A sheath for a syringe needle (14). The sheath (18) includes an enlarged diameter shield affixed to the end of the sheath (18) for protecting a user’s fingers from needle (14) insertion. Alternate embodiments include a transferrable shield being initially affixed to the end of a syringe but transferrable to a sheath (18) as the syringe is engaged with a sheathed needle (14).
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SYRINGE NEEDLE SHEATH AND SHIELD

TECHNICAL FIELD

The present invention relates to syringes usable, for example, in administering hypodermic injections, and more particularly relates to a shield for preventing the accidental insertion of a syringe needle into the fingers of a user when reinserting the needle into a sheath.
BACKGROUND ART

Syringes have multiple uses in the medical and related arts. For example, syringes are used to draw blood from patients by puncturing veins (venipuncture), a procedure wherein a sharp hollow needle is passed through the skin and into the vein of the patient and blood is drawn through the needle into the syringe by means of a vacuum supplied by withdrawing a plunger within the syringe. By way of further example, syringes are used to administer drugs to patients by injection, wherein a syringe containing the desired quantity of liquid drug is forced by a plunger into muscle tissue of a patient by means of a hollow needle inserted into the muscle. There are many other uses for syringes in the medical field, as well as in the related fields of dentistry, veterinary medicine and biological and medical research.

Presently available syringes include hollow elongated sheaths for enclosing the needle when not in use. Typically, for standard sizes of needles, such sheaths have openings on the order of 0.5 cm. and maximum outer diameters on the order of 1.0 cm. It is quite common for the syringe user, after using the syringe, to accidentally "miss" the opening in the sheath when attempting to resheath the needle and insert the needle into a finger. In other words, when attempting to resheath the needle, due to haste or carelessness, the user when attempting to resheath the needle fails to guide the needle into the sheath but instead inserts the needle into a finger or other part of the hand.
The problem of accidental insertions is more than just one of momentary pain. Obviously, in most situations, the syringe has been used in treating a sick patient or animal. Quite often, these persons or animals are infected with communicable diseases. The syringe user bears substantial risk of contracting disease from accidental insertions of the syringe needle. Moreover, syringes are often used to administer powerful drugs or, in veterinary or research fields, chemicals that may be poisonous to humans. Accidental insertion of a needle poses risk to the user in these situations as well.

In considering the art of disposable medical apparatus, a primary factor is the packaging of a product. In order to minimize shipping and storage expenses, disposable products, such as hypodermic needles and sheaths, have heretofore been packaged in as small containers as possible. Therefore, it is quite important when designing a disposable medical product to keep in mind the goal of compact packaging.

It is thus apparent that a need presently exists for a means of protecting a syringe user's fingers from accidental needle insertion when attempting to resheath a used needle. Moreover, any such provision for protection of a user's fingers preferably will be designed in a way to minimize space requirements for packaging. At present, there is no method or apparatus fulfilling these needs.
SUMMARY OF THE INVENTION

The present invention provides a new and useful improvement in syringe needle sheaths which protects a user's fingers from accidental insertion by a needle. In preferred form, an enlarged diameter shield is disposed upon the open end of a needle sheath. The shield has a frusto-conical interior surface to guide the needle into the sheath body. The invention also provides for the economical packaging of the shield. In preferred form, the shield is removably attached to the end of the syringe and is transferred to the open end of the sheath when the needle is attached to the syringe.
BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the invention and its advantages will be apparent from the Detailed Description taken in conjunction with the accompanying Drawings in which:

FIGURE 1 is a side view of a conventional needle, sheath and syringe end;
FIGURE 2 is a side view of a conventional double needle, sheaths and syringe end;
FIGURE 3 is an exploded view of the double needle and sheaths of FIGURE 2;
FIGURE 4 is a side view of the improved needle sheath of the present invention for use with a single needle;
FIGURE 5 is an end view of the needle and sheath of FIGURE 4;
FIGURE 6 is a perspective view of an improved sheath for a single needle sealed in accordance with the present invention;
FIGURE 7 is an exploded view of improved sheaths for use with a double needle;
FIGURES 8a, 8b and 8c are partially broken away side views of the transferrable shield of the present invention adapted for use with a single needle system;
FIGURES 9a and 9b are partially broken away side views of a transferrable shield adapted for use with a double needle system; and
FIGURES 10a and 10b are partially broken away side views of an alternative embodiment of the transferrable shield for a double needle system.
DETAILED DESCRIPTION

Referring initially to FIGURE 1, a conventional single needle, sheath and syringe end are shown to illustrate a prior art single needle system.

Syringe 10 includes tapered tip 12, having a smooth converging outer surface. Needle 14 is attached to base 16. Sheath 18 is shown in engagement with base 16, such that the sheath is firmly, but removably, attached to needle 14 and base 16.

Base 16 includes a diverging inner surface 20 tapered and sized to permit frictional engagement of base 16 with syringe tip 12. Prior to use of the syringe, the user frictionally engages tip 12 with base 16 to attach the needle to the syringe. Sheath 18 may then be removed from engagement with base 16, thereby exposing needle 14 for use. After use, the user attempts to resheath needle 14 by guiding sheath 18 over needle 14. To accomplish this task, the user must engage the end of needle 14 with a relatively small diameter opening, typically 0.5 cm., in the end of sheath 18.

Referring now to FIGURES 2 and 3, a double needle and sheath system is shown. The double needle system illustrated is manufactured by Becton-Dickenson & Co. and marketed under the brand name VACUTAINER. Typically, a double needle system includes specially made syringe 30 having internal threads 32 in tip 34. Needle and sheath assembly 36 includes a long sheath 38 and a short sheath 40 sealed and attached to one another by paper label 42. Prior to use, short sheath 40 is removed from frictional engagement with end 50 of long sheath 38, thereby exposing short needle 52 and
external threads 54. External threads 54 are sized to mate with internal threads 32 of syringe tip 34. Gripping long sheath 38, the user engages threads 54 and 32 to firmly attach the needle assembly to syringe 30. Long sheath 38 is then removed from frictional engagement with base 56 of long needle 58 prior to use of the syringe. After use, the user must resheath long needle 58 with long sheath 38 to prepare the syringe for disposal. As with the conventional single needle system, long needle 58 must be inserted into a relatively small diameter opening in the end of long sheath 38.

FIGURE 4 illustrates an embodiment of the invention adapted for use with a single needle system. Sheath 70 includes elongated hollow sheath body 72, end wall 74 located at one end of sheath body 70 for sealing sheath body 72, and an enlarged diameter shield element 76. Shield element 76 is located at the opposite end of sheath body 72 from end wall 74. Shield element 76 has an outer dimension that is substantially larger than the opening diameter of sheath body 72. For example, a typical form of this embodiment includes a shield that is 2.0 cm. across compared to a sheath body opening of 0.5 cm. Moreover, in preferred form, shield element 76 has a tapered, converging inner surface 78. Needle and base assembly 80 is shown partially within sheath 70.

In FIGURES 4 and 5, shield 76 is shown having hexagonal cross-sections. The provision of the hexagonal outer surface helps prevent the rolling of a sheath 70 on a horizontal surface. It should be appreciated, however, that shield element 76 can have
polygonal cross-sections having any number of sides and is not limited to the hexagonal configuration.

FIGURE 6 illustrates the preferred form of packaging the single needle embodiment of the present invention just described. Needle and sheath assembly 90 includes a single needle (not shown). Needle and sheath assembly 90 includes enlarged diameter shield element 92 having, by way of example only, circular cross-sections. Covering the open end of shield element 92 is seal 94. Seal 94 may be manufactured from any number of paper, foil or plastic materials. Tab 96 is provided for the removal of seal 94 from sheath 90 prior to use of the enclosed needle. Alternatively, perforations 98 may be provided to enable puncture of seal 94 with the tip of a syringe to enable attachment of the needle.

Referring now to FIGURE 7, an embodiment of the invention for use with the double needle system is illustrated. Double needle assembly 110 is identical to the one shown in FIGURE 3, including short needle 112 and long needle 114. Short sheath 116 includes short sheath body 118 and end wall 119. Shield element 120 is enlarged in comparison with the opening in short sheath body 118. Long sheath 122 is similarly constructed, including long sheath body 124, end wall 126 and shield element 128. As illustrated by the broken lines, shield element 128 includes a frusto-conical converging inner surface 130. Shield element 120 of short sheath 116 is similarly provided. Outer surface 138 of short sheath 116 and inner surface 140 of long sheath 122 are sized to provide frictional engagement between the two sheaths.
Before use, short sheath 116 and long sheath 122 are joined by a printed paper seal 132, shown approximately equally divided between the two sheaths in FIGURE 3. Mating serrated edges 134 and 136 are provided to facilitate the breaking of seal 132. The printed paper seal provides a visual indication that a resheathed double needle has been used, due to the unlikelihood that the printing on the two portions of the seal will be exactly or closely matched when the sheaths are reconnected. The serrated edges are optional and are provided to facilitate the breaking of seal 132.

Referring now to FIGURES 8a, 8b and 8c, a transferrable shield element for use with a single needle system is illustrated. In conventional practice, needle and sheaths are packaged separately from syringes. It is possible that use of the embodiments of the invention described above, where the shield element is permanently affixed to the sheath body, may cause a packaging problem due to the enlarged diameter of the shield element. One of the primary features of the shield element is that it is substantially larger than the sheath body, thus protecting the fingers of the user. A syringe, on the other hand, is conventionally much larger in comparison to a corresponding needle and sheath.

To overcome the potential packaging problem caused by using fixed shield elements, an alternate embodiment of the invention involves a shield element that is transferrable from a syringe end to a sheath body prior to resheathing of the needle. As shown in FIGURE 8a, conventional needle and sheath assembly includes a sheath 150, needle base 152 and a needle
(not shown) within the sheath. Syringe 154 includes tip 156 sized for engagement with base 152. Removably attached to the end of syringe 154 is shield body 158. Shield body 158 has a syringe end 160 and needle end 162, syringe end 160 being sized much more largely than needle end 162 to provide protection of the user's fingers when resheathing the needle. Syringe end 160 includes lip 164 sized to engage ridge 168 on syringe 154.

Referring now to FIGURE 8b, as base 152 is engaged with syringe tip 156, needle end 162 of shield body 158 becomes engaged with sheath 150. This is accomplished by the engagement of lip 170 with ridge 172 of sheath 150. It should be appreciated that the lip and ridge attachment system just described is exemplary only and any number of attachment methods could be used without departing from the scope of the invention.

Referring now to FIGURE 8c, transfer of shield body 158 to sheath 150 is accomplished as the now-attached needle and syringe are withdrawn from sheath 150. The gripping force of the syringe end of the shield body is less than the gripping force of the sheath end of the shield body, such that as syringe 154 and sheath 150 are separated, lip 164 releases ridge 168 while lip 170 and ridge 172 remain fast. After the syringe and needle are used, the user can resheath the needle, and shield body 158, now attached to sheath 150, will protect the user's fingers from accidental insertion.

A similar embodiment of the invention to the ones just described is shown in FIGURES 9a and 9b, such embodiment being adapted for a double needle
system. Before use, shield body 180 is removably attached to syringe 182 by means of lips 184 and ridges 188. After a short sheath (not shown) is removed to expose short needle 190, needle and long sheath assembly 192 is ready for engagement with syringe 182. As threads 194 on the double needle are engaged with threads 196 of the syringe end, frictional surfaces 198 and 200, of shield body 180 and long sheath 202 respectively, engage. As shown in FIGURE 9b, as the syringe and double needle, now attached, are withdrawn, shield body 180 remains attached to long sheath 202. The gripping force of lips 184 and ridge 188 is less than the gripping force of frictional surfaces 198 and 200.

Still another alternate embodiment of the invention is illustrated in FIGURES 10a and 10b. To provide a more secure attachment of the shield body to the long sheath than that of the embodiment shown in FIGURES 9a and 9b, shield body 210 and long sheath 212 are provided with mating threads 214 and 216 respectively. Threads 214 and 216 are of the same pitch as threads 218 and 220 of syringe 222 and double needle 224 respectively. Shield body 210 is removably attached to syringe 222 by means of lip 226 and ridge 228. As shown in FIGURE 10b, shield body 210 is threadably engaged with long sheath 212 simultaneously with the threaded engagement of double needle 224 and syringe 222. It may be preferable to use the embodiment shown in FIGURES 10a and 10b over the embodiment shown in FIGURES 9a and 9b, particularly when a more secure attachment of the shield body and long sheath is desired.
While certain embodiments of the present invention have been described in detail herein and shown in the accompanying Drawings, it will be evident that various further modifications are possible without departing from the scope of the invention.
CLAIMS

1. An improved sheath for a syringe needle comprising an elongated hollow sheath body, an end wall located at one end of the sheath body for sealing the sheath body, and a shield element located at the other end of the sheath body being sized more largely than the sheath body to guard a syringe user's fingers from needle insertion.

2. The sheath of Claim 1 wherein the shield element has a converging inner surface for guiding the needle into the sheath body.

3. The sheath of Claim 2 wherein the shield element inner surface is frusto-conical.

4. The sheath of Claim 1 wherein the shield element outer surface is polygonal in cross-section to prevent rolling of the sheath on a horizontal surface.

5. The sheath of Claim 1 further comprising a removable seal on the shield element for sealing the sheath, the seal including means for admitting a syringe tip into the sheath for needle attachment to the syringe tip.

6. The sheath of Claim 5 wherein said means for admitting includes perforations in the seal defining an entry point into the sheath.

7. The sheath of Claim 1 being adapted for use with a double needle system, further comprising a
second sheath body with associated end wall and shield element, and means for removably attaching the shield elements to each other.

8. The sheath of Claim 7 further comprising a printed seal overlaying portions of the shield elements to provide a visual indication when the shield elements have been separated.
9. A shield for protecting a syringe user's fingers from needle insertion comprising a shield body having a syringe end and a sheath end, the syringe end being sized more largely than the sheath end, means for removably attaching the syringe end to a syringe, and means for engaging the sheath end to a needle sheath, the shield body being removable from the syringe after engagement with the needle sheath such that the shield is transferrable from the syringe to the needle sheath prior to resheathing a needle attached to the syringe.

10. A shield of Claim 9 adapted for use with a threaded double needle system, further including threads formed within the sheath end of the shield, size to engage threads formed upon the sheath body, the shield being removably attached to a syringe prior to use and being engaged with the sheath when a threaded double needle is engaged with the syringe.
# INTERNATIONAL SEARCH REPORT

**International Application No.** PCT/US85/00003

## I. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both National Classification and IPC

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  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed

**IV. CERTIFICATION**

**Date of the Actual Completion of the International Search**

11 February 1985

**Date of Mailing of this International Search Report**

25 FEB 1985

**International Searching Authority**

ISA/US

**Signature of Authorized Officer**

[Signature]

Form PCT/ISA/210 (second sheet) (October 1981)