HYPODERMIC NEEDLES IN BLISTER PACKAGE

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FIG. 1

FIG. 2

FIG. 3

FIG. 4

FIG. 5

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This invention relates to a blister package for disposable hypodermic needles in which the hypodermic needles are stored in a sterile environment and which package can be readily opened for the attachment of the hypodermic needle to a hypodermic syringe while maintaining sterility of the hypodermic needle.

With the reduction in labor costs due to automation in the production of hypodermic needles, it is becoming important to be able to package hypodermic needles for use, which means that the hypodermic needles must be sterile and maintained sterile during storage and must be readily removed from the sterile package at time of use with a minimum of time and dexterity on the part of the operator, and without the risk of compromising sterility.

When hypodermic needles were to be used many times, the professional user could sterilize new hypodermic needles with the old group and treat them alike. For one time use, that is, disposable hypodermic needles, it is more convenient to have the hypodermic needles arrive at the user's office in sterile condition, attach them to a hypodermic syringe without breaking sterility, use the hypodermic needle once and discard it.

Such single use insures a fresh, clean, sharp hypodermic needle for each patient and prevents any chance of cross bacterial or viral infection. Certain viruses which can be transferred by reuse of hypodermic needles are very hardy and will live under sterilizing cycles which kill all bacteria and higher forms of life. Such viruses are hard to detect. From time to time, hypodermic needles have been suspected of being the carrier for viral infections.

The present new package contains a hypodermic needle between two sheets of plastic, at least one of which is preferably transparent. One of the sheets is flat and the other has a blister drawn down into the sheet of a shape to contain the hypodermic needle, including its hub, and a tearing edge extending beyond the hub of the hypodermic needle to aid in breaking open the blister.

Whereas it is preferred that both sheets of plastic be transparent, either or both can be opaque. When transparent, the contents of the package can be easily seen and visually inspected for possible defects and also inspected by the user for size and shape to be sure that the hypodermic needle selected is satisfactory for an intended use.

While it is preferred that the instructions and identification indicia be printed on one of the sheets, such indicia, and instructions, of course, be given separately, it is convenient to print on the upper side of the lower strip so that the printing is sealed within the package and there is no chance of smearing or smudging the ink.

One or more hypodermic needle packages may be formed from a pair of sheets of plastic. It is convenient to have a plurality of hypodermic needles packaged together for purposes of convenience or bulk purchase rather than individual needles. It is preferred that such sheets have separation lines so that the individual hypodermic needles in their packages may be separated.

Further details of the invention are disclosed in the following description in connection with the drawings which illustrate specific embodiments of the present invention, the full scope of which is set forth in the appended claim. Other advantages, objectives and novel features are apparent from the drawings in which:

FIGURE 1 is a pictorial representation of a sheath of packaged hypodermic needles.

FIGURE 2 is a top view of a single hypodermic needle in its package.

FIGURE 3 is a side view in section of a single hypodermic needle in its package.

FIGURE 4 is a view similar to FIGURE 3, but with the package having been broken open for use.

FIGURE 5 is a sectional view along line 5—5 of FIGURE 3.

A flat transparent sheet of cellulose acetate plastic 11 is cut to a size and shape sufficient to give rigidity to the finished package. A thickness of about 0.005 inch gives good results. The thickness of the sheet is exaggerated in the figures for purposes of clarity. The upper part of the package is formed from a transparent plastic sheet 12 whose external dimensions are the same as the bottom sheet and is formed by clamping a sheet of plastic over a mold which is heated sufficiently to soften the plastic, and the mold is evacuated to draw the blister to shape. The upper sheet 12 has the blister 13 of such a size that it will contain the entire hypodermic needle, including the hub, and has a tear ridge 14 extending beyond the mold of the portion which will contain the hub of approximately the same width as the hub-containing portion and which extends on a diagonal towards the original sheet surface.

By so drawing the blister from the flat sheet, the portion of the sheet which forms the blister is thinned in the drawing. As shown in FIGURE 5, the two blister sides 15 are of about the same size as the blister top 16 as it extends over the hub. Thus, the periphery is approximately three times the initial dimension. Thus, if the original sheet is about 0.005 inch thick, the blister will be drawn to about one-third of this and usually runs from a minimum of about 0.0015 to a maximum of 0.0025 inch. It is preferred that the drawing mold have rounded edges of avoid sharp corners in the blister.

The top of the bottom mold sheet is printed with such indicia and instructions as seem desirable, the size and length of the hypodermic needle, the trademark of the manufacturer and instructions to a user as to how to open the package.

The blistered mold sheet is inverted, a hypodermic needle placed in each blister, and the bottom mold sheet placed over the assembly. The entire assembly is then sealed together. The plastic should be one which is heat sealable. The perimeters of the two sheets are sealed together. Whereas a multiple seal die may be used in which the sealing is accomplished all at one time, it is convenient to form the longitudinal seals 17 between separate blisters and then at a later time a front seal 18 and a rear seal 19 are formed across the front and the rear of the package. In forming the longitudinal seals, a wire may be placed between the heated members forming the seal so that a separation line 20 is formed in the sheets as a zone of weakness so that the separate hypodermic needles in their blisters may be broken apart without destroying the integrity of the individual sterile seals.

Whereas, other methods may be used, such as accomplishing sterilization before the final seal is formed, it is more convenient and more reliable to completely form the packages and then sterilize the package and its contents by a sterilizing gas which penetrates the sheets of plastic. A convenient gas for this purpose is ethylene oxide which is usually used at from 10% to 20% concentration in an inert gas, such as carbon dioxide, to prevent the formation of explosive mixtures. A plurality of packaged hypodermic needles is placed in a chamber, the chamber evacuated slowly to permit air trapped in the
packages to escape, and then the ethylene oxide-carbon dioxide mixture is admitted under pressure which forces the ethylene oxide through the plastic sheet material, thus sterilizing the inside of the package and the hypodermic needle therein. A pressure of two or three atmospheres for eighteen hours guarantees sterility. The pressure is reduced and the ethylene oxide allowed to escape by diffusion or by flushing with an inert gas and then air. The rate of change of pressure is kept such that the blisters are not broken.

Inasmuch as pressure is built up in the individual packages, it is preferred that each blister be reinforced by a protective seal 21, which seal is closely adjacent to the edges of the blister on each side. This protective seal reinforces the package by uniting the upper blistered sheet and the flat sheet of plastic just adjacent to the blister, thus reducing the span and area over which the internal pressure can operate.

These seals may be accomplished by special formed dies so that a group of seals may be formed at a single time, or standard heat sealing equipment can be used in which a heated member with a nonadhesive face, such as polytetrafluoroethylene, is used to prevent the plastic from sticking to the heated members and each seal is separately formed. Such methods of sealing are well known.

The temperature of seal depends somewhat on the composition of the plastic sheet. A cellulose acetate sheet is very satisfactory in that it may be formed and sealed at conveniently obtainable temperatures and is permeable to ethylene oxide as a sterilizing gas. Other sheet materials, including cellulose butyrate or cellulose propionate or polystyrene, and sterilizing agents such as propylene oxide may be substituted if desired. The sheet material can be any plastic that is heat sealable, sterilizing gas permeable, and susceptible to deep drawing.

The hypodermic needle consists of the hollow needle cannula 22 itself and the needle hub 23. Conveniely, the needle hub is a standard Luer hub which may have a Luer lock flange tips 24. These Luer lock flange tips extend up towards and are close to the top of the blister.

For opening, the individual hypodermic needle in its blister package is separated from the remainder of the group and bent on a bend line 25. This line may be indicated on the sheet, but is not a zone of weakness. As the sheets are bent along this line, which is just under the hypodermic needle hub, the top of the blister 16 is drawn against the edge of the hypodermic needle hub, and being thin, fractures. This permits the tearing ridge to pull away from the hub exposing the opening in the hypodermic needle hub. Any contamination remains on the sheet so that the hypodermic needle hub is sterile. The tip of the hypodermic syringe is placed in the hypodermic needle hub, and twisted to engage the Luer lock flange tips if a Luer lock syringe is being used. The hypodermic needle can then be withdrawn from the blister and is sterile, untouched by human hands. To be readily fracturable and yet strong enough to withstand sterilizing and shipping hazards, the top of the blister over the hub should have a thickness of not less than about 0.001 inch, nor greater than about 0.003 inch.

1. Claim:
   A hypodermic needle package which contains an individual hypodermic needle sterilely until time for use and which may be readily opened by fracture of the blister and which then presents the hypodermic needle hub for attachment to a hypodermic syringe without comprising sterility, which comprises: a flat sheet of heat sealable material and a blistered sheet of heat sealable material, about 0.005-inch thick, having a shaped blister conforming to the approximate shape of a hypodermic needle and thinned to about 0.0015 to 0.0025 inch at the hub-containing portion of the sheet with a tear ridge portion of the blister extending diagonally from the needle- and hub-containing portion of the blister, towards and intersecting at an acute angle with said flat sheet, said sheets being heat sealed together around the edges, and additionally in protective seals adjacent to the edge of the blister, and a hypodermic needle having sharp rear corners in the blister contacting the blister, whereby the blister extends over the sharp corners and may be easily ruptured by bending the sealed together sheets adjacent said hub whereby the thinned portion bears against the hypodermic needle hub, thus stretching said thin portion so that it ruptures, using the flat sheet as a fulcrum, to expose said hub for insertion of a hypodermic syringe without comprising sterility.

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