

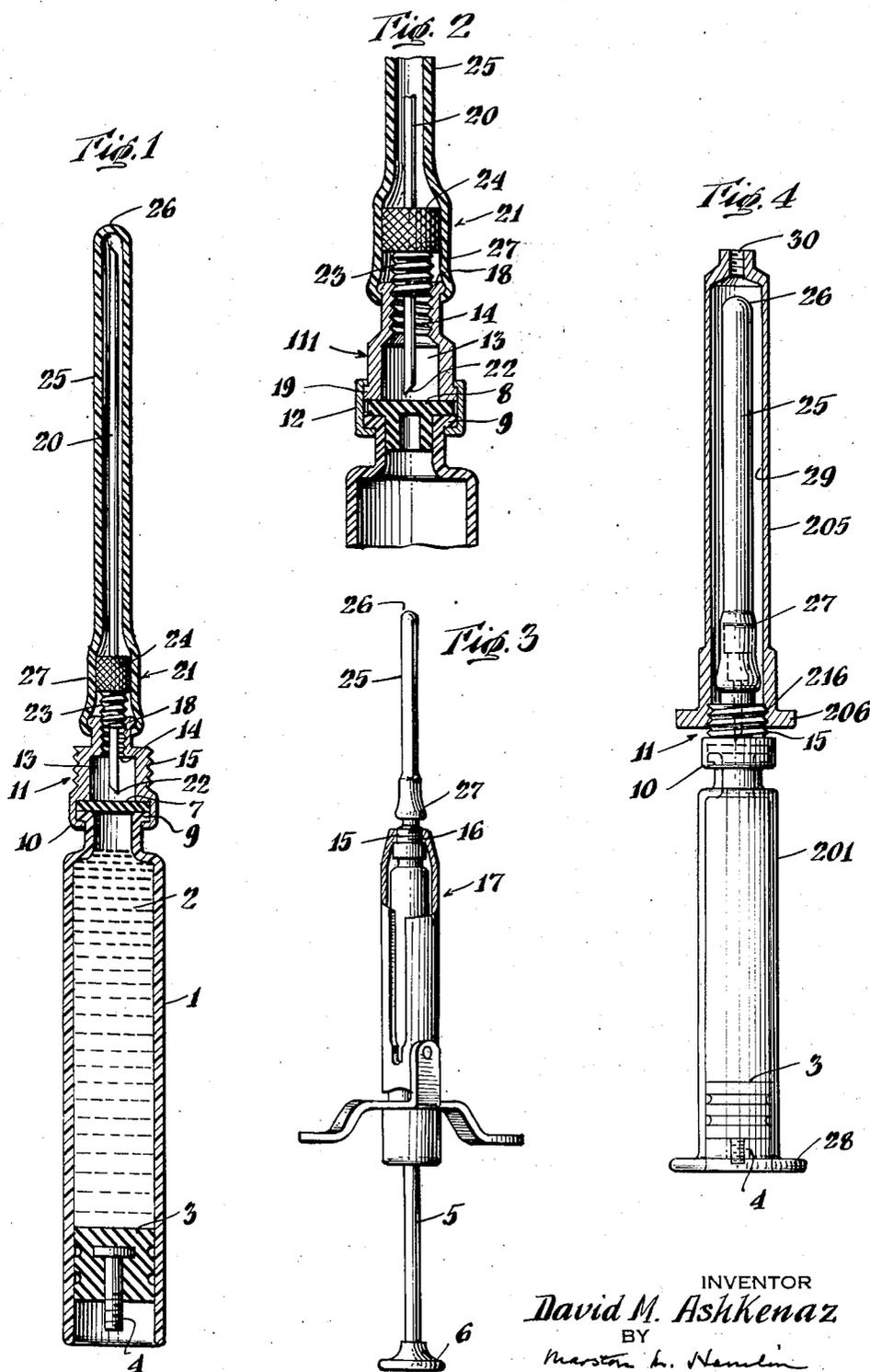
April 1, 1958

D. M. ASHKENAZ  
CARTRIDGE-NEEDLE UNIT

2,828,742

Filed May 2, 1957

2 Sheets-Sheet 1



INVENTOR  
*David M. Ashkenaz*  
BY  
*Marston L. Hamilton*  
ATTORNEY

April 1, 1958

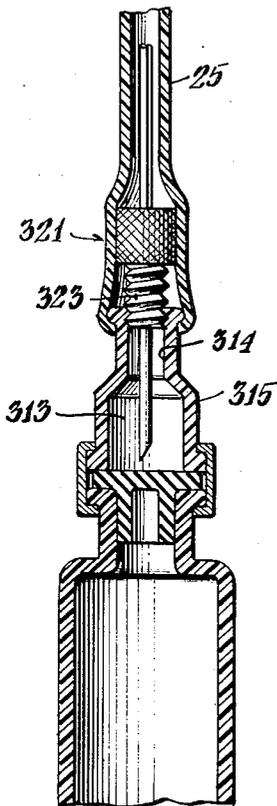
D. M. ASHKENAZ  
CARTRIDGE-NEEDLE UNIT

2,828,742

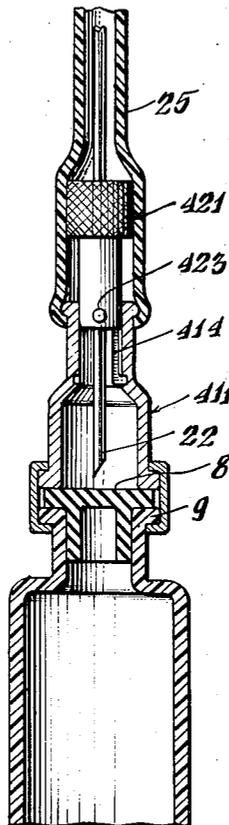
Filed May 2, 1957

2 Sheets-Sheet 2

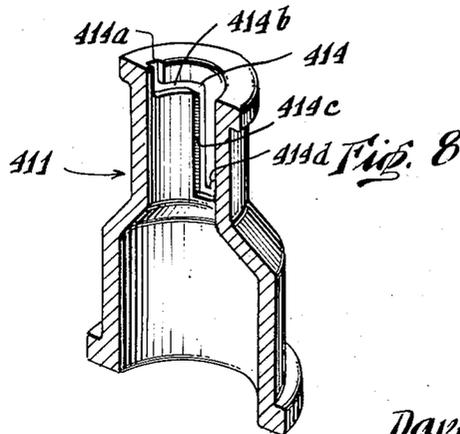
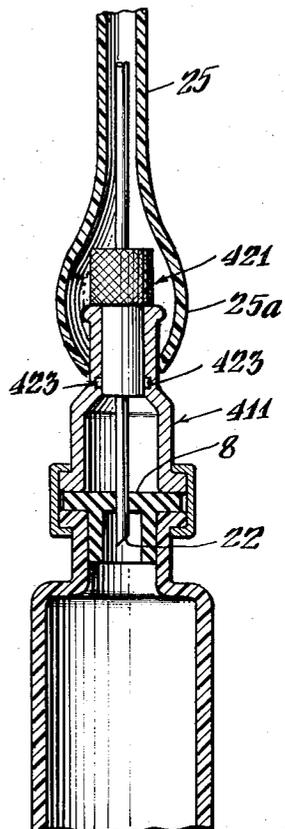
*Fig. 5*



*Fig. 6*



*Fig. 7*



INVENTOR  
*David M. Ashkenaz*  
BY  
*Marston L. Hamilton*  
ATTORNEY

1

2,828,742

## CARTRIDGE-NEEDLE UNIT

David M. Ashkenaz, Bala-Cynwyd, Pa., assignor to American Home Products Corporation, New York, N. Y., a corporation of Delaware

Application May 2, 1957, Serial No. 656,716

14 Claims. (Cl. 128—218)

This invention relates to a cartridge-needle unit for use in injection syringes which provides for separation of injection needle for medicament before use, assures rigidity of needle during injection, and permits maintenance of sterility.

More particularly it relates to a unit having a ferrule crimped around the flanged end of a medicament-containing tube and securing a penetrable closure to the tube end, a double-pointed hollow injection needle fixedly mounted in a hub, the ferrule and hub being provided with adjustable and interengaged mounting means, and a flexible protective sheath surrounding needle, hub and a portion of the ferrule, the needle hub being mounted in the ferrule in such a position that one point of the needle is close to but does not penetrate the tube closure and adapted on manipulation to cause the needle to penetrate the tube closure. The adjustable interengaged mounting means may be complementary male and female threads. Alternatively the hub may be provided with a self-tapping thread, or a bayonet joint may connect hub and ferrule instead of a continuous thread.

The use of injection syringes with preloaded cartridges has become standard practice. In some cases such cartridges are supplied with an attached sterile needle protected by a rubber sheath, so that the cartridge and needle may be loaded into the syringe as a unit. With this arrangement, two modifications are possible: the needle may be mounted so that it penetrates the tube closure and is in communication with the tube contents, or it may be mounted so that its proximal point is close to but does not penetrate the closure. The former arrangement is highly satisfactory with modern stainless steel needles and many medicaments. In some cases, however, it is desirable to keep the injectable drug out of contact with all metal until the time of injection and in these cases the latter arrangement is preferred. The former arrangement has the advantage that it is easy to mount the needle rigidly on the cartridge, but all previous efforts to realize the latter arrangement as far as I know suffer from the defect that the needle mounting is insecure and wobbly.

Accordingly it is one object of this invention to provide a cartridge-needle unit in which the needle is rigidly mounted on the cartridge both in position of communication and in position of non-communication with the cartridge contents.

Another object of my invention is to provide a unit of this kind having means for maintaining sterility of needle and hub prior to use.

A further object of my invention is to provide a unit of this kind adapted to be used in a conventional syringe body.

A still further object of my invention is to provide a unit of this kind adapted to be used as a syringe per se of the disposable or "throw away" type.

My invention also includes an injection cartridge having a novel ferrule adapted to receive and maintain an injection needle with threaded hub and protective sheath

2

in non-communicating position relative to the cartridge contents.

Other objects, advantages and features of my invention will be apparent from the following disclosure.

The accompanying drawing illustrates in detail preferred embodiments of my invention, but the drawing and accompanying description are intended to be exemplary only and not to limit my invention, the scope of which is defined in the appended claims.

In the drawing:

Fig. 1 represents a somewhat enlarged longitudinal sectional view of one embodiment of my cartridge needle unit;

Fig. 2 is a still further enlarged sectional view of the ferrule-hub portion of Fig. 1 slightly modified;

Fig. 3 is a partly sectionalized view of my unit mounted in a conventional metal syringe body;

Fig. 4 is a partly sectionalized view of my invention applied to a disposable syringe;

Fig. 5 is a sectional view of my invention provided with a self-tapping thread; and

Figs. 6, 7 and 8 are sectional views of my invention provided with a bayonet joint.

In the drawing a tube 1 containing an injectable drug 2 is closed at its proximal end by a slidable plunger 3 provided with a threaded stud 4 adapted to engage a push rod 5 having a thumb piece 6. The distal end of tube 1 is closed by a penetrable closure which may be a flat disc 7 or a flanged stopper 8. The closure is seated on and compressed against a flange 9 by means of a crimped skirt 10 integral with ferrule 11. Alternatively the crimping means may be a separate flanged collar 12 as shown in Fig. 2. Ferrule 11 has a central bore 13 which is slightly contracted and provided with a female thread 14 at its distal end. The exterior of ferrule 11 is provided with a male thread 15 adapted to mate with the female thread 16 in the distal end of a syringe 17 as shown in Fig. 3. Distally from thread 15 the ferrule is narrowed, and the narrowed portion is provided with a fillet or flange 18 at or near its distal end. Ferrule 11 shown in Fig. 2 differs from ferrule 11 in two respects. It is provided with a flange 19 at its proximal end to furnish a bearing for crimping collar 12 and its body lacks the male thread 15 of ferrule 11. This type of ferrule is suitable for use in syringes in which the cartridge is secured against longitudinal movement by endwise pressure on the proximal end of the cartridge.

A double-pointed injection needle 20 is fixedly mounted in a hub 21 with its proximal point 22 projecting beyond the hub as shown in Figs. 1 and 2. At its proximal end the hub is provided with a male thread 23 mating with female thread 14 of the ferrule. The distal end of the hub is enlarged and is knurled as shown at 24.

When assembled for packaging, hub 21 is screwed into ferrule 11 far enough so that the hub is firmly seated in the ferrule and point 22 of the needle is close to but does not penetrate closure 7 or 8 of tube 1 as shown in Figs. 1, 2, 4 and 5. The lengths of threaded portions of hub 23 and ferrule 14, and the length of the portion of the needle projecting proximally through the hub are such that, when knurled portion of hub 24 is screwed home on distal end of ferrule 11, point 22 of needle 20 penetrates closure 7 or 8, and the needle communicates with the contents 2 of tube 1.

Needle 20 is provided with a sheath 25 of rubber or similar flexible elastomer. This sheath is closed at the distal end 26 and at its proximal end 27 fits snugly over knurled portion of hub 24 and fillet 18. This sheath has a double function; it serves to maintain the sterility of needle 20 and hub 21, and its friction on the hub and on fillet 18 of ferrule 11 or 111 prevents accidental penetration of closure 7 or 8 by the needle.

In assembly the cartridge-needle unit is sterilized by any suitable conventional method.

To give an injection, the user slips the unit of Figs. 1-3 into a syringe and secures it, either by screwing it in as shown in Fig. 3 or by locking it endwise, depending on the type of syringe. He then grips the sheath with his fingers opposite the knurled portion of the hub 24 and screws the hub home on the ferrule, thus causing the needle to penetrate the tube closure. This is a simple manipulation and, because of the construction of the cartridge-needle unit, results in a firmly seated and rigidly held needle. The firmness and rigidity are due to the compressive effect of the screw threads and the metal-to-metal contact of hub and ferrule, features not found in any prior units known to me.

Up to this point there is no need for the user to take precautions against contamination of the needle since it is still protected by the sheath. It is thus possible for a number of syringes to be prepared and laid out at one time, e. g. when multiple injections are to be given to one or a series of patients.

When ready, the user slips off the sheath and makes the injection.

Application of my invention to a disposable or "one shot" syringe is illustrated in Fig. 4. In such syringes the drug-containing tube 201 itself serves as the syringe body. It is provided with a finger flange 28, and push rod 205 doubles as a protective needle cover. The push rod has an outside diameter sufficiently small to pass through the bore of tube 201 and has an internal bore 29 sufficiently large to accommodate needle and sheath. It is provided at its proximal end externally with a flange 206, serving as a thumb piece, and internally with a female thread 216 mating with male thread 15, and serving to retain the rod 205 in position until the syringe is used. At its distal end rod 205 is provided with a female thread 30 adapted to mate with the thread on stud 4.

The user of the syringe of Fig. 4 first removes rod 205 from hub 11, affixes it by thread 30 and stud 4 to plunger 3 and manipulates hub 24, as described in connection with Figs. 1-3, to cause the proximal end 22 of needle to penetrate the cartridge closure 7. Then, immediately before injection, he slips off sheath 25 to expose the sterile needle.

Ferrule 15, instead of being provided with an internal thread as shown in Figs. 1 and 2, may be made of a material such as aluminum or a synthetic plastic 315, Fig. 5, susceptible of self-tapping. The distal part of the central bore 313 is then made smooth as at 314 instead of being threaded. Self-tapping thread 232 on hub 321 then forms its own thread in bore 314 when the hub 321 is screwed home. Otherwise this modification functions like that of Figs. 1 and 2.

Figs. 6, 7 and 8 illustrate a modification in which a bayonet joint is substituted for a continuous thread as the adjustable interconnected mounting means. In fact a bayonet joint may be considered as a special case of a screw-threaded joint. In this modification two pins 423 projecting from the proximal end of hub 421 engage two angled or tortuous grooves 414 spaced at 180° in the distal portion of the bore of ferrule 411. In the embodiment shown each groove 414 has two longitudinal portions 414a and 414c and two circumferential portions 414b and 414d.

In assembling this unit, the cartridge having been filled and ferrule 411 crimped on its flange 9, the needle hub 421 is inserted in ferrule 411, pins 423 entering groove portions 414a, and sheath 25 is drawn over needle and hub as shown in Fig. 6.

To prepare for injection, hub 421 is grasped through sheath 25, rotated to move pins 23 through groove portions 414b, pressed proximally to cause needle point 22 to penetrate closure 8 while pins 423 move down groove portions 414c, and further rotated to lock pins 423 in

groove portions 414d. Meanwhile the flexibility of sheath 25 permits it to bulge outwards as at 25a; Fig. 7 illustrates this position of the elements of the unit. On removal of sheath 25, the unit is ready for injection.

The embodiment shown in Figs. 5-8 is adapted either for use in a syringe body as shown in Fig. 3 or in a disposable syringe as shown in Fig. 4.

From the above description it will be seen that I have provided a cartridge-needle unit having a hollow needle firmly mounted out of contact with the cartridge contents but adapted by simple manipulation to be brought into communication with the cartridge contents, in which position it is held rigidly and without wobble. The unit is adapted to be packaged and distributed with the needle and hub in sterile condition and protected against contamination; accidental penetration of the cartridge closure by the needle is eliminated.

In the specification and claims "distal" is used to denote a position or direction towards the needle and "proximal" a position or direction towards the plunger.

I claim:

1. A cartridge-needle unit comprising a ferrule crimped around the flanged end of a drug-containing tube, a penetrable closure secured to the flanged end of the tube by the crimped ferrule, a double-pointed hollow injection needle fixedly mounted in a hub, the ferrule and hub being provided with adjustable and interengaged mounting means, and a flexible protective sheath surrounding needle, hub and a portion of the ferrule, the needle hub being mounted in the ferrule in such a position that one point of the needle is close to but does not penetrate the penetrable tube closure and being adapted on manipulation of the adjustable interengaged mounting means to further enter the ferrule, cause the needle to penetrate the tube closure and seat the needle firmly in the unit in communication with the contents of the tube.

2. A unit as defined in claim 1 in which the ferrule is provided on its distal portion with a fillet and the proximal end of the sheath surrounds the fillet as well as the needle hub.

3. A cartridge-needle unit as defined in claim 1 in which the interengaged mounting means comprises a screw thread.

4. A cartridge-needle unit as defined in claim 1 in which the interengaged mounting means comprises a pin and a tortuous groove.

5. A cartridge-needle unit comprising a ferrule having an axial bore, crimped around the flanged end of a drug-containing tube, and securing a penetrable closure to the flanged end, a double-pointed hollow injection needle fixedly mounted in a hub externally threaded to mate with the axial bore of the ferrule, and a flexible protective sheath surrounding needle, hub and a portion of the ferrule, the needle hub being screwed into the ferrule such a distance that one point of the needle is close to but does not penetrate the tube closure and being adapted on manipulation to cause the needle to penetrate the closure.

6. A cartridge-needle unit as defined in claim 5 in which the ferrule is provided with internal threads to mate with the threads on the hub.

7. A cartridge-needle unit as defined in claim 5 in which the thread on the hub is a self-tapping thread and the ferrule is of sufficiently soft material to permit tapping by the thread of the hub.

8. A unit as defined in claim 5 in which the ferrule is provided with an external thread on its proximal portion.

9. In combination a syringe body having a barrel adapted to receive a cartridge-needle unit, an internally threaded hole in the distal end of the barrel, a cartridge-needle unit as defined in claim 8, contained in the barrel, the external thread on the ferrule engaging the internal thread in the hole in the distal end of the barrel and securing the cartridge against longitudinal movement.

5

10. In combination a syringe body having a barrel adapted to receive a cartridge-needle unit, means to secure a cartridge-needle unit against longitudinal movement, and a cartridge-needle unit as defined in claim 5 contained in the barrel.

11. A cartridge adapted to be packaged with an injection needle mounted thereon, comprising a tube having a flange end, a penetrable closure on the flanged end and a ferrule crimped around the flanged end and securing the closure to the tube, said ferrule being provided with an internal thread and an external fillet in its distal portion.

12. A cartridge as defined in claim 11 in which the ferrule has an external thread on its proximal portion.

13. An injection syringe of the disposable type comprising in combination a drug-containing tube having an external finger flange at its proximal end and closed at its proximal end by a slidable plunger provided with an exposed threaded stud, said tube having a restricted flanged opening at its distal end, a penetrable closure disposed across the flanged opening, a ferrule provided with crimping means crimped around the flange of the tube opening and securing the penetrable closure thereto, said ferrule being provided with an external thread around its proximal portion and its distal portion being provided with an exterior fillet and an internal bore, a double-pointed injection needle rigidly affixed in a hub having on its proximal portion an external thread mating with the internal bore of the ferrule and having an enlarged distal portion, the lengths of the bore of the ferrule, the external thread of the hub and the portion of the needle extending proximally from the hub being so chosen that the hub and ferrule can be engaged without causing the proximal point of the needle to penetrate the penetrable tube closure, but the proximal point of the needle is caused to penetrate the closure when the hub is screwed home on the ferrule, a flexible sheath closed at its distal end surrounding the needle and at its proximal end drawn friction-tight over the enlarged portion of the hub and the fillet on the ferrule, a rigid tubular shield surrounding the sheathed needle

6

and secured to the syringe by an internal thread at its proximal end mating with the external thread on the ferrule, the internal diameter of the shield being sufficient to accommodate needle and sheath while its external diameter is smaller than the internal diameter of the drug-containing tube, the shield also having an internal thread at its distal end mating with the stud on the plunger, whereby the shield can serve as a push rod in making an injection.

14. In an injection syringe of the disposable type comprising a drug-containing tube closed by a plunger at its proximal end and having a restricted flanged opening at its distal end closed by a penetrable closure, an affixed injection needle, a flexible sheath surrounding the needle and a combination push-rod-shield surrounding the sheathed needle, the improvement that comprises: a ferrule provided with crimping means crimped around the flange of the tube opening and securing the penetrable closure thereto, said ferrule being provided with an external thread around its proximal portion and its distal portion being provided with an exterior fillet and an interior thread, a double-pointed injection needle rigidly affixed in a hub having on its proximal portion an external thread mating with the internal thread of the ferrule and having an enlarged distal portion, the lengths of the internal thread of the ferrule, the external thread of the hub and the portion of the needle extending proximally from the hub being so chosen that the external and internal threads can be engaged without causing the proximal point of the needle to penetrate the penetrable tube closure while the proximal point of the needle is caused to penetrate the closure when the hub is screwed home on the ferrule, and a flexible sheath closed at its distal end surrounding the needle and at its proximal end drawn friction-tight over the enlarged portion of the hub and the fillet on the ferrule.

#### References Cited in the file of this patent

#### UNITED STATES PATENTS

1,961,490	Hein	June 5, 1934
2,745,403	Goldberg	May 15, 1956

U. S. DEPARTMENT OF COMMERCE  
PATENT OFFICE  
**CERTIFICATE OF CORRECTION**

Patent No. 2,828,742

April 1, 1958

David M. Ashkenaz

It is hereby certified that error appears in the printed specification of the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 1, line 17, for "needle for" read == needle from ==; column 3, line 51, for "232" read == 323 ==; column 4, line 72, after the figure "8" strike out the comma; column 5, line 8, for "flange" read == flanged ==; line 25, for "it" read == its ==.

Signed and sealed this 6th day of May 1958.

(SEAL)

Attest:

KARL H. AXLINE  
Attesting Officer

ROBERT C. WATSON  
Commissioner of Patents