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 Serial No. 60/634,486 filed on December 9, 2004 and is related to commonly owned and assigned U.S. Application Serial No. 10/601,212, filed June 20, 2003, the contents of both of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] 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.

2. Description of Related Art

[0003] 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.

[0004] 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.

[0005] 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.

[0006] 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.

[0007] 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.

[0008] 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.

[0009] 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

[0010] It is an object of the present disclosure to provide a user-filled fixed needle syringe having a small gauge needle.

[0011] 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.

[0012] 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.

[0013] 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.

[0014] It is a further object to provide a fixed needle syringe having a moveable piston with a self-sealing, pierceable membrane.

[0015] 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.

[0016] 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.

[0017] 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.

[0018] An injection kit is also provided. The kit includes an injection assembly, a retraction assembly, and a breech loadable fixed needle syringe.

[0019] 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

[0020] FIG. 1 is a sectional view of an exemplary embodiment of a fixed needle syringe according to the present disclosure;

[0021] FIG. 2 is a partially exploded perspective view of the fixed needle syringe of FIG. 1 in use with an automatic injection device; and

[0022] FIG. 3 is a sectional view of the fully assembled automatic injection device of FIG. 2.

DETAILED DESCRIPTION OF THE INVENTION

[0023] 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.

[0024] 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.

[0025] Advantageously, syringe 10 is configured so that compartment 14 can be filled with medicine through piston 18.

[0026] 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.

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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 syringe10.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] Injection assembly 42 can operate substantially as disclosed in commonly owned and assigned U.S. Application Serial No. 10/601,212, filed June 20, 2003, the contents of which are incorporated by reference herein.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

CLAIMS

Claim 1. A fixed needle syringe comprising:

a medicine compartment;

a hypodermic needle in fluid communication with 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.

Claim 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.

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

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

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

Claim 6. The fixed needle syringe of claim 1, wherein said piston is a self-sealing, pierceable material.

Claim 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 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.

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

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

Claim 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 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.

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

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

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

Claim 14. A method of injecting a medicine, comprising:

introducing a medicine supply needle into a medicine compartment of a fixed needle syringe through a hollow plunger and a piston of said fixed needle syringe; and

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

Claim 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.

Claim 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.

Claim 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.

Claim 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.

Claim 19. An injection kit comprising:

a breech loadable fixed needle syringe;

an injection assembly; and

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

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

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

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