

[72] Inventor **George H. Keller**
Ridgewood, New Jersey
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 [73] Assignee **Becton, Dickinson and Company**
East Rutherford, New Jersey
a corporation of New Jersey

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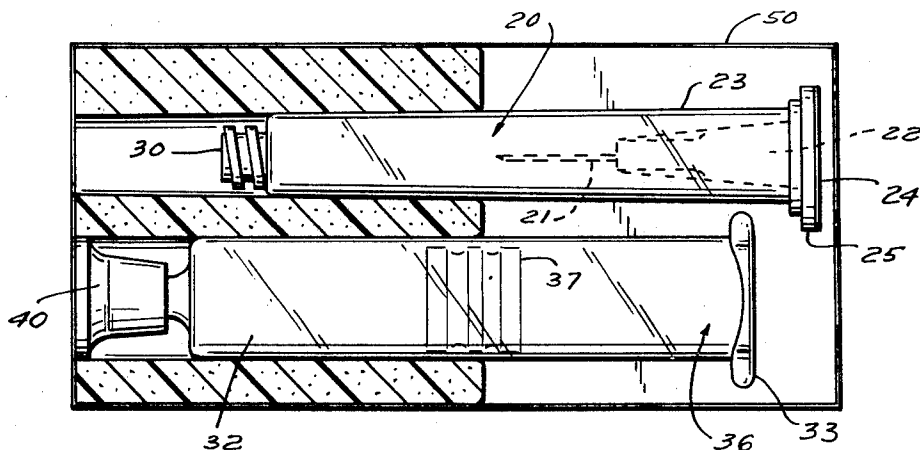
Primary Examiner—William T. Dixon, Jr.
Attorney—Kane, Dalsimer, Kane, Sullivan and Kurucz

[54] **SELF-CONTAINED PACKAGED NEEDLE ASSEMBLY**
10 Claims, 11 Drawing Figs.

[52] **U.S. Cl.**..... **206/63.2,**
128/218, 206/43
 [51] **Int. Cl.**..... **A61b**
17/06, A61m 5/18, A61m 5/32
 [50] **Field of Search**..... **206/63.2,**
17.5, 43, 65; 128/218, 218(P); 217/35, 27

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ABSTRACT: A self-contained packaged needle assembly is provided for connection to a syringe to form a syringe assembly. A needle is mounted on a hub which in turn is adapted to be mounted on the forward end of a syringe barrel having a stopper therein. Shield means having an open end portion is removably mounted on the hub so as to encompass the needle. The open end of the shield means is adapted to receive a removable closure to thereby form a sealed package for the needle and hub. A portion of the shield means is also adapted to protect the needle when the closure is removed and the syringe barrel is connected to the hub. Finally, a portion of the shield means is adapted to be connected to the stopper to thereby form a plunger for the syringe assembly.



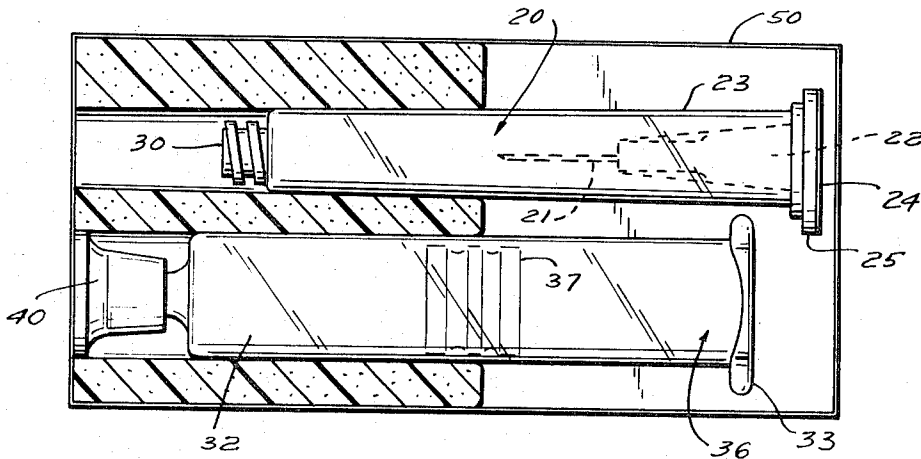


FIG. 1

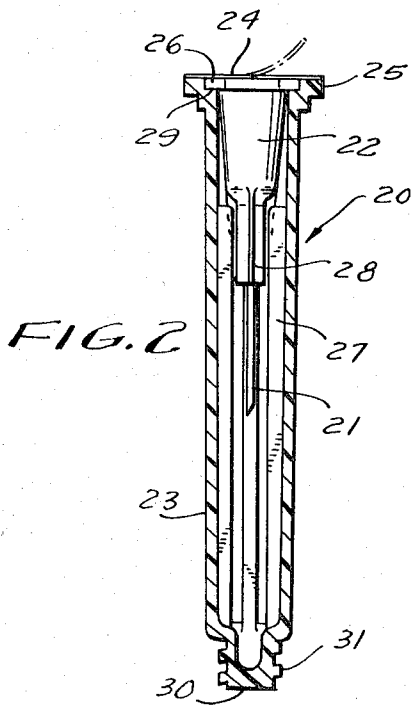


FIG. 2

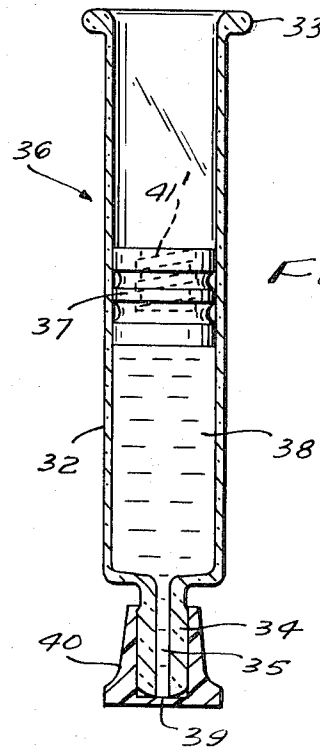


FIG. 3

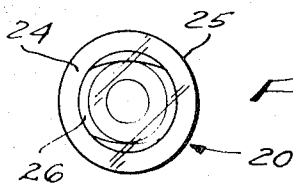


FIG. 4

INVENTOR
GEORGE H. KELLER

BY
Lane, Dehmer, Kane Sullivan & Smith
ATTORNEYS

FIG. 5

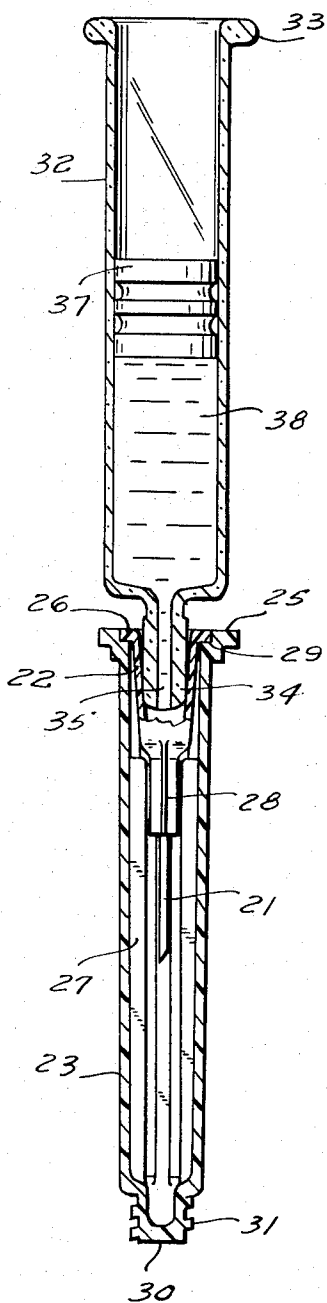


FIG. 6

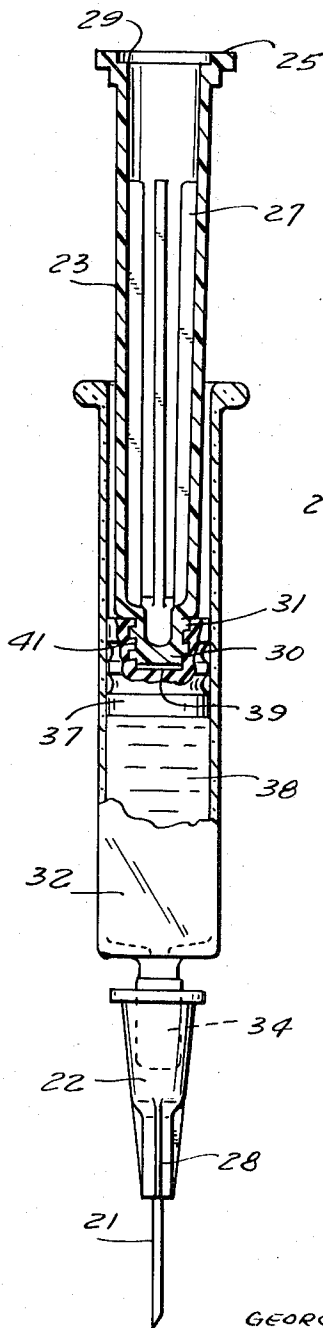
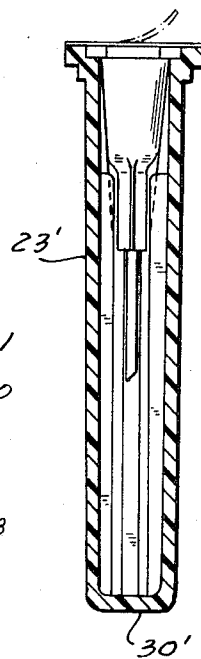


FIG. 2a



INVENTOR
GEORGE H. KELLER

BY
Kane, DeBorja, Kane, Sullivan & Smith
ATTORNEYS

FIG. 7

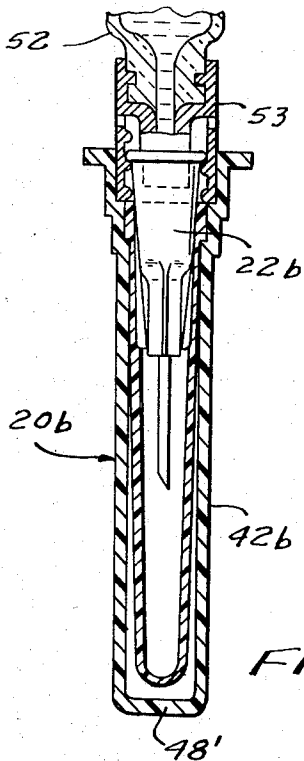
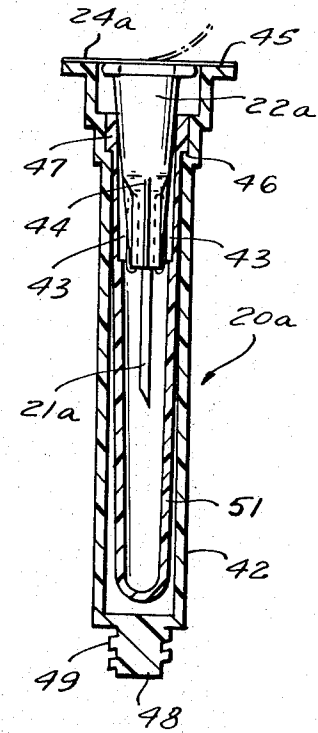


FIG. 8

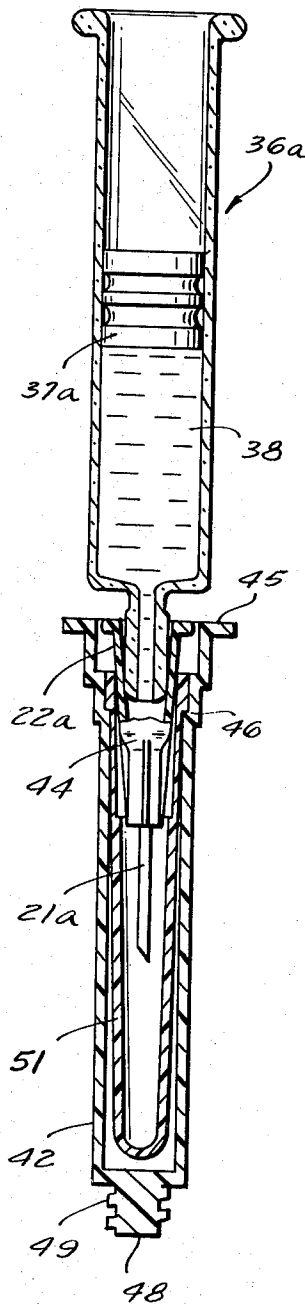
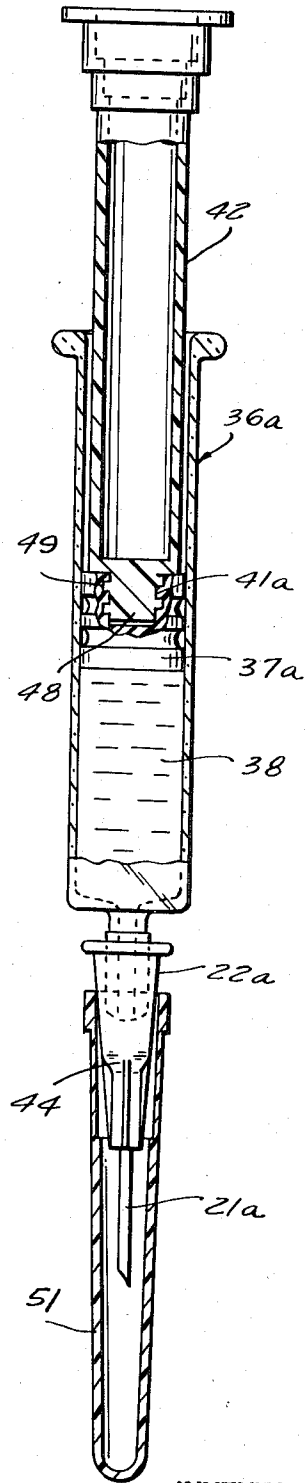


FIG. 9



INVENTOR
GEORGE H. KELLER

BY
Kane, Dahmer, Kane, Sullivan & Smith
ATTORNEYS

SELF-CONTAINED PACKAGED NEEDLE ASSEMBLY

BACKGROUND OF THE INVENTION

In the syringe and syringe assembly art, particularly in the packaging thereof, there are certain aspects that warrant consideration and concern to the manufacturer. For instance, it is important that packaging means be provided which will protect the needle portion of the syringe assembly during shipping, handling and storage often to the extent of protecting the sterility of the needle itself. It is important that the needle be protected against accidental damage prior to use and also must be retained in aseptic condition up until the time immediately prior to use. Furthermore, in syringe assemblies commonly in use in the market today, particularly those with a predetermined dose sealed in the barrel of the syringe itself, and after the syringe has been attached to the needle and hub portion to form a syringe assembly, a plunger is required to activate the syringe assembly by forcing the stopper downward into the syringe barrel and the liquid within the barrel into the needle for injection purposes. Therefore, it is readily apparent that a device which will assist in protecting the needle during handling, shipping and storage from the danger of damage or loss of sterility and which also may function as a shield for the needle and hub when it is attached to a syringe barrel and finally which will act as a plunger for the syringe assembly itself when an injection is to be made would be an extremely valuable and advantageous article in the art. This is particularly true when efficiency of operation, manufacturing, shipping and handling costs are considered. Furthermore, it would also be advantageous if the device which acts as a package, shield and plunger could be manufactured as a multimember unit so that it may function as both a shield and a plunger simultaneously. This would enable the user to protect the needle from exterior contact up until immediately prior to use. Naturally, the material which is used for the multipurpose unit would have to be of a low cost and rigid type of material to satisfy the above discussed requirements. Although there are many articles on the market which will satisfy any one or two of the above discussed functions, there appear to be none available which will satisfy the multipurpose function and use suggested above which will have a low manufacturing cost, be efficient and easy to handle and which will provide a compact and complete self-contained packaged needle assembly for shipping, storage and handling purposes. Naturally, the device envisioned would be adaptable for use with syringe barrels well known and in use in the market today.

SUMMARY OF THE INVENTION

With the above in mind, the principal objectives of this invention are to provide a self-contained packaged needle assembly wherein the shielding means functions as a package in assisting in protecting the aseptic condition of a needle contained within, protects the needle simultaneously from possible damage, will function as a shield for the needle when the needle and its hub is attached to a syringe adapted to receive it prior to use and which is removable from the needle so that it may be used as a plunger for the completed syringe assembly by means of its attachment to the stopper contained within the syringe barrel so that the entire assembly may be utilized in injecting a fluid into a patient's system. Furthermore, a multimember shield means is envisioned whereby when one portion thereof is removed to act as a plunger, another portion of the shield means will remain in protective shielding position over the needle and attached to the hub so that the needle may be completely protected even after the syringe assembly including plunger portion is connected up to and until immediately prior to use. The shield means envisioned is rigid and lightweight in construction, economical to produce, compact and efficient to use so that it may be easily manufactured, shipped, handled and stored until its use is desired. The self-contained packaged needle assembly including the novel shield means is naturally manufactured so that it is adaptable for use with common types of predetermined unit dose syringe barrels readily available and common in the art.

A self-contained packaged needle assembly is provided for connection to a syringe to form a completed syringe assembly. A needle mounted on a hub which is adapted to be mounted on the forward end of a syringe barrel containing a stopper therein is connected to the shield means having an open end portion which is removably mounted on the hub so as to encompass the needle. The open end portion of the shield means is adapted to receive a removable closure to thereby form a sealed package for the needle and hub. A portion of the shield means is adapted to protect the needle when the closure is removed and the syringe barrel is connected to the hub. A further portion of the shield means is adapted to be connected to the stopper within the syringe barrel thereby forming a plunger for the completed syringe assembly to facilitate the insertion of fluid from the syringe assembly to a patient.

Numerous other objectives and advantages will become apparent from the following detailed description which is to be taken in conjunction with the accompanying drawings illustrating somewhat preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a sectional end view of a self-contained packaged needle assembly of this invention shown in packaged relationship with a syringe with which it may be assembled for use;

FIG. 2 is a sectional elevation view of a self-contained packaged needle assembly of this invention;

FIG. 2a is a sectional elevation view of a modified form of a self-contained packaged needle assembly of this invention;

FIG. 3 is a sectional elevation view of a syringe barrel adapted to receive the assembly of FIG. 2;

FIG. 4 is a top plan view of the self-contained packaged needle assembly of FIG. 2;

FIG. 5 is a sectional elevation view of a self-contained packaged needle assembly of this invention after the closure has been removed and a syringe barrel has been connected thereto;

FIG. 6 is a sectional elevation view thereof showing the shield portion having been removed from the needle and hub and connected to the stopper in the syringe barrel thereby forming a plunger for the completed syringe assembly;

FIG. 7 is a sectional elevation view of an alternative embodiment of a self-contained packaged needle assembly of this invention;

FIG. 8 is a sectional elevation view thereof with the closure having been removed and a syringe barrel having been connected to the hub of the needle assembly;

FIG. 8a is a sectional elevation view of a modified form of the alternative embodiment with the closure having been removed and a second type of syringe barrel having been connected to the hub of the needle assembly; and

FIG. 9 is a sectional elevation view thereof with the plunger portion of the shield means having been connected to the stopper in the syringe barrel so as to form a plunger for the completed syringe assembly.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

One embodiment of the invention is depicted in FIGS. 2, 4, 5 and 6 and may be described as a self-contained packaged needle assembly including a needle 21 mounted within an opening in a hub 22 so that there is a continuous passageway from the top of hub 22 through to the tip of needle 21. Any common type of bonding means is employed for this interengagement such as an epoxy bond. A needle 21 and hub 22 are housed within tubular member 23 which may be formed of any common type of rigid plastic material. Finally, a closure 24 seals the upper end of hub 22 and member 23 so as to form a completed sealed self-contained packaged needle assembly 20. Closure 24 may also be of any common type of material to form the seal, for example, a heat sealed piece of paper has been found to perform adequately. Naturally, other bonding means will also work satisfactorily. Closure 24 is sealed to the upper peripheral lip 25 of member 23 and if

desirable in addition to the upper peripheral lip 26 of hub 22. The needle 21 and hub 22 would then be sealed within the package and then resterilized to insure that it will be contained in an aseptic condition.

For protective purposes, hub 22 and needle 21 are fixed in position within member 23 to prevent movement thereof within the package and possible damage to the needle or hub or possibly the piercing of member 23 by needle 21. This is principally accomplished by means of longitudinal internally spaced ribs 27 which are interspaced between corresponding ribs 28 on the lower portion of hub 22. In this manner, hub 22 is relatively rigidly positioned within member 23. Longitudinal ribs 27 also assist in preventing the bending or displacement of needle 21. An internal shoulder 29 formed by surfaces of member 23 near its upper end form a resting surface for peripheral lip 26 of hub 22. This interengagement between shoulder 29 and lip 26 serves two functions. First it helps to rigidly fix the needle and hub assembly within member 23 and second it holds hub 22 in rigid position when a syringe is being attached thereto. At the lower and closed end of member 23 is a tubular extension 30 which has a threaded outer surface 31 the purpose of which will be discussed below.

FIG. 3 displays a common type of syringe barrel which is adapted to be connected to the needle and hub shown for the purposes of example in this disclosure. Naturally, the principal of the self-contained packaged needle assembly of this invention is readily adaptable to many other types of well known syringe assemblies. However for demonstration purposes, it can be seen in FIG. 3 that it is comprised of a cylindrical or tubular barrel 32 having an upper open flanged end 33 and a lower tubular extension 34 adapted to receive thereon a particular size and shape hub. A passageway 35 exposes the interior of barrel 32 with the exterior of the syringe 36 at its lower end. A stopper 37 is positioned within barrel 32 at a predetermined location so as to insure that a predetermined dose of fluid 38 is located in barrel 32 between stopper 37 and the lower end 39 of syringe barrel 32. A cap 40 is positioned over the lower end 34 of syringe barrel 32 so as to be in tight frictional engagement with extension 34 and normally seal the lower end of passageway 35. Among other materials, cap 40 may be constructed of a rubber material which may be removed from extension 34 when it is desirable to attach syringe barrel 32 to a needle and hub assembly. Naturally, the syringe barrel would have to be inverted from the position shown to one with extension 34 vertically above barrel portion 32 prior to removal of cap 40 in order to prevent loss of fluid through passageway 35.

Stopper 37 may also be constructed of a rubber material as well as other known materials and contains a threaded central recess 41' extending from the stopper upper surface into its central portion. Normally, syringe barrel 32 is constructed of a glass material or any other type of materials utilized in the art.

A discussion of FIGS. 2, 5 and 6 will demonstrate how this particular embodiment of the invention functions. In FIG. 2, it is shown in phantom how closure 24 may be peeled off and removed from member 23 so as to permit access to hub 22 and break the seal thereby ending the sterile interior condition of the package 20. However, needle 21 is still well protected by member 23 and is in a relatively aseptic condition.

Rubber cap 40 is then removed from extension 34 of syringe barrel 36 which has been inverted and extension 34 is positioned within hub 22 to arrive at the position of the syringe assembly shown in FIG. 5. Under these conditions, you will note that member 23 still forms a shield for needle 21 and hub 22 to protect them from damage and also to protect the aseptic condition of needle 21. When it is then desired to administer dose 38 within syringe barrel 32, member 23 is removed from its shielding position and placed within the upper open end of syringe barrel 32 so that threaded outer surface 31 of extension 30 may be interengaged with the threaded inner surface of recess 41' of stopper 37. In this manner, member 23 now forms a plunger for the completed syringe assembly. Needle 21 may be then inserted into the patient and member 23

depressed to inject fluids 38 into the patient. From the above discussed sequence of operations it can be seen how member 23 serves three principal functions. First it provides a packaging means to aid and protect the needle and hub assembly during handling, shipping and storage prior to use, it protects the needle and hub after it has been attached to the syringe but prior to its injection into a patient and it forms a plunger for the completed syringe assembly when it is desired to inject a dose of predetermined amount of fluid into a patient.

A modification of member 23 is illustrated in FIG. 2a. The modified form is designated by the reference numeral 23' and the difference lies in the lower end of the member. Member 23' does not have an extension 30, but merely has a closed lower end 30'. Member 23' may act as plunger without being attached to stopper 37 with end 30' merely contacting the upper surface of stopper 37 or it may merely be used as a shield with a separate plunger utilized with the assembly.

An alternative embodiment is disclosed in FIGS. 7-9. In this embodiment, similar elements are designated by a subscript "a" after the same reference numeral as used in the previously discussed embodiment. Turning to FIG. 7, you will note that the self-contained packaged needle assembly 20a includes a needle 21a affixed to hub 22a. Furthermore, a closure 24a is employed similar to that in the previous embodiment. The principal difference in the embodiment lies in the shield means which together with closure 24a form the package to maintain needle 21a and hub 22a in a sterile condition. The shield means includes an inner member 51 and an outer member 42 both of tubular configuration which are in concentric relationship to one another.

The upper portion of inner member 51 engages hub 22a and fixes hub 22a in position, in particular, to the extent which hub 22a may extend within member 51. This is due principally to the tubular shape of member 51 in contrast to the conical shape of hub 22a where the upper portion of hub 22a is of a wider diameter than the inner diameter of member 51 and the lower portion of hub 22a is of a lesser diameter than the inner diameter of inner member 51. Further assisting in maintaining hub 22a and needle 21a in fixed position within member 51 are longitudinal ribs 43 which are in spaced relationship around the inner circumference of member 51 and which are interspaced between longitudinal ribs 44 on the outer surface of the lower portion of hub 22a. Conflict between ribs 43 and 44 assist in preventing rotation between hub 22a and member 51 and ribs 43 also assist in preventing hub 22a and needle 21a from moving about loosely within member 51 thereby alleviating the danger of possible damage to needle 21a or the piercing of the sidewalls of members 51 and 42. Members 51 and 42 in this position serve the same function as member 23 of the previously discussed embodiment in that they form a majority of the self-contained sealed package to maintain the sterility of needle 21a and hub 22a. In this respect, the double thickness presented by the two members 51 and 42 in contrast to the single thickness of member 23 aids in giving additional protection in this respect.

Turning to member 42, which is in complete surrounding relationship to inner member 51 and has an upper portion which further encloses the upper portion of hub 22a within a rigid member, this member 42 also has an upper peripheral lip 45 which serves to form a sealing surface for closure 24a which once again may be of a paper material heat sealed on lip 45. An internal shoulder 46 also serves to form a resting surface for the underside of the upper flanged portion 47 of inner member 51. With closure 24a in position and member 42 in position about inner member 51 this shoulder assists in maintaining inner member 51 in tight engagement with hub 22a. Furthermore, the inherent shape of outer member 42 wherein it has a slightly smaller inner diameter in its upper portion than its lower portion provides for a tight frictional engagement between outer member 42 and inner member 51 which assists in maintaining their engaging relationship in their upper areas.

It should also be noted that outer member 42 has a lower tubular extension 48 extending from its lower end which has an

outer threaded surface 49 which as will be discussed later serves a similar function to the similar extension of member 23 in the previous embodiment.

Turning to FIG. 8 when closure 24a is removed as shown in phantom in FIG. 7, a syringe barrel 36a similar to that shown in the previous embodiment may be interengaged by means of a frictional engagement within hub 22a in a similar manner as FIG. 8, the previous embodiment. At this point, as shown in FIG. 8 both inner member 51 and outer member 42 serve as a shield for needle 21a and hub 22a to maintain both the aseptic condition of these parts as well as protecting these parts from damage. It may be pointed out at this point that members 51 and 42 may be constructed of a similar material as that of member 23 in the previously discussed embodiment. Naturally, it is readily apparent that once again double members 51 and 42 afford even more protection to needle 21a than does member 23 afford to needle 21 in FIG. 5.

Then, as shown in FIG. 9, outer member 42 may be removed from inner member 51 and placed within the upper end of syringe barrel 36a. Threaded surface 49 may then be placed into threaded interengagement with threaded recess 41a of stopper 37a so that outer member 42 becomes a plunger for the completed syringe assembly. In this particular embodiment you will note that now we have a completed syringe assembly which in addition to having member 42 serve as a packaging means, a shielding means, and a plunger, we also have an additional shielding means 51 so that needle 21a may still be protected when outer member 42 is in position as a plunger. Consequently, the syringe assembly may be completed at any reasonably desired length of time prior to the time of use and the needle 21a will still be protected, then when the injection is actually desired, inner member 51 may be removed from needle 21a and needle 21a may be inserted into the patient, plunger 42 depressed and the desired dose of fluid 38 may be injected into the patient.

A modification of the alternative embodiment of FIGS. 7-9 is demonstrated as FIG. 8a. Naturally many other modifications are readily apparent. In FIG. 8a, the only difference in structure of the needle assembly, designated as 20b with the subscript b being added to all like parts as those present in needle assembly 20a, lies in the lower end 48' which has a closed flattened configuration rather than being a threaded extension. This modification is similar in construction and operation to that discussed in regard to lower ends 30 and 30' of the illustrated examples of the initially discussed embodiment.

Also demonstrated in FIG. 8a is the manner in which assembly 20a or 20b may be attached to one of the many other common types of syringes with which it may be utilized. The syringe 52 depicted in FIG. 8a is of glass construction and has a metallic connection piece 53 mounted on its lower end. This metal connecting piece 53 is adapted to be mounted on the exterior of hub 22b as well as the interior in contrast to the previously discussed syringes where extension 34 is mounted only on the interior of hubs 22 and 22a.

This type of connection is facilitated by the wider interior diameter adjacent the upper end of members 42 and 42b which provides clearance for connecting piece 53 to extend between the inner surface of the upper end of members 42 and 42b and the outer surface of hubs 22a and 22b respectively and engage the hub to form the assembled syringe assembly.

In FIG. 1, it is demonstrated how one or more combinations of a self-contained packaged needle assembly and a syringe barrel container a particular unit dose may be packaged together compactly in disassembled form within a particular package. It can be easily seen how one, five, ten or many more similar combinations may be packaged within one compact protective package 50. Package 50 may be constructed of a low cost expanded foam type of rigid material such as expanded molded polystyrene with individual chambers for each particular element and then shipped, handled and stored in this compact arrangement for prolonged periods of time. The rigid type of expanded foam package whether it be

polystyrene or not affords additional protection to the aseptic packaged needle assembly 20 and syringe barrel and dose assembly 36. When it is desired to administer a dose, package 50 need only be opened and one package needle assembly 20 and one syringe barrel assembly 36 need be removed and assembled in the previously discussed manner.

Thus, the several aforementioned objects and advantages are most effectively attained. Although several somewhat preferred embodiments have been disclosed and described in detail herein, it should be understood that this invention is in no sense limited thereby but is to be determined by the scope of the appended claims.

I claim:

1. A self-contained packaged needle assembly for connection to a syringe to form a syringe assembly comprising; a needle mounted on a hub with said hub being adapted to be mounted on the forward end of a syringe barrel having a stopper therein, the outer surface of a portion of the hub being substantially frustoconical in configuration, shield means having an open end portion removably mounted on said hub so as to encompass said needle, the inner surface portion of said shield which engages with said frustoconical portion of said hub being tapered to substantially conform with the taper on said frustoconical portion and having a slightly smaller diameter than the frustoconical portion so that when said hub and shield are assembled a tight frictional engagement will occur thereby assuring a positive retention of said shield on said hub, the tapered interengagement between shield and hub facilitating the centering of said needle and hub within said shield during assembly, the open end portion of said shield means adapted to receive a removable closure to thereby form a sealed package for said needle and hub, a portion of said shield means being adapted to protect said needle when said closure is removed and the syringe barrel is connected to said hub, and a portion of said shield means being adapted to be connected to said stopper to form a plunger for the syringe assembly.

2. The invention in accordance with claim 1 wherein said shield means includes a single member having an upper peripheral laterally extending lip to receive said closure and an extension from its lower closed end, the extension having a threaded outer surface to be connected to said stopper, and a shoulder on the upper inner surface portion of said member to removably engage and hold said needle and hub within said assembly.

3. The invention in accordance with claim 2 wherein there are longitudinal ribs extending from the inner surface of said member to facilitate the maintenance of said hub and needle in fixed position within said member.

4. Shield means for a self-contained packaged needle assembly to be attached to a syringe for forming a syringe assembly comprising; an open end portion thereof being adapted to be mounted on a hub connected to a needle so that said needle is enclosed by said shield means, the hub being of the type having an outer surface portion of substantially frustoconical configuration and the inner surface portion of said shield which engages with said frustoconical portion of said hub being tapered to substantially conform with the taper on said frustoconical portion and having a slightly smaller diameter than the frustoconical portion so that when said hub and shield are assembled a tight frictional engagement will occur thereby assuring a positive retention of said shield on said hub, the tapered interengagement between shield and hub facilitating the centering of said needle and hub within said shield during assembly, said open end portion adapted to receive a removable closure to thereby form a sealed package for said needle and hub, a portion of said shield means being adapted to protect said needle when said closure is removed and the syringe is connected to the hub, and a portion of said shield means being adapted to be connected to a stopper and the barrel of the syringe to form a plunger for the syringe assembly.

5. The invention in accordance with claim 4 wherein said shield means includes a single member having an upper peripheral laterally extending lip to receive the closure and an extension from its lower closed end, the extension having a threaded outer surface to be connected to the stopper, and a shoulder on the upper inner surface portion of said member to removably engage and hold the needle and hub.

6. The invention in accordance with claim 5 wherein there are longitudinal ribs extending from the inner surface of said member to facilitate the maintenance of the hub and needle in fixed position within said member.

7. A self-contained packaged needle assembly for connection to a syringe to form a syringe assembly comprising; a needle mounted on a hub with said hub being adapted to be mounted on the forward end of a syringe barrel having a stopper therein, shield means having an open end portion removably mounted on said hub so as to encompass said needle, the open end portion of said shield means adapted to receive a removable closure to thereby form a sealed package for said needle and hub, a portion of said shield means being adapted to protect said needle when said closure is removed and the syringe barrel is connected to said hub, a portion of said shield means being adapted to be connected to said stopper to form a plunger for the syringe assembly, said shield means including an inner member having its upper inner surface removably engaging said hub to retain said hub in position with said needle enclosed and protected said inner member, an outer member enclosing said inner member, hub and needle, said outer member having an upper peripheral laterally extending lip to receive said closure and an extension extending from its lower closed end, said extension having a threaded outer surface for connection to a stopper, a shoulder on the upper inner surface portion of said outer member to removably engage with and facilitate the holding of said inner member in position in engagement with said hub, and said outer member being removable from said inner member thereby permitting said outer member to be connected to said

stopper while said inner member is still positioned on said hub and protecting said needle.

8. The invention in accordance with claim 7 wherein there are longitudinal ribs extending from the inner surface of said inner member to facilitate the maintenance of said hub and needle in fixed position within said inner member.

9. Shield means for a self-contained packaged needle assembly to be attached to a syringe for forming a syringe assembly comprising; an open end portion thereof being adapted to be mounted on a hub connected to a needle so that said needle is enclosed by said shield means, said open end portion adapted to receive a removable closure to thereby form a sealed package for said needle and hub, a portion of said shield means being adapted to protect said needle when said closure is removed and the syringe is connected to the hub, a portion of said shield means being adapted to be connected to a stopper and the barrel of the syringe to form a plunger for the syringe assembly, said shield means including an inner member having its upper inner surface adapted to removably engage the hub to retain the hub in position with the needle enclosed and protected by the inner member, said outer member adapted to enclose the inner member, hub and needle, said outer member having an upper peripheral laterally extending lip adapted to receive a closure and an extension extending from its lower closed end, said extension having a threaded outer surface adapted for connection to a stopper in a syringe barrel, a shoulder on the upper inner surface portion of said outer member to removably engage with and facilitate the holding of said inner member in position in engagement with the hub, and said outer member being removable from said inner member thereby permitting said outer member to be connected to the stopper while said inner member is still positioned on said hub and protecting said needle.

10. The invention in accordance with claim 9 wherein there are longitudinal ribs extending from the inner surface of said inner member to facilitate the maintenance of the hub and needle in fixed position within said inner member.

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