Oct. 22, 1968 G. H. KELLER 3,406,686

PREFILLED SYRINGE

Filed Jan. 15, 1965 3 Sheets-Sheet 1

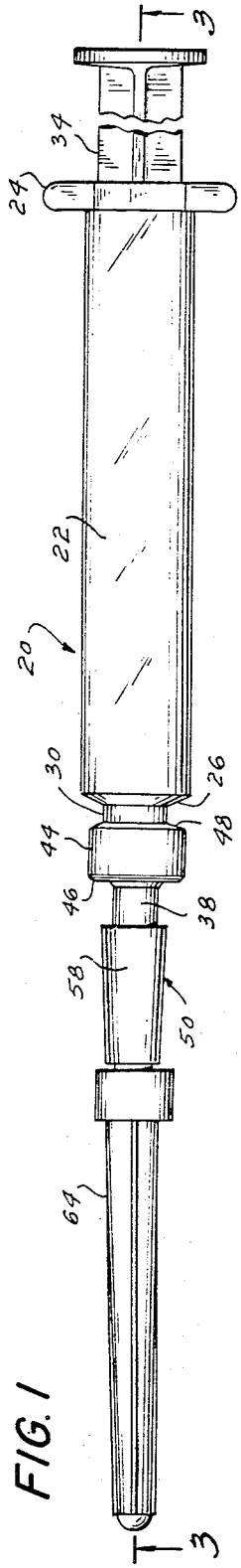

FIG. 1

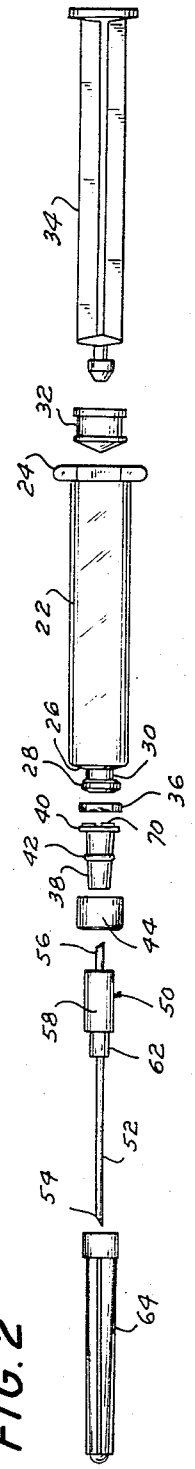

FIG. 2

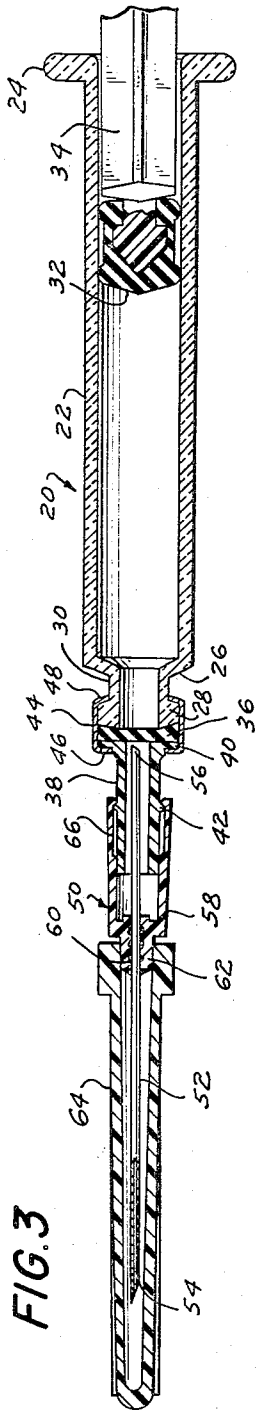

FIG. 3

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Oct. 22, 1968 G. H. KELLER 3,406,686

PREFILLED SYRINGE

Filed Jan. 15, 1965 3 Sheets-Sheet 2

FIG. 4

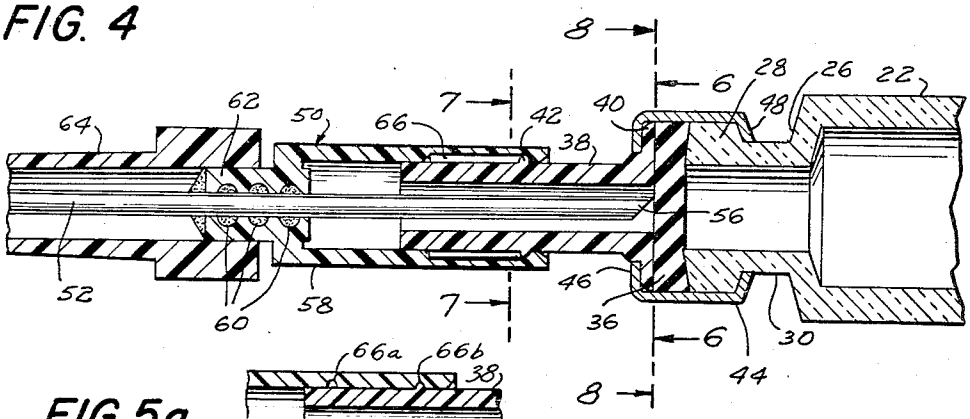


FIG. 5a

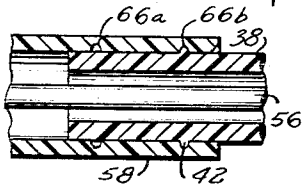


FIG. 5

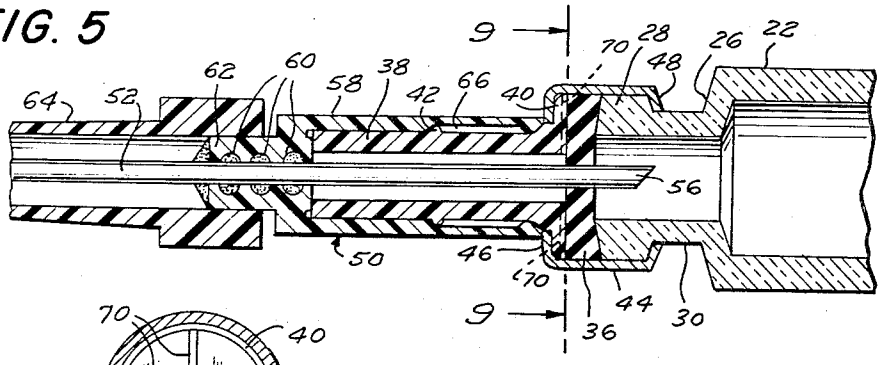


FIG. 6

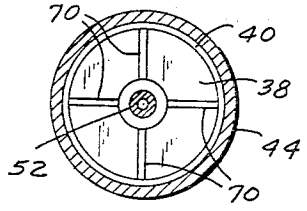


FIG. 7

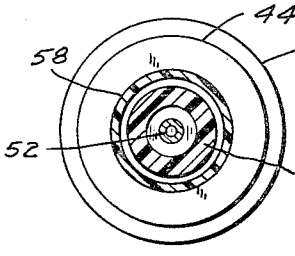


FIG. 8

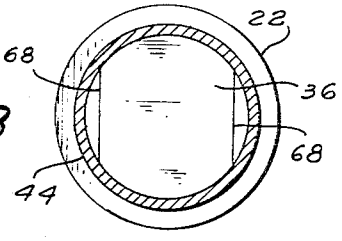
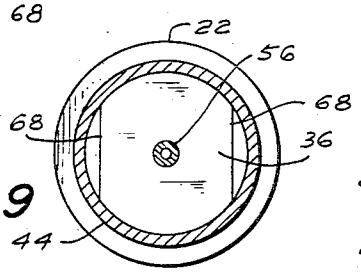


FIG. 9



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Oct. 22, 1968 G. H. KELLER 3,406,686

PREFILLED SYRINGE

Filed Jan. 15, 1965 3 Sheets-Sheet 3

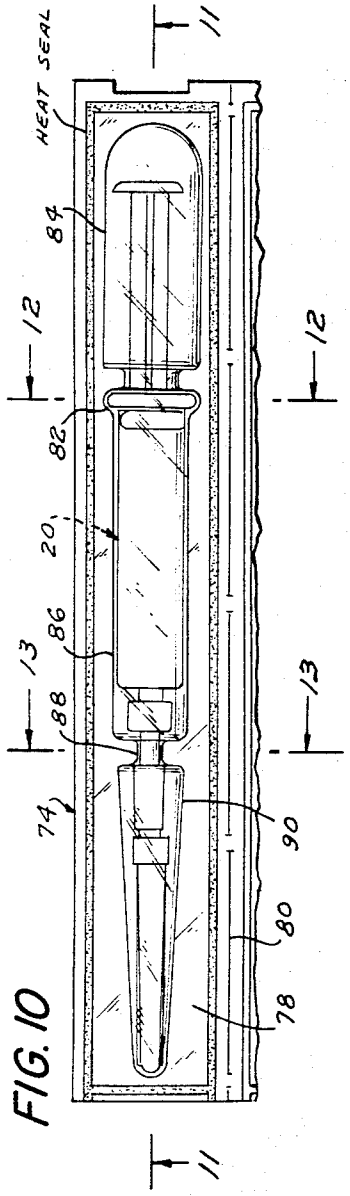

FIG. 10

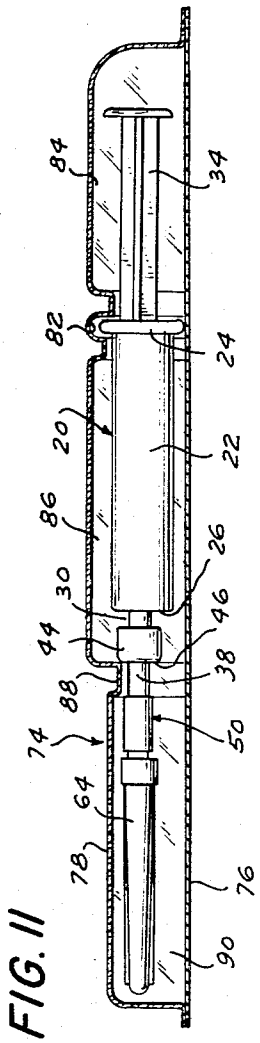

FIG. 11

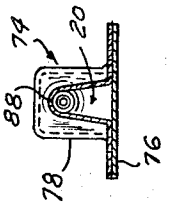

FIG. 13

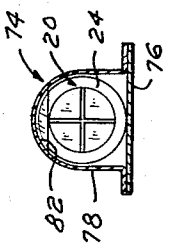

FIG. 12

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United States Patent Office 3,406,686
Patented Oct. 22, 1968

3,406,686

PREFILLED SYRINGE

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Filed Jan. 15, 1965, Ser. No. 425,786
7 Claims. (Cl. 128—218)

ABSTRACT OF THE DISCLOSURE

A prefilled syringe having a barrel to hold medicament. The rear end of the barrel is sealed by means of a rubber stopper and the forward end is sealed by means of a rubber diaphragm. A ferrule maintains the rubber diaphragm in sealing relationship and also secures a tubular hub support to the forward face of the diaphragm. A tubular hub is mounted on the exterior of the support. The hub is secured in a concentric manner on a doubled ended needle. Cooperating surfaces on the needle hub and hub support determine the armed and unarmed position of the syringe at which the inner penetrating end of the needle has penetrated the rubber diaphragm and the position at which the inner end of the needle is spaced therefrom and poised to be inserted therethrough respectively. The syringe assembly incorporates construction that permits effective gas sterilization of the syringe subassemblies prior to filling of the barrel with medicament. Additionally, a package for the assembly is provided with structure which cooperates with surfaces of the syringe to maintain the syringe in unarmed position and a needle shield protects the forward end of the needle and is mounted on the hub in a manner which facilitates arming of the syringe.

This invention relates generally to a prefilled syringe construction and, more particularly, to a syringe construction providing for separation of medicament and hypodermic needle prior to use.

In many instances, it is extremely desirable to maintain a medicament or injectable substance out of contact with all metal including that of a hypodermic needle whether or not of the stainless steel variety until such time as it is desired to perform the injection. In this connection, many of the modern day drugs have a remarkable corrosive effect on the stainless steel commonly employed for hypodermic needle constructions. With time, the degradation or corrosion is appreciable. Therefore, a prepacked or prefilled syringe ready for immediate use and having a shelf life as much as one, two, three or more years has been in extreme demand. Attempts to rectify this situation and satisfy this demand have not proven satisfactory to meet all of the commercial demands and requirements.

It is, therefore, a principal object of this invention to provide an improved prefilled syringe construction satisfying the requirements of isolation of medicament and hypodermic needle in an improved manner and until an injection is desired.

Another object is to provide a prefilled syringe construction of this type which is capable of being readily and effectively assembled following filling of the syringe barrel with medicament by the drug or pharmaceutical house and at the filling site.

A further object is to provide a prefilled syringe capable of being easily filled through a relatively wide mouth by the medicament manufacturer or supplier.

Still another object is to provide a prefilled syringe having improved structural conformation and cooperation permitting acceptable gas sterilization of syringe subassemblies and subsequent assembly under aseptic conditions following the filling operation.

A still further object is the provision of a sterile prefilled syringe capable of providing tampering evidence of the assembly and indication that the syringe does not satisfy the necessary requirements for performing optimum and safe injection of the medicament.

A prefilled syringe assembly in accordance with this invention will include a syringe barrel for containing the medicament, the rear end of the interior of the barrel being sealed by means of a rubber stopper and the forward end being sealed by means of a rubber diaphragm. A ferrule serves to maintain the rubber diaphragm in sealing relationship and, at the same time, also secures to the forward face of the diaphragm a hub support. This support is tubular in configuration and is adapted to receive on its exterior a hub secured in a concentric manner on a double bevel ended hypodermic needle. Cooperating surfaces on the needle hub and hub support determine the "armed" and "unarmed" position of the syringe at which the inner penetrating end of the needle has penetrated the rubber diaphragm to communicate its lumen with the interior of the barrel and the position at which the inner end of the needle is spaced from the diaphragm and poised to be inserted therethrough, respectively. A needle shield protects the forward penetrating end of the needle and is mounted on the hub in a manner to facilitate arming of the syringe.

The syringe assembly incorporates construction that permits effective gas sterilization of the syringe subassemblies prior to the filling or charging of the interior of the barrel with the selected medicament. Towards this end, the rubber diaphragm and rear end of the hub support cooperate with the ferrule in providing ports and passageways for access of the gas in order that it may be exposed to the necessary internal surfaces of this forward subassembly.

In order to assure the maintenance of sterility of the prepackaged assembly, tamper evidence is additionally introduced and, consequently, assurance that the assembly is in fact ready for a hypodermic injection. In this connection, the structure creating the tamper evidence, in accordance with the present invention, may assume one of a number of different forms. The disclosed structure is in the packaging of the syringe assembly. This package cooperates with surfaces of the syringe assembly in maintaining the syringe unarmed position. If the parts of the syringe are in other than that permitted by the surfaces of the package, an indication will be provided of the arming of the syringe and/or failure of the intended sealed and sterile condition of the assembly.

Other objects and advantages will become apparent from the detailed description which is to be taken in conjunction with the accompanying drawings illustrating somewhat preferred embodiments of this invention and in which:

FIG. 1 is a side elevational view of a prepackaged syringe incorporating the teachings of the present invention;

FIG. 2 is an exploded elevational view thereof;

FIG. 3 is a longitudinal sectional view thereof along the line 3—3 of FIG. 1;

FIG. 4 is an enlarged fragmentary sectional view showing the disposition of parts of the syringe while unarmed and poised ready for penetration of the sealing diaphragm;

FIG. 5 is a similar view showing the disposition of parts upon arming of the syringe with the inner end of the needle penetrating the diaphragm;

FIG. 5A is a fragmentary sectional view showing an alternative form of construction for determining the syringe armed and unarmed positions;

FIG. 6 is a cross-sectional view taken along the line 6—6 of FIG. 4;

FIG. 7 is a cross-sectional view taken along the line 7—7 of FIG. 4;

FIG. 8 is a cross-sectional view taken along the line 8—8 of FIG. 4;

FIG. 9 is a cross-sectional view taken along the line 9—9 of FIG. 5;

FIG. 10 is a top plan view of the syringe assembly packaged in accordance with an exemplary embodiment of the tamperproof provisions of this invention;

FIG. 11 is a longitudinal sectional view taken along the line 11—11 of FIG. 10;

FIG. 12 is a cross-sectional view taken along the line 12—12 of FIG. 10; and

FIG. 13 is a cross-sectional view taken along the line 13—13 of FIG. 10.

In the drawings, a prefilled syringe **20** is shown in assembled condition containing a medicament or other preparation which, in a number of contemplated applications, is preferably out of contact with the typically employed stainless steel hypodermic needle. The medicament is adapted to be contained in a barrel **22** having a rear flanged end **24** and a forward reduced tip **26** having a flanged end **28** and inner groove **30**. The rear end of the interior of the barrel **22** is adapted to be sealed or closed by means of a rubber stopper **32** which may have one of a number of fittings for engagement with a plunger **34** in order to act as a piston in expelling the contents of the barrel. It will be appreciated that the barrel having this rearwardly located stopper **32** may be aseptically filled with the selected medicament through the relatively wide mouth of the tip **26** following sterilization. The sterile forward subassembly may then be aseptically assembled on the tip **26**.

In accordance with the present invention, the forward end of the syringe barrel **22** is sealed by a penetratable rubber diaphragm **36**. This diaphragm is effective in sealing off the bore of the tip and is adapted to be penetrated by the inner end of a double ended needle for purposes of providing access to this bore and, consequently, the contents of the barrel. A tubular hub support **38** is disposed forwardly of the diaphragm **36** and is formed with a radially extending flange **40** at its rear end for association directly with the forward face of the diaphragm. At an intermediate location, a radial rib **42** is provided on the exterior of the tubular wall of the support for cooperating with surfaces of a hypodermic hub in determining the syringe "unarmed" and "armed" positions. A ferrule **44**, which may partake of aluminum, is adapted to secure both the support **38** and the diaphragm **36** to the tip **26**. In this connection, a radially inwardly extending flange **46** engages the forward face of the radial flange **40** of the support, with the rear end of the ferrule adapted to be crimped or suitably worked to provide a retaining lip **48** which engages with the rear of the tip flange **28**. It should be understood at this juncture that neither the tip **26** nor the exterior surfaces of the ferrule **44** can serve to receive or cooperate with the typical hub of a hypodermic needle assembly for purposes of defining an "unarmed" and "armed" surface in an acceptable manner. This results from the experienced difficulty in maintaining acceptable tolerances of the outer dimensions of the tip **26** incident to modern day glass working techniques. With this in mind, the nedle hub would have a poor fit with the glass tip and, in most instances, would be "wobbly" thereby detracting both structurally and functionally from acceptable syringe construction and certainly would raise some question as to whether a proper injection can be made.

A hypodermic needle assembly **50** having particular application along with this invention comprising a cannula **52** having a forward bevelled penetrating end **54** and a rear bevelled penetrating end **56**. This cannula or needle **52** is secured to a hub **58**. A number of strategically located recesses **60** for receiving a suitable adhesive having bonding affinity for the cannula **52** serves to facilitate this securement both through bonding and the mechanical interlock of this construction. An epoxy bonding system has proven satisfactory particularly in those instances when a stainless steel cannula **52** is employed. The forward end **62** of the hub **58** is in the form of a reduced boss providing a surface cooperable with a protective needle shield **64**, as shown. The rear end of the hub **58** is opened and is adapted to advantageously fit over the forward tubular portion of the hub support **38**. An annular recess **66** in the hub **50** is adapted to receive the radial rib **42** in cooperating therewith for purposes of determining the desired forward extreme of the needle assembly **50** at which the inner penetrating end **56** of the cannula is poised for penetration of the diaphragm **36** and the inner penetrating position at which the inner bevelled end **56** penetrates the diaphragm **36** to thereby expose the contents of the barrel **22** for injection purposes. Naturally, instead of a single enlarged recess **66**, a pair of spaced accommodating grooves for the radial rib **42** could have been provided. This alternative embodiment which in some instances is preferred is illustrated in FIG. 5A. The inherent resiliency and elasticity of most synthetic organic resins from which the hub **52** is ordinarily fabricated would permit this form of cooperating structure. This rib and groove arrangement defines the "unarmed" and "armed" positions. A positive position for the "armed" condition facilitates shield removal and minimizes the possibility of unarming an "armed" syringe.

Prior to filling of the syringe and assembly of the forward and rear parts, as shown in the several views, it is extremely desirable to provide means for sterilizing the forward and rear parts or subassemblies of the unit. An effective technique today is that of gas sterilization. The construction of this invention lends itself most readily to this approach. In this connection in the forward subassembly, the diaphragm **36** is provided with one or more peripheral cutout sectors **68**. The inner or rear face of the flange **40** of the hub support **38** is provided with a network of radial slots **70**. In this manner, the gas employed in the selected sterilizing technique will be permitted to penetrate between the ferrule **44**, the cutout sectors **68**, the radial slots **70** and hypodermic needle **52**, its lumen and exterior surfaces. It should be understood that the radial slots will be closed by the diaphragm **36** due to the nature of the diaphragm material upon assembly of this forward subassembly on the barrel tip **26**.

The barrel **22** and rear stopper **32**, constituting the rear subassembly, will also have been sterilized in a suitable manner. The barrel **22** with stopper is then filled with the selected medicament while maintaining steriliity. The sterile forward and rear parts of the syringe unit are then assembled under aseptic conditions.

In this manner, a sterile prefilled hypodermic syringe assembly **20** of improved construction and operation is contributed to the art.

Referring now to the packaging of the syringe assembly **20** and particularly the exemplary embodiment of tamper evidence contemplated herein, this assumes the form of a package of the prefilled syringe **20**. This package **74** comprises a backing sheet **76** and a molded syringe contour receiving tray **78** suitably bonded thereto. The sheet **76** may be formed of a suitable paper which permits penetration of gas during ordinary gas sterilization techniques and of a type which facilitates the desired tamperproof evidence. This sheet **76** is covered with a heat sealable material or a suitable bonding agent for adherence with the material of the tray **78** which in a successful application of this invention was styrene. A number of prefilled syringes **20** may be packaged simultaneously by employing elongated sheets and a molded series of trays in accordance with mass production techniques. Under these circumstances, the spaced prefilled packaged syringes may be readily separated from one another by means of interrupted slits **80** of a design to allow easy separation of the syringe units.

Referring now to the tray **78**, it will be noted that it

forms, together with the backing sheet **76**, a number of compartments which receive the various parts of the syringe **20**. Thus, an annular groove **82** is provided for receiving the flanged end **24** of the barrel **22** in cooperating to fix the disposition of the syringe in the package **74**. A compartment **84** to the rear of the groove **82** accommodates the exposed portions of the plunger **34**. An intermediate compartment **86** accommodates the barrel **22** as well as its tip **26** together with the ferrule **44**, mounted thereon. An annular reduced neck **88** of the molded tray **78** advantageously nests into the space between the rear end of the hub **50** and the forward face of the inwardly extending radial flange **46** of the ferrule **44**. In this manner, the unarmed condition of the syringe **20** is maintained and assured during packaging and immediately prior to use. In the event the reduced neck **88** is not in the described and illustrated nesting relationship with respect to the needle hub and ferrule, a sign is immediately created which may cast doubt as to the condition of the syringe and its sterility. A failure of the desired nesting could indicate tampering of the syringe as well as its package. The forward compartment **90** accommodates the forward part of the needle assembly **50** as well as the shield **64** in a manner to assure the desired association of these parts with the remainder of the syringe **20**.

Assuming the tamper evidence does not indicate a breakdown of any sort in the desired relationship of parts and the maintenance of sterile conditions, the syringe **20** may be utilized by merely stripping the sheet **76** away from its associated tray **78** to expose the contained syringe **20**. The syringe **20** may now be armed by forcing the needle assembly rearwardly by applying a deliberate force thereto through the shield **64** to cause the inner penetrating end **56** of the needle **52** to penetrate the diaphragm **36** affording communication between the interior of the barrel **22** and its contained medicament and the lumen of the needle. The shield **64** may now be removed to expose the outer penetrating end **54** of the needle. The needle will then be caused to penetrate the skin tissue at the desired location and the plunger **34** depressed or forced forwardly to expel the contained medicament.

Thus, it will be appreciated by those skilled in the art that the aforenoted objects and advantages amongst others are most effectively attained by means of the present invention. The prepackaged medicament is rather effectively separated from the hypodermic needle during storage and the contemplated shelf life of the syringe to eliminate any problem of corrosion or degradation of the needle or possible deleterious effect on the packaged medicament. In those contemplated rare instances where the material of the diaphragm **36** may have an adverse affect on the contained medicament, an inert or nontoxic type of shield or diaphragm may be interposed between the rubber diaphragm **36** and the forward face of the barrel tip flange **28** or, for that matter, substituted for this diaphragm. An exemplary satisfactory material for this shield would be in the nature of Teflon.

Although a single somewhat preferred embodiment of this invention has been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby and its scope is to be taken by that of the appended claims.

I claim:

1. A prepackaged syringe assembly comprising a tubular barrel containing a medicament and having a restricted forward flanged end and rear end, a plunger closing the rear end of the barrel, a penetrable diaphragm sealing the forward end of the barrel, a plastic needle hub support of tubular configuration having a substantially uniform inner diameter along its length and having a radially outwardly extending flange at its rear end disposed against the diaphragm, a ferrule securing both the support and diaphragm to the barrel flanged forward end, a double pointed hypodermic needle having its rear end proximal the forward face of the diaphragm, a hub having a reduced forward end secured by epoxy resin intermediate the needle ends and having a rear end tubular in configuration in substantial concentric relation with respect to the needle, the tubular rear end of the hub being disposed over the forward end of the hub support in substantial telescopic and sliding relationship such that substantially all of the surface of said rear end of the hub which engages with the forward end of the hub support is positioned over the outer surface of the forward end of the hub support, an annular rim on the outer face of the hub support intermediate its ends and an annular recess on the inner face of the tubular rear end of the hub which interengage and operate to determine the syringe unarmed position at which said rear end of the needle is proximal the forward face of the diaphragm and an unarmed position at which the rear end of the needle is forced to penetrate the diaphragm upon application of deliberate force to the hub to communicate the lumen of the needle with the interior of the barrel, a protective needle shield disposed around the forward end of the needle and has a closed forward end and an open rear end, said rear end being mounted on the reduced forward end portion of the needle hub, and finger gripping means on the hub permitting the hub to be gripped and the shield stripped therefrom.

2. The invention in accordance with claim **1** wherein a tamper-evidence means is associated with the syringe for indicating a predetermined unarmed disposition of parts of said syringe, said tamper-evidenced means being a package within which the syringe is encased, said package having separate and sealed parts and positioning means for positioning the syringe in the package in a predetermined manner and spacing means defined by surfaces of the package to determine a predetermined selected relationship between the rear end of the hub and forward face of the ferrule, said parts comprise a substantially flat sheet and a molded tray heat sealed to said sheet and conforming generally to the outline of said syringe.

3. A hypodermic needle, hub and support assembly for attachment to the forward restricted flanged end of a tubular syringe barrel adapted to contain a medicament, said assembly comprising a penetrable diaphragm adapted to seal the forward end of the barrel, a plastic needle hub support of tubular configuration having a substantially uniform inner diameter along its length and having a radially outwardly extending flange at its rear end disposed against the diaphragm, a ferrule associated with both the support and diaphragm for securing both the support and diaphragm to the barrel flanged forward end, a double pointed hypodermic needle having its rear end proximal the forward face of the diaphragm, a hub having a reduced forward end secured by epoxy resin intermediate the needle ends and having a rear end tubular in configuration in substantial concentric relation with respect to the needle, the tubular rear end of the hub being disposed over the forward end of the hub support in a substantial telescopic and sliding relationship such that substantially all of the surface of said rear end of the hub which engages with the forward end of the hub support is positioned over the outer surface of the forward end of the hub support, an annular rim on the outer face of the hub support intermediate its end and an annular recess on the inner face of the tubular rear end of the hub which interengage and operate to determine the syringe unarmed position at which the rear end of the needle is proximal the forward face of the diaphragm and an armed position at which the rear end of the needle is forced to penetrate the diaphragm upon application of deliberate force to the hub to communicate the lumen of the needle with the interior of the barrel, a protective needle shield disposed around the forward end of the needle and having a closed forward end and an open rear end, said rear end being mounted on the reduced forward end of the needle hub, and finger gripping means

on the hub permitting the hub to be gripped and the shield stripped therefrom.

4. A hypodermic needle, hub and support assembly for attachment to the forward restricted flanged end of a tubular syringe barrel adapted to contain a medicament, said assembly comprising a penetrable diaphragm adapted to seal the forward end of the barrel, a needle hub support of tubular configuration having a radially outwardly extending flange at its rear end disposed against the diaphragm, a ferrule associated with both the support and diaphragm for securing both the support and diaphragm to the barrel flange forward end, a double pointed hypodermic needle having its rear end proximal the forward face of the diaphragm, a hub having a forward end secured intermediate the needle ends and having a rear end tubular in configuration in substantial concentric relation with respect to the needle, the tubular rear end of the hub being disposed over the forward end of the hub support in a substantial telescopic and sliding relationship, the inner face of the tubular end of the hub and the outer face of the forward end of the support presenting annular raised and recessed portions which operate to determine the syringe unarmed position at which the rear end of the needle is proximal the forward face of the diaphragm and armed position at which the rear end of the needle is forced to penetrate the diaphragm upon application of deliberate force to the hub to communicate the lumen of the needle with the interior of the barrel, a protective needle shield disposed around the forward end of the needle and having a closed forward end and an open rear end, said rear end being mounted on the forward end of the needle hub, surfaces on said diaphragm and the rear support flange being recessed and raised to define gas passageways for facilitating gas sterilization of said syringe.

5. A hypodermic needle, hub and support assembly for attachment to the forward restricted flanged end of a tubular syringe barrel adapted to contain a medicament, said assembly comprising a penetrable diaphragm adapted to seal the forward end of the barrel, a needle hub support of tubular configuration having a radially outwardly extending flange at its rear end disposed against the diaphragm, a ferrule associated with both the support and diaphragm for securing both the support and diaphragm to the barrel flanged forward end, a double pointed hypodermic needle having its rear end proximal the forward face of the diaphragm, a hub having a forward end secured intermediate the needle ends and having a rear end tubular in configuration in substantial concentric relation with respect to the needle, the tubular rear end of the hub being disposed over the forward end of the hub support in a substantial telescopic and sliding relationship, the inner face of the tubular rear end of the hub and the outer face of the forward end of the support presenting annular raised and recessed portions which operate to determine the syringe unarmed position at which the rear end of the needle is proximal the forward face of the diaphragm and unarmed position at which the rear end of the needle is forced to penetrate the diaphragm upon application of deliberate force to the hub to communicate the lumen of the needle with the interior of the barrel, a protective needle shield disposed around the forward end of the needle and having a closed forward end and an open rear end, said rear end being mounted on the forward end of the needle hub, surfaces on said diaphragm and the rear support flange being recessed and raised to define gas passageways for facilitating gas sterilization of said syringe, the periphery of said diaphragm being cut out and the rear face of the rear support flange being provided with at least one recess adapted to communicate with both surfaces of said needle and the cutout.

6. A hypodermic needle, hub and support assembly for attachment to the forward restricted flanged end of a tubular syringe barrel adapted to contain a medicament, said assembly comprising a pentrable diaphragm adapted to seal the forward end of the barrel, a needle hub support of tubular configuration having a radially outwardly extending flange at its rear end disposed against the diaphragm, a ferrule associated with both the support and the diaphragm for receiving both the support and diaphragm to the barrel flanged forward end, a double pointed hypodermic needle having its rear end proximal the forward face of the diaphragm, a hub having a forward end secured intermediate the needle ends and having a rear end tubular in configuration in substantial concentric relation with the respect to the needle, the tubular rear end of the hub being disposed over the forward end of the hub support in a substantial telescopic and sliding relationship, the inner face of the tubular rear end of the hub and the outer face of the forward end of the support presenting annular raised and recessed portions which operate to determine the syringe unarmed position at which the rear end of the needle is proximal the forward face of the diaphragm and an armed position at which the rear end of the needle is forced to penetrate the diaphragm upon application of deliberate force to the hub to communicate the lumen of the needle with the interior of the barrel, surfaces of said diaphragm and the rear support flange being recessed and raised to define gas passageways for facilitating gas sterilization of said syringe.

7. A hypodermic needle, hub and support assembly for attachment to the forward restricted flanged end of a tubular syringe barrel adapted to contain a medicament, said assembly comprising a penetrable diaphragm adapted to seal the forward end of the barrel, a needle hub support of tubular configuration having a radially outwardly extending flange at its rear end disposed against the diaphragm, a ferrule associated with both the support and the diaphragm for securing both the support and the diaphragm to the barrel flanged forward end, a double pointed hypodermic needle having its rear end proximal the forward face of the diaphragm, a hub having a forward end secured intermediate the needle ends and having a rear end tubular in configuration in substantial concentric relation with respect to the needle, the tubular rear end of the hub being disposed over the forward end of the hub support in a substantial telescopic and sliding relationship, the inner face of the tubular rear end of the hub and the outer face of the forward end of the support presenting annular raised and recessed portions which operate to determine the syringe unarmed position at which the rear end of the needle is proximal the forward face of the diaphragm and an armed position at which the rear end of the needle is forced to penetrate the diaphragm upon application of deliberate force to the hub to communicate the lumen of the needle with the interior of the barrel, surfaces of said diaphragm and the rear support flange being recessed and raised to define gas passageways for facilitating gas sterilization of said syringe, the periphery of said diaphragm being cut out and the rear face of the rear support flange being provided with at least one recess adapted to communicate with both the surfaces of said needle and the cutout.

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