April 30, 1968 W. H. ADELBERGER 3,380,450

STERILE DISPOSABLE PLASTIC PREFILLED SYRINGE

Filed May 10, 1965 2 Sheets-Sheet 1

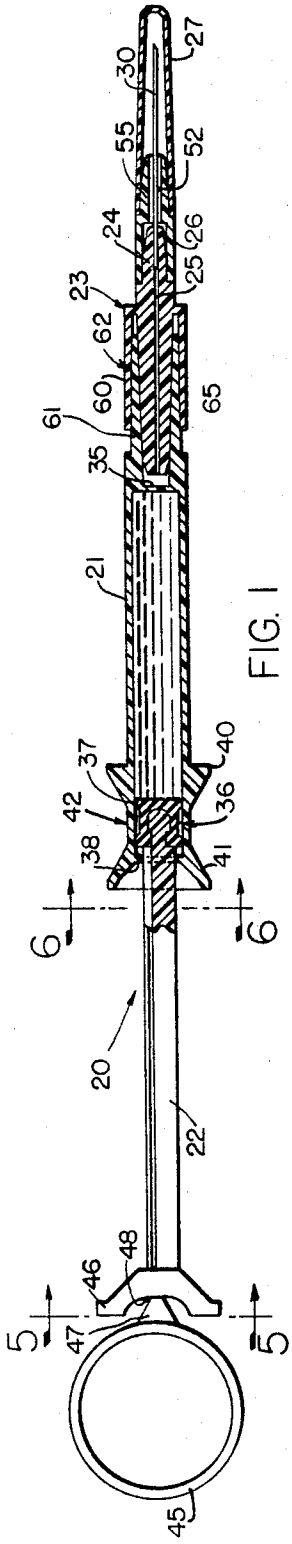


FIG. 1

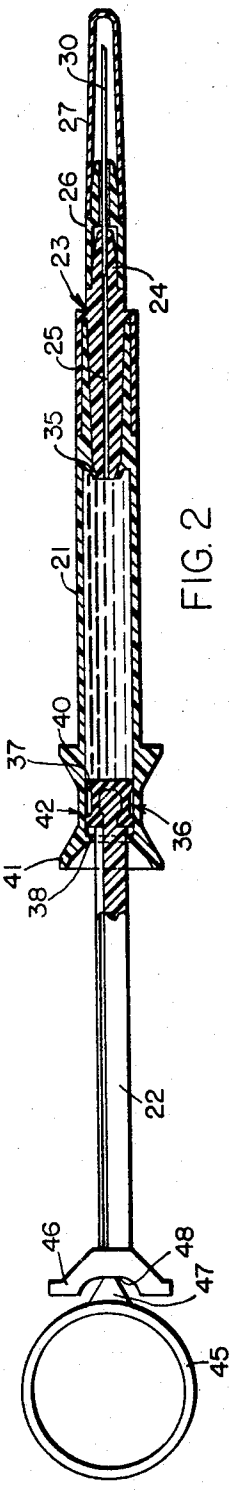


FIG. 2

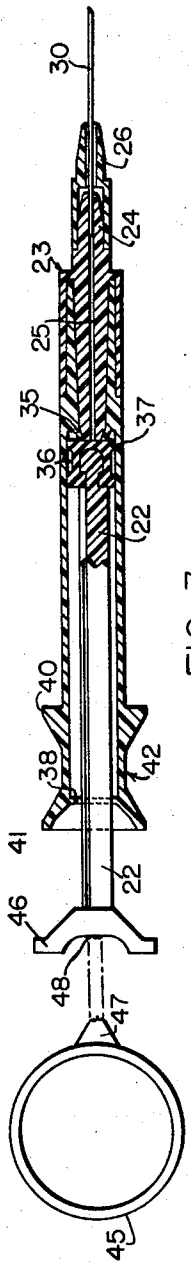


FIG. 3

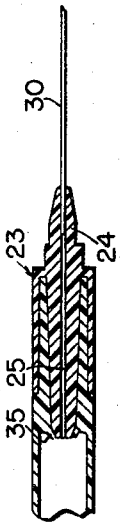


FIG. 4

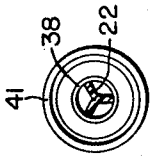


FIG. 6

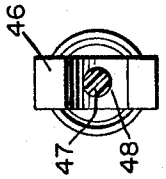


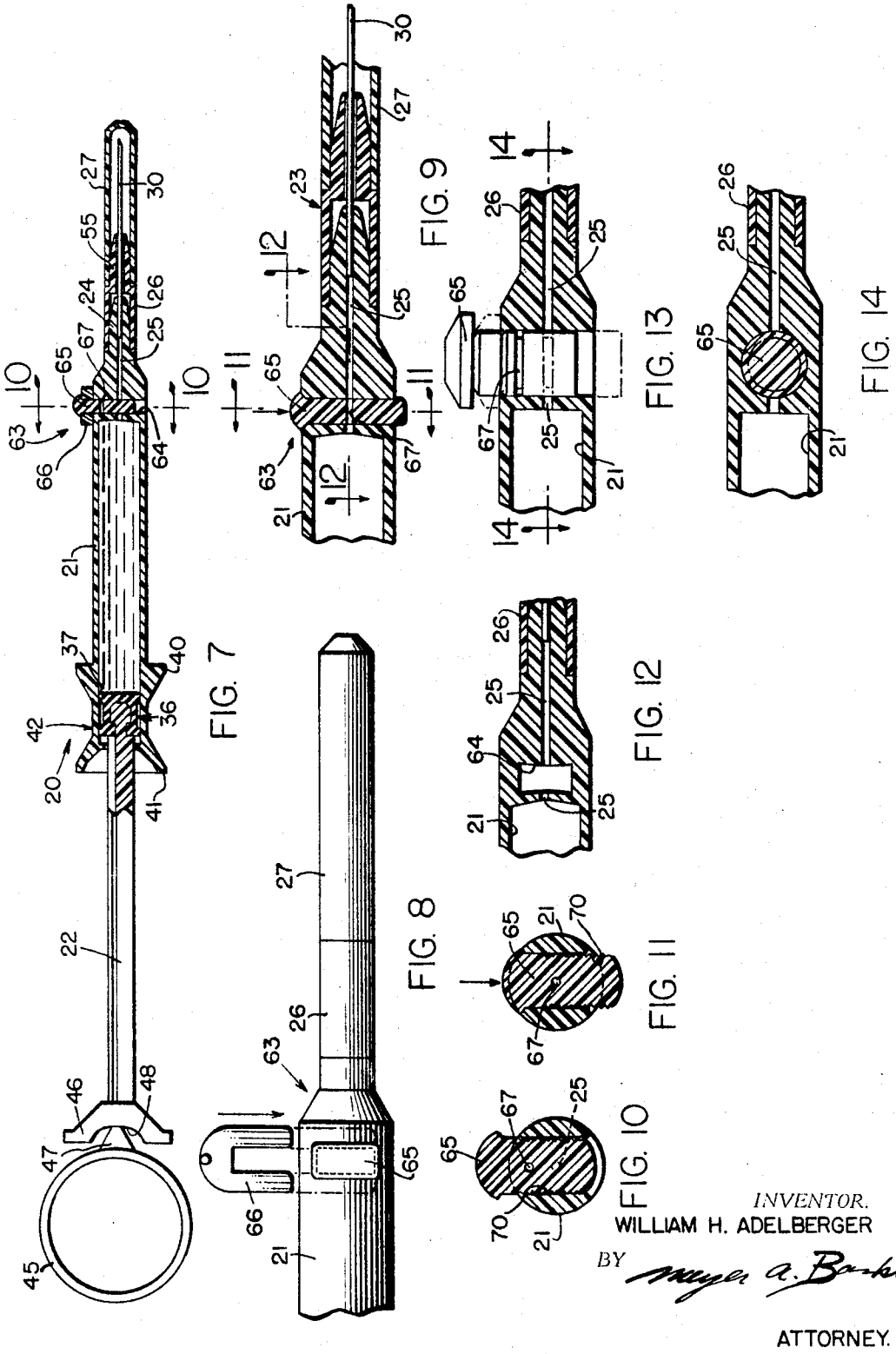
FIG. 5

INVENTOR.
WILLIAM H. ADELBERGER
BY Meyer A. Baskin
ATTORNEY.

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STERILE DISPOSABLE PLASTIC PREFILLED SYRINGE

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INVENTOR.
WILLIAM H. ADELBERGER
BY Wayne A. Bradley
ATTORNEY.

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STERILE DISPOSABLE PLASTIC PREFILLED SYRINGE

William H. Adelberger, Coral Gables, Fla.
(3823 Shannon Road, Cleveland Heights, Ohio 44118)

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10 Claims. (Cl. 128—218)

ABSTRACT OF THE DISCLOSURE

This invention is in the art of sterile hypodermic injection devices which are prefilled at a central source of supply by a wholesale drug manufacturer, for example, and delivered to the ultimate user, such as doctors, dentists, medics, and others. After the sealed in medication contained in the ampule is used for injection, including an aspiration action when desired, the entire device may be thrown away since it is made of relatively inexpensive material. Means are provided for the use and sheathing of multiple lengths of needles, easy disposal of the thumb ring, when not desired, and other advantages are clearly set out in the following detailed objects, descriptive specification and related patent drawings.

This invention relates to hypodermic injection devices and, more particularly, to disposable plastic syringes which are adapted to be furnished prefilled and sealed as sterile units which may be stored until used and then discarded.

Previous attempts have been made to provide a single dosage disposable hypodermic syringe including an ampule containing the liquid solution of medication for a hypodermic injection, and a steel cannula or needle plunger and other parts, all of which is disposable after the medication in the ampule has been injected.

This invention provides many improvements in such generally related prior art devices, which improvements are novel, useful and have many advantages and desirable characteristics not contained nor disclosed in any previously known structures.

It is the principle of this invention to provide an improved disposable preloaded hypodermic syringe means to functionally vary the effective length of the needle and to provide novel means to select the particular length of needle desired to be used.

Another object of this invention is to provide novel dual sheathing means for protecting the needle of the syringe throughout its length and sealing and maintaining it in sterile condition from the time of loading the syringe and sterilizing it until used.

A further object is to provide novel assembly and coupling means for the dual length sheathing and sterile sealing device of this invention.

A still further object is to provide novel means of opening the sealed liquid medication ampule for flow through the needle when ready to use which is efficient, inexpensive to manufacture, positive in operation and facile in use.

Yet another object of this invention is the inclusion of a functionally and structurally improved and completely novel arrangement of a "thumb" ring in a disposable hypodermic syringe, which is associated with the plunger of the syringe and used to perform an aspirating action when desirable, which permits retraction of the plunger in a "controlled" two-way fashion.

Another object is to provide a novel "thumb" ring connection with the plunger which may be easily removed from the assembly to convert the disposable "two-way" syringe into a palm rest push type plunger injection type syringe, as desired.

These and many other objects and advantages of the present invention will become readily apparent from the following detailed description of one form thereof illustrated in the accompanying drawings, wherein:

FIGURE 1 is a longitudinally extending cross-sectional view of the complete hypodermic syringe illustrating its appearance when it is preloaded with liquid medication sealed therein, sterilized, and ready for storage and subsequent use;

FIGURE 2 is a similar longitudinal cross-sectional view of the syringe shown in FIGURE 1, but illustrating the relative position on the parts after the needle retaining base has been moved rearwardly to puncture the seal and permit the liquid medication to flow into the hollow hypodermic needle, step one of the operation;

FIGURE 3 is another longitudinal cross-sectional view of the syringe, similar to FIGURES 1 and 2, but illustrating the relative position of the parts when the outer end of the two-part protective sheath has been removed to expose the outer end portion of the needle and the plunger has been pushed completely inwardly and the medication expelled from the syringe, step two of the operation;

FIGURE 4 is a fragmentary longitudinal cross-section of the end portion of the syringe, as shown in FIGURES 1, 2 and 3, but illustrating the relation of the parts when the inner end of the two-part protective sheath has also been removed to expose a greater length of the needle;

FIGURE 5 is a cross-sectional view taken on the line 5—5 of FIGURE 1 in the directions indicated by the arrows;

FIGURE 6 is a cross-sectional view taken on the line 6—6 of FIGURE 5 in the direction indicated by the arrows;

FIGURE 7 is a longitudinally extending cross-sectional view of a modified form of the hypodermic syringe similar to FIGURE 1, but disclosing an alternative sealing means which comprises a slide gate valve, shown in closed position;

FIGURE 8 is an enlarged fragmentary top elevation of the sheathed needle end of the syringe illustrated in FIGURE 7, illustrating in exploded position a horseshoe washer detail for locking said slide gate valve sealing means in closed position;

FIGURE 9 is an enlarged detail cross-section of the slide gate valve seal of FIGURE 7 in open position to permit passage of liquid medication to the hollow hypodermic needle;

FIGURE 10 is an enlarged cross-section taken on line 10—10 of FIGURE 7 in the direction indicated by the arrows of the slide gate valve shown in closed liquid sealing position;

FIGURE 11 is an enlarged cross-section taken on the line 11—11 of FIGURE 9 in the direction indicated by the arrows of the slide gate valve shown in open flow-through position;

FIGURE 12 is an enlarged detail fragmentary cross-section view taken on line 12—12 of FIGURE 9 in the direction of the arrows;

FIGURE 13 is an enlarged detail fragmentary cross-section of a slightly modified slide gate valve which may be of resilient compressible material, and

FIGURE 14 is a cross-section taken on line 14—14 of FIGURE 13 in the direction of the arrows.

Referring now in detail to the drawings in which like characters of reference refer to like parts throughout the several views, there is illustrated in FIGURE 1 in longitudinal cross-section, a hypodermic disposable syringe numbered 20 in general.

It may be made of plastic, or any desirable inexpensive material, preferably molded. It is contemplated that the syringe, indicated generally by numeral 20, including a cylindrical liquid medication containing barrel 21, a dis-

charge plunger shaft 22, slidable needle base 23 in general, "long" needle hub 24, having longitudinal liquid passage bore 25, and a two-part needle sheath 26 and 27, and other parts, may all be molded of inexpensive plastic material and that the entire syringe will be disposed of and thrown away after one use or single injection has been made.

A conventional hollow bored hypodermic needle 30, of stainless steel or other material, which is of any desired gauge, bore and length, is permanently fixed in the slidable hub 23, as shown in FIGURES 1, 2, 3 and 4, by the molding operation or the use of a suitable adhesive or in any other manner. Needle 30 is in alignment with the longitudinally extending liquid passage bore 25 of "short needle" hub 55 and adapted to receive, pass and discharge the liquid medication contained in barrel 21 in the conventional well-known manner.

A membrane seal 35, which may be of aluminum foil or any other suitable easily ruptured material 15, is fixed at the needle end of the cylindrical barrel 21, or the membrane may be cast integrally therewith in a leakproof manner to prevent egress of the liquid medication contained in barrel 21.

Adjacent the opposite end of barrel 21 the inner end of the plunger 22 is tipped by a resilient piston head member 36 and is arranged during assembly of the preloaded disposable syringe in the position shown in FIGURE 1. Head member 36 may be of rubber or other compressible material and has an outside diameter closely equalling the inside diameter of barrel 21, but snugly slidable in the barrel 21.

The resilient compressible piston head member 36 is radially outwardly flanged at 37 to expand and engage the inner cylindrical surface of container cylinder 21 at all times to provide a leak-proof seal and prevent egress of the liquid medication at the plunger end. An annular inwardly extending flange member 38 is formed adjacent the outer end of barrel 21 which serves as a stop, preventing outward withdrawal of plunger piston head member 36 when the device is assembled. The stop 38 may assume any form.

It is thus apparent that any kind of liquid medication or narcotic may be pre-loaded into barrel 21 at the point of assembly and that it will remain effectively sealed within barrel 21 between head member 36 at the outer end of barrel 21 and the inner sealing membrane 35.

It is to be noted that the outer end of the cylindrical barrel 21 is flanged radially outwardly at 40 and 41 forming a finger rest groove 42 therebetween. In use, the first, or index, finger and second finger of the operator will be placed in groove 42 to grip and hold the syringe 20 when using it. The extreme outer end of plunger 22 has molded integrally therewith a thumb ring 45 and an annular or other shaped palm rest 46.

The thumb ring 45 is joined to palm rest portion 46 of plunger 22 by a relatively small connecting member 47 at the bottom of a recess 48 in palm rest 46. The reduced cross-sectional area of member 47 permits easy breaking away of the thumb ring 45 when desired. The connecting member 47 is preferably tapered inwardly toward the bottom of recess 48. This will insure the fracture point to be well within recess 48 so that any projecting broken plastic edges will not injure the operator when using palm rest 46.

At this juncture the utility of this particular novel arrangement should be noted.

If the operator desires to use the plastic disposable syringe of this invention as an aspirator, he merely inserts his thumb in ring 45 and proceeds to follow the well-known aspirating technique. If the operator does not wish to employ the aspirating principle and, therefore, does not need thumb ring 45, he firmly grasps syringe 20 and snaps off the ring by fracturing connecting member 47. The hypodermic syringe is then used for straight injection of the liquid medication contained in barrel 21 through needle 30 by exerting inward pushing pressure against palm rest 46. FIGURE 3 illustrates the palm rest 46 with thumb ring 45 broken away.

This novel means of providing a dual function of thumb ring aspirator type syringe and push type palm rest injection syringe in one pre-loaded sterile disposable plastic device has many important advantages.

The novel structure and arrangement of parts which provides the utility of both a "long" needle and a "short" needle in a single sterile preloaded disposable plastic syringe is of great importance and has many advantages. It comprises the two-part needle sheath 26–27. The outer end portion of slidable needle base 23 is reduced in diameter at 24 to form a hub upon which inner needle sheath 26 is removably and telescopically mounted. A tight friction fit between the outer diameter of plastic needle sheath 26 is provided as shown in the drawings. Sheath 26 has a central bore 52 through which the hypodermic needle 30 passes.

The outer diameter of inner needle sheath 26 is reduced at 55 to form a hub upon which the outer needle sheath 27 is removably telescopically mounted. A tight friction fit between the outer diameter of plastic hub 55 of inner needle sheath 26 and the inner diameter of outer needle sheath 27 is provided as shown. Sheath 27 forms a hollow elongated protective cover for hypodermic needle 30 and is closed at its extreme end.

The assembly and operation of the sterile disposable pre-loaded plastic syringe of this invention is as follows:

The barrel 21 is filled with the desired liquid medication under maximum sterile conditions after all of the structural elements have been completely sterilized. The tipped piston head 36 of plunger 22 with its radially outwardly extending compressible flanges 37 closes and seals the outer end of barrel 21. Membrane 35 which is of any well-known foil type, such as aluminum foil, tin foil, or a film of "Saran," or "Cel-O-Seal," or other material, seals the other end of barrel 21. Membrane 35 may be cast and molded integrally with barrel 21 if desired. Thus, the liquid medication, or opiate, will be maintained in sterile condition from the time the cylindrical barrel 21 of the plastic disposable syringe is filled or pre-loaded at the pharmaceutical laboratory, or other place of manufacture, until used. The stop 38 on the plunger operating end of syringe 20 prevents withdrawal of plunger shaft 22 from the syringe.

Slidable needle base 23, in which needle 30 is suitably embedded in a permanent fixed leakproof manner, comprises an outer cylindrical shell or sheath 60 which surrounds a reduced cylindrical hub 61 formed at the discharge end of cylindrical barrel 21. (Right end as viewed in FIGURES 1, 2 and 3 of the drawings.) Shell 60 is adapted to slide inwardly towards the barrel 21 on hub 61, but is restrained from such movement by a spot heat sealing operation temporarily and lightly connecting shell 60 and hub 61, as at 62 in the drawings. Any other conventional breakaway method of lightly joining slidable shell 60 and hub 61 may be employed. An inner portion of the needle base 23 comprising an elongated cylindrical projectile-shaped member 65 is located within the discharge end of barrel 21 adjacent membrane seal 35 and in alignment therewith.

When the operator desires to use the syringe 20 his first step is to slide needle base 23 horizontally towards the seal 35. (To the left as shown in the drawings.) This is accomplished by applying the amount of energy necessary to break the heat sealed spot connection at 62 between needle base 23 which lightly joins the outer shell 60 to hub 61. This connection is to be arranged to rupture under light pressure and thus the inner end of member 65 will puncture or tear membrane foil seal 35 open and release the liquid medication and permit it to be ejected through aperture 25 in needle base 23 and the hollow hypodermic needle 30 upon advancing plunger shaft 22 and its resilient head 36.

If the operator desires to use a "long" needle, he removes sheaths **26** and **27** simultaneously by simply pulling off sheath **26** which is held in its nested telescopic position through its snug frictional fit on hub **24**. This action exposes the needle **30** throughout its entire length from its pointed tip to the outer end of needle base **23** in which it is fixedly mounted.

If the operator desires to use a "short" needle, he removes only the outer sheath **27** from the hub **61** on which it is frictionally mounted. In this situation needle **30** will only be exposed from the outer end of sheath **26** to the needle point. Sheath **26** will continue to cover part of needle **30** resulting in operative effect on a "shorter" needle.

The advantages of the disposable prefilled plastic syringe of this invention are manyfold. They eliminate the necessity of assembling various component parts at the point of use. The syringe is pre-filled, pre-sterilized and entirely disposable after use. It provides a positive aspiration, positive view of the aspiration area. The lightweight of the plastic syringe results in increased tactile sense. An easy "instant" choice of a long or short needle in a single device is a time saving advantage and also cuts the inventory necessary to meet requirements as to lengths in half. Patient apprehension is reduced due to absence of the conventional glass and metallic syringes now in popular use. Possibility of injury to the patient or operator by shattered glass is entirely eliminated because of all plastic construction. Storage and inventory problems of currently used components, including assortments of needles in many lengths and gauges, separately bottled liquid medications in solutions, extra glass and metal syringes and plungers is eliminated. Substantial work time savings on part of auxiliary personnel otherwise required to clean, sterilize, assemble, load and other maintenance labor required in the use of currently employed types of equipment. Free, easy and more positive movement of the slidable resilient plunger head within the cylindrical barrel facilitates more accurate pinpoint position of the needle bevel than any heretofore available hypodermic syringes.

An alternative form of sealing and releasing means for the liquid medication pre-loaded in the barrel **21** of this syringe is illustrated in FIGURES 7 and 14. This modification of the invention comprises a vertically movable gate valve indicated generally by the numeral **65**.

In all other respects, including the snap-off thumb ring **45**, palm rest **46**, plunger operating shaft **22**, plunger piston head **36**, solution container cylinder barrel **21**, dual function two-part needle sheaths **26** and **27**, hypodermic needle **30**, and other operating components are the same as the first described form.

Gate valve **65** is substituted for membrane seal **35**.

In the alternative form illustrated in FIGURES 7, 8, and 9, the needle base is molded or formed integrally with the cylindrical barrel rather than slidable thereon as in the first described form. A transverse rectangular slot **64** extends through the discharge end portion of the cylindrical fluid container barrel **21** (slot **64** extends vertically as viewed in FIGURES 7 and 9) a gate type valve **65** is slidably fitted for up and down movement in vertical slit **64**. The valve is preferably of resilient compressible material adapted to expand tightly against the walls of slot **64** and effect a seal to close the bore **25** formed in end of cylindrical fluid container **21** which extends longitudinally through the needle base to needle **30**.

Gate valve **65** has transverse aperture **67**.

When valve **65** is in raised position, as in FIGURE 7, aperture **67** is out of alignment with bore **25** and the fluid is sealed within cylindrical barrel **21**. The valve **65** may have an outwardly flanged shoulder at its upper outer end to accommodate a conventional horeshoe shaped removable key **66**. In FIGURE 8, a plan view, key **66** is shown in exploded disengaged position. It may be moved in direction of the arrow to engage under side of flanged top of valve **65**.

When the operator desires to condition the syringe for use he merely removes key **66** and pushes slidable gate valve **65** downwardly to align aperture **67** with bore **25** to position shown in FIGURE 9.

FIGURES 10, 11, and 12 illustrate another form of controlling gate valve **65**. Here slot **64** has slightly convex walls. The side edges of the valve are serrated at **70** to aid position maintenance. This provides a tight seal.

FIGURES 13 and 14 illustrate another modification. The compressible resilient slidable valve **65** is round in cross-section but otherwise the operation is identical with the form illustrated in FIGURES 7, 8, and 9.

The manufacture and sale of the disposable syringe disclosed herein without pre-loading is contemplated. It is apparent that the novel features of this structure may be utilized for injecting liquid medication contained in separate glass, rubber stopped bottles.

It is particularly contemplated that the dual or multi-sheath arrangement which is a part of this invention may be used separately and apart from the syringe disclosed herein. Separate sterilized containers for the novel sheath arrangement which provides a "long" and "short" needle effect may be produced independently of the other features of this invention.

It is to be understood that this invention is not to be limited to the specific constructions and arrangements shown and described by way of example, and it will be apparent to those skilled in the art that many changes may be made without departing from the principles of the invention. The use of other materials is contemplated as are shapes and relative sizes of the various components.

I claim:

1. A disposable pre-loaded hypodermic injection syringe comprising a container portion adapted to receive and retain the fluid to be injected, said container being open at one end, a resilient piston head disposed interiorly of said container and reciprocal therein, means comprising a plunger rod connected to said piston head for selectively reciprocating said piston head to inject said fluid, means cooperating with said reciprocal plunger rod to seal said open end, membrane sealing closure means in the opposite end of the container to seal the fluid within the container, a needle base slidably mounted on said container adjacent the sealing membrane and adapted to rupture said membrane to permit release of the fluid, breakaway means to maintain said slidable needle base immobile on the container away from the sealing membrane, a hollow hypodermic needle fixedly mounted in the outer end of said slidable needle base arranged to receive the fluid from the container when the membrane has been ruptured upon inward movement of the needle base, a hub formed on an outwardly projecting end of said needle base, a sheath member mounted on said hub by a frictional fit and arranged to enclose an inner portion of said needle, a second hub formed on an outwardly projecting end of said sheath member, a second sheath member mounted on said second hub by a frictional fit and arranged to enclose the outer portion of said needle, said second sheath member being closed at its outer end, stop to prevent withdrawal of the piston head from the container.

2. A disposable hypodermic syringe, as described in claim **1**, including a thumb ring formed at the outer end of the plunger, a palm rest formed on the outer end of said plunger inwardly of said thumb ring and an easily fracturable connecting member adapted to join said thumb ring and palm rest and to be broken away when desired.

3. A disposable preloaded hypodermic injection syringe, as described in claim **2**, wherein the outer end of the palm rest is recessed and the portion of the fracturable connecting member which joins the thumb ring to the

palm rest and plunger is fixed to the bottom of said recess.

4. A disposable preloaded hypodermic syringe, as described in claim 1, wherein the needle base is formed integrally with the fluid container, a longitudinal bore extending from the fluid container to the needle, and means for maintaining the fluid within the container comprises, a transverse-slidable gate valve having an aperture extending through said valve, a slot formed in said needle base in which said gate valve is slidably mounted, said gate valve being adapted to be maintained in a position wherein the longitudinal bore is blocked and the fluid sealed within the container and slidable into a position wherein the aperture of the valve is in alignment with the bore of the container to permit ejection of the fluid therethrough from the container to the needle.

5. A disposable preloaded hypodermic syringe, as described in claim 4, wherein the transversely slidable gate valve may be maintained in sealing position with its aperture out of alignment with the alignment with the longitudinal bore of the fluid container by a removable retaining key.

6. A disposable preloaded hypodermic syringe, as described in claim 4, having a transversely extending slot formed therein, a slidable gate valve closure of resilient compressible material adapted for a frictional leak-proof sliding fit within said slot in a manner whereby the aperture of the gate valve and bore of the container may be maintained out of respective alignment to seal the fluid within the container, and aligned to permit ejection of the fluid from the container.

7. A disposable hypodermic syringe comprising a cylindrical container portion which is flanged radially outwardly on one end to form a finger rest groove, a piston head reciprocal therein, a plunger rod disposed at one end of said container and connected to said piston head, a breakaway fracturable thumb ring joined to the other end of said plunger shaft, a needle base operatively mounted at the other end of said container portion, a hypodermic needle fixed in said needle base, multi-sectional separable sheath means adapted to enclose the entire exposed portion of said needle or only portions thereof as desired, wherein the multiple needle sheath enclosure means includes a hub of lesser diameter than the needle base projecting outward therefrom surrounding and parallel to the needle, an open ended sheath removably mounted in a frictional fitting manner on said hub, said open ended sheath of a length to enclose only an inner portion of said needle, a hub of lesser diameter than the open ended sheath projecting outwardly therefrom surrounding and parallel to the needle, a second sheath removably mounted in a frictional fitting manner on the hub of said open ended sheath and of a length to enclose the remaining outer length of the needle, said second sheath being closed at its outer end, all of said sheaths being concentrically located around the cannula, with the interior sheaths having an aperture in the forward end through which the needle extends.

8. A disposable hypodermic syringe comprising a cylindrical container portion which is flanged radially outwardly on one end to form a finger rest groove, a piston head reciprocal therein, a plunger rod disposed at one end of said container and connected to said piston head,

a breakway fracturable thumb ring joined to the other end of said plunger shaft, a needle base operatively mounted at the other end of said container portion, a hypodermic needle fixed in said needle base, multi-sectional separable sheath means adapted to enclose the entire exposed portion of said needle or only portions thereof as desired wherein the multi-sectional separable sheath means comprises a plurality of frictionally connected needle enclosure sheaths each shorter than the entire length of the needle and arranged to surround the needle, sheath section being independently separable from the other in a manner to permit exposure of various lengths of the needle as desired, all of said sheaths being concentrically located around the cannula, with the interior sheaths having an aperture in the forward end through which the needle extends.

9. A disposable hypodermic needle and protective enclosure assembly for use with a hypodermic syringe comprising a disposable base in which the needle is fixedly mounted, a plurality of disposable needle surrounding open ended protective sheaths of predetermined lengths, said open ended sheaths being slidably removably connected in series with each other, the innermost sheath being removably connected with the needle base, and an outer closed end sheath removably connected with the outermost open ended sheath, all of said sheaths being concentrically located around the cannula, with the interior sheaths having an aperture in the forward end through which the needle extends.

10. A disposable hypodermic needle and protective enclosure assembly for use with a hypodermic syringe comprising a disposable base in which the needle is mounted, and a disposable needle enclosing protective multi-sectional sheath, means to maintain each section of said sheath in connected relationship with its adjacent section in a manner to enclose the needle throughout its length, said connection maintaining means being adapted to permit easy disconnection of one section of said sheath from another section and from enclosing relationship with the needle and a breakaway thumb ring adapted to operate said needle for aspiration procedures and to be easily broken away for injection procedures, each sheath section being of predetermined lesser length than the needle, all of said sheaths being concentrically located around the cannula, with the interior sheaths having an aperture in the forward end through which the needle extends.

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RICHARD A. GAUDET, *Primary Examiner.*

D. L. BAKER, *Assistant Examiner.*

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,380,450 April 30, 1968

William H. Adelberger

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

In the drawings, Sheet 1, Fig. 1, change the numeral "65" to -- 59 -- and extend a lead line therefrom to the projectile-shaped inner portion of base 23 that extends within the hub 61. Column 2, line 32 "Figure 5" should read -- Figure 1 --. Column 4, line 60, "member 65" should read -- member 59 --; line 70, "inner end of member 65" should read -- inner end of member 59 --. Column 5, line 9, "from the hub 61" should read -- from the hub 55 --.

Signed and sealed this 4th day of November 1969.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents