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Killinger

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[54] **VIAL AND SYRINGE ASSEMBLY**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. Nos. 212,592, Dec. 27, 1971, and Ser. No. 287,661, Sept. 11, 1972.

[52] **U.S. Cl.**..... **128/272,** 128/DIG. 26, 206/63.2 R

[51] **Int. Cl.** **A61j 1/06**

[58] **Field of Search**..... 128/218 R, 218 D, 218 NV, 128/218 M, 218 N, 218 C, 218 F, 220, DIG. 26, 215, 272, 216, 218 DA; 206/63.2 R, 43 R

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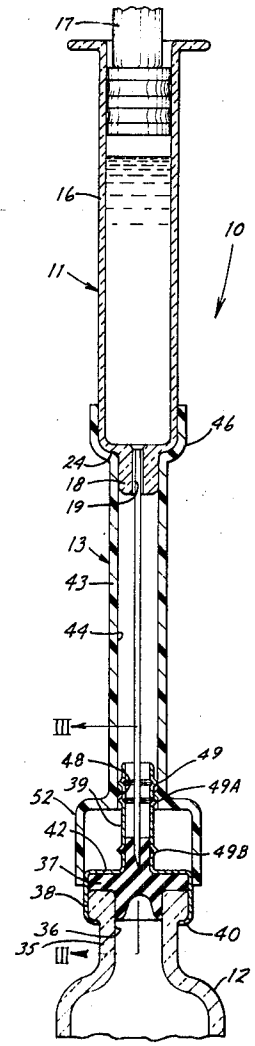
[57] **ABSTRACT**

A syringe having a needle connected to one end thereof and a hollow cylindrical chamber adapted for communication with said needle. A vial has a sealed opening and a hollow cylindrical portion of reduced diameter extending beyond the seal. The needle is slidably receivable into the reduced portion of the vial for perforating the seal to communicate with and between the interiors of the hollow chamber and the vial. An elongated tubular sheath extends between and is slidably supported upon the syringe and the vial.

5 Claims, 9 Drawing Figures



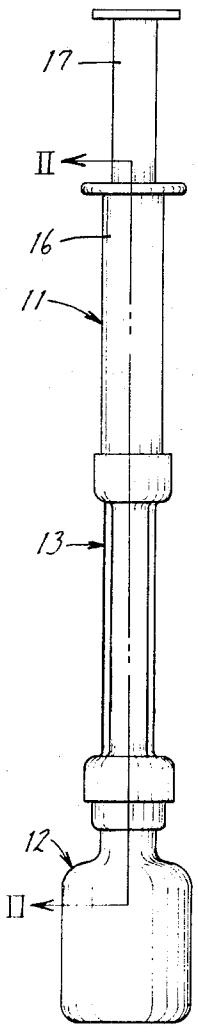


Fig. 1

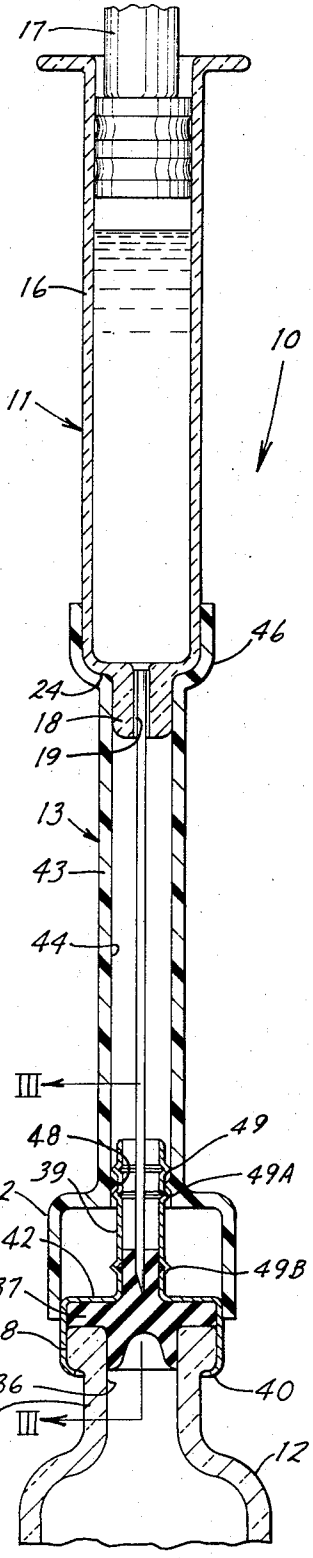


Fig. 2

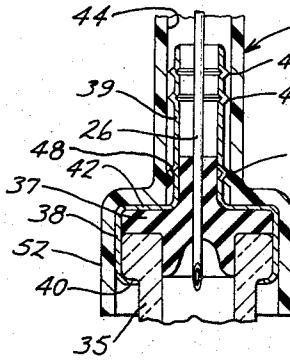


Fig. 3

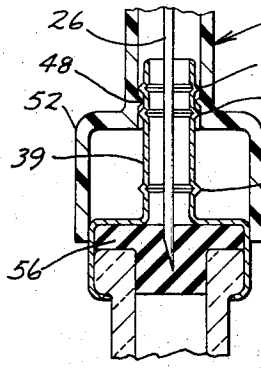


Fig. 4

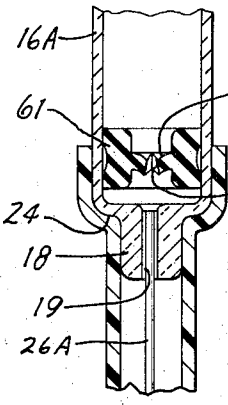


Fig. 7

Fig. 5

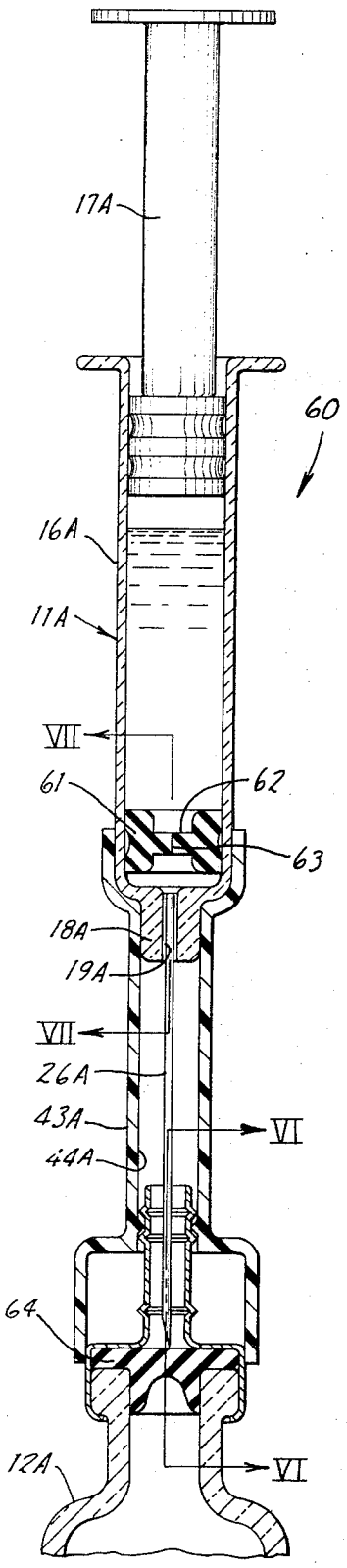


Fig. 6

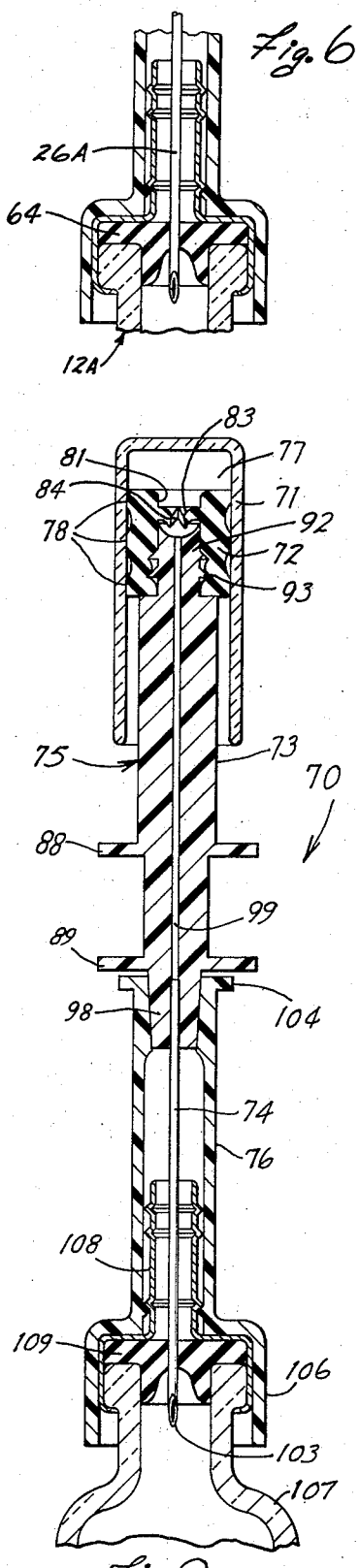


Fig. 9

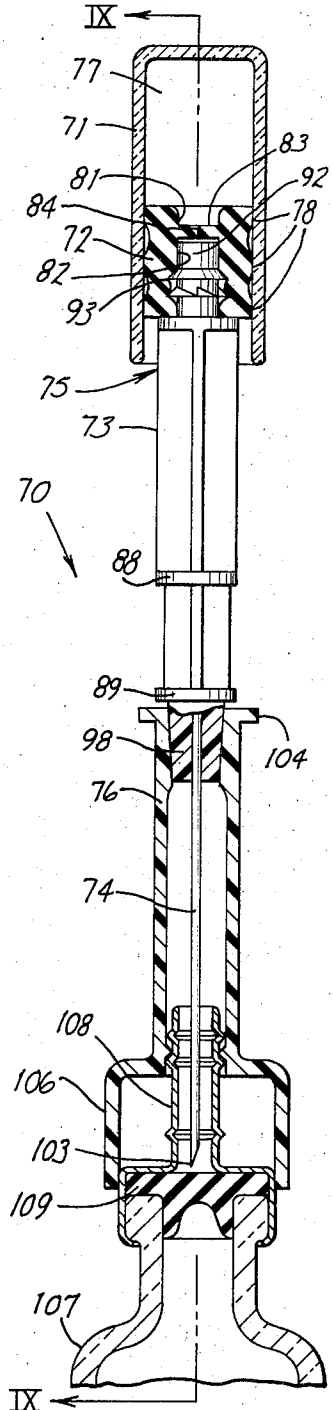


Fig. 8

VIAL AND SYRINGE ASSEMBLY

This application is a continuation-in-Part of Patent application, Ser. No. 212,592 filed Dec. 27, 1971, and entitled "Vial And Syringe Combination," and Ser. No. 287,661 filed Sept. 11, 1972, entitled "Compact Syringe."

BACKGROUND OF THE INVENTION

This invention relates in general to a device for storing and administering medicaments and, more particularly, to a type thereof including a sealed syringe holding a diluent, a sealed vial holding a medicament and interconnecting means for holding the syringe and vial together and for effecting selective communication between said syringe and said vial, whereby said diluent can be mixed with said medicament and thereafter administered to a patient by a needle which is attached to the syringe and is associated with the connecting means.

Persons familiar with the preparation and use of parenteral medicaments have long been aware of the fact that certain medicaments tend to lose their effectiveness rather soon after they are mixed with a diluent in preparation for administration. Thus, they must be stored in a dry or non-liquid condition and then mixed with a diluent, preferably just before the medicament is administered to a patient. Obviously, any other procedure would risk an incorrect dosage of the medicament.

In the past, it has been common practice to furnish separate vials of dry medicament and diluent and to use a conventional syringe for transferring the diluent from one vial to another for the purpose of mixing the two in order to administer the medicament. This arrangement involves the risk of contamination, the risk of an improper dose and even the risk of mixing the wrong ingredients, where the administration of the medicament must be or could be made by unskilled persons.

Numerous attempts have been made to solve the foregoing problems as by furnishing syringes and/or vials connected together so that the supply and the administration means are part of a package which is more readily useable. However, most existing combinations or packages involving a medicament and a diluent have not proven satisfactory, heretofore, for a variety of reasons. For example, they have not satisfactorily avoided contamination, they have been too delicate for conventional storing and handling procedures, they have been too susceptible to accidental actuation whereby the materials are prematurely mixed and, in general, they have been almost as complicated to operate as the previous devices upon which they were intended to improve.

Accordingly, a primary object of this invention is the provision of a syringe and vial assembly with a connecting structure therebetween whereby the sterility of the diluent in the syringe and the medicament in the vial are maintained during the mixing of the diluent and the medicament and, at the same time, the cannula for the syringe is shielded from contamination during the mixing and up to the very moment of administration of the diluted or dissolved medicament to a patient.

A further object of this invention is the provision of a syringe and vial assembly, as aforesaid, in which injectable medicaments can be safely stored for relatively

long periods of time, as in drug stores, clinics and doctors' offices, along with a suitable diluent in a single package capable of mixing the diluent and medicament without any likelihood of contaminating the injecting needle, the diluent or the medicament.

A further object of this invention is the provision of an assembly, as aforesaid, which is rugged so that it cannot be readily damaged during shipment or storage, which is constructed so that accidental mixing of the diluent and the medicaments is positively opposed and yet wherein intentional mixing of the medicament and the diluent can be effected safely, easily and quickly in preparation for injection with the syringe by any person qualified to perform such an injection.

Other objects and purposes of this invention will become apparent to persons familiar with apparatus of this type upon reading the following description and examining the accompanying drawings, in which:

FIG. **1** is a side elevational view of a syringe and vial assembly embodying the invention.

FIG. **2** is an enlarged sectional view taken along the line II—II in FIG. **1.**

FIG. **3** is a sectional view taken along the line III—III in FIG. **2.**

FIG. **4** is a sectional view similar to FIG. **2** and showing an alternate seal for the vial.

FIG. **5** is a sectional view similar to that in FIG. **2** and disclosing alternate structure in the syringe and vial.

FIG. **6** is a sectional view taken along the line VI—VI in FIG. **5** and showing parts thereof in different relative working positions.

FIG. **7** is a sectional view taken along the line VII—VII in FIG. **5** showing parts in different relative working positions.

FIG. **8** is a central sectional view similar to FIG. **2** and disclosing an alternate syringe construction.

FIG. **9** is a sectional view taken along the line IX—IX in FIG. **8** showing the parts in different operating positions.

For convenience in description, the terms "upper," "lower" and words of similar import will have reference to the syringe and vial assembly or parts thereof as appearing in FIGS. **1, 5** and **8.** The terms "inner," "outer" and derivatives thereof will have reference to the geometric center of the assembly and major components thereof.

SUMMARY OF THE INVENTION

The objects and purposes of the invention, including those set forth above, have been met by providing a syringe and vial assembly including a syringe containing a diluent, a sealed vial containing a medicament, which may be liquid or dry, and a connection structure which includes a needle connected to the syringe and extending toward the vial. The connection structure is arranged so that the sharpened end of the needle can be held spaced from the chamber within the vial. However, by effecting relative movement of the vial and syringe toward each other, the needle pierces the seal or stopper, thereby communicating with and between the interiors of the syringe and the vial. Accordingly, the diluent can be moved through the needle from the syringe into the vial after which the medicament is dissolved in the diluent and thereafter returned to the syringe by actuating the plunger thereof in the reverse direction. The syringe and needle are now removed from the outer sheath of the connecting structure so that the

needle is exposed and can be injected into the patient for administering the dissolved or diluted medicament.

DETAILED DESCRIPTION

The syringe and vial assembly **10** (FIGS. **1** and **2**) is comprised of a syringe **11** connected to a vial **12** by an intermediate structure **13.** The syringe **11** has a barrel **16** and plunger **17** which may be of conventional structure. The lower open end portion **18** of the barrel **16** is of reduced diameter and has an opening **19** into which the upper end of the needle or cannula **26** is snugly received and firmly held. The reduced portion **18** forms a shoulder **24** at the lower end of the main body of the barrel **16.** The cannula **26** is sharpened at its lower end.

The vial **12** has a neck **35** with an opening **36** which is closed by a seal, such as the flanged stopper **37,** which is in turn held in place by the enlarged, integral collar **38** at the lower end of the sleeve **39.** That is, the sleeve **39** has an integral shoulder **42,** which bears downwardly against the flange of the stopper **37,** and the collar **38** has a rolled edge **40** which holds it tightly upon the neck **35** of the vial **12.**

A substantially cylindrical sheath **43** (FIG. **2**) is capable of extending from surrounding engagement with the lower end of the barrel **16** to surrounding engagement with the enlarged collar **38** of sleeve **39.** Said sheath **43** has a central cylindrical opening **44** the upper portion of which is sleeved snugly but slidably upon the lower end **18** of barrel **16.** Said sheath **43** has an upper enlarged portion **46** with an inside diameter approximately equal to the outside diameter of the main body of the barrel **16** adjacent the reduced portion **18.**

The lower end of the wall defining the central opening **44** (FIG. **3**) has an annular, inwardly projecting ridge **48** which coacts with outwardly projecting, annular ridges on the sleeve **39.** In this case, there are two ridges **49** and **49A** near the upper end of the sleeve and one ridge **49B** near the lower end. The ridge **48** is located between the upper two ridges **49** and **49A** when the lower end of the cannula **26** is spaced from, or at least is not penetrating through, the stopper **37.** The sheath **43** can be moved downwardly relative to the sleeve **39** into a position where the ridge **48** is below the lowermost ridge **49B,** at which time the needle **26** penetrates completely through the stopper **37.** Also, during this movement, the enlarged collar **38** on the sleeve **39** is slidably but snugly moved further into the opening defined by the enlarged portion **52** at the lower end of the sheath **43** and coaxial with the central opening **44.**

OPERATION

The organization and operation of the syringe and vial assembly (FIG. **1**), to which this application applies, will be apparent to skilled persons upon reading the foregoing description. However, for convenience, such assembly and operation will now be summarized briefly.

In preparation, the vial **12** (FIG. **2**) may be filled with a medicament, which may be a liquid or a dry powdery material produced by evaporative procedures. The stopper **37,** which is held in place by the collar **38** on the sleeve **39,** will be unperforated.

The syringe **11** may contain a liquid and have a plunger **17** within the upper end of the barrel **16.**

The sheath **43** is sleeved upwardly over the cannula **26** until the upper end **46** of the sheath **43** slightly overlaps the lower end of the barrel **16,** and the lower end **18** of the barrel **16** is snugly disposed within the upper end of the opening **43.** The assembled sheath **43** and syringe barrel **16** can now be simultaneously held in one hand while the vial **12** is engaged in the other hand, and the sleeve **39** on the vial **12** is first inserted into the opening in the enlarged lower end **52** of the sheath and then slid into the lower end of the central opening **44.** This sliding connection will be terminated when the ridge **48** on the wall defining the central opening **44** is located between the ridges **49** and **49A** on the sleeve **39.** At this time, the lower end **52** of the sheath **43** will be telescoped slightly over the enlarged collar **38** of the sleeve **39,** and the lower sharpened end of the needle **26** will be embedded in, but will not penetrate through, stopper **37.**

The assembly **10** (FIG. **2**) is now in condition for shipment and/or storage as long as desired. While the diluent has been disclosed in the syringe and the medicament in the vial, this situation can be reversed. In such case, the plunger will be near the lower end of the barrel **16** because its first function will be to withdraw fluid from the vial.

When it becomes desirable to administer the medicament, the vial and syringe are simultaneously urged toward each other so that the cannula perforates and extends completely through the stopper **37** (FIG. **3**), thereby communicating with and between the chambers within the barrel **16** and the vial **12** (FIG. **2**). The plunger **17** is now moved downwardly within the barrel **16** whereby the liquid within the barrel is transferred through the cannula into the vial.

By a gentle shaking action, the powdered or liquid material within the vial is mixed with the diluent from the syringe. The assembly **10** is now inverted from its FIG. **1** position and the plunger **17** is pulled away (downwardly) from the barrel **16** whereby the mixture of diluent and medicine is transferred into the syringe.

The sheath **43** and vial **12** are now moved downwardly away from the syringe so that the lower end of the cannula **26** is exposed. The liquid medicine can now be administered to the patient in a perfectly normal and conventional manner.

The stopper **37** of FIG. **3** may be replaced by the stopper **56** (FIG. **4**) in which the lower end of cannula **26** is also embedded to seal the end thereof. In both of these embodiments, the embedding of the pointed tip of the needle into the stopper (**37** or **56**) prevents accidental, premature discharge or leaking of the diluent from the barrel **16** through the needle **26.**

However, in the modified syringe and vial assembly **60** of FIG. **5,** a cylindrical seal or valve **61,** preferably fabricated from a resiliently flexible material such as synthetic rubber, is disposed within the lower end of the barrel **16A.** The seal **61** has a centrally disposed, transverse membrane **62** with a slit **63** therein which normally remains closed and, accordingly, prevents seepage or leakage of the diluent from within the barrel **16A** until the plunger **17A** is positively urged downwardly toward said seal. Under such urging, the membrane **62** opens along the slit **63,** as shown in FIG. **7,** so that the diluent can move through the seal and thence into and through the needle **26A.**

Because of the seal **61** in the assembly **60**, the lower tip of the needle **26A** can be spaced from the stopper **64** during storage of the assembled and filled syringe assembly **60**. However, when the syringe **11A** is moved toward the vial **12A**, the needle **26A** (FIG. **6**) pentrates completely through the stopper **64**. The syringe of FIG. **5** is then gently shaken to mix the diluent with the medicament after which said syringe assembly is inverted. The plunger **17A** is moved away from the barrel **16A** whereby the mixture of diluent and medicament in the diluted or dissolved form is drawn from the vial, back through the seal **61** and into the barrel. If the seal **61** moves with the plunger **17A** as it is retracted, there is no problem because the plunger will move the seal **61** along with it during the subsequent injection of the medicine into the patient.

The modified syringe and vial assembly **70** (FIG. **8** and **9**) is comprised of a barrel **71**, a piston **72** disposed within said barrel **71**, a rod **73** connected at one end to said piston, and a cannula **74** connected to the other end of the rod **73**. The piston **72** and rod **73** may be referred to in combination as a plunger **75**. A sheath **76** is provided to cover the cannula prior to use thereof.

The barrel **71** is cup-shaped, preferably cylindrical, axially elongated and it may be fabricated from glass, plastic or some other substantially rigid material.

The piston **72**, which is fabricated from an elastomeric material, such as synthetic rubber, is substantially cylindrical in shape and slightly larger in outside diameter than the inside diameter of said barrel **71**, which with said piston defines a chamber **77**. The piston **72** preferably has a plurality, here three, of radially extending, spaced ridges **78** which improve the sealing engagement between it and the inner wall of the barrel **71**.

In a preferred embodiment of the invention, the piston has two coaxial recesses **81** and **82** in the opposite axial ends thereof, which recesses are spaced from each other to form a relatively thin membrane **83** integral with the piston **72**. The membrane **83** has a slit **84** substantially diametrical thereof and therethrough whereby said membrane acts as a valve obstructing the flow of fluids through the piston under circumstances where the pressure on opposite sides of the membrane is substantially equalized.

The rod **73** (FIG. **8**) is elongated and, throughout most of its length, is X-shaped in cross section in order to minimize the amount of material utilized while maintaining adequate strength and rigidity in said rod. There are two annular and radially disposed flanges **88** and **89** (FIG. **9**) integral with said rod and located near the lower end thereof. The lower flanges **88** and **89**, as shown in FIG. **9**, are elongated transversely of said rod **73** in one diametrical direction, and they are so spaced with respect to each other that the first and second fingers of a normal adult hand can be inserted between these two flanges for controlling the movement of the rod **73** relative to the barrel **71**.

The rod **73** has an integral, upwardly extending and substantially cylindrical stem **92** which is of approximately the same diameter as the inside diameter of the cylindrical recess **82** in the piston **72**. The stem **92** has an upper, annular flange **93**, the peripheral surface of which is beveled so that it slopes downwardly and outwardly away from the stem and thereby resists disengagement of the stem from within the piston **72** after it is inserted into the recess **82**.

The lower end of the rod **73** is provided with an integral nozzle **98** which is coaxial and substantially cylindrical, but preferably has an outer surface which converges slightly downwardly. A passageway **99** extends substantially coaxially completely through the rod **73** including the stem **92** and nozzle **98**. The rod **73** may be fabricated from plastic, glass or any other convenient material. When the stem **92** is properly disposed within the recess **82**, the upper end of the stem **92** is preferably spaced a short distance from the membrane **83**.

The cannula **74** may be substantially conventional with a sharpened tip **103** at the lower end thereof. The upper end of the cannula **74** is firmly embraced by and affixed to the tapered nozzle **98** so that the cannula communicates with the passageway **99**.

The sheath **76** is substantially cylindrical, relatively narrow in cross section and open at both ends thereof. Said sheath has, at least at its upper end, an upwardly diverging inner surface designed to sleeve snugly upon and frictionally engage the outer surface of the nozzle **98**. Said sheath **76** is preferably provided at its upper edge with a radially outwardly extending flange **104** to facilitate assembly.

The lower end of the sheath **76**, including the enlarged end **106**, may be identical with the corresponding structure in the sheath **43A**, described above. Also, the vial **107**, the sleeve **108** and the stopper **109** may be substantially identical to the corresponding parts of the assembly **60** disclosed in FIG. **5** and discussed above.

Normally, the barrel **71** will be placed in an upwardly opening position and filled with a fluid, such as a diluent, prior to the assembly of the syringe. The piston **72**, having been connected to the stem **92** of the rod **73**, will then be inserted into the chamber **77** of the barrel **71**. Usually, piston **72** wil be moved downwardly into the barrel **71** so that any air on top of the liquid can escape up through the slit in the membrane **83** and be expelled from the syringe. At the same time, the air leaving the barrel, which will normally be sterile, will purge non-sterile air from within the passageway **99** in the rod **73**. The sheath **76** is then telescopically mounted upon the nozzle **98** so that accidental disengagement therebetween is not likely to occur. The sheath **76** is then mounted upon the sleeve **108** and the vial **107** whereby the syringe and vial assembly **71** are ready for storage or shipment, as desired.

When it becomes desirable to use the syringe assembly **71**, the syringe is moved toward the vial until the needle **74** penetrates the stopper **109**. The medicine and diluent are mixed and drawn back into the barrel **71**. The sheath and vial are then removed from the syringe so that the cannula **74** is exposed. The syringe barrel **71** is then placed in the hand of the operator so that the first and second fingers of such hand are disposed between the flanges **88** and **89** on opposite sides of the rod **73**. The upper closed end of the barrel **71** is pressed against the palm of the same hand, roughly adjacent the thumb. Thus, by moving the first and second fingers toward the thumb, the piston **72** is moved into the barrel **71** whereupon the liquid in the chamber **77** is expelled through the slit in the membrane **83**, through the passageway **99** and into the cannula **74** from which it is discharged.

Although particular preferred embodiments of the invention have been disclosed in detail for illustrative purposes, it will be recognized that variations or modifications of the disclosed apparatus, including the rearrangement of parts, lie within the scope of the present invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A device for storing and administering a medicament, comprising:

syringe means having an elongated cylindrical barrel of a first outside diameter defining a chamber therein, one end of said barrel having an opening therethrough for communication with said chamber;

said barrel having an annular hub portion associated with the other end thereof and having a small opening extending axially therethrough for communication with said barrel chamber, said annular hub portion being of a second outside diameter which is substantially smaller than said first diameter and which terminates in a shoulder which extends outwardly and joins with the outer wall of said barrel;

vial means having a chamber therein, said vial means including a mouth portion defining an opening therethrough for communication with said vial chamber;

said vial means also having a neck portion of reduced diameter projecting outwardly from said mouth portion and containing an opening therethrough adapted to communicate with the opening defined by said mouth portion for permitting communication with said vial chamber;

perforable seal means fixedly positioned between said neck portion and said mouth portion for blocking said opening through said mouth portion for sealing said vial chamber;

cannula means having one end fixed within said small opening for communication with said barrel chamber, the other end of said cannula means being slidably disposed within said neck portion of reduced diameter, said other end of said cannula means being pointed and positioned adjacent said seal means for perforating same; and

removable tubular sheath means surrounding said cannula means and extending between said syringe means and said vial means for connecting same together, said sheath means including an elongated center portion having a first bore of approximately said second diameter extending therethrough;

said tubular sheath means including a first enlarged annular end portion integrally connected to one end of said center portion and defining a second bore having a diameter substantially equal to said first diameter, said first end portion being fixedly connected to the one end of said center portion by a first end wall extending radially therebetween, said first end portion surrounding and being snugly engaged with said one end of said barrel and said first end wall being abutted against said shoulder whereby said hub portion is disposed within and snugly engages said center portion;

said sheath means including a second enlarged annular end portion integrally connected to the other end of said center portion and defining a third bore therein having a diameter substantially greater than the diameter of said first bore, said second end portion being fixedly connected to the other end of said center portion by a second end wall extending radially therebetween, said second end portion surrounding and being snugly and slidably engaged with the mouth portion of said vial means and said second end wall being spaced from the free end of said mouth portion, the free end of said neck portion projecting into said center portion of said sheath means, whereby said sheath means can be slidably moved toward said vial means until the second end wall abuts the free end of said mouth portion for causing the pointed end of said cannula means to perforate said seal means.

2. A device according to claim **1**, wherein the first and second end portions and the center portion of said sheath means are all of substantially uniform wall thickness.

3. A device according to claim **1**, further including detent means coacting between said sheath means and said vial means for normally maintaining said sheath means in a position preventing perforation of said seal means by said cannula means, said detent means including coacting annular projections formed on said neck portion and said center portion.

4. A device for storing and administering a medicament, comprising:

hollow cylindrical barrel means having a closed axial end and an open axial end;

elastomeric piston means sealingly and slidably disposed within said barrel means for movement lengthwise thereof, said piston means having a central opening therethrough in a direction substantially parallel with the direction of movement of said piston means;

closure means yieldably obstructing the flow of liquid from said barrel means, said closure means comprising a membrane integral with said piston means and extending across said opening, said membrane having a slit therethrough;

elongated rod means having an end portion adjacent one end thereof extending into and firmly held within said opening in said piston means, said rod means having a central passage therethrough and being longer than said barrel means, whereby said rod means projects outwardly through the open axial end of said barrel means;

said rod means having an annular hub portion adjacent the other end thereof, and laterally projecting grip means fixed to said rod means near said other end thereof, said grip means being spaced axially inwardly from said hub portion;

vial means having a chamber therein, said vial means including a mouth portion defining an opening therethrough for communication with said vial chamber;

said vial means also having a neck portion of reduced diameter projecting outwardly from said mouth portion and containing an opening therethrough adapted to communicate with the opening defined by said mouth portion for permitting communication with said vial chamber;

perforable seal means fixedly positioned between said neck portion and said mouth portion for blocking said opening through said mouth portion for sealing said chamber;

cannula means having one end fixed within the hub portion of said rod means and communicating with the central passage extending therethrough, said cannula means projecting outwardly from said rod means in substantial alignment therewith and being pointed at the other end thereof, the other end of said cannula means being slidably disposed within said neck portion of reduced diameter and being positioned adjacent said seal means for perforating same; and

removable tubular sheath means surrounding said cannula means and extending between said rod means and said vial means for connecting same together, said sheath means including an elongated center portion having a first bore extending therethrough;

said tubular sheath means including a first annular end portion integrally connected to one end of said center portion, said first end portion surrounding and being snugly engaged with said hub portion;

said sheath means including a second annular end portion which is integrally connected to and enlarged relative to the other end of said center portion, said second end portion defining a second bore therein having a diameter substantially greater than the diameter of said first bore, said second end portion being fixedly connected to the one end of said center portion by an end wall extending radially therebetween, said second end portion surrounding and being snugly and slidably engaged with the mouth portion of said vial means and said end wall being spaced from the free end of said mouth portion, the free end of said neck portion projecting into said center portion of said sheath means, whereby said sheath means can be slidably moved toward said vial means until the end wall abuts the free end of said mouth portion for causing the pointed end of said cannula means to perforate said seal means.

5. A device according to claim **4,** wherein the cylindrical hub portion of said rod means converges in a direction toward the free end thereof, and wherein said first end portion defines therein a cylindrical opening which diverges toward the free end thereof for snug frictional engagement with said hub portion.

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