United States Patent

Welch

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[54] SELF-CONTAINED DISPOSABLE SYRINGE

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[52] **U.S. Cl.** ..... **128/218 S,** 128/221

[51] **Int. Cl.** **A61m 05/00**

[58] **Field of Search** ..... 128/215, 218 P, 128 D, 218 S, 128/221

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[57] **ABSTRACT**

A self-contained disposable syringe including a syringe barrel with an open rear end and a needle mounted on the forward end. The needle has a passage therethrough which communicates with the interior of the barrel. A plunger is positioned within the syringe barrel and is movable with respect to the barrel. A needle shield is normally positioned in sealing engagement with the forward end of the syringe barrel and surrounds the needle so as to protect the needle from damage and loss of sterility. A removable seal on the rear end of the syringe barrel normally provides a compact sealed self-contained disposable syringe in sterile condition and suitable for shipment and storage. The needle shield is adapted for removal from the forward end of the barrel and is adapted for engagement with the rear end of the plunger to form finger gripping means on said plunger to facilitate the movement of the plunger with respect to the barrel when the sealed syringe is open for use.

10 Claims, 2 Drawing Figures

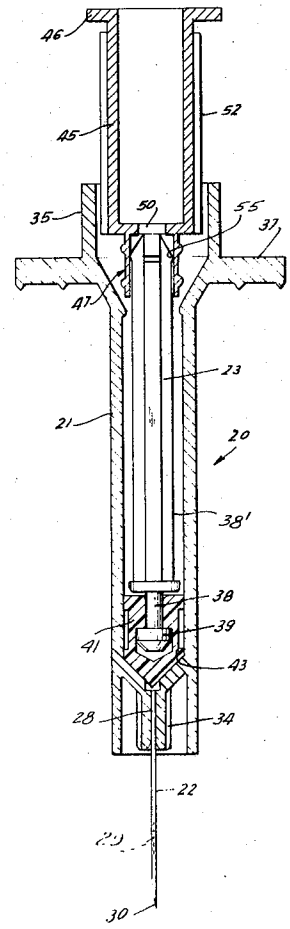


FIG. 1

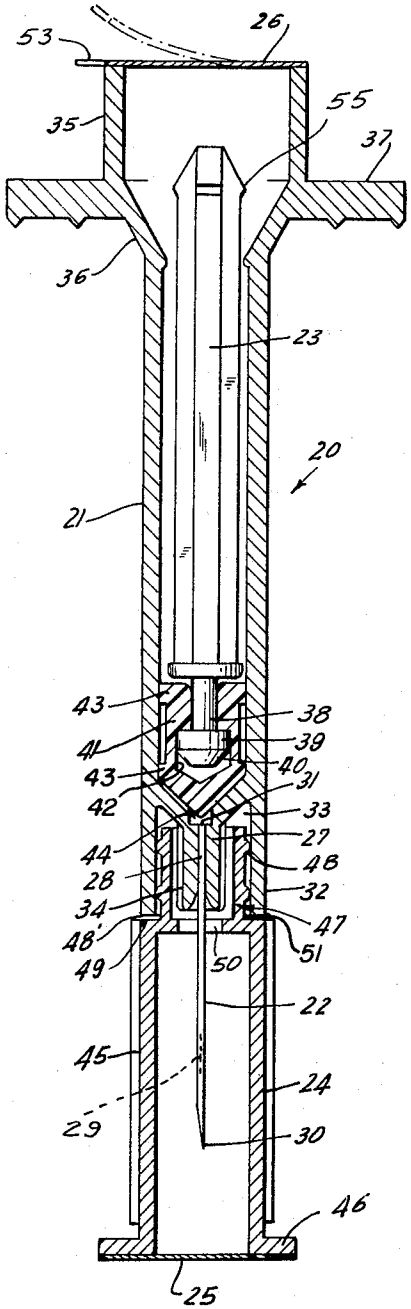
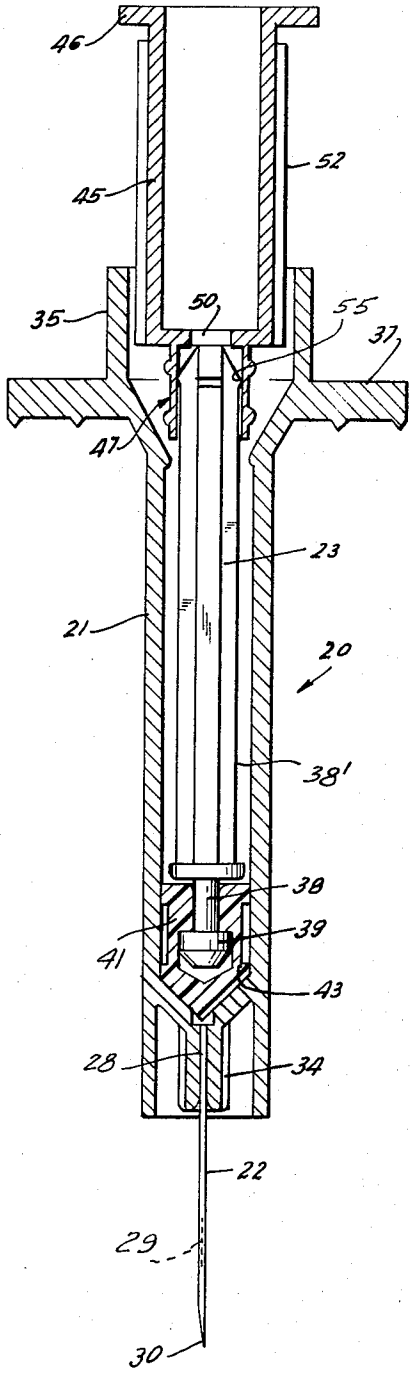


FIG. 2



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SELF-CONTAINED DISPOSABLE SYRINGE

BACKGROUND OF THE INVENTION

In normal commercial production, disposable syringes are generally contained in a packaging medium which entails the use of one or more elements to contain and protect the syringe from damage during shipment and handling. Additionally, the packages employed are designed to retain the syringe in a sterile condition during the shipping, handling and storage thereof until it is desired to use the syringe.

Packages of this type tend to be bulky and consequently consume more storage space per unit than is desirable. Furthermore, when the package is opened and the syringe removed there are often portions of the package which have to be removed by fracture or some other means and then discarded.

Naturally with a packaging medium employed to contain each individual syringe or a multiplicity of syringes, the cost of providing the packaging contributes significantly to the overall cost of each individual disposable syringe. It is desirable that a disposable syringe be manufactured at as low a cost as possible thereby facilitating the sale of a disposable syringe at a low price. Furthermore, as previously discussed, the use of a packaging medium to contain the syringe adds additional and unnecessary bulk to each individual syringe which can significantly detract from valuable storage space in a hospital or other storage area.

From the above comments, it is readily apparent from the state of the art that it would be extremely advantageous to provide a syringe which consists of the usual components of plunger, needle, needle shield and barrel and also constitutes its own package which will maintain a sterile interior prior to use as well as protect the frangible portions of the syringe such as the needle from damage. Furthermore, it would also be advantageous to provide such a syringe which may be easily disassembled from its packaging arrangement and assembled into its operating arrangement with a minimum amount of effort and time. This would be advantageous in providing a syringe which is equivalent to the preassembled syringe in package form now on the market where no assembly steps are necessary. Therefore, the syringe which forms its own package should be readily and easily adaptable from its packaged configuration to its assembled configuration in as few steps and as quickly as possible.

SUMMARY OF THE INVENTION

With the above considerations in mind, among the primary objectives of this invention is to provide a syringe including a plunger, needle, needle shield and barrel which in normal assembly forms its own package and will maintain a sterile interior prior to use. No additional packaging components are required with the exception of a paper or plastic cover sealed to the end of the barrel and possibly the shield if desired. The self-contained syringe will maintain the interior portions thereof in a sterile condition during shipping, handling and storage and additionally will protect the frangible portions of the assembly such as the needle. Furthermore, a minimum number of components are involved since no parts are used as a package which allows the syringe and package combination of this invention to be manufactured at a cost approximately equal to that of the usable disposable syringe without the additional cost of the package means. Naturally, this provides a syringe having a minimum bulk since there are no excess parts and therefore the required storage space per unit is considerably decreased. Still further, an object of this invention is to provide a self-contained disposable syringe wherein in the preparation of the syringe for use, the time required for this preparation is minimized since no components need be removed or disassembled and discarded. The shield is adapted to be removed from the needle and assembled to the plunger rod in one motion thereby transforming the package syringe into a syringe ready for immediate use quickly and efficiently.

In summary, a self-contained disposable syringe is provided which includes a syringe barrel having an open rear end and a needle mounted on the forward end thereof. The needle has a passage therethrough communicating with the interior of the barrel. A plunger is normally positioned within the barrel and is movable with respect to the syringe barrel. A needle shield is normally in sealing engagement with the forward end of the syringe barrel and in surrounding relationship with the needle so as to protect the needle from damage and loss of sterility. Removable sealing means is positioned on the rear end of the syringe barrel thereby normally providing a compact sealed, self-contained disposable syringe in sterile condition and suitable for shipment and storage. The needle shield is adapted for removal from the forward end of the barrel and adapted for engagement with the rear end of the plunger to form finger gripping means on the plunger to facilitate the movement of the plunger with respect to the barrel when the sealed syringe is opened for use.

With the above objects, among others, in mind reference is had to the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a central sectional view of the selfcontained disposable syringe of this invention shown in its normally sealed sterile packaged condition; and

FIG. 2 is a central sectional view thereof showing the syringe with its components in their unpackaged condition and with the syringe assembled for immediate use.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 of the drawing shows the self-contained disposable syringe **20** of the invention in its sterile packaged form. The syringe assembly in package form basically consists of a syringe barrel **21**, a needle **22**, a plunger **23** and a needle shield **24**. In the embodiment shown, both open ends of the package are sealed with separate sealing means. Sealing means **25** covers the end of needle shield **24** distal from syringe barrel **21** and sealing means **26** covers the rear end of syringe barrel **21**.

Syringe barrel **21** is a conventional type of syringe barrel which is constructed of a plastic material which lends itself readily to disposability. The syringe barrel is hollow and of a general cylindrical configuration and has a reduced forward cylindrical end portion **27**. Reduced portion **27** has a bore **28** therethrough which communicates at its forward end with the exterior of the syringe barrel and at the rear end with the interior of syringe barrel **21**. It may also be noted that the portion of syringe barrel **21** immediately adjacent the forward reduced portion is tapered into a conical configuration to facilitate flow of fluid into and out of the syringe barrel and also proper engagement with the stopper mounted on the forward portion of plunger **23** as will be discussed in greater detail below.

The forward tip of the bore **28** is flared outwardly to facilitate reception of the needle **22** when it is combined with syringe barrel **21** in the formation of the syringe assembly. Needle or cannula **22** is a common commercial type of syringe needle metallic in nature and having a bore **29** therethrough. The forward end of cannula or needle **22** has a pointed puncture tip **30** for insertion into a fluid source. The rear end **31** of cannula **22** generally has a blunt configuration and communicates with the interior of the main body portion of barrel **21**. Cannula **22** may be retained in position within reduced forward end **27** by any common bonding means such as an epoxy resin. Reduced forward end **27** has a number of spaced longitudinal ribs **34** on its outer surface to provide additional rigidity and strength to end **27**.

Extending from the main portion of barrel **21** is an annular skirt **32** which has the same outer diameter as the main portion of barrel **21** and a larger inner diameter than forward reduced portion **27** of syringe barrel **21**. It is not necessary that skirt **32** have the same outer diameter as the main portion

of barrel 21. Annular skirt 32 as shown extends at least as far forward as the forward tip of reduced portion 27 and is substantially concentric with reduced portion 27 and needle 22. Skirt 32 does not necessarily have to extend as far forward as the tip of portion 27. The recess 33 formed between the outer surface of reduced portion 27 and skirt 32 forms a reception space for a portion of needle shield 24 as will be discussed in greater detail below.

The rear end portion 35 of syringe barrel 21 has a larger inner and outer diameter than the main body portion of barrel 21 and is connected thereto by means of a tapered integral conical shaped portion 36 which is of the same diameter at its rear end as rear portion 35 and has the same diameter at its forward end as the main body portion of barrel 21. The purpose of this larger diameter portion 35 on the syringe barrel 21 is for readily facilitating the engagement of needle shield 24 with plunger 23 as will be discussed in greater detail below. A pair of diametrically opposed finger gripping flanges 37 extend outwardly from syringe barrel 21 intermediate the larger diameter upper portion 35 and the main portion of syringe barrel 21. These flanges facilitate the gripping of the syringe when it is in actual use.

Plunger 23 may assume a variety of different configurations with the principal criteria being that it be a rigid member preferably of a low cost material such as plastic and be of a length which permits it to be located entirely within syringe barrel 21 when the selfcontained disposable syringe 20 is in the sealed packaged condition. A plurality of spaced longitudinal ribs 38' extend almost the entire length of plunger 23 with the exception of its forward end portion. These ribs 38' serve to rigidify plunger 23 and also form an engaging surface for shield 24 when it is connected to plunger 23 to form the finger gripping portion of plunger 23 when the syringe is opened and prepared for use. A retaining lug 55 is on the plunger adjacent the rear end thereof to assist in maintaining shield 24 in position on the rear end of plunger 23 during use. Lug 55 engages with the inner surface of the forward portion of the shield in a tight frictional engagement to provide increased retention force to hold the shield in position on the plunger.

The forward end portion of plunger 23 is in the form of a small diameter cylindrical projection 38 terminating in a flanged tip 39. The point of engagement between projection 38 and flanged tip 39 forms a shoulder 40 to facilitate engagement and retention of a flexible stopper 41 mounted on the forward end of plunger 23. Stopper 41 may be constructed of any common type of elastomeric material commonly used in the art today such as a flexible rubber or plastic material. Furthermore, alternatively, the stopper may be formed integrally with the plunger as one member. Stopper 41 has a recess 42 interiorly thereof to receive flanged tip 39 as shown in the drawings. In this manner, stopper 41 is mounted to plunger 23 and is moved longitudinally within barrel 21 as plunger 23 is moved longitudinally within barrel 21. A pair of annular projections 43 on stopper 41 frictionally engage with the inner surface of syringe barrel 21 to form a sealing surface therebetween so that when plunger 23 is withdrawn in a normal manner, fluid may be drawn into the cavity 44 formed between the forward tip of stopper 41 and the rear end 31 of cannula 22. It can be readily seen that the steps of operating the syringe are similar to those employed in the operation of syringes of this type.

Turning to needle shield 24, which also may be constructed of a common type of plastic material, it will be noted that the main body portion 45 is cylindrical in configuration and has substantially the same inner and outer diameter as a portion of syringe barrel 21. This provides for a substantial uniform diameter intermediate the end portions of the syringe assembly 20 when in its sealed condition. In this sealed condition, needle shield 24 has one end proximal the syringe barrel 21 and one end distal the syringe barrel 21. The distal end 46 has a flange on the circumference of its outer edge to receive sealing means 25 by an adhesive bond or other common fastening means. The proximal end 47 has a reduced outer diameter substantially less than the outer diameter of the main body portion 45 of needle shield 24. This reduced end portion 47 of needle shield 24 is substantially cylindrical in configuration. The outer surface of reduced end portion 47 has a pair of annular rings 48 in parallel relationship to one another and projecting therefrom. The resultant outer diameter on reduced portion 47 provided by annular rings 48 and the engagement between the inner diameter of skirt 32 form a tight frictional engagement when reduced end portion 47 is inserted into recess 33 provided between skirt 32 and reduced forward portion 27 of syringe barrel 21. The engagement occurs with sufficient friction so that when the deformation of rings 48 occurs, reduced proximal end 47 will snap into position within the forward end of syringe barrel 21 thereby forming a seal therebetween thereby preventing contamination of needle 22.

As shown in FIG. 1, the ends may be sealed by means 25 and 26 at each end of disposable syringe 20 respectively. The type of material utilized for sealing means 25 and 26 may vary according to the type of sterilization process used. If the disposable syringe 20 is to be gas sterilized, the material utilized for sealing means 25 and 26 would be in the form of a porous paper which is gas permeable and which will maintain sterility after the gas sterilization process. Naturally the gas sterilization process utilized is one commonly known in the art. If other methods of sterilization are to be employed such as by radiation, sealing means 25 and 26 may take the form of an impermeable paper, plastic, paper-foil, laminate or other similar material in which case the syringe would be hermetically sealed and sterilized. Naturally, if this method is to be employed, sealing means 25 may be eliminated and the main portion of shield 24 including its distal end 46 may be formed of an integral plastic material. The shown design configuration would be changed to facilitate manufacture of shield 24. The reason this may be accomplished will be discussed below when it will be readily seen that there is no necessity that the distal end 46 of needle shield 24 be opened for operation of the syringe. However, for purposes of the embodiment shown in FIGS. 1 and 2 sealing means 25 and 26 are in the form of a gas permeable paper and disposable syringe 20 as shown in FIG. 1 has been gas sterilized and appears in its sealed condition.

It also should be noted that there may or may not be engagement between the forward lip 48' of syringe barrel 21 and shoulder 49 fall at the juncture between reduced proximal end 47 and main body portion 45 of needle shield 44. Engagement between rim 48' and shoulder 49 indicates that needle shield 24 is completely seated within recess 33 of syringe barrel 21. However, as can be seen from FIG. 1, the sealing engagement substantially occurs between the outer rings 48 on proximal end 47 and the inner surface of skirt 32. It should also be noted that an opening 50 is provided to permit communication with the hollow cylindrical proximal end 47 and the main body portion 45 of needle shield 24. As depicted, this facilitates reception of needle 22 within needle shield 24 through opening 50. It should also be kept in mind that in addition to the use of a gas permeable paper for sealing means 25 and 26 when gas sterilization is employed, a gas permeable plastic material such as nylon may also be utilized. When sealing means 25 and 26 takes the form as shown in FIG. 1, it may be bonded to the respective ends of syringe assembly 20 by any common means. Furthermore, it is not necessary even for gas sterilization that sealing means 25 be at the distal end 46 of needle shield 24. When the disposable syringe 20 is shown in its sealed and packaged condition as in FIG. 1, a heat mark 51 may be located at the juncture of rim 48' and shoulder 49 so as to be utilized as a tamper-proof indicator thereby providing a readily usable means of determining if the sterility of the interior of disposable syringe 20 may have been affected by previous removal of shield 24.

No additional components are required to provide a completely packaged, self-contained disposable syringe 20 as shown in FIG. 1. Needle shield 24 performs the usual function

of protecting the needle from damage and in addition it protects the sterility of the needle, and as will be discussed in greater detail below provides for an extension to plunger rod **23** permitting it to be used in a normal manner when the syringe is opened and used. It should be kept in mind that the plunger prior to use is preferably enclosed completely within syringe barrel **21** thus allowing sealing means **26** to be positioned over the rear end of syringe barrel **21** to assist in providing sterility protection and if so desired, a hermetic seal.

FIG. **2** illustrates the self-contained disposable syringe in unpackaged condition and ready for immediate use. All that need be done to accomplish this positioning is to withdraw needle shield **24** from the forward end of syringe barrel **21** by supplying sufficient force to overcome the frictional engagement between proximal end **47** and the forward end of syringe barrel **21**. Needle shield **24** may then be inverted and projected onto the rear end portion of plunger **23**. This exposes needle **22** for projection into whatever medium is desired.

The unpackaging of syringe **20** may be accomplished in a one-step operation, that is by merely removing needle shield **24** from its sealing position at the forward end of syringe barrel **21** and by removing sealing means **26** and engaging proximal end **47** of needle shield **24** with the rear end of plunger **23**. The syringe is then ready for operation with finger gripping means being provided on the main body portion **45** of needle shield **24** and flanges **37** on syringe barrel **21**. In fact, in order to assist the gripping surface provided by body portion **45** of needle shield **24** there are a plurality of spaced longitudinal ribs **52** on the outer circumference of body portion **45** of needle shield **25**.

If desired, sealing means **26** may first be removed before shield **24** is positioned on plunger **23** rather than just merely punctured. To facilitate this step, a tab **53** as shown in FIG. **1** may be provided to facilitate the removal of sealing means **26** from the rear surface of the syringe barrel **21** to which it is fastened by common means such as an adhesive.

The engagement between the proximal end **47** of needle shield **24** and the rear end of plunger **23** is by means of a frictional engagement between the inner surface of proximal reduced end **47** and the outer surface of ribs **38** on plunger **23**. The frictional engagement may be of a tight nature due to the deformability of the plastic members so that a snap-on result may once again be achieved thereby providing a positive engagement so that when needle shield **24** is moved longitudinally plunger **23** will simultaneously be moved longitudinally and there will be little or no danger of disengagement therebetween. As previously discussed, to facilitate reception of part of body portion **45** of needle shield **24** within syringe barrel **21** the rear portion **35** of syringe barrel **21** is of an expanded inner and outer diameter. This also facilitates the rapid and easy engagement between needle shield **24** and plunger **23** as well as the reception of body portion **45** of needle shield **24** within the forward end portion of syringe barrel **21**. Since it is not necessary to provide a sealing engagement within syringe barrel **21** where needle shield **24** engages with plunger **23**, this engagement may take a variety of forms in addition to the one described above as long as the engagement can be easily made and will facilitate the movement of plunger **23** as needle shield **24** is moved. There are many types of frictional or snap-on engagements well known in the art as well as threaded connections which may be employed to achieve substantially the same result. All that need be kept in mind is that a rapid and easy engagement be achieved to facilitate rapid and efficient transfer of the self-contained disposable syringe **20** from a sealed packaged condition to an opened ready to use condition.

As shown in FIG. **2**, syringe **20** is in a ready to use position whereby the puncture end **30** of needle **22** may then be inserted into a fluid source and connected needle shield **24** and plunger **23** may be withdrawn thereby withdrawing connected stopper **41** and drawing fluid into recess **44** of syringe **21** through needle **22** until the desired amount has been collected. Needle **22** may then be withdrawn from the source of the fluid and combined needle shield **24** and plunger **23** may be projected forward thereby projecting stopper **41** forward and ejecting the fluid through needle **22** into its ultimate reception area. The tapered forward end of the main body portion of syringe barrel **21** facilitates the flow of fluid in both directions through needle **22** as stopper **41** is moved along the interior of syringe barrel **21**. As shown, the forward end portion of stopper **41** may assume a configuration which approximates the configuration of the tapered forward portion of barrel **21** to assist in projecting the greatest possible amount of fluid from within syringe barrel **21**. As previously discussed, the sealing engagement between annular projections **43** on stopper **41** and the inner surface of barrel **21** prevents passage of fluid or air between the forward and rear ends of stopper **41**.

Since the syringe is disposable, once it has been used it may be then discarded. All of the components are of a low cost economical material so that disposability may be readily attained due to the low cost of the syringe.

The resultant self-contained disposable syringe has a number of significant features which are obvious advantages over the known art. Among these are the fact that a minimum number of components are involved since no parts are used as a package with the exception of sealing means where necessary such as sealing means **25** and **26** as shown in FIG. **1**. This allows the syringe package combination to be manufactured for a cost approximately equal to that of the usual diSposable syringe without its package thereby saving the extra cost involved in providing a packaging means for the disposable syringe. This also facilitates the provision of a syringe having a minimum amount of bulk since there are no excess parts and thereby permits the storage of a greater number of units per given storage area.

Furthermore, the preparation prior to use of this syringe is minimized since no components need be removed and discarded. The shield can be removed from the needle and assembled to the plunger rod in one motion.

Thus, the above discussed objectives and advantages of this invention are most effectively attained.

I claim:

1. A self-contained disposable syringe comprising:

a hollow syringe barrel having a substantially cylindrical main body portion and a rear end portion having an open rear end and a larger diameter than that of said main body portion, and needle mounting means at the forward end of the barrel;

the needle having a passage therethrough communicating with the interior of the barrel;

a plunger including a stopper portion and a rod portion movable with respect to said syringe barrel and normally positioned within said barrel the rod portion being mounted to the rear portion of said stopper portion and extending rearwardly therefrom through said barrel main body portion and terminating adjacent said rear end portion when said stopper portion is positioned in the forward end of the barrel main body portion;

a needle shield having sealing means thereon to normally position said shield in sealing engagement with the forward end of said syringe barrel and in surrounding noncontacting relationship with respect to said needle so as to protect the needle from damage and loss of sterility;

removable and piercable sealing means on the rear end of the syringe barrel thereby normally providing a compact sealed self-contained disposable syringe in sterile condition and suitable for shipment and storage; and

said needle shield adapted for removal from the forward end of said barrel and adapted for engagement with the rear end of the plunger and having an external diameter to permit one end of said shield to be placed within the rear end portion of the barrel to provide an axial extension of and to form exterior finger gripping means on said plunger to facilitate the movement of said plunger with respect to said barrel when the sealed syringe is opened

for use to permit operation of the syringe without the use of any additional parts.

2. The invention in accordance with claim 1 wherein the syringe barrel has a reduced forward end portion having a bore therethrough communicating with the interior of said barrel, said needle being mounted in the bore of said reduced portion of said syringe barrel and extending forwardly therefrom, an annular skirt extending from said syringe barrel in concentric surrounding relationship with said forward reduced portion of the barrel, said shield having a substantially hollow cylindrical configuration and having a reduced one end portion, at least one annular projection on the reduced end of said shield, the reduced end of said shield having an inner diameter and an outer diameter which permits the reduced end portion of the shield to be inserted between the interior of the skirt and the exterior of the reduced forward end of the syringe barrel with tight frictional engagement between the annular projections on the reduced end of the shield and the inner surface of the skirt of the syringe barrel thereby providing a sealing engagement between the shield and the syringe barrel, a shoulder formed where the reduced end portion of the shield meets the remainder of the shield, said shoulder engaging with the forward rim of said skirt when said reduced end of said shield is engaged with said syringe barrel thereby facilitating the seating engagement between said shield and said syringe barrel.

3. The invention in accordance with claim 2 wherein said plunger has a resilient member mounted on the forward end thereof with a portion of said resilient member engaging in sealing frictional engagement with the inner wall of said syringe barrel and slidable with respect thereto to facilitate the drawing of liquid into said barrel upon retraction of said plunger and projection of said fluid from said barrel upon protraction of said plunger.

4. The invention in accordance with claim 2 wherein said plunger is cylindrical in configuration and has a plurality of spaced longitudinal ribs extending from the outer surface thereof along its entire length with the outer diameter of said ribs being less than the inner diameter of the syringe barrel located rearward of the reduced forward portion thereof, the reduced forward end of said shield having an inner diameter substantially the same as the outer diameter of the longitudinal ribs on the plunger so that when said needle shield is removed from engagement with the forward end portion of said syringe barrel and said sealing means is removed from the rear end of said syringe barrel, the reduced end portion of said needle shield may be frictionally engaged with the rear end of said plunger to thereby form said finger gripping handle for said plunger to facilitate operation of said syringe.

5. The invention in accordance with claim 2 wherein the major portion of said needle shield other than said reduced end portion has a series of longitudinal projections thereon to facilitate the gripping and handling of said needle shield when it is being removed from frictional engagement with the forward end of the said syringe barrel, when it is being brought into tight frictional engagement with the rear end of the plunger and when it is being utilized as a finger gripping means to slidably move said plunger with respect to said syringe barrel.

6. The invention in accordance with claim 2 wherein the rear end portion of said syringe barrel has a pair of diametrically opposed flanges adjacent the forward end of said larger diameter rear end portion of said syringe barrel to facilitate gripping of said syringe during use.

7. The invention in accordance with claim 1 wherein said plunger, syringe barrel and needle shield are composed of a plastic material.

8. The invention in accordance with claim 1 wherein said sealing means on the rear end of said barrel is of a gas permeable paper material adhesively engaged with the rear edge of the syringe barrel to facilitate gas sterilization of said syringe in its normal sealed condition.

9. The invention in accordance with claim 8 wherein the end of said shield distal from said reduced end portion is sealed by means of a gas permeable paper covering bonded thereto to thereby facilitate the gas sterilization of said syringe in the normally sealed condition.

10. The invention in accordance with claim 1 wherein said sealing means is composed of an impermeable material thereby facilitating the provision of a hermetically sealed syringe adapted for sterilization by radiation.

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