

[54] **RIGID CONTAINER ASSEMBLY FOR SYRINGE**

[57] **ABSTRACT**

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[73] Assignee: **Sherwood Medical Industries, Inc.**

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[56] **References Cited**

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A rigid packaging container assembly for protecting, and assisting the arming of a sealed prefilled syringe barrel and insertable needle assembly including a sheath surrounding the needle assembly, slidable on the barrel and having a shoulder which engages a portion of the needle assembly to permit the operator to grasp the sheath and fully insert the needle assembly from a partially inserted position, with a sheath retainer surrounding the sheath and having a plurality of shelf projections extending through openings in the sheath and engageable with the underside of the syringe barrel to limit sliding movement of the sheath retainer upwardly along the syringe barrel so that a cooperating cap insertable within the sheath retainer and engageable with a portion of the sheath prevents movement of the sheath when the syringe is in its packaged condition thereby preventing arming of the syringe until the cover or cap is removed. There are also provided a plurality of tabs extending from the sheath so that in the disassembled condition of the container with only the sheath surrounding the needle assembly, the syringe will not be permitted to roll on a supporting surface.

10 Claims, 8 Drawing Figures

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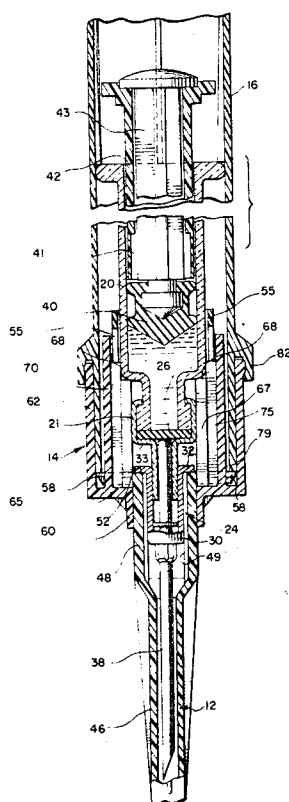


Fig. 2

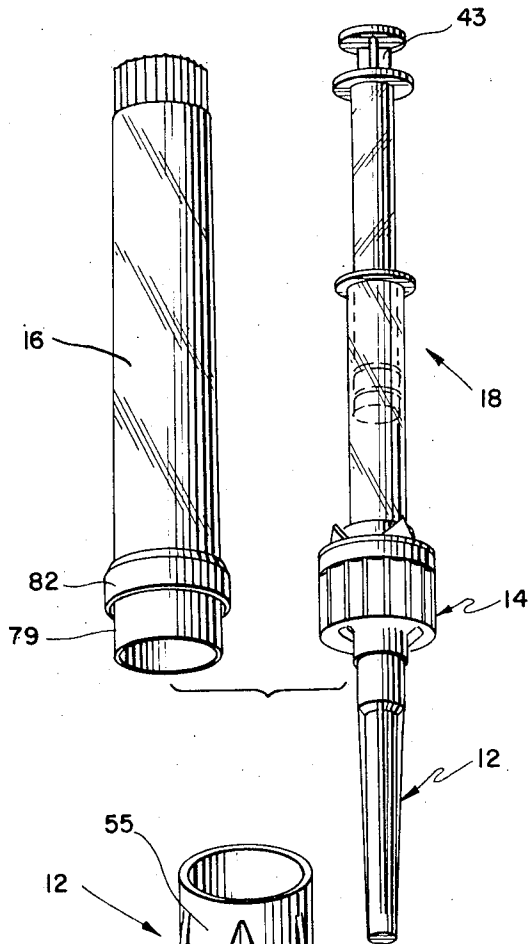


Fig. 1

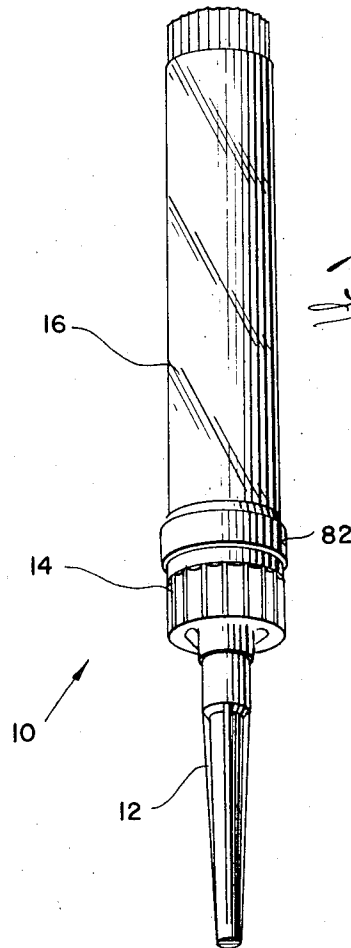


Fig. 3

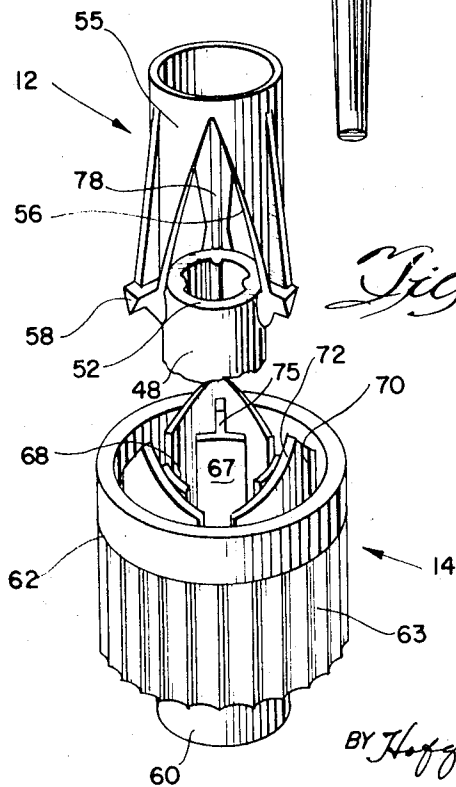
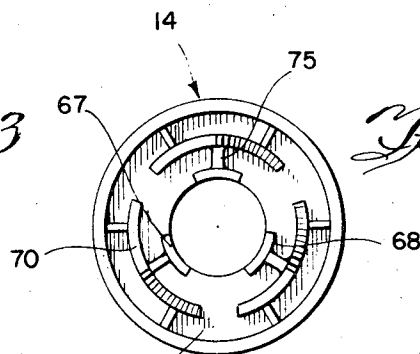
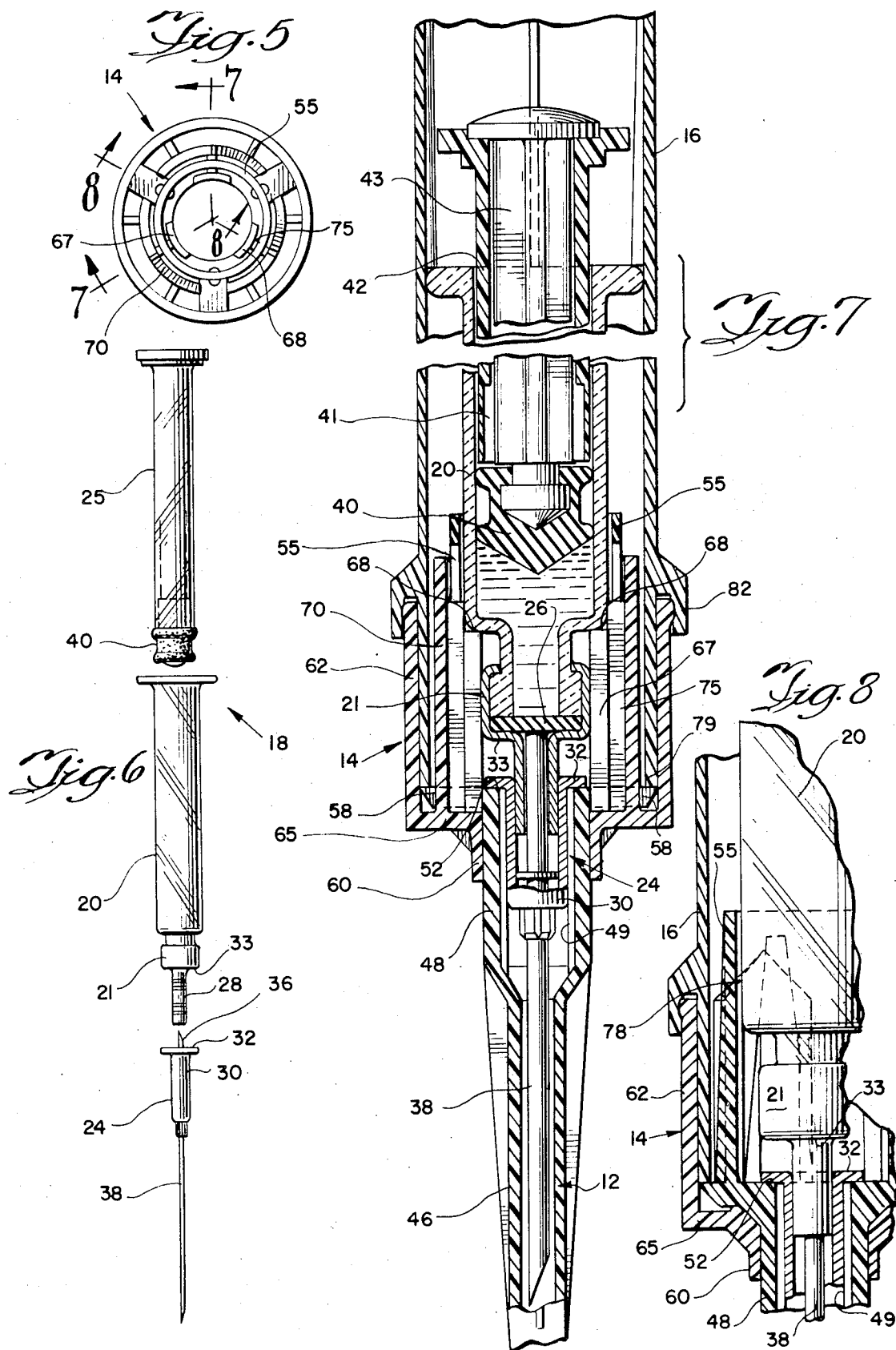


Fig. 4



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RIGID CONTAINER ASSEMBLY FOR SYRINGE

BACKGROUND OF THE PRESENT INVENTION

There have in the past been provided various types of syringes for injecting medicament into a patient. These syringes generally require direct operator contact during arming and use. One type of syringe of this general construction is a prefilled single dose syringe where the barrel is filled with the proper medicament prior to inserting a self-connectable needle assembly through a pierceable seal at the bottom of the syringe barrel. Such syringes have in the past required the operator during arming to manually grasp the needle assembly and force it upwardly through the seal into communication with the medicament within the syringe barrel. This increases the likelihood of contaminating the syringe as well as damaging the syringe and needle assembly. The likelihood of damage is particularly acute in present day syringes where they are constructed as inexpensively as possible, consistent with safe use, to permit the entire syringe and needle assembly to be disposed of after a single use.

It is therefore a primary object of the present invention to provide a rigid sheath and container assembly for a prefilled syringe that protects the syringe and needle assembly from contamination of damage, and assists in arming the syringe in a proper manner preparatory to injection of the medicament into the patient.

SUMMARY OF THE PRESENT INVENTION

In accordance with the present invention a rigid sheath and container assembly is provided for a prefilled syringe of the type having a needle assembly shiftable from an inactive position out of communication with the medicament within the syringe barrel to an active position in full communication preparatory to patient injection. A sheath is provided for the needle assembly which serves the twofold function of protecting the needle assembly as well as inserting the needle assembly to its fully armed position as the operator grasps the sheath and urges it upwardly toward the cylinder barrel.

It is however undesirable that the sheath be permitted to "arm" the syringe inadvertently and to prevent this means are provided for limiting upward movement of the sheath when the container is in its assembled condition. Toward this end an annular sheath retainer member is slidable over the sheath. A plurality of inwardly projecting shelf members from the retainer extend through openings in the sheath and engage the lower end of the cylinder barrel to prevent movement of the retainer upwardly. A cover for the syringe is insertable within the retainer and engages tabs on the sheath within the retainer, preventing relative movement between the sheath and the sheath retainer when the container is assembled. Since the retainer cannot move upwardly relative to the cylinder barrel and since the cover prevents relative movement between the sheath and the sheath retainer, the sheath is prevented from arming the syringe by being locked from moving toward the cylinder barrel when the cover or syringe cap is in position.

For the purpose of aligning the openings in the sheath with the projections in the retainer as the retainer is slid over the sheath, a plurality of camming

lobes are provided on the sheath retainer which engage the tabs on the sheath retainer to rotate the same to the proper angular orientation with respect to the sheath as the sheath retainer is moved upwardly around the sheath. Moreover the sheath tabs, described above, serve also to prevent rolling of the syringe on any horizontal surface that it may be placed after removal of the sheath retainer and cover.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a sheath and container assembly for a syringe according to the present invention;

FIG. 2 is a perspective view of a sheath and container assembly for a syringe accordingly to the present invention with the container cap removed from the assembly;

FIG. 3 is a partly fragmentary exploded view of the sheath and sheath retainer, somewhat enlarge from the FIGS. 1 and 2;

FIG. 4 is a top elevation of the sheath retainer;

FIG. 5 is a top elevation of the sheath with the sheath retainer in its surrounding position;

FIG. 6 is an exemplary prefilled syringe with which the present sheath and container assembly may be advantageously employed;

FIG. 7 is an enlarged fragmentary section of the present sheath and container assembly with the syringe shown in its unarmed position taken generally along line 7—7 of FIG. 5; and

FIG. 8 is a fragmentary section taken generally along line 8—8 of FIG. 5 illustrating another portion of the sheath and retainer assembly in position with an unarmed syringe.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings and particularly FIGS. 1 and 2, the present sheath and container assembly 10 is illustrated adapted for use in protecting a single dose syringe prior to use and assisting in arming the syringe preparatory to use. The assembly 10 consists generally of a needle assembly sheath 12 which protects the needle assembly and assists in arming the syringe, and a sheath retainer 14 that assists in controlling arming movement of the sheath 12 and serves as one end of an integral cap 16. The container 10 is adapted to protect and assist in arming a syringe of the general type shown at 18 in FIGS. 2 and 6.

Such syringes are seen to consist of a cylindrical barrel member 20, a connector 21, a needle assembly 24 and a plunger assembly 25. The connector 21 has a puncturable seal therein such as shown at 26 in FIG. 7 and a friction fitting 28 that receives and holds a fitting 30 in both a lower unarmed position such as shown in FIG. 7 and a fully seated armed position (not shown) in which flange 32 engages the underside portion 33 of the connector 21. During movement from the unarmed position, in which the fitting 30 is frictionally retained on connector portion 28, to the armed position of the needle assembly 24, a pointed end 36 of needle 38 pierces the seal 26 and provides communication between the needle and the interior of barrel 20. One advantage in this type of syringe is that it may be prefilled sometime prior to use and requires only a

small shifting movement of the needle assembly 24 to arm the syringe and break the aseptic seal.

The syringe 18 is filled with the plunger assembly 25 removed and thereafter the plunger assembly 25 is inserted with a resilient piston 40 squeezed within an opening 41 in a tubular sleeve 42. After the piston 40 on a plunger 43 of the assembly 25 contacts the medicament within the barrel 20, it is in the position of FIG. 2, then the sleeve 42 is pulled upward relative to the plunger 43 for releasing the piston 40 within the barrel 20 and sealing the medicament within the barrel free from air contamination.

During packaging, with the needle assembly 24 in its frictionally retained, but unarmed position shown in FIG. 7, the sheath 12 is inserted over the needle assembly to the position shown in FIG. 7. As shown clearly in FIGS. 3 and 7, the sheath 12 includes a tapered, closed lower portion 46 extending a significant distance below the needle 38, a slightly tapered frusto-conical portion 48 having ribs 49 which are sized to engage the sides of needle fitting 30 and also having a shoulder 52 which engages the underside of the needle fitting flange 32. The sheath 12 has an enlarged annular portion 55 extending upwardly from the frusto-conical portion 48 and having a plurality of inverted V-shaped openings 56 therein which, when in the position shown in FIGS. 7 and 8, expose portions of the lower end of barrel member 20 for a purpose more fully described hereinafter. Extending radially outwardly adjacent the juncture of the sheath sections 48 and 55 are three triangularly shaped, radially projecting tabs 58 which serve both to prevent rolling of the syringe when protected only by the sheath 12 and also to assist in locking the sheath against inadvertent arming.

The annular upper portion 55 of the sheath 12 has ribs 78 thereon as shown in FIG. 8 which slidably engage the outside of the barrel 20 so that the barrel may be snugly received therein. This fit in conjunction with the ribs 49 on the sheath engaging the fitting 30 of the needle assembly 24 maintains proper alignment between the needle assembly and the syringe barrel 20.

After the sheath 12 is positioned as shown in FIG. 7, the sheath retainer 14 is inserted over the lower end of the sheath 12 and moved upwardly to the position shown in FIG. 7. As shown more clearly in FIGS. 3 and 7, the sheath retainer 14 has a reduced annular portion 60 which slides over and engages the slightly conical portion 48 of sheath 12. Interconnected with portion 60 is a main enlarged annular portion 62 which has a ribbed outer surface 63 as shown in FIG. 3 to facilitate manipulation. Projecting upwardly from a lower annular wall 65 of the retainer 14 are three arcuate, axially extending segments 67 having upper shelf portions 68 that engage the underside of barrel member 20 for the purpose of limiting the upward movement of the retainer 14 with respect to the barrel member 20. The segmental projections 67 are of sufficient length so that the retainer 14 when shifted axially to its limit position shown in FIG. 7, will not move the sheath 12 to a position causing arming of the needle assembly 24. The segmental projections 67 each extend within one of the inverted V-shaped openings 56 shown in FIG. 3 in the sheath 12.

For the purpose of rotatably aligning the segmental projections 67 on the sheath retainer 14 with the

openings 56 in the sheath as the retainer is moved axially up the sheath toward the position of FIG. 7, V-shaped, arcuate segmental cam lobes 70 are provided also extending upwardly from the base 65 of the retainer 14. The V-shaped upper surfaces 72 of the lobes 70 engage the triangularly shaped radial tabs 58 on the sheath 12 as the retainer 14 is inserted rotating the segmental projections 67 into alignment with the openings 56. As seen more clearly in FIGS. 4 and 5, an interconnecting web portion 75 extends radially between each of the segments 67 and the adjacent lobe 70. As seen in FIGS. 5 and 7, the annular portion 55 of the sheath fits between the lobes 70 and the segments 67 on the retainer 14.

For the purpose of preventing the upward arming movement of the sheath 12 when the cover 16 is in position, the cover has an annular lower portion 79 of sufficient length so that it engages the upper surface of the tabs 58 on the sheath 12. The frictional engagement between the annular portion 79 and the inside of the retainer 14 in conjunction with an annular retainer lip 82, releasably lock the cover to the retainer, although the retension force may be overcome manually during disassembly. This retension force however is sufficient to prevent relative movement between tabs 58 and the retainer 14 which, in turn, through the action of the shelf portions 68 prevent the upward movement of the sheath 12 when the cover 16 is in position. Thus the operator may not arm the syringe while the cover or cap 16 is in the position shown in FIGS. 7 and 8.

The assembly of the rigid sheath and container 10 is apparent from the above description. The complete operation of the container 10 in conjunction with the syringe 18 will be more clearly understood from the following brief description of disassembly and use.

Assuming the syringe 20 to be prefilled and the needle assembly positioned in its disarmed but frictionally engaged position shown in FIG. 7, and the container to be assembled, disassembly is only begun when the syringe is to be used. The cover 16 is removed freeing the tabs 58 on the sheath 12. The operator may then with one hand grasp the syringe barrel 20 and with the other hand pull the sheath 12 upwardly driving shoulder 52 against flange 32, piercing the seal 26 and thus arming the syringe 20. The retainer 14 may be slid downwardly over the sheath 12 and the syringe and sheath placed on a table while the patient is prepared for the medication injection. During this time the tabs 58 prevent the syringe from rolling. After preparation of the patient the sheath 12 is removed from the needle assembly and the syringe is ready for medicament injection in accordance with conventional procedure.

We claim: of

1. A sheath and cap assembly for a syringe of the type having a barrel, a connector and a needle assembly insertable in said connector, comprising: a needle assembly sheath engageable laterally with a portion of said needle assembly, said sheath having an annular upper portion surrounding and engaging the lower portion of the syringe barrel, said sheath having a shoulder engageable with a portion of said needle assembly to shift the needle assembly from a partly inserted to a fully inserted position in said barrel, a sheath retainer surrounding and engaging said sheath and having a plurality of radially inwardly projecting shoulders engage-

able with said barrel to limit movement on the sheath retainer and to prevent the sheath retainer from activating the sheath to insert the needle assembly, projection means on said sheath and extending within said sheath retainer, and a syringe cap insertable within said sheath retainer and engageable with said sheath projection means to prevent movement of the sheath toward the barrel.

2. A sheath and cap assembly for a syringe of the type having a barrel, a connector and a needle assembly insertable in said connector as defined in claim 1, wherein said sheath has a plurality of openings therein for exposing the bottom portion of the barrel to the radial projections of the sheath retainer, camming lobes on said sheath retainer for relatively positioning said openings with said sheath retainer projections upon relative movement between said sheath and said sheath retainer.

3. A sheath and cap assembly for a syringe of the type having a barrel, a connector and a needle assembly insertable in said connector as defined in claim 2, wherein said sheath has a plurality of tabs extending radially outwardly and defining said sheath projection means, said cap having an end portion engageable with said tabs and selectively preventing movement of said sheath toward the barrel.

4. A sheath assembly for a syringe having a barrel and a self-connecting needle assembly, comprising: a sheath for said needle assembly, means on said sheath engageable with said needle assembly when in a partly inserted position in said barrel for moving said needle assembly to a fully inserted position, said sheath having openings therethrough exposing portions of said barrel, a sheath retainer engageable with and surrounding said sheath and having shelf projections extending through said openings and engageable with said barrel to limit axial movement of the sheath retainer to a position wherein the sheath does not insert the needle assembly, and other means selectively engageable with said sheath and said sheath retainer to prevent relative movement therebetween when the sheath is in a position where the needle assembly is partly inserted, said sheath having means engageable with said barrel to limit lateral movement of the barrel with respect to the needle assembly.

5. A sheath assembly for a syringe having a barrel and a self-connecting needle assembly as defined in claim 4 including means for rotatably aligning the openings and the shelf projections in response to axial movement of the sheath retainer with respect to the sheath.

6. A sheath assembly for a syringe having a barrel and a self-connecting needle assembly as defined in claim 4 wherein said sheath has a plurality of generally radially extending tabs for preventing rolling of the syringe with the sheath in position, said other means selectively engageable with the sheath and the sheath retainer being engageable with said tabs to prevent movement of said sheath relative to the barrel to prevent a full insertion of the needle assembly.

7. A sheath assembly for a syringe having a barrel member, and a needle assembly connected to said bar-

rel member for relative movement therewith between an unarmed position and an armed position in which an interior end portion of the needle assembly is in fluid communication with the interior of said barrel member, comprising a removable sheath member surrounding and protecting an exterior portion of said needle assembly and movable in a direction toward said barrel member in response to a manually applied force thereon in said direction to move said needle assembly in said direction to the armed position, a sheath retainer member connected with and surrounding said sheath member and extending adjacent said sheath member for only a portion of the length of said sheath member, a removable cover member separably connected in engagement with said retainer member in the assembled condition of the sheath assembly, and engagement means on said sheath member engageable with at least one of the other of said members in the assembled condition of the sheath assembly to limit relative movement between said sheath member and said barrel member for preventing movement of said needle assembly to the armed position.

8. The sheath assembly according to claim 7 wherein one of said members includes other engagement means engageable with said barrel member to limit axial movement of said barrel member toward said sheath member when the sheath assembly is in the assembled condition.

9. The sheath assembly according to claim 8 wherein said other engagement means is integrally connected with said retainer member.

10. A sheath assembly for a syringe having a barrel member, and a needle assembly connected to said barrel member for relative movement therewith between an unarmed position and an armed position in which an interior end portion of the needle assembly is in fluid communication with the interior of said barrel member, comprising a removable sheath member surrounding and protecting an exterior portion of said needle assembly and movable in a direction toward said barrel member in response to a manually applied force thereon in said direction to move said needle assembly in said direction to the armed position, a sheath retainer member engageable with and surrounding said sheath member, a removable cover member connected with said retainer member in the assembled condition of the sheath assembly, and engagement means on said sheath member engageable with at least said cover member in the assembled condition of the sheath assembly whereby said sheath member is maintained substantially immovable relative to said retainer and cover members to limit relative movement between said sheath member and said barrel member for preventing movement of said needle assembly to the armed position, said retainer member having a reduced annular portion slidable on said sheath member and an integral enlarged annular portion connected to said cover member, said cover member being closed at one end thereof, and said sheath, retainer, and cover members together enclosing the entire syringe in the assembled condition of the sheath assembly.

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