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Stumpf et al.

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[54] **BREECH LOADED SYRINGE AND METHOD OF BREECH LOADING SAME**

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[52] **U.S. Cl.** .....**128/218 P,** 53/57

[51] **Int. Cl.** **A61m 5/00**

[58] **Field of Search** ..128/218 R, 218 P, 218 M, 220; 53/57

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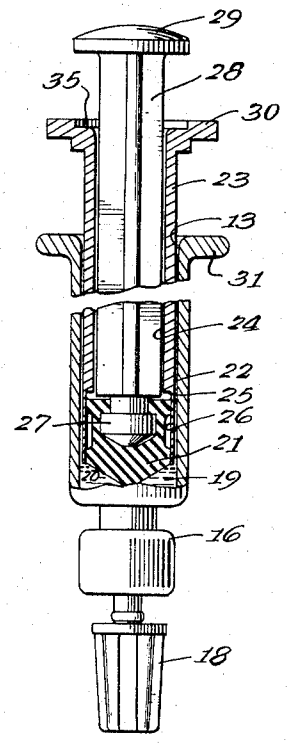
[57] **ABSTRACT**

A syringe wherein a piston is moved axially through a tubular barrel to deliver liquid medicament and the like outwardly through a needle connected through an inner end of the barrel. A control is provided for selectively deforming the piston to permit the barrel to be preloaded with the liquid medicament through the breech end thereof with the piston being brought into engagement with the liquid while a fluid bypass passage is provided around the piston to the breech end of the barrel, thereby to vent air outwardly from the space between the piston and the liquid medicament during the insertion of the piston.

8 Claims, 9 Drawing Figures



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SHEET 1 OF 2

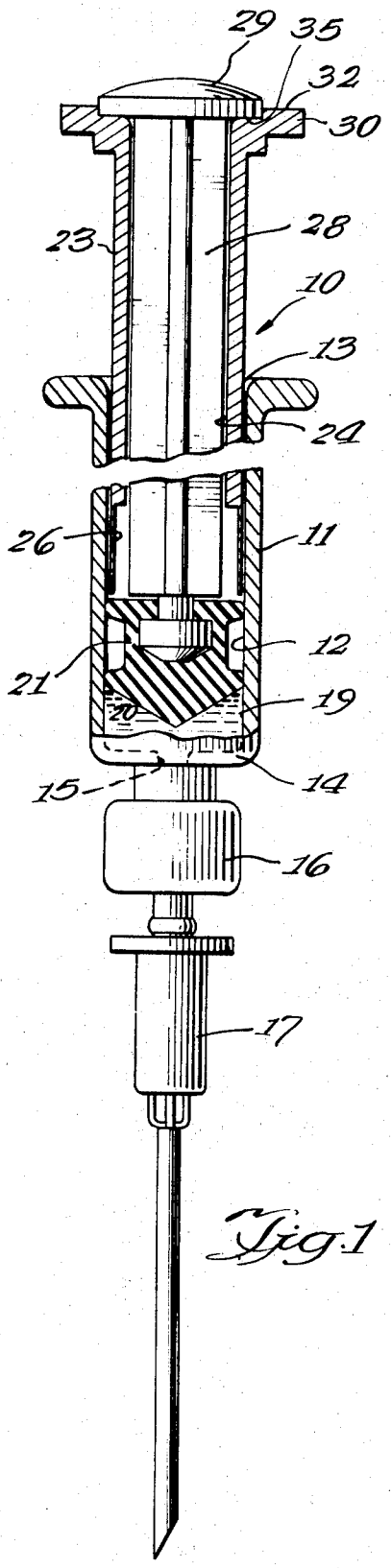

Fig. 1

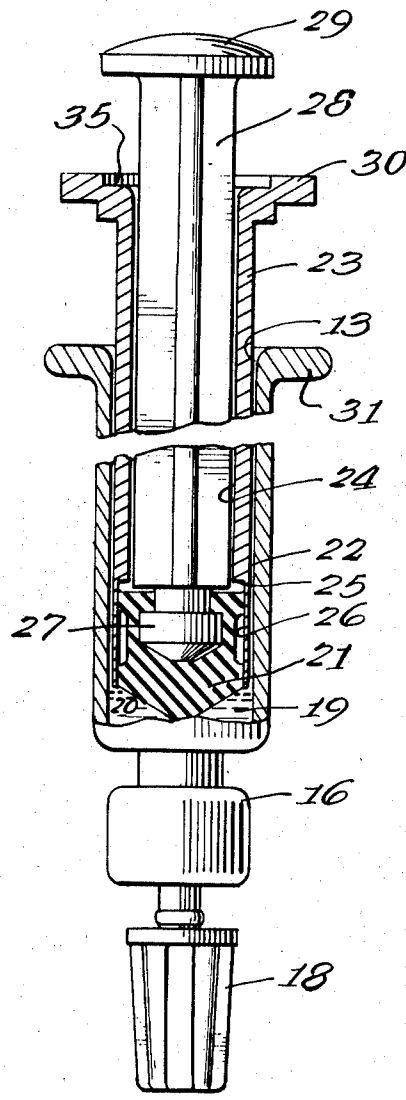

Fig. 2

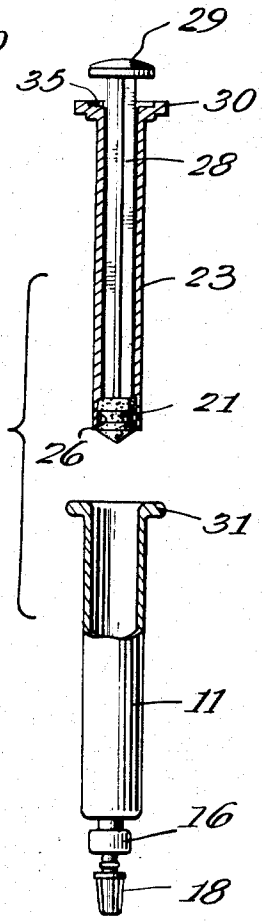

Fig. 3

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Fig. 4

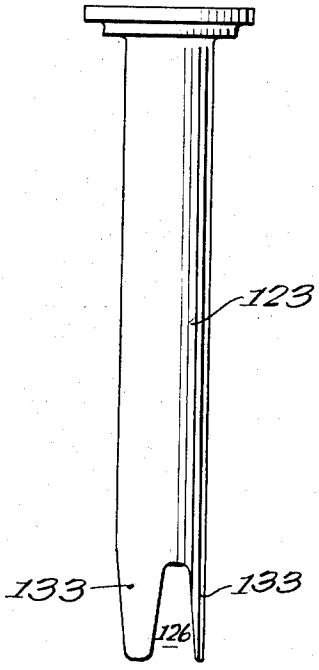


Fig. 6

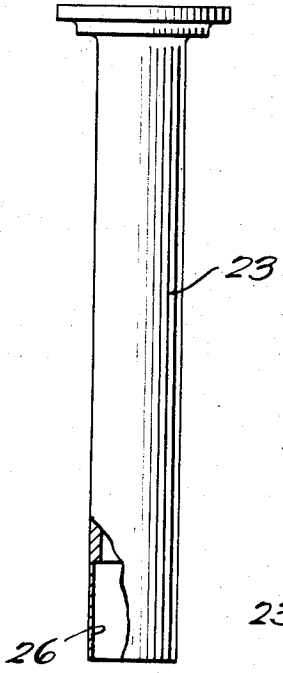


Fig. 8

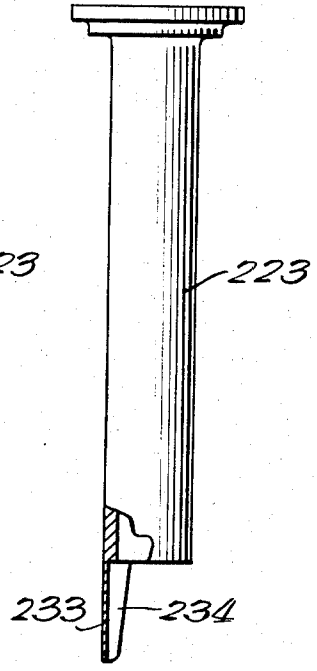


Fig. 5

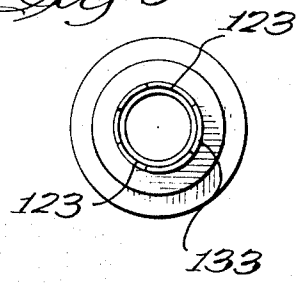


Fig. 7

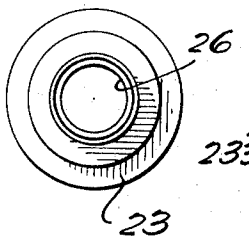
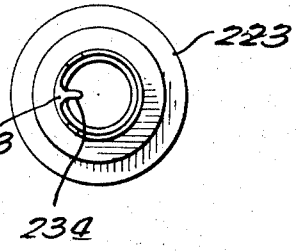


Fig. 9



BREECH LOADED SYRINGE AND METHOD OF BREECH LOADING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to syringes and in particular to piston-type syringes.

2. Description of the Prior Art

In the conventional piston syringe, the filling of the syringe is effected through the needle connecting end. Such a method of filling the syringe is undesirable where the filled syringe is to be stored, such as where the syringe comprises a prefilled syringe. Further, such needle end filling is inimical to good aseptic techniques. Illustratively, it has been found that the narrow lumens of the needle or needle connector tip become clogged by the dried medicament.

One attempted method of resolving this problem has been to load the syringe through the breech end of the barrel. Such a loading of the syringe provides improved storage characteristics where air is removed from between the piston and liquid medicament upon insertion of the piston. Thus, in the prior art devices for providing such breech loading, needles, rods, valves, conical shaped sleeves, etc. have been employed to permit venting of the trapped air. Not only are such means relatively expensive, but also, such means have been found to lead to contamination of the liquid medicament.

SUMMARY OF THE INVENTION

The present invention comprehends an improved syringe structure wherein the piston, during insertion through the breech end of the barrel into engagement with the previously deposited liquid medicament, is deformed so as to provide a bypass vent. The deforming means may comprise a tubular element adapted to receive the piston under compression and having a clearance with the barrel permitting movement of the inner end of the element through the breech end of the barrel into juxtaposition with the liquid medicament wherein the trapped air is vented through the clearance space between the sleeve and the barrel. Upon reaching the fully inserted position, the piston is removed from its position within the sleeve end thereby permitting the piston to expand into sealed sliding engagement with the barrel wall. The piston may be carried on the inner end of a shaft extending from the piston to outwardly of the barrel outer end.

In one specific embodiment of the invention, the shaft extends coaxially through a tubular sleeve having a bore radially enlarged at its inner end to define a piston receiving recess. The tubular sleeve also has a recess at its outer end for receiving in nested relationship the thumb piece of the shaft. Movement between the shaft and the sleeve may be effected manually to provide the selective deformation and release of the piston.

Alternatively, the piston may be deformed by a rib element on the inner end of the sleeve which extends the length of the piston to deform an outer wall portion thereof radially inwardly and thereby form a fluid bypass passage permitting the air to be vented from the barrel during the insertion of the piston. If desired, a plurality of such rib elements may be provided to form a plurality of such bypass passages for venting during the piston insertion step.

Thus, the invention comprehends an improved method of filling a syringe with liquid medicament including the steps of introducing the liquid medicament through the breech end of the syringe barrel, inserting a resilient piston through the breech end while concurrently deforming the piston to define a fluid bypass passage around the piston to the breech end for venting air from the barrel as the piston is moved to the liquid medicament, and discontinuing the deforming of the piston upon the piston reaching the liquid medicament to cause the piston to have sealed sliding engagement with the barrel. The filling of the syringe may be effected to provide a prefilled syringe unit which may be stored for subsequent use as desired. In such case, the needle end of the syringe is maintained sealingly closed. Alternatively, the syringe will be breech filled at the time of use by the above indicated steps.

BRIEF DESCRIPTION OF THE DRAWING

Other features and advantages of the invention will be apparent from the following description taken in connection with the accompanying drawing wherein:

FIG. 1 is a fragmentary enlarged front view of a syringe embodying the invention with portions broken away to illustrate the invention;

FIG. 2 is a view similar to that of FIG. 1 but illustrating the arrangement of the syringe during the piston inserting operation;

FIG. 3 is an exploded view with portions broken away illustrating the arrangement of the piston and sleeve assembly prior to insertion into the syringe barrel;

FIG. 4 is a front view of one form of sleeve thereof;

FIG. 5 is a fragmentary bottom end view thereof;

FIG. 6 is a front view of the sleeve used in the syringe shown in FIGS. 1–3, with a portion broken away to provide a clear illustration of the invention;

FIG. 7. is a bottom end view of the sleeve of FIG. 6;

FIG. 8 is a front view of still another modified form of sleeve thereof with a portion broken away to illustrate the invention; and

FIG. 9 is a bottom end view of the sleeve of FIG. 8.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the exemplary embodiment of the invention as disclosed in FIGS. 1-3 of the drawing, a syringe generally designated **10** is shown as having a conventional tubular barrel **11** defining a chamber **12** opening axially outwardly through an outer end **13**. The inner end **14** of the barrel **11** is provided with an outlet **15** opening into a connector **16** for attaching a needle, such as conventional needle **17**, in fluid transfer association with the inner end of the barrel. In the illustrated embodiment, the connector comprises a conventional luer lock connector, it being understood that any suitable needle connecting means may be utilized. Prior to the installation of the needle **17** onto the connector **16**, connector **16** may be conventionally closed by a conventional cap **18**, as shown in FIGS. **2** and **3**.

The syringe **10** may comprise a prefilled syringe wherein a body of liquid, such as liquid medicament **19**, is provided in the portion **20** of the chamber **12** inwardly of a piston **21**. In the illustrated embodiment, the liquid **19** is delivered into the chamber **12** through the outer end **13** in a breech loading operation. The

piston 21 is then brought into the chamber 12 through the outer end 13 to engage the liquid 19 as shown in FIG. 2. To permit such insertion of the piston, a bypass passage 22 is provided around the piston from the inner chamber portion 20 to the outer opening 13 whereby air may be vented from the chamber 12 as the piston is moved downwardly therethrough to the position of FIG. 2.

The invention comprehends the provision of the vent passage 22 by means of a tubular element, or sleeve, 23 having an outside diameter slightly smaller than the inside diameter of the barrel 11. The bore 24 of sleeve 23 is stepped at 25 to define a radially enlarged inner end bore portion 26 adapted to receive the piston 21 as shown in FIG. 2. Piston 21 is preferably formed of a resilient material, such as neoprene rubber, to permit the ready compression thereof into the bore portion 26 of the sleeve 23 as by urging the sleeve axially forward relative to the piston 21 until the piston is encased in portion 26 as shown in FIG. 3. The piston is secured to an end connector portion 27 of a shaft 28 having an outer thumb piece 29. Shaft 28 extends coaxially through the bore 24 of sleeve 23. As shown in FIG. 2, shaft 28 is somewhat smaller in transverse dimension than the diameter of bore 24, permitting the ready axial movement of the shaft 28 therethrough when desired. To provide relative movement between the shaft 28 and sleeve 23 and to provide for the movement of the sleeve 23 into the barrel 11, the outer end of the sleeve is provided with a flange 30. Flange 30 is spaced outwardly of the conventional outturned flange 31 of the barrel to permit the user to insert his fingers under flange 30 with his thumb on thumb piece 29 and thereby readily effect a movement of the piston 21 inwardly from the end portion 26 when desired. Thus by maintaining the piston 21 in contact with the liquid medicament 19 and urging the sleeve 23 outwardly, the lower end of the sleeve is withdrawn from the piston permitting the piston to expand radially into sliding sealing engagement with the barrel wall in bore portion 20 thereby to permit subsequent controlled delivery of the liquid medicament outwardly through needle 17 as desired.

The flange 30 of the sleeve 23 has a recess 35 formed in the upper surface 32 which recess 35 is of a size and shape to receive in nested relationship the thumb piece 29 of the shaft 28 when the shaft is fully depressed relative to the sleeve 23. In moving the shaft 28 relative to the sleeve 23 from the position of FIG. 2 to the position of FIG. 1, the thumb piece 29 will nest in the recess 35 and create the appearance of a one piece plunger unit.

In the normal use, the piston 21 may be provided retracted within bore portion 26 as shown in FIG. 3, permitting the movement of the assembled piston and sleeve 23 into the barrel 11 as discussed above. However, alternatively, the piston may be mounted on the shaft end 27 inwardly of the sleeve (in the arrangement seen in FIG. 1) and inserted into the open end 13 of the barrel 11. The piston is then caused to move into the bore portion 26 by a combination of forces directed by the user's fingers on the outer surface 32 of the flange 30 and the fluid pressure within the bore 12 ahead of the piston 21 thereby to cause the piston to move axially into the sleeve bore end 26. Once the piston is fully received in bore end 26, further movement of the assembly may be effected as discussed above as the sleeve and piston structure are now disposed in the arrangement shown in FIG. 2. This method of bringing the piston into the bore end 26 at the time of assembly is advantageous where the piston 21 is formed of a material which may take a permanent set if stored within the sleeve bore 24 for a protracted period of time. The piston 21, sleeve 23, and shaft 28 may, of course, be assembled together by inserting the shaft 28 through the sleeve 23, and then mounting the piston 21 onto the inner end 27 of the shaft so that these parts occupy the relative positions shown in FIG. 1. The piston is deformed to provide a vent passage around the piston 21 by effecting relative movement between the shaft with the piston connected thereto, and the sleeve. In the illustrated embodiment of FIGS. 1–3, such relative movement positions the piston 21 in the sleeve bore end 26 and this effects deformation of the piston by urging peripheral portions thereof radially inwardly, the piston being retained in the bore end 26 by the inherent resiliency thereof.

Thus, the syringe 10 provides an improved structure permitting prefilling of the syringe in an aseptic manner by a breech loading of the liquid medicament therein. As indicated above, the liquid medicament may be retained in the prefilled syringe by the subsequent installation of the piston 21 as discussed above, whereby the piston may be brought into engagement with the upper surface of the liquid by a vented movement of the piston through the barrel, thereby maintaining the aseptic condition of the breech loaded syringe. When the syringe is to be used, the cap 18 is removed and the needle 17 installed on the connector 16 in the conventional manner whereupon the liquid medicament may be delivered through the needle by suitable manipulation of the shaft 28 by the user's fingers engaging flange 31 and thumb piece 29.

The invention comprehends broadly providing a means for deforming the piston 21 during its insertion through the bore 12 to define a bypass passage 22 whereby the bore 12 is vented to facilitate the movement of the piston fully to the position of FIG. 2. As discussed above, in one form, the means for forming the bypass passage 22 may comprise means for receiving the piston under compression within one end of the tubular sleeve 23. The sleeve construction is illustrated in FIGS. 6 and 7. As will be obvious to those skilled in the art, other forms of piston deforming means may be provided within the scope of the invention. Illustratively, in FIG. 4, a sleeve 123 is shown to comprise a sleeve similar to sleeve 23 but having a plurality of circumferentially spaced end prongs 133 which effectively distort the piston when the piston is retracted into the space 126 radially within the prongs. In the illustrative embodiment of FIG. 4, three such prongs are provided spaced 120° about the axis of the sleeve. In FIGS. 8 and 9, a further modified form of sleeve 223 is shown to comprise a sleeve having a depending prong 223 provided with a radially inwardly projecting rib 234 which effectively distorts the piston to define an air bypass vent passage for venting the barrel during the installation of the piston.

Each of the sleeves 23, 123, and 223 is similar to the others and functions in a similar manner except as otherwise noted. In each embodiment, means are pro-

vided for deforming the piston during insertion thereof into the barrel bore to define a vent passage. The deforming means are carried on an elongated element which extends to outwardly of the barrel serving as a means for effecting a separation of the deforming means from the piston after the piston reaches the desired fully inserted position whereby the piston may then function in the normal manner within the barrel. As will be obvious to those skilled in the art, the element carrying the deforming means may have other configurations in addition to the tubular sleeve configuration of the illustrative embodiments. The different parts of these syringes may be made of suitable materials, such as plastics, permitting relative ease of sterilization. Thus, the syringes may comprise one-time use, prefilled syringes.

The foregoing disclosure of specific embodiments is illustrative of the broad inventive concepts comprehended by the invention.

I claim:

1. In a syringe having a tubular barrel defining a chamber opening axially through the outer end of the barrel, and a needle connecting portion at the inner end of the barrel for connecting a needle in fluid flow association with said chamber, the improvement comprising:

a resilient piston arranged to have sealing sliding engagement with the barrel in said chamber; first means secured to said piston and extending from said piston to outwardly of said outer end for moving said piston into said chamber through said outer end during insertion thereof in said barrel and for moving said piston to discharge fluid from said chamber in response to a manually applied force on said first means during operational use of the syringe; and second means carried by said first means and extending from within said chamber to outwardly of said outer end, said second means being movable in one direction relative to said first means to deform said piston

for forming fluid bypass means around said piston for venting the chamber portion forward of said piston, and movable in the direction opposite said one direction relative to said first means

for removing the fluid bypass means whereby the piston sealingly engages with the barrel to force fluid from said chamber through said needle connecting portion as an incident of movement of said piston in said chamber toward said inner end in response to said applied force on said first means.

2. In a syringe having a tubular barrel defining a chamber opening axially through the outer end of the barrel, and a needle connecting portion at the inner end of the barrel for connecting a needle in fluid flow association with said chamber, the improvement comprising:

a resilient piston arranged to have sealing sliding engagement with the barrel in said chamber;

first means secured to and extending from said piston to outwardly of said outer end for manipulating said piston during operational use of the syringe; and

second means carried by said first means, said first and second means being relatively movable

a. for forming fluid bypass means around said piston for venting the chamber portion forward of said piston, and

b. for removing the fluid bypass means whereby the piston is in sealing engagement with the barrel to force fluid from said chamber through said needle connecting portion as an incident of movement of said piston in said chamber toward said inner end, said second means comprising means having a tubular inner end removably receiving said piston, and means for causing axial removal of said piston from said tubular inner end, said second means having a clearance with said barrel defining said fluid bypass means to said outer end of the barrel, said second means also having an axially inner end for retaining the piston axially inwardly of said tubular end subsequent to said removal.

3. In a syringe having a tubular barrel defining a chamber opening axially through the outer end of the barrel, and a needle connecting portion at the inner end of the barrel for connecting a needle in fluid flow association with said chamber, the improvement comprising:

a resilient piston arranged to have sealing sliding engagement with the barrel in said chamber;

first means secured to and extending from said piston to outwardly of said outer end for manipulating said piston during operational use of the syringe; and

second means carried by said first means and extending from within said chamber to outwardly of said outer end, said first and second means being selectively relatively movable.

a. for forming fluid bypass means around said piston for venting the chamber portion forward of said piston, and

b. for removing the fluid bypass means whereby the piston is in sealing engagement with the barrel to force fluid from said chamber through said needle connecting portion as an incident of movement of said piston in said chamber toward said inner end in response to an applied force on said first means, said second means comprising means removably extending the length of said piston between said piston and said barrel for deforming said piston to form a plurality of fluid bypass passages between the deformed piston and the barrel which communicate with said outer end of the barrel, said passages defining said fluid bypass means, said second means comprising a plurality of angularly spaced elements providing said fluid bypass means.

4. In a syringe having a tubular barrel defining a chamber opening axially through the outer end of the barrel, and a needle connecting portion at the inner end of the barrel for connecting a needle in fluid flow association with said chamber, the improvement comprising:

a resilient piston arranged to have sealing sliding engagement with the barrel in said chamber;

first means extending from said piston to outwardly of said outer end for manipulating said piston during operational use of the syringe; and

second means carried by said first means and extending from within said chamber to outwardly of said outer end, said first and second means being selectively relatively movable

a. for forming fluid bypass means around said piston for venting the chamber portion forward of said piston, and

b. for removing the fluid bypass means whereby the piston is in sealing engagement with the barrel to force fluid from said chamber through said needle connecting portion as an incident of movement of said piston in said chamber toward said inner end, said second means comprising a tubular element having an axial bore provided with a portion at the inner end of said tubular element of greater diameter than other portions of said bore for receiving said piston, said tubular element removably extending the length of said piston between the piston and said barrel for deforming the piston to define said fluid bypass means between the deformed piston and the barrel which communicate with said outer end of the barrel.

5. The method of filling a syringe having a barrel with a bore open at the breech end of the barrel for receiving a liquid medicament during the filling of the syringe, and a shaft and piston assembly comprising a resilient piston for sliding sealing engagement with the barrel in the bore, and a shaft connected to the piston and responsive to an applied force thereon for moving the piston toward the inner end of the barrel to discharge the medicament from the bore during operational use of the syringe comprising the steps of:

providing said shaft and piston assembly with a relatively movable elongate member adapted to deform said piston upon movement thereof in one direction relative to said shaft;

moving said elongate member in said one direction relative to said shaft to deform said piston;

inserting said piston and shaft assembly and said elongate member into the bore through the breech end thereof;

moving the shaft and piston assembly and elongate member toward the inner end of the barrel with said piston deformed to provide fluid bypass means within the barrel from a point ahead of said piston to said breech end for venting air from the barrel as said piston is moved toward the liquid medicament; and moving said elongate member in the direction opposite said one direction relative to said shaft to cause said piston to have sealed sliding engagement with the barrel.

6. The method of filling a syringe with liquid medicament of claim 5 wherein substantially the entire piston is deformed away from contact with the barrel during the step of moving the shaft and piston assembly and the elongate member toward the inner end of the barrel.

7. The method of filling a syringe with liquid medicament of claim 5 wherein only a portion of the piston is deformed away from contact with the barrel during the step of moving the shaft and piston assembly and the elongate member toward the inner end of the barrel.

8. The method of filling a syringe with liquid medicament of claim 5 wherein the step of moving said second means in said one direction relative to said first means to deform said piston is performed prior to the step of inserting said shaft and piston assembly into the breech end of the barrel, and said piston is maintained deformed by said elongate member until it is substantially moved to the liquid medicament.

* * * * *