PASSIVE REUSE PREVENTION SYRINGE THAT USES A FLANGE LOCK

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a passive reuse prevention syringe that uses a flange lock. More specifically, aspects of the present invention relate to a syringe that includes a flange lock disposed at an open proximal end of a syringe barrel for engaging a locking flange disposed on a plunger rod. The flange lock engages the locking flange so as to prevent removal of the plunger rod from the syringe barrel and disable the syringe.

Description of Related Art

[0002] Hypodermic syringe products are generally intended for a single use only, in part, to address concerns related to the spread of disease associated with reuse of such products and to deter other misuse. Attempts have been made to provide a solution to these concerns. Some of these attempts have provided injection systems that require a specific, affirmative act to destroy the syringe after the intended injection either by using a separate device for destroying the syringe or providing a syringe assembly with frangible zones so that the syringe could be rendered inoperable by the application of force. Although many of these devices work quite well, they do require the specific intent of the user followed by the affirmative act to destroy or render the syringe inoperable. These devices are not effective with a user having the specific intent to reuse the hypodermic syringe.

[0003] Attempts have also been made to provide a syringe assembly that is automatically disabled or rendered inoperable after a single or select number of uses. Such syringe assemblies present specific challenges because they must not prevent filling or use under normal conditions. Moreover, certain automatic locking and disabling devices only allow for a fixed dosage amount to be supplied by the syringe before the syringe is disabled.

SUMMARY OF THE INVENTION

[0004] Accordingly, there is a general need for a single use syringe that includes a locking and disabling mechanism that does not operate automatically but that is passively activated through normal use of the syringe. Consequently, a user who has the specific intent to reuse the syringe will actuate the mechanism through normal use of the syringe without consciously realizing that the syringe has been disabled. Such a mechanism will limit the

ability of users to reuse the syringe while avoiding the unnecessary costs and dosage limitations of automatic devices.

[0005] The present invention overcomes many of the deficiencies present in the prior art by providing a syringe that offers the utility of a traditional syringe along with reuse prevention features and requiring a low force required to activate the reuse prevention mechanism. According to an embodiment of the present invention, the syringe includes a passive reuse prevention mechanism that is activated by the user through normal use of the syringe though the user may not be aware or realize that the mechanism has been activated. The syringe allows for variable dosing, which is important for some procedures, but can also be adapted to deliver fixed doses if required and can be used for injections and/or reconstitution of dry drugs. The syringe is scaleable from the smallest syringe sizes to the largest syringe sizes and allows for reductions of cost compared to current reuse prevention syringes. The syringe is provided with a one or two piece plunger assembly having a sealing surface on a plunger head and a plunger rod, which is engaged by the flange lock on the syringe barrel. Upon or just prior to final injection of the contents of the syringe, the syringe is rendered disabled due to the engagement between flange lock and a locking flange on the plunger rod.

[0006] According to an embodiment of the present invention, a syringe assembly is provided. The syringe assembly includes a syringe barrel having an inside surface defining a chamber, an open proximal end, a distal end, and an outlet disposed adjacent the distal end in fluid communication with the chamber; a plunger assembly disposed at least partially within the syringe barrel, including an elongate plunger rod having a proximal end, a distal end, and a locking flange formed thereon between the proximal and distal ends; a plunger head having a distal sealing surface, the plunger rod being engageable with the plunger head such that the plunger rod is capable of moving the plunger head within the chamber of the syringe barrel through an injection cycle; and a flange lock disposed at the open proximal end of the barrel. During the injection cycle, the flange lock engages the locking flange of the plunger rod so as to prevent removal of the plunger rod from the syringe barrel.

[0007] The flange lock includes a plurality of flexible protrusions distributed around a periphery of the open proximal end of the syringe barrel. The protrusions are integral with the open proximal end of the syringe barrel and may extend proximally from the open proximal end of the syringe barrel or distally from the open proximal end of the syringe

barrel into the chamber of the barrel. The syringe barrel further includes an outwardly extending flange at the open proximal end thereof.

[0008] The plunger rod has a cylindrical shape defining an outer surface and the flexible protrusions of the flange lock are adapted to flex toward the inside surface of the barrel as the plunger rod is inserted into the chamber of the barrel. During the injection cycle, the protrusions slide along the outer surface of the plunger rod and engage the locking flange on the plunger rod so as to retain the plunger assembly in a bottomed out position and disable the syringe assembly.

[0009] The locking flange on the plunger rod tapers outwardly from the outer surface of the plunger rod so as to form a distally facing beveled surface and a proximally facing abutment surface. Ends of the flexible protrusions slide over the distally facing beveled surface of the locking flange during the injection cycle and engage the proximally facing abutment surface so as to retain the plunger assembly in the bottomed out position. The plunger rod further includes a tamper prevention disk located proximal to the locking flange so as to prevent tampering with the engagement between the locking flange and the flange lock and an outwardly extending flange at a proximal end thereof. The plunger rod has a variable diameter and tapers inwardly toward the flange lock.

[0010] The plunger head further includes a distal wall, the distal wall having the distal sealing surface defined thereon; a proximal wall, spaced from the distal wall; and a central portion extending between the distal wall and the proximal wall, the central portion having a cylindrical core portion and a plurality of equally spaced fin portions extending radially from the cylindrical core portion. The distal wall of the plunger head perimetrically engages the inner surface of the barrel so as to seal the chamber of the barrel.

[0011] The distal end of the plunger rod is slidably connected to the plunger head such that during the injection cycle the plunger rod slides with respect to the plunger head. The plunger head includes a cylindrical connecting portion extending from the proximal wall of the plunger head, the cylindrical connecting portion having an annular lip at a proximal end thereof. The plunger rod has a hollow cylindrical shape defining an outer surface and an inner diameter, the inner diameter of the plunger rod having an internal annular ring adapted to engage the annular lip of the cylindrical connecting portion such that the internal annular ring of the plunger rod is able to slide over the annular lip in the distal direction and retain the annular lip of the cylindrical connecting portion within the plunger rod. The plunger rod slides with respect to the cylindrical connecting portion of the plunger head such that the

internal annular ring of the plunger rod engages the annular lip of the cylindrical connecting portion during aspiration and the distal end of the plunger rod engages the proximal wall of the plunger head during injection. A force necessary to advance the plunger rod relative to the plunger head during the injection cycle between aspiration and injection is less than a force necessary to sustain injection.

[0012] The plunger rod further includes an annular flange extending from the outer surface of the plunger rod at the distal end of the plunger rod, the annular flange having a diameter slightly less than or equal to a diameter of the inside surface of the syringe barrel. The plunger head may be made from a plastic material or an elastomeric material.

[0013] According to a further aspect of the present invention, a method of actuating a syringe assembly is provided. The method includes the step of providing a syringe assembly that includes a syringe barrel having an inside surface defining a chamber, an open proximal end, a distal end, and an outlet disposed adjacent the distal end in fluid communication with the chamber; a plunger assembly disposed at least partially within the syringe barrel, including an elongate plunger rod having cylindrical shape defining an outer surface, a proximal end, a distal end, and a locking flange formed thereon between the proximal and distal ends; a plunger head having a distal sealing surface; and a flange lock disposed at the open proximal end of the barrel, the flange lock including a plurality of flexible protrusions extending proximally from the open proximal end of the syringe barrel and distributed around a periphery of the open proximal end of the syringe barrel. The plunger head is inserted into the chamber of the syringe barrel to a position proximate to the distal end of the syringe barrel such that the protrusions of the flange lock fold into the chamber toward the inside surface of the syringe barrel and spring back after insertion of the plunger head is completed. The plunger rod is inserted into the chamber of the syringe barrel such that the protrusions of the flange lock fold into the chamber toward the inside surface of the syringe barrel and are held in a folded position by the outer surface of the plunger rod. The distal end of the plunger rod is connected with the plunger head such that the plunger rod is slidable with respect to the plunger head. The plunger assembly is drawn from the position proximate to the distal end of the syringe barrel in a proximal direction with the plunger head in an extended position from the distal end of the plunger rod so as to aspirate the chamber of the syringe barrel. The plunger assembly is advanced within the chamber of the syringe barrel so that the plunger rod slides with respect to the plunger head to a collapsed position with respect to the plunger head. The plunger assembly is further advanced within the chamber of the syringe barrel.

The locking flange on the plunger rod is engaged with the protrusions of the flange lock so as to retain the plunger assembly in a locked position at least partially within the chamber of the syringe barrel and disable the syringe assembly.

[0014] Further details and advantages of the invention will become clear upon reading the following detailed description in conjunction with the accompanying drawing figures, wherein like parts are designated with like reference numerals throughout.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** is a side view of a passive reuse prevention syringe assembly in accordance with an embodiment of the present invention.

[0016] **FIG. 2** is a side view of a syringe barrel and flange lock of the syringe assembly shown in **FIG. 1**.

[0017] **FIG. 3** is a rear perspective view of the syringe barrel and flange lock of **FIG. 2**.

[0018] **FIG. 4** is a rear view of the syringe barrel and flange lock of **FIG. 2**.

[0019] **FIG. 5** is a rear perspective view of a plunger rod of the syringe assembly shown in **FIG. 1**.

[0020] **FIG. 6** is a side view of the plunger rod of **FIG. 5**.

[0021] **FIG. 7** is a rear perspective view of a plunger head of the syringe assembly shown in **FIG. 1**.

[0022] **FIG. 8** is a side view of the plunger head of **FIG. 7**.

[0023] **FIG. 9** is a side view of the syringe barrel and flange lock and the plunger head of the syringe assembly prior to insertion of the plunger head into the chamber of the syringe barrel.

[0024] **FIG. 10** is a side view of the syringe barrel and flange lock and the plunger head of the syringe assembly as the plunger head is inserted into the chamber of the syringe barrel.

[0025] **FIG. 11** is a partial cross-sectional side view of the syringe barrel and flange lock and the plunger head of the syringe assembly showing the plunger head in a bottomed out position within the chamber of the syringe barrel.

[0026] **FIG. 12** is a partial cross-sectional side view of the syringe assembly as the plunger rod is inserted into the chamber of the syringe barrel.

[0027] **FIG. 13** is a partial cross-sectional side view of the syringe assembly as the plunger rod is inserted further into the chamber of the syringe barrel.

[0028] **FIG. 14** is a partial cross-sectional side view of the syringe assembly prior to aspiration of the syringe barrel as the plunger rod engages the plunger head.

[0029] **FIG. 15** is an enlarged partial cross-sectional side view of the syringe assembly after completion of an injection cycle showing the plunger assembly in a locked position.

[0030] **FIG. 16** is an enlarged partial side view of the syringe assembly of **FIG. 15** further illustrating an engagement between the flange lock and the plunger rod.

[0031] **FIG. 17** is an enlarged partial cross-sectional side view of the syringe assembly of **FIG. 15** further illustrating an engagement between the plunger rod and the plunger head.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0032] For purposes of the description hereinafter, spatial orientation terms, if used, shall relate to the referenced embodiment as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments described hereinafter may assume many alternative variations and embodiments. It is also to be understood that the specific devices illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

[0033] Referring to **FIG. 1**, a syringe assembly **10** according to an embodiment of the present invention is shown. The syringe assembly **10** includes a syringe barrel **20** and a plunger assembly **30**. As shown in **FIGS. 1-4**, the syringe barrel **20** has an open proximal end **23** and a distal end **21** opposite to the open proximal end **23**. The syringe barrel **20** has an inside surface **24**, which defines a chamber **25**. The syringe barrel **20** also includes an outlet **11** disposed on the distal end **21** of the syringe barrel **20**. The outlet **11** is in fluid communication with the chamber **25** of the syringe barrel **20**. A needle cannula **12** may be attached to the outlet **11** such that an interior of the needle cannula **12** is in fluid communication with the chamber **25** of the syringe barrel **20**. As shown, the syringe barrel **20** may have a cylindrical or substantially cylindrical shape, and may include an outwardly extending flange **22** at the open proximal end **23**, though it is to be appreciated that the syringe barrel **20** may be formed in any suitable shape. Additionally, the syringe barrel **20** may be injection molded from thermoplastic material such as polypropylene and polyethylene according to techniques known to those of ordinary skill in the art, though it is

to be appreciated that the syringe barrel **20** may be made from other suitable materials and according to other applicable techniques.

[0034] Also as shown in **FIG. 1**, the needle cannula **12** may be secured within the outlet **11** by a chemical adhesive, such as epoxy, or may be mechanically affixed to the outlet **11** according to known techniques. For instance, the outlet **11** may be modified to receive a separate needle hub thereon via a standard luer taper fitting or luer lock fitting. The syringe assembly **10** may also include a protective cap (not shown) disposed over the outlet **11** to protect the needle cannula **12** prior to use and to prevent accidental needle sticks of persons handling the syringe assembly **10** prior to use. An annular ridge **13** may be formed on the distal end **21** of the syringe barrel **20** to facilitate attachment of a protective cap or a standard needle hub over the outlet **11**.

[0035] With further reference to **FIGS. 1-4**, a flange lock **26** is disposed at the open proximal end **23** of the barrel **20**. The flange lock **26** includes a plurality of flexible protrusions **27** distributed around a periphery of the open proximal end **23** of the syringe barrel **20** and extend from the open proximal end **23** of the syringe barrel **20** to free ends **271**. As shown, the protrusions **27** are integral with the open proximal end **23** of the syringe barrel **20**, though it is to be appreciated that the flange lock **26** and protrusions **27** may be formed separately and attached to the syringe barrel **20** by techniques known to those of ordinary skill in the art. As shown in **FIGS. 2-4**, in an initial condition, the protrusions **27** extend proximally from the open proximal end **23** of the syringe barrel **20**. As shown in **FIGS. 1** and **16**, the protrusions are adapted to be folded to extend distally into the chamber **25** and flex toward the inside surface **24** of the syringe barrel **20**. Alternatively, the flange lock **26** may be formed such that the protrusions **27** extend distally into the chamber **25** or parallel to the open proximal end **23** of the barrel **20** in an initial condition.

[0036] With reference to **FIGS. 1, 5**, and **6**, the plunger assembly **30** is disposed at least partially within the syringe barrel **20**. The plunger assembly **30** includes an elongate plunger rod **31** having a cylindrical shape defining an outer surface **39**. The plunger rod **31** has a proximal end **311** defined by an outwardly extending flange **36** and a distal end **312** defined by an annular flange **32**. A locking flange **34** is formed on the plunger rod **31** between the proximal **311** and distal **312** ends. Specifically, the locking flange **34** is located on the plunger rod **31** approximately two-thirds of the length of the plunger rod **31** from the distal end **312** of the plunger rod **31** such that the plunger rod **31** may be inserted nearly the full length of the chamber **25** of the syringe barrel **20** without engaging the flange lock **26**.

[0037] As shown in **FIGS. 5** and **6**, the locking flange **34** tapers outwardly from the outer surface **39** of the plunger rod **31** so as to form a distally facing beveled surface **341** and a proximally facing abutment surface **342**. A large diameter portion **343** of the plunger rod **31** is located directly proximal of the proximally facing abutment surface **342** of the locking flange **34**. The plunger rod **31** also includes tamper prevention disk **35** located proximal to the locking flange **34**. The plunger rod **31** has a variable diameter. Specifically, the plunger rod **31** includes a portion **33** that tapers inwardly toward the locking flange **34**. The plunger rod **31** also includes a uniform diameter portion **331** located between the inwardly tapering portion **33** and the distally facing beveled surface **341** of the locking flange **34**. The plunger rod **31** may be inserted into the chamber **25** of the syringe barrel **20** in a packaged state. Preferably, in the packaged condition, the plunger rod **31** will be inserted into the syringe barrel **20** such that the protrusions **27** expand to conform to the inwardly tapering portion **33** and/or the uniform diameter portion **331** of the plunger rod **31**, *i.e.*, the portion of the plunger rod **31** having the smallest diameter. This reduces deformation of the protrusions **27** prior to use so as to ensure that the protrusions **27** will be sufficiently elastic to engage the large diameter portion **343** and the proximally facing abutment surface **342** of the locking flange **34** to prevent removal of the plunger rod **31** from the syringe barrel **20**.

[0038] As shown in **FIGS. 14-16**, the tamper prevention disk **35** is sized and spaced from the locking flange **34** such that the tamper prevention disk **35** prevents healthcare workers and others from tampering with an engagement between the flange lock **26** on the syringe barrel **20** and the locking flange **34**. Also, as shown in **FIGS. 15** and **17**, the plunger rod **31** is hollow and has an inner diameter **37**. The inner diameter **37** of the plunger rod **31** includes an internal annular ring **38** adjacent to the distal end **312** of the plunger rod **31**. Further, the annular flange **32** at the distal end **312** of the plunger rod **31** has a diameter slightly less than or equal to the diameter of the inside surface **24** of the syringe barrel **20**, such that the flange **32** is able to engage against the free ends **271** of the protrusions **27** of the flange lock **26** to prevent removal of the plunger rod **31** from the syringe barrel **20**. The annular flange **32** also stabilizes the position of the plunger rod **31** within the syringe barrel **20** and facilitates alignment of the distal end **312** of the plunger rod **31** within the chamber **25** and the connection to plunger head **40**, as will be discussed below.

[0039] With reference to **FIGS. 7** and **8**, the plunger assembly **30** also includes a plunger head **40**. The plunger head **40** includes a distal wall **41** and a proximal wall **42**. The distal wall **41** has a distal sealing surface **46** of the plunger head **40** defined thereon. As shown in

FIGS. 15 and 17, the distal wall 41 of the plunger head 40 perimetrically engages the inside surface 24 of the syringe barrel 20 so as to seal the chamber 25 of the syringe barrel 20 during use of the syringe assembly 10. The distal and proximal walls 41, 42 of the plunger head 40 are spaced by a central portion 43 of the plunger head 40 that extends between the distal and proximal walls 41, 42 of the plunger head 40. The central portion 43 has a cylindrical core portion 45 and a plurality of fin portions 44 extending radially from the cylindrical core portion 45, which may be equally spaced about the cylindrical core portion 45. As shown, there are four fin portions 44, though there could be more or less so long as the distal wall 41 of the plunger head 40 is suitably supported against canting, thus breaking a sealing engagement between the distal wall 41 and the inside surface 24 of the syringe barrel 20 during use.

[0040] As shown in FIGS. 7 and 8, the plunger head 40 further includes a cylindrical connecting portion 47 extending from the proximal wall 42 of the plunger head 40. The cylindrical connecting portion 47 includes an annular lip 48 at a proximal end thereof. As shown, the cylindrical connecting portion 47 is integrally connected to the proximal wall 42 of the plunger head 40 by a neck portion 49. It is to be appreciated that the cylindrical connecting portion 47 may be formed separately from the plunger head 40 and attached to the proximal wall 42 of the plunger head 40 by an adhesive or may be mechanically affixed to the proximal wall 42 according to known techniques.

[0041] The plunger head 40 may be integrally molded from either a soft plastic material, such as polyurethane, or alternatively may be formed from a rubber or elastomeric material depending upon choice. Such versatility and interchangeability within the syringe assembly 10 is advantageous because all plastic components can be used in markets where cost is extremely important and an elastomeric plunger head 40 can be used in markets with a strong preference for such components. It is to be appreciated that the plunger head can be formed in different shapes and according to other techniques known to be suitable to those of ordinary skill in the art.

[0042] As shown in FIGS. 13-15 and 17, the distal end 312 of the plunger rod 31 is engageable with the cylindrical connecting portion 47 of the plunger head 40 so that the plunger rod 31 is able to move the plunger head 40 within the chamber 25 of the syringe barrel 20 through an injection cycle. Particularly, the distal end 312 of the plunger rod 31 is slidably connected to the plunger head 40 such that during the injection cycle the plunger rod 31 slides with respect to the plunger head 40. The cylindrical connecting portion 47 fits

within the inner diameter **37** of the hollow plunger rod **31** such that the internal annular ring **38** of the plunger rod **31** is able to engage the annular lip **48** of the cylindrical connecting portion **47** by sliding over the annular lip **48** in the distal direction and thereafter retain the annular lip **48** of the cylindrical connecting portion **47** with the plunger rod **31** so as to slidably connect the distal end **312** of the plunger rod **31** with the plunger head **40**. During an injection cycle, the distal end **312** of the plunger rod **31** slides with respect to the cylindrical connecting portion **47** of the plunger head **40** such that the internal annular ring **38** of the plunger rod **31** engages the annular lip **48** of the cylindrical connecting portion **47** during aspiration of the syringe barrel **20** and the distal end **312** of the plunger rod **31** passes over the cylindrical connecting portion **47** and abuttingly engages the proximal wall **42** of the plunger head **40** during injection of the contents of the syringe barrel **20**.

[0043] Referring to **FIGS. 9-17**, operation of the syringe assembly **10** according to an embodiment of the present invention will now be described in detail. As shown in **FIGS. 9-11**, at an initial state of the syringe assembly **10**, the plunger head **40** is inserted into the chamber **25** of the syringe barrel **20** via the open proximal end **23** to a position proximate to the distal end **21** of the syringe barrel **20**, particularly a bottomed out position within the chamber **25**. As the plunger head **40** is inserted into the chamber **25**, the protrusions **27** of the flange lock **26** will fold into the chamber **25** toward the inside surface **24** of the syringe barrel **20**. Once the plunger head **40** passes through the flange lock **26**, the protrusions **27** may spring back into their initial condition. It is to be appreciated that the syringe assembly **10** may be packaged with the plunger head **40** already fully inserted into the chamber **25** of the syringe barrel **20** and with the plunger rod **31** inserted into the chamber **25** of the syringe barrel **20** and attached to the plunger head **40**, as shown in **FIG. 14**. Alternatively, the plunger head **40** and the plunger rod **31** may be packaged separately from the syringe barrel **20** and then manually inserted by a healthcare worker or technician prior to use.

[0044] As shown in **FIGS. 12-14**, the plunger rod **31** is then inserted into the chamber **25** via the open proximal end **23** of the syringe barrel **20** so as to be disposed at least partially within the chamber **25**. As the plunger rod **31** is inserted into the chamber **25**, the protrusions **27** of the flange lock **26** fold into the chamber **25** toward the inside surface **24** of the syringe barrel **20** and are held in a folded position by the outer surface **39** of the plunger rod **31**. As the plunger rod **31** is further inserted into the chamber **25**, the distal end **312** of the plunger rod **31** will come into engagement with the cylindrical connecting portion **47** of the plunger head **40**, as discussed above, so as to connect the distal end **312** of the plunger rod **31** with the

plunger head **40** such that the plunger rod **31** is slidable with respect to the cylindrical connecting portion **47** of the plunger head **40**.

[0045] During aspiration, the plunger rod **31** is drawn from the syringe barrel **20** in the proximal direction. As this occurs, the plunger rod **31** may initially slide with respect to the cylindrical connecting portion **47** of the plunger head **40** until the internal annular ring **38** of the plunger rod **31** engages the annular lip **48** of the cylindrical connecting portion **47** and the plunger head **40** is drawn proximally by the plunger rod **31** in an extended position so as to aspirate the chamber **25** of the syringe barrel **20**.

[0046] Once the desired aspiration of the chamber **25** of the syringe barrel **20** is completed, the plunger rod **31** is advanced within the chamber **25** of the syringe barrel **20**. As the plunger rod **31** is advanced, the distal end **312** of the plunger rod **31** slides with respect to cylindrical connecting portion **47** of the plunger head **40** until the distal end **312** of the plunger rod **31** engages the proximal wall **42** of the plunger head **40** in a collapsed position. The plunger assembly **30** is then further advanced within the chamber **25** of the syringe barrel **20** with the plunger head **40** being pushed through the chamber **24** by the distal end **312** of the plunger rod **31** so as to inject the contents of the chamber **25** into a patient. Thus, it is to be appreciated that a force necessary to advance the plunger rod **31** relative to the plunger head **40** during the injection cycle between aspiration and injection is less than a force necessary to sustain injection of the contents of the chamber **25** of the syringe barrel **20**. By providing a collapsible plunger assembly **30** with a slidable connection between the plunger rod **31** and the plunger head **40**, the plunger head **40** can be initially packaged in a bottomed out condition, *i.e.*, abutting or adjacent to the distal end **21** of the syringe barrel **20**. This results in less air being drawn into the chamber **25** of the syringe barrel **20** during aspiration and prior to injection. It is to be appreciated that the plunger assembly **30** could alternatively be formed with the plunger head **40** integral with the plunger rod **31** or otherwise non-slidably connected to the plunger rod **31** according to known techniques.

[0047] As shown in **FIGS. 15** and **16**, during the injection cycle, the protrusions **27** of the flange lock **26** slide along the outer surface **39** of the plunger rod **31** and engage the locking flange **34** of the plunger rod **31** upon or substantially upon completion of the injection cycle so as to retain the plunger assembly **30** in a bottomed out position with the distal sealing surface **46** of the plunger head **40** abutting, or nearly abutting, against the distal end **21** of the syringe barrel **20** to prevent removal of the plunger rod **31** from the syringe barrel **20**, thereby retaining the plunger assembly **30** in a locked position at least partially within the chamber **25**

of the syringe barrel **20** and disabling the syringe assembly **10**. More particularly, as the plunger head **40** reaches the bottomed out position and the contents of the chamber **25** of the syringe barrel **20** are fully injected to complete the injection cycle, the ends **271** of the flexible protrusions **27** slide over the distally facing beveled surface **341** of the locking flange **34** and engage the proximally facing abutment surface **342** so as to retain the plunger assembly **30** in the bottomed out position. Alternatively, the locking flange **34** may be positioned on the plunger rod **31** such that the locking flange **34** moves distally beyond the flange lock **26** during the injection cycle prior to full injection of the contents of the syringe barrel **20** so as to prevent removal of the plunger rod **31** from the syringe barrel **20**.

[0048] While several embodiments of a passive reuse prevention syringe that uses a flange lock and method were described in the foregoing detailed description, those skilled in the art may make modifications and alterations to these embodiments without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The invention described hereinabove is defined by the appended claims and all changes to the invention that fall within the meaning and the range of equivalency of the claims are embraced within their scope.

WHAT IS CLAIMED IS:

Claim 1: A syringe assembly, comprising:

a syringe barrel having an inside surface defining a chamber, an open proximal end, a distal end, and an outlet disposed adjacent the distal end in fluid communication with the chamber;

a plunger assembly disposed at least partially within the syringe barrel, comprising an elongate plunger rod having a proximal end, a distal end, a locking flange formed thereon between the proximal and distal ends, and a plunger head, the plunger rod being engageable with the plunger head such that the plunger rod is adapted to move the plunger head within the chamber of the syringe barrel through an injection cycle; and

a flange lock disposed at the open proximal end of the barrel,

wherein the plunger rod has a cylindrical shape defining a cylindrical outer surface extending from the distal end of the plunger rod to the proximal end of the plunger rod and the locking flange is formed on the outer surface of the plunger rod,

wherein the flange lock is integral with the open proximal end of the syringe barrel, and

wherein during the injection cycle, the flange lock engages the locking flange of the plunger rod so as to retain the plunger head at or near a bottomed out position abutting the distal end of the syringe barrel and to prevent removal of the plunger rod from the syringe barrel, and

wherein the flange lock is configured to slidingly engage the cylindrical outer surface of the plunger rod during the injection cycle prior to engaging the locking flange of the plunger rod.

Claim 2: The syringe assembly according to claim 1, wherein the flange lock includes a plurality of flexible protrusions distributed around a periphery of the open proximal end of the syringe barrel.

Claim 3: The syringe assembly according to claim 2, wherein the protrusions extend proximally from the open proximal end of the syringe barrel.

Claim 4: The syringe assembly according to claim 2, wherein the protrusions extend distally from the open proximal end of the syringe barrel into the chamber of the barrel.

Claim 5: The syringe assembly according to claim 2,

wherein the flexible protrusions of the flange lock are adapted to flex toward the inside surface of the barrel as the plunger rod is inserted into the chamber of the barrel, and

during the injection cycle, the protrusions slide along the outer surface of the plunger rod and engage the locking flange on the plunger rod so as to retain the plunger assembly in the barrel of the syringe and disable the syringe assembly.

Claim 6: The syringe assembly according to claim 5, wherein

the locking flange on the plunger rod tapers outwardly from the outer surface of the plunger rod so as to form a distally facing beveled surface and a proximally facing abutment surface, and

ends of the flexible protrusions slide over the distally facing beveled surface of the locking flange during the injection cycle and engage the proximally facing abutment surface so as to retain the plunger assembly in the barrel of the syringe.

Claim 7: The syringe assembly according to claim 1, wherein the plunger rod further includes a tamper prevention disk located proximal to the locking flange so as to prevent tampering with the engagement between the locking flange and the flange lock.

Claim 8: The syringe assembly according to claim 1, wherein the plunger rod has a variable diameter.

Claim 9: The syringe assembly according to claim 8,

wherein the plunger rod tapers inwardly toward the flange lock.

Claim 10: The syringe assembly according to claim 1,wherein the plunger head further comprises:

a distal wall, the distal wall having a distal sealing surface defined thereon;

a proximal wall, spaced from the distal wall; and

a central portion extending between the distal wall and the proximal wall, the central portion having a cylindrical core portion and a plurality of fin portions extending radially from the cylindrical core portion, and

wherein the distal wall of the plunger head perimetrically engages the inner surface of the barrel so as to seal the chamber of the barrel.

Claim 11: The syringe assembly according to claim 1, wherein the distal end of the plunger rod is slidably connected to the plunger head.

Claim 12: The syringe assembly according to claim 11, wherein

the plunger head includes a cylindrical connecting portion extending from a proximal wall of the plunger head, the cylindrical connecting portion having an annular lip at a proximal end thereof,

the plunger rod has a hollow cylindrical shape defining an outer surface and an inner diameter, the inner diameter of the plunger rod having an internal annular ring adapted to engage the annular lip of the cylindrical connecting portion such that the internal annular ring of the plunger rod is able to slide over the annular lip in the distal direction and retain the annular lip of the cylindrical connecting portion within the plunger rod, and

the plunger rod slides with respect to the cylindrical connecting portion of the plunger head such that the internal annular ring of the plunger rod engages the annular lip of the cylindrical connecting portion during aspiration and the distal end of the plunger rod engages the proximal wall of the plunger head during injection.

Claim 13: The syringe assembly according to claim 12, wherein a force necessary to advance the plunger rod relative to the plunger head during the injection cycle between aspiration and injection is less than a force necessary to sustain injection.

Claim 14: The syringe assembly according to claim 12, wherein the plunger rod further includes an annular flange extending from the outer surface of the plunger rod at the distal end of the plunger rod, the annular flange having a diameter slightly less than or equal to a diameter of the inside surface of the syringe barrel.

Claim 15: A plunger assembly for a syringe, the plunger assembly comprising:

an elongate plunger rod having a proximal end, a distal end, and a locking flange formed thereon between the proximal and distal ends; and

a plunger head, the plunger head including a cylindrical connecting portion,

wherein the plunger rod is engageable with the plunger head such that the plunger head is adapted to move the plunger head within the chamber of a syringe barrel through an injection cycle,

wherein the distal end of the plunger rod is connected to the plunger head such that the distal end of the plunger rod slides with respect to the plunger head during the injection cycle,

wherein during the injection cycle, the locking flange of the plunger rod is configured to engage a flange lock on the syringe so as to prevent removal of the plunger rod from the syringe barrel, and

wherein the plunger rod has a hollow cylindrical shape defining an outer surface and an inner diameter, and the cylindrical connecting portion of the plunger head fits within the inner diameter of the plunger rod.

Claim 16: The plunger assembly according to claim 15, wherein the locking flange on the plunger rod tapers outwardly from the outer surface of the plunger rod so as to form a distally facing beveled surface and a proximally facing abutment surface.

Claim 17: The plunger assembly according to claim 15, wherein the plunger rod further includes a tamper prevention disk located proximal to the locking flange so as to prevent tampering with the engagement between the locking flange and the flange lock.

Claim 18: The plunger assembly according to claim 15, wherein the plunger head further comprises:

a distal wall, the distal wall having a distal sealing surface defined thereon;

a proximal wall, spaced from the distal wall; and

a central portion extending between the distal wall and the proximal wall, the central portion having a cylindrical core portion and a plurality of fin portions extending radially from the cylindrical core portion,

wherein the distal wall of the plunger head is configured to perimetrically engage an inner surface of the syringe barrel so as to seal the chamber of the syringe barrel.

Claim 19: The plunger assembly according to claim 15, wherein

the cylindrical connecting portion of the plunger head extends from a proximal wall of the plunger head and has an annular lip at a proximal end thereof,

the inner diameter of the plunger rod has an internal annular ring adapted to engage the annular lip of the cylindrical connecting portion such that the internal annular ring of the plunger rod is able to slide over the annular lip in the distal direction and retain the annular lip of the cylindrical connecting portion within the plunger rod, and

the plunger rod slides with respect to the cylindrical connecting portion of the plunger head such that the internal annular ring of the plunger rod engages the annular lip of the cylindrical connecting portion during aspiration and the distal end of the plunger rod engages the proximal wall of the plunger head during injection.

Claim 20: The plunger assembly according to claim 15, wherein the plunger rod further includes an annular flange extending from the outer surface of the plunger rod at the distal end of the plunger rod.