Jan. 15, 1963 P. A. STEVENS 3,073,307

NEEDLE HUB AND SHEATH STRUCTURE

Filed Oct. 28, 1959

2 Sheets-Sheet 1

Fig. 1

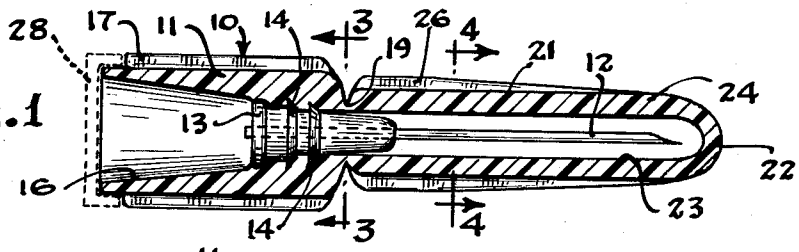


Fig. 2

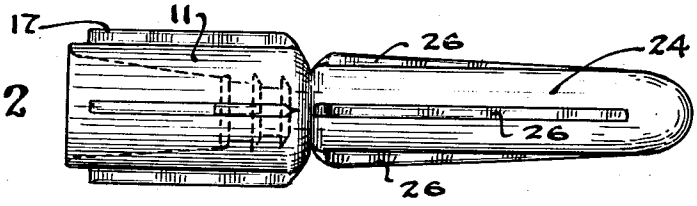


Fig. 3

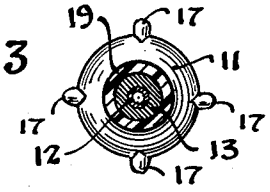
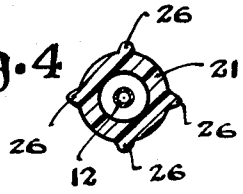


Fig. 4



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2 Sheets-Sheet 2

Fig. 5

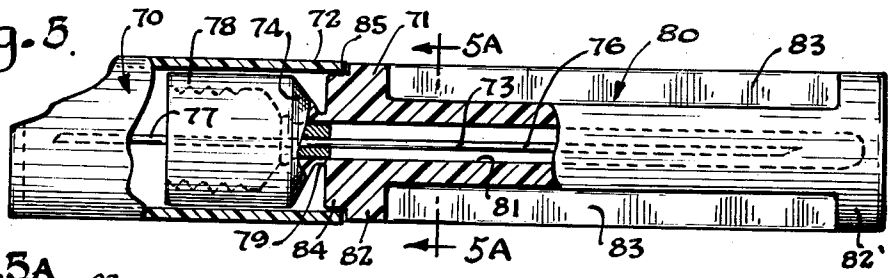


Fig. 5A

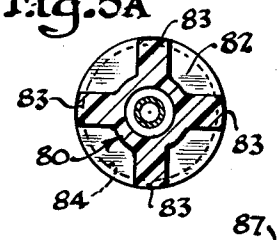


Fig. 6A

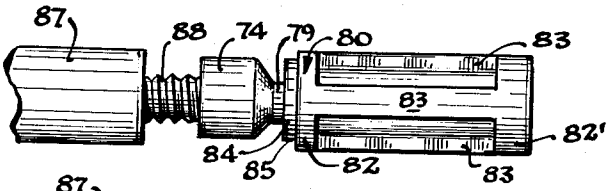


Fig. 6B

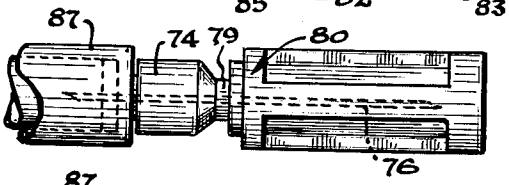
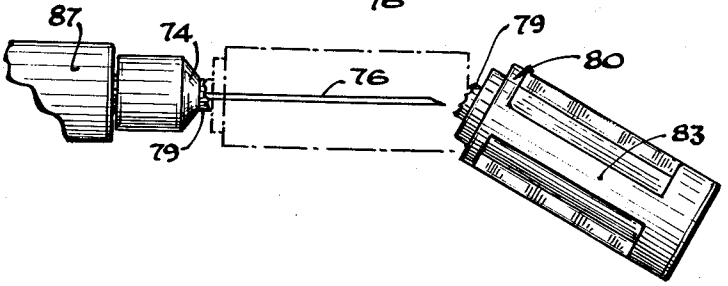


Fig. 6c



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NEEDLE HUB AND SHEATH STRUCTURE

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Filed Oct. 28, 1959, Ser. No. 849,243
4 Claims. (Cl. 128—221)

The present invention relates generally to improved means for protecting a needle cannula, and more particularly to an improved disposable needle hub and cannula sheath structure adapted to being mounted on the outlet end of a hypodermic syringe and other apparatus for administering medicaments.

In the medicinal arts, hypodermic syringes with hypodermic needles detachably mounted thereon are widely used to administer medicaments, and for such use it is very important that the cannula of the hypodermic needle remain undamaged and in its original sterile condition until used. Thus, whether the hypodermic needle is sold as a separate sterilized unit or detachably mounted on a hypodermic syringe containing a medicinal preparation, means must be employed to maintain the cannula of the hypodermic needle in its original sterile condition and protected against physical damage. Generally, the cannula is enclosed in a detachable protective sheath which is frictionally engageable with a portion of the needle hub or the cannula with the sheath being removable from the cannula immediately before using. And, since the protective sheath for the cannula of the hypodermic needle hub assembly, of necessity, must be readily removable from the cannula, quite frequently a sheath is accidentally or deliberately removed from a cannula between the time of manufacture and ultimate use, thereby exposing the cannula to contamination and damage. Moreover, the sheaths heretofore devised for disposable hypodermic needles intended to be detachably mounted on the outlet end of a hypodermic syringe could be readily removed and replaced in the original position on the cannula without the ultimate user being aware of such exposure to contamination and damage. Thus, the previously devised protective sheath means for a cannula of a hypodermic needle hub unit which is adapted to being detachably mounted on the outlet end of a hypodermic syringe have failed to insure absolutely that the sterility of the needle cannula has been maintained or that the needle cannula has not been physically damaged.

Other means heretofore devised for protecting a hypodermic needle cannula which is fixed in a hub suitable for mounting on a hypodermic syringe outlet have included strip packages and individual rubber, plastic or glass envelopes or cartridges sealably enclosing the needle and hub. Each of the foregoing means requires using additional packaging materials and additional handling of the needles, thereby resulting in a higher percentage of damaged and contaminated needles and also greatly increasing the overall cost. However, none of these prior art means provides a completely satisfactory means of conveniently and aseptically mounting a hypodermic needle hub on the discharge outlet of a hypodermic syringe, nor affords means for connecting the needle hub unit to a medicinal vial of ampule without substantially increasing the danger of contaminating a portion of the needle cannula.

Heretofore it has also been suggested that a hypodermic needle cannula be fusibly sealed at a point intermediate the ends thereof in a frangible glass tube with the outer end of the glass tube being sealed to enclose one end of the cannula. However, none of these glass units or structures were adapted to being detachably

mounted on the outlet end of a hypodermic syringe. Thus, these suggested structures were not concerned with the problem of protecting a cannula of detachable hypodermic needle hub structures which are usable with a hypodermic syringe. It is also evident that these structures were not suited for commercial production methods of handing and packaging because of the fragility of the thin glass walls, and the glass structures also were objectionable because of the sharp cutting edges which resulted when the glass sleeve was fractured to expose the needle cannula.

It is, therefore, an object of the present invention to provide a more practical and economical detachable hypodermic needle hub-sheath structure which is adapted to protect a hypodermic needle cannula.

It is a further object of the present invention to provide an improved tamper-proof sheath means for a cannula of a detachable hypodermic needle hub structure for mounting on the outlet end of a hypodermic syringe.

It is an additional object of the present invention to provide an improved unitary cannula sheath and hub structure which facilitates detachably mounting the hypodermic needle hub on a hypodermic syringe hub adapter.

It is still another object of the present invention to provide an improved and more economical unitary sheath-cartridge container for a detachable hypodermic needle hub assembly adapted to protect the needle cannula thereof against contamination and physical damage, both during the storage thereof and when removing the sheath therefrom.

Other objects of the present invention will be apparent to those skilled in the art, from the detailed description and appended claims when read in conjunction with the accompanying drawings wherein:

FIGURE 1 is a longitudinal vertical sectional view of a hypodermic needle hub and integral sheath embodying the present invention with a hypodermic needle cannula mounted therein shown in side elevation;

FIG. 2 is a side elevational view of the hypodermic needle hub and sheath shown in FIGURE 1;

FIG. 3 is a vertical sectional view along the lines 3—3 of FIGURE 1;

FIG. 4 is a vertical sectional view along the line 4—4 of FIGURE 1;

FIGURE 5 is a side elevational view partially in vertical section showing a further modified form of integral hub-sheath assembly forming a needle container.

FIG. 5*a* is a vertical sectional view along the line 5*a*—5*a* of FIG. 5;

FIGS. 6*a*, 6*b* and 6*c* show schematic view of the three stages of mounting the hub sheath assembly of FIG. 5 onto a syringe body.

The improved hypodermic needle hub structure of the present invention broadly comprises a hypodermic needle hub section of a non-vitreous material adapted to be fixedly mounted on the discharge outlet of a hypodermic syringe, and which has a severable but integral needle cannula sheath section sealably closed at its outer end and integrally joined at the inner end thereof with the hub section to sealably enclose one end of a needle cannula mountable therein. The integral sheath section is readily severable from the hub section by twisting, or the like manipulation of the sheath relative to the hub section which avoids bending transversely. The improved hub structure of the present invention is preferably provided between the outer end of the hub and the inner end of the sheath sections with a connecting section integral with both the hub and sheat sections and having a reduced wall thickness to facilitate removal of the sheath from the hub section. In one preferred embodiment of the present invention, the integral sheath and hub sections are molded

as an integral unit of a non-vitreous plastic material, such as plasticized polyethylene plastic, with an integral reduced diameter section of the said non-vitreous thermoplastic material formed between the sheath and the hub sections. The foregoing sheath hub structure can, of course, consist of the unitary sheath and hub structure with a needle cannula molded therein, or the integral sheath and hub structure per se can be provided with a cannula at any time after the molding thereof by press-fitting a cannula into the axial opening of the hub-sheath structure.

It will be understood that other ways and means of providing an integral sheath hub structure can be used instead of molding the sheath and hub as a unitary structure, and other ways and means of providing a readily severable connecting section between the hub and the sheath besides providing a reduced diameter section can be employed in various embodiments of the present invention. Thus, for example, a premolded thermoplastic sheath of a non-vitreous thermoplastic resin, such as plasticized polyethylene of methamethacrylate, can be fusibly joined to a hub section of a similar thermoplastic material so as to form a unitary sheath hub structure having a similar appearance and form as in the above-described embodiment of the present invention. Also, the novel integral sheath and needle hub structure can be formed of premolded longitudinal sections, for example, of thermoplastic material having a reduced diameter section preformed therein so that following assembly by fusibly joining opposed longitudinal sections, the sheath is subsequently removable therefrom in the same manner as with the previously described preferred embodiment of the present invention. And, instead of providing a connected section between the sheath and hub having a reduced thickness, a line of weakness can be provided between the hub and the sheath without substantially altering the thickness of the connecting section, as by embedding in the material between the hub and the cannula a narrow strip of material of different properties which yields more readily under a twisting stress than does the material from which the hub and sheath are made.

In the embodiment of the present invention shown in FIGS. 1–4 of the drawing, a hypodermic needle hub assembly **10** having a generally cylindrical hub body section **11** is provided with an axially disposed hypodermic needle cannula **12** which is fixedly secured to the hub body section **11** by means of a suitable ferrule or eyelet retaining ring section **13** formed on one end thereof. The ring section **13** is preferably provided with a plurality of projections **14** or indentations which provide for suitable frictional engagement between the needle cannula and the hub to securely hold the needle in the hub section **11** against longitudinal and rotatable movement. The inner end surface **16** of the hub body section **11** is provided with a standard Luer taper for engagement with the correspondingly Luer tapered discharge outlet of a conventional hypodermic syringe (not shown). The outer surface of the body section of the hub section **11** has a plurality of preferably longitudinally extending projections **17** which serve to facilitate gripping the hug firmly for manipulation thereof when mounting the hub section on the outlet end of the hypodermic syringe and when twisting a cannula sheath section relative thereto.

Extending forwardly from the front surface of the hub body section **11** and integrally joined therewith by a relatively thin frangible section **19**, is a cannula sheath **21**. The sheath **21** has its outer end **22** sealably closed and has an axial passage **23** extending the length thereof of somewhat larger diameter than the exterior diameter of the cannula **12**. The outer surface **24** of the sheath **21** is preferably provided with a plurality of longitudinal projections **26** extending radially outwardly which provide a finger-gripping surface for manipulation of the sheath. If desired, sterile cotton can be placed within the Luer tapered end section **16** of the hub body section **11**, or a protective cap **28** can be placed over the end section **16** of the hub to serve as a bacterial filter to prevent contamination following sterilization.

It will be apparent from the foregoing description, that in the improved integral hub-sheath structure of the present invention, the cannula **12** is completely enclosed by a sheath **21** which is integrally joined with the needle hub **11** so that there is no possible passage between the hub **11** and the sheath **21** for bacteria or contamination to enter. Moreover, the sheath **21** cannot be removed from the cannula **12** without leaving clear evidence of the sheath having been separated from the hub **11**. When the hypodermic needle is to be used for administration of a medicament, however, the needle assembly can be easily mounted on a hypodermic syringe having a male Luer-type adapter on the discharge or outlet end thereof prior to removing the sheath **21**. And, immediately before injection through the cannula **12**, the sheath **21** is separated from the hub section **11** by gripping the hub section **11** between the fingers of one hand and the sheath **21** between the fingers of the other hand and applying a twisting, breaking force which completely severs the connecting section **19** joining the sheath **21** to the hub body section **11**. The sheath **21** is then withdrawn from the cannula **12**, and the cannula **21** of the needle hub assembly is for the first time since leaving the manufacturer exposed to the atmosphere and can be used in the usual manner without sterilizing without fear or apprehension that the needle cannula has been previously exposed to contamination, or otherwise physically damaged.

The needle container assembly **70** shown in FIG. *5* comprises a needle hub and sheath cartridge section **71** and a cap section **72** mounted on one end of section **71**. The novel needle hub and sheath cartridge section **71** is formed of a double-ended cannula **73** securely fixed in the hub body section **74** with a forwardly extending administration cannula portion **76** and a rearwardly extending ampule or vial closure piercing cannula portion **77** having a length somewhat shorter than the administration cannula portion **76** but extending substantially beyond the end of the hub body section **74**. The hub body section **74** has a rearwardly extending cylindrical section **78** which is adapted to threadably engage the helical threads of a hypodermic syringe outlet (see FIG. *6a*). The forwardly end of the hub body section **74** is undercut to form a small diameter section **79** which is integrally connected with the hub section **74** at one end and at the other end with a large diameter sheath portion **80**. The sheath **80** has an axial opening or passage **81** therein extending outwardly to a point spaced inwardly a short distance from the outer end of the sheath portion **80** and is adapted to sealably enclose the administration cannula portion **76**.

The sheath **80** is also provided with generally cylindrical end sections **82**, **82'** having a diameter slightly larger than the diameter of the hub body section **74**. A plurality of radially extending longitudinal rib sections **83** connect the end sections **82**, **82'** and provide a gripping surface for holding and manipulating the sheath cartridge section **71**. The end section **82** is also provided with a reduced diameter cylindrical section **84** and a shoulder abutment surface **85** for retaining thereon the cylindrical cartridge cap section **72** which encloses the end of the hub to prevent bacterial contamination.

When using the needle container assembly **70**, with a syringe body **87** having an externally screw-threaded discharge outlet **88**, the cap **72** is removed from the needle cartridge assembly and the cylindrical section **78** of the hub is mounted in threading engagement with the syringe outlet **88** by holding the sheath portion **80** between the fingers and rotating the sheath portion **80** and the hub section **74** formed integrally therewith relative to the threaded discharge outlet **88** to threadably engage the hub **74** on the syringe outlet **88** (see FIGS.

6a, 6b). Immediately before the syring is to be used for injecting a medicament, the sheath portion **80** which is still sealably and integrally joined to the hub section **74**, is removed therefrom by twisting to break the small diameter connecting section **79**, and the sheath portion is removed and discarded (see FIG. 6c).

While the improved disposable needle hub and sheath structure of the present invention can be made by any of the several ways described herein, or by other methods known or obvious to those skilled in the art, one particularly convenient method of manufacturing and assembling the needle hub and integral sheath embodiment shown in the drawing, comprises injection molding as a unit the integral hub and sheath structure with a reduced diameter connection section formed between the hub and sheath sections and providing an axial opening in said structure adapted to retain fixedly therein a needle cannula. A multi-cavity divided mold having mold insert elements and means for injecting a thermoplastic material therein can be used for the above injection molding operation. At any time after the integral sheath and hub structure is removed from the mold insert element, a needle cannula preferably having a boss or enlarged eyelet retaining section secured thereto which frictionally engages in an axial passage in the hub body section, is inserted into the hub wherein it is fixedly secured against both longitudinal and rotatable movement.

The integral hub and sheath structures shown in FIGS. 11 and 12 can be fabricated in the same manner as above described and are provided during the molding operation, or subsequently thereto, if desired, with thread engaging means on the outer surface of the respective hub sections for threadably engaging the outlet in a syringe body.

The non-vitreous thermoplastic materials suitable for use in the present invention include thermoplastic resins, both natural and synthetic, including methamethacrylate, styrene, polyamides, and polyethylene resins. Other non-vitreous thermoplastic materials which will yield or part under a twisting force without forming sharp cutting edges, or the like, can be used. It is also important that the material does not require bending transversely of the longitudinal axis in order to separate the sheath from the hub, since this would tend to dull the needle point or bend the needle cannula. And, while non-vitreous thermoplastic materials are the preferred class of materials used in the present invention, it is also possible to use non-vitreous thermosetting materials, if the selected molding technique requires such materials.

It will be apparent to those skilled in the art that the needle hub-sheath structure of the present invention provides an improved disposable hypodermic needle structure for use in the medicinal arts in conjunction with a hypodermic syringe or other apparatus for administering medicaments which in addition to insuring the sterility of the needle cannula greatly increases the convenience and ease of using said disposable needles. Thus, the present hub-sheath structure makes it possible to sealably enclose the needle cannula within an integral sheath and yet permits the convenient and rapid separation and removal of the sheath simply by applying a rotational or twisting movement of the sheath relative to the hub and without applying a crushing force thereto or bending the sheath transversely which would in some instances bend the cannula or otherwise harm the point thereof.

I claim:

1. A disposable hypodermic needle containing unit for protectively enclosing at least one end of a hypodermic needle cannula which comprises; a disposable non-vitreous plastic needle hub-supporting section with an axial passage extending therethrough, said hub-supporting section adapted to fixedly engage an enlarged diameter hub section formed on a hypodermic needle cannula spaced longitudinally from a penetrating point at an end thereof, a pointed hypodermic needle cannula with an enlarged diameter hub section fixedly formed thereon and sealably mounted in said hub-supporting section with a portion of said enlarged diameter hub section extending axially beyond the end of said hub-supporting section, a sheath section extending axially from said end of said hub-supporting section and having an axially extending recess therein connecting with said axial passage, a reduced diameter sealably connecting said end of said hub-supporting section with said sheath section and said frangible section being disposed intermediate the ends of said enlarged diameter hub section and in engagement with said enlarged diameter hub section, said sheath section adapted to sealably enclose said hypodermic needle cannula from said cannula hub section to said point when said cannula hub section is in sealing engagement with said hub-supporting section, and said sheath section adapted to be severable from said hub-supporting section without destroying said sheath section only by rotation of said sheath section about said extending portion of said enlarged diameter hub section which serves as a pivotal support during rotation of said sheath section; thereby permitting removal of said sheath section without damaging said cannula.

2. A disposable hypodermic needle containing unit as in claim 1, wherein said hub-supporting section has generally cylindrical wall surfaces extending axially in a direction opposite from said sheath section with a removable cap member protectively enclosing the other end of said hub-supporting section.

3. A disposable hypodermic needle containing unit as in claim 2, wherein said hub-supporting section has removably mounted on the other end thereof a form-retaining cap member which protectively closes said other end.

4. A disposable hypodermic needle containing unit as in claim 1, wherein said sheath section has an enlarged transverse section adjacent said frangible section with a removable cap member mounted on said enlarged transverse section for protectively enclosing said hub-supporting section and the other end of said cannula.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,073,307 January 15, 1963

Peter A. Stevens

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

Column 6, line 19, after "diameter" insert -- circumferentially extending frangible section --.

Signed and sealed this 6th day of August 1963.

(SEAL)
Attest:

ERNEST W. SWIDER
Attesting Officer

DAVID L. LADD
Commissioner of Patents