SYRINGE ASSEMBLY HAVING DISABLING MECHANISM

FIELD OF THE INVENTION

The present invention relates to syringe assemblies and particularly to syringe assemblies having an automatic disabling mechanism.

BACKGROUND

Throughout the world the multiple use of hypodermic syringe products which are intended for single-use only, is instrumental in drug abuse and in the transfer of contagious diseases. Intravenous drug users who routinely share and re-use syringes are a high-risk group with respect to the AIDS virus. Also, the effects of multiple use are a major concern in some countries where repeated use of syringe products during mass immunization programs may be responsible for the spread of many diseases. Re-use of single-use hypodermic syringe assemblies is also instrumental in the spread of drug abuse even in the absence of infection or disease.

Many attempts have been made to remedy this problem. Most notable are early contributions which relied on a specific act to destroy the syringe after use either by using a destructive device or providing a syringe assembly with frangible zones so that the syringe could be rendered inoperable by the application of force. Other attempts involve the inclusion of structure which would allow the destruction or defeating of the syringe function to a conscious act by the syringe user. Although many of these devices work quite well, they do require the specific intent of the user followed by the actual act to destroy or render the syringe inoperable. These devices are not effective with a user having the specific intent to re-use the hypodermic syringe. Accordingly, there was a need for a single-use hypodermic syringe which after use will become inoperable or incapable of further use automatically without any additional act on the part of the user. The automatic function is much harder to provide because the means for rendering the syringe inoperable must not prevent its filling or use under normal conditions.

A single-use syringe which automatically disables after injection is taught in U.S. Patent No. 4,973,310 to Kosinski. This syringe contains a locking element positioned in the syringe barrel between the plunger rod and the inside surface of the barrel. In use, the syringe allows the user to draw a pre-selected amount of medication into the chamber of the barrel and deliver this medication, as through

injection, into the patient. Any attempt to withdraw the plunger to use the syringe a second time will cause the locking element to embed itself into the inside surface of the syringe barrel to prevent proximal motion of the plunger rod.

There is still a need for a single-use syringe which will allow a pre-selected number of plunger rod strokes before the automatic disabling mechanism activates. For example, four strokes of the plunger may be required to complete the injection process, such as when the syringe assembly is used to draw a diluent into the syringe barrel, dispense the diluent into a vial containing the substance to be reconstituted, drawing back the reconstituted medication into the syringe and then delivering the contents of the syringe into the patient.

SUMMARY OF THE INVENTION

The present invention is directed to a syringe assembly having a passive disabling mechanism. The disabling mechanism enables variable dosages by the syringe assembly and enables a selected number of cycles or strokes by the plunger rod before being disabled. In one preferred embodiment, the disabling mechanism provides two aspirating and two dispensing cycles before being disabled. The assembly enables the aspiration and dispensing of a selected volume of a diluent into a vial to reconstitute a drug, pharmaceutical agent, or other substance and then aspirating the reconstituted substance back into the syringe. A selected volume of the reconstituted substance can be injected or delivered to a patient where the volume of the substance that is delivered can be the same or different than the volume of the substance aspirated into the syringe barrel. The syringe is automatically disabled after the injection or delivery stroke.

The disabling mechanism is actuated by the axial movement of the plunger rod with respect to the syringe barrel and to the stopper, by moving the plunger rod in the aspirating direction. The stopper is coupled to the plunger rod through structure that allows limited axial movement of the stopper with respect to the plunger rod. The disabling mechanism is moved through a series of stages by reversing the direction of the axial movement of the plunger rod with respect to the stopper to move the mechanism in a step-wise manner to the disabling position. The disabling position of the mechanism is attained by the relative movement between the plunger rod and the stopper and is not dependent on the position of the stopper within the syringe barrel or the length of the stroke by the stopper. In this manner,

the syringe assembly is able to dispense a desired volume of the drug or other substance, and the disabling mechanism can be actuated after the final dispensing or injection stroke regardless of the position of the stopper in the syringe barrel. By actuating the disabling mechanism, the stopper cannot be retracted to aspirate another dose into the syringe barrel but allows any substance remaining in the syringe barrel to be dispensed.

The present syringe assembly provides an improvement over prior art devices by allowing a variable dose of diluent, chosen by the user at the time of use, to be drawn into the syringe, dispensing the diluent into a vial containing a substance to be reconstituted, drawing a selected amount of the reconstituted substance back into the syringe and then delivering the contents of the syringe. The selected amount of the reconstituted substance may be equal or less than the full volume reconstituted at the discretion of the user. The syringe assembly is automatically disabled after the final injection stroke. After the injection stroke of the syringe plunger, the disabling mechanism is activated to prevent axial movement of the stopper toward the proximal end of the syringe barrel thereby preventing the stopper from being removed and preventing reuse of the syringe to draw fluid into its chamber.

When the present syringe assembly has two or more detents on the stopper and one or more detents in the plunger rod, the maximum number of strokes the syringe assembly will allow can be varied by the initial position of the locking element with respect to the stopper detents and the plunger rod detents.

The present syringe assembly provides an improvement over prior art devices by providing a structure wherein the elements which allow the lost motion between the plunger rod and the stopper are contained internally within the plunger rod, safe from attempts to deflect the syringe barrel and plunger to defeat the locking mechanism. If these elements were on the outside of the plunger rod, it may be possible to deflect the barrel to contact the elements and defeat the locking mechanism.

Another important advantage of the present invention is that in many embodiments, detents and discontinuities that function to achieve the desired result are annular, so that rotating the plunger rod with respect to the barrel will not distort, damage or defeat the locking element. A single use syringe will not be effective if it can be easily manipulated to overcome the locking mechanism for removing the components for re-assembly and reuse.

A further major advantage of the present invention is the single frangible zone in the stopper. In many designs there is no single point where a breaking feature may be added effectively and two or more components will have to be orchestrated to break under the same applied force to the plunger rod in an attempt to defeat the locking mechanism. In the present invention only one area needs to be weakened and it is centrally located safe from outside manipulation.

An operable syringe assembly having a passive disabling structure includes a barrel having a side wall with an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall having a passageway therethrough in fluid communication with the chamber. An elongate plunger rod includes a proximal end and an open distal end having an interior surface defining a cavity therein with at least one detent on the interior surface of the plunger rod. A secondary cavity is included at the proximal end of the cavity in the plunger rod. The secondary cavity has a distal end and a proximal end and includes a contact surface and at least one discontinuity in the cavity. A stopper includes a sealing element having a peripheral surface forming a seal with the inside surface of the barrel, and a post extending proximally from the sealing element having a proximal end and a distal end. There are at least two post detents on the post. A secondary post extends proximally axially from the proximal end of the post. The secondary post includes a proximal end and a distal end and at least one discontinuity on its surface. The secondary post is positioned at least partially in the secondary cavity of the plunger rod. Structure for limiting motion is provided to allow the stopper to move freely axially with respect to the plunger rod for a limited distance so that the plunger rod can move while the stopper remains stationary in the barrel and for transferring proximally and distally directed forces applied to the plunger rod to the stopper. In some embodiments the distance of this lost motion between the stopper and the plunger rod is determined by the secondary post contacting a contact surface in the secondary cavity of the barrel and the discontinuity on the secondary post contacting the secondary cavity discontinuity in the plunger rod. Any combination of discontinuities in the secondary cavity and/or on the secondary post that provide for a limited distance of lost motion is within the purview of the present invention. A locking element includes a central body portion having an aperture therethrough, at least one cantilevered leg extending distally outwardly from the body portion, and at least one finger element extending inwardly into the aperture. The cantilevered leg

includes a sharp-free end directed outwardly for engaging the inside surface the barrel and the inside surface of the plunger rod. The locking element is initially positioned with the sharp-free end contacting the interior surface of the plunger rod proximally of the at least one detent in the plunger rod. The post is positioned in the aperture of the locking element wherein the finger element is contacting the proximal most of the at least two post detents, so that applying a proximally-directed force to the plunger rod while holding the barrel causes the plunger rod to move proximally with respect to the stopper until the free end of the cantilevered leg moves distally along the inner surface of the plunger rod cavity to the at least one detent in the cavity and the structure for limiting motion causes the stopper to move with the plunger rod in a proximal direction for a selected distance. Subsequently applying a distally directed force to the plunger rod to discharge fluid from the chamber causes the plunger rod to move in a distal direction along with the locking element due to its engagement with the at least one detent in the cavity until the structure for limiting motion causes the stopper to move distally along with the plunger rod to discharge fluid from the chamber. Subsequently applying a proximally-directed force to the plunger rod will cause the plunger rod to move proximally with the free end of the cantilevered leg moving relatively distally along the inside surface of the plunger rod past the distal end of the plunger rod so that the cantilevered leg engages the inside surface of the barrel to help prevent proximal movement of the stopper for rendering the syringe assembly unusable.

Other embodiments may include a plunger rod with two axially-spaced detents, and a post with three axially-spaced post detents so that the plunger rod can be moved distally two times before proximal motion of the plunger rod causes the locking element to engage the inside surface of the barrel.

The two axially-spaced detents of the plunger rod may include two axially-spaced steps, each having a blunt surface at its distal end extending inwardly from the interior surface of the plunger rod.

Some or all of the three axially-spaced post detents may include an incline surface extending proximally inwardly and a blunt surface at the distal end of each of the inclined surfaces extending radially inwardly.

The syringe assembly may include a locking element having two cantilevered legs positioned on opposite sides of the central body portion.

The structure for limiting free axial motion of the stopper with respect to the plunger rod may include at least one motion limiting discontinuity on the secondary post positioned to engage at least one motion limiting discontinuity in the secondary cavity. The at least one motion limiting discontinuity on said secondary post may include an outwardly directing projection and the at least one motion limiting discontinuity in the plunger rod secondary cavity may include an inwardly directed projection.

The syringe assembly may include a radial projection or cam surface on the stopper positioned to contact and force the cantilevered leg outwardly when excessive proximal force is applied to the plunger rod in an attempt to overcome the locking element's engagement of the inside surface of the barrel.

The syringe assembly may further include a frangible zone on the stopper which allows the plunger rod to disconnect from the stopper sealing element during application of excessive proximally-directed force to the plunger rod in an attempt to overcome the locking element's engagement of the inside surface of the barrel. The frangible zone may comprise an area of reduced cross-sectional area which is weaker than the post and the secondary post in areas outside of the zone. The frangible zone is positioned within the plunger rod. Only one frangible zone is necessary.

The syringe assembly may have a discontinuity on the inside surface of the barrel side wall positioned to engage the sharp-free end of the locking element when the sharp-free end is in contact with the inside surface of the barrel.

The syringe assembly may include a distal wall on the barrel having an elongate tip extending distally therefrom having a passageway in fluid communication with the passageway with the distal wall of the barrel. The syringe assembly may also further include a needle cannula having a distal end, a proximal end and a lumen therethrough. The proximal end of the needle cannula is connected to the distal end of the barrel so that the lumen is in fluid communication with the passageway.

Another embodiment of an operable syringe assembly of the present invention having passive disabling structure includes a barrel comprising a side wall having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall having a passageway therethrough in fluid communication with the chamber. An elongate hollow plunger rod having a proximal

end, an open distal end and an interior surface defining a cavity is provided. A stopper includes a sealing element with a peripheral surface forming a seal with the inside surface of the barrel and a post projecting proximally from the sealing element. A locking element includes a central body portion having at least one cantilevered leg extending distally outwardly from the body portion. The at least one leg includes a sharp free and directed outwardly for engaging the inside surface of the barrel. The locking element is movably engaged with the post and movably engaged with the plunger rod interior surface. Structure is provided for indexing the locking element distally in the plunger rod during proximal motion of the plunger rod to draw fluid into the chamber and for indexing the locking element distally on the post of the stopper during distally directed motion of the plunger rod for delivering fluid from the chamber through the passageway. Structure is also provided for limiting axial free movement of the stopper with respect to the plunger rod to allow the indexing of the locking element and for applying proximally and distally directed forces to the stopper through the plunger rod.

The locking element may be made of sheet metal such as stainless steel and the stopper may be integrally formed of thermoplastic material.

Another embodiment of an operable syringe assembly of the present invention includes structure for controlling the free axial motion of the stopper with respect to the plunger rod to help prevent accidental or unintended movement of the plunger rod with respect to the stopper to avoid cycling the passive disabling elements of the syringe assembly while not using it for its intended purpose. Structure for controlling free axial motion of the stopper with respect to the plunger may include the inwardly directed projection on the plunger rod having a free end frictionally contacting the outside surface of the secondary post increasing the force required to move the stopper with respect to the plunger rod.

The structure for controlling the free axial motion of the stopper with respect to the plunger rod may also include a proximal recess in the outside surface of the secondary post adjacent to the outwardly directed projection on the secondary post and a distal recess in the outside surface of the secondary post spaced from the proximal recess wherein the distance between the proximal distal recesses corresponds to the free axial motion of the stopper with respect to the plunger rod, with the free end of the inwardly directed projection being in the distal recess when the seal of the stopper is closest to the plunger rod and in the proximal recess when

the seal of the stopper is furthest from the plunger rod. The force applied to the plunger rod to move the free end of the inwardly directed projection out of either of the recesses is greater than the force required to move the free end along the outside surface of the secondary post between the recesses, thereby holding the stopper in its distal most and proximal most positions until the application of the greater force. It is preferred that the recesses in the secondary post are configured so that when the stopper and the plunger rod are in their extreme positions with respect to each other, the free end of the inwardly directed projection preferably exerts substantially zero force on the surface of the recesses and desirably no more than 25% of the force the inwardly directed projection exerts on the outside surface.

The structure for controlling may include a distal recess in the outside surface of the secondary post near the distal end of the secondary post, wherein the free end of said inwardly directed projection is in the distal recess when the seal of said stopper is closest to the plunger rod so that the force applied to said plunger rod to move the free end of the inwardly directed projection out of the distal recess is greater than the force required to move the free end along the outside surface of the secondary post thereby holding said stopper in its position with respect to the plunger rod until the application of said greater force.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the syringe assembly of the present invention.

Fig. 2 is a side-elevational end view of the proximal end of the syringe assembly of Fig. 1.

Fig. 3 is a cross-sectional view of the syringe assembly of Fig. 1 taken along line 3-3.

Fig. 4 is a perspective view of the plunger rod of the syringe assembly viewed from its proximal end.

Fig. 5 is a perspective cross-sectional view of the plunger rod viewed from its distal end.

Fig. 6 is a perspective view of the locking element of the syringe assembly viewed from its distal end.

Fig. 7 is a perspective view of the locking element viewed from its proximal end.

Fig. 8 is a perspective view of the stopper of the syringe assembly viewed from its proximal end.

Fig. 9 is an exploded perspective view of the syringe assembly.

Fig. 10 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly before use.

Fig. 11 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly after the first aspiration stroke.

Fig. 12 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly during a first dispensing stroke.

Fig. 13 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly at the start of a second aspiration stroke.

Fig. 14 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly after a second aspiration stroke.

Fig. 15 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly during a second dispensing stroke.

Fig. 16 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing the syringe assembly after a second dispensing stroke.

Fig. 17 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 3 showing a position of the internal components including additional structure for preventing reuse in the event of an attempt to withdraw the plunger rod after the second dispensing stroke.

Fig. 18 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 16 showing the further interaction of the additional structure to prevent reuse.

Fig. 19 is an enlarged partial cross-sectional view similar to the syringe assembly of Fig. 18 showing a discontinuity in the syringe barrel for engaging the locking element.

Fig. 20 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 19 showing the breaking of the stopper at a frangible zone.

Fig. 21 is an enlarged partial cross-sectional view of an alternative embodiment of the syringe assembly of the present invention.

Fig. 22 is a side-elevational view of an alternative stopper of the syringe assembly of the present invention.

Fig. 23 is an enlarged partial cross-sectional view of a syringe assembly using the stopper of Fig. 22 showing the syringe assembly before injection.

Fig. 24 is an enlarged partial cross-sectional view showing the interaction between the stopper and plunger rod of the syringe assembly of Fig. 23.

Fig. 25 is an enlarged partial cross-sectional view of the syringe assembly of Fig. 23 showing the syringe assembly after the second aspiration stroke.

Fig. 26 is an enlarged partial cross-sectional view showing the interaction between the stopper and plunger rod of the syringe assembly of Fig. 25.

DETAILED DESCRIPTION

[Referring to Figs. 1-18, a syringe assembly **20** having passive disabling features includes a barrel **21** and a plunger assembly **22**. Barrel **21** includes a cylindrical side wall **23** having an inside surface **24** defining a chamber **25** for retaining fluid. The barrel further includes an open proximal end **27** and a distal end **28** including a distal wall **29** having a passageway **32** therethrough in fluid communication with the chamber. In this embodiment, the distal wall of the barrel includes an elongate tip **31** extending distally therefrom and having a passageway therethrough in fluid communication with the passageway in the distal wall. In this embodiment, barrel **21** also includes a needle cannula **37** having a proximal end **38**, a distal end **39** and a lumen **40** therethrough. The proximal end of the needle cannula is attached to elongate tip **31** so that the lumen of the needle cannula is in fluid communication with passageway **32** in the barrel. A needle hub may also be attached to the proximal end of the needle cannula. In this configuration the needle hub engages the elongate tip to establish fluid communication between the lumen and the passageway in the barrel.

Plunger assembly **22** includes an elongate plunger rod **43**, a stopper **81** and a locking element **71**. Plunger rod **43** includes a proximal end **44**, an open distal end **45** and interior surface **46** defining a cavity **47** therein. The interior surface of the plunger rod preferably includes at least one detent. In this embodiment the at least one detent on the interior surface of the plunger rod includes two annular axially spaced detents **49** on the interior surface of the cavity. Each detent comprises a step **50** having a blunt surface **51** at its distal end. As will be explained in more detail hereinafter, the present invention can function without detents on the interior surface of the plunger rod. The plunger rod also includes a secondary cavity **52** at a proximal end of cavity **47**. The secondary cavity preferably includes a distal end **53** having a distal contact surface **61**, a proximal end **54** having a proximal contact

surface **55**, and at least one discontinuity therein. In this embodiment the discontinuity comprises one or more inwardly directed projections **56**. The secondary cavity is preferably smaller than cavity **47**. The primary purpose of the secondary cavity is to interact with the stopper so that the stopper is free to move axially with respect to the plunger rod for a limited distance. As will be seen hereinafter, this lost motion which allows the plunger rod to move independently of the stopper allows the locking element to index through a sequence of positions which end in the locking of the stopper in the barrel to prevent further use.

Stopper **81** includes a preferably circularly-shaped sealing element **82** having a peripheral surface **83** forming a seal with the inside surface of the barrel. A post **85** extends proximally from the sealing element and has a proximal end **87**, a distal end **88** and preferably at least two detents on its surface. In this embodiment, the at least two post detents includes three axially-spaced post detents **89**. Each post detent preferably but not necessarily, includes an inclined surface **91** and a blunt surface **92** at the distal end of each inclined surface. As will be explained in more detail hereinafter it is within the purview of the present invention to include an embodiment having a post without detents. A secondary post **93** extends proximally axially from the proximal end of post **85**. The secondary post includes a proximal end **94**, a distal end **95** and at least one discontinuity on its surface. In this embodiment discontinuity **96** is a radial projection having a distally-facing surface **97** thereon. The secondary post is positioned at least partially in the secondary cavity of the plunger rod. As mentioned hereinabove, the plunger rod is free to move axially with respect to the stopper for a limited distance which, in this embodiment, is controlled in one direction by the proximal end of the secondary post contacting proximal contact surface **55** in the secondary cavity and/or the proximal most detent **89** and distal contact surface **61** of the secondary cavity, and in the other direction by the secondary post discontinuity contacting the secondary cavity discontinuity in the plunger rod.

Locking element **71** includes a central body portion **72** having an aperture **73** therethrough. Preferably, at least one cantilevered leg extends distally outwardly from the body portion. In this embodiment, there are two cantilevered legs **74** extending distally outwardly from opposite sides of body portion **72**. A plurality of cantilevered legs or other spring and/or resilient structures for engaging the interim surface of the plunger rod and the inside surface of the barrel are within the purview

of the present invention. At least one finger element **75** extends inwardly into said aperture. In this embodiment the finger element extends proximally inwardly from the aperture. Each of the cantilevered legs preferably includes a sharp-free end **76** directed outwardly from engaging the inside surface of the barrel. The sharp-free end of the cantilevered leg can be formed in any configuration capable of engaging the inside surface of the barrel, such as a sharp edge or one or more pointed teeth and the like. The locking element may be made of a variety of materials, or combinations of materials, however, it is preferred to have a sharp-free end made of metal, and it is also preferred that the entire locking element be integrally formed from sheet metal such as stainless steel.

In this embodiment, plunger assembly **22** may be assembled by inserting locking element **71** into the distal end of plunger rod **43**. The post of stopper **81** is then inserted into the distal end of the plunger rod through aperture **73** of locking element **71** so that cantilevered legs **74** extend towards circularly-shaped sealing element **82** of the stopper as illustrated in Fig. 9. The plunger assembly is then inserted into barrel **21** through open proximal end **27** to the initial position illustrated in Figs. 3 and 10. Also, the syringe assembly may be assembled by inserting locking element 71 into the distal end of the plunger rod and inserting stopper 81 into the open proximal end of barrel 21, and then inserting the locking element/plunger rod into the proximal end of the syringe barrel.

In the initial position of the syringe assembly, locking element **71** is positioned with its sharp-free end **76** contacting the interior surface of the plunger rod proximally of axially-spaced steps **50**. Post **85** on stopper **81** is positioned in aperture **73** of locking element **71** so that finger element **75** contacts the post proximally of two of the three axially-spaced post detents **89**. The proximal end of the secondary post **93** is near or contacting contact surface **55** in proximal end **52** of the secondary cavity in the plunger rod, and the inclined surface of the most proximal post detent **89** is near or contacting contact surface **61** at the distal end of the secondary cavity. Contact between the proximal end of the secondary post and contact surface **55** in the secondary cavity and/or contact between the proximal most post detent, and contact surface **61** defines the proximal most motion of the stopper with respect to the plunger rod. Both contacts are preferred for stronger resistance to excessive distally directed force on the plunger rod. Stopper **81** further includes stabilizing member **84** positioned proximally with respect to sealing element **82** and having an outer

dimension complementing the outer dimension of the sealing element as illustrated in Fig. 10. Stabilizing member **84** has an outer dimension which is preferably less than the sealing element to assist in stabilizing the stopper to maintain the seal between the peripheral surface of the sealing element and the side surface of the barrel, and to maintain the stopper and post alignment substantially parallel to the axis of the syringe barrel.

As will be shown, the operation of the plunger assembly of this embodiment includes a first aspiration stroke followed by a first dispensing or injection stroke, a second aspirating stroke and a final dispensing or injection stroke after which the syringe will become disabled if another aspiration stroke is attempted. The disabling elements prevent or inhibit movement of the stopper in a proximal aspirating direction thereby limiting the function of the syringe assembly to a single use. The number of strokes in this embodiment is controlled by the number of axially-spaced detents in the plunger rod and the number of axially-spaced post detents on the stopper. However, the actual strokes the syringe may make will be determined by the position of the locking element with respect to the detents in the plunger rod and the detents on the stopper at the time of first use. For example, a syringe with two detents in the plunger rod and three stopper post detents on the stopper can be supplied to the user as a syringe capable of two strokes or four strokes. This is an important feature of the invention since a single syringe assembly can be provided with different stroke limitations before disabling.

Referring to Fig. 11, the syringe assembly may now be used to draw liquid, such as sterile water diluent into the chamber of the barrel by applying a proximally directed force F to a thumb press **57** on the proximal end of the plunger rod while holding the syringe barrel. This causes the plunger rod to move proximally with respect to the stopper until distally-facing surface **97** on discontinuity **96** of the secondary post contacts inwardly-directed projections **56** on the plunger rod. At the same time, the free ends of cantilevered legs **74** move distally along an interior surface **46** of the plunger rod and snap past blunt surface **51** of the proximal-most axially-spaced steps **50.** The stopper can now be moved proximally, through action of the plunger rod, until the desired volume is in the chamber, as determined by the user. It is an important feature of this invention that the user determines the volume, rather than the structure of the disabling mechanism dictating the volume as in some prior art devices.

Liquid diluent **33** in the chamber may now be dispensed into a vial of dry medication such as lyophilized medication, for reconstitution. As illustrated in Fig. 12, the first dispensing stroke is accomplished by applying force F to the plunger rod, in a distal direction, while holding the barrel. A barrel flange **30** is provided on the proximal end of the barrel to help control motion of the barrel during use of the syringe assembly. As the plunger rod moves distally, locking element **71** moves with the plunger rod dragging the locking element with it so that finger element **75** on the locking element slides from the proximal-most to the next proximal-most detent by riding up inclined surface **91** and falling into second of three post detents **89**. When the plunger rod contacts the stopper by action of the proximal end of the secondary post and contact surface **55** in the plunger rod and/or the proximal most post detent and contact surface **61**, the stopper will begin moving in a distal direction along with the plunger rod to dispense liquid diluent from the chamber into, for example, a vial of lyophilized medication.

When the diluent and the lyophilized medication are mixed, the syringe assembly of the present invention may now be used to withdraw the reconstituted, ready-to-inject medication into the chamber of the syringe barrel, as best illustrated in Figs. 13 and 14. By applying a proximally-directed force F to the plunger rod while holding the syringe barrel, the plunger rod will move in a proximal direction while locking element **71** will remain relatively stationary due to its connection to the post detent on the stopper. Proximal motion of the plunger rod causes the locking element to move relatively distally along the inside surface of the plunger rod so that the sharp-free ends **76** of the cantilevered legs move from the proximal-most axially-spaced step **50** in the plunger rod to the second more-distal axially-spaced step **50**. Proximal motion of the plunger rod also causes distally-facing surface **97** on discontinuity **96** of the secondary post to contact inwardly-directed projections **56** in the secondary cavity so that the stopper now moves proximally with the plunger rod drawing reconstituted medication **34** into chamber **25** of the syringe barrel to an amount determined by the user. The amount of medication drawn into the chamber, and therefore the maximum amount of medication that can be delivered, is determined by the user at the time of use and not by the placement of the components at the time of manufacture.

The syringe assembly of the present invention is now ready for a second and final dispensing or injection stroke which is best illustrated in Figs. 15 and 16.

Medication **34** is delivered to the patient by applying a distally-directed force F to the plunger rod causing the plunger rod to move in a distal direction with respect to the barrel. As the plunger rod advances in a distal direction engagement of sharp-free ends **76** of the locking element with the most distal blunt surface **50** of axially-spaced steps **50** moves the locking element distally so that finger element **75** of the locking element rides over the distal-most inclined surface **91** of the post detents distally to the most distal post detent **89**. When the distally-moving plunger rod contacts the stopper, both the stopper and plunger rod move toward the distal end of the barrel to dispense the contents of the chamber through the passageway.

The syringe assembly has now been used and is ready to be discarded. Any attempt to move the plunger rod in a proximal direction with respect to the barrel to refill the syringe assembly for further use will cause the locking element to disable the syringe. Specifically, as best illustrated in Figs. 17 and 18, applying force F to the plunger rod in a proximal direction will allow the plunger rod to move a short distance until the sharp-free ends **76** of the locking element snap past the distal end of the plunger rod and engage inside surface **24** of barrel **21**. In addition, a radial projection in the form of cam surface **58** on the stopper is positioned to force sharp-free ends **76** of the locking element further into the syringe barrel wall as more proximally-directed force is used in an attempt to improperly reuse the syringe. The cam surface may be annular or there may be one or more individual cam surfaces positioned to contact the locking element cantilevered legs. Cam surface **58** also includes a stop **59** to limit the distance the stopper moves in a proximal direction which helps prevent the reuse of the syringe. It is desirable to limit the proximal motion of the stopper to a distance that will only allow the syringe to take in a volume of less than 10% of the medication dose. Accordingly, increased force to pull the plunger rod out of the syringe barrel results in increased force of engagement of the sharp-free ends of the locking element into the barrel.

It is also within the purview of the present invention to provide a discontinuity, such as a recess or projection, on the interior surface of the barrel, as illustrated in Fig. 19 to further improve the engagement of the sharp-free end of the locking element with the interior surface of the barrel. In Fig. 19, syringe barrel **21** includes a barrel discontinuity in the form of an inwardly-directed projection **35** on inside surface **24** of the barrel. In this embodiment, projection **35** is an annular ring projecting into the barrel and extending 360° around the inside surface. The discontinuity may be in

the form of an annular projection, an annular recess or one or more projections or recesses shaped to engage sharp-free ends **76** of locking element **71** to further increase the grip of the locking element on the inside surface of the barrel.

The syringe assembly of the present invention also includes a frangible zone on stopper **81** positioned distally from discontinuity **96** on secondary post **93** for allowing the plunger rod to disconnect from the stopper sealing element during the application of excessive, proximally-directed force to the plunger rod in an attempt to overcome the locking element's engagement of the inside surface of the barrel. As illustrated in Figs. 19 and 20, the frangible zone in this embodiment preferably comprises a zone of reduced cross-sectional area **98** which is weaker in tension than the post **85** and secondary post **93** in areas outside of the zone. It should be noted that the frangible zone can be achieved in many ways such as forming portions of the stopper separately and assembling them using adhesive or mechanical connector in the area of the frangible zone, altering the area of the zone to be weaker than surrounding material, forming the stopper of different materials using the weakest material to form the zone and the like. The zone of reduced cross-sectional area illustrated herein is merely representative of these many possibilities all of which are in the purview of the present invention. The frangible zone is an important feature of the present invention since the weakest area of the syringe assembly can be located in one position and carefully controlled for the force of breaking or disconnecting, without needing to compromise other elements of the syringe assembly by having to create multiple frangible zones. The frangible zone is also preferably located within the plunger rod where it is difficult to access from outside of the syringe barrel for the purpose of defeating the single-use structure of the syringe assembly.

Referring to Fig. 21, an alternative embodiment of the syringe assembly of the present invention is illustrated. This embodiment functions similarly to the embodiment of Figs. 1-18 with the exception that there are no detents on the stopper post or in the plunger rod cavity. As described above, embodiments of Figs. 1-18 include a barrel having a relatively smooth inside surface to which the sharp-free ends of the cantilevered legs of the locking element engage. In the embodiments shown in Figs. 19 and 20 the barrel includes an inwardly-directed projection. The purpose of this projection is to improve the grip of the free ends of the cantilevered legs on the inside surface of the barrel to more strongly resist the application of a

proximally-directed force on the plunger to defeat the locking mechanism after the syringe has been used. If the sharp-free ends of the cantilevered legs are sharp enough and angled properly they should be able to resist such force without addition of an inwardly-directed projection on the inside surface of the barrel. Likewise, the detents on the stopper post and the interior surface of the plunger rod in the embodiment of Figs. 1-18, are provided to assure that locking element will index properly with each stroke of the plunger with respect to the barrel placing the locking element in position to disable the syringe at the completion of the last delivery stroke. Detents also allow more latitude in the design of the plunger rod, stopper and locking element such as being able to use a broader range of materials, and to use looser, more cost-effective tolerances. However, the invention will function without detents on the stopper post and in the plunger rod if an adequately sharp and resilient element is used with compliant materials. Specifically, as shown in Fig. 21, syringe assembly **120** includes a barrel **121** having a cylindrical side wall **123** and an inside surface **124** defining a chamber **125** for retaining fluid. An elongate plunger rod **143** includes an open distal end **145** having an interior surface **146** defining a cavity **147** therein. A stopper **181** includes a sealing element **182** having a peripheral surface forming a seal with the inside surface of the barrel. A post **185** extends proximally from the sealing element having a proximal end **187** and a distal end **188**. Locking element **171** includes a central body portion **172** having an aperture therethrough. Cantilevered legs **174** bend distally-outwardly from opposite sides of body portion **172**. At least one finger element **175** bends proximally-inwardly from the aperture. Each of the cantilevered legs has a sharp free end **176** directed outwardly for engaging inside surface **124** of the barrel and interior surface **146** of the plunger rod. The sharp free end of each cantilevered leg is configured to move relatively freely in a distal direction and to resist proximally-directed motion by engaging the surface which is contacts. Likewise, finger element **175** is configured to move distally along the post of the stopper but to resist proximal motion along the post by engaging the stopper post. In all other aspects this embodiment functions similarly to the embodiment of Figs. 1-18.

Figs. 22-26 illustrate another alternative embodiment of the syringe assembly of the present invention. This embodiment functions similarly to the embodiment of Figs. 1-18 except that the stopper includes additional features on the secondary post to control the free axial motion of the stopper with respect to the plunger rod.

Stopper **281** includes a preferably circular-shaped sealing element **282** having a peripheral surface **283** forming a seal with the inside surface of the barrel, a post **285** extends proximally from the sealing element and has a proximal end **287**, a distal end **288** and preferably at least two detents on its surface. In this embodiment the at least two post detents include three axially-spaced detents **289**. Each post detent preferably, but not necessarily, includes an incline surface **291** and a blunt surface **292** at the distal end of each inclined surface. A secondary post **293** extends proximally axially from the proximal end of post **285**. The secondary post includes a proximal end **294**, a distal end **295** and at least one discontinuity on its surface. In this embodiment, discontinuity **296** is a radial projection having a distally-facing surface **297** thereon. Outside surface **277** of the secondary post includes a proximal recess **279** adjacent to distally facing surface **297** and a distal recess **280** spaced from the proximal recess. The distance between the proximal recess and the distal recess corresponds to the free axial motion of the stopper with respect to the plunger rod. Free end **62** of inwardly directed projection **56** on plunger rod **43** is in distal recess **280** when seal **283** of the stopper is closest to the plunger rod and proximal recess **279** when the seal of the stopper is furthest from the plunger rod. The force that must be applied to the plunger rod to move free end **62** of inwardly directed projection **56** out of either of the recesses is greater than the force required to move the free end along outside surface **277** of the secondary post between the recesses, thereby holding the stopper in its distal most and proximal most positions until the application of the greater force. It is preferred that the recesses in the secondary post are configured so that when the stopper and the plunger rod are at extreme positions with respect to each other and the free end of the inwardly directed projection is in either of the recesses that the inwardly directed projection be in a relatively stress-free condition. In these positions, the inwardly directed projection exerts little or no force on the surface of the recesses. This helps avoid the possibility of any creep in the thermoplastic components between time of manufacture and time of use and, accordingly, helps insure consistent performance from syringe to syringe.

It is an important advantage of the present embodiment that the plunger cannot inadvertently or through incidental minor forces applied before use, be cycled back and forth with respect to the stopper advancing the locking element without drawing fluid into or out of the chamber. This configuration does not preclude the

intentional cycling of the plunger rod with respect to the stopper before use to reduce the number of cycles the syringe can have before the locking element prevents further cycling or use.

Even without the proximal and distal recesses, the frictional force between the free end of the inwardly directed projection and the outside surface of the secondary post will help prevent inadvertent or unintended cycling of the plunger rod with respect to the barrel. The configuration of the transitional area between the proximal and/or distal recesses and the outside surface of the secondary post can be configured, such as by using the curvilinear cam surface, to help keep the transitional forces in a range that is lower than the force required to move the stopper along the inside of the barrel. Also, the inwardly directed projection can be configured in many ways to cooperate with the proximal and distal recesses and the outside surface of the secondary post, and the proximally inwardly directed projection and the relatively straight geometric transitions between the recesses and the surfaces of the secondary post as shown herein are merely representative of the these many possibilities, all of which are in the purview of the present invention.

While various embodiments have been chosen to illustrate the invention, it will be appreciated that changes and modifications can be made without departing from the scope of the invention.

WHAT IS CLAIMED IS:

1. An operable syringe assembly having passive disabling structure comprising:

a barrel including a side wall having an inside surface defining a chamber for retaining fluid, an open proximal end and a distal end including a distal wall having a passageway therethrough in fluid communication with said chamber;

an elongate plunger rod including a proximal end and an open distal end having an interior surface defining a cavity therein, at least one detent on said interior surface at said distal end of said plunger rod, a secondary cavity at a proximal end of said cavity, said secondary cavity having a distal end and a proximal end, said secondary cavity having a contact surface and at least one discontinuity in said secondary cavity;

a stopper including a sealing element having a peripheral surface forming a seal with said inside surface of said barrel, a post extending proximally from said sealing element having a proximal end and a distal end, at least two post detents on said post, a secondary post extending axially from said proximal end of said post, having a proximal end, a distal end, an outside surface and at least one discontinuity on said outside surface, said secondary post being positioned at least partially in said secondary cavity;

means for limiting free axial motion of said stopper with respect to said plunger rod for a limited distance and for applying proximally and distally directed forces to said stopper through said plunger rod;

means for controlling free axial motion of said stopper with respect to said plunger rod;

a locking element including a central body portion having an aperture therethrough, at least one cantilevered leg extending distally outwardly from said body portion, and at least one finger element extending proximally inwardly into said aperture, said at least one leg having a sharp free end directed outwardly for engaging said inside surface of said barrel;

said locking element being positioned with said sharp-free end contacting said interior surface of said plunger rod proximally of said at least one detent in said plunger rod, said post being positioned in said aperture of said locking element wherein said at least one finger element is contacting the proximal most of said at least two post detents, so that applying a proximally directed force to said

plunger rod while holding said barrel causes said plunger rod to move proximally with respect to said stopper until said free end of said cantilevered leg moves distally along said inner surface of said plunger rod cavity to said at least one detent in said cavity and said means for limiting motion causes said stopper to move along with said plunger in a proximal direction for a selected distance, and subsequently applying a distally directed force to said plunger rod to discharge fluid from said chamber through said passageway causes said plunger rod to move in a distal direction along with said locking element due to its engagement with said at least two post detents until said means for limiting motion causes said stopper to move distally with said plunger rod to discharge fluid from said chamber, after which applying proximally directed force to said plunger rod will cause said plunger rod to move proximally with said free end of said cantilevered leg moving distally along said interior surface of said cavity past said distal end of said plunger rod so that said at least one cantilevered leg engages said inside surface of said barrel to help prevent proximal movement of said stopper to render said syringe assembly unusable.

2. The syringe assembly of claim 1 wherein said at least one detent in said plunger rod includes two axially spaced detents and said at least two detents on said post includes three axially spaced post detents so that said plunger rod can be moved distally two times before proximal motion of said plunger rod causes said locking element to engage said inside surface of said barrel.

3. The syringe assembly of claim 2 wherein said two axially spaced detents in said plunger rod include two axially spaced steps each having a blunt surface at its distal end extending inwardly from said interior surface.

4. The syringe assembly of claim 2 wherein said three axially spaced post detents each include a blunt distally facing surface at a extending radially outwardly.

5. The syringe assembly of claim 2 said at least one cantilevered leg of said locking element includes two cantilevered legs positioned on opposite sides of said central body portion.

6. The syringe assembly of claim 5 further including two radial projections on said stopper positioned to engage and force said two cantilevered legs outwardly when excessive proximally directed force is applied to said plunger rod in an attempt to overcome said locking element's engagement of said inside surface of said barrel.

7. The syringe assembly of claim 1 wherein said means for limiting said free axial motion of said stopper with respect to said plunger rod includes at least one motion limiting discontinuity on said secondary post positioned to engage at least one motion limiting discontinuity in said secondary cavity.

8. The syringe assembly of claim 7 wherein said at least one motion limiting discontinuity on said secondary post comprises an outwardly directed projection and said at least one motion limiting discontinuity in said secondary cavity comprises an inwardly directed projection having a free end.

9. The syringe assembly of claim 8 wherein said means for controlling free axial motion of said stopper with respect to said plunger rod includes said free end of said inwardly directed projection frictionally contacting said outside surface of said secondary post increasing the force required to move said stopper with respect to said plunger rod.

10. The syringe assembly of claim 9 wherein said means for controlling further includes a proximal recess in said outside surface of said secondary post adjacent to said outwardly directed projection on said secondary post and a distal recess in said outside surface of said secondary post spaced from said proximal recess, the distance between said proximal and said distal recesses corresponds to said free axial motion of said stopper with respect to said plunger rod, with said free end of said inwardly directed projection being in said distal recess, when said seal of said stopper is closest to said plunger rod and in said proximal recess when said seal of said stopper is furthest from said plunger rod, wherein the force applied to said plunger rod to move said free and said inwardly directed projection out of either of said recess is greater than the force required to move said free end along said outside surface of said secondary post between said recesses,

thereby holding said stopper in its distal most and proximal most positions until the application of said greater force.

11. The syringe assembly of claim 10 wherein said recesses in said secondary post are configured so that when said stopper and said plunger rod are in their extreme positions with respect to each other, said free end of said inwardly directed projection exerts substantially zero force on the surface of said recesses.

12. The syringe assembly of claim 10 wherein said recesses in said secondary post are configured so that when said stopper and said plunger rod are in their extreme positions with respect to each other, said free end of said inwardly directed projection exerts a force on the surface of said recesses which is less than 25% of the force said free end exerts on said outside surface of said secondary post.

13. The syringe assembly of Claim 9 wherein said means for controlling further includes a distal recess in said outside surface of said secondary post near said distal end of said secondary post, wherein said free end of said inwardly directed projection is in said distal recess, when said seal of said stopper is closest to said plunger rod, wherein the force applied to said plunger rod to move said free and said inwardly directed projection out of said distal recess is greater than the force required to move said free end along said outside surface of said secondary post, thereby holding said stopper in its proximal most position with respect to said plunger rod until the application of said greater force.

14. The syringe assembly of claim 13 wherein said recess in said secondary post is configured so that when said stopper is in its proximal most position with respect to said plunger rod, said free end of said inwardly directed projection exerts substantially zero force on the surface of said recess.

15. The syringe assembly of claim 13 wherein said recess in said secondary post is configured so that when said stopper is in its proximal most position with respect to said plunger rod, said free end of said inwardly directed projection exerts a force on the surface of said recess which is less than 25% of the force said free and exerts on said outside surface of said secondary post.