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2,737,948

DISPOSABLE CARTRIDGE FOR HYPODERMIC SYRINGE

Filed Aug. 23, 1954

FIG. 1

FIG. 2

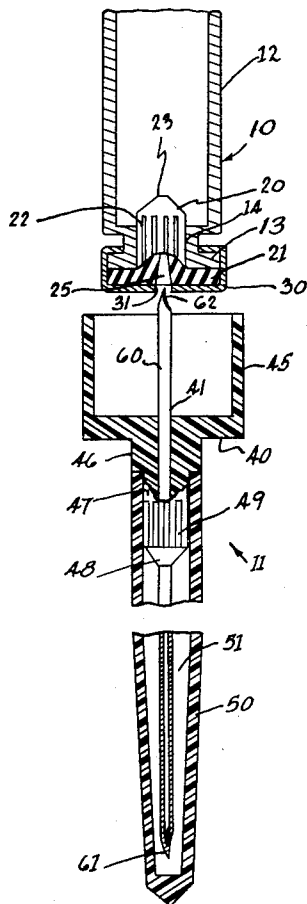
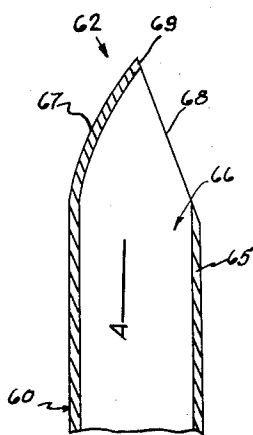


FIG. 3

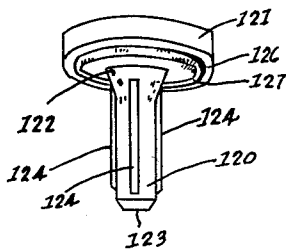


FIG. 5

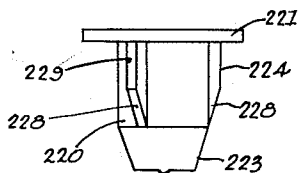


FIG. 6

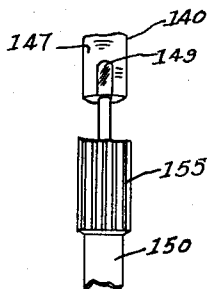
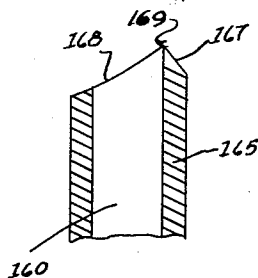


FIG. 4



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DISPOSABLE CARTRIDGE FOR HYPODERMIC SYRINGE

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6 Claims. (Cl. 128—215)

This invention is a continuation in part of my copending application, "Disposable Cartridge for Hypodermic Syringe," filed January 4, 1952, and bearing S. N. 264,992. More particularly, the invention relates to an improved hypodermic syringe assembly and has especial reference to a novel form of a pre-filled, disposable combined needle and ampule assembly for dispensing various medicaments.

As indicated in said prior copending application, various forms of pre-loaded hypodermic syringe assemblies including needle bearing cartridges containing liquid medicaments have heretofore been devised. In such devices, the cartridge normally comprises a fragile glass vial or ampule containing the medicament and which is sealed at one end by a movable rubber plunger member and at the other end by an immovable but perforatable stopper or closure member. In accordance with the invention set forth in said copending application, the vial or ampule is adapted to support a covered or sheathed hollow hypodermic needle in firm union with the vial and in position to be manipulated in a relatively simple manner to perforate the closure stopper and establish communication between the contents of the vial and a flesh piercing end on the needle. After use, the exhausted assembly is discarded including the needle.

In such type assembly, it is exceedingly difficult to maintain a substantially sterile condition in the component parts, and at the same time, facilitate rapid inexpensive assembly of the same. Another difficulty with hypodermic syringes of this type is the provision of an adequate and substantially foolproof seal at the puncturable end of the vial or ampule. As will be readily understood, a corollary to this problem is the provision of means for guiding and/or directing the associated needle into the puncturable stopper during manufacture of the assembly and ultimately through the stopper during use of the device in the field.

Accordingly, one of the principal objects of this invention is to provide an improved hypodermic syringe assembly of the aforementioned type which overcomes these various disadvantages. A further object of this invention is to provide an improved cartridge end seal. Another object of this invention is to provide an improved needle unit facilitating rapid manufacture and assembly of the component parts. Other objects and advantages of this invention will become apparent from the description and claims which follow.

Having broadly disclosed the invention, reference will now be made to the accompanying drawings in specifically setting forth preferred forms of the improved construction, and in which:

Fig. 1 is a sectional view, partly in elevation, of a preferred embodiment of the improved disposable hypodermic syringe cartridge assembly according to the present invention with the component parts positioned for assembling the needle unit on the cartridge unit.

Fig. 2 is an enlarged sectional view along the axial

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center line of the needle employed in the construction of Fig. 1 illustrating an improved stopper piercing end.

Fig. 3 is a perspective view illustrating a modified form of puncture stopper for use with the cartridge assembly of Fig. 1.

Fig. 4 is a fragmentary sectional view of a modified form of needle.

Fig. 5 is a side elevation view of a modified form of closure stopper.

Fig. 6 is a fragmentary elevation view of a modified form of needle holder and cover construction.

Referring now to the drawings, the improved hypodermic syringe assembly of the present invention includes a cartridge or ampule generally indicated 10, and a needle unit generally indicated 11, operably associated therewith. As will be appreciated, the needle unit is in position to be inserted directly onto the adjacent end of the cartridge unit to bring the needle into piercing relationship with the closure member of the cartridge and to unite the needle and cartridge in a semi-permanent union which will withstand handling and the like manipulation without causing loss of sterility.

The cartridge unit consists of an elongated, hollow glass vial or cylinder 12 which may be closed at one end (not shown) by means of a reciprocable plunger forming a hermetical seal with the internal wall of the glass cylinder in a manner known in the art. The other end of the cylinder includes an opening 14 which is sealed by means of a stopper member 20. The stopper is preferably formed of a resilient elastomeric material, such as rubber, and which includes an external radially directed flange 21 for overlapping the axial face of an enlarged annular neck 13 at the open end of the cylinder. Normally, the diameter of the flange 21 is chosen to be identical with the diametrical extent of annular neck 13. The stopper 20 is provided with a plurality of spaced radially directed peripheral fins 22 extending between flange 21 and a lower truncated nose portion 23. The stopper also includes an indentation or inwardly directed recess 25 in the front face of flange 21 at about its geometrical center leaving a thin wall separating the needle from the contents of the cartridge.

A closure cap or hermetical seal member 30 is provided to overlie the face of stopper flange 21 and to compress the same against neck 13 as by crimping the closure cap behind the annular neck of the vial in the manner indicated. Preferably, the closure cap comprises a cylindrical, cup-like, metallic ferrule of a non-corrosive material such as aluminum, and is adapted to be secured over the closure stopper 20 by spinning the extended peripheral edge of the ferrule into tight contact with the reduced vial neck behind lip 13. The ferrule includes a central aperture 31 which is adapted to be aligned with the recess 25 in the face of stopper 20.

The fin members 22 on the closure stopper normally extend radially of the main surface of the stopper for a distance between .05 and .3 mm. and are integral with the main body of the stopper. This construction has been found to be exceedingly effective in facilitating insertion of the resilient and normally hard to handle stopper into the vial, the fins serving to vent air from the vial during insertion of the stopper, thereby preventing subsequent unseating of the stopper. The fins also assist nose portion 23 in centrally positioning the stopper body within the vial opening. Moreover, fins 22, upon being brought into contact with the internal wall surface of the vial opening, are resiliently displaced radially inwardly towards the center of the stopper and concomitantly force the unribbed portions of the stopper radially outwardly into a more firm frictional fit with the vial wall. As will be readily understood, this provides an exceedingly effective

tive fluid-tight seal. Additionally, provision of the fin construction compensates for manufacturing deformities such as variations in the thickness of the body portion of the stopper member and for other physical irregularities which are normally unavoidable in the mass production of

The needle unit 11 comprises a needle holder 40 formed as a stepped cylinder member having an axially extending sleeve-like flange or skirt 45, a cylindrical portion 46, and a reduced cylindrical forward end portion 47. The holder 40 is preferably molded of a resilient elastic material such as a polyethylene resin, although any resilient plastic, rubber-like material is suitable. Alternatively, the holder can be formed in whole or in part of a relatively hard material including metal so long as the extended axial flange or sleeve portion 45 includes flexibility or resiliency in a direction transverse to the axis of the assembly. The axially directed sleeve 45, in effect, forms an annular skirt which is adapted to fit tightly over the ferrule 30 of the cartridge unit in sealing relationship therewith, and for which purpose the sleeve 45 must include some radial play in order to provide a firm frictional fit and yet be able to slide over the ferrule. If desired, the peripheral portion of the sleeve may be slightly flared outwardly to facilitate assembly over the ferrule 30.

The holder 40 is adapted to integrally carry a hollow hypodermic needle 60 which for this purpose includes a central perforation or passageway 41 in which the needle 60 can be imbedded in any known manner, as for example, by molding unit 40 with needle 60 in position, or by cementing needle 60 in passageway 41, or by heat treating at least a portion of the holder 40 in the region of passageway 41 to shrink fit or bond the same to the needle.

The lower reduced cylindrical end portion 47 of the holder includes a plurality of axially directed radial vents which may take the form of flattened areas, grooves or recesses 49, spaced about the periphery of the holder. These grooves or recesses merge with the forward truncated nose 48 of the holder and cooperate with a cylindrical needle cover member 50. As will be more readily understood by reference to said prior copending application, the cover member 50 is adapted to enclose the sterile flesh piercing end 61 of needle 60, and for this purpose, is firmly mounted on the reduced cylindrical portion 47 but releasably secured thereto by means of a tight but manually movable fit, the cover 50 being adapted to be slipped off of the reduced portion by pulling it axially outwardly. Provision of the grooves or flute-like construction 49 in the lower portion of the reduced cylindrical end 47 serves to facilitate rapid removal of the cover 50 from the needle holder by allowing atmospheric air to enter the pocket 51 of the cover as the cover is being withdrawn from the holder end. While the cover is preferably applied to the needle before the needle is assembled on the cartridge, the vents on the needle holder are also advantageous in preventing entrapment of air within pocket 51 when the cover is applied subsequent to assembly of the cartridge and needle. It will be readily understood that the cover is thereby more firmly and securely mounted on end portion 47 while at the same time minimizing a possible source of contamination by reducing the amount of air entrapped in pocket 51.

In order to further assist and facilitate assembly of the complete unit in a short period of time and without incurring excessive breakage or contamination of the component parts, the needle unit 60 is formed with a particular construction preventing a novel stopper piercing end 62. The details of this construction will be more readily appreciated by reference to Fig. 2 showing the end of such needle in an enlarged cross-sectional view. As there shown, the needle comprises a hollow, cylindrical body 65 having a central passageway 66 for transporting medicament from one end of the needle to the other. In accordance with the present invention, the stopper

piercing end 62 of the needle is formed by bending, grinding or otherwise shaping one peripheral wall portion of the needle to have a curvature transversely of the axis A of the needle in the manner indicated in the drawings so that the needle point is spaced radially inwardly from the outer periphery of the needle and the side wall of the stopper recess 25. This geometric configuration can be readily obtained by simply cutting the needle on an angle and grinding the outer periphery of the leading edge. It may also be obtained to a greater degree by bending the end of the hollow stem to provide a curved wall portion 67 followed by cutting and grinding of the bent needle stem along a plane which intersects the curved surface 67 at an acute angle with the axis A of the needle to present a boundary surface 68 forming a stopper piercing point 69 which may be substantially aligned with the center line A of the needle. The angle at which boundary surface 68 is formed may vary widely but is preferably between 10 and 45 degrees. Likewise, the degree of curvature of wall portion 67 may vary widely. In any event, the arrangement is such that the piercing point 69 so formed is spaced radially inwardly from the outer periphery of the main needle body 60 and the side walls of the stopper recess 25.

By reason of the above described improved construction, and in cooperation with the recess 25 in the center of the stopper 20, the needle assembly 11 can be rapidly and easily moved into a firm self-supporting union with cartridge unit 10 without danger of the needle snagging in the side walls of recess 25. As reference to Fig. 1 will indicate, axial movement of the needle unit toward the cartridge unit will serve to bring needle 60 into proximity with the central aperture or perforation 31 in ferrule 30, and, in the event the needle is misaligned therewith, the particular configuration of the needle serves to center the needle therein and into recess 25 of the stopper. Continued movement of the needle assembly serves to seat skirt 45 on the ferrule 30 and to imbed the end 69 of the needle in the recess of the resilient stopper, the latter action taking place with the curved surface 67 of the needle serving to bulge or retract the resilient material of the stopper away from point 69. This also effectively assists the subsequent cutting action of boundary 68 and point 69 whereby a slit of substantially uniform character is incised through the thin wall of the stopper body separating the needle from the contents of the cartridge without danger of occluding the passage 66 with any particles of the stopper matrix. It also has been observed that the provision of this geometric shape to the stopper piercing end of the needle materially assists in holding the needle in axial alignment with the center of the stopper, so that the needle will emerge from the stopper at about the center of nose 23. As will be readily understood, such operation facilitates use of the flesh piercing end 61 of the needle in a more efficient manner.

A modified form of closure stopper which is similar in construction and function to the stopper 20 of Fig. 1 is illustrated in Fig. 3 of the drawings. This stopper is adapted to be used with the assembly of Fig. 1 and comprises an improvement over the stopper of Fig. 1. As shown, this improved form of stopper includes an upper annular seating flange 121 which is provided with a centrally located axially directed recess (not illustrated) in a manner identical to the recess 25 in the stopper 20. Flange 121 includes an integral depending stem portion 120 which is sloped or truncated as at 122 to present a gradually tapering juncture between the flange and the stem. The mean diameter of portion 122 is selected to be slightly larger than the opening 14 in the cartridge. Stem 120 terminates in a frusto-conical nose portion 123 and integrally carries axially extending, radially directed, spaced rib members 124, comprising three in number. The ribs 124 terminate immediately above the nose portion 123 and merge with the truncated

portion 122 in the manner indicated in the figure. Ribs 124 are normally formed of a height between 0.05 and 0.3 millimeter.

In order to increase the sealing effect of the underface 126 of flange 121, this face is provided with a raised, axially directed annular rib 127 at a point substantially midway between the stem juncture and the peripheral edge of the flange. This rib is preferably formed of a height between point 0.01 and 0.1 millimeter with any desired width. With this arrangement, the stopper 120, when forced through the opening 14 in the neck of a cartridge 12, most effectively closes the opening in a hermetical seal, the flange rib 127 firmly contacting the face of the cartridge neck 13 in such manner as to be deformed while the truncated portion 122 of the stem is compressed by firm engagement with the walls of the opening. It will thus be understood that the longitudinal ribs 124 which are depressed radially inwardly during insertion of the stopper into the cartridge are continuously resiliently urged radially outwardly into engagement with the cylindrical wall to effectively provide sufficient frictional force to off-set retraction of the stopper from the opening. This serves to retain rib 127 and juncture 122 in effective sealing engagement with the cartridge neck.

As shown in Fig. 4 of the drawings, the location of the stopper piercing point of the needle radially inwardly of the needle periphery can be obtained by grinding or shaving the inner side wall of the needle along a line inclined towards the axis of the needle. This operation can be formed by conventional grinding and/or metal cutting equipment and generally can take place in two steps. The first step involves cutting or grinding the open end of the needle at a relatively large angle to the needle axis to form a boundary surface or edge 168 corresponding to boundary surface 68 in Fig. 2. Subsequently, the needle is cut, shaved or ground along a line making a relatively small angle with the axis of the needle to form a secondary boundary surface 167 wholly contained within the width of the needle wall 165. This second surface makes a juncture with the boundary surface 168 to provide a piercing or cutting point at 169 which is positioned internally of the exterior needle wall surface. It will be apparent that point 169 is not located close to the center line or axis of the needle, but practical experience has shown that the positioning of the point to lie within the periphery boundary of the needle wall, in cooperation with a deeply recessed cleft in the closure stopper, will serve to effectively guide the needle unit with respect to the cartridge during assembly of the device.

A further modified form of closure stopper is illustrated in Fig. 5 of the drawing. This stopper is adapted to be used interchangeably in the cartridge unit of Fig. 1, and as shown comprises a cylindrical, relatively short body 220 formed with a truncated terminal end 223 and a relatively thin sealing flange 221. The body portion of the stopper is provided with three equidistant ribs or fins 224 which extend laterally from the body for a distance of between 0.5 and 0.2 millimeter. The ribs or fins merge with the flanged end of the stopper body and with the beginning of the truncated lower portion 223, the lower end of the ribs being inclined, as shown at 228, to provide a wedging function which serves to facilitate insertion of the stopper into the cartridge. The face of flange 221 also is provided with a deep needle reserving recess (not illustrated).

A particular feature of this form of closure stopper is the elimination of any necessity for employing a subsidiary sealing flange structure on the inner face of flange 221. The short length of the radial ribs of fins employed has been found to be effective in securely locking the stopper within the cartridge neck, the ribs being compressed during insertion of the stopper into the cartridge neck in such manner as to flex or bend them at about the juncture of the vertical surface 229 and the inclined surface 228. This forms a tight friction lock with the cartridge wall.

At the same time, it will be understood that the ribs permit escape of gas or air from within the cartridge during application of the stopper.

Fig. 6 illustrates a further modified construction employed according to the invention. As shown, the lower end 147 of the needle holder 140 can be provided with opposed flattened areas 149 in lieu of the grooved construction of Fig. 1.

The flat areas 149 can be formed in any desired manner and of any desired size with a minimum of expense and are as effective as grooves 49 in permitting air to escape from the cover member 150 as it is being inserted over the end 147 of the holder. In addition, the small extent of areas 149 allows the cover to become more firmly seated on the holder and insures the maintenance of the sterility of the needle. Because of the more positive fit between the holder and cover provided by this form of the invention, it is preferred to provide cover 150 with raised flutes or serrations 155 in order to facilitate easy removal of the cover. With the fluted construction, the holder can be readily slipped off holder 140 by a single twisting motion.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope hereof, it is to be understood that this invention is not limited, except as defined in the appended claims.

What is claimed is:

1. An improved disposable combined ampule and needle assembly for use in hypodermic syringes comprising, an ampule having an elongated hollow body member having an annular neck about an open end, a stopper sealing the open end of said body member, means sealing the other end of said body member, said stopper including a stem portion and a radially directed flange portion, said stem portion including longitudinally extending radially directed ribs, in contact with the end opening of said body member, a recess formed in substantially the center of said flange portion of said stopper on the face opposite said stem portion, a needle holder longitudinally slidably connected to said ampule and including a stepped cylindrical configuration having a reduced diameter first end portion and an enlarged diameter axially extending tubular skirt portion at the other end, a hollow pointed needle rigidly carried by said needle holder and including a stopper piercing end and a needle cover member releasably secured to said cylindrical portion on said needle holder and hermetically sealing said needle.

2. The combination set forth in claim 1 in which said reduced diameter end portion of said holder includes axially extending radially directed grooves for admitting air from the cover during removal of said cover member from said end portion for protecting said piercing end of the needle.

3. The combination set forth in claim 1 in which the stopper piercing end of said needle includes a piercing point positioned radially inwardly from the outer periphery of the main body of said needle and formed by a curved peripheral wall of said needle joining a cutting edge formed at an angle to the axis of said needle.

4. An improved disposable combined ampule and needle assembly for use in hypodermic syringes comprising, an ampule having an elongated hollow body member having an annular neck about an open end, a stopper sealing the open end of said body member, means sealing the other end of said body member, said stopper including a stem portion and a radially directed flange portion, said stem portion including longitudinally extending radially directed ribs, in contact with the end opening of said body member, a recess formed in substantially the center of said flange portion of said stopper on the face opposite said stem portion, a needle holder longitudinally slidably connected to said ampule and including a stepped cylindrical configuration having a

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reduced diameter first end portion and an enlarged diameter axially extending tubular skirt portion at the other end, a hollow pointed needle rigidly carried by said needle holder and including a stopper piercing end protruding past the terminal edge of said tubular skirt portion and a flesh piercing portion extending beyond said reduced end portion, and a needle cover member releasably secured to said cylindrical portion on said needle holder and hermetically sealing said needle, a reduced diameter end portion of said holder including axially extending radially directed grooves for admitting air from the cover during removal of said cover member from said end portion for protecting said piercing end of the needle, and in which the stopper piercing end of said needle includes a piercing point positioned radially inwardly from the outer periphery of the main body of said needle and formed by a curved peripheral wall of

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said needle joining a cutting edge formed at an angle to the axis of said needle.

5 5. The combination set forth in claim 1 in which said stopper member includes a raised annular rib on the face of said radial flange adjacent said longitudinal extending ribs for cooperating with the end face of the annular neck of said body member to hermetically seal a medication in said body member.

10 6. The combination set forth in claim 5 in which the said stem portion of said stopper includes a truncated section joining the said radial flange, and said longitudinal stem ribs merge with said conical section at a slight distance from said flange.

15 **References Cited** in the file of this patent

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