

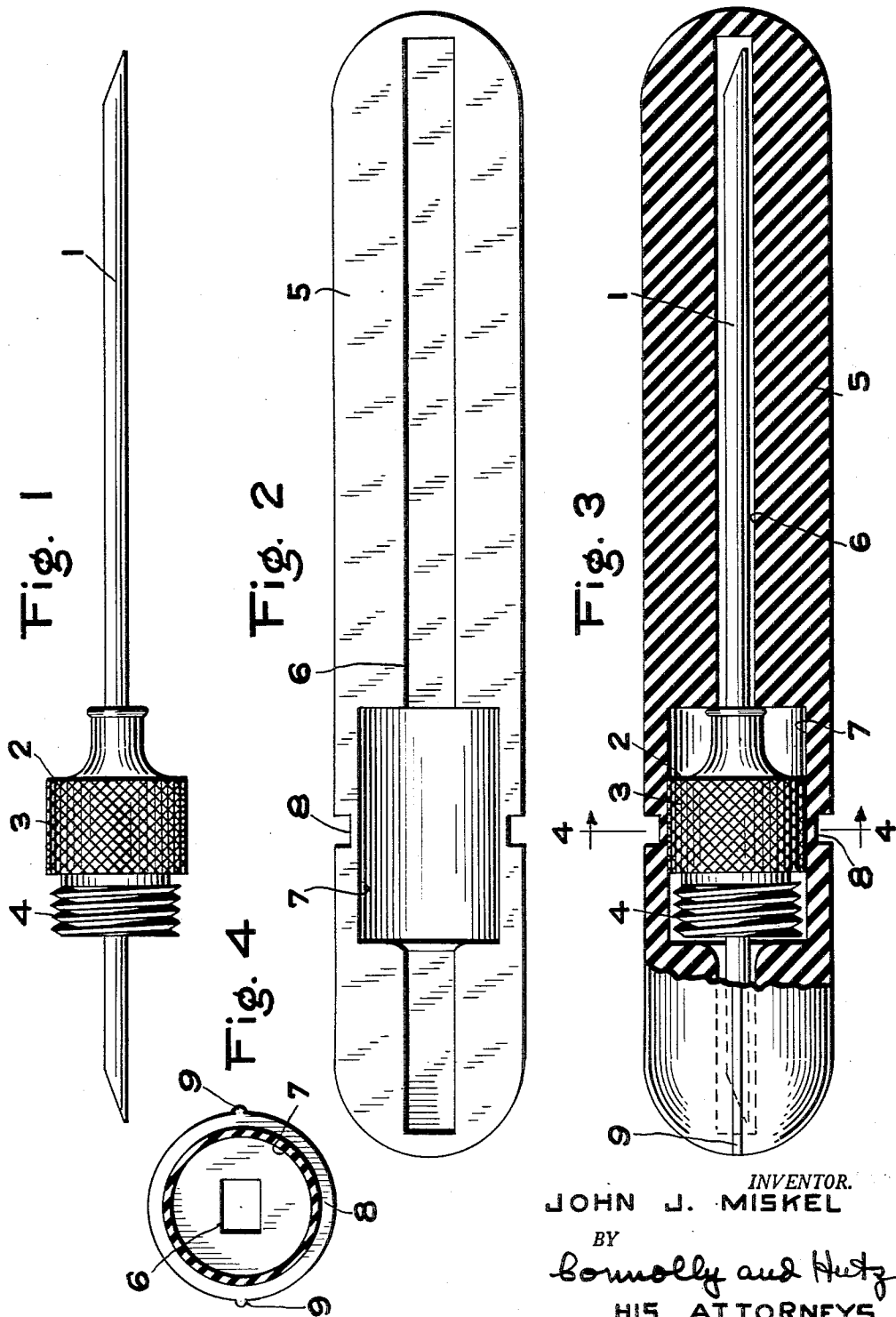
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METHOD OF ENCASING AND STERILIZING NEEDLES

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METHOD OF ENCASING AND STERILIZING NEEDLES

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This invention relates to encased needles, and more particularly, to a hypodermic syringe needle which is encased in a protective casing of plastic material, and to methods for manufacturing the same.

The distribution, storage and handling of hypodermic syringe needles prior to use presents many problems, due to the delicate nature of the needles and the need for maintaining them in a sterile condition free from contamination. The usual hypodermic needle consists of a long thin cannula or tube of stainless steel having at least one sharpened end for injection purposes, and an enlarged portion or hub intermediate its ends for affixing the needle to a medicament ampule or syringe. Frequently both ends are sharpened to facilitate insertion of the needle into the resilient stoppers or diaphragms employed for sealing such medicament ampules. Obviously, these needles are extremely delicate and do not readily lend themselves to the rugged treatment which is sometimes demanded, as in the Armed Forces.

While numerous attempts have been made to meet these problems through various protective sheaths, covers, strip packages, and the like, such measures have not been demonstrated to be satisfactory under all practical conditions of use. Difficulties are frequently encountered with breakage of the seal about the needle and a resulting contamination thereof. Furthermore, many protective covers which might otherwise be suitable are not properly adapted for the task of inserting the needle into a medicament ampule. In addition, the problem of providing hypodermic syringe needles with a satisfactory protective cover is further complicated by a number of manufacturing difficulties.

In accordance with the present invention, however, the above problems are obviated by enveloping the hypodermic syringe needle completely within a protective casing of thermosetting plastic material which is molded about the needle under such conditions that it will effect complete sterilization of the needle therein contained. For a better understanding of the invention, reference is made to the accompanying drawings, wherein Fig. 1 shows one form of a hypodermic syringe needle which may be employed in accordance with the invention; Fig. 2 shows one of the two longitudinal preformed sections employed in the manufacture of the encased needle of this invention; Fig. 3 is an elevation partly in longitudinal section showing the completed casing with a needle therewithin; and Fig. 4 is a section along line 4—4 of Fig. 3.

Referring to Fig. 1 of the drawings, element 1 is a conventional stainless steel needle provided with sharpened ends and a metallic collar or hub 2, the outer periphery of which is knurled, as indicated at 3. The collar is also provided with a threaded portion 4 to facilitate attachment of the needle to the barrel of a hypodermic syringe not shown. The needle and collar may be constructed of a variety of materials and may assume other configurations, as will be apparent to those skilled in the art. The casing or sheath which is to surround the needle structure is fabricated from two matching preformed,

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longitudinal sections of a thermosetting plastic material, one form of which is shown in Fig. 2. This preformed section consists of an elongated body, generally indicated at 5, having a longitudinal recess 6 in the central portion thereof and running substantially the length of the preform. The purpose of the recess 6 is to accommodate the needle 1. In addition, an enlarged recess 7 is also provided to accommodate the collar 2 on the needle. In order to facilitate a clean transverse rupture of the casing after encasement of the needle is completed, the body 5 is provided with an area of reduced cross-section, or a scored portion, 8 in circumferential relationship to recess 7 which accommodates the needle collar. This point of reduced cross-sectional area is preferably situated in the central portion of recess 7 so that the needle may later be retained firmly in one portion of the ruptured casing while the section of the needle exposed by removal of the other portion of the ruptured casing is inserted into a syringe ampule.

The completed article is formed by placing the needle between two of the matching preformed sections described above, and subjecting the same to heat and pressure in a mold under suitable conditions to effect curing of the thermosetting plastic material and thereby completely seal the needle therewithin. The product so obtained is illustrated in Fig. 3 and the corresponding sectional view of Fig. 4. As indicated therein, the needle is completely encased between the two sections 5, which are fused together along the dividing line 9 originally separating the same. The needle is readily prepared for use by rupturing the casing along the scored portion 8. This is accomplished by firmly grasping the casing on each side of the scored portion and twisting one side with respect to the other. The scored portion is preferably molded in contact with the knurled portion 3 of the collar in order to retain the needle and prevent undesirable movement thereof with respect to the casing. However, the dimensions of the needle recess 6 with respect to the needle are preferably such that a slight tolerance, say 0.5 to 1.0 mm., exists between the outer periphery of the needle and the recess walls to permit the casing to be readily withdrawn from the needle and to obviate the sticking of any plastic material thereto. In other words, the casing is slidably spaced from the outer periphery of the needle. Only a relatively thin barrier of plastic material is necessary or desirable about the collar portion of the needle. On the other hand, the thickness of the casing surrounding the needle should be substantially greater, say at least twice its thickness about the collar, in order to insure adequate protection of the needle. The cross-section of recess 6 may assume any convenient configuration, such as the rectangular configuration shown in Fig. 4, or it may be circular. Various indicia may be applied to the outside of the casing during the molding operation or inscribed thereon after said operation, and the entire casing may be coated with a lacquer or other suitable coating to improve its appearance and render it further impervious to moisture.

The manufacture of a needle completely protected by a casing of molded plastic material is obviously complicated if ordinary molding techniques are employed. For instance, if a body of molten plastic material is permitted to come in direct contact with the needle, much of the material will stick to the needle, and more serious, clogging of the needle is apt to result. The provision of a protective stylus within the needle does not obviate the danger of such occurrences. While such a stylus can be employed with the subject invention, the provision of a stylus is rendered unnecessary by employing preformed sections of plastic material as described. The flow of plastic material is thereby substantially reduced, and the final molding operation can be accomplished without

clogging the needles or having the material adhere thereto.

A wide variety of thermosetting plastic materials are useful in this invention, including vulcanite or vulcanized rubber, phenol-aldehyde resins, glyptal or glycerol-phthalic anhydride resins, melamine-formaldehyde resins and the synthetic rubbers, such as butadiene-acrylonitrile (Buna N), butadienestyrene (Buna S), neoprene and butyl rubber. In the case of rubber, various vulcanizing agents, such as sulphur, are employed to advantage. Natural rubber is preferred for reasons of economy. It has been found that the thermosetting plastics, i. e., plastics which harden when heated, are less apt to cause undesirable sticking and/or clogging with respect to the needle than are the thermoplastics. In particular, the thermosetting plastics may be maintained at sterilization conditions without serious danger of encountering these adverse effects.

In preparing the aforesaid preformed sections, the thermosetting plastic material is preferably molded at relatively low temperatures for a time sufficient to effect only partial curing or polymerization. Alternatively, however, the plastic material may be cold molded without polymerization taking place. During the final molding operation a temperature of from about 300° to 450° F. at conventional molding pressures for a period of about 15 minutes to one hour is generally adequate for most purposes. Of course, the lower the temperature, the greater will be the time required to complete the curing of the plastic material and to effect the desired sterilization. In most cases a temperature of 400° F. for one-half hour provides complete curing and at the same time, complete sterilization. When natural rubber is employed, the preform operation is advantageously conducted at a temperature of about 320° F. for ten minutes to effect partial vulcanization, while the final vulcanization of the completed casing is accomplished at approximately the same temperature for about twenty minutes. The molding pressures for both the preform and final molding operation may vary considerably. However, a pressure of from 1000 to 2000 pounds per square inch is usually sufficient in preparing the preform, whereas a somewhat higher pressure, such as from 3000 to 4000 pounds per square inch, is employed during the final molding operation.

The encased needles are, of course, stored and transported in a sealed condition. When it is desired to use a needle, the casing is grasped and twisted as indicated above in order to cause a transverse rupture in the region about the needle collar. The shorter section protecting that portion of the needle which is to be affixed to a medicament ampule, is removed and discarded while grasping the other section of the casing firmly, preferably near the point of separation between the two sections at the needle collar. The exposed portion of the needle, generally the shorter of the two portions, is then inserted into the medicament ampule and the collar is threaded into the syringe

barrel in which the ampule is contained. The other section of the needle casing is then removed, leaving the needle in condition for an injection without need for any sterilization except at the site of the injection. Of course, the stopper or diaphragm of the medicament ampule may be sterilized, if necessary, before inserting the needle therein.

The product obtained in accordance with this invention is sterile and impervious to moisture, as well as other contaminants, including the various pathogenic microorganisms. The needles so encased are sufficiently rugged to stand up under the severest conditions which may be encountered in the field.

Resort may be had to such modifications and equivalents as fall within the spirit of the invention and the scope of the appended claims.

I claim:

1. A method for encasing a hypodermic syringe needle in a sterile, protective casing of plastic material which comprises preforming two sections of thermosetting plastic material, each section being provided with a thin longitudinal recess to accommodate a needle and an enlarged recess to accommodate a needle collar, placing between said sections a needle having an enlarged collar portion thereon intermediate its ends, and hermetically sealing the combination at a temperature and pressure sufficient to cure said plastic and sterilize said needle and providing an integral protective casing thereabout.

2. A method for encasing a hypodermic syringe needle in a sterile, protective casing of rubber which comprises forming two partially vulcanized sections of rubber in a mold, each section being provided with a thin longitudinal recess to accommodate a needle and an enlarged recess to accommodate a needle collar, placing between said sections a needle having an enlarged collar portion thereon intermediate its ends, and hermetically sealing the combination at a temperature and pressure sufficient to complete vulcanization of said rubber and sterilize said needle and providing an integral protective casing of rubber thereabout.

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