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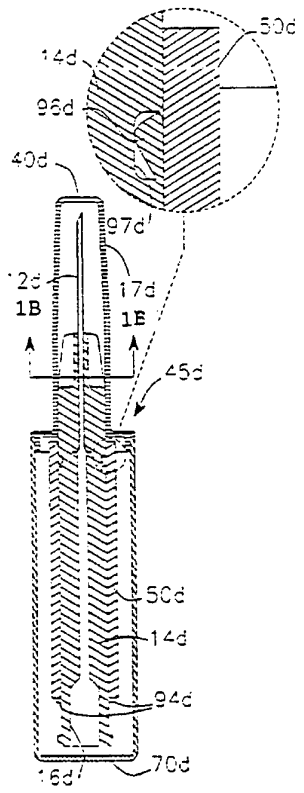
(54) Title: HYPODERMIC NEEDLE SHIELD

(57) Abstract

A detachable needle assembly (10d) is provided with a needle shield (50d) supported for telescoping movement on the needle hub (14d), with the shield being movable over an end portion of the hub. A cover cap (40d) is supported over said hub end portion prior to use of the device, preferably by mounting of said cover cap directly on said hub end portion.



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HYPODERMIC NEEDLE SHIELD

This invention relates to "safety" detachable syringe needles which can be safely used and discarded with minimal chance of accidental pricking of a finger or other body part of the nurse or other health care worker handling the syringe and attending to its use.

There is a manifest need for safety syringe needles, as evidenced by a number of patents issued in recent years which are directed to the problem of preventing accidental pricking. The increasing incidence of AIDS and the presence of other serious infectious diseases have stimulated the effort to provide an acceptable safety syringe needle that is practical. Various proposals for providing a protective extendible needle shield are set forth in the following patents, among others:

Haber et al.	Re. 33,585
Sampson et al.	4,573,976
Braginetz	4,666,435
Wanderer et al.	4,693,708
Spencer, Treesa A.	4,702,738
Spencer, John E.	4,723,943
Poncy	4,816,022
Byrne et al.	4,826,490
Hernandez	4,840,185
Poncy	4,842,587
Mathiesen et al.	4,861,338
Poncy	4,961,730
Haber et al.	4,892,523
Haber, Terry	4,915,702
Hogan	4,923,283
Page et al.	4,943,282
Ejlersen et al.	4,976,701
Le et al.	5,011,492
Juhasz, Paul R.	5,061,251
Parry	5,104,384

Several of the these patents relate to hub-supported shields. In U.S. Patent 4,826,490 to Byrne et al., an extensible shield is slidingly supported on a

hub of hollow cross-section such that the majority of the cross-section contains fluid being injected, thus presenting a potential of overdose, particularly when small dosages are administered in small syringes. In the three patents to Poncy listed above, an extensible shield is slidingly supported on a hub and retracts over the syringe with which the needle is used, the range of movement necessary to cover the needle being considerably more than the length of the hub sliding surface, so that the shield must be wider than the syringe with which the needle is used, and the device is bulky and, even so, is not universal to all usual sizes of syringe. In U.S. Patent 5,011,479 to Le et al., an extensible shield is slidingly supported on a double-connector intermediate member that is affixed through a first connector to the needle and through a second connector to the syringe. The health care worker must make two connections, as described at col. 4, lines 51 ff. In U.S. Patent 5,104,384 to Parry, an extensible shield is mounted radially within an outer sleeve which is fixed to the hub and longitudinally extends therefrom over about half the unsupported length of the needle. This arrangement only allows the extensible shield to be withdrawn from approximately half the unsupported length of the needle, so that the unsupported length of the needle is about twice the usable (insertable) needle length, resulting in either a flimsy arrangement or a usable needle length that is impractically short.

U.K. Patent 924,734 to Linder (not listed above) is of interest since it shows a hub supported extensible barrel element which is part of a spring-powered needle projecting system. Linder's barrel does not operate as a shield but on the contrary remains stationary while the needle advances, and leaves the needle tip exposed after use. Furthermore, assuming that

Linder's barrel can be said to "retract" when it, while stationary, experiences relative advancement of the needle, such "retraction" exposes no more than a fraction of the length of the needle, which would be an impractical arrangement for an extensible needle shield.

Extensible shields for syringe needles which are not hub-mounted have also been provided, and further demonstrate the felt need there has been for practical and widely acceptable safety syringe needles. The remainder of the patents listed above are generally in this category. In U.S. Patent 4,666,435 to Braginetz, a extensible needle shield is mounted on a syringe vial. In U.S. Patent 4,840,185 to Hernandez, a shield is provided on the barrel of the vacuum tube holder which itself forms an extension of the syringe barrel. In U.S. Patent 4,861,338 to Mathiesen et al., a needle shield is a continuation of the syringe barrel, and the needle holder is turned by the syringe plunger to advance and retract the needle. In U.S. Patent 4,976,701 to Ejlersen et al., a double ended needle is shielded by a cap fixed to the "cartridge 11, 14, 15" by an "intermediate member" having a "rear part 23" and a "front part 24", or the cap 65 is threaded on the cartridge jacket 50, so that essentially the shield is an extension of the cartridge barrel. In U.S. Patent 4,923,283 to Hogan, in which the needle is used in a tubing arrangement rather than with a syringe, a needle shield slides down the flexible tubing and over the needle.

Most of the foregoing patents represent efforts to respond to the need for an acceptable safety syringe needle that is practical -- a safety device of simple design, one which is convenient to manipulate and use, requires little or no training, and does not materially affect dosage amounts even for syringes of the smallest sizes.

The present invention provides such a device. The present invention provides a device whose manner of use will be self-evident and natural to nurses and other medical workers. The invention provides a device which may be used without modification of syringes already widely in use, and does not materially affect accuracy of dosage even when used with syringes of the smallest sizes. The invention is so perfectly in accord with present nursing practice that it requires no departure whatsoever from procedures that are presently widely used, other than simply advancing a shield when a needle is withdrawn from the patient.

An accepted and widely used hypodermic syringe design uses detachable needles which are supplied in sterile packages and are adapted to be attached to any one of a number of sizes of syringe barrels by a standard coupler or end connection provided at the distal end of each syringe. A commercial example is the "Leur-Lok" needle sold commercially Becton Dickinson & Company. The syringe-associated coupler members for receiving the needles may be constant or standard in size for various sizes of syringes, so that one of the detachable needles can be attached to a syringe of any size.

A feature of the present invention is the provision of a retractable shield associated with such detachable needles for hypodermic syringes. The design of the parts is such is such that the shield and detachable needle together provide a self-contained assembly or package that is independent of the syringe to which the needle is mounted, while at the same time being conveniently usable on all sizes of syringe from the smallest to the largest without compromise of dosage accuracy. It is not necessary to make two connections. The retracted shield can uncover the entire unsupported length of the needle, so that the needle's unsupported

length need be no greater than its usable length, making for a sturdy arrangement that does not impractically restrict the usable length of the needle.

The objects and advantages of the invention will become clearer from the following description of specific embodiments, and from the accompanying drawings, in which:

FIG. 1 is a somewhat schematic cross-sectional view of a detachable needle assembly embodying the invention, shown in packaged condition with a cover body as well as a cover cap to furnish a complete package if desired.

FIG. 1A is a view on an enlarged scale of a small portion of FIG. 1.

FIG. 1B is a view taken on the plane of line 1B-1B in FIG. 1.

FIG. 2 is a cross-sectional view taken on a plane 90 degrees removed from that of FIG. 1, and showing the cover body removed and the remainder of the device affixed to a syringe by a Leur lock type connection.

FIG. 2A is a view on an enlarged scale of a small portion of FIG. 2.

FIG. 2B is a cross-sectional view of a detachable needle assembly very similar to that shown in FIG. 2, and with the parts similarly positioned (except for the omission of a cover cap), illustrating certain alternatives as to hub fabrication and connector fittings. For simplicity, FIG. 2B is not shown as a counterpart of FIG. 2 as shown, but of FIG. 2 as it would have appeared if viewed on a plane 45 degrees removed from the viewplane of FIG. 2. By this rotation of viewplane, there is no inconsistency in the fact that FIG. 2B does not show any detents equivalent to any of those shown in other figures.

FIG. 3 is a view on the same plane as FIG. 2 showing the cover cap removed and the needle shield extended.

FIG. 3A is a view on an enlarged scale of a small portion of FIG. 3.

FIG. 4 is a view taken on the same plane as FIG. 1, also showing the needle shield extended, and showing the device optionally disconnected from the syringe.

FIG. 4A is a view on an enlarged scale of a small portion of FIG. 4.

FIG. 5 is a sketch of the cover cap.

FIG. 6 is a somewhat schematic cross-sectional view of a detachable needle assembly illustrative of the prior art, shown attached to a syringe but prior to removal of a plastic shell or cover associated with the detachable needle.

FIG. 6A is an end view of only the hub elements shown in FIG. 6 (the coupler elements and plastic shell or cover elements shown in FIG. 6 are omitted) taken from the plane of line 6A-6A in FIG. 6.

Drawings are referred to above as being somewhat schematic because no attempt has been made to portray mold draft angles, reinforcing ribs, precise relations as to relative wall thicknesses, and like details which persons skilled in the art of injection molding or other appropriate manufacturing methods may utilize as a matter of routine design.

For a better understanding of the invention, detachable needles of the prior art will first be described. These may be of the type illustrated by the detachable needle generally indicated by the reference numeral 10 in FIG. 6. The detachable needle 10 includes a needle proper 12 and a needle hub 14. The needle is anchored to the hub and extends coaxially from

the distal end of the hub. An open mouth 16 in the proximal or lower end of the hub provides inlet means for fluids passing through the hub. The mouth 16 also forms a bore 20 extending upwardly to a seat 22 for receiving a hollow male coupler member 24 which has a central passage 28. The seat 22 provides interior annular socket means for the male coupler member 24. The member 24 is integrally formed as part of the coupler generally indicated by the reference numeral 30. The coupler 30 is a standardized fitting or coupler member fixed to the end of syringe barrel 32. The syringe barrel may have any one of a number of standard diameters, ranging from a diameter only slightly larger than male member 24 of the fitting 30 up to four or more times the outside diameter of fitting 30. The hub 14 also has a radially extending flange means comprising a pair of radially extending flanges 26 adapted to threadedly engage the interior threads 34 of fitting 30. When the flanges 26 are turned down in the threads 34, the male coupler member 24 is tightened into the seat 22, and the central passage 28 is sealingly connected to the hub passage 23 which leads to the needle 12. Sometimes the parts are proportioned such that the penetration of the male member is limited by bottoming of the flanges in the threaded part of the fitting rather than by bottoming of the male member on a seat or lengthwise taper fit (not shown in FIG. 6, but see taper fit of male member 24′ of fitting 30′ in FIG. 2B, to be later described and illustrating a device contemplated by the present invention used with such a fitting), which may still give an adequate seal if the fit of the male member in the bore is sufficiently close, i.e., is a good "press fit." Syringes of smallest diameter are not provided with the threaded female part of the connector fitting, but only with the male member, and sealing must be accomplished by pushing the parts

together lengthwise rather than twisting them to tighten down a threaded connection. When this is the case, a gentle taper fit may be preferable to the seating illustrated in FIG. 6 or to a press fit arrangement in which the male member does not bottom.

A plastic shell or cover cap 40 is provided which may have a slightly tapered fit (not shown in FIG. 6) on the hub 14 such that the cover 40 is spaced above the needle when seated as far as possible on upper or distal end of the hub in the position shown in FIG. 6. Prior to use, and prior to being coupled to a syringe, the assembly as so far described (of course excluding the coupling 30 and syringe barrel 32) may be supplied in a sterile flexible package or envelope (not shown).

When the detachable needle is to be used, the user removes the sterile assembly from its sterile packaging, grasps the shell or cover 40 in the vicinity of the hub 14, and connects the assembly to a syringe 32 by inserting the flanges 26 into the threads 34 of the syringe coupler 30 and twisting the hub to tighten the flanges down in the threads until the male member 24 of the coupler is received tightly in the seat 22. When the detachable needle is tightly coupled to the syringe, the plastic shell or cover is removed by twisting and pulling it off the hub.

When the worker grasps the cover 40 in the vicinity of the hub 40, sterility at this location on the cover is destroyed, but that is of no consequence, since sterility of the detachable needle and of the interior passages between the syringe and the needle tip is preserved.

Following uncovering of the needle, medication may be aspirated into the syringe. If this is done at a point remote from the patient, the cover 40 (the interior of which is still sterile at this point)

may be replaced on the distal or upper end of the hub 14 to temporarily re-cover the needle and protect needle sterility until use, the cover of course being again removed prior to injection of the medication. If it is not necessary to protect the sterility of the needle between aspiration of medication and medication, the needle is not temporarily re-covered between these steps.

Following use, the needle is no longer sterile. If the needle is not shielded following use, obviously a risk is presented to health care personnel and others required to handle or dispose of the used devices. Following use, the needle 12 may be again re-covered with the cover 40 (which, inconveniently, has to have been saved when originally removed) by applying the cover over the "front" or distal end of the needle. Doing so involves moving the cover in the proximal direction while the cover is closely adjacent the needle tip and, moreover, involves moving the cover over the needle from beyond the needle tip, thereby presenting a substantial risk of a needle prick to a possibly harried and distracted health care worker.

If the needle is to be detached from the syringe following use, the user must either proceed while the needle is still exposed by grasping the hub and twisting it in order to back the flanges 26 out of the threads 24, thereby risking a prick from the exposed needle during such backing-out, or must re-cover the needle in the manner previously described, with the attendant risk of pricking at that stage.

The invention presents a needle which may be safely shielded after use by shield means which is conveniently manipulated solely from the proximal end of the needle assembly, thus avoiding direct exposure to the needle tip or any need to grasp parts located beyond the needle tip. At the same time, the present invention may

be used in place of the detachable needles of the prior art with little or no modification of the practices of the prior art in using needles of that general type, and without modification of existing syringes used with detachable needles.

An embodiment of the invention is shown in FIGS 1-5. A detachable needle generally indicated by the reference numeral 10d (FIG. 2) includes a needle proper 12d and a needle hub 14d. As shown, the hub 14d is preferably of generally cylindrical configuration. The needle 12d is anchored to the hub 14d and extends coaxially from the distal end of the hub. The distal end of the hub may terminate in four tapered ribs or ears 17d spaced at 90 degree intervals around the hub, as shown, which provide anti-rotation clutch means in association with other elements, as described below.

An open mouth in the proximal or lower end of the hub provides inlet means for fluids passing through the hub. The mouth also forms a bore 20d extending upwardly into a or seat 22d for receiving the hollow male coupler member 24d associated with a standard coupler of the type previously described.

The hub 14d also has radially extending flange means comprising a pair of radially extending flanges 26d adapted to threadedly engage the interior threads of fitting 30. When the flanges 26d are turned down in the threads, the male coupler member is tightened into the seat 22d, and the central passage 28 of the male coupler member is sealingly connected to the hub passage 23d which leads to the needle 12d, to establish a fluid flow path whose cross-sectional area along almost all, if not all, its longitudinal extent within the hub is a minority of the cross-sectional area of the hub itself.

Prior to use, the exposable portion 15d of the needle 12d is covered by a cover cap 40d which is

removably and replaceably mounted on support portion 41d of the hub 14d, such support portion being associated with the upper or distal end of the hub. The cover cap 40d has annular flange means generally indicated at 45d and which may, as shown, include a radially extending portion 47d and lip 49d (FIG. 5). The cover cap is preferably tapered as shown to inherently provide stop means to define the fully seated position of the cover cap on the hub. To lock the cover cap and hub together against relative rotation, interference ribs 44d (FIG. 1B) may be provided formed integrally with the cover cap 40b and extending longitudinally a short distance at the same lengthwise portion of the assembly at which the ribs 17d are located. The ribs 44d and 17d thus together provide anti-rotation clutch means when the cover cap 40d is seated on the hub 14d. (Similar tapering and provision of interacting anti-rotation clutch means has been included in prior-art devices such as described above in connection with FIG. 63, but these details are described herein for completeness.)

The detachable needle assembly 10d is provided with a shroud or shield 50d which is slidingly supported on the hub 14d for telescoping movement from retracted position seen in FIGS. 1 and 2 to extended position seen in FIGS. 3 and 4. The shield 50 d is supported on support portion 43d of the hub in retracted position and on support portion 41d of the hub in extended position. In the shield-retracted position, the entire length of the needle outside the hub is exposed, as shown. The portion of the cylindrical exterior of the hub that is underneath the shield constitutes a sliding-fit surface on which the shield is supported in its telescoping movement, and the longitudinal extent of such sliding-fit surface is substantially no less than the distance of travel of the shield between extended and

retracted positions, and is actually somewhat greater in this embodiment. Such sliding fit-surface is not necessarily continuous, but can be interrupted by lightening holes, grooves, chambers, or the like (not shown) for material and weight saving, if desired.

It is to be noted that all points of support of the shield 50d on the hub 14d are themselves supported entirely via the engagement of the screw-down connection means of the detachable needle assembly 10d with the syringe-mounted locking means 30, and that such telescoping support is self-established by the detachable needle assembly and does not depend to any significant degree, or to any degree whatsoever in the illustrated embodiment, on structural support or interaction of the shield with any elements associated with the syringe 32. Thus, the telescoping support of the needle shield 50d on the needle hub 14d is a substantially self-established attribute of the detachable needle assembly 10d. It is further to be noted that the shield 50d, along its length when in its retracted position, is radially spaced, by the majority of the cross-sectional area of the hub, from corresponding lengthwise portions of the fluid flow path that is established by passages 23d and 28.

The shield 50d is provided with suitable detent and guide means whereby (1) the shield is locked, preferably permanently, in its extended position once it is moved to that position, (2) the shield is prevented or stopped from moving beyond its extended position and becoming detached, and (3) the shield is locked against rotation relative to the hub.

Such detent and guide means may include for example two guide grooves 91d formed in the shield 50d as seen in FIGS. 2 and 3. Each groove 91d receives a groove follower or detent 90d molded integrally with the hub 14d and joined thereto by a living hinge whereby the

detents 90d may be hinged inwardly into their associated pockets 92d formed in the body of the hub 14d. Each groove 91d terminates at the proximal end of the shield in an endwall 93d (FIG. 3A).

During assembly of the parts, as the shield is slipped over the hub, the outer sides of the endwalls engage the sloping outer sides of the detents 90d to thereby cause the detents to hinge inwardly until the radially inner peripheries of the end walls 93d pass over the detents 90d. As the end walls pass completely over the detents 90d, the latter spring into position in the grooves 91d.

The detent and guide means also include the detents 96d also molded integrally with the hub 14d and each joined thereto by a living hinge whereby the detents 96d may be hinged inwardly into their associated pockets 97d formed in the body of the hub 14d as shown in FIG. 1A.

During assembly of the parts, as the shield is slipped over the hub, the detents 96d may be hinged inwardly with a suitable tool (not shown) to allow the bore of the shield 50d to start to pass over the detents 96d and hinge them into the pockets 97d. The bore of the shield continues to restrain the detents in inwardly hinged condition as assembly of the shield on the hub is then completed by moving the shield downwardly until the bottom end thereof abuts a stop ridge 94d formed near the bottom or proximal end of the hub.

When, during or after removal of the needle from a patient, the shield is moved to its extended position, the bottom end of the shield passes clear of the detents 96d which are then free to spring outwardly their unbiased position and act as a stop against the bottom end of the shield 50d to thereby permanently lock the shield in extended position, as best

seen in FIG. 4A. At the same time, the detents 90d engage the inner side of the end walls 93d, as best seen in FIG. 3A, to thereby prevent the shield from moving beyond its extended position and becoming detached from the hub. The engagement of the detents 90d with the sidewalls of the grooves 91d locks the shield against rotation relative to the hub in both the retracted and extended positions of the shield, and during movement of the shield between those positions.

FIG. 2B is a cross-sectional view of a detachable needle assembly very similar to that shown in FIG. 2, and with the parts similarly positioned (except for the omission of a cover cap), illustrating certain alternatives as to hub fabrication and connector fittings.

From a manufacturing standpoint it may be advantageous to fabricate the hub of two elements or more that are welded, sealed, adhered or otherwise permanently combined together, such as elements a and b which form hub 14d' as illustrated in FIG. 2B. Element a is flangeless, and has a cylindrical rather than tapered radially outer surface, but otherwise may have proportions similar to a conventional needle hub, so that it can be manufactured and mount a needle in a similar manner. If the cylindrical outer surface is difficult to provide due to mold draft requirements or other molding constraints, a tapered filler or spacer collar (not shown) can be slipped over a tapered outer surface of element a, in complementary relationship, to impart a cylindrical outer surface for the support portion 41d of the hub, and the spacer then welded to or otherwise permanently combined with the remainder of the hub.

Element b of hub 14d' may be a solid centrally passaged member as shown on which element a is permanently welded or otherwise joined as illustrated.

It will be understood that any of the hubs of the various embodiments of the invention can be similarly formed as a similar composite of elements permanently joined together. Also, although the illustrated hub 14d is of solid design radially outwardly of its central passages, it may be designed otherwise, as by being chambered or provided, say, with lightening holes or grooves (not shown), or by having radially inner and outer portions spaced by a flange or flanges (not shown).

FIG. 2B further illustrates a common form of fitting 30' which differs from the fittings 30 shown in the other drawings in that the male member 24' of fitting 30' is gently tapered to be received in a gently tapered seat or socket 22d', rather than bottoming on a sharply angled seat such as seat 22d, or on a radially extending seat. This is a common form of fitting, and accordingly it will be understood that it may be preferable to modify the shapes of mouth 16d to form a gently tapered seat or socket similar to seat or socket 22d', rather than the sharply angled seat illustrated.

The product of FIGS. 1-5 may be supplied as a sterile package. For this purpose, a cover body 70d may be provided, the mouth of which engages the annular flange means 45d of the cover cap 40d, as seen in FIG. 1. The releasable joint between these parts may be such as to be contamination-proof, or may be covered by a tape, shrink-wrap-label, or the like (not shown) for such purpose and so as to provide tamper-evident means. The cover body 70d, together with the cover cap 40d, provides an outer rigid envelope which encloses and encapsulates the assembly comprising the needle 12d, hub 14d and shield 50d. This rigid envelope mounts such assembly firmly within itself so that the contained parts are anchored and do not rattle around.

A flange (not shown), extending radially from the shield 50d at its lower or proximal end, may be provided, constituting finger-engageable means for powering the advance of the shield from retracted to extended position. Such flange could be at the same longitudinal location as the groove endwall 93d, and may be of arbitrary thickness in the longitudinal direction. If the cover body 70d is used as a packaging element for the device, the radial extent of such flange can be no greater than the inside radius of the cover body, and may match this radius to desirably provide mutual support between the lower end of the assembly and the lower end of the cover body 70d. Such flange can have an arbitrarily large radius if a cover body 70d or like packaging element is not used. It will be noted that such flange would remain remote to the tip of the needle at all times during shield-extending movement. If no such flange is provided, the outer surface of the shield 50d can be knurled, coated, or otherwise treated to improve finger engageability.

When the product of FIGS. 1-5 is to be used, the health care worker removes the cover body 70d from the cover cap 50d by twisting these two cover elements relative to each other to open the joint between them, first removing any tape, shrink-wrap strap or the like. The cover body is then discarded. When the health care worker opens the sterile package and handles the several elements of the assembly, sterility on the exterior of cover cap 40d, shield 50d and hub 14d may be destroyed, but sterility of the detachable needle and of the interior passages between the syringe and the needle tip is well protected by the container-like configuration of these elements.

When the cover body is removed and discarded, the flanges 26d become exposed. Grasping the

cover cap 40d near its lower or proximal end, i.e., in the vicinity of the support portion 41d of the hub, the health care worker connects the assembly to a syringe 32 by inserting the flanges 26d into the threads of the syringe coupler 30 and twisting the assembly to tighten the flanges down in the threads until the male member 24 is received in the seat 22d. The necessary twisting force is imparted from the cap to the hub via the anti-rotation clutch means provided by engagement between the ribs 17d and 44d.

The cover cap is then removed by the health care worker by pulling it upwardly away from the hub, exposing the exposable portion 15d of the sterile needle. Medication is then aspirated in the usual manner to fill the syringe 32. If the aspiration is not performed at the patient's bedside, sterile conditions must be maintained while the syringe is transported to the patient. For this purpose, the cover cap is slid over the needle and replaced on the hub, protection against pricking being provided by the annular flange means 47d, behind which the health care worker's thumb and forefinger are naturally positioned as the cover cap is grasped. It is to be further noted that at this stage the needle is still sterile, so that pricking at this time would amount to no more than an inconvenience even were it to occur. It is still further to be noted that this recapping with the flanged cover cap 40d is perfectly consistent with present good practice -- that of protecting a sterile needle, following aspiration of medication, by re-covering the needle with a cover cap (non-flanged) such as the cover cap 40, as previously described.

At the patient's bedside, the cover cap, if it has been used to re-cover the needle, is again removed, and the injection is performed. Again, this is

perfectly consistent with present good practice. When the injection is completed, and as the needle is removed from the patient, or immediately after removal, the health care worker moves the shield 50d from its retracted to its extended position, by finger engagement with the previously described flange at the lower or proximal end of the shield (not shown), or with the exterior of the shield barrel proper. The shield 50d becomes permanently locked at its extended position by engagement of the detents 96d with the bottom or proximal end of the shield as best seen in FIG. 4A, thus permanently shielding the now-contaminated needle. At the same time, accidental removal of the shield by over-extension is prevented by engagement of the detents 90d with the endwalls 93d of the grooves 91d as best seen in FIG. 3A.

At this point, the shield and hub remain locked against relative rotation by the engagement of the detents 90d with the sides of the slots 91d, as also best seen in FIG. 3A. Thus either the shield or the hub may be grasped to rotate the assembly in the loosening direction to back the flanges 26d out of the syringe-mounted locking means 30 and detach the needle and hub from the syringe. The detachable needle assembly may then be disposed of, the needle remaining shielded by the shield at all times.

To be noted is the fact that the invention can be used with the same syringes as have been used with the detachable needles of the prior art, without any modifications of such known types of syringes.

While presently preferred embodiments of the invention have been described, additions, deletions, modifications and refinements in the invention can be made without departing from the fair teachings thereof. For example, the annular flange means 45d can be formed

with a skirt extending downwardly over at least the topmost or distal portion of the hub 50d, and the releasable joint between these parts accordingly be located nearer to the bottom or proximal end of the device. The shield may be lightly spring-loaded for extension. The extension-locking detents 96d may be replaced by detents that remain concealed in the extended position of the shield, or by other detent arrangements. While the cover cap 40d is preferably, as shown and described, supported directly on the hub, never contacting the retracted needle shield 50d, less preferably the two may lightly touch, or the cover cap may even be mounted on the retracted shield with light frictional contact (the cover thereby being supported via the hub only indirectly), with the shield held in retracted position by restraining means which is strong enough to allow removal (and reinstalling and re-removal) of the cover cap without extending the needle shield. In such case, the restraining means, although strong enough for the purposes just mentioned, is nevertheless weak enough so that, at the proper time, it can be readily manually overcome in order to extend the needle shield. Still other arrangements are possible. The scope of the invention is intended to be defined by the following claims, and is not intended to be limited to specific details of the foregoing disclosure except to the extent, if any, fairly required by proper interpretation of the claims.

WHAT IS CLAIMED IS:

1. A needle and cover assembly comprising a needle hub, said hub having proximal and distal ends and being adapted to be releasably attached to a syringe at its proximal end to thereby support the remainder of the assembly as a self-supported assembly mounted on the syringe via the hub, inlet means at the proximal end of the hub for receiving medication, a needle anchored to the hub at the distal end of the hub, said needle having an exposable portion extending outwardly from the distal end of the hub coaxially therewith to the tip of the needle, a cover cap removably and replaceably supported over the distal end of the hub in covering relationship with said exposable portion of the needle, said support of said cover cap being provided entirely by the remainder of said self-supported assembly independently of any other structure, and a needle shield mounted on the hub, said shield being movable in the longitudinal direction, after removal of the cover cap but independently of and later than said removal, from a retracted position nearer to said proximal end of the hub, in which retracted position said exposable portion of the needle is exposed, to an advanced position further from said proximal end, in which advanced position the needle shield surrounds said exposable portion of the needle, said needle shield in its retracted position exposing at least the majority of the length of that portion of the needle which extends from the distal end of the hub.

2. A device as in claim 1, said removal of the cover cap being free of any linkage or frictional contact with said shield.

3. A device as in claim 1, a cover body enclosing the proximal end of said hub and releasably engaging said cover cap when said cover cap is supported on said remainder of said self-supported assembly, whereby said cover cap and cover body together form a package completely enclosing said hub, needle and shield.

4. A device as in claim 1, including locking means for locking said shield in said advanced position upon its advance thereto.

5. A device as in claim 1, including anti-rotation clutch elements on said cover cap and said hub, said elements being interengageable against relative rotation of said cap and hub when said cover cap is supported on said remainder of said self-supported assembly.

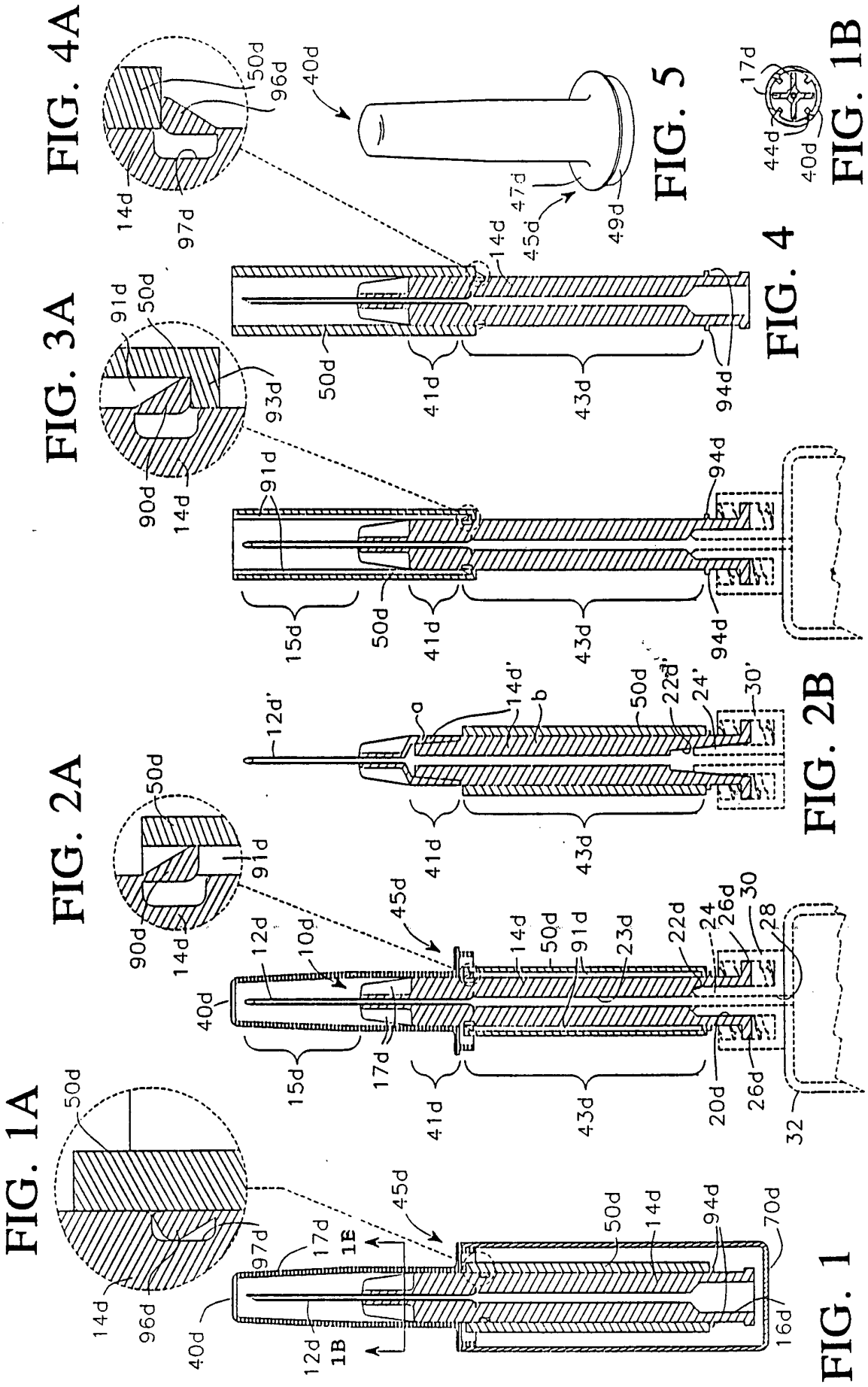
FIG. 1A
FIG. 2A
FIG. 3A
FIG. 4A
FIG. 1
FIG. 2
FIG. 3
FIG. 2B
FIG. 4
FIG. 5
FIG. 1B
50d
96d
14d
97d
40d
91d
90d
93d
12d
10d
45d
17d
1E
1B
15d
41d
43d
94d
70d
16d
23d
22d
24
26d
30
28
20d
32
12d'
14d'
a
b
22d'
24'
30'
47d
49d
44d

FIG. 6A

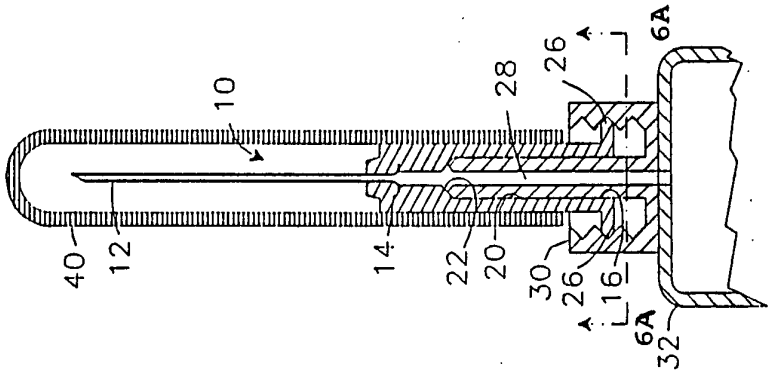

FIG. 6
PRIOR ART

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/02137

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61M 5/00
US CL :604/110
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/110, 187, 192, 198, 263

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,098,403, (SAMPSON), 24 March 1992. See entire document.	1-5
A	US, A, 4,813,940, (PARRY), 21 March 1989. See entire document.	1-5
A	US, A, 5,061,251, (JUHASZ), 29 October 1991. See entire document.	1-5
A	US, A, 4,693,708, (WANDERER ET AL.), 15 September 1987. See entire document.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search	Date of mailing of the international search report
17 MAY 1994	JUN 27 1994
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer for JOHN YASKO, JR.
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