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(54) **BREECH LOADED FIXED NEEDLE SYRINGE AND AUTOMATIC INJECTION DEVICE HAVING THE SAME**

(75) Inventors: **Richard David Gillespie**, Athens, TX (US); **Doug Owen Crow**, Ben Wheeler, TX (US)

Correspondence Address:
Charles N.J. Ruggiero
Ohlandt, Greeley, Ruggiero & Perle, L.L.P.
10th Floor
One Landmark Square
Stamford, CT 06901-2682 (US)

(73) Assignee: **PHARMA-PEN HOLDINGS, INC.**

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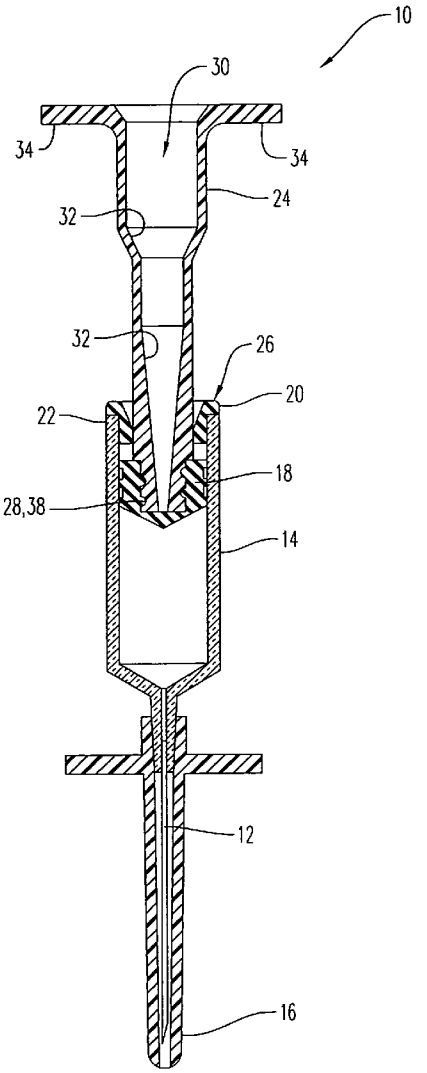
(57) **ABSTRACT**

A fixed needle syringe having a medicine compartment, a hypodermic needle, a piston, and a plunger is provided. The hypodermic needle is in fluid communication with the medicine compartment. The piston is slideably disposed in the medicine compartment. The plunger is secured to the piston. The plunger has a bore defined therethrough, where the bore allows access to the piston through the plunger.



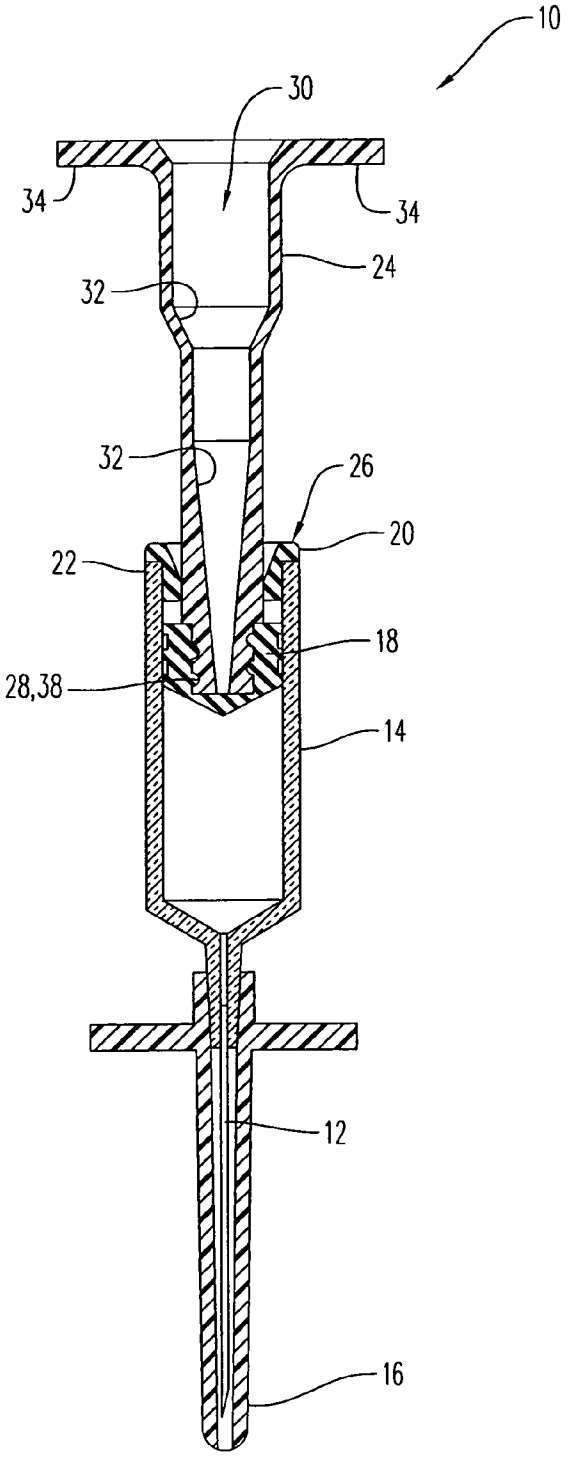


FIG. 1

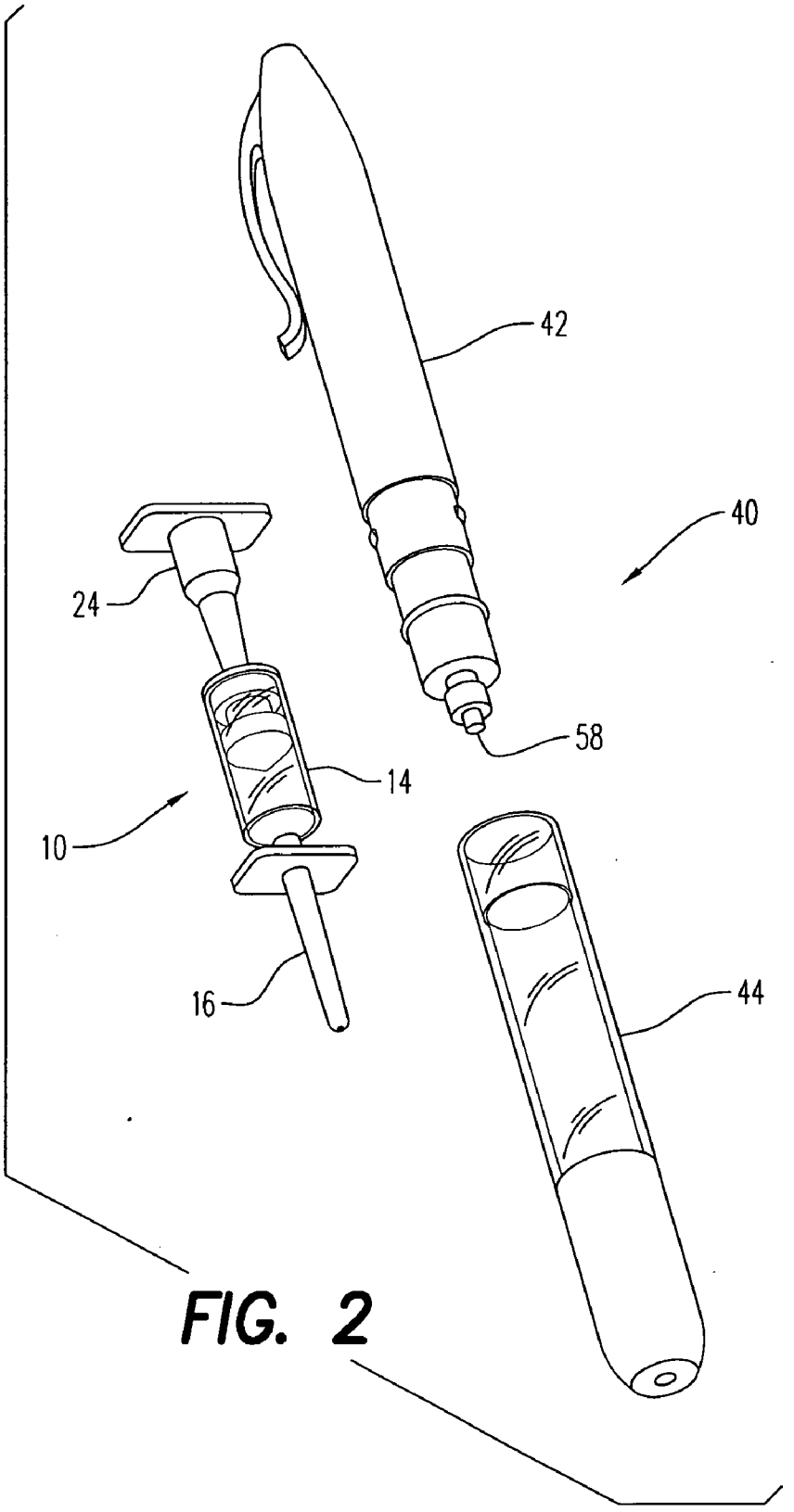


FIG. 2

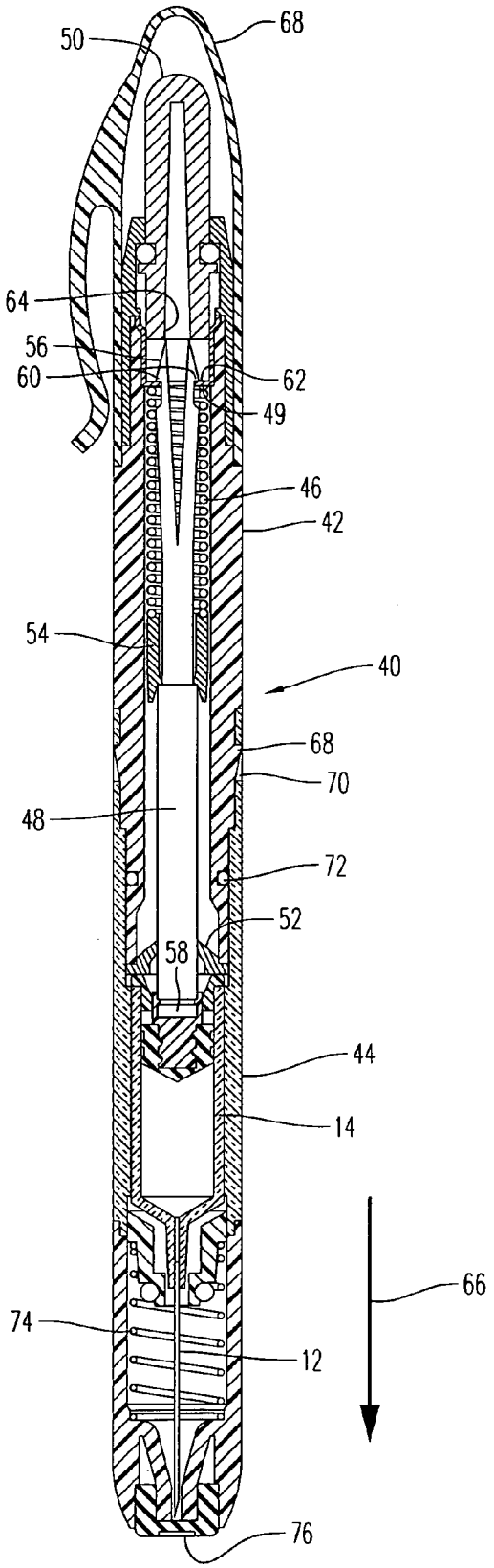


FIG. 3

BREECH LOADED FIXED NEEDLE SYRINGE AND AUTOMATIC INJECTION DEVICE HAVING THE SAME

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority of U.S. Provisional Application Ser. No. 60/634,486 filed on Dec. 9, 2004 and is related to commonly owned and assigned U.S. application Ser. No. 10/601,212, filed Jun. 20, 2003, the contents of both of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present disclosure is related to fixed needle syringes. More particularly, the present disclosure is related to breech loaded fixed needle syringes and automatic injection devices having the same.

[0004] 2. Description of Related Art

[0005] Fixed needle syringes typically include a needle fixed to and in fluid communication with a medicine compartment. A plunger, often acting on an elastomeric piston in the medicine compartment, is used fill the medicine compartment by drawing-in or aspirating (hereinafter "aspirating") drug solutions from another container such as a medicine vial or ampoule, purge any air from the medicine compartment, and expel medicine from the compartment into the tissue at the injection site.

[0006] During the aspiration process, the needle of the syringe is inserted through a septum of a medicine vial. Then, the plunger is pulled to draw medicine from the vial into the medicine compartment of the syringe. Thus, the needle in such fixed needle syringes is designed to withstand the stress imparted during insertion through the septum and designed to allow sufficient fluid flow during the aspiration process.

[0007] The amount of pain and/or discomfort associated with injection of a medicine is, at least in part, dependent upon the size or gauge ("gauge") of the needle. Unfortunately, the larger the needle gauge, the greater the damage to tissue at the injection site and more pain inflicted upon the person receiving the injection.

[0008] The gauge of the needle for a syringe filled at the time of use is, typically, limited by the column strength of the needle when inserting and withdrawing the needle from the medicine vial. Long, thin needles are more prone to fail in buckling while attempting to puncture the septum of the medicine vial. Thus, a fixed needle syringe filled by aspiration typically has a larger gauge needle than would otherwise be necessary to avoid needle buckling.

[0009] Further, the gauge is a limiting factor in aspirating drug solutions from another container, as the flow of fluid from the medicine vial into the syringe is determined, in part, by the inner diameter and length of the needle, the viscosity of the drug solution, and the differential pressure available to cause fluid flow; the maximum pressure during aspiration being atmospheric pressure. A high viscosity drug requires a larger inner diameter needle, and hence a larger gauge needle, to aspirate the drug solution from the medicine vial into the syringe within a reasonable time frame as compared to a low viscosity drug. Again, fixed needle syringes filled by aspiration typically have a larger gauge needle than would otherwise be necessary to avoid filling delays.

[0010] Many medicines can be injected using automatic injection devices having a fixed needle syringe therein. Typical automatic injection devices allow the medically untrained user to automatically inject a medicine by manually trigging the automatic injection. Some prior automatic injection devices also automatically retract the needle after injection.

[0011] Accordingly, it has been determined by the present application that there is a continuing need for fixed needle syringes and automatic injection devices that overcome or mitigate the aforementioned and other deleterious effects of prior devices.

BRIEF SUMMARY OF THE INVENTION

[0012] It is an object of the present disclosure to provide a user-filled fixed needle syringe having a small gauge needle.

[0013] It is another object to provide a fixed needle syringe that can be loaded with fluid medicament without the need to aspirate the medicament through the same needle that is later used to penetrate the tissue and provide a conduit for flow into the injection site.

[0014] It is another object to provide a fixed needle syringe that removes the size limitations on the hypodermic needle associated with the dual use of the hypodermic needle of the prior art, i.e. the prior art's requirement for the same needle to be used as a conduit from the original medicine vial into the fixed needle syringe and also from the fixed needle syringe into the recipient of the injection.

[0015] It is a further object to provide a breech loadable medicine cartridge having a movable piston with a threaded inner area and a pierceable membrane.

[0016] It is a further object to provide a fixed needle syringe having a moveable piston with a self-sealing, pierceable membrane.

[0017] It is still a further object to provide a medicine cartridge having a syringe guide removeably connectable to a movable piston, where the syringe guide has an inner diameter that receives a hypodermic needle for penetrating the piston membrane and filling the cartridge through the membrane penetration.

[0018] These and other objects of the present disclosure are provided by a fixed needle syringe having a medicine compartment, a hypodermic needle, a plunger, and a piston. The hypodermic needle is in fluid communication with the medicine compartment. The piston is slideably disposed in the medicine compartment. The plunger is removeably securable to the piston. The plunger has a bore defined therethrough, where the bore allows access to the piston through the plunger.

[0019] A method of injecting a medicine is also provided. The method includes urging medicine from a medicine supply needle into a medicine compartment of a fixed needle syringe through a hollow plunger and a piston element of the syringe; removing the hollow plunger from the piston;

inserting the fixed needle syringe in a first assembly so that a hypodermic needle resides proximate a lower seal of the first assembly; and securing a second assembly to the first assembly so that a driven rod of the second assembly is proximate the piston element.

[0020] An injection kit is also provided. The kit includes an injection assembly, a retraction assembly, and a breech loadable fixed needle syringe.

[0021] The above-described and other features and advantages of the present disclosure will be appreciated and understood by those skilled in the art from the following detailed description, drawings, and appended claims.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0022] **FIG. 1** is a sectional view of an exemplary embodiment of a fixed needle syringe according to the present disclosure;

[0023] **FIG. 2** is a partially exploded perspective view of the fixed needle syringe of **FIG. 1** in use with an automatic injection device; and

[0024] **FIG. 3** is a sectional view of the fully assembled automatic injection device of **FIG. 2**.

DETAILED DESCRIPTION OF THE INVENTION

[0025] Referring to the figures and in particular to **FIG. 1**, an exemplary embodiment of a fixed needle syringe **10** according to the present disclosure is shown. Syringe **10** includes a hypodermic needle **12** in fluid communication with a medicine compartment **14**. In some embodiments, syringe **10** can include a removable protective cover **16** disposed over hypodermic needle **12**.

[0026] Syringe **10** also includes a piston **18** slideably disposed in medicine compartment **14**. Preferably, syringe **10** includes a syringe end cap **20** at a breech end **22** of medicine compartment **14** to prevent inadvertent withdrawal of piston **18** from the medicine compartment.

[0027] Advantageously, syringe **10** is configured so that compartment **14** can be filled with medicine through piston **18**.

[0028] It has been determined by the present disclosure that the size of the hypodermic needle is limited by the forces imposed on hypodermic needle **12** during aspiration. Advantageously, syringe **10** disassociates the forces imposed on hypodermic needle **12** during aspiration from those imposed during injection. By doing so, the size of hypodermic needle can be reduced.

[0029] Thus, hypodermic needle **12** does not need to be sized to have enough column strength to withstand the stresses associated with inserting the hypodermic needle into a medicine vial. In addition, the point of hypodermic needle **12** is not at risk of dulling as a result of inserting into the medicine vial. As a result of the above, the size of hypodermic needle **12** can be reduced, while still maintaining adequate flow during injection into the patient.

[0030] Syringe **10** has a small inner and outer diameter hypodermic needle **12** that reduces user discomfort during needle insertion and injection. Preferably, hypodermic needle **12** has an inner and outer diameter that are matched to the viscosity of the medicine being injected and the column forces imposed on the hypodermic needle during injection—rather than the forces imposed on the hypodermic needle during aspiration.

[0031] In some embodiments, hypodermic needle **12** has a slenderness ratio that is maximized to reduce the discomfort associated with needle insertion into the user. As used herein, the slenderness ratio is defined as the length in inches[RG1] of the hypodermic needle divided by outer diameter of the hypodermic needle in inches. Here, the slenderness ratio of hypodermic needle **12** is limited only by the strength needed to penetrate the tissue at the injection site. Hypodermic needle **12** can have a slenderness ratio of at least about 60. In some embodiments, hypodermic needle **12** can have a slenderness ratio of up to about 120. Preferably, hypodermic needle **12** has a slenderness ratio of about 85. Thus, hypodermic needle **12** can have a slenderness ratio of between about 60 and about 120, and any subranges therebetween.

[0032] In other embodiments, hypodermic needle **12** has a flow ratio that is below a level at which medicine compartment **14** can be filled, within a practical amount of time, via aspiration through the needle. As used herein, the flow ratio is defined as the maximum flow rate in cubic centimeters per minute (cc/min) through the hypodermic needle during aspiration divided by the length in inches of the hypodermic needle. Under normal atmospheric conditions, the maximum pressure differential during aspiration is approximately 14.7 pounds per square inch at sea level. As used herein, a practical amount of time is less than about 30 seconds. Thus, if it takes longer than 30 seconds to fill medicine compartment **14** via aspiration, it is deemed, for the purposes of this application, impractical.

[0033] Hypodermic needle **12** can have a flow ratio of less than about 2.0. In some embodiments, hypodermic needle **12** can have a flow ratio of less than about 1.8. Preferably, hypodermic needle **12** has a flow ratio of less than about 1.5. Since medicine compartment **14** is not filled via aspiration through hypodermic needle **12**, syringe **10** advantageously is not limited to high flow ratios and, rather, can have a flow ratio of less than about 2.0.

[0034] For example at a flow ratio of less than about 2 and a needle length of about 1 inch, hypodermic needle **12** has a maximum flow rate during aspiration that is less than about 2 cc/min.

[0035] Syringe **10** includes a plunger **24** moveably disposed through an opening **26** in syringe end cap **20**. In some embodiments, plunger **24** can be removably secured to piston **18**. For example, piston **18** can include an internal thread **28** and plunger **24** can include a corresponding external thread **38**. In this manner, threads **28**, **38** can be used to selectively secure and/or un-secure plunger **24** and piston **18**.

[0036] Plunger **24** includes a hollow or bore **30** defined therethrough. Advantageously, bore **30** allows access to plunger **18** through rod **24**. Preferably, bore **30** includes one or more needle guiding surfaces **32** defined therein. In use, a supply needle (not shown) that is used in lieu of the injecting hypodermic needle **12** to access the medicament solution from its supply container is inserted into bore **30**,

through piston **18**, and into medicine compartment **14**. Piston **18** is made of a self-sealing, pierceable material such as that commonly used as a medicine vial septum and can include materials such as, but not limited to silicone or butyl rubber.

[**0037**] In this manner, compartment **14** can be filled through piston **18** at breech end **20**. Surfaces **32**, if present, can assist in guiding the supply needle into piston **18**.

[**0038**] Once medicine compartment **14** is filled, the supply needle (not shown) can be withdrawn from medicine compartment **14**, through piston **18**, and from bore **30**. Any air or other gases within medicine compartment **14** can be removed by simply turning syringe **10** so that the air is proximate hypodermic needle **12** (e.g., hypodermic needle **12** is directed vertically), and depressing plunger **24** to expel the air through hypodermic needle **12**. In use, the user simply removes protective cover **16**, if present, inserts hypodermic needle **12** into the body, and depresses plunger **24** to inject the desired dose of medicine from compartment **14**.

[**0039**] In some embodiments, plunger **24** can include one or more gripping portions **34**. Gripping portions **34** can be used to steady plunger **24** during the filling and/or use of syringe **10**.

[**0040**] In addition to being useful during manual injection discussed above, it is contemplated by the present disclosure for syringe **10** to find use with an automatic injection and retraction device **40**, such as that shown in **FIGS. 2 and 3**.

[**0041**] Some automatic injection devices have the capability of generating more force on the piston than can be normally applied manually, making it possible to utilize a smaller hypodermic needle to effectuate the same injection flow rate as compared to what the human hand can accomplish. It has been determined by the present disclosure that this design feature is easier to exploit to the advantage of the injection recipient if the aforementioned limitations associated with drug aspiration through a small gauge hypodermic needle are removed.

[**0042**] Device **40** includes a power-injection assembly **42** and a power-retraction assembly **44** as shown in **FIGS. 2 and 3**. Device **40** reduces tissue damage and discomfort associated with the injection through the use of syringe **10** having hypodermic needle **12** with the smaller outer diameter as discussed above with respect to the syringe.

[**0043**] When use of device **40** is needed, syringe **10** can be filled in the manner discussed above. Next, plunger **24** can be removed from syringe **10** and the syringe, once the guard **16** has been removed, can be operatively disposed in device **40**.

[**0044**] Device **40** is, preferably, an automatic injection apparatus that extends hypodermic needle **12** from within the device, injects a single, pre-measured dose of medicine from compartment **14** into a user, and automatically retracts the hypodermic needle into the assembly after the injection is completed.

[**0045**] Injection assembly **42** can operate substantially as disclosed in commonly owned and assigned U.S. application Ser. No. 10/601,212, filed Jun. 20, 2003, the contents of which are incorporated by reference herein.

[**0046**] Alternately, injection assembly **42** can be as shown in **FIGS. 2 and 3**. Here, injection assembly **42** includes an injection spring **46**, a driven rod **48**, an activation button **50**, a splitter device **52**, and a coupling **54**.

[**0047**] Injection spring **46** is disposed about driven rod **48** between a spring retainer **49** and coupling **54**, where the coupling selectively engages the injection spring to driven rod **48**.

[**0048**] Activation button **50** is configured to selectively release the energy in injection spring **46** to driven rod **48**. In the illustrated embodiment, driven rod **48** includes a locking end **56** and a driving end **58**. Driving end **58** is configured to act on piston **18** to urge medicine from compartment **14** as will be described in detail below.

[**0049**] In one embodiment, locking end **56** includes two or more tines **60** that are resiliently biased outward so that the tines are remote from one another. Tines **60** engage a locking surface **62** on spring retainer **49** when biased from one another. Activation button **50** includes a releasing surface **64**. Force in the injecting direction **66** applied to activation button **50** causes releasing surface **64** to compress tines **60** toward one another such that driven rod **48** is disengaged from locking surface **62**.

[**0050**] Injection spring **46** is maintained in a normally compressed or stressed condition between spring retainer **49** and coupling **54**. Upon release of tines **60**, the stored energy in spring **46** acts on spring retainer **49** and coupling **54** to drive driven rod **48** in an injection direction **66**.

[**0051**] Injection spring **46** drives driven rod **48** in injection direction **66** until coupling **54** abuts splitter device **52**. The force of splitter device **52** on coupling **54** causes the coupling to disengage from driven rod **48**. The disengagement of coupling **54** from driven rod **48** frees the driven rod from the force of injection spring **46** and, thus, allows the driven rod to be moved in a direction opposite the injection direction **66** by power-retraction assembly **44**.

[**0052**] Device **40** can be configured to inject medicine from compartment **14** intramuscularly, interoccularly, subcutaneously, and/or intradermally. For example, splitter device **52** can be secured in injection assembly **42** for movement along injection direction **66**. Varying the location of splitter device **52** along injection direction **66** can change the stroke of injection assembly **42** by changing the point at which the splitter device uncouples injection spring **46** from driven rod **48**.

[**0053**] In the illustrated embodiment, injection assembly **42** includes a cap **68** disposed over activation button **50**. Cap **68** can mitigate inadvertent depression of activation button **50** and, thus, can prevent premature activation of injection assembly **42**.

[**0054**] In a preferred embodiment, injection and retraction assemblies **42**, **44** are secured to one another in a snap fit manner so that the assemblies cannot be removed from one another after assembly. For example, injection assembly **42** can include one or more outwardly depending tabs **68** that are received in a corresponding number of openings **70** defined in retraction assembly **44**. As injection assembly **42** is inserted into retraction assembly **44**, tabs **68** act on the retraction assembly to elastically deform the inner dimension of the tube. Once tabs **68** are received by openings **70**,

the inner dimension of retraction assembly **44** returns to its original dimension to secure the tabs in the openings.

[**0055**] In the assembled state, injection assembly **42** and retraction assembly **44** preferably maintain compartment **14** hermetically sealed therebetween. For example, injection assembly **42** can include a sealing member **72** such as, but not limited to an o-ring. Once injection and retraction assemblies **42**, **44** are secured together, sealing member **72** cooperates with the interior of the retraction assembly to form a hermetic radial seal. In the illustrated embodiment, sealing member **72** is positioned below openings **70** to provide the hermetic seal below the snap fit connection between tabs **68** and openings **70**.

[**0056**] Power-retraction assembly **44** includes a second or retraction spring **74** and a lower seal **76**. Retraction spring **74** is substantially weaker than injection spring **46**. When assembled, needle **12** is positioned proximate lower seal **76**. During use, injection spring **46** overcomes the force of retraction spring **74** to compress the retraction spring and move compartment **14** in injection direction **66** so that needle **12** pierces lower seal **76** and tissue at the injection site. In addition, injection spring **46** moves driving end **58** of driven rod **48** in injection direction **66** to expel medicine from compartment **14** through needle **12**.

[**0057**] At the point where piston **18** has been moved to complete the injection of medicine from compartment **14**, driven rod **48** has moved in injection direction **66** a sufficient distance for coupling **54** to contact splitter device **52**, which disengages the coupling from the driven rod and terminates the influence injection spring **46** has upon the driven rod. Once injection spring **46** is disengaged, the now compressed retraction spring **74** urges needle **12**, compartment **14**, and driven rod **48** in a direction opposite injection direction **66** until the needle recedes behind lower seal **76**.

[**0058**] In the embodiment where injection and retraction assemblies **42**, **44** are permanently secured to one another, retraction of needle **12** into the retraction assembly renders device **40** safe from inadvertent injury by the needle **12** and, thus, renders the device **40** safe for disposal.

[**0059**] In one embodiment of the present disclosure, device **40** and syringe **10** can be provided in an unassembled state in a terminally sterilized kit (not shown) for assembly and use. Here, the kit can include injection assembly **42** and retraction assembly **44**, as well as syringe **10**. In addition, as a matter of convenience to the user; the kit can also include one or more injection site cleaning swabs, such as a pre-packaged alcohol swab. For example, injection assembly **42**, retraction assembly **44**, and syringe **10** can be contained in a sealed package, such as a plastic or TYVEC package. In some embodiments, the package can be terminally sterilized.

[**0060**] It should also be noted that the terms "first", "second", "third", "upper", "lower", and the like may be used herein to modify various elements. These modifiers do not imply a spatial, sequential, or hierarchical order to the modified elements unless specifically stated.

[**0061**] While the present disclosure has been described with reference to one or more exemplary embodiments, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted for elements thereof without departing from the scope of the present disclosure. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the disclosure without departing from the scope thereof. Therefore, it is intended that the present disclosure not be limited to the particular embodiment(s) disclosed as the best mode contemplated, but that the disclosure will include all embodiments falling within the scope of the appended claims.

1. A fixed needle syringe comprising:

a medicine compartment;

a hypodermic needle in fluid communication with said medicine compartment, said hypodermic needle being permanently fixed to said medicine compartment;

a piston slideably disposed in said medicine compartment; and

a plunger secured to said piston, said plunger having a bore defined therethrough, said bore allowing access to said piston through said plunger and said piston being made of a self-sealing, pierceable material.

2. The fixed needle syringe of claim 1, further comprising an end cap at a breech end of said medicine compartment, said end cap preventing withdrawal of said piston from said medicine compartment.

3. The fixed needle syringe of claim 1, wherein said plunger is removably secured to said piston.

4. The fixed needle syringe of claim 3, wherein said plunger is removably secured to said piston by a threaded connection.

5. The fixed needle syringe of claim 1, further comprising one or more needle guiding surfaces defined in said bore of said plunger.

6. (canceled)

7. A fixed needle syringe comprising:

a medicine compartment;

a self sealing piston slideably disposed in said medicine compartment;

a hypodermic needle in fluid communication with and permanently fixed to said medicine compartment, said hypodermic needle having a slenderness ratio of between about 60 and 120; and

a plunger secured to said self sealing piston, said plunger having a bore therethrough, said bore allowing access to said self sealing piston through said plunger.

8. The fixed needle syringe of claim 7, wherein said slenderness ratio is about 85.

9. The fixed needle syringe of claim 7, wherein said hypodermic needle has a flow ratio of less than about 2.

10. A fixed needle syringe comprising:

a medicine compartment;

a self sealing piston slideably disposed in said medicine compartment;

a hypodermic needle in fluid communication with and permanently fixed to said medicine compartment, said hypodermic needle having a flow ratio of less than about 2; and

a plunger secured to said self sealing piston, said plunger having a bore defined therethrough, said bore allowing access to said self sealing piston through said plunger.

11. The fixed needle syringe of claim 10, wherein said flow ratio is less than about 1.8.

12. The fixed needle syringe of claim 10, wherein said flow ratio is less than about 1.5.

13. The fixed needle syringe of claim 10, wherein said hypodermic needle has a slenderness ratio of between about 60 and 120.

14. A method of injecting a medicine, comprising:

introducing a medicine supply needle into a medicine compartment of a permanently fixed needle syringe through a hollow plunger and a self-sealing, pierceable piston of said fixed needle syringe; and

urging medicine from said medicine supply needle into said medicine compartment.

15. The method of claim 14, further comprising:

removing said hollow plunger from said piston;

inserting said syringe in a first assembly so that a hypodermic needle of said fixed needle syringe is proximate a lower seal of said first assembly; and

securing a second assembly to said first assembly so that a rod of said second assembly is proximate said piston.

16. The method of claim 15, further comprising:

placing said lower seal on an injection site; and

releasing an injection spring in said second assembly to drive said rod in an injection direction, said rod moving said hypodermic needle through said lower seal into said injection site and moving said piston to expel said medicine from said medicine compartment through said hypodermic needle.

17. The method of claim 16, further comprising moving a retraction spring of said first assembly to a compressed state as said rod moves in said injection direction.

18. The method of claim 17, further comprising:

disconnecting said injection spring from said rod so that said retraction spring moves said hypodermic needle through said lower seal in a direction opposite said injection direction.

19. An injection kit comprising:

a breech loadable fixed needle syringe having a hypodermic needle permanently fixed to a medicine compartment, a self-sealing, pierceable piston slideably disposed in said medicine compartment, and a hollow plunger removably secured to said piston so that said medicine compartment is fillable through said hollow plunger and said piston;

an injection assembly; and

a retraction assembly, said injection and retraction assemblies being configured to operatively secure said syringe therein.

20. The injection kit of claim 19, further comprising one or more injection site antiseptic swabs.

21. The injection kit of claim 19, further comprising a package containing said syringe, said injection assembly, and said retraction assembly.

22. The injection kit of claim 21, wherein said package is terminally sterilized.

23. A method of injecting a medicine, comprising:

urging medicine into a medicine supply needle into a medicine compartment of a permanently fixed needle syringe through a hollow plunger and a self-sealing, pierceable piston in said fixed needle syringe;

withdrawing said medicine supply needle from said permanently fixed needle syringe;

turning said permanently fixed needle syringe so that air in said medicine compartment is proximate a hypodermic needle of said permanently fixed needle syringe; and

depressing said hollow plunger to expel said air through said hypodermic needle.

24. The method of claim 23, further comprising:

removing said hollow plunger from said self-sealing, pierceable piston;

inserting said fixed needle syringe in a first assembly so that said hypodermic needle is proximate a lower seal of said first assembly; and

securing a second assembly to said first assembly so that a rod of said second assembly is proximate said self-sealing, pierceable piston.

25. The method of claim 24, further comprising:

placing said lower seal on an injection site; and

releasing an injection spring in said second assembly to drive said rod in an injection direction, said rod moving said hypodermic needle through said lower seal Into said injection site and moving said self-sealing, pierceable piston to expel said medicine from said medicine compartment through said hypodermic needle.

26. The method of claim 25, further comprising:

moving a retraction spring of said first assembly to a compressed state as said rod moves in said injection direction; and

disconnecting said injection spring from said rod so that said retraction spring moves said hypodermic needle through said lower seal in a direction opposite said injection direction.

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