

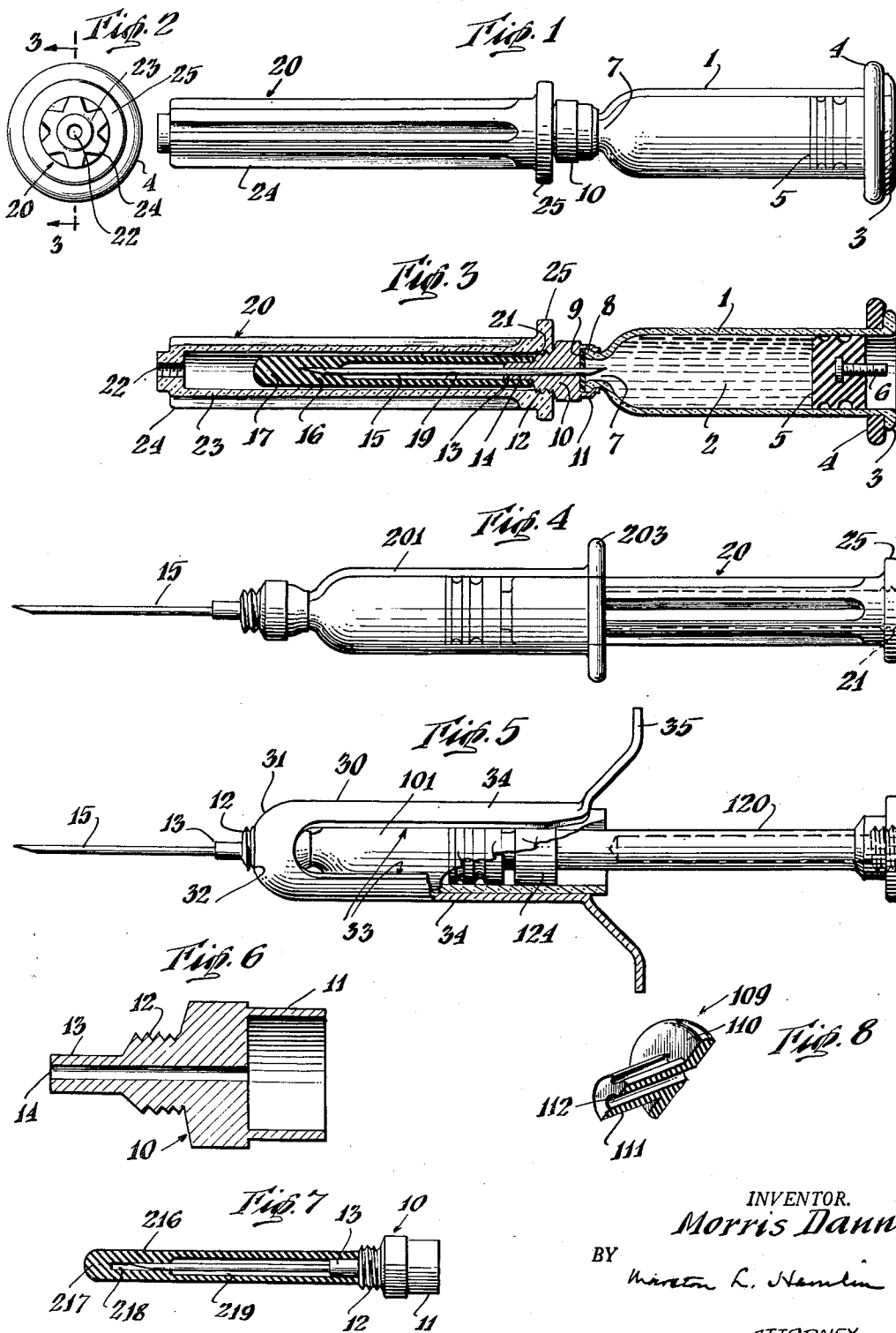
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CARTRIDGE-SYRINGE UNIT

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CARTRIDGE-SYRINGE UNIT

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This invention relates to a cartridge-syringe unit and more particularly to such a unit comprising a transparent cartridge, preferably of glass, containing an injectable material, one end of the cartridge being sealed by a slidable rubber plunger having a threaded connection in its exposed end, the other end of the cartridge being contracted to a small flanged opening, a closure such as a gasket or pierced rubber stopper sealing the small opening, an injection needle piercing and mounted in the closure, a ferrule surrounding the flange of the small opening and the portion of the needle adjacent the closure and fixedly securing needle and closure to the cartridge, the ferrule being provided with a male thread on a portion spaced from the cartridge and having a portion of reduced diameter extending beyond the thread, a flexible sheath surrounding the part of the needle extending outside the cartridge and ferrule, one end of the sheath fitting snugly over the reduced portion of the ferrule, the other end of the sheath sealing the distal end of the needle, and a rigid tubular cover surrounding and protecting the needle and sheath, the shank of said cover having an outside diameter less than the inside diameter of the cartridge, the cover being provided with a female thread at its cartridge end engaging the male thread of the ferrule and a thread at its distal end adapted to engage the threaded connection in the plunger, the tubular cover serving as a plunger rod when the unit is in use for injection; the unit also has one or more finger pieces such as a flange or wings on or associated with the cartridge, adapted to be engaged by the fingers of the hand to oppose thumb pressure when the syringe is being used for injection.

The advent of antibiotics has increased the importance of injection syringes to the physician. Disposable or "one shot" syringes have become popular because they save the physician's time and because improvements in materials and manufacturing methods have brought their cost within reasonable limits. Numerous syringes of this type have been developed, but none has been completely satisfactory.

Disposable syringes may be divided roughly into two types—those which are packaged with the needle outside the cartridge but adapted to be inserted through the cartridge closure before use, and those which are packaged with the needle piercing the cartridge closure ready for use and the outer end of the needle provided with a removable plug to retain the contents of the cartridge until required for injection. It is clear

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that the latter type has the advantage of being easier to use and requiring less manipulation by the physician. Hitherto, however, the problems of providing a sterile cover for the needle, a satisfactorily rigid mounting and a sterile, non-leaking seal for the distal end of the needle have not been satisfactorily solved.

Accordingly it is an object of my invention to provide a disposable injection syringe unit that is economical to produce in sterile condition and avoids the necessity of inserting a needle into an ampule before use.

It is a further object of my invention to provide a syringe unit of this type embodying a glass container for the injectable drug, because of the superior transparency and chemical and dimensional stability of glass.

Embodiments of my invention are illustrated in the figures of the accompanying drawing, but these figures are intended to be exemplary only and not to limit my invention, the scope of which is defined in the appended claims.

An ampule, plunger and associated parts constitute the cartridge of my unit. A double-cannula injection needle rigidly mounted in a ferrule, the ferrule, a needle sheath and an ampule closure constitute the needle assembly, and a needle cover completes the unit. In use, the ampule, of course, contains an injectable drug, but this drug per se forms no part of my invention.

In the drawings:

Fig. 1 is a side elevation of a preferred embodiment of my invention as packaged;

Fig. 2 is an end elevation of the unit shown in Fig. 1;

Fig. 3 is a cross section on line 3—3 of Fig. 2;

Fig. 4 is a side elevation of a slightly modified syringe unit prepared for injection;

Fig. 5 is a further modified form of syringe unit prepared for injection;

Fig. 6 is an enlarged section of a ferrule before assembly;

Fig. 7 is a section of a modified sheath mounted on a needle-ferrule unit; and

Fig. 8 is a perspective section of a modified cartridge closure.

In the drawings indicium 1 represents the shell of an ampule, preferably of glass, containing an injectable drug 2. One end of the ampule may be flared as at 3 to provide a seat for an annular rubber finger piece 4. This end of the ampule is sealed by a slidable rubber plunger 5, molded with a brass inset 6 provided with a male thread. The opposite end of the ampule is drawn out to

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a narrow opening 7 and provided with a flange 8. This end of the ampule is sealed by a rubber disc or gasket 9, which is pressed firmly against flange 8 by ferrule 10, made for example of tin or aluminum, thus providing a liquid-tight closure. This ferrule is held firmly in place by an integral thin skirt 11 which is rolled or crimped around flange 8. The body of ferrule 10 is provided with a male thread 12 and is further extended in a cylindrical or slightly conical portion 13 of reduced diameter. The ferrule is provided with a cylindrical bore 14 in which injection needle 15 is rigidly mounted with a liquid-tight joint as by swaging. As may be seen in Fig. 3, the proximal end of needle 15 pierces gasket 9 so that the needle is in communication with the interior of the ampule 1.

Surrounding needle 15, as the unit is packaged, is a sheath 16 of a moderately elastic material such as natural rubber, synthetic rubber or other synthetic elastomer. The inner bore 19 of the sheath is of such a diameter that it slips easily over the needle and its proximal end, when in position, forms a bacteria-tight joint around the reduced end 13 of ferrule 10. The distal end of the sheath is integrally closed at 17, the lengths of sheath and of closure being such that, when the sheath is in position (Fig. 3), the distal end of needle 15 partially pierces and is embedded in the closure and is effectively sealed against leakage.

A modified form of sheath is shown at 216 in Fig. 7. In this modification the distal end of the sheath 217, instead of being solid and pierced by the needle as at 17 (Fig. 3), is provided with an extension 218 of the main bore 219, the extension having a smaller bore than the diameter of the cannula of the needle and thus gripping and forming a liquid-tight seal around the distal end of the needle.

A modified form of cartridge closure is shown in Fig. 8. A small rubber or neoprene stopper 109 is provided with a thin flange 110, having a diameter approximately the same as flange 8 of the cartridge, and a vented shank 111 having a diameter to provide a squeeze fit in opening 7 and a length to fill the restricted neck of the cartridge, thus reducing waste of the injected drug due to the dead space in the neck. Shank 111 is pierced by hole 112 of a size to provide a tight fit around the needle.

To protect the needle in packaging, shipment and storage, I provide a rigid tubular cover 20. This cover doubles as plunger rod is using the syringe unit for injections, and accordingly the outside diameter of its shank is less than the inside diameter of ampule 1. To secure the cover in packaged position, it is provided with a female thread 21 at one end which is of a size and pitch to cooperate with thread 12 of ferrule 10. In packaged position, screwed home on the ferrule, it provides firm and rigid protection for the needle and sheath against mechanical damage. The other end of cover 20 is also provided with a thread 22 adapted to engage plunger 5. In Figs. 1, 3-5 the thread 22 is a female thread of the same size and pitch as the male thread of inset 6, but alternatively the cover may have a male thread and the plunger a female thread.

The plunger rod shown in Figs. 1-4 has cylindrical body 23 provided with 4 longitudinal ribs 24 serving to aline and center the rod in ampule 1, the diameter through the ribs being small enough to provide an easy sliding fit in the ampule. The plunger rod is also advantageously

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provided with flange 25 at one end to furnish a comfortable thumb piece when the syringe is used for injection. The needle-cover-plunger-rod may conveniently be made of a transparent plastic material, though this is not essential.

An alternative form of plunger rod is shown at 120 (Fig. 5). This is also a hollow threaded rod serving as needle cover when the unit is packaged, but it lacks the longitudinal ribs 24 of rod 20. Instead, flange 124 centers the rod in the ampule.

Modified forms of ampules are shown in Figs. 4 and 5. In Fig. 4 an ampule 201 is shown having a flange 203 sufficiently wide to make the use of rubber finger piece 4 unnecessary, the flange itself fulfilling this function.

In Fig. 5 an ampule 101 is illustrated having no flange. Instead, the ampule is surrounded by a sleeve 30 which may be of brass or other relatively rigid sheet material. The sleeve is in the form of a cut-away cylinder partially closed at one end 31. This end is pierced by an internally threaded hole 32 into which the ferrule 10 screws by means of threaded portion 12. Broad slots 33 are cut on opposite sides of the sleeve from a point near the closed end all the way to the open end, thus in effect forming this portion of the sleeve into two segments 34 joined at one end but separated at the other. These segments are extended and bent outwards at the separated ends to form finger pieces 35. The segments 34 have a certain amount of elasticity and are of such internal diameter as to exert a moderate pressure on ampule 101. This, combined with the threaded hole 32 which receives thread 12 of the ferrule, insures a firm mounting of the cartridge unit in the sleeve and offers no interference to packaging the cartridge-syringe unit with the tubular plunger-rod-cover 20 or 120 in position around the needle and sheath, since screw thread 12, as shown in Fig. 5, extends beyond end 31 of the sleeve a sufficient distance to engage thread 21 of the cover firmly. The slots 33 provide visibility of the entire contents of the cartridge, which is necessary when aspirating to determine whether a blood vessel has been pierced.

The selection of the type of ampule to use—whether with the rubber finger piece 4, the wider flange 203, or the sleeve 30 with finger pieces 35—is largely a matter of cost, since all function satisfactorily in use. Under some conditions a flangeless ampule 101 with sleeve 30, will cost less than a flanged ampule, but this is not always the case.

The steps in assembling and filling my unit may be as follows:

1. The ampule is washed.
2. The plunger is inserted.
3. Plunger and ampule are sterilized dry at 130° C. for 2½ hours.
4. Needle, ferrule, closure and sheath are washed and assembled.
5. The needle assembly is sterilized dry at 130° C. for 2½ hours.
6. The ampule is filled aseptically.
7. The needle assembly is mounted aseptically on the filled ampule.
8. The assembly is inspected.
9. If satisfactory, the ferrule is crimped or rolled around the flange of the ampule.
10. The needle cover is applied and the syringe is packed.

These operations may all be performed manu-

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ally, or they may be mechanized to such a degree as is economically warranted.

In use, the physician receives the unit packaged with the cover-plunger-rod surrounding needle and sheath as shown in Figs. 1-3, the ampule being charged with 1, 5, 10 ml. or other desired amount of drug 2. The entire interior of the cartridge-needle assembly, the exterior of the needle and extension 13 of the ferrule are sterile. The physician removes cover 20 by unscrewing it from the ferrule 10 and attaches it to plunger 5 by engaging thread 22 with the inset 6 or other threaded device on the plunger and screwing the rod home. So far no particular care need be exercised to avoid contamination, since no parts of the unit entering the patient's tissues and likely to cause infection are exposed. In fact this operation can be completed and the unit laid aside some time before use. When ready to give the injection, the physician merely pulls sheath 20 off, exposing the sterile needle, and proceeds in the conventional way. The transparency of ampules 1, 101, and 201, and the cut-away slots 33 of sleeve 30, permit visual examination of the contents of the ampule at all times, e. g. when the physician withdraws the plunger slightly to determine whether the needle has entered a blood vessel.

My syringe has numerous advantages over those hitherto available. Owing to the method of mounting the needle on the ampule, the ampule may be made of glass. This is believed an advantage in comparison with syringes of synthetic plastic material because of the transparency, strength and chemical inertness of glass; furthermore glass offers a complete barrier to evaporation while some evaporation may occur through the walls of plastic syringes. The fact that the needle cover is screwed to the ferrule makes it nearly impossible to dislodge it accidentally; if this should occur, the needle is still protected against contamination by the sheath. The sheath has a further advantage. It sometimes happens that a physician or nurse is interrupted when about to give an injection. Here there is the possibility that a conventional syringe with the needle exposed may inadvertently be laid down and the needle contaminated. With my syringe this possibility is eliminated or greatly reduced, since the sheath is only withdrawn from the needle immediately before insertion, and the needle thus remains protected to the last minute. This feature also permits preparation in advance of a number of syringes for a series of injections by unscrewing the needle cover and attaching it to the plunger of each syringe. The syringes can then be laid out without particular precaution. The sheaths protect the needles, and each sheath is only withdrawn as the injection is about to be made.

The syringes of my invention can be made inexpensively and are primarily designed to be of the disposable type, i. e. intended for use once only. Multiple use, however, is not excluded under special conditions where resterilization and refilling may be warranted.

From this disclosure it will be seen that I have devised a new, practical and economical syringe and described preferred embodiments. Various modifications may be made without departing from the spirit of my invention, the scope of which is defined in the following claims.

In the disclosure and claims the term "proximal" is used to denote a direction towards the

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plunger end of the syringe, and the term "distal" a direction towards the needle end.

I claim:

1. A cartridge-syringe unit consisting of (1) a cartridge, (2) a needle assembly and (3) a needle cover, the cartridge comprising a transparent ampule sealed at the proximal end by a slidable plunger having a threaded connection at its exposed end, the distal end of the ampule being contracted to a small flanged opening; the needle assembly comprising a double cannula injection needle rigidly mounted in a ferrule and projecting from each end of the ferrule, a closure for the distal end of the ampule, said needle and ferrule being securely mounted on the distal end of the ampule with one cannula penetrating the closure, the ferrule being provided with a male thread around a middle portion and having a round portion of reduced diameter at its distal end surrounding the needle, and a flexible tubular sheath surrounding the needle, the proximal end of the sheath fitting snugly around the round portion of reduced diameter of the ferrule, and the distal end of the sheath being closed and securely sealing the distal end of the needle; and the needle cover comprising a tubular shank of sufficient internal diameter to pass easily over the needle sheath, being removably mounted around the needle and sheath by means of a female thread meshing with the male thread of the ferrule, the shank of the cover having an external diameter less than the internal diameter of the ampule and being provided with a thread at its distal end adapted to mesh with the threaded connection of the slidable plug of the ampule, whereby the cover may serve as a push rod when the syringe is used for injection.

2. A cartridge-syringe unit as defined in claim 1 in which the ampule is of glass formed into a flange at the proximal end.

3. A cartridge-syringe unit as defined in claim 1, in which the ampule is of glass formed without a flange at its proximal end, the ampule being surrounded by a close-fitting cylindrical sleeve, the sleeve being provided with at least one longitudinal slot exposing the contents of the ampule to view, the distal end of the sleeve being partially closed and having a threaded opening meshing with the male threads of the ferrule, and the proximal end being formed into diverging wings adapted to serve as finger pieces when the syringe is used for injection.

4. A cartridge-syringe unit as defined in claim 1 in which the ferrule is secured to the ampule by an integral cylindrical skirt compressed around the flange of the ampule.

5. A cartridge-syringe unit as defined in claim 1 in which the lumen of the sheath when in position on the ferrule extends beyond the distal end of the needle, and the bore at the distal end of the sheath is of a slightly less diameter than the external diameter of the needle for a longitudinal distance sufficient to fit snugly around the open end of the needle and seal it.

6. In a cartridge-syringe unit comprising a cartridge, an injection needle communicating with the interior of the cartridge, and a needle cover, the needle cover being adapted to serve as a push rod when the syringe is used for injection, the improvement which comprises in combination: a transparent glass ampule contracted to a small flanged opening at its distal end, a flexible closure for the opening secured to the ampule by a ferrule compressed around the flange, and a double-cannula injection needle

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rigidly mounted in the ferrule, one cannula projecting through the flexible closure into the ampule, the other cannula projecting outwardly, the ferrule being provided with a male thread and the needle cover being provided at its proximal end with a female thread meshing with the male thread on the ferrule, the threads cooperating to secure the needle cover about the needle against accidental displacement prior to injection.

7. In a cartridge-syringe unit as defined in claim 6 the further improvement that the ampule is surrounded by a close-fitting cylindrical sleeve with at least one longitudinal slot exposing the contents of the ampule to view, the distal end of the sleeve being partially closed and having a threaded opening meshing with the male threads of the ferrule, and the proximal end being formed into diverging wings adapted to serve as finger pieces when the syringe is used for injection.

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8. In a cartridge-syringe unit as defined in claim 6 the further improvement that the needle is provided with a flexible tubular sheath of an outside diameter substantially less than the inside diameter of the needle cover, the sheath being adapted to slip easily from the needle, the proximal end fitting snugly over a round extension of the ferrule, and the distal end being closed and effectively sealing the needle against leakage.

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