

[54] **SYRINGE AND METHOD**

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[51] Int. Cl. **A61m 05/22**

[58] Field of Search.....128/215, 216, 218 R, 218 P,
128/218 M, 218 D, 220, 272; 222/386;
417/550, 555

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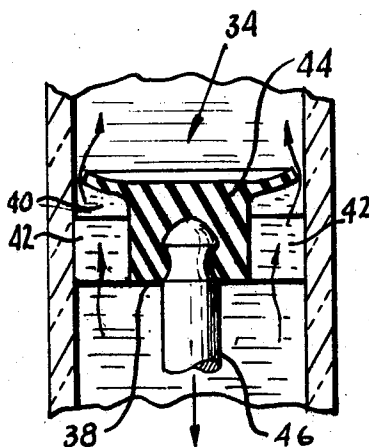
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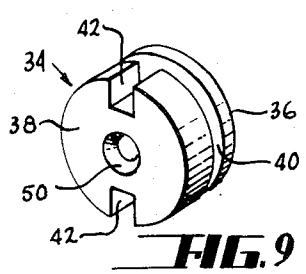
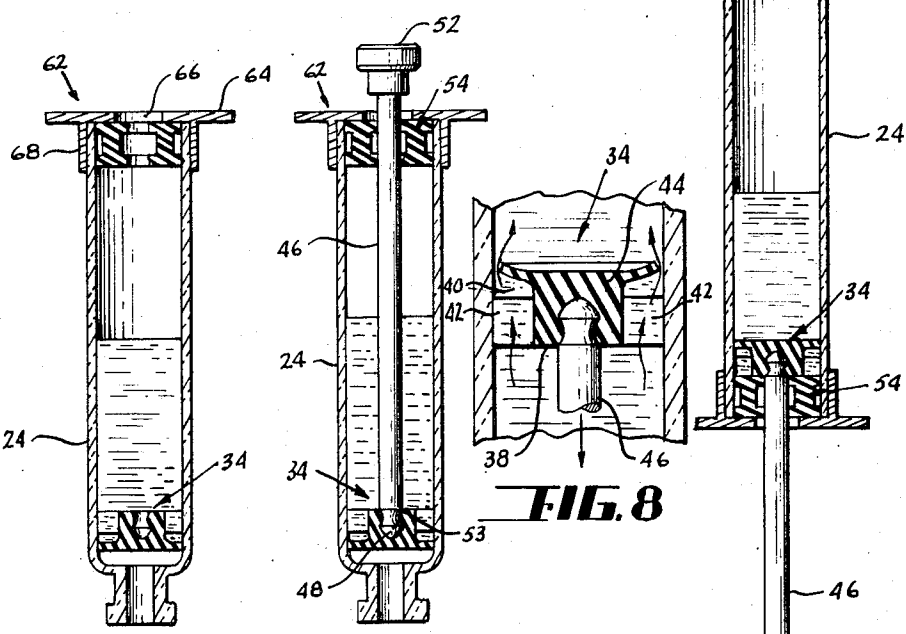
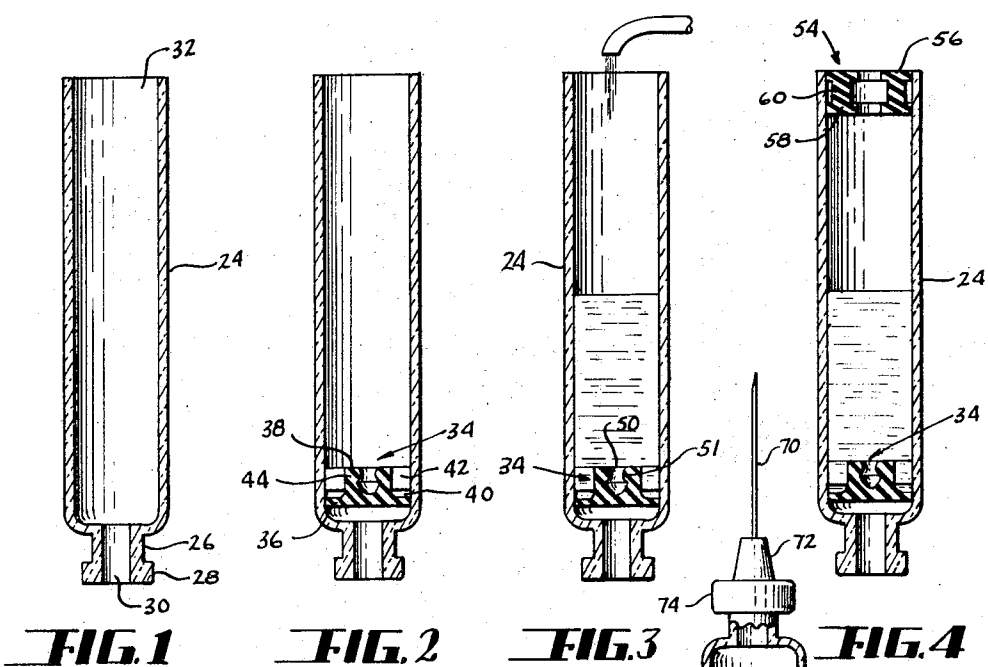
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[57] **ABSTRACT**

A syringe assembly utilizes a one way valve which comprises a compliant plate portion adapted to partition a syringe barrel. The compliant plate portion moves in response to pressures developed within the syringe barrel and the valve includes a brace portion which limits compliance of the plate portion to pressures exerted in a given direction. Due to compliance by the plate portion, fluid can flow within the syringe barrel and around the plate portion when the pressure acting on the fluid is in the opposite direction but, by reason of the compliant plate being braced, cannot flow through the valve when a pressure is developed in said given direction. Two embodiments of the valve are disclosed. Three methods of assembly are disclosed; one wherein a medicine is confined within the syringe assembly under a positive pressure, another wherein the medicine is confined under atmospheric pressure, and a third wherein two components of medicine are confined in separate syringe compartments. A preferred mode of syringe activation is disclosed wherein a traveling seal closing one end of the syringe is caused to cling to the syringe valve so as to maintain the syringe in readiness for aspiration.

7 Claims, 23 Drawing Figures





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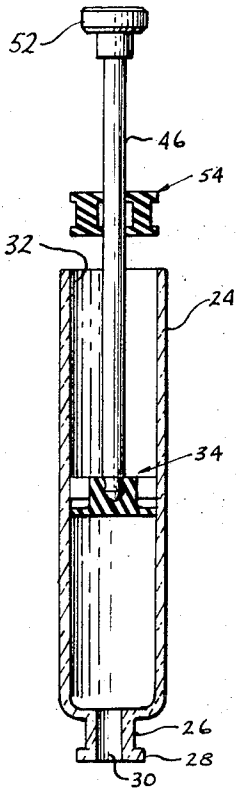


FIG. 10

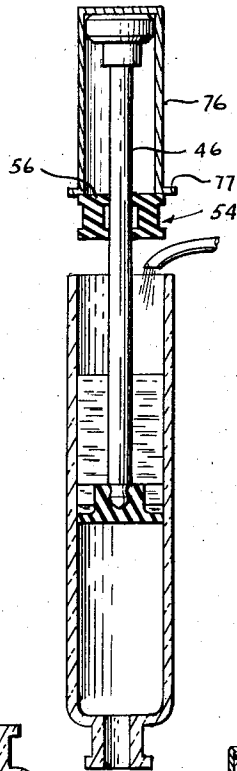


FIG. 11

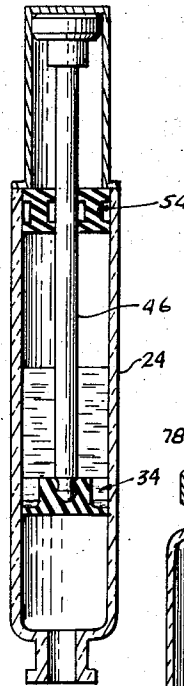


FIG. 12

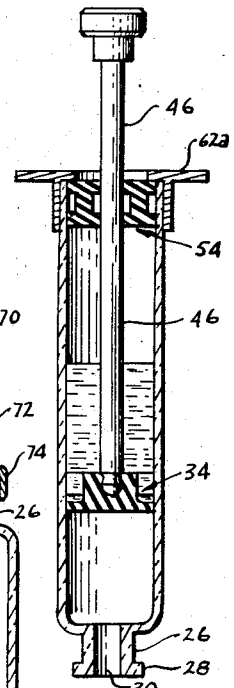


FIG. 13

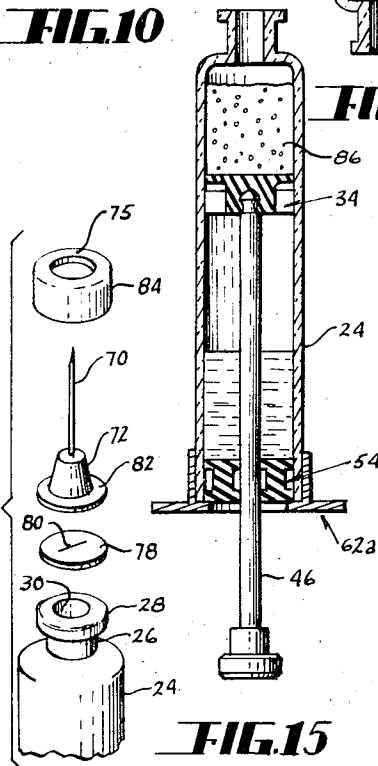


FIG. 14

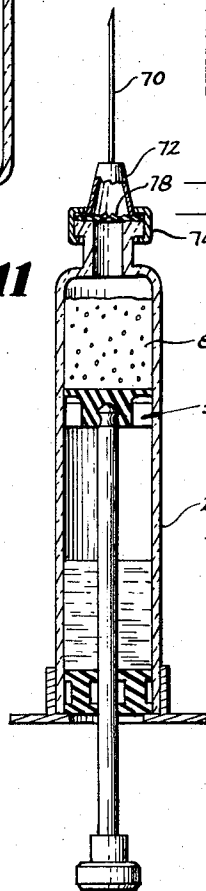


FIG. 15

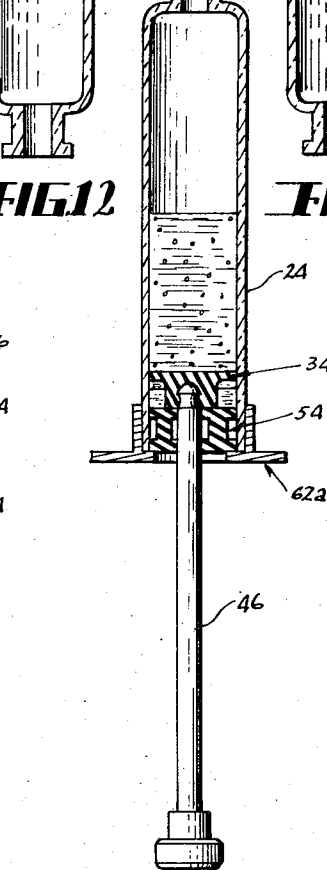


FIG. 16

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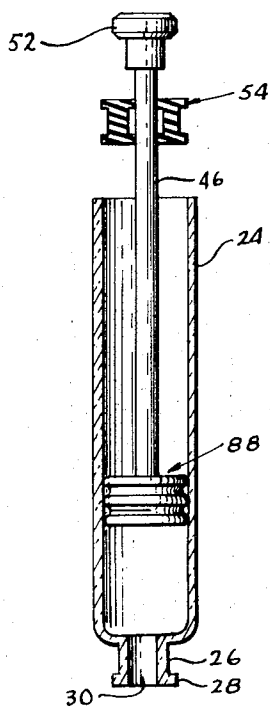


FIG. 18

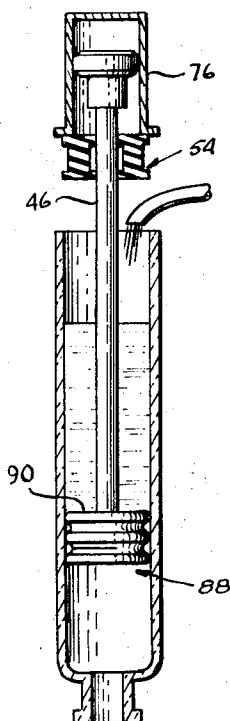


FIG. 19

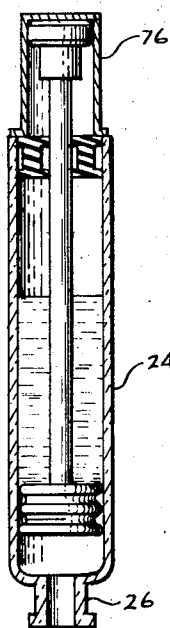


FIG. 20

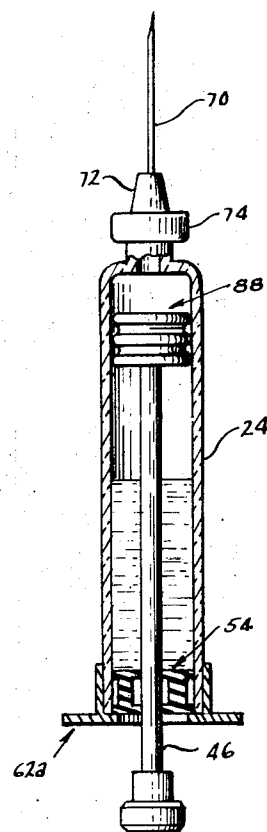


FIG. 21

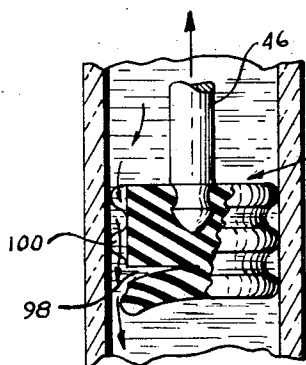


FIG. 23

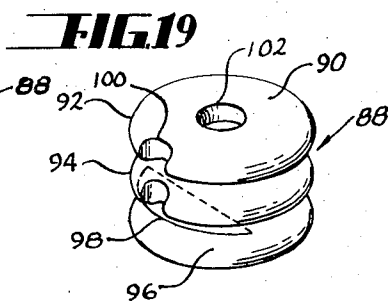


FIG. 22

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SYRINGE AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a syringe and more particularly to a hypodermic syringe having a plurality of modes of assembly including one mode which permits two compartment storage of a two compartment medicine.

2. Description of the Prior Art

Syringe devices which employ a one way valve to separate two components of a medicine intended for mixture immediately before hypodermic injection are known in the prior art. One prior art design involves an expansible sleeve which is disposed axially in the syringe barrel and expands in response to pressure developed in a given axial direction to release a liquid component for mixture with a powder component. In addition to requiring relatively expensive tooling for its production, the prior art valve has the likelihood of becoming occluded by reason of the powder component encircling the sleeve so as to block its operation. Other one way valve devices known in the prior art utilize detachable plugs of various sorts which pop free of the valve when a sufficient pressure is developed in the proper direction. Such valves also require expensive tooling and present the problem that the plug once freed from the valve may move to a position where it blocks passage of the medicine to a hypodermic needle. All one way valves known in the prior art are typically of complicated construction and unreliable operation.

SUMMARY OF THE INVENTION

The one way valve of the present invention utilizes a compliant plate which transversely seals a syringe barrel and which is braced by an integrally attached brace portion. The brace portion inhibits compliance by the plate to pressures exerted in one direction but does not interfere with compliance by the plate to pressures exerted in the opposite direction. The compliant plate is a desirable improvement because it can be used to separate liquid and powder components of a medicine while presenting a smooth face to the powder component such that the powder component cannot interfere with the operation of the valve. The smooth face of the compliant plate also permits the valve to make a type of vacuum interface to a movable seal which causes the seal to cling to and travel with the valve, thus keeping the syringe device in readiness for prompt aspiration at any time after a hypodermic injection has been undertaken. The simplicity of the syringe construction allows alternative methods of assembly, one in which a medicine is confined under a positive pressure and another in which a medicine is confined under atmospheric pressure.

One object of the present invention is to provide a new and improved syringe valve.

Another object of the present invention is to provide new and improved methods of syringe assembly.

A third object of the present invention is to provide an improved mode of syringe activation.

Other objects and advantages reside in the construction of parts, the combination thereof, the method of manufacture and the mode of operation, as will become more apparent from the following description.

In the drawings,

FIG. 1 is a sectional view of a conventional syringe barrel.

FIG. 2 is a sectional view of the syringe barrel and showing a preferred one way valve parked adjacent one end of the syringe barrel.

FIG. 3 illustrates a liquid medicine being added to the syringe barrel which is again shown in section.

FIG. 4 is a section view of the syringe barrel after addition of a seal to its inlet opening.

FIG. 5 is a section view of the syringe barrel after addition of a retaining flange encircling its inlet opening.

FIG. 6 is a section view of the syringe barrel after an actuator rod has been passed through the seal to engage the one way valve.

FIG. 7 is an elevation view of the syringe barrel after attachment of a needle thereto and illustrating the condition of the syringe after activation thereof.

FIG. 8 is a fragmentary section view illustrating the condition of the one way valve during activation of the syringe.

FIG. 9 is a perspective view illustrating the one way valve of the preferred embodiment.

FIG. 10 is a section view illustrating commencement of the assembly of the preferred embodiment as a two compartment syringe.

FIG. 11 illustrates the addition of an assembly tool and a liquid component to the syringe assembly of FIG. 10.

FIG. 12 is a section view illustrating the syringe assembly after a closure thereof with aid of the assembly tool shown in FIG. 11.

FIG. 13 is a section view of the syringe after removal of the assembly tool and attachment of a retaining flange.

FIG. 14 is an exploded perspective view of a syringe needle assembly.

FIG. 15 is a section view illustrating the syringe assembly of FIG. 13 after addition of a powder component.

FIG. 16 is a section view illustrating the two compartment syringe after attachment of the needle assembly of FIG. 14.

FIG. 17 is a section view illustrating the condition of the syringe assembly of FIG. 16 after activation thereof to mix its liquid and powder components.

FIG. 18 is a section view illustrating a modified one way valve and illustrating commencement of the assembly of the modified valve to confine a liquid medicine under ambient pressure.

FIG. 19 is a section view illustrating the addition of a liquid medicine over the modified valve.

FIG. 20 is a section view illustrating use of a tool to seat a seal above the liquid medicine added in FIG. 19.

FIG. 21 is a section view illustrating a completed assembly of the modification.

FIG. 22 is a perspective view of the modified valve.

FIG. 23 is a section view illustrating the condition of the modified valve during activation of the completed syringe of FIG. 21.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings in greater detail, the preferred embodiment in various steps of its assembly is illustrated in FIGS. 1-9. FIG. 1 illustrates a conven-

tional glass syringe barrel which is cylindrical throughout its length except at one end thereof where the wall of the barrel converges inwardly to form a neck 26 which is relatively short and cylindrical and which terminates with an enlarged flange 28. The neck 26 has a central bore 30 therethrough which communicates with the interior of the syringe barrel. The opposite end of the syringe barrel has a relatively large opening 32 whose internal diameter is the same as the internal diameter of the syringe barrel throughout the major portion of its length.

Received within the syringe barrel, as shown in FIG. 2, is a one way valve 34 best illustrated in FIGS. 8 and 9. The valve includes a pliant wall or plate 36 having a circular outer periphery which is sized to slidably seal against the interior cylindrical wall of the syringe barrel 24.

Spaced from the wall 36 as it appears in FIG. 9 is a brace member or brace plate 38. The brace plate 38 has a generally cylindrical outer peripheral wall which is sized to interfit the interior wall of the syringe barrel. The axial length and diametric size of the brace plate 38 is sufficient to prevent any appreciable cocking of the valve 34 within the syringe barrel and also to prevent any appreciable transverse or radial excursions from its position of concentricity within the syringe barrel.

The valve 34 is preferably of one piece construction, there being a central core 44 integral with the pliant plate 36 and the brace plate 38 which anchors the pliant plate 36 to the brace plate 38. As appears in FIG. 8 an annular undercut or slit shown at 40 encircling the core 44 separates an outer annular peripheral portion of the plate 36 from the plate 38. The undercut 40 is somewhat exaggerated in the drawings so as to clearly illustrate its presence.

Extending longitudinally throughout the axial length of the brace plate 38 and disposed at diametrically opposite peripheral positions thereof are openings or slots 42 which establish fluid communication between the undercut 40 to one end of the brace plate 38 and the opposite end of the brace plate 38. As appears in FIG. 8 the interior regions of the slots 42 define the outer walls for the previously mentioned core 44.

The face or end wall of the plate 38 which is opposite the pliant wall 36 has a centrally located cavity 50 which has an annular bead 51 constricting the opening into the cavity 50. This cavity with its constricting bead is designed to interfit a bayonet extension 48 formed on an actuator rod 46. The bayonet extension 48 has an annular groove 53 to receive the aforementioned constricting bead 51 and thus interlock the bayonet extension to the brace plate 38.

The valve 34 is preferably formed with any suitable pliant plastic or rubber material which has been approved for use in appliances which dispense medicines.

The end of the actuator rod 46 which is opposite the bayonet extension 48 is provided with a plunger head 52. The plunger head 52 can be an integral part of the rod 46 but for reasons of manufacturing economy may also be press fitted or adhesively secured to the rod 46. The syringe barrel 24 is preferably glass so as to prevent undue friction and possible seizure between the syringe barrel and the valve 34, however, other suitably stiff medically approved materials may also be

used for the syringe barrel. Likewise, the actuator rod 46 is preferably glass but may comprise another suitably stiff medically approved material. To provide good lubrication between the valve 34 and the glass wall of the syringe barrel 24, it is desirable, although not essential, that the peripheral portions of the valve 34 which will engage the glass wall of the syringe barrel be precoated with a medically approved lubricant such as a silicone oil.

Sized for receipt within the opening 32 to the syringe barrel 24 is a seal member 54 which comprises annular walls 56 and 58 supported in spaced concentric relation by an integral cylinder spacer 60. The inner diameter of the spacer 60 preferably exceeds the diameter of the rod 46. Likewise, the outer diameter of the spacer 60 is preferably smaller than the interior diameter of the syringe barrel 24 except at the neck portion of the syringe barrel. The annular walls 56 and 58 are both sized to have an interior periphery which slidably seals against the outer surface of the actuator rod 46 and an outer periphery which slidably seals against the interior wall of the syringe barrel 24. The seal 54 is preferably constructed of a relatively stiff but nevertheless pliant medically approved material such as polyethylene.

Assuming the seal 54 to have been inserted within the barrel 24 to the position illustrated in FIG. 4, the seal is trapped or locked within the syringe barrel by means of a flange member or retainer 62 as appears in FIG. 5. The flange member 62 comprises a cylindrical sleeve 68 sized to receive the outer diameter of the syringe barrel 24. Integral with the sleeve 68 is a preferably circular plate 64 which is larger in diameter than the sleeve 68 and which has a centrally located aperture 66 which is sufficiently large in diameter with respect to the actuator rod 46 to leave an air passage through the plate 64 after both the rod 46 and flange member 62 have been assembled to the syringe as appears in FIG. 6.

The flange member 62 is preferably formed of a heat shrinkable material such as polyethylene so that it may be strongly attached by heat shrinkage to the outer wall of the syringe barrel 24.

As will be later explained, the diameter of the plate 64 is sufficiently large in relation to the outer diameter of the sleeve 68 that an operator may engage his fingers under the plate 64 and, with the same hand, press his thumb against the plunger head 52 to operate the syringe device in a customary manner.

FIG. 7 illustrates a conventional needle attachment to the syringe barrel 24. The needle 70 is a conventional hollow needle or cannula. Affixed to and supporting the needle 70 is a conventional hub 72. The hub 72 has an outwardly projecting flange adapted to seal against the lower wall of the flange 28 as it appears in FIG. 1. The seal is accomplished in conventional fashion by spinning a retaining ring 74 over the upper surface of the flange 28 formed on the syringe barrel 24. The described manner of needle attachment is commonly employed in syringe manufacture and, while not requiring a full disclosure at this point in the specification, will be more fully described in a later part of this specification.

PREFERRED MODE OF ASSEMBLY AND USE — ONE COMPARTMENT SYRINGE

In the preceding paragraphs of this description, the basic structural elements which can be assembled to produce the preferred embodiment have been described. In the following paragraphs the preferred methods of assembly and use of the preferred embodiment will be described.

FIG. 1 illustrates an empty one piece syringe barrel. In the preparation of the preferred embodiment this syringe barrel and all other syringe parts are clean and sterile. In a first step of syringe assembly the valve 34, which has been coated at its periphery with the aforementioned medically approved silicone oil, is chased through the opening 32 to firm contact with the constrictive neck portion of the syringe, care having been taken that the end of the valve 34 which contacts the constriction to the neck 26 is the pliant plate 36. The approximate condition of the syringe after this step is illustrated in FIG. 2, in which it will be noted that the actuator rod 46 has not been engaged to the valve 34. As earlier noted, the size of the undercut 40 has been exaggerated in the drawings and, while it appears that the plate 36 can disengage the interior wall of the syringe barrel by pivoting into the undercut 40, the plate 36 and undercut 40 are sized to assure a positive seal to the syringe barrel even when the plate 36 touches and is thus braced by the plate 38.

FIG. 3 illustrates the next step of syringe assembly in which a prepared and measured dosage of medicine is placed in the syringe barrel and in contact with the upper surface of the brace plate 38, as it appears in FIG. 3. Minor amounts of air may remain entrapped in the slots 42 and in the undercut 40 but, as will be explained, such minor air entrapment will be unimportant. Also, while a preference has been indicated for introduction to the syringe barrel of an already prepared medicine, separate ingredients for the medicine may be added to and mixed within the syringe barrel. The medicine will not leak from the syringe barrel because the plate 36 seals against the interior wall of the syringe barrel.

FIG. 4 reveals the next step of the assembly wherein the seal 54 has been pressed into the opening 32 to the interior of the syringe barrel. As previously indicated, the annular walls 56 and 58 are sized to seal against the interior wall of the syringe barrel. To make allowance for irregularities in the syringe barrel, which is generally not a perfect cylinder, a good seal between the annular walls 56 and 58 and the interior of the syringe barrel requires a very slight oversize in the diameter of the walls 56 and 58 and therefore the seal 54 must be literally pressed into the opening 32. For reasons to more fully appear, the seal is not pushed inwardly beyond a position flush with the opening 32.

FIG. 5 reveals the next step of assembly wherein the retaining flange 62 has been heat shrunk around the opening 32 to the syringe barrel 24.

In the next step of the syringe assembly the end of the actuator rod 46 which carries the bayonet extension 48 is pushed through the center of the seal 54 and the bayonet extension forced into its cavity or socket 50. The bayonet extension preferably is not larger in diameter than the balance of the actuator rod 46. To assure a fluid tight seal between the inner peripheries of the an-

nular walls 56 and 58 of the seal 54 and the rod 46, these inner peripheries will be somewhat undersized and the exertion of some force will be required to press the bayonet extension as well as the rod 46 through the center of the seal 54. In actual practice this force may be sufficient to move the seal 54 slightly inwardly of the syringe barrel, but this tendency of the seal to move inwardly will be quickly offset by the interior syringe pressure necessarily resulting from an inward movement of the seal. As the rod 46 moves downwardly to engage in the cavity 50, the continued entry of the rod 46 will reduce the space available for the air trapped between the seal 54 and the liquid medicine above the valve 34 with the result that the entrapped air will experience a rise in pressure above that of the ambient atmosphere. This rise in pressure will cause the seal 54 to back into firm engagement with the plate 64 of the flange member 62. This rising pressure will also assure a firm seal between the pliant plate 36 and the constricted end of the syringe barrel 24. The result is that the movement of the actuator rod 46 into the interior of the syringe barrel will have generated a positive pressure within the syringe barrel which tends to hold the seal 54 and the valve 34 firmly against their respective ends of the syringe barrel. This positive pressure results from the fact that no air was permitted to escape the syringe barrel as the rod 46 reduced the interior volume of the syringe barrel. When the bayonet extension to the actuator rod 46 has been firmly seated in its socket 50, the bead 51 firmly grips the bayonet extension to assure that the actuator rod 46 will not be inadvertently retracted so as to release the positive pressure which has been deliberately built into the syringe assembly.

The syringe assembly is now in the condition illustrated in FIG. 6 and is in a stable and sterile condition suitable for prolonged storage and/or shipment of the syringe and its contents.

The needle assembly described with reference to FIG. 7 may be applied before storage and shipment or, alternatively, a temporary cap, not shown, may be applied for storage and/or shipment and the needle assembly later applied at any appropriate time for final use of the syringe in the manners to be described.

In the preferred mode of use, which takes place after the needle assembly shown in FIG. 7 has been applied, the syringe is held with the needle pointed upwardly and the actuator rod 46 drawn downwardly. Since the needle is pointed upwardly, the liquid medicine contained within the syringe barrel will be resting on the annular wall 58 of the seal 54 and will be surrounding the actuator rod 46. The air which is also confined within the syringe barrel except any trapped in the valve 34 will therefore be disposed above the liquid medicine and below the valve 34. As the valve 34 is drawn downwardly toward the seal 54, the pressure of the confined air will momentarily increase as the valve 34 is drawn away from the constricted end of the syringe barrel. However, the pliant plate 36 is exposed to ambient atmosphere by virtue of the hollow center in the needle cannula. After only a short downward movement of the valve 34, a sufficient clearance will exist between the constricted end of the syringe barrel and the plate 36 that the pressure underlying the plate 36 will lift the outer periphery of the plate 36 to the

general position illustrated in FIG. 8, thus allowing the air entrapped within the syringe barrel to commence an escape to the ambient atmosphere. The escape passage proceeds through the slots 42 in the brace plate 38, through the undercut 40 between the outer periphery of the plate 36 and the interior wall of the syringe barrel and upwardly through the needle 70.

As the actuator rod 46 is continuously drawn downwardly, all of the air which had been entrapped under the valve 34 will escape to a position above the valve 34. With continued downward movement the valve 34 will be drawn downwardly through the liquid medicine present in the syringe barrel to ultimate abutment with the annular wall 58 of the seal 54. The flow of liquid through the slots 42 and the undercut 40 will purge all air from the valve 34 with the result that all air that had been present in the syringe barrel after the preparation illustrated in FIG. 6 will have been released to a position above the liquid as it appears in FIG. 7.

It may be noted that not all of the liquid medicine introduced into the syringe barrel has been placed to the top surface of the pliant plate 36, as it appears in FIG. 7. Thus, a fraction of the liquid medicine will remain in the slots 42 and in the undercut 40 and this fraction will not be available for ejection from the syringe barrel.

The next step in the use of the syringe is the conventional step of moving the actuator rod 46 upwardly to displace all air remaining in the syringe barrel. As this upward displacement proceeds, the seal 54 will rise with the valve 34 as if firmly attached thereto. The reason for this phenomenon is that the pliant plate 36 will be sealing against the interior wall of the syringe barrel and the liquid medicine entrapped between the pliant plate 36 and the annular wall 58 of the seal 54 will behave as an inexpandible mass. As those skilled in the art will understand, the seal 54 and the valve 34 will cling together as if a vacuum had been drawn between them and a substantial force will be required to separate these two elements.

After all air has been displaced from the syringe barrel by an upward movement of the actuator rod 46 (this being revealed by a movement of liquid through the upwardly pointing needle 70), the syringe is prepared for a hypodermic injection in the usual fashion. A common practice to assure that the injection is reaching a desired portion of the body is to briefly draw back on the actuator rod 46 so as to produce a pressure reduction in the needle. This pressure reduction will very quickly draw available blood into the syringe barrel, thus revealing whether or not the needle cannula has been placed in communication with a blood vessel. The presently described syringe assembly is admirably suited to this purpose since the seal 54 and the valve 34 lock together for the reasons described and aspiration will immediately and directly follow any retracting movement of the actuator rod 46.

PREFERRED MODE OF ASSEMBLY AND USE — TWO COMPARTMENT SYRINGE

The method of syringe assembly and use described with reference to FIGS. 1-8 related to a syringe which would contain a prepared liquid medicine. Some medicinal preparations are known to have a short shelf life when in the liquid form and would have an unreliable medicinal value if stored or shipped in the liquid

form. Frequently, however, such medicines will have a much greater and sometimes indefinite shelf life if an active portion can be stored in a dry powder form and mixed with a liquid ingredient or solvent just prior to the time the medicine is to be injected into a patient's tissue. Alternatively, it is sometimes possible to store the medicine as two separated liquid components each having a good shelf life.

For the convenient handling of medicines of these types, two compartment syringes have been developed. The preferred embodiment of the present invention is particularly well suited for two compartment storage of a medicinal preparation. The manner in which the preferred embodiment can be assembled for two compartment storage and convenient mixing of the medicinal ingredients in both compartments immediately prior to hypodermic injection is illustrated in FIGS. 10-17 of the drawings.

The initial step in the assembly of a two compartment syringe is illustrated in FIG. 10 which illustrates the valve 34 positioned at an intermediate position along the length of the syringe barrel. The pliant plate 36 of the valve 34 confronts the constrictive neck of the syringe barrel while the brace plate 38 confronts the opposite opening 32 of the syringe barrel. It will be noted that the seal 54 has already been placed on the actuator rod 46 and located near the plunger head 52. It will also be noted that the rod 46 has already been attached to the valve 34 by means of the previously described bayonet extension 48.

Since the valve 34 is parked only about halfway along the length of the syringe barrel and the seal 54 is positioned near the plunger head 52, there will be a sufficient clearance between the seal 54 and the inlet opening 32 to allow a liquid component of the medicine to be poured into the inlet opening 32 so that it can rest above the valve 34, as appears in FIG. 11.

The objective of the next step in the assembly is to advance the seal 54 into the inlet opening 32 so that the inlet opening 32 can be positively closed with aid of the flange member 62. A practical problem, however, is that of moving the seal 54 into the inlet opening 32 without compressing the gas in the upper part of the syringe barrel. The most obvious reason for wanting to avoid a positive pressure above the fluid to be stored in the syringe is that the positive pressure will operate against the pliant wall 36 so as to tend to break the seal between the pliant wall and the interior wall of the syringe barrel. This would permit a fluid leak and defeat the purpose of obtaining separate storage compartments in the syringe barrel. Of course at this point in the assembly, the valve 34 is free to move in any direction to compensate for a positive pressure above the liquid component and a leakage of liquid through the valve is not likely to occur. Nevertheless, it is desirable to take precautions that will assure an absence of a positive pressure in the storage compartment that is being created between the seal 54 and the valve 34.

Theoretically a positive pressure above the liquid that has been placed as in FIG. 11 can be avoided by training the employee who would assemble the syringe to move the rod 46 in unison with the seal 54 as the seal is advanced into the inlet opening 32. This will allow the seal 54, rod 46 and the valve 34 to move inwardly

of the syringe barrel as a unit and thereby prevent the development of a positive pressure above the liquid component. To eliminate the possibility of error, however, the preferred mode of assembly is illustrated in FIGS. 11 and 12.

FIG. 11 illustrates a tool 76 which is an elongated cylinder restricted or closed at one end and of internal diameter sufficient that it will pass freely over the plunger head 52. By deliberate design the plunger head 52 has been made small enough to allow the use of the tool 76.

The plunger head 52 is small enough in diameter in relation to the seal 54 that the tool 76 can be moved telescopically over the plunger head 52 to engage the annular wall 56 of the seal.

For the proper use of this tool, it is only important that the valve 34 be initially parked at a position within the syringe barrel which places the plunger head 52 a distance above the syringe barrel which exceeds the interior length of the tool 76 augmented by the axial length of the seal 54. Assuming this condition exists, the tool 76 is first passed telescopically around the plunger head 52 to engage the seal 54. The tool is then advanced downwardly as appears in FIG. 12 to slide the seal 54 downwardly on the rod 46. This motion assumes that the seal 54 will more readily slide on the rod 46 than will the valve 34 slide in the syringe barrel 24. This is a condition readily achieved by designing the snugness of fit of the valve 34 against the interior wall of the syringe barrel.

By reason of the recited condition relating to the projective length of the rod 46 above the syringe barrel, the closed or constricted end of the tool 76 will engage the plunger head 52 at some point in its downward travel before the seal 54 engages the inlet opening 32. As soon as the tool 76 contacts the plunger head 52, unison movement of the rod 46, the seal 54 and the valve 34 will commence. This unison movement will continue until the seal has been projected fully into the inlet opening 32. Preferably, as shown in FIG. 12, the tool 76 has a radially outwardly extending flange 77 of diameter larger than the syringe barrel so that the downward movement of the tool will stop by reason of contact with the syringe barrel at the same time the seal 54 has fully entered the inlet opening 32.

By use of the tool 76 as described, positioning of the seal 54 within the inlet opening without a development of positive pressure between the seal 54 and the valve 34 is readily accomplished. The tool operates with equal effectiveness whether operated manually or by machine.

After the seal 54 has been positioned as described, the tool 76 is removed and a flange member 62a shrink fitted into encircling relation to the inlet opening 32 of the syringe barrel. It will be noted that the flange member 62a has a central aperture in its plate 64 which is sufficiently large in diameter to pass the plunger head 52, but also sufficiently small in diameter to trap the seal 54 so that the seal cannot be withdrawn from the interior of the syringe barrel 24.

Having positioned the flange member 62a as shown in FIG. 13, the syringe assembly is inverted as shown in FIG. 15 and a second component of a two component medicine added through the bore 30 above the valve 34. The second component may be a dry powder as shown at 86.

A needle assembly illustrated in FIG. 14 is next engaged to the flange 28 of the syringe barrel. The needle assembly illustrated in FIG. 14 is different than that described with reference to FIG. 7 in only one important respect. Interposed between the flange 82 on the needle hub and the flange 28 of the syringe barrel is a circular elastomeric diaphragm 78 having a centrally located slit 80. The slit 80 is deep enough that the diaphragm is cut through its entire thickness. It will be noted however that the slit 80 is confined to the center of the diaphragm 78 and therefore the periphery of the diaphragm remains intact.

The diaphragm 78 is sized diametrically to snugly seat within a needle retaining member 84. It will be noted that the retaining member as shown in FIG. 14 is a cylindrical ring with an inwardly directed annular flange 75. The internal diameter of the member 84 is large enough to telescopically receive the flange 28 on the syringe barrel 24.

The assembly proceeds by first passing the needle 70 through member 84 so that its flange 82 contacts the flange 75. The diaphragm 78 is then seated within the member 84 in overlying relation to the needle flange 82. The syringe flange 28 on the syringe barrel is then placed in member 84 to contact the diaphragm 78. With conventional spinning equipment commonly used to attach needles of the general type disclosed to syringe barrels, the upper portion of the member 84 is spun inwardly so as to grip or entrap the flange 28 on the syringe barrel.

The member 84, after completion of this spinning operation, is the retaining ring previously identified by the number 74. As well understood in the art, this spinning operation has the effect of drawing the needle flange 82 toward the syringe flange 28 with the result that the diaphragm 78 is compressed at its outer periphery. Since the diaphragm is elastomeric, it will behave as a hydraulic medium as its periphery is compressed and the peripheral pressure on the diaphragm will cause the elastomeric material to displace inwardly toward the center of the diaphragm.

There are two desirable results that follow. The first result is that the slit 80 is pinched to a firmly closed position. The second desirable result is caused by designing the needle hub 72 to a larger diameter at its mouth than the bore 30 which passes through the barrel flange 28. Since the needle hub is larger in diameter where it contacts the diaphragm 78, the elastomeric material displaced to the center of the diaphragm for the reasons discussed will seek relief from its confinement by moving toward the needle hub. This causes the central part of the diaphragm to move upwardly, as viewed in FIG. 16, and this gives the slit 80 a predisposition to its being opened by a pressure from within the syringe barrel and a resistance to its being opened by a pressure from outside the syringe barrel.

While this predisposition of the diaphragm is preferred for the purposes of the present invention, it is to be understood that such predisposition can be eliminated by making the mouth of the needle hub equal to the diameter of the bore 30 and can be reversed by making the mouth of the needle hub smaller than that of the bore 30.

With the needle assembled as shown in FIG. 16, the preferred embodiment has been assembled to the point where it is in condition for storage, shipment and use as

desired. During storage and shipment, the diaphragm 78 protects the cannula from clogging by any medicine being stored in the second compartment between the valve 34 and the diaphragm 78. Not shown, but conventional in the syringe art, is a needle sheath which may be seated on the needle hub 72 to prevent dirt from contacting and perhaps entering the needle 70. Since this sheath is common in the trade, a specific illustration of the sheath is unnecessary.

At such time as it is desired to activate the two compartment syringe for an injection, the syringe is held in the position illustrated in FIG. 16, i.e., with the needle pointed upwardly, and the fluid component first introduced into the syringe resting on the seal 54. The actuator rod 46 is then drawn downwardly to pull the valve 34 downwardly against the seal 54. This will cause the liquid component resting on the seal 54 to pass to the top side of the valve 34 and, as previously explained, establish a good vacuum seal between the valve 34 and the seal 54. At the same time the fluid component that passes to the top side of the valve 34 will mix with whatever liquid or powder component was initially positioned between the valve 34 and the diaphragm 78. Shaking may be employed at this time to assure a thorough mix between the two components.

It will be noted that the described operation by which the valve 34 was pulled downwardly to the seal 54 is accomplished without generating any significant pressure against the diaphragm 78 and therefore under circumstances where the slit 80 will remain closed.

Having completed the mixture of the two components in the described two compartment syringe, the syringe is prepared for an injection of the medicine in the conventional fashion. The first step of course is to continue holding the syringe so that the needle points upwardly and to raise the plunger head 52 so as to displace all air from the syringe. As previously explained, the vacuum seal developed between the valve 34 and the seal 54 will cause the seal 54 to move with the valve 34. This phenomenon will occur notwithstanding the fact the valve 34 must exert some pressure against the diaphragm 78 so as to open the slit 80 and permit air to escape from within the syringe barrel through the needle 70.

After all air has been displaced from the syringe barrel, a hypodermic injection can be made and aspiration effected as desired. It will be noted of course that the previously explained predisposition of the diaphragm 78 will make aspiration more difficult since the predisposition of the diaphragm must be overcome to effect an aspiration. This is considered desirable since it requires that aspiration be the result of a deliberate act on the part of an operator. Nevertheless, as previously explained, the degree and nature of the diaphragm predisposition can be adjusted and the resistance to aspiration as a part of the process of injecting the medicine can be adjusted accordingly.

MODIFICATION

In the preceding remarks a preferred embodiment of the syringe structure and preferred modes of assembly and operation of the syringe structure were described. In one of the described modes of assembly, the syringe was assembled as a one compartment syringe for a liquid medicine. In another mode of assembly, the syringe

was assembled as a two compartment syringe for a two component medicine which could be mixed immediately before injection.

FIGS. 18-23 disclose a modified valve which is functionally comparable and structurally interchangeable with the valve 34 of the preferred embodiment. These figures also illustrate a modified mode of syringe assembly. It will be recalled that the one compartment mode of assembly described with reference to FIGS. 1-8 resulted in storage of a liquid medicine under a positive pressure. In some cases, particularly where the medicine has a volatile ingredient and storage or shipment may occur under uncontrolled temperature conditions, the positive pressure assembly as previously described may be unacceptable. The following description of the syringe assembly depicted in FIGS. 18-23 will reveal that it is possible to assemble either the preferred embodiment or the modification illustrated in these figures under conditions where a positive pressure is not developed and the likelihood of an unacceptable pressure correspondingly reduced.

The modified valve is identified by the reference number 88 and is shown in detail in FIGS. 22 and 23. The valve comprises a brace member 90 and a compliant plate 96 integrally attached thereto. The valve is molded as a one piece resilient piston having three axially spaced peripheral beads. The first two beads are numbered 92 and 94, and an axially disposed peripheral slot 100 traverses both of the beads 92 and 94.

Separating the bead 94 and the compliant plate 96 throughout approximately one-half their area is a transverse undercut 98. The remaining area of the plate 96 which confronts the brace member 90 is integrally attached to the brace member 90. As appears in FIG. 22, the undercut 98 frees an approximate semicircular area of the plate 96 from the brace member 90 and the transverse slot 100 is aligned at approximately the peripheral center of the semicircular portion of the plate 96 that has been freed from the brace member 90. As will later appear more fully, the construction of the valve 88 is such that the compliant plate 96 can bend downwardly away from the brace member 90, as shown in FIG. 23, to permit fluid to pass entirely through the valve.

The drawings illustrate the undercut 98 as a thin slit of the type that could be made with a sharp knife. However, those skilled in the art will recognize that the undercut can be molded into the piston and may have a thickness somewhat larger than would result from a knife cut. The axial thickness of the undercut is desirably as small as possible, however, so that an upward flexure of the plate 96, as it appears in FIG. 23, cannot also produce an axial fluid passage extending entirely through the length of the valve 88. Thus, it is desirable that the undercut 98 be thin so that the brace member 90 can perform its function of bracing the compliant plate 96 against a pressure which is directed upwardly, as the valve appears in FIG. 23.

It is apparent from an inspection of FIGS. 22 and 23 that the modified valve 88 will function in the same fashion as the valve 34 in all material respects and is fully interchangeable with the valve 34. It will be noted of course that the valve 34 has been disclosed as possessing two diametrically disposed axial slots, whereas

the valve 88 has only a single axial slot. As the valve 34 is pulled through a liquid medicine, the two axial slots in the valve 34 permit a liquid to act equally at diametrically opposite portions of the pliant plate 36 and thus the valve 34 will not tend to twist or cock in the syringe barrel as the valve is pulled through a liquid. However, since the valve 88 has only a single slot 100, this valve will have a tendency to twist or cock in the syringe barrel as it is pulled through a liquid. It is therefore desirable that the valve 88 have the two annular beads 92 and 94 sized to snugly fit the interior wall of the syringe barrel so that these beads can cooperate to resist the tendency of the valve 88 to become cocked within the syringe barrel.

The valve 88 is equipped with a bayonet socket 102 to receive the bayonet extension of an actuator rod such as the previously discussed rod 46.

As above indicated, the valve 88 is interchangeable with the valve 34 and thus is amenable to use in a one compartment positive pressure syringe assembly as described with reference to FIGS. 1-7. It is also amenable to use in a two compartment syringe assembly as described with reference to FIGS. 10-17. FIGS. 18-21 illustrate the assembly of a one compartment atmospheric pressure syringe. For convenience these figures depict the modified valve 88, but it is to be understood that the method depicted in FIGS. 18-21 will be equally applicable to a syringe assembly which includes the valve 34 of the preferred embodiment.

The initial steps of an atmospheric pressure single compartment syringe assembly are revealed in FIG. 18. The first step is to place the seal 54 adjacent the plunger head 52 of the actuator rod 46. The bayonet extension of the actuator rod is then engaged into the bayonet socket 102 of the valve 88. The valve 88 is then chased a substantial distance into an empty syringe barrel 24.

As appears in FIG. 19, a liquid medicine is then charged into the syringe barrel above the valve 88 so that it rests upon the brace member 90. The tool 76 is then used as before to press the seal 54 into the syringe barrel and assure that unison movement takes place between the seal 54 and the actuator rod 46 before the seal 54 has commenced its advance into the syringe barrel inlet opening 32.

After the assembly has thus reached the position illustrated in FIG. 20, a flange member 62a is shrunk fit to lock the seal 54 within the syringe barrel and the needle 70 applied in either of the manners previously described. Since the assembly of FIGS. 18-21 is not being described as a two compartment assembly, there is no reason for the assembly securing the needle 70 to include the diaphragm 78.

The syringe assembly is now in condition for storage and/or shipment of the liquid medicine confined between the seal 54 and the valve 88.

The preferred position for activating the syringe preparatory to an injection is illustrated in FIG. 21. The syringe barrel is gripped with the needle pointing up and the plunger head 52 drawn downwardly. The fluid pressure thereby developed between the seal 54 and the valve 88 forces first air, then the liquid medicine, through the slot 100 and against the pliant plate 96. This causes the pliant plate to bend away from the brace member 90 to the approximate position illus-

trated in FIG. 23, allowing the valve 88 to move downwardly through the air and then through the liquid medicine which had been under storage in the syringe barrel. As previously described in reference to the preferred embodiment, the movement of the valve through the liquid medicine will purge the valve of any entrapped air and thus provide a strong vacuum seal between the valve 88 and the seal 54.

Once the plunger head 52 has been drawn to firmly position the valve 88 against the seal 54, the plate 96 springs back to seal against the interior wall of the syringe barrel and the syringe assembly can be prepared for an injection in the usual fashion. First, the plunger head 52 is raised with respect to the syringe barrel to displace all air in the syringe barrel. For the reasons previously described, the seal 54 will cling to the valve 88 and thus at the time an injection commences the syringe assembly is prepared to respond quickly to any aspirating effort.

It will be noted that the syringe assembly described with reference to FIGS. 18-21 created a condition in which a liquid medicine could be stored and shipped while in contact with air introduced into the syringe at ambient atmospheric pressure, thus removing the objection that might sometimes exist to storage of a liquid medicine under an initially positive pressure.

In previous paragraphs, a preference for activating the syringe assembly by drawing its valve downwardly through a fluid component while the syringe needle points upwardly has been stressed. As explained, the reason for activating the syringe in this manner is to assure production of a strong vacuum condition between the valve and the seal 54. Those skilled in the art will realize however that activation of the syringe in this manner is not an absolute prerequisite to successful use of the syringe. Thus, the syringe can be activated in any gravitational position, but when activated in positions other than the preferred position, as described, the presence of air between the seal 54 and the valve 34 or the valve 88, as the case may be, reduces the efficiency with which the seal 54 will cling to the valve and increases the possibility that the seal 54 will fail to closely follow the valve on injection. Should a substantial gap exist between the seal 54 and the valve 34 or 88 at the time aspiration is desired, the process of aspiration will be delayed because a longer reverse pull of the plunger head 52 will be required to initiate aspiration. Ordinarily, aspiration can nevertheless be initiated, but the purpose for the aspiration tends to have been defeated. Thus, the operator aspirates to learn whether or not blood can be drawn into the syringe. If he attempts aspiration and does not quickly see blood (assuming the needle was to enter a vein or artery), he may be misled as to the nature of the tissue the needle has actually entered.

Directing attention to the two valve embodiments disclosed in the present application, it will be noted that both have a number of desirable features. As one example, both valves when used in the above described two compartment assembly present a smooth face on the plate 36 to a powder component that may be stored in the compartment which resides between the plate 36 and the needle 70. This smooth face on the plate 36 allows an assembled two compartment syringe to be jostled or vibrated during shipment without powder enter-

ing the valve mechanism so as to interfere with the intended operation of the valve.

Another advantage is that the valve is conveniently molded as a one piece resilient body. In the preceding specification both embodiments of the valve have been described as comprising a compliant plate and a brace plate. It is not to be inferred from this language that the brace plate is a rigid body. Rather, in both embodiments of the valve herein disclosed the brace plate is merely rendered less compliant by having a thickness greater than the compliant plate.

A further desirable feature of the valve embodiments of the present invention is that in each case the axially disposed slot or passage which permits fluid flow through the brace portion of the valve confronts an unattached area of the plate portion which is larger than the cross sectional area of the slot or passage and which is contiguous with a part of the periphery of the plate portion. This construction enables fluid under pressure in one direction to act against a relatively large area of the plate portion which is not attached to the brace portion so as to bend the unattached area away from sealing engagement with the syringe barrel. At the same time this construction allows the brace portion sufficient support for the unattached area of the plate portion that the plate portion will not bend away from the interior wall of the syringe barrel in response to a fluid pressure in the opposite direction.

Another desirable feature of the valve embodiments of the present application is that they are designed to make intimate engagement with the seal 54 over a substantial portion of the cross sectional area of the seal, thus affording the seal 54 a maximum opportunity to cling to the valve at the time of hypodermic injection.

Although a preferred embodiment of this invention has been described, it will be understood that various changes may be made within the scope of the appended claims.

Having thus described my invention, I claim:

1. In a syringe device, the combination comprising a tubular syringe barrel, a unitary valve transversely partitioning said syringe barrel, and an actuator rod projecting from said valve through one end of said barrel, there being an annular space between said actuator rod and the interior wall of said barrel, seal means slidably engaging the interior wall of said syringe barrel and slidably receiving said actuator rod to close said annular space adjacent said one end of said syringe barrel, said valve comprising an imperforate pliant plate portion having an outer periphery sized to slidably seal against the interior wall of said barrel, said valve including a brace portion integrally attached to one side of said plate portion, said valve having a slit extending transversely between said plate portion and said brace portion, said slit communicating with said interior wall of said syringe barrel, said slit separating a first area of said plate portion from an approximately equal second area of said brace portion, said brace portion having means contacting said interior wall to prevent cocking of said brace portion within said syringe barrel, said brace portion having an end wall facing said one end of said syringe barrel, said actuator rod attached centrally to said end wall, said brace portion having one or more openings through said end wall disposed between said

actuator rod and said interior wall, said one or more openings passing through a portion of said second area of said brace portion which is less than the entirety of said second area.

2. The combination of claim 1 wherein said syringe barrel has a cylindrical interior wall and said plate portion has a circular outer periphery.

3. The combination of claim 2 wherein said brace portion is generally cylindrical, said one or more openings comprising one or more axially disposed slots in the cylindrical periphery of said brace portion, said means contacting said interior wall comprising a peripheral portion of said brace portion.

4. The combination of claim 3 wherein said slit is an annular undercut partially separating said plate portion and said brace portion.

5. A syringe device comprising: a tubular syringe barrel having an opening at each end thereof, a unitary valve disposed in said barrel and partitioning said barrel between said openings, said valve including an imperforate pliant plate portion slidably sealing to said syringe barrel and confronting one of said openings, said valve including a brace portion disposed between said plate portion and the other of said openings and integrally attached to said plate portion, said valve having a slit extending transversely between said plate portion and said brace portion, said slit communicating with the interior wall of said syringe barrel, said slit separating a first area of said plate portion from an approximately equal second area of said brace portion, said brace portion having an end wall facing said other of said openings, an actuator rod attached centrally to said end wall projecting outwardly of said syringe barrel through said other of said openings, an annular seal member having an outer periphery slidably sealing to the interior wall of said syringe barrel and an inner periphery slidably sealing to said rod, said seal member and said plate portion cooperating with the interior wall of said syringe barrel to provide a first compartment receiving said brace portion and encircling a portion of said actuator rod, said brace portion having one or more passages through said end wall, said one or more passages disposed between said actuator rod and said interior wall, said one or more passages passing through a portion of said second area of said brace portion which is less than the entirety of said second area.

6. The syringe device of claim 5 including cannula means affixed to said syringe barrel for communication with said one opening, and including a perforated diaphragm interposed between said cannula means and said one opening, said perforated diaphragm and said plate portion cooperating with said syringe barrel to define a second compartment of said syringe device.

7. In the method of pressurizing a syringe device having a valve member and a seal member spaced within a syringe barrel and means limiting the spacing between said valve and seal members, the step of advancing a rod adapted to engage said valve member and of length greater than said limited spacing through said seal member to engagement with said valve member whereby the advance of said rod towards said valve member diminishes the interior volume of said syringe barrel between said valve member and said seal member.

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