 to be inserted into the patient to a penetration depth in the skin, or alternatively beyond the distal surface of the guard, by a distance of up to about 15 mm. In one arrangement, this distance is about between 10 mm and 14 mm. In an
- ²⁵ arrangement for jet injection of epinephrine for instance, a penetration depth or distance beyond the guard is between about 11 mm and about 17.0 mm, and, in other arrangements, between about 13 to about 15 mm. Jet injection with this length needle improves the distribution of the medicament in the patient tissue compared to non-jet injection. Other exposed needle lengths can be selected for jet injection to different depths below the skin, with, in certain arrangements, an overall penetration length of between about 0.5 mm and about 20 mm. In certain arrangements, the needle guard is
- configured for retracting from a protecting position, in one embodiment covering the entire needle 24 (See FIG. 2), to an injecting position, in which the desired length of the end of the needle 24 is exposed (See FIG. 5).
 [0039] In some arrangements, the spring 62 and the prefilled syringe 18 are configured to jet inject the medicament. Thus, the spring 62 applies a force on the plunger 28 that is sufficient to elevate the pressure within the fluid chamber 22 to a level high enough to eject the medicament from the needle 24 as a jet. Jet injection is to be understood as an
- ³⁵ injection with sufficient velocity and force to drive the medicament to locations remote from the needle tip **26.** In manual and auto-injector-type injections, in which the injection pressures are very low, the medicament exits the needle tip inside the patient and is typically deposited locally around the needle in a bolus. On the other hand, with the present jet injection device **10**, the medicament is jet injected distally or in other directions, such as generally radially by the elevated pressure jet, which beneficially improves the distribution of the medicament after the injection and keeps a large bolus from forming
- that can detrimentally force the medicament to leak back out of the patient around the needle or through the hole left behind by the needle after it is removed.
 [0040] Referring to the graph shown in FIG. 6, numeral 78 represents the point in time when device 10 is fired, and numeral 80 represents the point in time of completion of the medicament injection, in certain arrangements when the
- ⁴⁵ the injection, and numeral **84** represents the final and low pressure during the injection. Since the spring **62** of one arrangement has a linear spring constant and an injection-assisting needle is used to puncture the skin before commencing the injection, the pressure drops substantially linearly from the start of the injection **78** until the injection is completed. The final pressure **84** at the end **80** of the injection is sufficiently elevated so that even at the end of the firing
- stroke of ram 60, the medicament is still jet injected, and a very small amount or none of the medicament is deposited
 in a bolus around the needle tip 26.
 [0041] In one arrangement, the peak pressure during the injection is less than about 68.95 bar (1,000 p.s.i.), in one arrangement less than about 34.47 (500 p.s.i.), and in another arrangement less than about 24.13 (350 p.s.i.). At the end 80 of the injection, the pressure 84 applied to the medicament in the fluid chamber 22 is in one arrangement at least

about 5.52 bar (80 p.s.i.), in one arrangement at least about 6.21 bar (90 p.s.i.), and in another arrangement at least
about 6.89 bar (100 p.s.i.). In one arrangement of the invention, the initial pressure 82 is around 22.75 bar (330 p.s.i.),
and the final pressure is about 12.41 bar (180 p.s.i.), while in another arrangement the initial pressure 82 is about 20.68 (300 p.s.i.), dropping to around 7.58 bar (110 p.s.i.) at the end 80 of the injection. The needles used in these arrangements are between 26 and 28 gauge, and are in certain arrangements around 27 gauge, but alternatively other needle gages

can be used where the other components are cooperatively configured to produce the desired injection. In an arrangement for jet injection of epinephrine for instance, certain arrangements of the needles are between 20 and 25 gauge, and in other arrangements, 22 gauge. In one arrangement, the components of the injector **10** are configured to jet inject the medicament to a subterraneous injection site.

- ⁵ **[0042]** The amount of medicament contained and injected from fluid chamber **22** is in one arrangement between about 0.02 mL and about 4 mL, in certain arrangements less than about 3 mL, and in other arrangements is around 1 mL. Larger volumes may also be selected depending on the particular medicament and dosage required. In one arrangement, the prefilled syringe is assembled into the remaining parts of the jet inj ector **10** already containing the desired amount of medicament. In one arrangement, the prefilled syringe contains about 1 mL of medicament.
- 10 [0043] In one arrangement, injection rates are below about 0.75 mL/sec., in one arrangement preferably below about 0.6 mL/sec., in one arrangement at least about 0.2 mL/sec., in one arrangement at least about 0.3 mL/sec, and in other arrangements at least about 0.4 mL/sec. In one arrangement, the injection of the entire amount of medicament is completed in less than about 4 seconds, in one arrangement in less than about 3 seconds, and in other arrangements in less than about 2.5 seconds. In one arrangement, the medicament injection takes at least about 1 second, in one
- ¹⁵ arrangement at least 1.5 seconds, and in other arrangements at least about 1.75 seconds. In one arrangement, the injector **10** injects the medicament at about 0.5 mL/sec., completing the injection of 1 mL in about 2 seconds. [0044] U.S. Pat. No. 6,391,003 discloses several experimental results of pressures that can be applied to medicament in a glass cartridge, using 26 and 27 gauge needles. The following table illustrates injections with different peak pressures that can be used with glass prefilled syringes:

20

25

	Pressure and Time (sec.) to Inject 1 cc		
	Pressure	26 Gauge needle	27 Gauge needle
-	150 p.s.i.	2.1	4.2
	200 p.s.i.	1.9	3.9
	240 p.s.i.	1.7	3.3
_	375 p.s.i.	1.4	3.1

- [0045] It is foreseen that higher pressures and flow rates will be used with shorter needle penetration into the patient skin to achieve jet injections to a particular desired depth substantially without medicament leakback.
 [0046] It has been found that using the jet injection of the present device, short needles can be used to inject medicament
- to different parts of the skin, in certain arrangements subcutaneously, substantially without any leakback. Using a needle 24 that extends by about 2.5 mm from the needle guard **66**, a 27 gauge needle **24**, and a pressure in the fluid chamber **22** peaking at around 20.68 (300 p.s.i.) and ending at around 6.89 (100 p.s.i.), resulting in a flow rate of about 0.5 mL/sec.,
- 1 mL of medicament has been found to successfully be injected without leakback in close to 100% of the tested injections. Thus, the needle-assisted jet injector **10** of the present invention permits jet injection of the medicament using a very short needle reliably regardless of the thickness of the patient's skin or the patient's age, weight or other typical factors that complicate non-jet injecting with short needles.
- 40 [0047] FIGS. 7 and 8 show another arrangement of the present invention that uses a prefilled syringe that has a long, but smaller-diameter configuration than the arrangement of FIG. 2. While in the arrangement of FIG. 2, the firing spring 62 extends into the bore of the prefilled syringe 18 during the firing stroke, the narrower prefilled syringe 88 of injector 86 does not provide as much space to accommodate a spring. Consequently, the ram 90 of injector 86 includes a bell portion 92 defining a hollow interior 94 that is configured to receive the proximal end of the prefilled syringe 88 and the
- ⁴⁵ syringe support 96 when the injector 86 is fired. Similarly, a bell-receiving space 98 is defined around the exterior of the prefilled syringe 88 and syringe support 96 to receive the bell portion 92 during the firing. The bell portion 92 includes a spring seat 100 extending radially outwardly and configured and disposed to seat a compression spring 102. When the trigger mechanism 56 is activated and the device 86 is fired, spring 102 acts against seat 100 to drive the ram 90 against plunger 104 to jet inject the medicament from the fluid chamber 106. As a result, after firing, the spring 102
- radially surrounds the prefilled syringe 88. The outer housing portion 108 is wider than outer housing portion 14 of injector 10 to accommodate the bell portion 92 and larger diameter spring 102.
 [0048] One available long configuration syringe with a 1 mL capacity has a cylindrical syringe body portion with a diameter of 8.15 mm, which would in certain arrangements be used in the injector of FIGS. 7 and 8, while one available shorter configuration syringe of the same capacity has a cylindrical syringe body portion with a diameter of 10.85 mm,
- which would in certain arrangements be used in the injector of FIGS. 1 and 2. While the arrangement with a bell portion 92 can be used with wider/shorter syringes, in certain arrangements, the prefilled syringes have an outer diameter cylindrical wall of less than about 10 mm, and in other arrangements less than about 9 mm.

[0049] Injector 86 also includes a cap 110 fitted around the needle guard 66, and associated with the outer housing

7

108 to prevent retraction of the needle guard **66** and the triggering of the device **86**. Additionally, the cap **110** seals off the needle tip **26** and can be removed prior to using the device **86**. In one arrangement, the cap **110** is configured to fit over the needle guard **66** in a snap-fit association therewith, such as by including a narrower diameter portion **112** associated with an enlarged diameter portion **114** of the needle guard **66**.

- ⁵ **[0050]** Additionally, injector **86** employs a syringe cushion cap **116** that extends around the outside of the syringe flange **34** from the syringe cushion **118** to help trap and retain the prefilled syringe **88**. In one arrangement, a cushion cap **122** is connected to the cushion **118** and is, in certain arrangements, of unitary construction therewith. The cushion cap **122** abuts the distal end of the syringe body **120** to radially position and hold the proximal end of the body **120** while the needle **24** is being inserted into the patient. Similarly to the arrangement of FIG. 2, the syringe holder **96** is associated
- ¹⁰ with the housing in a substantially fixed position, such as by mounting portion **124**, which traps protrusions **126** of the syringe holder.

[0051] Referring to FIG. 9, injector **128** has a needle guard **130** configured to retract further into the injector housing than the injector of FIGS. 1 and 2 or FIG. 5 before the trigger mechanism **52** fires the jet injection. The injector in this figure is shown in a position in which the trigger mechanism **52** is being released and about to fire the injection. The

- ¹⁵ distance **76** by which the needle extends past the guard **130** or the distal surface of the guard **130** that contacts the skin in certain arrangements between about 12.5 and 13 mm. In one arrangement, the guard is preferably configured to reextend to a protecting position after the device is fired and removed from the patient, such as under the bias of spring **72**, and is locked in that position by locking members **132**, as known in the art to prevent reuse on the injector.
- [0052] In other arrangements, the guard length, the location of the guard injecting position with respect to the needle tip (including the guard throw between the protecting and injecting positions), and the length of the needle from the syringe body can be selected to allow for shallower or deeper needle insertions before the device is fired, providing lesser or greater distances **76**, respectively. In one arrangement, the guard is kept from sliding further back than substantially at the firing position, to better control in insertion depth into the patient.
- [0053] While illustrative arrangements of the invention are disclosed herein, it will be appreciated that numerous modifications and other arrangements may be devised by those skilled in the art. For example, the features for the various arrangements can be used in other arrangements, such as the needle and guard cap of FIGS. 7 and 8, which can be applied to the arrangement of FIG. 1. Therefore, it will be understood that the appended claims are intended to cover all such modifications and arrangements that come within the scope of the present invention

30

40

45

50

55

Claims

- 1. An injector (10), comprising:
- ³⁵ a prefilled syringe (18), a housing (12), an energy source (62), a trigger mechanism (52) and an interference component (134);

wherein the prefilled syringe (18) comprises a container portion (20) defining a fluid chamber (22) containing a medicament, an injection-assisting needle (24) disposed at the distal end of the chamber (22), having an injecting tip (26) configured for piercing an insertion location, and defining a fluid pathway in fluid communication with the chamber (22) for injecting the fluid from the chamber (22) into an injection site, and a plunger (28) movable within the fluid chamber (22);

wherein the housing (12) comprises a retractable guard (66) that is movable between a protecting position in which the needle (24) is disposed within the guard (66) and an injecting position in which the tip (26) of the needle (24) is exposed for insertion to the insertion point, and a syringe support (16) supportively mounting the prefilled syringe (18) in the housing;

wherein

- the housing (12) houses the prefilled syringe (18) and is configured for allowing insertion of the needle (24) at the injection location to an insertion point that is at a penetration depth below the surface,

- the energy source (62) is configured for biasing the plunger (28) with a force selected to produce an injecting pressure on the medicament in the fluid chamber (22) to jet inject the medicament from the fluid chamber (22) through the needle (24) to the injection site,

- the trigger mechanism (52) is operably associated with the energy source (62) for activating the energy source (62) to jet inject the medicament, wherein the trigger mechanism (52) is configured for activating the energy source (62) after the retractable guard (66) is retracted from the protecting position,

- the interference component (134) is provided adjacent to the retractable guard (66) and is configured to interfere with the movement of the retractable guard (66) from the protecting position toward the injecting position and prevents movement of the retractable guard (66) until a breakaway force is exceeded,

wherein the interference component (134) is a latch coupled to the housing (12) that is configured to cause resistance to the movement of the retractable guard (66) when the retractable guard (66) is moved at least partially from the protecting position toward the injecting position,

- wherein a breakaway force is configured to be applied to the retractable guard to overcome the resistance to movement of the retractable guard caused by the interference component (134),
- wherein a triggering force is the force needed to activate with the trigger mechanism (52) the energy source (62) to jet inject the medicament, and

wherein the breakaway force is a distinct force from the triggering force and greater than the force provided by a spring (72) that biases the needle guard (66) in an extended position , and the latch includes at least one abutment arm (136) extending distally from a proximal end (138),

wherein the abutment arm (136) comprises at least one tapered portion (140), an engagement portion (142) axially adjacent to the at least one tapered portion (140), the engagement portion (142) having a surface that is angled relative to a slope of the tapered portion (140), and the angled surface of the engagement portion surface extending radially outwardly from a proximal end of the tapered portion (140) with respect to the longitudinal axis,

wherein the interference component (134) further includes a flap (144) radially adjacent to the abutment arm (136) extending distally from the proximal end (138).

- 2. The injector of claim 1, wherein the energy source and prefilled syringe are configured such that the injecting pressure remains between about 0.5516 MPa (80 p.s.i.) and about 6.895 MPa (1000 p.s.i.) during injection of the medicament.
 - **3.** The injector of claim 2, wherein the energy source and prefilled syringe are configured such that the injecting pressure remains below about 3.4475 MPa (500 p.s.i.) and above about 0.62005 MPa (90 p.s.i.) during the injection of the medicament.
- 25

30

5

10

15

20

- **4.** The injector of claim 2, wherein the energy source and prefilled syringe are configured to produce the injecting pressure that remains at least at about 0.6895 MPa (100 p.s.i.) during the injection of the medicament.
- 5. The injector (10) of claim 1, wherein the prefilled syringe (18) has a distal portion in which the injection-assisting needle (24) is located, and a proximal portion opposite the distal portion; and the syringe support (16) axially supports the proximal portion of the pre-filled syringe (18) during the injection of the medicament, such that the distal portion of the prefilled syringe (18) is substantially unsupported in an axial direction.
- 6. The injector (10) of claim 1, further comprising a ram (60) that is biased by the energy source (62) against the plunger (28) to produce the injecting pressure, wherein the ram (60) comprises a bell portion on which the energy source (62) is seated, and the bell portion defines a hollow interior configured for receiving the prefilled syringe (18) when the device is fired, such that the energy source (62) surrounds the prefilled syringe (18), and wherein the energy source (62) comprises a spring.
- The injector (10) of claim 6, wherein the retractable guard (66) is operably associated with the trigger mechanism (52) to activate the energy source (62) when the guard (66) is retracted to the injecting position.
 - 8. The injector (10) of claim 1, wherein the energy source (62) is configured for biasing the plunger (28) with the force selected to produce the injecting pressure on the medicament in the fluid chamber (22) to jet inject the medicament from the fluid chamber (22) through the needle (24) to the injection site.

Patentansprüche

50

55

45

1. Ein Injektor (10), umfassend:

eine vorgefüllte Spritze (18), ein Gehäuse (12), eine Energiequelle (62), einen Auslösemechanismus (52) und eine Interferenzkomponente (134);

wobei die vorgefüllte Spritze (18) einen Behälterabschnitt (20), der eine Fluidkammer (22) definiert, die ein Medikament enthält, eine Injektionsunterstützungsnadel (24), die am distalen Ende der Kammer (22) angeordnet ist und eine Injektionsspitze (26) aufweist, die zum Durchstechen einer Einführungsstelle konfiguriert ist und einen Fluidweg in Fluidverbindung mit der Kammer (22) zum Injizieren des Fluids aus der Kammer (22) in eine

Injektionsstelle definiert, und einen Kolben (28) umfasst, der innerhalb der Fluidkammer (22) beweglich ist; wobei das Gehäuse (12) eine einziehbare Schutzvorrichtung (66) umfasst, die zwischen einer Schutzposition, in der die Nadel (24) innerhalb der Schutzvorrichtung (66) angeordnet ist, und einer Injektionsposition, in der die Spitze (26) der Nadel (24) zum Einführen in die Injektionsstelle freiliegt, beweglich ist, und eine Spritzenhalterung (16), die die vorgefüllte Spritze (18) stützend in dem Gehäuse hält; wobei

 - das Gehäuse (12) die vorgefüllte Spritze (18) aufnimmt und so konfiguriert ist, dass es das Einführen der Nadel (24) an der Injektionsstelle bis zu einem Einführungspunkt ermöglicht, der sich in einer Eindringtiefe unterhalb der Oberfläche befindet,

 - die Energiequelle (62) so konfiguriert ist, dass sie den Kolben (28) mit einer Kraft vorspannt, die so gewählt ist, dass sie einen Injektionsdruck auf das Medikament in der Fluidkammer (22) erzeugt, um das Medikament aus der Fluidkammer (22) durch die Nadel (24) zur Injektionsstelle zu injizieren,

- der Auslösemechanismus (52) betriebsfähig mit der Energiequelle (62) verbunden ist, um die Energiequelle
 (62) zu aktivieren, um das Medikament strahlförmig zu injizieren, wobei der Auslösemechanismus (52) so konfiguriert ist, dass er die Energiequelle (62) aktiviert, nachdem die einziehbare Schutzvorrichtung (66) aus der Schutzposition zurückgezogen ist,
- die Interferenzkomponente (134) benachbart zu der einziehbaren Schutzvorrichtung (66) vorgesehen ist und konfiguriert ist, um die Bewegung der einziehbaren Schutzvorrichtung (66) von der Schutzposition in Richtung der Injektionsposition zu stören und eine Bewegung der einziehbaren Schutzvorrichtung (66) zu verhindern, bis eine Abreißkraft überschritten wird,

wobei die Interferenzkomponente (134) ein mit dem Gehäuse (12) gekoppelter Riegel ist, der so konfiguriert ist, dass er der Bewegung der einziehbaren Schutzvorrichtung (66) einen Widerstand entgegensetzt, wenn die einziehbare Schutzvorrichtung (66) zumindest teilweise aus der Schutzposition in Richtung der Einspritzposition bewegt wird,

wobei eine Abreißkraft so konfiguriert ist, dass sie auf die einziehbare Schutzvorrichtung ausgeübt wird, um den durch die Interferenzkomponente (134) verursachten Widerstand gegen die Bewegung der einziehbaren Schutzvorrichtung zu überwinden,

wobei eine Auslösekraft die Kraft ist, die benötigt wird, um mit dem Auslösemechanismus (52) die Energiequelle
 (62) zu aktivieren, um das Medikament zu injizieren, und

wobei die Abreißkraft eine von der Auslösekraft verschiedene Kraft ist, die größer ist als die Kraft, die von einer Feder (72) bereitgestellt wird, die den Nadelschutz (66) in eine ausgefahrene Position vorspannt, und der Riegel mindestens einen Anschlagarm (136) aufweist, der sich distal von einem proximalen Ende (138) erstreckt,

- wobei der Anschlagarm (136) mindestens einen sich verjüngenden Abschnitt (140), einen Eingriffsabschnitt (142), der axial an den mindestens einen sich verjüngenden Abschnitt (140) angrenzt, umfasst, wobei der Eingriffsabschnitt (142) eine Oberfläche aufweist, die relativ zu einer Neigung des sich verjüngenden Abschnitts (140) abgewinkelt ist, und die abgewinkelte Oberfläche der Oberfläche des Eingriffsabschnitts sich von einem proximalen Ende des sich verjüngenden Abschnitts (140) in Bezug auf die Längsachse radial nach außen erstreckt,
 - wobei die Interferenzkomponente (134) ferner eine Klappe (144) aufweist, die radial an den Anschlagarm (136) angrenzt und sich distal vom proximalen Ende (138) erstreckt.
 - Injektor nach Anspruch 1, wobei die Energiequelle und die vorgefüllte Spritze so konfiguriert sind, dass der Injektionsdruck während der Injektion des Medikaments zwischen etwa 0,5516 MPa (80 p.s.i.) und etwa 6,895 MPa (1000 p.s.i.) bleibt.

 Injektor nach Anspruch 2, wobei die Energiequelle und die vorgefüllte Spritze so konfiguriert sind, dass der Injektionsdruck während der Injektion des Medikaments unter etwa 3,4475 MPa (500 p.s.i.) und über etwa 0,62005 MPa (90 p.s.i.) bleibt.

- Injektor nach Anspruch 2, wobei die Energiequelle und die vorgefüllte Spritze so konfiguriert sind, dass sie den Injektionsdruck erzeugen, der während der Injektion des Medikaments bei mindestens etwa 0,6895 MPa (100 p.s.i.) bleibt.
- 55

45

50

5

10

25

5. Injektor (10) nach Anspruch 1, wobei die vorgefüllte Spritze (18) einen distalen Abschnitt, in dem sich die die Injektion unterstützende Nadel (24) befindet, und einen dem distalen Abschnitt gegenüberliegenden proximalen Abschnitt aufweist; und die Spritzenhalterung (16) den proximalen Abschnitt der vorgefüllten Spritze (18) während der Injektion

des Medikaments axial abstützt, so dass der distale Abschnitt der vorgefüllten Spritze (18) in einer axialen Richtung im Wesentlichen nicht abgestützt ist.

- 6. Injektionsvorrichtung (10) nach Anspruch 1, die ferner einen Stößel (60) umfasst, der durch die Energiequelle (62) gegen den Kolben (28) vorgespannt wird, um den Injektionsdruck zu erzeugen, wobei der Stößel (60) einen Glockenabschnitt umfasst, auf dem die Energiequelle (62) sitzt, und der Glockenabschnitt einen hohlen Innenraum definiert, der so gestaltet ist, dass er die vorgefüllte Spritze (18) aufnimmt, wenn die Vorrichtung ausgelöst wird, so dass die Energiequelle (62) die vorgefüllte Spritze (18) umgibt, und wobei die Energiequelle (62) eine Feder umfasst.
- Injektor (10) nach Anspruch 6, wobei die einziehbare Schutzvorrichtung (66) betriebsmäßig mit dem Auslösemechanismus (52) verbunden ist, um den Auslösemechanismus (52) zu veranlassen, die Energiequelle (62) zu aktivieren, wenn die Schutzvorrichtung (66) in die Injektionsposition zurückgezogen ist.
- Der Injektor (10) nach Anspruch 1, wobei die Energiequelle (62) so konfiguriert ist, dass sie den Kolben (28) mit der Kraft vorspannt, die ausgewählt ist, um den Injektionsdruck auf das Medikament in der Fluidkammer (22) zu erzeugen, um das Medikament aus der Fluidkammer (22) durch die Nadel (24) zur Injektionsstelle zu injizieren.

Revendications

20

40

55

1. Injecteur (10), comprenant :

une seringue préremplie (18), un logement (12), une source d'énergie (62), un mécanisme de déclenchement (52) et un composant d'interférence (134) ;

- ²⁵ la seringue préremplie (18) comprenant une partie conteneur (20) définissant une chambre de fluide (22) contenant un médicament, une aiguille (24) d'aide à l'injection disposée à l'extrémité distale de la chambre (22), ayant une pointe (26) d'injection conçue pour percer un lieu d'insertion, et définissant un trajet de fluide en communication fluidique avec la chambre (22) afin d'injecter le fluide depuis la chambre (22) dans un site d'injection, et un piston (28) mobile à l'intérieur de la chambre de fluide (22) ;
- le logement (12) comprenant une protection (66) rétractable qui est mobile entre une position de protection dans laquelle l'aiguille (24) est disposée à l'intérieur de la protection (66) et une position d'injection dans laquelle la pointe (26) de l'aiguille (24) est exposée pour l'insertion au niveau du point d'insertion, et un support de seringue (16) monté de manière à pouvoir supporter la seringue préremplie (18) dans le logement ;
- le logement (12) logeant la seringue préremplie (18) et étant conçu pour permettre l'insertion de l'aiguille
 (24) au niveau de la localisation d'injection au niveau d'un point d'insertion qui se trouve à une profondeur de pénétration en-dessous de la surface,

 - la source d'énergie (62) étant conçue pour solliciter le piston (28) avec une force sélectionnée pour produire une pression d'injection sur le médicament dans la chambre de fluide (22) afin d'injecter par jet le médicament depuis la chambre de fluide (22) à travers l'aiguille (24) vers le site d'injection,

- le mécanisme de déclenchement (52) étant fonctionnellement associé à la source d'énergie (62) pour l'activation de la source d'énergie (62) pour injecter par jet le médicament, le mécanisme de déclenchement (52) étant conçu pour activer la source d'énergie (62) après que la protection (66) rétractable est rétractée de la position de protection,
- le composant d'interférence (134) étant disposé adjacent à la protection (66) rétractable et étant conçu pour interférer avec le mouvement de la protection (66) rétractable depuis la position de protection vers la position d'injection et empêcher le mouvement de la protection (66) rétractable jusqu'à ce qu'une force de séparation soit dépassée,
- 50 le composant d'interférence (134) étant un verrou accouplé au logement (12) qui est conçu pour entraîner une résistance au mouvement de la protection (66) rétractable lorsque la protection (66) rétractable est déplacée au moins partiellement depuis la position de protection vers la position d'injection,

une force de séparation étant conçue pour être appliquée à la protection rétractable pour surmonter la résistance au mouvement de la protection rétractable causée par le composant d'interférence (134),

une force de déclenchement étant la force requise pour activer avec le mécanisme de déclenchement (52) la source d'énergie (62) afin d'injecter par jet le médicament, et

la force de séparation étant une force distincte de la force de déclenchement et supérieure à la force fournie par un ressort (72) qui sollicite la protection d'aiguille (66) dans une position étendue, et le verrou comprenant

au moins un bras de butée (136) s'étendant au plan distal d'une extrémité proximale (138),

le bras de butée (136) comprenant au moins une partie effilée (140), une partie d'engagement (142) axialement adjacente à la au moins une partie effilée (140), la partie d'engagement (142) ayant une surface qui est inclinée par rapport à une pente de la partie effilée (140), et la surface inclinée de la surface de la partie d'engagement s'étendant radialement vers l'extérieur depuis une extrémité proximale de la partie effilée (140) par rapport à l'axe longitudinal,

le composant d'interférence (134) comprenant en outre un rabat (144) radialement adjacent au bras de butée (136) s'étendant au plan distal de l'extrémité proximale (138).

- Injecteur selon la revendication 1, la source d'énergie et la seringue préremplie étant conçues de sorte que la pression d'injection demeure entre environ 0,5516 MPa (80 ppc) et environ 6,895 MPa (1 000 ppc) durant l'injection du médicament.
- Injecteur selon la revendication 2, la source d'énergie et la seringue préremplie étant conçues de sorte que la pression d'injection demeure inférieure à environ 3,4475 MPa (500 ppc) et au-dessus d'environ 0,62005 MPa (90 ppc) durant l'injection du médicament.
 - 4. Injecteur selon la revendication 2, la source d'énergie et la seringue préremplie étant conçues pour produire la pression d'injection qui demeure au moins d'environ 0,6895 MPa (100 ppc) durant l'injection du médicament.
 - 5. Injecteur (10) selon la revendication 1, la seringue préremplie (18) ayant une partie distale dans laquelle l'aiguille (24) d'aide à l'injection est localisée, et une partie proximale opposée à la partie distale ; et le support de seringue (16) supportant axialement la partie proximale de la seringue préremplie (18) durant l'injection du médicament, de sorte que la partie distale de la seringue préremplie (18) est sensiblement non supportée dans un sens axial.
- 25

20

5

- 6. Injecteur (10) selon la revendication 1, comprenant en outre un coulisseau (60) qui est sollicité par la source d'énergie (62) contre le piston (28) afin de produire la pression d'injection, le coulisseau (60) comprenant une partie cloche sur laquelle la source d'énergie (62) est logée, et la partie cloche définissant un intérieur creux conçu pour recevoir la seringue préremplie (18) lorsque le dispositif est armé, de sorte que la source d'énergie (62) entoure la seringue préremplie (18), et la source d'énergie (62) comprenant un ressort.
- Injecteur (10) selon la revendication 6, la protection (66) rétractable étant fonctionnellement associée au mécanisme de déclenchement (52) pour amener le mécanisme de déclenchement (52) à activer la source d'énergie (62) lorsque la protection (66) est rétractée vers la position d'injection.
- 35

30

8. Injecteur (10) selon la revendication 1, la source d'énergie (62) étant conçue pour solliciter le piston (28) avec la force sélectionnée pour produire la pression d'injection sur le médicament dans la chambre de fluide (22) pour injecter par jet le médicament depuis la chambre de fluide (22) à travers l'aiguille (24) vers le site d'injection.

40

45

50

55







FIG.4













FIG.10A



FIG. 10B



FIG. 11

REFERENCES CITED IN THE DESCRIPTION

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

Patent documents cited in the description

- US 2011144594 A1 [0001] [0002]
- US 6102896 A [0001] [0002]
- US 2012004608 A1 [0002]

- WO 03095003 A1 [0002]
- US 6391003 B [0044]