United States Patent

Gomez et al.

[15] **3,636,950**

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[54] DISPOSABLE CARTRIDGE FOR ADMIXING TWO COMPONENTS OF INJECTABLE MEDICAMENT

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[21] Appl. No.: **775,726**

[52] **U.S. Cl.** ..... **128/218 M**, 128/218 D, 128/272

[51] **Int. Cl.** **A61m 05/00**

[58] **Field of Search** ..... 128/218, 218 M, 218 N, 218 NV, 128/218.1, 218.1 P, 272, 220, 218 R, 218 D, 218 P

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[57] **ABSTRACT**

A cartridge unit for use in, or as a syringe, and comprising two chambers, each for containing a separate component of the final injectable mixture, wherein one of said chambers is detachably mounted on the unit, the other chamber is provided in the unit, and means are provided for communicating said two chambers and then causing the contents of the removable chamber to be introduced into the other chamber, whereafter the detachable chamber is removed to permit attachment of a push rod to the plunger or stopper when the unit is to be used.

7 Claims, 5 Drawing Figures

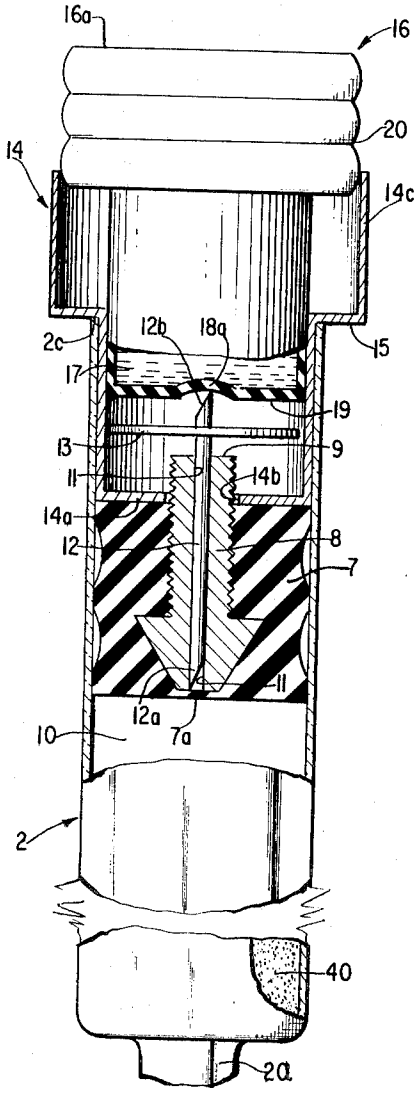


FIG. 1

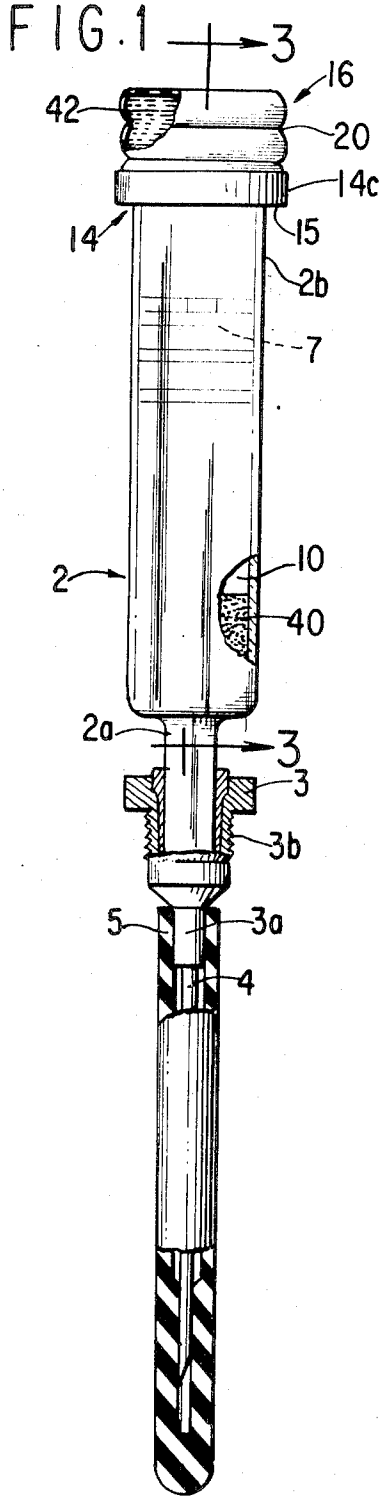


FIG. 2

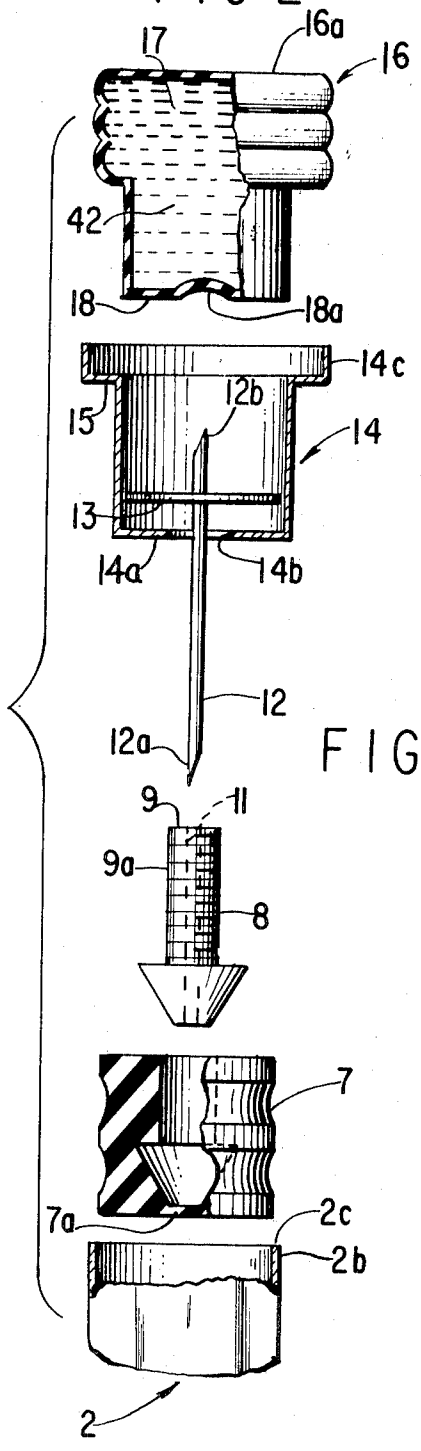


FIG. 4

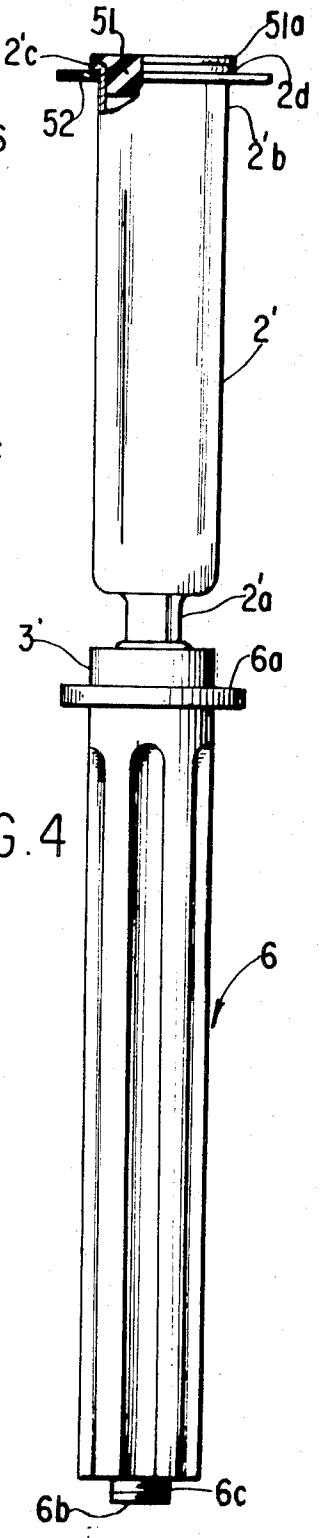


FIG. 3

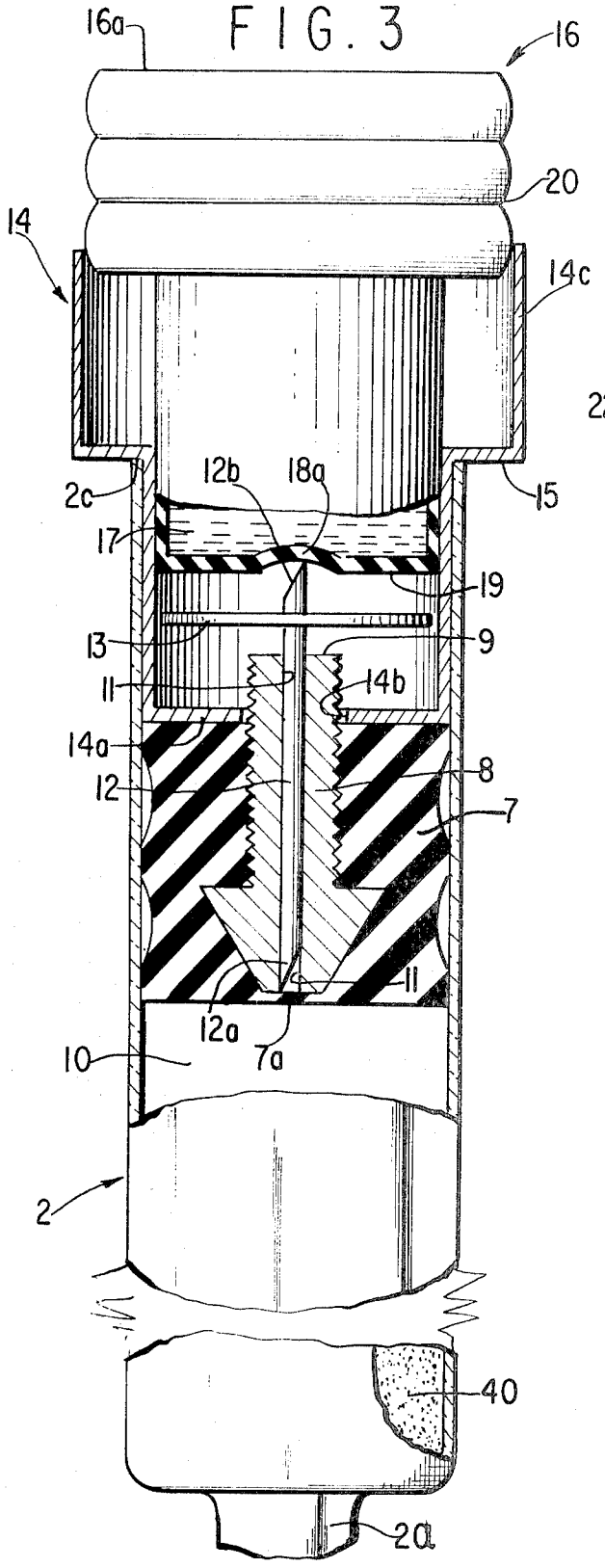
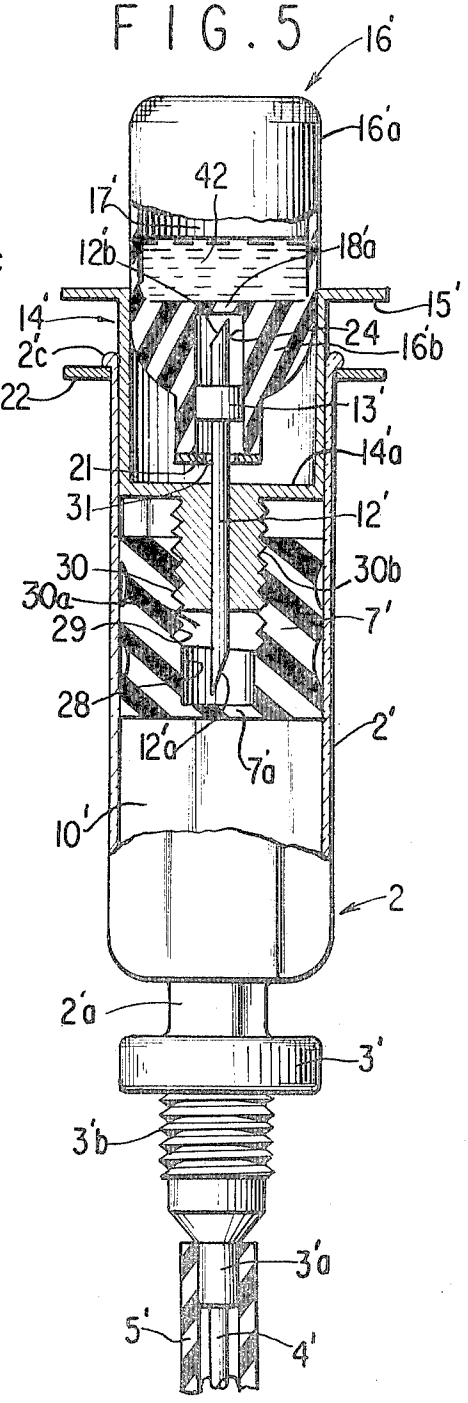

16a
16
20
14
14c
2c
12b
18a
15
17
19
13
9
11
14b
14a
12
8
7
11
12a
7a
10
2
40
2a

FIG. 5


16'
16'a
42
17'
12'b
18'a
15'
14'
24
2'c
16'b
22
13'
14'a
21
31
12'
30
30b
30a
7'
29
28
12'a
7'a
2'
10'
2
2'a
3'
3'b
3'a
5'
4'

DISPOSABLE CARTRIDGE FOR ADMIXING TWO COMPONENTS OF INJECTABLE MEDICAMENT

BACKGROUND OF THE INVENTION

This invention relates generally to hypodermic syringes, and more particularly to a cartridge unit, ampule-needle assembly, or the like, adapted for admixing two different components contained separately in sealed compartments thereof prior to use, whereby a sterile therapeutic mixture or composition may be injected as desired.

In many instances, it is necessary that, preparatory to injecting certain therapeutic mixtures or compositions, the different components thereof, which may be unstable when mixed, are maintained separately until used. In other instances, it is necessary to reconstitute a drug, which is preferably stored in dry form, by dissolving or suspending it in a liquid medium.

Conventional devices for accomplishing the foregoing purposes usually include at least two separate compartments, each of which contains one of the components of the therapeutic composition. Just before injection of the therapeutic composition comprising the mixed components is to be made with the device, said components are admixed in situ. Obviously, such mixing must be done in a sterile manner without loss of either component to assure the required proportions, and hence, potency of the medicament to be injected. This is usually accomplished by one of a number of generally known expedients. For example, the mixing may be brought about (a) by at least partially removing a common wall or partition provided between two chambers, each containing one of the components; e.g., as disclosed in U.S. Pat. No. 2,636,493 and U.S. Pat. No. 2,766,766; (b) by the breaking of a separating wall or membrane upon application of hydrostatic pressure; e.g., as in U.S. Pat. No. 3,351,058 and U.S. Pat. No. 2,708,438; or (c) by elaborate valving arrangements; e.g., as disclosed in U.S. Pat. No. 3,326,215 and U.S. Pat. No. 2,665,687; and also (d) by providing for the piercing of a chamber-separating wall or membrane by a cannula needle; e.g., as in U.S. Pat. No. 3,098,483 and U.S. Pat. No. 3,327,710. Generally, such devices of the various types exemplified in said patents are either complicated in structure, bulky, cumbrous and/or do not permit facile attachment of a push rod to the stopper or plunger of the cartridge unit at the time of use.

SUMMARY OF THE INVENTION

In view of the foregoing, it is an object of the present invention to provide a new and improved cartridge unit for containing two separate components in two separate compartments to assure that there is no mixing together of said components until the desired time.

It is another object of the present invention to provide a cartridge unit possessing the desired advantages of segregated storage, mixing and injection capability.

A further object of the invention is to provide a new and improved cartridge unit of the type described, wherein the separate components are initially maintained in separately sealed chambers and may be rapidly and thoroughly mixed together at the desired time without exposing the chambers externally, thus eliminating the possibility of spillage or contamination of the components both before and after mixing.

Another object of the invention is to provide such a cartridge unit wherein one chamber thereof may be detachably mounted on the unit, whereby, after the contents thereof is transferred to the chamber which is permanently provided in the unit, said one chamber may be removed to permit insertion of the unit into a syringe and attachment of the plunger rod of the latter to the stopper of the unit, which may then be used for injection.

It is another object of the present invention to provide such a cartridge unit which may be used in a syringe or as a fully disposable syringe per se.

It is yet another object of the invention to provide such a cartridge unit wherein commercially available ampule-needle assemblies comprising a single chamber for medicament may readily be modified to obtain the two chambered mixing structure of the invention.

Still another object of the invention is to provide such a cartridge unit wherein, subsequent to the mixing operation, the modifying structure is removable, whereby a commercially available ampule-needle assembly may then be used in its usual manner.

It is another object of the present invention to provide such a cartridge unit wherein at least one wall of the detachably mounted chamber thereof is formed of a flexible material so that when pressure is applied thereto (i.e., when the internal volume is decreased by compressing said one wall) the removable chamber is caused first to communicate with the second chamber containing a second component of the composition, and thereafter, the component in the removable chamber is caused to be transferred to said second chamber.

The foregoing, and other features, objects and advantages of the present invention are attained by the provision of a new and improved cartridge unit wherein there is provided a rigid tubular member forming the main body of the assembly and providing a first chamber having a distal closed end and a proximal open end. A reciprocable stopper is positioned in said tubular member and seals off a portion of the first chamber including the distal end thereof. In a preferred embodiment of the invention, a stud is anchored in the stopper and extends axially thereof with a portion protruding therefrom toward the proximal end of the first chamber and the distal end directed towards a penetrable area of the stopper. The stud has an axial channel extending completely therethrough wherein there is positioned, for axial movement therein, a cannula, which has a piercing point at either end, and is hereinafter referred to as a "double-pointed cannula." The double-pointed cannula has the distal end thereof located adjacent the penetrable area of the stopper. The cannula has a laterally projecting element affixed thereto at the proximal end thereof which is normally positioned proximally away from the proximal end of the stud and is adapted to limit the distal movement of the cannula in the axial chamber upon abutment of the laterally projecting element with the transverse web of the distal end of a mounting bushing. The mounting bushing is removably positioned in the proximal end of the rigid tubular body and has an aperture in said web thereof through which the stud protrudes. Associated with the aperture are connecting means for removably attaching the bushing to the stud, thereby to prevent undesired movement of the plunger when the chamber is depressed. Preferably, such connecting means comprise a male screw thread on the proximal end of the stud and a complementary female screw thread in the aperture in the web of the bushing.

Positioned in the mounting bushing, which functions as a housing therefor, is a movable sack providing a sealed chamber and having at least one wall thereof which may move inwardly of the sack to reduce the volume of the chamber provided thereby. The distal wall of the sack is of a penetrable material, and when the sack is positioned in the mounting bushing, said wall overlies the proximal end of the double-pointed cannula.

In a preferred embodiment of the invention, the wall of penetrable material is faced, at least in part, with a rigid portion which functions to limit the distal travel of the sack in the bushing when the laterally projecting element of the cannula and/or proximal edge of the stud in the stopper is abutted by said rigid portion. Preferably, the mounting bushing is provided at its proximal end with a lateral projection extending outwardly of the tubular body when mounted therein and functioning as a finger rest, only during premanipulation of the cartridge unit for the mixing operation as will appear hereinafter.

In another embodiment of the invention, the stud in the plunger is omitted and, instead, the plunger is provided with an axially disposed bore extending from the proximal surface of the plunger to a point close to but not through the distal sur-

face thereof. The bore is provided with a female screw thread. The bushing, instead of having an aperture provided with a female screw thread, has a proximally disposed nipple having an axial bore completely therethrough adapted to receive the distal end of the double-pointed cannula. The outer surface of the nipple is provided with a male screw thread complementary to the female screw thread of the bore of the plunger, whereby the bushing may be removably connected to the plunger. In this embodiment, the removable sack is preferably provided with a neck at the distal end in which there is an axial bore, in this case, extending through the distal surface of the neck but terminating at the proximal end thereof, which is closed by a transverse web of penetrable material functioning as a seal for the chamber in the removable sack. The bore has a diameter to permit reciprocation therein of a piston permanently affixed to the proximal region of the double-pointed cannula. The distal end of the bore has a restriction therein defining a reduced diameter which permits reciprocation of the double-pointed cannula therethrough but functions as a stop for the piston affixed thereto, thus limiting distal reciprocation of the cannula-piston assembly. Reciprocation of said assembly in the proximal direction is limited by abutment of the piston with the proximal transverse web of the bore, after the proximal end of the double-pointed cannula has penetrated said web.

The nature of the invention will more readily appear on a reading of the descriptions of several preferred embodiments thereof set forth below, with reference to the drawings wherein:

FIG. **1** is a side elevational view of a cartridge unit assembly embodying the invention, with portions of the structure broken away to disclose the contents of the sack and tubular barrel and the interior structures of the ferrule and cannula assembly;

FIG. **2** is an exploded view of the proximal portion of the assembly illustrated in FIG. **1**;

FIG. **3** is an axial cross section of the assembly shown in FIG. **1**, taken on line **3**—**3** thereof;

FIG. **4** is a side elevational view of a modification of the unit of FIGS. **1**–**3**, wherein the sack, cannula, and bushing assembly is omitted, and instead, there is a removable cover positioned in the proximal open end of the unit, and a dual purpose cannula guard and push rod is attached to the distal end of the unit; and

FIG. **5** is a vertical cross section of the proximal end of the unit disclosed in FIG. **4**, with the cover removed and a bushing and modified sack and needle assembly inserted therein.

Referring now to the drawings, and particularly FIGS. **1**, **2**, and **3**, the cartridge unit disclosed therein comprises a tubular barrel **2** to which is affixed, on a distal neck **2***a* thereof, a plastic ferrule or hub **3** and a metal injection cannula **4**. As will be recognized by those skilled in the art, ferrule **2** may, alternatively, be of metal, as is conventional and shown, for example, in U.S. Pat. No. 2,671,450. Cannula **4** is provided with a removable cannula sheath **5** of rubber which is frictionally mounted on a distal portion **3***a* of ferrule **3**, to encase cannula **4**, as also appears in said patent.

Sealingly mounted within barrel **2**, but reciprocally movable therein, is a resilient plunger or stopper **7** having a stud **8** anchored axially therein with the proximal end **9** thereof protruding from said plunger **7**. Said stud **8** has a male screw thread **9***a* thereon adapted for selective attachment thereto of a plunger rod of a syringe, not shown, but which may be of the structure disclosed, for example, in U.S. Pat. No. 2,671,450. Tubular barrel **2** per se, the plunger **7** therein, and neck **2***a* at the distal end of barrel **2**, enclose a first chamber **10** in which may be contained the first component **40**, which may be a solid or liquid, of the medicament.

Positioned in the proximal end **2***b* of tubular barrel **2** is a bushing **14** of plastic. Bushing **14** has, at the distal end thereof, a transverse web **14***a* within which is centrally provided a female-threaded aperture **14***b* of a diameter to permit attachment of said bushing **14** screw threadedly on the complementary male thread **9***a* provided on the proximal end **9** of stud **8**, as best seen in FIG. **3**. The proximal portion **14***c* of bushing **14** is of a larger diameter than the remainder thereof and is connected to the latter by an annular extension **15** which functions as a limiting stop with respect to the insertion of bushing **14** in barrel **2** upon abutment of said extension **15** with the edge **2***c* of the proximal end **2***b* of barrel **2**. Annular extension **15** serves also as a finger rest when the device is being utilized in the mixing operation, as referred to in greater detail hereinafter.

In accordance with this preferred embodiment of the present invention, stud **8** has an axial bore **11** completely therethrough. Positioned for reciprocation in said bore **11** is a double-pointed cannula **12**. As assembled (i.e., prior to use of the device in the mixing operation) and as appears in FIG. **3**, the distal end **12***a* of cannula **12** is positioned adjacent a pierceable area **7***a* located at the distal end of plunger **7**. The proximal end **12***b* of the double-pointed cannula **12**, on the other hand, protrudes beyond the proximal end **9** of stud **8** and hence within bushing **14** when the latter is attached to stud **8**. At said proximal end **12***b*, cannula **12** has axially affixed thereto a laterally projecting disk **13**, which is positioned proximally of web **14***a* of bushing **14**. The diameter of disk **13**, as shown, is greater than that of the centrally located aperture **14***b* in web **14***a* of bushing **14** and substantially that of the interior of bushing **14** for purposes which will also appear hereinafter.

Positioned in bushing **14** is a sack **16** which encloses a second chamber **17** containing a second component **42**, which may be a solid or a liquid, of the medicament to be mixed with the first component **40** in the first chamber **10**. Sack **16** is provided with a distal surface **18**, which, in this instance has been sealed at reentrant area **18***a* after the liquid has been introduced into chamber **17**. Said area **18***a* is penetrable by the proximal end **12***b* of double-pointed cannula **12**, as referred to hereinafter.

Sack **16** is provided at the proximal region of its circumferential surface with bellows folds **20**, whereby, upon suitable pressure on the proximal end **16***a* of sack **16**, said region may be collapsed, thereby to reduce the volume of the second chamber **17** provided therein which contains the second component **42**.

In the assembly of the conventional cartridge portion of the embodiment of the invention just described, plastic ferrule **3** and metal cannula **4** may be permanently mounted on the distal neck end **2***a* of the tubular barrel **2**, as described, for example, in U.S. Pat. No. 3,278,357. Cannula **4** may be provided with a cannula sheath **5**, manually, or by a device described, for example, in U.S. Pat. No. 3,188,727. Thereafter, the first component **40** of the medicament is introduced into first chamber **10** in barrel **2**, and plunger **7** may be inserted into barrel **2** by apparatus described, for example, in Serial No. 513,136 filed Dec. 10, 1965, which has matured into U.S. Pat. No. 3,391,518.

Alternatively, if desired, ferrule **3** may be of metal and attached, with the cannula affixed thereto previously to barrel **2**, by apparatus described, for example, in U.S. Pat. No. 3,247,641. In this alternative assembly, the procedural steps are quite different. Thus, the plunger **7** is inserted first; then, with the tubular barrel **2** inverted so that the open end thereof faces upwardly, the contents of the first chamber **10** may be introduced, and thereafter the assembly consisting of ferrule **3** and cannula **4** may be crimpingly attached to the tubular barrel **2**, as by said apparatus of U.S. Pat. No. 3,247,641.

As will appear to those skilled in the art, the modes of the assembly of the parts described immediately above form no part of the present invention, and may be varied as found desirable.

Reverting now to the assembly of the above desired embodiment of the mixing structure of the present invention, double-pointed cannula **12**, with disk **13** affixed thereto, is first inserted via the open proximal end of bushing **14** into the distal region thereof. Disk **13** riding within bushing **14** functions as

positioning means for double-pointed cannula 12 so that the distal end 12*a* of the latter protrudes through aperture 14*b* in web 14*a* of bushing 14, while the proximal end 12*b* of cannula 12 with the disk 13 affixed thereto is positioned within the distal end of bushing 14. Thereafter, sack 16, which already contains the second component 42 of the medicament sealed in the second chamber 17 thereof as referred to before, is introduced into said bushing 14, whereby the surface 18 of sack 16 faces distally towards the proximal end of web 14*a* of bushing 14, but is spaced therefrom to avoid penetrating abutment of penetrable area 18*a* with the distal end 12*b* of double-pointed cannula 12, for a purpose which will also appear presently.

As part of the assembly of this embodiment of this invention, bushing 14, with double-pointed cannula 12 and sack 16 positioned therein as just described, is next inserted into the proximal end 2*b* of barrel 2. As the distal end of said assembly is inserted into barrel 2, double-pointed cannula 12 is maintained in position by disk 13 bearing within bushing 14 so that distal end 12*a* of double-pointed cannula 12 is aligned with bore 11 of stud 8 and enters said bore. Said assembly is inserted further into barrel 2 until the portion of web 14*a* of bushing 14 which surrounds screw-threaded aperture 14*b* thereof abuts the proximal edge 9 of stud 8. Bushing 14 is then rotated for screw threadedly attaching it to stud 8 by means of said screw-threaded aperture 14*b* and complementary male screw thread 9*a* of stud 8. Rotation of bushing 14 is continued until annular extension 15 thereof abuts edge 2*c* of tubular barrel 2. In such arrangement of the parts, double-pointed cannula 12 is positioned within bore 11 of stud 8 with the distal end 12*a* thereof located adjacent penetrable area 7*a* of plunger 7, and plunger 7 is retained against any inadvertent reciprocal movement.

Just prior to the use of the device by the doctor, nurse, or other party performing the injection of medicament into the patient, sack 16 may be urged distally in bushing 14, until area 18*a* of sack 16 abuts the proximal end 12*b* of double-pointed cannula 12 and begins to urge it distally in bore 11 of stud 8 until the distal end 12*a* of double-pointed cannula 12 abuts area 7*a* of plunger 7. As sack 16 is urged further distally in bushing 14, and depending upon the relative penetrability characteristics of area 18*a* and 7*a*, first one and then the other of said areas is penetrated by the respective ends 12*b* and 12*a* of double-pointed cannula 12. As will be understood, during these operations, plunger 7 is maintained substantially in the position shown in FIG. 3, because of the attachment of stud 8 thereof to bushing 14 as described above.

Regardless of the sequence of penetration, when sack 16 is ultimately pressed home within bushing 14, area 18*a* of sack 16 is fully pierced by the proximal end 12*b* of double-pointed cannula 12, area 7*a* of plunger 7 is fully pierced by the distal end 12*a* of double-pointed cannula 12, and the laterally projecting disk 13 on double-pointed cannula 12 is abutted on its proximal surface, by the distal surface of web 18 of sack 16, and on its distal surface by the proximal end 9 of stud 8. In such relationship of parts, said first chamber 10 in tubular barrel 2 is in communication with second chamber 17 in sack 16 via double-pointed cannula 12.

Finger pressure is next applied to proximal end 16*a* of sack 16 to reduce the volume of second chamber 17 therein and hence to force the second component 42 thereof through double-pointed cannula 12 into first chamber 10 in tubular barrel 2 containing the first component 40 of the medicament. The entire device may be shaken manually or otherwise agitated to cause appropriate mixing of the second component 42 with the first component 40 in chamber 10.

Subsequently to the mixing operation, bushing 14 is unscrewed from stud 8, and thereafter is lifted out of the proximal end 2*b* of tubular barrel 2, to carry therewith both sack 16 and double-pointed cannula 12.

At the time of use for actual injection, the cartridge unit comprising tubular barrel 2, ferrule 3, cannula 4, cannula sheath 5, plunger 7, and the mixed medicament in chamber 10, may simply be inserted into a syringe of the type described in U.S. Pat. No. 2,671,450, referred to hereinbelow and the plunger pushrod of said syringe screw threadedly attached to stud 8 of plunger 7. Thereafter, as is conventional, cannula sheath 5 may be removed to uncover cannula 4 and the device utilized for the usual injecting operation, including aspiration, as desired.

In the embodiment of the invention disclosed in FIGS. 4–5, the barrel, ferrule and cannula structures are substantially identical to those of the embodiment disclosed in FIGS. 1–3, with the exceptions noted hereinafter. Accordingly, said substantially identical structures in FIGS. 4–5 are indicated by the same, but primed reference numerals. The structural and operational differences of the embodiment of FIGS. 4–5 when compared with that of FIGS. 1–3 will appear from the following description of the former.

As disclosed in FIG. 4, a cannula guard 6 is mounted on ferrule 3′ (FIG. 5) by means of the male screw thread 3′*b* on the latter and a complementary female screw thread within a first bore (neither of which screw thread or bore is visible in FIG. 4) in the proximal end 6*a* of cannula guard 6, thereby to cover the cannula sheath 5′ of cannula 4′ (FIG. 5). The general relationship of the cannula guard 6 to the remaining structure described hereinbefore is conventional and is disclosed in detail, for example, in U.S. Pat. No. 2,671,449. The single notable exception to the cannula guard 6 structure shown in said patent is that, in the present instance, instead of there being provided in the distal end of said guard 6 a second bore having a female screw thread therein adapted for attachment to a stud on the plunger 7′, there is provided, on said distal end of guard 6, a nipple 6*b* having a male screw thread 6*c* thereon for a purpose which will later appear.

A further and more important distinction of the FIGS. 4–5 embodiment from that depicted in FIG. 1–3 is that, in the former, the plunger 7′, the bushing 14′, the sack 16′, and the double-pointed cannula 12′ have modified structures now described.

Primarily, plunger 7′ is not provided with a stud. Instead, plunger 7′ is provided with an axial bore 28, in which is a female screw thread 29. The latter is complementary to the male screw thread 6*c* on nipple 6*b* of cannula guard 6. However, the distal end of bore 28 is closed by a penetrable area 7′*a* of plunger 7′. Bushing 14′ does comprise an annular extension 15′ at its proximal end. However, at its distal end, it is not provided with a female threaded aperture 14*b* in transverse web 14′*a* thereof. Instead web 14′*a* is provided with a distally disposed nipple 30 which has axially therethrough a bore 30*a* and, on its peripheral surface, a male screw thread 30*b*. Male screw thread 30*b* is also complementary to female screw thread 29 of bore 28, whereby nipple 30 may be removably attached to plunger 7′ as shown in FIG. 5.

Mounted in bushing 14′ is a sack 16′ which, in this instance, has the general configuration of an inverted plastic bottle, the neck 16′*b* of which is provided with an axial bore 24. Sack 16′ encloses a chamber 17′ which contains the second component 42 of the medicament to be injected. Bore 24, at its proximal end is separated from chamber 17′ of sack 16′ by a penetrable web 18′*a*. At the distal end of bore 24, there is affixed a restriction cap 21 which defines a smaller diameter opening 31 through which double-pointed cannula 12′ reciprocates. Affixed adjacent to the proximal end 12′*b* of cannula 12′ is a piston 13′ which is reciprocably mounted within bore 24. As will be apparent from FIG. 5, piston 13′ functions as a stop which limits reciprocation of double-pointed cannula 12′ distally when said piston 13′ engages with web 18′*a*, and proximally upon engagement of piston 13′ with restriction cap 21.

In the assembly of sack 16′ per se, the chamber 17′ of the latter is filled with the second component 42 and sealed. Double-pointed cannula 12′ with piston 13′ affixed is next inserted in bore 24 of neck 16′*b*. Thereafter, restriction cap 21 is pressed over distal end 12′*a* of cannula 12 and sealed to the distal end of neck 16′*b*.

As a further distinction of this modified embodiment of the invention, bushing **14'**, sack **16'**, and cannula **12'** may be provided to the ultimate user as a unit assembly separately of the cartridge unit comprising tubular barrel **2'**, stopper **7'**, ferrule **3'**, cannula **4'**, sheath **5'**, and guard **6**. In such case, the distal end **12'***b* protruding from bore **30***a* in nipple **30** of bushing **14'** may be covered by a cap (not shown) removably mounted on nipple **30** by means of a complementary female screw thread, and sack **16'** may be paper or plastic sealed (not shown) in bushing **14'**. Also for purposes of sterility, there is provided in the proximal end **2'***b* of tubular barrel **2'**, a removable cover **51** which is frictionally seated in the proximal end **2'***b* of barrel **2**, as shown in FIG. **4**. Cover **51** has a peripheral lip **51***a* overlying edge **2'***c* of barrel **2'**, which edge, in this case, is in the form of a bead **2***d*. The latter functions to retain an annular finger piece **52**, in a manner also disclosed in said U.S. Pat. No. 2,671,449.

In the use of the embodiment disclosed in FIGS. **4–5**, cover **51** is removed from tubular barrel **2'**; the cap, if provided on nipple **30** of bushing **14'** is removed to expose the distal end **12'***a* of cannula **12'**; and, again if provided, the seal of the sack **16'** to the bushing **14'** is broken. Thereafter, the user inserts the aforesaid unit assembly of bushing **14'**, sack **16'** and double-pointed cannula **12'** into the proximal end **2'***b* of barrel **2'** and then screws nipple **30** of bushing **14'** into the bore **28** of plunger **7'** by means of the complementary screw threads **30***b* and **29**, respectively (FIG. **5**).

In the mixing operation, the sequence of manipulation is generally similar to that described with respect to the embodiment in FIGS. **1–3**. Specifically, the sack **16'** is first pressed home in bushing **14'** until double-pointed cannula **12'** penetrates both web **18'***a* of sack **16'** and the penetrable area **7'***a* of plunger **7'**. Thereafter, pressure on (or squeezing of) the distal end **16'***a* of sack **16'** forces the first component **40** in chamber **17'** thereof through double-pointed cannula **12'** and into chamber **10'** in tubular barrel **2'** containing the second component **42** of the medicament. As in the previous embodiment, mixing as by agitation may be undertaken, followed then by removal of the bushing **14'**, sack **16'**, and double-pointed cannula **12'** assembly by first unscrewing nipple **30** of bushing **14'** from bore **28** in plunger **7'** and thereafter lifting said entire assembly out of barrel **2'** as a unit.

In the ultimate use of this embodiment of the invention for hypodermic injection, cannula guard **6** is unscrewed from ferrule **3'** to expose sheath **5'** which covers cannula **4'** (as shown in FIG. **5**). Cannula guard **6** is then attached to plunger **7'** by means of the complementary screw-threaded nipple **6***b* of the former and bore **28** of the latter. With the parts in such assembly, cannula sheath **5'** may be removed to expose cannula **4'** and the cartridge unit used as a completely disposable syringe per se by utilizing the finger piece **52** in grasping barrel **2'** while the thumb of the user is positioned on the proximal end **6***a* of cannula guard **6** which now functions as a push rod in the manner described in the aforesaid U.S. Pat. No. 2,671,449.

It will, of course, be understood that, although two specific and preferred embodiments of the invention have been described above in detail, many changes and modifications may be made, and said invention embodies in widely differing forms, without departing from the spirit and scope thereof, in its broader aspects coming within the language or scope of any one or more of the appended claims. Merely by way of example, the several parts may be made of various materials, such as glass, plastics, rubber or metal as desired; other ferrule-cannula assemblies may be utilized, or omitted; other finger piece, cannula sheath and/or guard assemblies may be employed, or omitted; the screw threads may be replaced by other connecting means, such as bayonet, ball and socket, or other frictional attachment means; the double-ended cannula may be provided with stop means other than the disc and piston shown; the bushing and the sack may be provided with complementary screw threads whereby the sack may be screwed into the bushing rather than pushed thereinto; the sack may be rigid and be provided with other volume reducing means, such as a piston; etc. Other variations, including interchange of specific element structures and/or assemblies, in the embodiments disclosed, will suggest themselves to those skilled in the art.

We claim:

1. A cartridge unit assembly adapted for selectively maintaining separately or admixing two components of a medicament composition, said assembly comprising:

a. a rigid tubular member forming the main body of said assembly and providing a first chamber adapted to contain a first component of a medicament and having a distal closed end and a proximal open end;

b. a reciprocable stopper, having a peripheral surface and positioned in said tubular member and sealing a portion of said first chamber including said proximal end thereof, said stopper having an axial bore therein extending inward from the proximal region of said stopper and being closed by a penetrable area in the distal region thereof;

c. a bushing, means mounting said bushing in said proximal open end of said tubular member, said bushing having an opening at its proximal end and having a transverse web at its distal end provided with a centrally located aperture therein;

d. a sack reciprocably mounted in said bushing and having a portion thereof extending from the proximal end of said bushing, said sack defining a second chamber adapted to contain a second component of a medicament, having a penetrable membrane closing the distal region thereof, and being provided with means for ejecting the contents of said second chamber;

e. a double-pointed cannula mounted in said bushing and having the proximal end thereof extending proximally interiorly of said bushing and terminating adjacent said penetrable area of said sack, and having the distal end thereof extending distally within said axial bore in said stopper and terminating adjacent the penetrable distal area of said stopper, said double-pointed cannula having stop means affixed thereto and positioned interiorly of said bushing, first and second abutment means mounted in said bushing distally and proximally of said stop means, respectively, for limiting both distal and proximal reciprocation of said double-pointed cannula within said bore of said stopper upon engagement of said stop means with said first and second abutment means, respectively, said first and second abutment means retaining said stop means within said bushing;

f. complementary connecting means provided in said bore in said stopper and on said transverse web of said bushing for removable attaching said bushing to said stopper.

2. A cartridge unit assembly as defined in claim **1**, wherein said sack is provided with a resiliently collapsible wall.

3. A cartridge unit assembly as defined in claim **1**, wherein stop means are provided on said bushing for abutment with the proximal end of said member for limiting distal entry of said bushing in said member.

4. A cartridge unit assembly as defined in claim **1**, wherein said connecting means comprise:

a stud which is mounted in said stopper, has an axial bore therethrough, and has a male screw thread on at least the proximal region thereof, and

said centrally located aperture of said bushing has a female screw thread therein.

5. A cartridge unit assembly as defined in claim **1**, wherein said first abutment means comprises a stud mounted in said stopper and said second abutment means comprises the distal end of said sack, and wherein said stop means affixed to said double-pointed cannula abuts, in the extreme distal reciprocation of said double-pointed cannula, with the proximal end of said stud mounted in said stopper and in the extreme proximal reciprocation of said double-pointed cannula, with the distal end of said sack.

6. A cartridge unit assembly as defined in claim **1**, wherein said connecting means comprises a female screw-threaded bore in said stopper and a male screw-threaded nipple

mounted on said bushing, said nipple having an axial bore therethrough communicating with said centrally located aperture in said bushing.

7. A cartridge unit assembly as defined in claim 6, wherein said cannula stop means comprises a piston affixed to said double-pointed cannula reciprocably mounted in a distally located axial bore in said sack, and wherein said first abutment means comprises restriction means located in the distal region of said bore, and wherein said second abutment means comprises said penetrable membrane of said sack which closes the proximal end of said bore, and said piston abuts, in the extreme distal reciprocation of said double-pointed cannula, with said restriction means, and in the extreme proximal reciprocation of said double-pointed cannula, with said penetrable membrane of said sack.

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