9605228-T 2103

REPLACED SHEETS SG
☑ Description : paged ..1.. to paged ..22..
☑ Claim(s) : paged ..23.. to paged ..34..
☑ Drawing(s) : paged ..1/4.. to paged ..4/4..
☑ Abstract : paged ..35.. to paged ..-..
DATE OF RECEIPT .....

1

HYPODERMIC SYRINGE WITH NEEDLE RETRACTION FEATURE

This invention relates to a hypodermic syringe, and more particularly, to a disposable hypodermic syringe having a needle which may be retracted into the cylindrical cavity of the barrel following use.

A typical hypodermic syringe includes a transparent cylindrical barrel, generally open at a proximal end, a plunger assembly movable within the barrel to dispense medication, and a needle assembly removably attached to the barrel at a distal end by means of a locking mechanism, such as Luer lock. During usage, medication is sealed within open side of the barrel by means of a rubber piston slipped over the distal end of the plunger. At the distal end of the syringe, sealing is accomplished through a sealant, such as an epoxy resin, extending between the outer surface of the needle and the lock hub carrying the needle. This sealant, and the locking mechanism fastening the needle assembly to the barrel, are also used to transmit the force, which may be as high as several pounds, required to insert the needle into the patient's body and to remove the needle after the injection process is complete.

The applications of hypodermic syringes within a health care facility require the availability of syringes varying particularly in needle length and diameter, and in the dosage capacity of the barrel. To satisfy this need, needles and the remaining portions of syringes are made commercially available both as assembled units, and as separate units allowing the attachment of a selected one of the various needle assemblies to a selected one of various barrels. The Luer lock fittings used to fasten the needle to the barrel form a basis for common, interchangeable parts.

It is thus desirable that any improved design for hypodermic syringes should include the capability of switching needles among the syringes. It is even more desirable that any improved design for hypodermic syringes

This Sheet Has Been Replaced

should be capable of using standard needle assemblies, and that the new needle assemblies should be usable in standard syringe barrels.

Modern medical practice dictates that, in order to eliminate a possible source of contagious disease, hypodermic syringes are used only once. There is a growing concern, even when syringes are discarded immediately after use, that health care workers may be accidently stuck by a hypodermic needle which has been used in the treatment of a patient having a serious communicable disease, such as AIDS or hepatitis. Used hypodermic needles have become an especially dangerous form of waste material, posing a danger to anyone handling trash from a health care facility and to anyone who might come into contact with such material after it has been dumped, and requiring special puncture resistant containers for disposal.

Another problem commonly associated with discarded hypodermic syringes is their potential use by drug abusers, who sometimes search waste material from health facilities for such devices. This practice obviously carries a significant risk of infection to these drug users and to others they may subsequently contact.

Conventional hypodermic syringes included an inward extending ring near the proximal opening of the barrel, which forms a stop, preventing the inadvertent removal of the plunger from the barrel. However, this ring is generally not rigid enough to prevent the deliberate, surreptitious removal of the plunger, as by a drug abuser.

One prior art solution to the aforementioned problems has been to enclose the needle in a sheath manually slipped over the needle end before and after use of the syringe. However, this technique still exposes health workers to the risk of being stuck with an infected needle as the sheath is slipped on, particularly when the needle is not properly aligned with the sheath opening. Furthermore, this technique does nothing to render the syringe useless to a drug abuser.

This Sheet Has Been Replaced



JUL 21 '95 03:15PM SHERWOOD LAW 314 241 5855 P.8

This Sheet Has Been Replaced

Another prior art solution to the aforementioned problems is breaking the needle from the syringe once it is used. While this procedure is followed in a number of health care facilities, there are still several disadvantages to this procedure. First, the broken needles are not necessarily enclosed in a way permitting their subsequent safe handling, and second, the additional handling of used needles by health care workers in the process of breaking the needles may increase the risk of their being accidently stuck by an infected needle.

One attractive solution to the aforementioned problems is in providing a syringe/needle assembly in which the needle may be retracted into the barrel of the syringe after use, so that the needle is held in an envelope formed by the barrel during disposal. The patent literature includes descriptions of devices of a first general type, in which a needle is fastened to a needle carrier which travels axially within the barrel. In its distal position, the carrier holds the needle ready for use at the distal end of the barrel. After the plunger assembly is moved to the distal end of the barrel, after dispensing the desired medication, the plunger assembly engages and locks onto the needle carrier. When the plunger assembly is subsequently withdrawn and returned to the proximal end of its travel, the needle is carried with the plunger until it is completely enclosed within the barrel. At this point, the syringe ready for proper and safe disposal. Examples of syringes of this type are found in U.S. Patent 4,710,170, issued to Haber et al on December 1, 1987; in U.S. Patent 4,790,822, issued to Haining on December 13, 1988; and in U.S. Patent 4,883,471, issued to Braginetz et al on November 28, 1989.

In the prior art devices, the needle is fastened to the needle carrier by conventional means. For example, needle may be fastened to a Luer lock hub, which, in turn, is screwed onto a threaded hole forming internal surfaces in the needle carrier. Thus, syringes of this kind have

the advantage of being capable of using standard needle assemblies of the types widely available for syringes not incorporating the safety feature of needle retraction. If the syringe is provided with its needle carrier at the distal position, an interchangeable needle may be screwed into the syringe from the distal end, in the conventional manner. However, the barrels of syringes of this type, of necessity, have relatively large openings at their distal ends, to accommodate the motion of the needle, together with a portion of the needle carrier as it is retracted into the barrel. This large opening, in turn, significantly increases the complexity and cost of the device by requiring fluid tight sealing around the outside of the needle carrier, so that medicine can be dispensed through the needle without leakage out of the distal end of the syringe.

Furthermore, the needle carrier of the prior art devices occupies a significant portion of the axial length of the barrel. The conservation of distance along this length is especially important in a syringe having a retractable needle because the space is needed for storage of the needle after use. Conventional syringes are built to particular sizes for convenient handling and use, as well as for various barrel capacities for medication. For example, the barrels of typical syringes having either three cubic centimeter and five cubic centimeter capacities are about 2.5 inches in length, with the difference in capacity being accomplished by varying the diameter. A typical long needle extends 1.5 inches from the end of the Luer hub to which it is attached. Including this hub, the length of the needle assembly is about 2.125 inches. Thus, the use of a needle carrier of the prior art requires lengthening the barrel beyond the length necessary for handling and capacity, thereby decreasing the ease and familiarity with which the syringe is handled and further increasing its costs of manufacture and distribution.

This Sheet Has Been Replaced



This Sheet Has Been Replaced



The device of U.S. Patent 4,883,471 to Braginetz et al mounts the needle carrier in a second piston. After the medication is dispensed, vent ports are opened by rotating a cap at the distal end of the syringe, so that the atmosphere is allowed to enter the syringe at the distal end of this second piston. The retraction of the piston, with the needle, is then accomplished by the differential pressure established as the plunger is withdrawn. However, rotating the cap in this way presents the health care worker with the inconvenience of an extra step in the process.

The patent literature also describes devices of a second general type, in which the needle assembly is loaded into the syringe barrel from inside the barrel, to stick outward through a relatively small opening in the distal end of the barrel. After the injection of medicine by means of the plunger assembly, the needle assembly is attached to the distal end of the plunger assembly to be retracted into the syringe barrel as the plunger assembly is pulled back toward the proximal end of the barrel.

While syringes of this type address the concerns expressed above relative to the use of a separate needle carrier, they lack the important ability to use conventional needle assemblies, which are adapted to be screwed into place using Luer couplings from outside the distal end of the barrel. In addition, if interchangeable needles are to be used in any way on the syringes, they must be attached by relatively difficult or complex means within the barrels. Further, by changing a needle through the barrel, the sterility of the barrel can be violated.

Some devices of this second general type, in which the needle is loaded from inside the barrel, include couplings between the needle assemblies and the distal ends of the barrels, which are connected and disconnected by the rotation of the needle assembly within the barrel, being described, for example, in U.S. Patent 4,507,117, issued to Vining et al on March 26, 1985; in U.S. Patent 4,675,005, issued to DeLuccia on June 23, 1987; in U.S. Patent

4,747,830, issued to Gloyer et al on May 31, 1988; in U.S. Patent 4,919,652, issued to Alter et al on April 24, 1990; and in U.S. Patent 4,986,813, issued to Blake III et al on January 22, 1991. While DeLuccia, Alter, and Blake III teach the use of threaded screw connections, Vining and Gloyer uses quick release, quarter turn types of connection. Vining also describes means for providing the syringe, before use, with the needle retracted for safe handling. A disadvantage of these syringes is the additional requirement that the plunger must be twisted after an injection is given, before disposal of the syringe with the needle assembly in a retracted position. This twisting is needed to engage the needle assembly to the plunger assembly, and to disengage the needle assembly from the distal end of the barrel. However, this requirement places a burden on health care workers in an emergency situation, and can be expected to result in a failure to properly retract needles in some units before disposal.

Other devices of this in which the needle is loaded through the barrel interior include means for engaging the proximal end of the needle assembly with a mechanism extending from the distal end of the plunger assembly as the plunger mechanism reaches the distal end of its travel in dispensing medicine through the needle. Such devices are described, for example, in one of the embodiments of U.S. Patent 4,675,005 to DeLuccia; in one of the embodiments of U.S. Patent 4,692,156 to Haller; and in U.S. Patent 4,804,370, issued to Haber et al on February 14, 1989. In this Haber device, the needle extends outward through a small hole at the distal tip of the syringe barrel. The proximal end of the needle is provided with a flange, and the plunger assembly is provided with a needle capturing receptacle which engages this flange as the plunger assembly is moved to the distal end of the barrel, so that the needle is subsequently retracted into the barrel as the plunger assembly is withdrawn.

This Sheet Has Been Replaced



While such devices are operable without requiring the additional step of twisting the plunger after medicine is dispensed, they are still inconvenient to use, when compared to conventional syringes, because they do not accept conventional needle assemblies, and because, if it is necessary to install any type of needle assembly, the installation procedure is relatively complex and would violate the integrity of the sterility.

An important consideration in the design of a hypodermic syringe is the ability of the device to transmit axial forces to the needle from the barrel and plunger. Forces as high as several pounds may be required, both to insert the needle into the patient, and to withdraw the needle from the patient during the process of giving an injection. If the needle is to be retracted into the barrel of the syringe, means must be provided to prevent this retraction during the insertion of the needle into the patient, due to the necessary application of force to the needle as it is inserted.

In the devices having needle assemblies connected to the barrels with screw threads or quarter turn fasteners, to be disconnected by rotation of the plunger after the medication is dispensed, these fasteners prevent premature retraction of the needle. These devices are shown, for example, in U.S. Patents 4,507,117, 4,675,005, 4,747,830, 4,919,652, and 4,986,813. While this method of holding the needle in place during injection is quite effective, the disadvantages of requiring the performance of the additional manual rotation step and non-standard components remains.

In those devices having means for engaging the proximal end of the needle assembly with a mechanism extending from the distal end of the plunger assembly, the connection between the needle and the barrel must be strong enough to hold the needle in place as it is inserted into the patient. Further, the needle must subsequently be pulled directly out of this connection for retraction.

This Sheet Has Been Replaced



This Sheet Has Been Replaced

Both of these actions are accomplished by applying an axial force to the needle. In the devices of U.S. Patent 4,692,156 to Haller, the needle is mounted in an aperture within a deformable tapered mounting post, which deforms to slide through a passage in the barrel during retraction. In other devices, as shown, for example in U.S. Patents 4,804,370 and 4,826,484 to Haber et al., the needle is retained by a tight fit within a distal hole of the barrel. This means that, for reliable operation, the force which must be applied for needle retraction, to overcome the attachment between the needle and the barrel, must be greater than the highest force expected during the insertion of the needle into the patient, together with a safety factor applied to cover variations in the process of manufacturing the syringe. If the needle is to be retracted during withdrawal from the patient, this force must be even higher. The requirement to apply such a large force places a significant burden on health care personnel and creates a potential danger to the patient.

The device described in U.S. Patent 4,710,170 to Haber et al includes a needle carrier which is held in place within the barrel by means of a quick release fastener. After the dispensing of medication is completed, the plunger is manually rotated to release the carrier from engagement with the barrel. Thus, a requirement to perform an additional step is placed on health care personnel.

The device described in U.S. Patent 4,790,822 to Haining includes a needle carrier which is held in place at the distal end of the barrel by opposing shoulders extending inward from the interior of the barrel. As the plunger is moved to the distal end of the barrel, a piston at the distal end of the plunger forces these shoulders apart, releasing the carrier to return with the plunger.

The patent literature also describes apparatus for causing the needle to be rotated transversely, about its attachment to the plunger as it is retracted into the barrel, to point toward a side of the barrel. This is done to

This Sheet Has Been Replaced

prevent accidental or deliberate extension of the needle through the hole in the distal end of the barrel, by means of pushing the plunger inward. In other words, this feature provides further safety for health care and trash disposal workers, and goes another step toward preventing the subsequent use of the syringe by drug abusers. For example, U.S. Patent 4,804,370, issued to Haber et al on February 14, 1989, describes needle capturing receptacle with legs, for capturing a flange at the proximal end of the needle. Two of the legs are shorter than the others, so the needle is rotated transversely as it is retracted. As described in U.S. Patent 4,986,813 to Blake III et al, a syringe includes a fitting fastening the needle assembly to the distal end of the plunger for retraction with a slot, extending inward from one side of the fitting, which is allowed to expand as the needle is fully retracted, throwing the needle out of alignment with the longitudinal axis of the plunger.

Blake III also describes the use of stopping surfaces extending into the barrel near its proximal end, angled to prevent removal of the plunger from the barrel, while allowing its assembly into the barrel as the syringe is fabricated. Such surfaces make it particularly difficult for a drug user to take the syringe apart to make it again operable or to retrieve the needle.

Thus, while the feature of needle retraction can be accomplished in a number of ways, the methods proposed in the prior art for providing this feature all have various disadvantages. What is needed is apparatus for providing needle retraction without substantially increasing the size or length of the syringe, as required when a separate needle carrier is employed, and without requiring the performance of an additional step, such as the rotation of the plunger, by health care personnel. Since health care facilities must carry a relatively large inventory of different sizes and types of syringes and needles, it is desirable that an improved syringe should accept the removal and

This Sheet Has Been Replaced

attachment of needles in the standard way, from outside the distal end of the barrel. It is further desirable that the needle be releasibly held in place by positive means, such as a latch or movable abutting surface, rather than by reliance on a tight fit. Also, since conventional hypodermic syringes are low cost items used in large quantities by health care facilities, it is particularly desirable that the feature of needle retraction should be provided by a mechanism which is inherently simple and low in manufacturing cost. In particular, any improved syringe ideally will use existing syringe parts or slight modified parts so that existing mold tooling can be used.

In accordance with one aspect of the invention, there is provided a hypodermic syringe including a container for ejecting fluid having an internal cavity between a fluid ejecting end thereof and a proximal end thereof. The container also has a piston assembly having a seal end movable from the proximal end to the fluid ejecting end to eject fluid and retractable towards the proximal end. The syringe further includes a needle attachment assembly affixed to the fluid ejecting end of the container, the needle attachment assembly having a hollow first column with an opening extending therethrough in fluid communication with the cavity. The column is tapered inward at a distal end thereof and has a plurality of slits from the distal end thereof towards the container separating a plurality of segments at the distal end. In addition, the syringe includes a needle subassembly, including a needle with hole extending axially therethrough, and a needle flange affixed remote from one end of the needle. A second hollow column extends from the flange towards the one end and is sized to fit within the first column opening such that the end of the segments are juxtaposed to one surface of the flange. The needle subassembly further includes means juxtaposed to the other side of the flange for holding the needle subassembly on the attachment assembly column. Finally, the syringe includes needle extractor means, including a third

hollow column affixed to the seal end of the piston assembly. The third column is sized such that the exterior thereof enters the first column and separates the segments so that the ends thereof are spaced from the one surface of the flange. The third column further is sized such that the interior thereof grabs the second column and the needle assembly, including the flange is retracted through the first column upon retraction of the piston assembly.

Preferred embodiments of the subject invention are hereafter described with specific reference being made to the following Figures, in which:

Figure 1 is an exploded isometric view of a hypodermic syringe built in accordance with the present invention;

Figure 2 is a longitudinal elevation of the syringe of Figure 1, being shown as ready to dispense medication;

Figure 3 is a fractional longitudinal cross-sectional elevation of the needle attachment portion of the syringe of Figure 1;

Figure 4 is a cross-sectional elevation similar to Figure 3, shown with the needle engaged for retraction into a barrel of the syringe;

Figure 5 is an elevational view of the proximal end of a needle of the syringe of Figure 1;

Figure 6 is a cross-sectional elevation similar to Figure 2, shown with the needle fully retracted after dispensing medication.

Figure 7 is a fractional longitudinal cross-sectional elevation of a proximal portion of a barrel of a conventional hypodermic syringe, showing a plunger of the syringe pulled outward against a ring used to prevent inadvertent removal of the plunger from the barrel;

Figure 8 is a cross-sectional elevation similar to Figure 7, showing an improved form of the ring of Figure 7;

This Sheet Has Been Replaced

Figure 9 is a fractional longitudinal elevation of an alternate structure for gripping a needle for retraction, showing a proximal portion of a needle within a Luer coupling, together with a distal tip of a needle extractor;

Figure 10 is a side view of a syringe useful with the invention which prevents forward movement of the plunger after the needle is withdrawn;

Figure 11 is a side view showing the withdrawn plunger of Figure 10; and

Figure 12 shows another version of the invention.

Referring first to Figure 1, an improved hypodermic syringe 10 of the subject invention includes a plunger assembly 12 slidable within a barrel 14 to dispense medication by means of a hole extending through a needle 16 within a needle assembly 17. This needle assembly 17 includes needle 16 and a Luer hub 18 by which the needle is removably attached to threaded hole 20 at the distal end of barrel 14. Luer hub 18 includes longitudinally extending external flutes 21, which aid in gripping needle assembly 17 for rotation as required to engage or disengage the threaded Luer connection. Needle assembly 17 may also be provided with a sheath (not shown), extending around the needle 16 and attachable to hub 18 to protect health care personnel from contact the sharp distal point 21a of the needle. Flutes 21 may also engage internal grooves extending longitudinally within the sheath to permit the rotation of the needle assembly without removing the sheath. Plunger assembly 12 includes an elongated slide 22 having gripping means 24 at its proximal end, an inward extending needle extractor 26, and an elastomeric piston 28 which extends over a disk shaped distal end portion 30 of slide 22, and around a flange 31 of extractor 26.

Figure 2 shows syringe 10 as ready to dispense medication 34 through needle 16. This medication 34 may have been drawn through needle 16 from a vial, not shown, as plunger assembly 12 was moved to the position shown near the proximal end 36 of barrel 14. Alternatively, the medi-

This Sheet Has Been Replaced



cation 34 may have been supplied to a health care facility as part of the syringe package. Elastomeric piston 28 forms a seal around the internal cylindrical surface 37 of barrel 14, so that pressure may be built up within the cylinder interior of barrel 14 by sliding plunger assembly 12 toward distal end 38, as required to dispense the medication 34 through needle 16, without substantial leakage of the medication 34 past piston 28.

A more detailed view of the relationships among slide 22, elastomeric piston 28, and needle extractor 26 is also provided in the cross-sectional view of Figure 4. Elastomeric piston 28 is essentially a hollow cylindrical structure having a large hole in one end, through which distal end portion 30 of slide 12 is inserted, and a smaller hole in the opposite end, through which flange 31 of needle extractor 26 is inserted. The elastic properties of piston 28 produce a clamping action to hold flange 31 against end portion 30. Alternatively, needle extractor 26 may be secured to end portion 30 by a suitable adhesive or may be molded as a part of the slide 22 and end portion 30 assembly. Since the proximal end surface 40 of flange 31 is slanted relative to the axis of hub portion 42 of extractor 26, hub portion 42 is slanted, at an acute angle to the longitudinal axis of barrel 14, when flange 31 and end portion 30 are held together in this way.

The manner by which needle 16 is attached to barrel 14 is shown particularly in Figure 3. A metal, or other hard material, collar 42a, including a hub 43 and a flange 44, is fastened to a proximal end of needle 16, preferably by a swaging procedure or an adhesive, to form a needle subassembly. Needle assembly 17 is formed when needle 16 is subsequently inserted through a needle receiving hole 45a in Luer hub 18, being pushed through this hole 45a until needle 16 extends through hub 18, with a distal side of flange 44 against an adjacent abutment surface 45 of the hub.

This Sheet Has Been Replaced



A sealant is preferably added to the annular space between needle 16 and the internal surface of needle receiving hole 45a. The need for this form of sealing exists because, while it is neither necessary nor desirable to produce a tight fit between needle 16 and hub 18, it is necessary to establish a partial vacuum within syringe 10 as plunger assembly 12 is pulled outward to fill the syringe with medication 34. Further, necessary to establish hydraulic pressure within syringe 10 as plunger 12 is subsequently pushed inward to inject the medication 34 into a patient. Thus, there is a need to prevent the inward leakage of air, or the outward leakage of medication, through the space between needle 16 and hub 18. However, it is necessary that the sealing agent does not permanently bond to the needle.

Several different types of sealants may be used to seal needle 16 and hole 45a. For example, a heavy grease, such as a petroleum jelly may be used for the sealant, as can a number of room temperature vulcanizing (RTV) silicone adhesives, or yieldable medical adhesives, such as the product available as Dymax Light Weld #190-M.

Flange 44 includes an annular shoulder preventing outward movement of needle 16 by contact with an adjacent internal abutment surface 45 of Luer hub 18. Luer hub 18 includes, at its proximal end, a conventional thread engaging flange 46, shaped as a disk with truncated sides, which engages an internal thread 48 within threaded hole 20 of barrel 14. In this way, needle assembly 17 is removably fastened to barrel 14. A number of different needle assemblies can be provided for interchangeable attachment in this manner, with such needle assemblies varying, for example, in the length and diameter of the needle.

Thus, while the needle retraction feature is provided by means which will be explained, the attachment of the needle to the syringe barrel is achieved by conventional means, through the use of a Luer connection allowing attachment from outside the distal end of the syringe bar-

This Sheet Has Been Replaced



rel. In fact, conventional needle assemblies, without provision for needle retraction, can be attached through this conventional connection to syringe barrel 14 built in accordance with the present invention, and needle assemblies 17 built in accordance with this invention can be attached to conventional syringe barrels. If parts made in accordance with this invention are assembled with conventional parts in either of these ways, the needle retraction feature will not be operative, but the syringes can still be used and disposed in conventional ways. This is a particular advantage to a health care facility, with an inventory of conventional needles and syringes, in the process of converting to the use of syringes having the needle retraction feature.

This needle attachment arrangement of the subject invention offers particular advantages, of ease of use and interchangeability with conventional parts, over the arrangements shown, for example, in U.S. Patent 4,826,484 to Haber et al, in which a needle must be pressed into a tight fitting hole from inside the barrel cavity. This needle attachment arrangement of the subject invention offers advantages over the arrangements of, for example, U.S. Patents 4,675,005 to DeLuccia, 4,747,830 to Gloyer et al, 4,919,652 to Alter et al, and 4,986,813 to Blake III et al, which require that the needle assembly must be screwed into a threaded hole, or into a quick release fastener, within the distal end of the barrel, from inside the barrel cavity.

During the process of handling syringe 10 before an injection is given and during the process of dispensing medication 34 by means of injection, needle 16 is held by the distal end of barrel 14, since flange 44 cannot pass through the smaller diameter distal opening of channel 50 provided at the distal end of coupling 51 of barrel 14. Thus, flange 44 provides an annular shoulder on each side,

This Sheet Has Been Replaced



serving in the transmission of any thrust forces in either direction, which may occur at the needle during the injection process.

Referring again to Figure 2, an injection is given to the patient in the conventional way, by moving plunger assembly 12 through the cylindrical interior of barrel 14. As plunger assembly 12 nears the distal end of barrel 14, distal tip 52 of the hub 42 portion of needle extractor 26 contacts funnel shaped internal surface 54 of barrel 14. As noted above, needle extractor 26 is maintained out of alignment with the axis of channel 50 by means of the engagement between slider end portion 30 and extractor flange 31. However, the angle of funnel shaped surface 54 is sufficient to ensure that tip 52 is guided into alignment with channel 50 with continued motion of plunger assembly 12 into barrel 14, when tip 52 in contact with surface 54.

Referring again to Figure 3, the distal end of coupling 51 is slanted slightly inward and has a series of inward extending slots 56 at a narrowed portion 60 of channel 50, separating the distal end of coupling 51 into plural segments 58. When extractor tip 52 is brought into engagement with needle hub 43, slots 56 are sized to receive hub 42 of extractor 26 and permit the expansion of the distal end of coupling 51 by the flexure of the segments 58 formed between slots 56. The expansion of segments 58 only occurs as extractor tip 52 is brought into the narrowed portion 60 at the extreme distal end of channel 50.

Thus, thrust forces required for the insertion of a portion of needle 16 into the patient are provided through the abutment of needle flange 44 and the ends 61 of segments 58 prior to the separation of segments 58. This structure provides a particular advantage over the prior art, for example, in U.S. Patent 4,826,484 to Haber et al, which requires that the thrust forces to be provided through a tight fit between the needle and a distal hole in the barrel, which fit is much more prone to failure than

This Sheet Has Been Replaced



the abutting structure of ends 61 against flange 44. With the structure of the present invention, sufficient force to deflect segments 58 outward is applied at the very end of the inward movement of plunger assembly 12, long after the needle is fully inserted in the patient and at the time the medicine is dispensed.

Further, the disengagement of the abutting structure of ends 61 against flange 44 is accomplished by deflecting segments 58 arranged to extend as cantilever springs. This structure has the significant advantage of requiring very low deflection forces compared to the those required by the structure of the prior art. For example, in U.S. Patent 4,790,822 to Haining, the abutting surfaces are provided as parts of shoulders extending inward from the wall of the syringe barrel, so that this wall must be deflected outward around all sides of the shoulders before the needle can be retracted with a needle carrier.

As shown in Figure 4, when the motion of plunger assembly 12 toward the distal end of barrel 14 has been completed, distal tip 52 of needle extractor 26 has moved through channel 50 to engage needle hub 43 for the retraction of needle 16. At this position, a wedge shaped gap 63 exists between proximal surface 40 of flange 31 and distal end 36 of slide 22 resulting from needle extractor 26 being guided into channel 50. Tip 52 has a tubular shape, which tightly holds needle hub 43. The expansion of coupling tip 58 with the insertion of extractor tip 52 enlarges the narrowed opening 60 of channel 50 to clear the diameter of flange 44, so that needle 16 may be retracted into barrel 14 with the subsequent pulling of plunger assembly 12 towards proximal end 36 of the barrel using gripping means 24.

As shown in Figures 3 and 4, as needle 16 is about to be retracted from the patient, it is held by flange 44 abutting against abutment surface 45 of Luer hub 18. Thus, as cylinder 14 is pulled rearward, needle 16 moves with cylinder 14 due to the abutment of flange 44 against Luer

This Sheet Has Been Replaced



hub 18. With this structure, the needle retraction feature is included in syringe 10 without significantly, if at all, increasing the length of the parts subsequently moved into the interior of barrel 14, as seen in Figure 6. Thus, it is not necessary to increase the length of barrel 14, beyond the normal length of barrel 14, which already is sufficient to hold needle 16 itself. A syringe with the size and length of a conventional syringe can be thus provided with the needle retraction feature using most existing parts. In this regard, a particular advantage is gained relative to the use of a separate needle carrier, slidably mounted to move in a syringe barrel cylinder, as shown, for example in U.S. Patents 4,710,170 to Haber et al, 4,790,822 to Haining, and 4,883,471 to Braginetz et al. Further, the needle holding structure of the present invention makes it unnecessary to seal around the large diameter of a separate needle carrier.

It is desirable to remove needle 16 from the patient by pulling plunger assembly 12 while pushing cylinder assembly 14 in order to maintain the distal end of cylinder assembly against the skin of the patient as needle 16 is drawn into cylinder 14. Referring to Figure 5, needle retraction using plunger assembly 12 may be accomplished by providing needle hub 43 with one or more ridges 64 to increase the thrust force which can be applied to extract needle 16 without breaking the bond between retraction assembly 26 and needle 16. In Figure 5, needle 16 is shown extending through an opening 88 in flange 44 and hub 43 permitting fluid communication through the opening 90 in needle 16. Alternatively, flange 44 and hub 43 may be integrally formed as a part of needle 16. Further, the internal surface of extractor hub 42 may also be provided with ridges, or reliance can be made on the ridges 64 of the hub 43 pressing into the relatively soft interior of plastic extractor hub 42.

This Sheet Has Been Replaced



The technique of using plunger assembly 12 to withdraw needle 16 has the advantage of providing an additional measure of safety, in that the needle is immediately retracted directly into a safe position. On the other hand, the technique of withdrawing the needle by pulling on cylinder 14 may be easier to perform, since it is fully consistent with conventional syringes and the medical personnel do not have to change the way in which syringe 10 is traditionally used. In the latter traditional case, needle 16 is drawn into barrel 14 after it is fully removed from the patient, as explained above.

The method of attachment between extractor 26 and needle 16 offers an advantage in simplicity of use over the methods of, for example, U.S. Patents 4,675,005 to DeLuccia, 4,747,830 to Gloyer et al, 4,919,652 to Alter et al, and 4,986,813 to Blake III et al, which require the rotation of the plunger after medication is dispensed, to disengage the needle from the syringe barrel and to engage it to the plunger.

As shown in Figure 6, after plunger assembly 12 has been completed withdrawn to its initial position as seen in Figure 2, needle 16 is completely enclosed within barrel 14. As the tip 21a of needle 16 clears the proximal end of opening 50, the clamping action of elastomeric piston 28 on flange 31 of extractor 26 tends to bring proximal end surface 40 of flange 31 into contact with distal end flange 30 of slider 22, thereby rotating needle 16 transversely, to point toward a side of barrel 14. If plunger assembly 12 is subsequently pushed inward, into barrel 14, tip 21a of needle 16 will dig into funnel shaped surface 54 of barrel 14, preventing its later exposure or reuse. Needle 16 is thus totally enclosed in a manner permitting its safe handling and disposal.

A further refinement in preventing the surreptitious disassembly of the syringe by a drug abuser after disposal may be employed, as best understood by examining the differences between Figures 7 and 8. Figure 7 shows a

This Sheet Has Been Replaced



cross-sectional view of the proximal portion 66 of a conventional syringe, with a conventional plunger 68 pulled outward, so that a flange 70 of plunger 68 rests against an inwardly extending ring 72. While this arrangement is adequate to prevent inadvertent removal of plunger 68 from the syringe, it is not difficult for a drug abuser to remove the plunger. In the structure shown in Figure 8, on the other hand, an improved ring 74 may alternately be provided, with a slanted surface 76 facilitating the insertion of plunger 68, as required in the assembly of the syringe, while a relatively flat annular surface 78 prevents removal of the plunger after disposal of the syringe. In this way, it is made particularly difficult for a drug abuser to remove the plunger to gain access to a needle held within cylindrical surface 37. Thus, the surreptitious disassembly and reassembly of the syringe may be prevented.

An alternative structure for attaching needle 16 to extractor 26 is shown in Figure 9, with like numerals being used to designate parts with like functions. In the Figure 9 structure, a needle subassembly 79 is formed when a collar 42a, including a needle hub 80 and a needle flange 44, is attached to a needle 16, preferably using a swaging process, between a distal needle portion 82 and a relatively short proximal needle portion 84. Needle hub 80 is directed toward distal needle portion 82. Luer hub 18 includes an enlarged cavity 84, into which needle hub 82 extends when distal needle portion 82 is fully inserted through needle receiving hole 45a. An abutting surface 45 of Luer hub 18 transmits thrust forces to a distal side of needle flange 44 when needle 16 is withdrawn from a patient. Proximal needle portion 84 may include a series of ridges 64 to increase the force which can be applied by extractor 26 to extract needle 16. Hole 86 within tip portion 52 mates with proximal needle portion 84.

As noted above with respect to Figure 6, the needle may be rotated transversely to prevent it being exposed or reused after the initial usage. Referring now to Figures

This Sheet Has Been Replaced



10 and 11, a syringe 100 having a barrel 102 and a plunger 104 from which a needle 105 is held, is shown which includes a spring clip 106 to also prevent the needle from being exposed or reused after initial usage. Clip 106, which has a spring bias radially outward, is held longitudinally between a plate 108 and the proximal end of the piston head 110 and radially by the interior 112 of barrel 102. In the compressed position, seen in Figure 10, clip 106 is generally in the shape of a compressed U and has a pair of lips 114 biased against the inner surface 112 of barrel 102.

As seen in Figure 11, after the handle 116 of plunger 104 is fully removed, the lips 114 of clip 106 radially expand to cover the end 118 of barrel 102. In this position, clip 106 prevents the re-depression of handle 116 and the re-exposure of needle 105. An inward extending ring 120 may be included to prevent outward movement of plunger 104, as described with respect to Figure 8. Clip 106, because of the spring construction thereof, is easily compressed to slide around ring 120 during the withdrawal of plunger 104. Thus, plunger is held firmly in the position shown in Figure 11, thereby preventing reuse of syringe 100 or re-exposure of needle 105.

Referring now to Figure 12, another version of a syringe 122 the subject invention is shown, in which a plunger 124 is a single molded piece of plastic sized to form a seal with the interior surface of a barrel 124. In addition, an extractor 126 is formed at the distal end of plunger 124 to interface with a needle assembly 128 similar to needle assembly 17 shown in Figure 1.

In using syringe 122, it may be necessary to aspirate a liquid into syringe prior to dispensing that same liquid into the patient. In aspirating the liquid, it is not desirable to grip the needle assembly 128 and withdraw it into barrel 124. Thus, when aspirating the fluid, plunger 122 should not be depressed entirely, such that extractor 126 grips the hub 130 of needle assembly 128. In

This Sheet Has Been Replaced



order to forewarn the user, one or more dimples 132 may be formed on extractor 126 at a position such that when extractor 126 enters the luer connector end of barrel 124, dimples present an resistance to further depression at a position just prior to extractor 126 engaging hub 120. The resistance would be a signal to the user of syringe 122 to cease applying force to plunger 124 and begin aspirating the liquid. After dispensing the liquid, the user of syringe 122 may depress plunger 124 with more force after noticing the resistance due to dimples 132 in order to overcome the resistance and cause extractor 126 to engage needle assembly 128, as described above.

An alternative to dimples 132 would be an inward facing ring 134 positioned on the interior surface of barrel 124. While both dimples 134 and ring 136 are shown in Figure 12, in practice, only one of these elements would be used.

While the invention has been described in its preferred forms or embodiments with some degree of particularity, it is to be understood that this description has been given only by way of example and that numerous changes in the details of construction, fabrication and use, including the combination and arrangement of parts, may be made without departing from the spirit and scope of the invention.

This Sheet Has Been Replaced



This Sheet Has Been Replaced

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A syringe (10) having a barrel (14) including a luer tip (50) and a needle assembly (17) detachably mounted on said luer tip (51), characterized by said needle assembly (17) including a hub (43) receiving said luer tip (51) and a needle (16) slidably positioned within said hub (43) and a flange (44) mounted thereon, said flange (44) being captured between said hub (43) and said luer tip (51) to immobilize said needle assembly (17).

2. The syringe (10) of claim 1, characterized in that said luer tip (51) further includes a coupling opening (50) extending therethrough and the distal end (61) of said luer tip (51) being expandable from a constricted position, wherein at least a distal portion of the coupling opening (50) is smaller than said needle flange (44), to an expanded position, wherein the coupling opening (50) is larger than said needle flange (44).

3. The syringe of one of claims 1 or 2, further characterized by an extractor (26) moveable within said barrel (14), said extractor (26) including at a distal end thereof a needle coupling (42) to connect said needle assembly (17) to said extractor (26) and a release face (52) to expand said luer tip (51) of said barrel (14).

4. The syringe of claim 3, further characterized in that the expandable distal end portion (61) of said luer tip (51) being segmented.

5. The syringe of claim 2, further characterized by an extractor (26) moveable within said barrel (14), a distal tip of said extractor (26) having a release face (52) smaller in diameter than said coupling opening (50) and

* C L M S *

This Sheet Has Been Replaced

larger in diameter than said flange (44) and a needle coupling (42) at a distal end of said extractor (26) to connect said needle assembly (17) to said extractor (26).

6. The syringe of claim 5, further characterized in that said needle coupling (42) is disposed on said extractor (26) with respect to said release face (52) such that when said needle assembly (17) is coupled to said extractor (26), said needle flange (44) is sufficiently proximate to said release face (61) that said expandable distal tip will not engage said flange (44) as said needle assembly (17) is withdrawn through the coupling opening (50).

8. The syringe of claim 6, further characterized in that the expandable distal end portion (61) of said luer tip (51) is segmented.

9. A syringe and detachable needle assembly combination (10) having a barrel (14) including a luer tip (51) and an internally threaded locking skirt (20) around said luer tip (51), said needle assembly (17) including a hub (18) and a needle (16), said hub (18) including a distal end, an open proximal end receiving said luer tip (51) and locking ears (46) extending outwardly from said hub (18) to engage said internal threads (48) of said locking skirt (20) to detachably lock said hub (18) to said barrel (14), characterized by a coupling opening (50) extending to a radially expandable distal end (61) of said luer tip (51) and said needle (16) having a flange (43, 44) mounted thereon, said needle (16) being slidably positioned through the distal end of said hub (18) with said flange (43, 44) being captured between said hub (18) and said luer tip (51) to immobilize said needle (16) against axial movement.

10. The syringe and needle assembly combination (10) of Claim 9 further characterized by said expandable end (61) of said luer tip (51) having a constricted position wherein

* C L M S *

This Sheet Has Been Replaced

the diameter of the coupling opening (50) is smaller than the diameter of said flange (43, 44) and an expanded position wherein the diameter of the coupling opening (50) is larger than the diameter of said flange (43, 44), and by an extractor (26) moveable within said barrel (14), said extractor (26) including, at a distal end thereof, a needle coupling (42) to connect said needle (16) flange (43, 44) to said extractor (26) and a release face (52) to expand said luer tip (51) of said barrel (14) to said expanded position when said needle (16) flange (43, 44) is coupled to said extractor (26).

11. A needle assembly (17), for use with a medical device (10) having a luer end (50) for sealable, detachable connection to said needle assembly (17), having a hub (18) including a needle passage (45a) extending from a distal end thereof and a luer tip passage extending from a proximal end thereof, said hub (18) having a proximal abutment (45) within the luer tip passage (46) characterized by a needle (16, 44) including a flange (44), said needle (16, 44) being slidably positioned through the needle passage (45a) of said hub (18) with said flange (44) abutted against said proximal abutment (45) of said hub (18).

12. The needle assembly (17) of Claim 11 further characterized by said needle (16, 44) having a coupling (43) thereon for connection to an extractor (26) of said medical device (10) adapted to pull said needle (16, 44) from the needle passage (45a) of said hub (18).

13. The needle assembly (17) of Claim 11 further being characterized in that said luer tip passage of said hub (18) is configured to position said flange (44) between said abutment (45) of said hub (18) and the distal end of the luer end (50) of a medical device (10) to which said needle assembly (17) can be attached.

* C L M S *

This Sheet Has Been Replaced

14. The needle assembly (17) one of Claims 11, 12 or 13 further characterized in that said abutment (45) of said hub (18) is positioned in the luer tip passage of said hub (18) such that when said needle assembly (17) is connected to the luer tip passage of said medical device (10), said flange (44) is captured between said abutment (45) of said hub (18) and the distal end of the luer end (50) of said medical device (10).

15. The needle assembly (17) of one of Claims 11, 12 or 13 further characterized in that sealant is within at least a portion of the needle passage (45a) of said hub (18) about said needle (16).

16. A needle assembly (17) for use with a medical device (10) having a luer tip (51) and an internally threaded locking skirt (20) around the luer tip (51) for sealable, detachable locked connection of such needle assembly (17) to such medical device (10), said needle assembly (17) having a hub (18) including locking ears (46) on the outside of said hub (18) configured to engage the internal threads (48) of the locking skirt (20) of the medical device (10) to which said hub (18) may be connected, a needle passage (45a) axially extending from a distal end of said hub (18), a luer tip passage axially extending from a proximal end of said hub (18) configured to receive the luer tip (51) of such medical device (10), and a proximally facing abutment surface (45 at the distal end of the luer tip passage characterized by said needle assembly (17) including a flange (44) and a needle (16), said needle (16) being slidably positioned through the needle passage (45a) of said hub (18) with said flange (44) abutted against said abutment surface (45) of said hub (18).

* C L M S *

This Sheet Has Been Replaced

17. The needle assembly (17) of Claim 16 characterized in that said needle (16) has a coupling (43) thereon for connection to an extractor (26) of the medical device (10) adapted to pull said needle (16) from the needle passage (45a) of said hub (18).

18. The needle assembly (17) of Claim 16 characterized in that said luer tip passage of said hub (18) includes a female luer taper.

19. The needle assembly (17) one of Claims 16, 17 or 18 characterized in that said luer tip passage of said hub (18) is configured to position said flange (44) between said abutment (45) of said hub (18) and the distal end of the luer tip (51) of the medical device (10) to which said needle assembly (17) may be attached.

20. The needle assembly (17) one of Claims 16, 17 or 18 characterized in that said abutment surface (45) of said hub (18) is positioned in the luer tip passage of said hub (18) such that when said needle assembly (17) is connected to the luer tip (51) of the medical device (10), said flange (44) is captured between said abutment surface (45) of said hub (18) and the distal end (61) of the luer tip (51) of the medical device.

21. The needle assembly (17) one of Claim 16, 17 or 18 characterized by sealant within at least a portion of the needle passage of said hub (18) about said needle.

22. A syringe (10) having a barrel (14) with a hollow interior (37) and a male luer tip (51) at a distal end of said barrel (14), said luer tip including a coupling opening (50) extending therethrough characterized by a distal end (61) of said luer tip (51) being expandable from a constricted position wherein at least a distal portion of the

* C L M S *

This Sheet Has Been Replaced

coupling opening (50) is smaller than a desired size to an expanded position wherein the coupling opening (50) is larger than the desired size.

23. The syringe (10) of claim 22, characterized in that the expandable distal end (61) portion of said luer tip (51) being segmented.

24. The syringe (10) one of claims 22 or 23 characterized by an extractor (26) moveable within said barrel (14), a distal tip (52) of said extractor (26) having a release face (42) smaller in diameter than said coupling opening (50) in the expanded position of said luer tip (51) and larger in diameter than said coupling opening (50) in the constricted position of said luer tip (51).

25. A syringe (10) for use with a needle assembly (17) having a hub (18) and a needle (16, 43 and 44) slidably removable from said hub (18), a barrel (14) having a hollow interior (37), and a male luer tip (51) at a distal end of said barrel (14), said luer tip (51) including a coupling opening (50) extending therethrough, characterized by, a distal end of said luer tip (51) being expandable from a constricted position, wherein at least a distal portion of the coupling opening (50) is smaller than a portion of said needle (16, 43 and 44) attached to said barrel (14), to an expanded position, wherein the coupling opening (50) is larger than said needle (16, 43 and 44) attached to said barrel (14).

26. The syringe (10 of claim 25, further characterized by an extractor (26) moveable within said barrel (14), said extractor (26) including at a distal end (51) thereof a release face (42) to expand said luer tip (51) of said barrel (14).

* C L M S *

This Sheet Has Been Replaced

27. The syringe (10) one of claims 25 or 26, characterized in that the expandable distal end portion of said luer tip (51) is segmented.

28. The syringe (10) of claim 25, further characterized by an extractor (26) moveable within said barrel (14), a distal tip (52) of said extractor (26) having a release face (42) smaller in diameter than said coupling opening (50) and larger in diameter than any portion of said needle (16, 43 and 44) that is removable from said hub (14) of said needle assembly (17) mounted on said barrel (14), and said extractor (26) having a needle coupling (42) at a distal end (52) thereof to connect said needle (16, 43 and 44) to said extractor (26).

29. The syringe (10) of claim 28, characterized in that said needle coupling (42) is disposed on said extractor (26) with respect to said release face (42) such that when said needle (16, 43 and 44) is coupled to said extractor (26), a portion of said needle (16, 43 and 44) that is larger than the coupling opening (50), when said luer tip (51) is in the constricted position, is sufficiently proximate said release face (42) that said expandable distal luer tip (51) will not engage any removable portion of the needle (16, 43 and 44) as the needle (16, 43 and 44) is withdrawn through the coupling opening (50).

30. The syringe (10) of claim 29, characterized in that the expandable distal end portion of said luer tip (51) is segmented.

31. A hypodermic syringe (10) including a needle (16), a barrel (14) having a generally cylindrical cavity (37) extending inward from a proximal end thereof, a needle attachment coupling (51) at a distal end thereof for attaching said needle (16) to said barrel (14), and a plunger (12) mounted to slide within said cavity (37), including a

* C L M S *

This Sheet Has Been Replaced

slide (22) extending outward from said cavity (37), a piston (28) forming a sealing engagement with said cavity (37), characterized by said needle attachment coupling (20, 51) including an attachment portion (20), a coupling opening (50) extending from said cavity (37), and a releasable abutment (51); a needle hub (18) including a mating portion (46) attached to said attachment portion (20) of said needle attachment coupling (20, 51), a proximal abutment surface (45), and a needle receiving hole (45a) extending therethrough from said proximal abutment surface (45) to a distal end of said hub (18); a needle subassembly (16, 43, 44) including said needle (16) and a needle flange (44) mounted between a distal portion of said needle (16) and a proximal portion of said needle subassembly (16, 43, 44), said proximal portion of said needle subassembly (16, 43, 44) extending into said coupling opening (50), and said needle flange (43, 44) extending outward between said proximal abutment surface (45) of said needle hub (18) and said releasable abutment portion (51) of said needle attachment coupling (20, 51); and a needle extractor (26) extending from a distal end of said plunger (12), said needle extractor (26) including gripping means (42) for engaging said proximal portion of said needle subassembly (16, 43, 44) when said plunger (12) is moved to a distal end of said cavity (37), said needle extractor (26) including release means (42) for moving said releasable abutment (51) from a blocking configuration, in which motion of said needle flange (44) past said releasable abutment (51) is prevented, to a released configuration, in which motion of said needle flange (44) past said releasable abutment (51) is permitted.

32. The hypodermic syringe (10) of Claim 31 characterized in that said releasable abutment (51) includes a plurality of segments (58) arranged around said coupling opening (50), forming a restriction of said coupling opening (50) to prevent passage therethrough of said needle flange

* C L M S *

This Sheet Has Been Replaced

(44); and in that a distal extractor tip (52) of said needle extractor (26) includes a tubular portion (42) having an inner surface forming said gripping means (42), and an outer surface forming said release means (42) by deflecting said segments (58) outward to permit passage of said needle flange (44) through said coupling opening (50).

33. The hypodermic syringe (10) of Claim 32 characterized in that said segments (58) are formed as integral portions of said barrel (14); in that said segments (58) are separated by slots (56) extending inward from distal surfaces of said segments (58), in a longitudinal direction along said barrel (14); and in that said segments (58) are formed to block passage of said needle flange (44) in an undeflected state.

34. The hypodermic syringe (10) of one of Claims 32 or 33 characterized in that said plunger (12) includes elastic means (31) for holding said distal extractor tip (52) disposed at an acute angle relative to a central axis of said cavity (37) in that said cavity (37) is of sufficient length to enclose said needle subassembly (16, 43, 44) when said proximal end of said needle subassembly (16, 43, 44) is held by said gripping means (42); and in that said cavity (37) includes, at a distal end, a funnel shaped surface (54) extending inward to said coupling opening (50).

35. The hypodermic syringe (10) of Claim 34 characterized in that said needle extractor (26) includes a proximal extractor surface (31) opposite said distal extractor tip (52), said proximal extractor surface (31) being inclined relative to an axis of said distal tip (52); in that said plunger (12) includes a plunger surface (30) extending perpendicularly to said central axis of said cavity (37); and in that said elastic means (28) holds said proximal extractor surface (31) against said plunger surface (30).

* C L M S *

This Sheet Has Been Replaced

36. The hypodermic syringe (10) of Claim 35 characterized in that said needle extractor (26) further includes an extractor hub (42) and an extractor flange (31), said extractor hub (42) extending between said distal extractor tip (52) and said extractor flange (31), said proximal extractor surface (31) being formed as part of said extractor flange (31); and in that said piston (28) includes an elastic distal piston portion (28) extending around said extractor flange (31), with said extractor hub (42) extending through an aperture in said distal piston portion (28), with said distal piston portion (28) holding said proximal extractor surface (31) against said plunger surface (30).

37. The hypodermic syringe (10) of one of Claims 31, 32 or 33 characterized in that said needle flange (44) is formed as part of a collar (42a) secured in place on said needle (16); and in that a hub (43) extending from a proximal side of said needle flange (44) is additionally part of said collar (42a), said hub (43) forming said proximal portion of said needle assembly (17).

38. The hypodermic syringe (10) of one of Claims 31, 32 or 33 characterized in that said needle flange (44) is formed as part of a collar (42a) secured in place on said needle (16), with a distal portion of said needle (16) extending from a distal side of said collar (42a), and with a proximal portion of said needle (16) extending from a proximal side of said collar (42a), said proximal portion of said needle (16) forming said proximal portion of said needle assembly (16, 43, 44); and in that a hub (43) extending from a distal side of said needle flange (44) is additionally part of said collar (42a).

* C L M S *

This Sheet Has Been Replaced

39. The hypodermic syringe (10) of one of Claims 31, 32, or 33 characterized in that said proximal portion of said needle subassembly (16, 43, 44) includes a ridge (64) formed to resist slippage when a tensile force is applied to said proximal portion of said needle (16).

40. The hypodermic syringe (10) of one of Claims 31, 32 or 33 characterized in that a sealant is applied within an annular space between said needle (16) and said needle hub (18).

41. The hypodermic syringe (10) of Claim 31 characterized in that said attachment portion (20) of said needle attachment coupling (20, 51) and said mating portion (46) of said needle hub (18) are engageable by relative rotation in a first direction and disengageable by relative rotation in a direction opposite said first direction; and in that said needle (16) and said needle hub (18) are together attachable and removable from a distal end of said needle attachment coupling (10, 51), from outside said barrel (14).

42. The hypodermic syringe (10) of Claim 31 further characterized by plunger travel limiting means (72, 74) for stopping outward motion of said plunger (12) beyond said distal end of said barrel (14).

43. A syringe (100) having a barrel (102) and a plunger (104) characterized by expanding means (106) radially held within said barrel (102) while said plunger (104) is positioned within said barrel (102), said expanding means (106) being expanded over an end (108) of said barrel (102) upon withdrawal after a certain distance of said plunger (104) from said barrel (102), thereby inhibiting repositioning of said plunger (104) within said barrel (102).

* C L M S *

JUL 21 '95 03:31PM SHERWOOD LAW
314 241 5855

This Sheet Has Been Replaced

44. The syringe (100) of claim 43 characterized by means (120) to limit the withdrawal of said plunger (104) from said barrel (102) to said certain distance.

45. The syringe (100) of claims 1, further characterized by expanding means (106) radially held within said barrel (14, 102) while said needle assembly (12 and 17, 104) is positioned within said barrel (14, 102), said expanding means (106) being expanded over a proximal end (108) of said barrel (14, 102) upon withdrawal after a certain distance of said needle assembly (12 and 17, 104) from said barrel (14, 102), thereby inhibiting re-positioning of said needle assembly (12 and 17, 104) within said barrel (14, 102).

44. The syringe (100) of claim 45 characterized by means (120) to limit the withdrawal of said needle assembly (12 and 17, 104) from said barrel (14, 102) to said certain distance.

45. The syringe of claim 1 further characterized by an extractor (26, 126) moveable within said barrel (14, 122) to be connected with said needle assembly (17, 128) and to withdraw said needle assembly (17, 128) into said barrel (14, 122), and by means (132, 134) to indicate the approaching connection between said extractor (26, 126) and needle assembly (17, 128) as said extractor (26, 126) moves towards said needle assembly (17, 128).

* C L M S *

ABSTRACT

A hypodermic syringe (10) permits a needle (16) to be fully retracted into the cylindrical cavity of the syringe barrel (14) following injection of medicine into a patient. The needle (16) is held on the distal end of the barrel (14) by an attachment hub (43), which includes an internal abutment surface to prevent outward movement of the needle (16). Inward movement of the needle (16) is prevented by an expandable restriction (51) of a distal barrel (14) opening, extending between the cylindrical cavity and the distal end of the barrel (14). Needle (16) includes a flange (44) held between the internal abutment surface of hub (43) and the expandable restriction (51). The distal end of the plunger (12) is fitted with a needle extractor (42), which, when depressed, grips the proximal end of the hub (43) and expands the expandable restriction (51) so that the needle (16) and flange (44) are pulled into the cylindrical cavity of the barrel (14) as the plunger (12) is pulled outward.

This Sheet Has Been Replaced



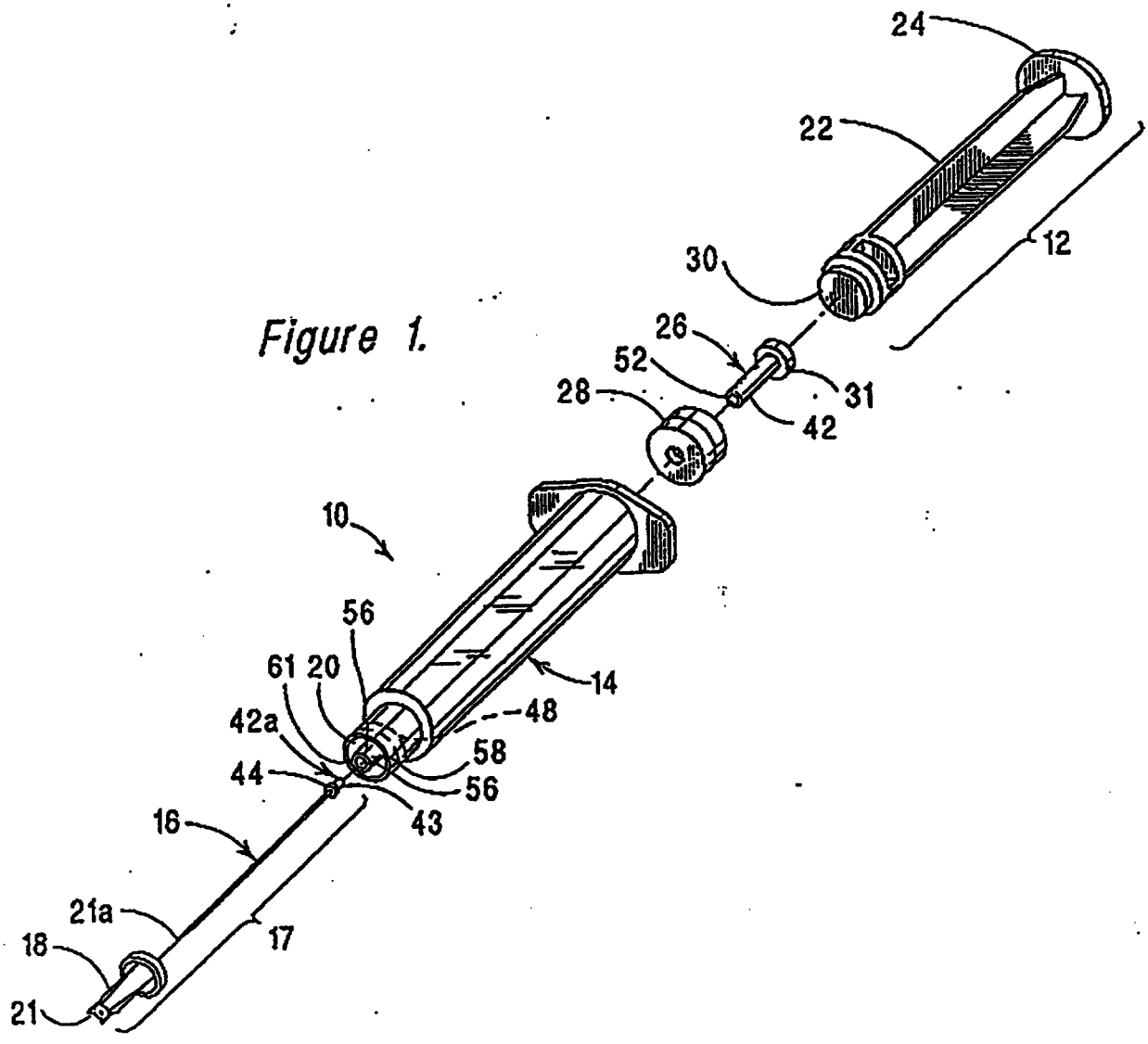


Figure 1.

This Sheet Has Been Replaced

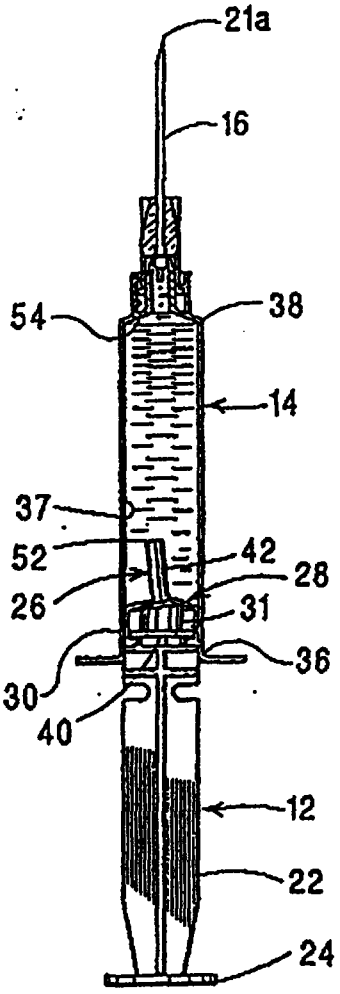


Figure 2.

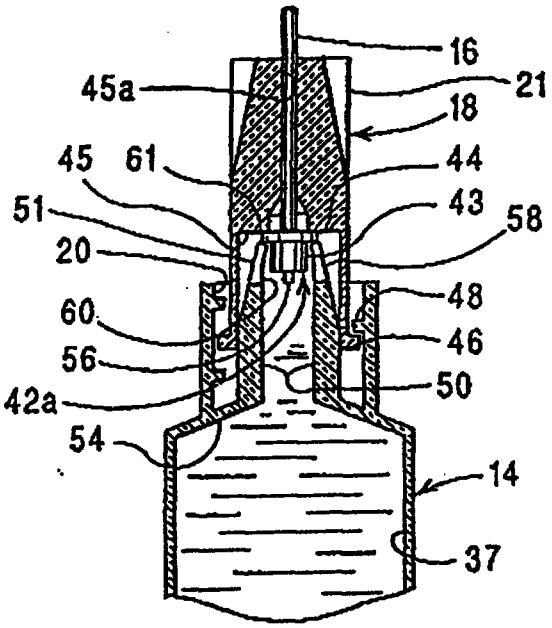


Figure 3.

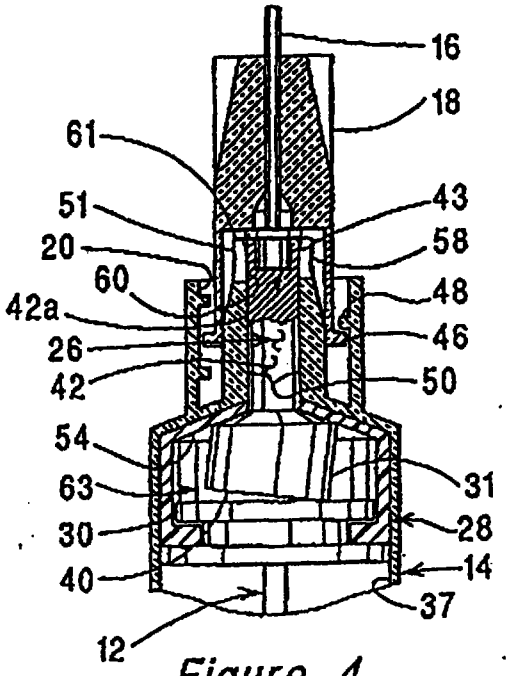


Figure 4.

This Sheet Has Been Replaced

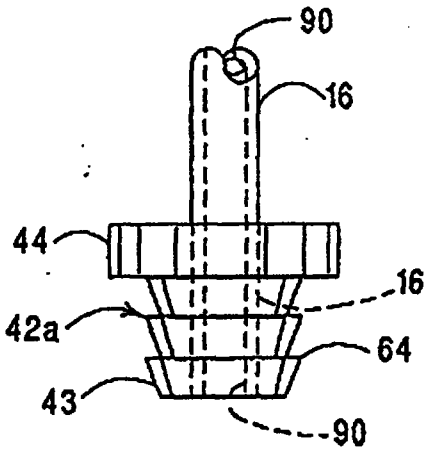
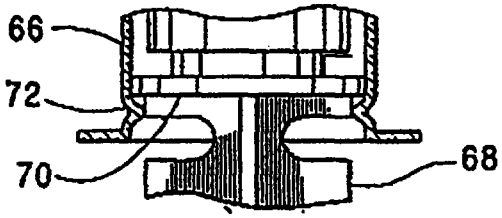


Figure 5.



PRIOR ART

Figure 7.

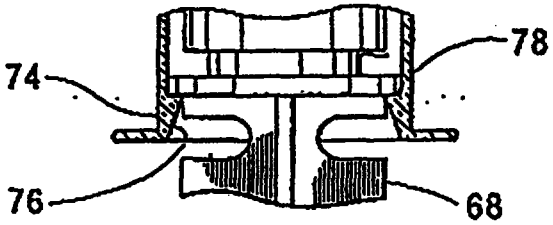


Figure 8.

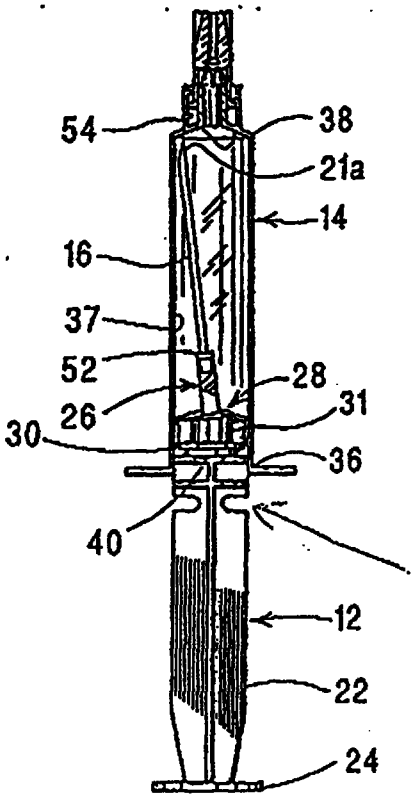


Figure 6.

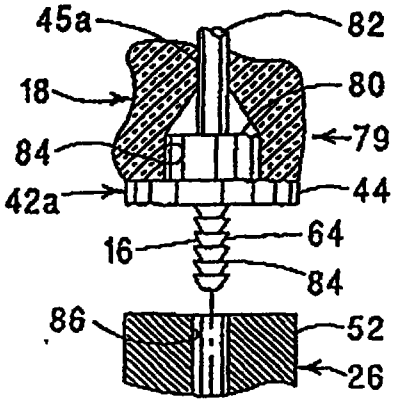


Figure 9.

This Sheet Has Been Replaced

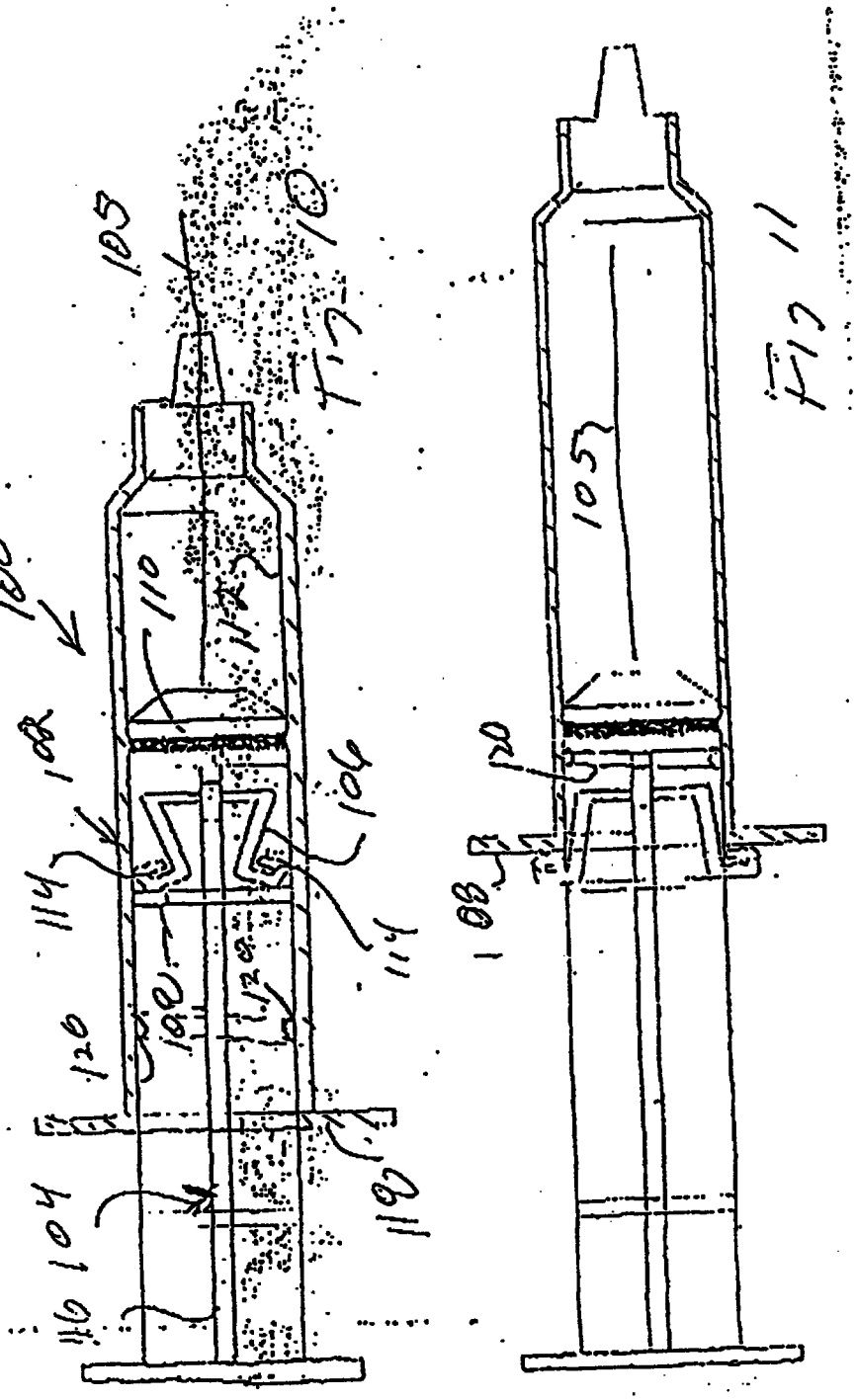


FIG 10

FIG 11

FIG 12

This Sheet Has Been Replaced

REPLACED SHEETS SG
☑ Description : paged ..... to paged .....
☑ Claim(s) : paged ..... to paged .....
☑ Drawing(s) : paged ..... to paged .....
☑ Abstract : paged ..... to paged .....
DATE OF RECEIPT .....

REPLACEMENT SHEETS SG
☑ Description : paged 1 to paged 32
☑ Claim(s) : paged 33 to paged 34
☑ Drawing(s) : paged 1/4 to paged 4/4
☑ Abstract : paged 1/1 to paged -
DATE OF RECEIPT 28/10/96

HYPODERMIC SYRINGE WITH NEEDLE RETRACTION FEATURE

This invention relates to a hypodermic syringe, and more particularly, to a disposable hypodermic syringe having a needle which may be retracted into the cylindrical cavity of the barrel following use.

A typical hypodermic syringe includes a transparent cylindrical barrel, generally open at a proximal end, a plunger assembly movable within the barrel to dispense medication, and a needle assembly removably attached to the barrel at a distal end by means of a locking mechanism, such as Luer lock. During usage, medication is sealed within open side of the barrel by means of a rubber piston slipped over the distal end of the plunger. At the distal end of the syringe, sealing is accomplished through a sealant, such as an epoxy resin, extending between the outer surface of the needle and the lock hub carrying the needle. This sealant, and the locking mechanism fastening the needle assembly to the barrel, are also used to transmit the force, which may be as high as several pounds, required to insert the needle into the patient's body and to remove the needle after the injection process is complete.

The applications of hypodermic syringes within a health care facility require the availability of syringes varying particularly in needle length and diameter, and in the dosage capacity of the barrel. To satisfy this need, needles and the remaining portions of syringes are made commercially available both as assembled units, and as separate units allowing the attachment of a selected one of the various needle assemblies to a selected one of various barrels. The Luer lock fittings used to fasten the needle to the barrel form a basis for common, interchangeable parts.

It is thus desirable that any improved design for hypodermic syringes should include the capability of switching needles among the syringes. It is even more desirable that any improved design for hypodermic syringes

This is the replacement sheet
Date: 28 OCT 1996

should be capable of using standard needle assemblies, and that the new needle assemblies should be usable in standard syringe barrels.

Modern medical practice dictates that, in order to eliminate a possible source of contagious disease, hypodermic syringes are used only once. There is a growing concern, even when syringes are discarded immediately after use, that health care workers may be accidently stuck by a hypodermic needle which has been used in the treatment of a patient having a serious communicable disease, such as AIDS or hepatitis. Used hypodermic needles have become an especially dangerous form of waste material, posing a danger to anyone handling trash from a health care facility and to anyone who might come into contact with such material after it has been dumped, and requiring special puncture resistant containers for disposal.

Another problem commonly associated with discarded hypodermic syringes is their potential use by drug abusers, who sometimes search waste material from health facilities for such devices. This practice obviously carries a significant risk of infection to these drug users and to others they may subsequently contact.

Conventional hypodermic syringes included an inward extending ring near the proximal opening of the barrel, which forms a stop, preventing the inadvertent removal of the plunger from the barrel. However, this ring is generally not rigid enough to prevent the deliberate, surreptitious removal of the plunger, as by a drug abuser.

One prior art solution to the aforementioned problems has been to enclose the needle in a sheath manually slipped over the needle end before and after use of the syringe. However, this technique still exposes health workers to the risk of being stuck with an infected needle as the sheath is slipped on, particularly when the needle is not properly aligned with the sheath opening. Furthermore, this technique does nothing to render the syringe useless to a drug abuser.

This is the replacement sheet

Date: 28 OCT 1996

Another prior art solution to the aforementioned problems is breaking the needle from the syringe once it is used. While this procedure is followed in a number of health care facilities, there are still several disadvantages to this procedure. First, the broken needles are not necessarily enclosed in a way permitting their subsequent safe handling, and second, the additional handling of used needles by health care workers in the process of breaking the needles may increase the risk of their being accidently stuck by an infected needle.

One attractive solution to the aforementioned problems is in providing a syringe/needle assembly in which the needle may be retracted into the barrel of the syringe after use, so that the needle is held in an envelope formed by the barrel during disposal. The patent literature includes descriptions of devices of a first general type, in which a needle is fastened to a needle carrier which travels axially within the barrel. In its distal position, the carrier holds the needle ready for use at the distal end of the barrel. After the plunger assembly is moved to the distal end of the barrel, after dispensing the desired medication, the plunger assembly engages and locks onto the needle carrier. When the plunger assembly is subsequently withdrawn and returned to the proximal end of its travel, the needle is carried with the plunger until it is completely enclosed within the barrel. At this point, the syringe ready for proper and safe disposal. Examples of syringes of this type are found in U.S. Patent 4,710,170, issued to Haber et al on December 1, 1987; in U.S. Patent 4,790,822, issued to Haining on December 13, 1988; and in U.S. Patent 4,883,471, issued to Braginetz et al on November 28, 1989.

In the prior art devices, the needle is fastened to the needle carrier by conventional means. For example, needle may be fastened to a Luer lock hub, which, in turn, is screwed onto a threaded hole forming internal surfaces in the needle carrier. Thus, syringes of this kind have

This is the replacement sheet

Date: 28 OCT 1996

the advantage of being capable of using standard needle assemblies of the types widely available for syringes not incorporating the safety feature of needle retraction. If the syringe is provided with its needle carrier at the distal position, an interchangeable needle may be screwed into the syringe from the distal end, in the conventional manner. However, the barrels of syringes of this type, of necessity, have relatively large openings at their distal ends, to accommodate the motion of the needle, together with a portion of the needle carrier as it is retracted into the barrel. This large opening, in turn, significantly increases the complexity and cost of the device by requiring fluid tight sealing around the outside of the needle carrier, so that medicine can be dispensed through the needle without leakage out of the distal end of the syringe.

Furthermore, the needle carrier of the prior art devices occupies a significant portion of the axial length of the barrel. The conservation of distance along this length is especially important in a syringe having a retractable needle because the space is needed for storage of the needle after use. Conventional syringes are built to particular sizes for convenient handling and use, as well as for various barrel capacities for medication. For example, the barrels of typical syringes having either three cubic centimeter and five cubic centimeter capacities are about 2.5 inches in length, with the difference in capacity being accomplished by varying the diameter. A typical long needle extends 1.5 inches from the end of the Luer hub to which it is attached. Including this hub, the length of the needle assembly is about 2.125 inches. Thus, the use of a needle carrier of the prior art requires lengthening the barrel beyond the length necessary for handling and capacity, thereby decreasing the ease and familiarity with which the syringe is handled and further increasing its costs of manufacture and distribution.

This is the replacement sheet

Date: 28 OCT 1994

The device of U.S. Patent 4,883,471 to Braginetz et al mounts the needle carrier in a second piston. After the medication is dispensed, vent ports are opened by rotating a cap at the distal end of the syringe, so that the atmosphere is allowed to enter the syringe at the distal end of this second piston. The retraction of the piston, with the needle, is then accomplished by the differential pressure established as the plunger is withdrawn. However, rotating the cap in this way presents the health care worker with the inconvenience of an extra step in the process.

The patent literature also describes devices of a second general type, in which the needle assembly is loaded into the syringe barrel from inside the barrel, to stick outward through a relatively small opening in the distal end of the barrel. After the injection of medicine by means of the plunger assembly, the needle assembly is attached to the distal end of the plunger assembly to be retracted into the syringe barrel as the plunger assembly is pulled back toward the proximal end of the barrel.

While syringes of this type address the concerns expressed above relative to the use of a separate needle carrier, they lack the important ability to use conventional needle assemblies, which are adapted to be screwed into place using Luer couplings from outside the distal end of the barrel. In addition, if interchangeable needles are to be used in any way on the syringes, they must be attached by relatively difficult or complex means within the barrels. Further, by changing a needle through the barrel, the sterility of the barrel can be violated.

Some devices of this second general type, in which the needle is loaded from inside the barrel, include couplings between the needle assemblies and the distal ends of the barrels, which are connected and disconnected by the rotation of the needle assembly within the barrel, being described, for example, in U.S. Patent 4,507,117, issued to Vining et al on March 26, 1985; in U.S. Patent 4,675,005, issued to DeLuccia on June 23, 1987; in U.S. Patent

This is the replacement sheet
Date: 28 OCT 1996

4,747,830, issued to Gloyer et al on May 31, 1988; in U.S. Patent 4,919,652, issued to Alter et al on April 24, 1990; and in U.S. Patent 4,986,813, issued to Blake III et al on January 22, 1991. While DeLuccia, Alter, and Blake III teach the use of threaded screw connections, Vining and Gloyer uses quick release, quarter turn types of connection. Vining also describes means for providing the syringe, before use, with the needle retracted for safe handling. A disadvantage of these syringes is the additional requirement that the plunger must be twisted after an injection is given, before disposal of the syringe with the needle assembly in a retracted position. This twisting is needed to engage the needle assembly to the plunger assembly, and to disengage the needle assembly from the distal end of the barrel. However, this requirement places a burden on health care workers in an emergency situation, and can be expected to result in a failure to properly retract needles in some units before disposal.

Other devices of this in which the needle is loaded through the barrel interior include means for engaging the proximal end of the needle assembly with a mechanism extending from the distal end of the plunger assembly as the plunger mechanism reaches the distal end of its travel in dispensing medicine through the needle. Such devices are described, for example, in one of the embodiments of U.S. Patent 4,675,005 to DeLuccia; in one of the embodiments of U.S. Patent 4,692,156 to Haller; and in U.S. Patent 4,804,370, issued to Haber et al on February 14, 1989. In this Haber device, the needle extends outward through a small hole at the distal tip of the syringe barrel. The proximal end of the needle is provided with a flange, and the plunger assembly is provided with a needle capturing receptacle which engages this flange as the plunger assembly is moved to the distal end of the barrel, so that the needle is subsequently retracted into the barrel as the plunger assembly is withdrawn.

This is the replacement sheet

Date: 28 OCT 1996

While such devices are operable without requiring the additional step of twisting the plunger after medicine is dispensed, they are still inconvenient to use, when compared to conventional syringes, because they do not accept conventional needle assemblies, and because, if it is necessary to install any type of needle assembly, the installation procedure is relatively complex and would violate the integrity of the sterility.

An important consideration in the design of a hypodermic syringe is the ability of the device to transmit axial forces to the needle from the barrel and plunger. Forces as high as several pounds may be required, both to insert the needle into the patient, and to withdraw the needle from the patient during the process of giving an injection. If the needle is to be retracted into the barrel of the syringe, means must be provided to prevent this retraction during the insertion of the needle into the patient, due to the necessary application of force to the needle as it is inserted.

In the devices having needle assemblies connected to the barrels with screw threads or quarter turn fasteners, to be disconnected by rotation of the plunger after the medication is dispensed, these fasteners prevent premature retraction of the needle. These devices are shown, for example, in U.S. Patents 4,507,117, 4,675,005, 4,747,830, 4,919,652, and 4,986,813. While this method of holding the needle in place during injection is quite effective, the disadvantages of requiring the performance of the additional manual rotation step and non-standard components remains.

In those devices having means for engaging the proximal end of the needle assembly with a mechanism extending from the distal end of the plunger assembly, the connection between the needle and the barrel must be strong enough to hold the needle in place as it is inserted into the patient. Further, the needle must subsequently be pulled directly out of this connection for retraction.

This is the replacement sheet

Date: 28 OCT 1996

Both of these actions are accomplished by applying an axial force to the needle. In the devices of U.S. Patent 4,692,156 to Haller, the needle is mounted in an aperture within a deformable tapered mounting post, which deforms to slide through a passage in the barrel during retraction. In other devices, as shown, for example in U.S. Patents 4,804,370 and 4,826,484 to Haber et al., the needle is retained by a tight fit within a distal hole of the barrel. This means that, for reliable operation, the force which must be applied for needle retraction, to overcome the attachment between the needle and the barrel, must be greater than the highest force expected during the insertion of the needle into the patient, together with a safety factor applied to cover variations in the process of manufacturing the syringe. If the needle is to be retracted during withdrawal from the patient, this force must be even higher. The requirement to apply such a large force places a significant burden on health care personnel and creates a potential danger to the patient.

The device described in U.S. Patent 4,710,170 to Haber et al includes a needle carrier which is held in place within the barrel by means of a quick release fastener. After the dispensing of medication is completed, the plunger is manually rotated to release the carrier from engagement with the barrel. Thus, a requirement to perform an additional step is placed on health care personnel.

The device described in U.S. Patent 4,790,822 to Haining includes a needle carrier which is held in place at the distal end of the barrel by opposing shoulders extending inward from the interior of the barrel. As the plunger is moved to the distal end of the barrel, a piston at the distal end of the plunger forces these shoulders apart, releasing the carrier to return with the plunger.

The patent literature also describes apparatus for causing the needle to be rotated transversely, about its attachment to the plunger as it is retracted into the barrel, to point toward a side of the barrel. This is done to

This is the replacement sheet

Date: 28 OCT 1996

prevent accidental or deliberate extension of the needle through the hole in the distal end of the barrel, by means of pushing the plunger inward. In other words, this feature provides further safety for health care and trash disposal workers, and goes another step toward preventing the subsequent use of the syringe by drug abusers. For example, U.S. Patent 4,804,370, issued to Haber et al on February 14, 1989, describes needle capturing receptacle with legs, for capturing a flange at the proximal end of the needle. Two of the legs are shorter than the others, so the needle is rotated transversely as it is retracted. As described in U.S. Patent 4,986,813 to Blake III et al, a syringe includes a fitting fastening the needle assembly to the distal end of the plunger for retraction with a slot, extending inward from one side of the fitting, which is allowed to expand as the needle is fully retracted, throwing the needle out of alignment with the longitudinal axis of the plunger.

Blake III also describes the use of stopping surfaces extending into the barrel near its proximal end, angled to prevent removal of the plunger from the barrel, while allowing its assembly into the barrel as the syringe is fabricated. Such surfaces make it particularly difficult for a drug user to take the syringe apart to make it again operable or to retrieve the needle.

Thus, while the feature of needle retraction can be accomplished in a number of ways, the methods proposed in the prior art for providing this feature all have various disadvantages. What is needed is apparatus for providing needle retraction without substantially increasing the size or length of the syringe, as required when a separate needle carrier is employed, and without requiring the performance of an additional step, such as the rotation of the plunger, by health care personnel. Since health care facilities must carry a relatively large inventory of different sizes and types of syringes and needles, it is desirable that an improved syringe should accept the removal and

This is the replacement sheet
28 OCT 1996
Date:

attachment of needles in the standard way, from outside the distal end of the barrel. It is further desirable that the needle be releasibly held in place by positive means, such as a latch or movable abutting surface, rather than by reliance on a tight fit. Also, since conventional hypodermic syringes are low cost items used in large quantities by health care facilities, it is particularly desirable that the feature of needle retraction should be provided by a mechanism which is inherently simple and low in manufacturing cost. In particular, any improved syringe ideally will use existing syringe parts or slight modified parts so that existing mold tooling can be used.

In accordance with one aspect of the invention, there is provided a hypodermic syringe including a container for ejecting fluid having an internal cavity between a fluid ejecting end thereof and a proximal end thereof. The container also has a piston assembly having a seal end movable from the proximal end to the fluid ejecting end to eject fluid and retractable towards the proximal end. The syringe further includes a needle attachment assembly affixed to the fluid ejecting end of the container, the needle attachment assembly having a hollow first column with an opening extending therethrough in fluid communication with the cavity. The column is tapered inward at a distal end thereof and has a plurality of slits from the distal end thereof towards the container separating a plurality of segments at the distal end. In addition, the syringe includes a needle subassembly, including a needle with hole extending axially therethrough, and a needle flange affixed remote from one end of the needle. A second hollow column extends from the flange towards the one end and is sized to fit within the first column opening such that the end of the segments are juxtaposed to one surface of the flange. The needle subassembly further includes means juxtaposed to the other side of the flange for holding the needle subassembly on the attachment assembly column. Finally, the syringe includes needle extractor means, including a third

This is the replacement sheet
28 OCT 1996
Date:

hollow column affixed to the seal end of the piston assembly. The third column is sized such that the exterior thereof enters the first column and separates the segments so that the ends thereof are spaced from the one surface of the flange. The third column further is sized such that the interior thereof grabs the second column and the needle assembly, including the flange is retracted through the first column upon retraction of the piston assembly.

Preferred embodiments of the subject invention are hereafter described with specific reference being made to the following Figures, in which:

Figure 1 is an exploded isometric view of a hypodermic syringe built in accordance with the present invention;

Figure 2 is a longitudinal elevation of the syringe of Figure 1, being shown as ready to dispense medication;

Figure 3 is a fractional longitudinal cross-sectional elevation of the needle attachment portion of the syringe of Figure 1;

Figure 4 is a cross-sectional elevation similar to Figure 3, shown with the needle engaged for retraction into a barrel of the syringe;

Figure 5 is an elevational view of the proximal end of a needle of the syringe of Figure 1;

Figure 6 is a cross-sectional elevation similar to Figure 2, shown with the needle fully retracted after dispensing medication.

Figure 7 is a fractional longitudinal cross-sectional elevation of a proximal portion of a barrel of a conventional hypodermic syringe, showing a plunger of the syringe pulled outward against a ring used to prevent inadvertent removal of the plunger from the barrel;

Figure 8 is a cross-sectional elevation similar to Figure 7, showing an improved form of the ring of Figure 7;

This is the replacement sheet

Date: 28 OCT 1996

Figure 9 is a fractional longitudinal elevation of an alternate structure for gripping a needle for retraction, showing a proximal portion of a needle within a Luer coupling, together with a distal tip of a needle extractor;

Figure 10 is a side view of a syringe useful with the invention which prevents forward movement of the plunger after the needle is withdrawn;

Figure 11 is a side view showing the withdrawn plunger of Figure 10; and

Figure 12 shows another version of the invention.

Referring first to Figure 1, an improved hypodermic syringe 10 of the subject invention includes a plunger assembly 12 slidable within a barrel 14 to dispense medication by means of a hole extending through a needle 16 within a needle assembly 17. This needle assembly 17 includes needle 16 and a Luer hub 18 by which the needle is removably attached to threaded hole 20 at the distal end of barrel 14. Luer hub 18 includes longitudinally extending external flutes 21, which aid in gripping needle assembly 17 for rotation as required to engage or disengage the threaded Luer connection. Needle assembly 17 may also be provided with a sheath (not shown), extending around the needle 16 and attachable to hub 18 to protect health care personnel from contact the sharp distal point 21a of the needle. Flutes 21 may also engage internal grooves extending longitudinally within the sheath to permit the rotation of the needle assembly without removing the sheath. Plunger assembly 12 includes an elongated slide 22 having gripping means 24 at its proximal end, an inward extending needle extractor 26, and an elastomeric piston 28 which extends over a disk shaped distal end portion 30 of slide 22, and around a flange 31 of extractor 26.

Figure 2 shows syringe 10 as ready to dispense medication 34 through needle 16. This medication 34 may have been drawn through needle 16 from a vial, not shown, as plunger assembly 12 was moved to the position shown near the proximal end 36 of barrel 14. Alternatively, the medi-

This is the replacement sheet

Date: 28 OCT 1996

cation 34 may have been supplied to a health care facility as part of the syringe package. Elastomeric piston 28 forms a seal around the internal cylindrical surface 37 of barrel 14, so that pressure may be built up within the cylinder interior of barrel 14 by sliding plunger assembly 12 toward distal end 38, as required to dispense the medication 34 through needle 16, without substantial leakage of the medication 34 past piston 28.

A more detailed view of the relationships among slide 22, elastomeric piston 28, and needle extractor 26 is also provided in the cross-sectional view of Figure 4. Elastomeric piston 28 is essentially a hollow cylindrical structure having a large hole in one end, through which distal end portion 30 of slide 12 is inserted, and a smaller hole in the opposite end, through which flange 31 of needle extractor 26 is inserted. The elastic properties of piston 28 produce a clamping action to hold flange 31 against end portion 30. Alternatively, needle extractor 26 may be secured to end portion 30 by a suitable adhesive or may be molded as a part of the slide 22 and end portion 30 assembly. Since the proximal end surface 40 of flange 31 is slanted relative to the axis of hub portion 42 of extractor 26, hub portion 42 is slanted, at an acute angle to the longitudinal axis of barrel 14, when flange 31 and end portion 30 are held together in this way.

The manner by which needle 16 is attached to barrel 14 is shown particularly in Figure 3. A metal, or other hard material, collar 42a, including a hub 43 and a flange 44, is fastened to a proximal end of needle 16, preferably by a swaging procedure or an adhesive, to form a needle subassembly. Needle assembly 17 is formed when needle 16 is subsequently inserted through a needle receiving hole 45a in Luer hub 18, being pushed through this hole 45a until needle 16 extends through hub 18, with a distal side of flange 44 against an adjacent abutment surface 45 of the hub.

This is the replacement sheet

Date: 28 OCT 1996

A sealant is preferably added to the annular space between needle 16 and the internal surface of needle receiving hole 45a. The need for this form of sealing exists because, while it is neither necessary nor desirable to produce a tight fit between needle 16 and hub 18, it is necessary to establish a partial vacuum within syringe 10 as plunger assembly 12 is pulled outward to fill the syringe with medication 34. Further, necessary to establish hydraulic pressure within syringe 10 as plunger 12 is subsequently pushed inward to inject the medication 34 into a patient. Thus, there is a need to prevent the inward leakage of air, or the outward leakage of medication, through the space between needle 16 and hub 18. However, it is necessary that the sealing agent does not permanently bond to the needle.

Several different types of sealants may be used to seal needle 16 and hole 45a. For example, a heavy grease, such as a petroleum jelly may be used for the sealant, as can a number of room temperature vulcanizing (RTV) silicone adhesives, or yieldable medical adhesives, such as the product available as Dymax Light Weld #190-M.

Flange 44 includes an annular shoulder preventing outward movement of needle 16 by contact with an adjacent internal abutment surface 45 of Luer hub 18. Luer hub 18 includes, at its proximal end, a conventional thread engaging flange 46, shaped as a disk with truncated sides, which engages an internal thread 48 within threaded hole 20 of barrel 14. In this way, needle assembly 17 is removably fastened to barrel 14. A number of different needle assemblies can be provided for interchangeable attachment in this manner, with such needle assemblies varying, for example, in the length and diameter of the needle.

Thus, while the needle retraction feature is provided by means which will be explained, the attachment of the needle to the syringe barrel is achieved by conventional means, through the use of a Luer connection allowing attachment from outside the distal end of the syringe bar-

This is the replacement sheet

Date: 28 OCT 1996

rel. In fact, conventional needle assemblies, without provision for needle retraction, can be attached through this conventional connection to syringe barrel 14 built in accordance with the present invention, and needle assemblies 17 built in accordance with this invention can be attached to conventional syringe barrels. If parts made in accordance with this invention are assembled with conventional parts in either of these ways, the needle retraction feature will not be operative, but the syringes can still be used and disposed in conventional ways. This is a particular advantage to a health care facility, with an inventory of conventional needles and syringes, in the process of converting to the use of syringes having the needle retraction feature.

This needle attachment arrangement of the subject invention offers particular advantages, of ease of use and interchangeability with conventional parts, over the arrangements shown, for example, in U.S. Patent 4,826,484 to Haber et al, in which a needle must be pressed into a tight fitting hole from inside the barrel cavity. This needle attachment arrangement of the subject invention offers advantages over the arrangements of, for example, U.S. Patents 4,675,005 to DeLuccia, 4,747,830 to Gloyer et al, 4,919,652 to Alter et al, and 4,986,813 to Blake III et al, which require that the needle assembly must be screwed into a threaded hole, or into a quick release fastener, within the distal end of the barrel, from inside the barrel cavity.

During the process of handling syringe 10 before an injection is given and during the process of dispensing medication 34 by means of injection, needle 16 is held by the distal end of barrel 14, since flange 44 cannot pass through the smaller diameter distal opening of channel 50 provided at the distal end of coupling 51 of barrel 14. Thus, flange 44 provides an annular shoulder on each side,

This is the replacement sheet

Date: 28 OCT 1996

serving in the transmission of any thrust forces in either direction, which may occur at the needle during the injection process.

Referring again to Figure 2, an injection is given to the patient in the conventional way, by moving plunger assembly 12 through the cylindrical interior of barrel 14. As plunger assembly 12 nears the distal end of barrel 14, distal tip 52 of the hub 42 portion of needle extractor 26 contacts funnel shaped internal surface 54 of barrel 14. As noted above, needle extractor 26 is maintained out of alignment with the axis of channel 50 by means of the engagement between slider end portion 30 and extractor flange 31. However, the angle of funnel shaped surface 54 is sufficient to ensure that tip 52 is guided into alignment with channel 50 with continued motion of plunger assembly 12 into barrel 14, when tip 52 in contact with surface 54.

Referring again to Figure 3, the distal end of coupling 51 is slanted slightly inward and has a series of inward extending slots 56 at a narrowed portion 60 of channel 50, separating the distal end of coupling 51 into plural segments 58. When extractor tip 52 is brought into engagement with needle hub 43, slots 56 are sized to receive hub 42 of extractor 26 and permit the expansion of the distal end of coupling 51 by the flexure of the segments 58 formed between slots 56. The expansion of segments 58 only occurs as extractor tip 52 is brought into the narrowed portion 60 at the extreme distal end of channel 50.

Thus, thrust forces required for the insertion of a portion of needle 16 into the patient are provided through the abutment of needle flange 44 and the ends 61 of segments 58 prior to the separation of segments 58. This structure provides a particular advantage over the prior art, for example, in U.S. Patent 4,826,484 to Haber et al, which requires that the thrust forces to be provided through a tight fit between the needle and a distal hole in the barrel, which fit is much more prone to failure than

This is the replacement sheet
Date: 28 OCT 1996

the abutting structure of ends 61 against flange 44. With the structure of the present invention, sufficient force to deflect segments 58 outward is applied at the very end of the inward movement of plunger assembly 12, long after the needle is fully inserted in the patient and at the time the medicine is dispensed.

Further, the disengagement of the abutting structure of ends 61 against flange 44 is accomplished by deflecting segments 58 arranged to extend as cantilever springs. This structure has the significant advantage of requiring very low deflection forces compared to the those required by the structure of the prior art. For example, in U.S. Patent 4,790,822 to Haining, the abutting surfaces are provided as parts of shoulders extending inward from the wall of the syringe barrel, so that this wall must be deflected outward around all sides of the shoulders before the needle can be retracted with a needle carrier.

As shown in Figure 4, when the motion of plunger assembly 12 toward the distal end of barrel 14 has been completed, distal tip 52 of needle extractor 26 has moved through channel 50 to engage needle hub 43 for the retraction of needle 16. At this position, a wedge shaped gap 63 exists between proximal surface 40 of flange 31 and distal end 36 of slide 22 resulting from needle extractor 26 being guided into channel 50. Tip 52 has a tubular shape, which tightly holds needle hub 43. The expansion of coupling tip 58 with the insertion of extractor tip 52 enlarges the narrowed opening 60 of channel 50 to clear the diameter of flange 44, so that needle 16 may be retracted into barrel 14 with the subsequent pulling of plunger assembly 12 towards proximal end 36 of the barrel using gripping means 24.

As shown in Figures 3 and 4, as needle 16 is about to be retracted from the patient, it is held by flange 44 abutting against abutment surface 45 of Luer hub 18. Thus, as cylinder 14 is pulled rearward, needle 16 moves with cylinder 14 due to the abutment of flange 44 against Luer

This is the replacement sheet

Date: 28 OCT 1996

hub 18. With this structure, the needle retraction feature is included in syringe 10 without significantly, if at all, increasing the length of the parts subsequently moved into the interior of barrel 14, as seen in Figure 6. Thus, it is not necessary to increase the length of barrel 14, beyond the normal length of barrel 14, which already is sufficient to hold needle 16 itself. A syringe with the size and length of a conventional syringe can be thus provided with the needle retraction feature using most existing parts. In this regard, a particular advantage is gained relative to the use of a separate needle carrier, slidably mounted to move in a syringe barrel cylinder, as shown, for example in U.S. Patents 4,710,170 to Haber et al, 4,790,822 to Haining, and 4,883,471 to Braginetz et al. Further, the needle holding structure of the present invention makes it unnecessary to seal around the large diameter of a separate needle carrier.

It is desirable to remove needle 16 from the patient by pulling plunger assembly 12 while pushing cylinder assembly 14 in order to maintain the distal end of cylinder assembly against the skin of the patient as needle 16 is drawn into cylinder 14. Referring to Figure 5, needle retraction using plunger assembly 12 may be accomplished by providing needle hub 43 with one or more ridges 64 to increase the thrust force which can be applied to extract needle 16 without breaking the bond between retraction assembly 26 and needle 16. In Figure 5, needle 16 is shown extending through an opening 88 in flange 44 and hub 43 permitting fluid communication through the opening 90 in needle 16. Alternatively, flange 44 and hub 43 may be integrally formed as a part of needle 16. Further, the internal surface of extractor hub 42 may also be provided with ridges, or reliance can be made on the ridges 64 of the hub 43 pressing into the relatively soft interior of plastic extractor hub 42.

This is the replacement sheet

Date: 28 OCT 1996

The technique of using plunger assembly 12 to withdraw needle 16 has the advantage of providing an additional measure of safety, in that the needle is immediately retracted directly into a safe position. On the other hand, the technique of withdrawing the needle by pulling on cylinder 14 may be easier to perform, since it is fully consistent with conventional syringes and the medical personnel do not have to change the way in which syringe 10 is traditionally used. In the latter traditional case, needle 16 is drawn into barrel 14 after it is fully removed from the patient, as explained above.

The method of attachment between extractor 26 and needle 16 offers an advantage in simplicity of use over the methods of, for example, U.S. Patents 4,675,005 to DeLuccia, 4,747,830 to Gloyer et al, 4,919,652 to Alter et al, and 4,986,813 to Blake III et al, which require the rotation of the plunger after medication is dispensed, to disengage the needle from the syringe barrel and to engage it to the plunger.

As shown in Figure 6, after plunger assembly 12 has been completed withdrawn to its initial position as seen in Figure 2, needle 16 is completely enclosed within barrel 14. As the tip 21a of needle 16 clears the proximal end of opening 50, the clamping action of elastomeric piston 28 on flange 31 of extractor 26 tends to bring proximal end surface 40 of flange 31 into contact with distal end flange 30 of slider 22, thereby rotating needle 16 transversely, to point toward a side of barrel 14. If plunger assembly 12 is subsequently pushed inward, into barrel 14, tip 21a of needle 16 will dig into funnel shaped surface 54 of barrel 14, preventing its later exposure or reuse. Needle 16 is thus totally enclosed in a manner permitting its safe handling and disposal.

A further refinement in preventing the surreptitious disassembly of the syringe by a drug abuser after disposal may be employed, as best understood by examining the differences between Figures 7 and 8. Figure 7 shows a

This is the replacement sheet

Date: 28 OCT 1996

cross-sectional view of the proximal portion 66 of a conventional syringe, with a conventional plunger 68 pulled outward, so that a flange 70 of plunger 68 rests against an inwardly extending ring 72. While this arrangement is adequate to prevent inadvertent removal of plunger 68 from the syringe, it is not difficult for a drug abuser to remove the plunger. In the structure shown in Figure 8, on the other hand, an improved ring 74 may alternately be provided, with a slanted surface 76 facilitating the insertion of plunger 68, as required in the assembly of the syringe, while a relatively flat annular surface 78 prevents removal of the plunger after disposal of the syringe. In this way, it is made particularly difficult for a drug abuser to remove the plunger to gain access to a needle held within cylindrical surface 37. Thus, the surreptitious disassembly and reassembly of the syringe may be prevented.

An alternative structure for attaching needle 16 to extractor 26 is shown in Figure 9, with like numerals being used to designate parts with like functions. In the Figure 9 structure, a needle subassembly 79 is formed when a collar 42a, including a needle hub 80 and a needle flange 44, is attached to a needle 16, preferably using a swaging process, between a distal needle portion 82 and a relatively short proximal needle portion 84. Needle hub 80 is directed toward distal needle portion 82. Luer hub 18 includes an enlarged cavity 84, into which needle hub 82 extends when distal needle portion 82 is fully inserted through needle receiving hole 45a. An abutting surface 45 of Luer hub 18 transmits thrust forces to a distal side of needle flange 44 when needle 16 is withdrawn from a patient. Proximal needle portion 84 may include a series of ridges 64 to increase the force which can be applied by extractor 26 to extract needle 16. Hole 86 within tip portion 52 mates with proximal needle portion 84.

As noted above with respect to Figure 6, the needle may be rotated transversely to prevent it being exposed or reused after the initial usage. Referring now to Figures

This is the replacement sheet

Date: 28 OCT 1996

10 and 11, a syringe 100 having a barrel 102 and a plunger 104 from which a needle 105 is held, is shown which includes a spring clip 106 to also prevent the needle from being exposed or reused after initial usage. Clip 106, which has a spring bias radially outward, is held longitudinally between a plate 108 and the proximal end of the piston head 110 and radially by the interior 112 of barrel 102. In the compressed position, seen in Figure 10, clip 106 is generally in the shape of a compressed U and has a pair of lips 114 biased against the inner surface 112 of barrel 102.

As seen in Figure 11, after the handle 116 of plunger 104 is fully removed, the lips 114 of clip 106 radially expand to cover the end 118 of barrel 102. In this position, clip 106 prevents the re-depression of handle 116 and the re-exposure of needle 105. An inward extending ring 120 may be included to prevent outward movement of plunger 104, as described with respect to Figure 8. Clip 106, because of the spring construction thereof, is easily compressed to slide around ring 120 during the withdrawal of plunger 104. Thus, plunger is held firmly in the position shown in Figure 11, thereby preventing reuse of syringe 100 or re-exposure of needle 105.

Referring now to Figure 12, another version of a syringe 122 the subject invention is shown, in which a plunger 124 is a single molded piece of plastic sized to form a seal with the interior surface of a barrel 124. In addition, an extractor 126 is formed at the distal end of plunger 124 to interface with a needle assembly 128 similar to needle assembly 17 shown in Figure 1.

In using syringe 122, it may be necessary to aspirate a liquid into syringe prior to dispensing that same liquid into the patient. In aspirating the liquid, it is not desirable to grip the needle assembly 128 and withdraw it into barrel 124. Thus, when aspirating the fluid, plunger 122 should not be depressed entirely, such that extractor 126 grips the hub 130 of needle assembly 128. In

This is the replacement sheet
28 OCT 1996
Date:

order to forewarn the user, one or more dimples 132 may be formed on extractor 126 at a position such that when extractor 126 enters the luer connector end of barrel 124, dimples present an resistance to further depression at a position just prior to extractor 126 engaging hub 120. The resistance would be a signal to the user of syringe 122 to cease applying force to plunger 124 and begin aspirating the liquid. After dispensing the liquid, the user of syringe 122 may depress plunger 124 with more force after noticing the resistance due to dimples 132 in order to overcome the resistance and cause extractor 126 to engage needle assembly 128, as described above.

An alternative to dimples 132 would be an inward facing ring 134 positioned on the interior surface of barrel 124. While both dimples 134 and ring 136 are shown in Figure 12, in practice, only one of these elements would be used.

While the invention has been described in its preferred forms or embodiments with some degree of particularity, it is to be understood that this description has been given only by way of example and that numerous changes in the details of construction, fabrication and use, including the combination and arrangement of parts, may be made without departing from the spirit and scope of the invention.

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A syringe (10) having a barrel (14) including a luer tip (50) and a needle assembly (17) detachably mounted on said luer tip (51), characterized by said needle assembly (17) including a hub (43) receiving said luer tip (51) and a needle (16) slidably positioned within said hub (43) and a flange (44) mounted thereon, said flange (44) being captured between said hub (43) and said luer tip (51) to immobilize said needle assembly (17).

2. The syringe (10) of claim 1, characterized in that said luer tip (51) further includes a coupling opening (50) extending therethrough and the distal end (61) of said luer tip (51) being expandable from a constricted position, wherein at least a distal portion of the coupling opening (50) is smaller than said needle flange (44), to an expanded position, wherein the coupling opening (50) is larger than said needle flange (44).

3. The syringe of one of claims 1 or 2, further characterized by an extractor (26) moveable within said barrel (14), said extractor (26) including at a distal end thereof a needle coupling (42) to connect said needle assembly (17) to said extractor (26) and a release face (52) to expand said luer tip (51) of said barrel (14).

4. The syringe of claim 3, further characterized in that the expandable distal end portion (61) of said luer tip (51) being segmented.

5. The syringe of claim 2, further characterized by an extractor (26) moveable within said barrel (14), a distal tip of said extractor (26) having a release face (52) smaller in diameter than said coupling opening (50) and

* C L M S *

This is the replacement sheet

28 OCT 1996

Date:

This Sheet Has Been Replaced

larger in diameter than said flange (44) and a needle coupling (42) at a distal end of said extractor (26) to connect said needle assembly (17) to said extractor (26).

6. The syringe of claim 5, further characterized in that said needle coupling (42) is disposed on said extractor (26) with respect to said release face (52) such that when said needle assembly (17) is coupled to said extractor (26), said needle flange (44) is sufficiently proximate to said release face (61) that said expandable distal tip will not engage said flange (44) as said needle assembly (17) is withdrawn through the coupling opening (50).

8. The syringe of claim 6, further characterized in that the expandable distal end portion (61) of said luer tip (51) is segmented.

9. A syringe and detachable needle assembly combination (10) having a barrel (14) including a luer tip (51) and an internally threaded locking skirt (20) around said luer tip (51), said needle assembly (17) including a hub (18) and a needle (16), said hub (18) including a distal end, an open proximal end receiving said luer tip (51) and locking ears (46) extending outwardly from said hub (18) to engage said internal threads (48) of said locking skirt (20) to detachably lock said hub (18) to said barrel (14), characterized by a coupling opening (50) extending to a radially expandable distal end (61) of said luer tip (51) and said needle (16) having a flange (43, 44) mounted thereon, said needle (16) being slidably positioned through the distal end of said hub (18) with said flange (43, 44) being captured between said hub (18) and said luer tip (51) to immobilize said needle (16) against axial movement.

10. The syringe and needle assembly combination (10) of Claim 9 further characterized by said expandable end (61) of said luer tip (51) having a constricted position wherein

This is the replacement sheet

* C L M S *

Date: 28 OCT 1996

This Sheet Has Been Replaced

the diameter of the coupling opening (50) is smaller than the diameter of said flange (43, 44) and an expanded position wherein the diameter of the coupling opening (50) is larger than the diameter of said flange (43, 44), and by an extractor (26) moveable within said barrel (14), said extractor (26) including, at a distal end thereof, a needle coupling (42) to connect said needle (16) flange (43, 44) to said extractor (26) and a release face (52) to expand said luer tip (51) of said barrel (14) to said expanded position when said needle (16) flange (43, 44) is coupled to said extractor (26).

11. A needle assembly (17), for use with a medical device (10) having a luer end (50) for sealable, detachable connection to said needle assembly (17), having a hub (18) including a needle passage (45a) extending from a distal end thereof and a luer tip passage extending from a proximal end thereof, said hub (18) having a proximal abutment (45) within the luer tip passage (46) characterized by a needle (16, 44) including a flange (44), said needle (16, 44) being slidably positioned through the needle passage (45a) of said hub (18) with said flange (44) abutted against said proximal abutment (45) of said hub (18).

12. The needle assembly (17) of Claim 11 further characterized by said needle (16, 44) having a coupling (43) thereon for connection to an extractor (26) of said medical device (10) adapted to pull said needle (16, 44) from the needle passage (45a) of said hub (18).

13. The needle assembly (17) of Claim 11 further being characterized in that said luer tip passage of said hub (18) is configured to position said flange (44) between said abutment (45) of said hub (18) and the distal end of the luer end (50) of a medical device (10) to which said needle assembly (17) can be attached.

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

14. The needle assembly (17) one of Claims 11, 12 or 13 further characterized in that said abutment (45) of said hub (18) is positioned in the luer tip passage of said hub (18) such that when said needle assembly (17) is connected to the luer tip passage of said medical device (10), said flange (44) is captured between said abutment (45) of said hub (18) and the distal end of the luer end (50) of said medical device (10).

15. The needle assembly (17) of one of Claims 11, 12 or 13 further characterized in that sealant is within at least a portion of the needle passage (45a) of said hub (18) about said needle (16).

16. A needle assembly (17) for use with a medical device (10) having a luer tip (51) and an internally threaded locking skirt (20) around the luer tip (51) for sealable, detachable locked connection of such needle assembly (17) to such medical device (10), said needle assembly (17) having a hub (18) including locking ears (46) on the outside of said hub (18) configured to engage the internal threads (48) of the locking skirt (20) of the medical device (10) to which said hub (18) may be connected, a needle passage (45a) axially extending from a distal end of said hub (18), a luer tip passage axially extending from a proximal end of said hub (18) configured to receive the luer tip (51) of such medical device (10), and a proximally facing abutment surface (45 at the distal end of the luer tip passage characterized by said needle assembly (17) including a flange (44) and a needle (16), said needle (16) being slidably positioned through the needle passage (45a) of said hub (18) with said flange (44) abutted against said abutment surface (45) of said hub (18).

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

17. The needle assembly (17) of Claim 16 characterized in that said needle (16) has a coupling (43) thereon for connection to an extractor (26) of the medical device (10) adapted to pull said needle (16) from the needle passage (45a) of said hub (18).

18. The needle assembly (17) of Claim 16 characterized in that said luer tip passage of said hub (18) includes a female luer taper.

19. The needle assembly (17) one of Claims 16, 17 or 18 characterized in that said luer tip passage of said hub (18) is configured to position said flange (44) between said abutment (45) of said hub (18) and the distal end of the luer tip (51) of the medical device (10) to which said needle assembly (17) may be attached.

20. The needle assembly (17) one of Claims 16, 17 or 18 characterized in that said abutment surface (45) of said hub (18) is positioned in the luer tip passage of said hub (18) such that when said needle assembly (17) is connected to the luer tip (51) of the medical device (10), said flange (44) is captured between said abutment surface (45) of said hub (18) and the distal end (61) of the luer tip (51) of the medical device.

21. The needle assembly (17) one of Claim 16, 17 or 18 characterized by sealant within at least a portion of the needle passage of said hub (18) about said needle.

22. A syringe (10) having a barrel (14) with a hollow interior (37) and a male luer tip (51) at a distal end of said barrel (14), said luer tip including a coupling opening (50) extending therethrough characterized by a distal end (61) of said luer tip (51) being expandable from a constricted position wherein at least a distal portion of the

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

coupling opening (50) is smaller than a desired size to an expanded position wherein the coupling opening (50) is larger than the desired size.

23. The syringe (10) of claim 22, characterized in that the expandable distal end (61) portion of said luer tip (51) being segmented.

24. The syringe (10) one of claims 22 or 23 characterized by an extractor (26) moveable within said barrel (14), a distal tip (52) of said extractor (26) having a release face (42) smaller in diameter than said coupling opening (50) in the expanded position of said luer tip (51) and larger in diameter than said coupling opening (50) in the constricted position of said luer tip (51).

25. A syringe (10) for use with a needle assembly (17) having a hub (18) and a needle (16, 43 and 44) slidably removable from said hub (18), a barrel (14) having a hollow interior (37), and a male luer tip (51) at a distal end of said barrel (14), said luer tip (51) including a coupling opening (50) extending therethrough, characterized by, a distal end of said luer tip (51) being expandable from a constricted position, wherein at least a distal portion of the coupling opening (50) is smaller than a portion of said needle (16, 43 and 44) attached to said barrel (14), to an expanded position, wherein the coupling opening (50) is larger than said needle (16, 43 and 44) attached to said barrel (14).

26. The syringe (10 of claim 25, further characterized by an extractor (26) moveable within said barrel (14), said extractor (26) including at a distal end (51) thereof a release face (42) to expand said luer tip (51) of said barrel (14).

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

27. The syringe (10) one of claims 25 or 26, characterized in that the expandable distal end portion of said luer tip (51) is segmented.

28. The syringe (10) of claim 25, further characterized by an extractor (26) moveable within said barrel (14), a distal tip (52) of said extractor (26) having a release face (42) smaller in diameter than said coupling opening (50) and larger in diameter than any portion of said needle (16, 43 and 44) that is removable from said hub (14) of said needle assembly (17) mounted on said barrel (14), and said extractor (26) having a needle coupling (42) at a distal end (52) thereof to connect said needle (16, 43 and 44) to said extractor (26).

29. The syringe (10) of claim 28, characterized in that said needle coupling (42) is disposed on said extractor (26) with respect to said release face (42) such that when said needle (16, 43 and 44) is coupled to said extractor (26), a portion of said needle (16, 43 and 44) that is larger than the coupling opening (50), when said luer tip (51) is in the constricted position, is sufficiently proximate said release face (42) that said expandable distal luer tip (51) will not engage any removable portion of the needle (16, 43 and 44) as the needle (16, 43 and 44) is withdrawn through the coupling opening (50).

30. The syringe (10) of claim 29, characterized in that the expandable distal end portion of said luer tip (51) is segmented.

31. A hypodermic syringe (10) including a needle (16), a barrel (14) having a generally cylindrical cavity (37) extending inward from a proximal end thereof, a needle attachment coupling (51) at a distal end thereof for attaching said needle (16) to said barrel (14), and a plunger (12) mounted to slide within said cavity (37), including a

This is the replacement sheet

* C L M S *

Date: 28 OCT 1996

This Sheet Has Been Replaced

slide (22) extending outward from said cavity (37), a piston (28) forming a sealing engagement with said cavity (37), characterized by said needle attachment coupling (20, 51) including an attachment portion (20), a coupling opening (50) extending from said cavity (37), and a releasable abutment (51); a needle hub (18) including a mating portion (46) attached to said attachment portion (20) of said needle attachment coupling (20, 51), a proximal abutment surface (45), and a needle receiving hole (45a) extending therethrough from said proximal abutment surface (45) to a distal end of said hub (18); a needle subassembly (16, 43, 44) including said needle (16) and a needle flange (44) mounted between a distal portion of said needle (16) and a proximal portion of said needle subassembly (16, 43, 44), said proximal portion of said needle subassembly (16, 43, 44) extending into said coupling opening (50), and said needle flange (43, 44) extending outward between said proximal abutment surface (45) of said needle hub (18) and said releasable abutment portion (51) of said needle attachment coupling (20, 51); and a needle extractor (26) extending from a distal end of said plunger (12), said needle extractor (26) including gripping means (42) for engaging said proximal portion of said needle subassembly (16, 43, 44) when said plunger (12) is moved to a distal end of said cavity (37), said needle extractor (26) including release means (42) for moving said releasable abutment (51) from a blocking configuration, in which motion of said needle flange (44) past said releasable abutment (51) is prevented, to a released configuration, in which motion of said needle flange (44) past said releasable abutment (51) is permitted.

32. The hypodermic syringe (10) of Claim 31 characterized in that said releasable abutment (51) includes a plurality of segments (58) arranged around said coupling opening (50), forming a restriction of said coupling opening (50) to prevent passage therethrough of said needle flange

This is the replacement sheet

* C L M S *

Date: 28 OCT 1996

This Sheet Has Been Replaced

(44); and in that a distal extractor tip (52) of said needle extractor (26) includes a tubular portion (42) having an inner surface forming said gripping means (42), and an outer surface forming said release means (42) by deflecting said segments (58) outward to permit passage of said needle flange (44) through said coupling opening (50).

33. The hypodermic syringe (10) of Claim 32 characterized in that said segments (58) are formed as integral portions of said barrel (14); in that said segments (58) are separated by slots (56) extending inward from distal surfaces of said segments (58), in a longitudinal direction along said barrel (14); and in that said segments (58) are formed to block passage of said needle flange (44) in an undeflected state.

34. The hypodermic syringe (10) of one of Claims 32 or 33 characterized in that said plunger (12) includes elastic means (31) for holding said distal extractor tip (52) disposed at an acute angle relative to a central axis of said cavity (37) in that said cavity (37) is of sufficient length to enclose said needle subassembly (16, 43, 44) when said proximal end of said needle subassembly (16, 43, 44) is held by said gripping means (42); and in that said cavity (37) includes, at a distal end, a funnel shaped surface (54) extending inward to said coupling opening (50).

35. The hypodermic syringe (10) of Claim 34 characterized in that said needle extractor (26) includes a proximal extractor surface (31) opposite said distal extractor tip (52), said proximal extractor surface (31) being inclined relative to an axis of said distal tip (52); in that said plunger (12) includes a plunger surface (30) extending perpendicularly to said central axis of said cavity (37); and in that said elastic means (28) holds said proximal extractor surface (31) against said plunger surface (30).

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

36. The hypodermic syringe (10) of Claim 35 characterized in that said needle extractor (26) further includes an extractor hub (42) and an extractor flange (31), said extractor hub (42) extending between said distal extractor tip (52) and said extractor flange (31), said proximal extractor surface (31) being formed as part of said extractor flange (31); and in that said piston (28) includes an elastic distal piston portion (28) extending around said extractor flange (31), with said extractor hub (42) extending through an aperture in said distal piston portion (28), with said distal piston portion (28) holding said proximal extractor surface (31) against said plunger surface (30).

37. The hypodermic syringe (10) of one of Claims 31, 32 or 33 characterized in that said needle flange (44) is formed as part of a collar (42a) secured in place on said needle (16); and in that a hub (43) extending from a proximal side of said needle flange (44) is additionally part of said collar (42a), said hub (43) forming said proximal portion of said needle assembly (17).

38. The hypodermic syringe (10) of one of Claims 31, 32 or 33 characterized in that said needle flange (44) is formed as part of a collar (42a) secured in place on said needle (16), with a distal portion of said needle (16) extending from a distal side of said collar (42a), and with a proximal portion of said needle (16) extending from a proximal side of said collar (42a), said proximal portion of said needle (16) forming said proximal portion of said needle assembly (16, 43, 44); and in that a hub (43) extending from a distal side of said needle flange (44) is additionally part of said collar (42a).

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

This Sheet Has Been Replaced

39. The hypodermic syringe (10) of one of Claims 31, 32, or 33 characterized in that said proximal portion of said needle subassembly (16, 43, 44) includes a ridge (64) formed to resist slippage when a tensile force is applied to said proximal portion of said needle (16).

40. The hypodermic syringe (10) of one of Claims 31, 32 or 33 characterized in that a sealant is applied within an annular space between said needle (16) and said needle hub (18).

41. The hypodermic syringe (10) of Claim 31 characterized in that said attachment portion (20) of said needle attachment coupling (20, 51) and said mating portion (46) of said needle hub (18) are engageable by relative rotation in a first direction and disengageable by relative rotation in a direction opposite said first direction; and in that said needle (16) and said needle hub (18) are together attachable and removable from a distal end of said needle attachment coupling (10, 51), from outside said barrel 14).

42. The hypodermic syringe (10) of Claim 31 further characterized by plunger travel limiting means (72, 74) for stopping outward motion of said plunger (12) beyond said distal end of said barrel (14).

43. A syringe (100) having a barrel (102) and a plunger (104) characterized by expanding means (106) radially held within said barrel (102) while said plunger (104) is positioned within said barrel (102), said expanding means (106) being expanded over an end (108) of said barrel (102) upon withdrawal after a certain distance of said plunger (104) from said barrel (102), thereby inhibiting repositioning of said plunger (104) within said barrel (102).

This is the replacement shee

* C L M S *

Date: 28 OCT 1996

This Sheet Has Been Replaced

44. The syringe (100) of claim 43 characterized by means (120) to limit the withdrawal of said plunger (104) from said barrel (102) to said certain distance.

45. The syringe (100) of claims 1, further characterized by expanding means (106) radially held within said barrel (14, 102) while said needle assembly (12 and 17, 104) is positioned within said barrel (14, 102), said expanding means (106) being expanded over a proximal end (108) of said barrel (14, 102) upon withdrawal after a certain distance of said needle assembly (12 and 17, 104) from said barrel (14, 102), thereby inhibiting re-positioning of said needle assembly (12 and 17, 104) within said barrel (14, 102).

44. The syringe (100) of claim 45 characterized by means (120) to limit the withdrawal of said needle assembly (12 and 17, 104) from said barrel (14, 102) to said certain distance.

45. The syringe of claim 1 further characterized by an extractor (26, 126) moveable within said barrel (14, 122) to be connected with said needle assembly (17, 128) and to withdraw said needle assembly (17, 128) into said barrel (14, 122), and by means (132, 134) to indicate the approaching connection between said extractor (26, 126) and needle assembly (17, 128) as said extractor (26, 126) moves towards said needle assembly (17, 128).

* C L M S *

This is the replacement sheet

Date: 28 OCT 1996

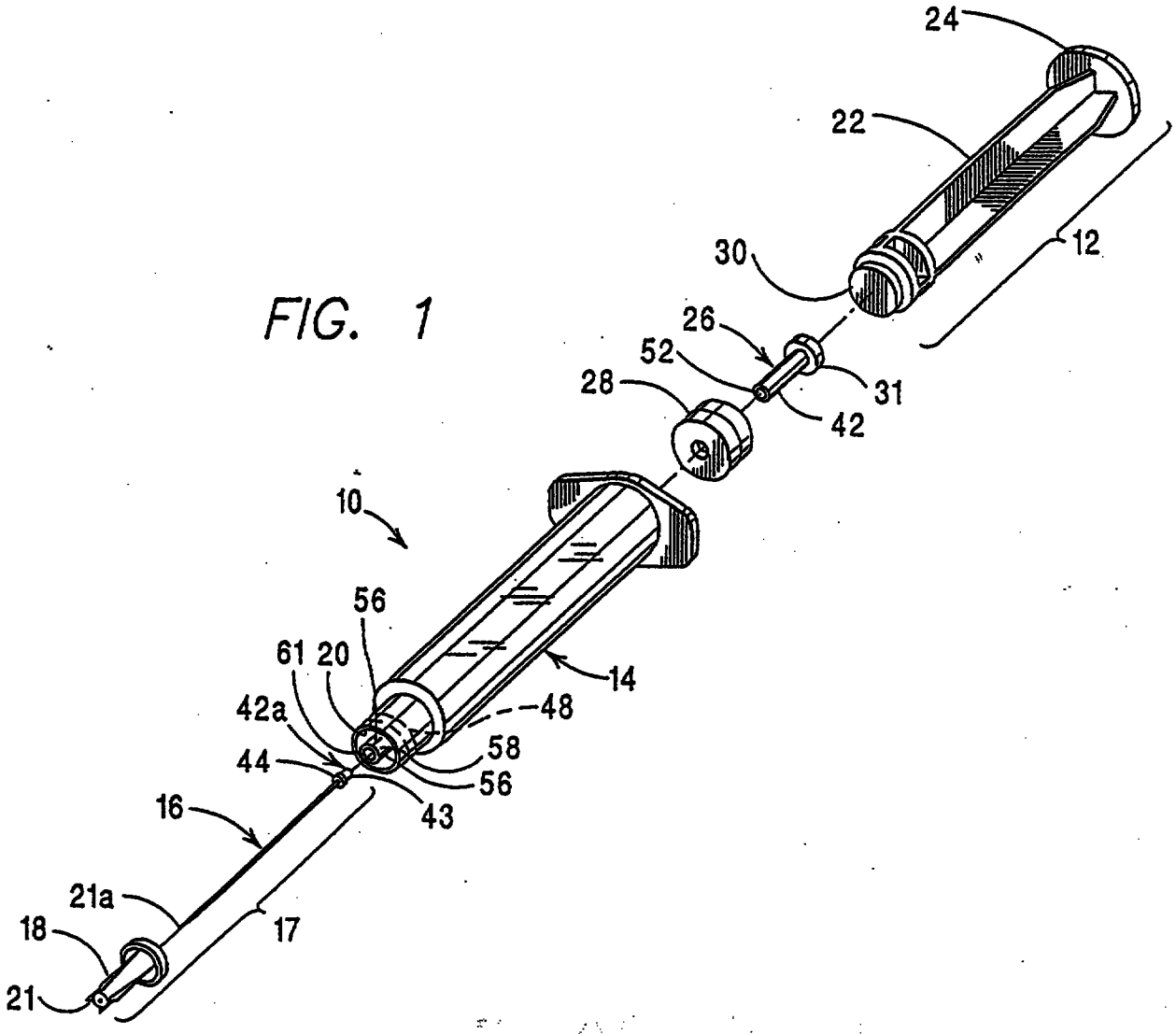


FIG. 1

This is the replacement sheet

Date: 28 OCT 1996

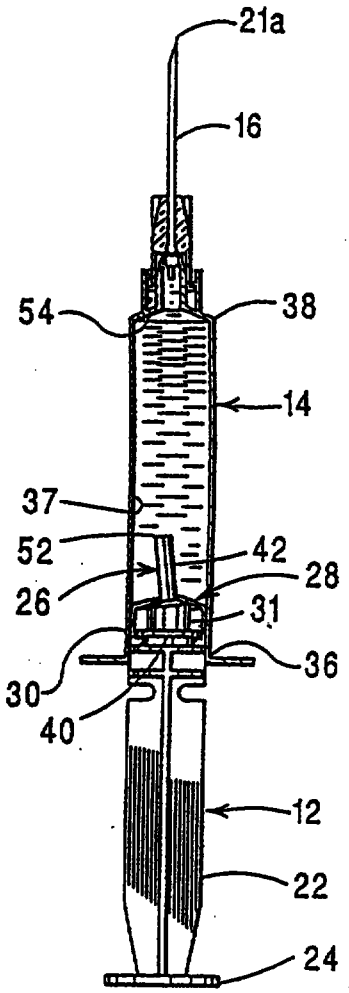


FIG. 2

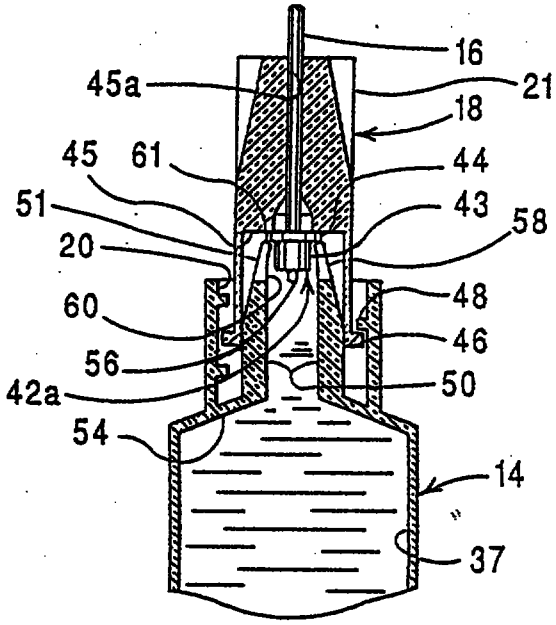


FIG. 3

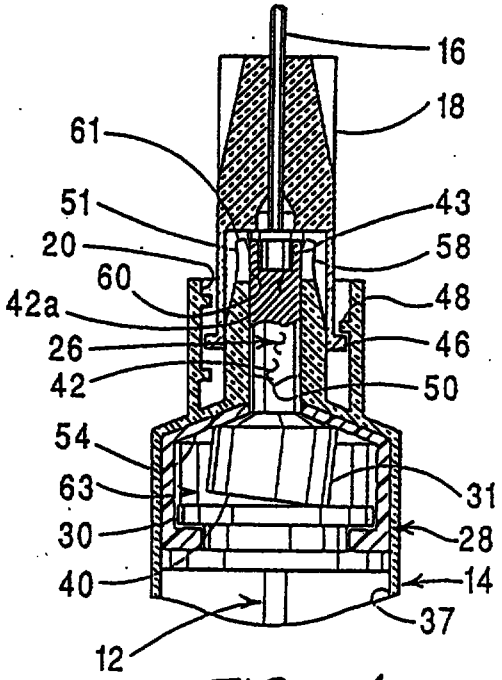


FIG. 4

This is the replacement sheet

Date: 28 OCT 1996

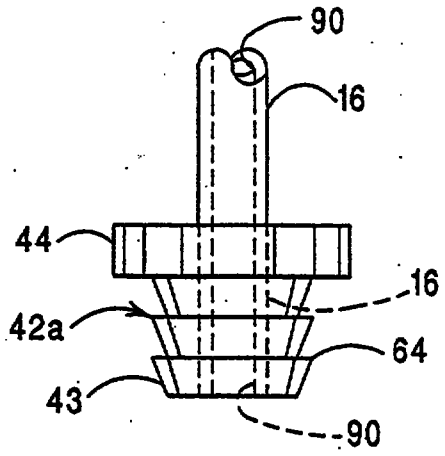
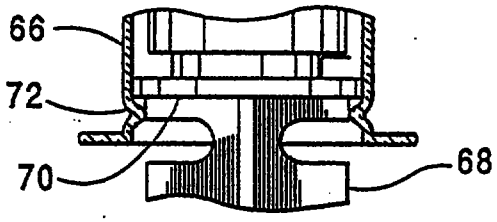


FIG. 5



PRIOR ART

FIG. 7

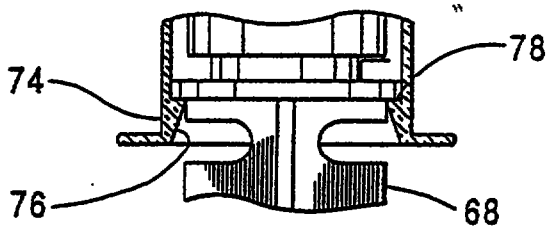


FIG. 8

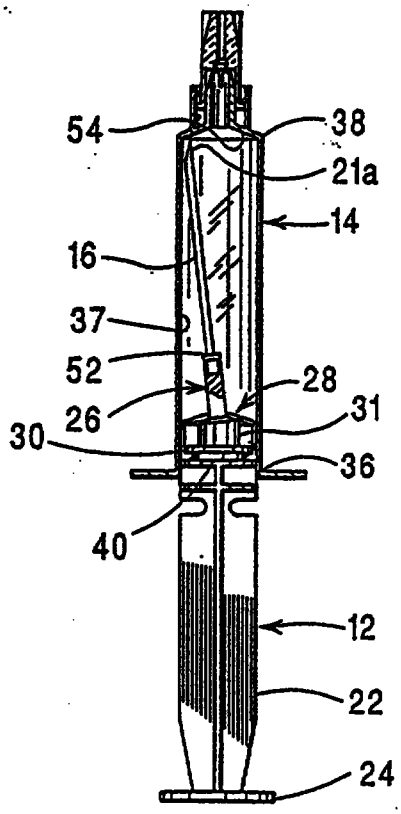


FIG. 6

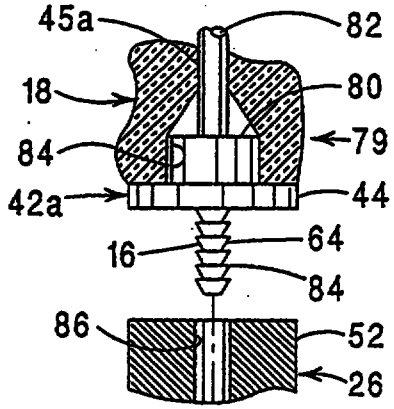


FIG. 9

This is the replacement sheet

Date: 28 OCT 1996

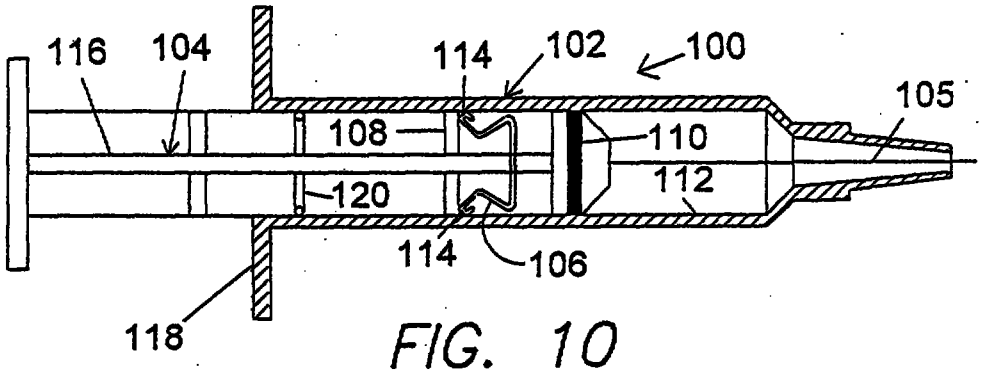


FIG. 10

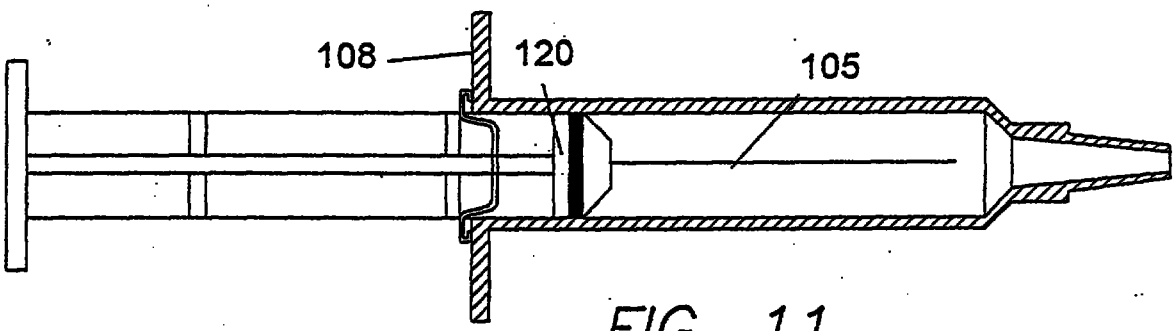


FIG. 11

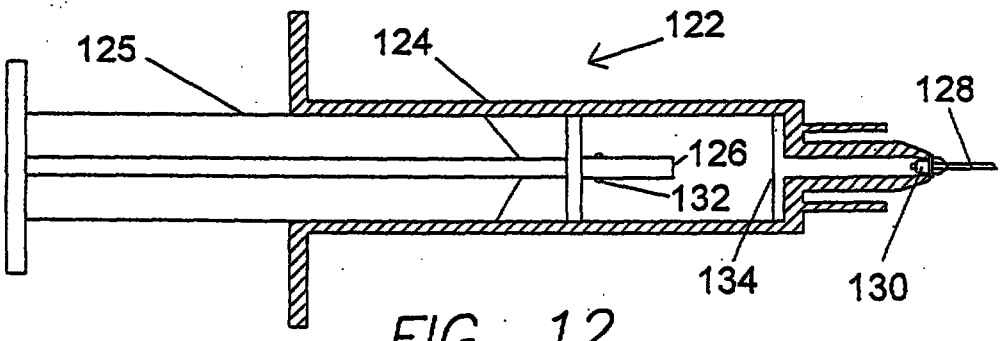


FIG. 12

This is the replacement sheet

Date: 28 OCT 1996

ABSTRACT

HYPODERMIC SYRINGE WITH NEEDLE RETRACTION FEATURE

A hypodermic syringe (10) permits a needle (16) to be fully retracted into the cylindrical cavity of the syringe barrel (14) following injection of medicine into a patient. The needle (16) is held on the distal end of the barrel (14) by an attachment hub (43), which includes an internal abutment surface to prevent outward movement of the needle (16). Inward movement of the needle (16) is prevented by an expandable restriction (51) of a distal barrel (14) opening, extending between the cylindrical cavity and the distal end of the barrel (14). Needle (16) includes a flange (44) held between the internal abutment surface of hub (43) and the expandable restriction (51). The distal end of the plunger (12) is fitted with a needle extractor (42), which, when depressed, grips the proximal end of the hub (43) and expands the expandable restriction (51) so that the needle (16) and flange (44) are pulled into the cylindrical cavity of the barrel (14) as the plunger (12) is pulled outward.

(Figure 1)

This is the replacement sheet

Date: 23 OCT 1996

CLAIMS:

1. A syringe (10) having a barrel (14) including a luer tip (51) and a needle assembly (17) detachably mounted on said luer tip (51), characterized by said needle assembly (17) including a hub (18) receiving said luer tip (51) and a needle (16) slidably positioned within said hub (18) and a flange (44) mounted on said needle (16), said flange (44) being captured between said hub (18) and said luer tip (51) to immobilize said needle assembly (17).

2. The syringe (10) of claim 1, characterized in that said luer tip (51) further includes a coupling opening (50) extending therethrough and a distal end (61) of said luer tip (51) being expandable from a constricted position, wherein at least a distal portion of the coupling opening (50) is smaller than said needle flange (44), to an expanded position, wherein the coupling opening (50) is larger than said needle flange (44).

3. The syringe of one of claims 1 or 2, further characterized by an extractor (26) moveable within said barrel (14), said extractor (26) including at a distal end thereof a needle coupling (42) to connect said needle assembly (17) to said extractor (26) and a release face (52) to expand said luer tip (51) of said barrel (14).

4. The syringe of claim 3, further characterized in that the expandable distal end portion (61) of said luer tip (51) is segmented.

5. The syringe of claim 2, further characterized by an extractor (26) moveable within said barrel (14), a distal tip of said extractor (26) having a release face (52) smaller in diameter than said coupling opening (50) and larger in diameter than said flange (44), and a needle coupling (42) at a distal end of said extractor (26) to connect said needle assembly (17) to said extractor (26).

REPLACEMENT SHEETS SG
☐ Description : paged ..... to paged .....
☑ Claim(s) : paged 23 to paged 23
☐ Drawing(s) : paged ..... to paged .....
☐ Abstract : paged ..... to paged .....
DATE OF RECEIPT 20/11/98
This is the replacement sheet
Date: 20 NOV 1998

* C L M S *

6. The syringe of claim 5, further characterized in that said needle coupling (42) is disposed on said extractor (26) with respect to said release face (52) such that when said needle assembly (17) is coupled to said extractor (26), said needle flange (44) is sufficiently distant from said expandable distal end (61) of said luer tip (51) that said expandable distal end (61) will not engage said flange (44) as said needle assembly (17) is withdrawn through the coupling opening (50).

8. The syringe of claim 6, further characterized in that the expandable distal end (61) of said luer tip (51) is segmented.

9. A syringe and detachable needle assembly combination (10) having a barrel (14) including a luer tip (51) and an internally threaded locking skirt (20) around said luer tip (51), a needle assembly (17) including a hub (18) and a needle (16), said hub (18) including a distal end, an open proximal end receiving said luer tip (51) and locking ears (46) extending outwardly from said hub (18) to engage internal threads (48) of said locking skirt (20) to detachably lock said hub (18) to said barrel (14), characterized by a coupling opening (50) extending to a radially expandable distal end (61) of said luer tip (51) and said needle (16) having a flange (43, 44) mounted thereon, said needle (16) being slidably positioned through the distal end of said hub (18) with said flange (43, 44) being captured between said hub (18) and said luer tip (51) to immobilize said needle (16) against axial movement.

10. The syringe and needle assembly combination (10) of Claim 9 further characterized by said expandable distal end (61) of said luer tip (51) having a constricted position wherein the diameter of the coupling opening (50) is smaller than the diameter of said flange (43, 44) and an expanded position wherein the diameter of the coupling opening (50) is larger than the diameter of said flange (43, 44), and by an extractor (26) moveable within said barrel (14), said extractor (26) including, at a distal end thereof, a needle coupling

(42) to connect said needle flange (43, 44) to said extractor (26) and a release face (52) to expand said luer tip (51) of said barrel (14) to said expanded position when said needle flange (43, 44) is coupled to said extractor (26).

11. A needle assembly (17), for use with a medical device (10) having a luer end (50) for sealable, detachable connection to said needle assembly (17), having a hub (18) including a needle passage (45a) extending from a distal end thereof and a luer tip passage (46) extending from a proximal end thereof, said hub (18) having a proximal abutment (45) within the luer tip passage (46), characterized by a needle (16, 44) including a flange (44), said needle (16, 44) being slidably positioned through the needle passage (45a) of said hub (18) with said flange (44) abutted against said proximal abutment (45) of said hub (18).

12. The needle assembly (17) of Claim 11 further characterized by said needle (16, 44) having a coupling (43) thereon for connection to an extractor (26) of said medical device (lO) adapted to pull said needle (16, 44) from the needle passage (45a) of said hub (18).

13. The needle assembly (17) of Claim 11 further being characterized in that said luer tip passage (46) of said hub (18) is configured to position said flange (44) between said abutment (45) of said hub (18) and the distal end of the luer end (50) of a medical device (10) to which said needle assembly (17) can be attached.

14. The needle assembly (17) of one of Claims 11, 12 or 13 further characterized in that said abutment (45) of said hub (18) is positioned in the luer tip passage of said hub (18) such that when said needle assembly (17) is connected to the luer tip passage (46) of said medical device (lO), said flange (44) is captured between said abutment (45) of said hub (18) and the distal end of the luer end (50) of said medical.device (lO).

* C L M S *

This is the replacement sheet

Date: 20 NOV 1998

15. The needle assembly (17) of one of Claims 11, 12 or 13 further characterized in that sealant is within at least a portion of the needle passage (45a) of said hub (18) about said needle (16).

16. A needle assembly (17) for use with a medical device (10) having a luer tip (51) and an internally threaded locking skirt (20) around the luer tip (51) for sealable, detachable locked connection of said needle assembly (17) to said medical device (lO), said needle assembly (17) having a hub (18) including locking ears (46) on the outside of said hub (18) configured to engage internal threads (48) of the locking skirt (20) of the medical device (lO) to which said hub (18) may be connected, a needle passage (45a) axially extending from a distal end of said hub (18), a luer tip passage axially extending from a proximal end of said hub (18) configured to receive the luer tip (51) of said medical device (lO), and a proximally facing abutment surface (45) at the distal end of the luer tip passage, characterized by said needle assembly (17) including a flange (44) and a needle (16), said needle (16) being slidably positioned through the needle passage (45a) of said hub (18) with said flange (44) abutted against said abutment surface (45) of said hub (18).

17. The needle assembly (17) of Claim 16, characterized in that said needle (16) has a coupling (43) thereon for connection to an extractor (26) of the medical device (10) adapted to pull said needle (16) from the needle passage (45a) of said hub (18).

18. The needle assembly (17) of Claim 16, characterized in that said luer tip passage of said hub (18) includes a female luer taper.

19. The needle assembly (17) of one of Claims 16, 17 or 18 characterized in that said luer tip passage of said hub (18) is configured to position said flange (44) between said abutment surface (45) of said hub (18) and a distal end (61)

of the luer tip (51) of the medical device (10) to which said needle assembly (17) may be attached.

20. The needle assembly (17) of one of Claims 16, 17 or 18 characterized in that said abutment surface (45) of said hub (18) is positioned in the luer tip passage of said hub (18) such that when said needle assembly (17) is connected to the luer tip (51) of the medical device (10), said flange (44) is captured between said abutment surface (45) of said hub (18) and a distal end (61) of the luer tip (51) of the medical device (10).

21. The needle assembly (17) of one of Claims 16, 17 or 18 characterized by sealant within at least a portion of the needle passage (45a) of said hub (18) about said needle (16).

22. A syringe (lO) having a barrel (14) with a hollow interior (37) and a male luer tip (51) at a distal end of said barrel (14), said luer tip including a coupling opening (50) extending therethrough, characterized by a distal end (61) of said luer tip (51) being expandable from a constricted position wherein at least a distal portion of the coupling opening (50) is smaller than a desired size to an expanded position wherein the coupling opening (50) is larger than the desired size.

23. The syringe (10) of claim 22, characterized in that the expandable distal end (61) of said luer tip (51) is segmented.

24. The syringe (10) of one of claims 22 or 23, characterized by an extractor (26) moveable within said barrel (14), a distal tip (52) of said extractor (26) having a release face (42) smaller in diameter than said coupling opening (50) in the expanded position of said luer tip (51) and larger in diameter than said coupling opening (50) in the constricted position of said luer tip (51).

* C L M S *

This is the replacement sheet

Date: 20 NOV 1998

25. A syringe (lO) for use with a needle assembly (17) having a hub (18) and a needle (16, 43 and 44) slidably removable from said hub (18), a barrel (14) having a hollow interior (37), and a male luer tip (51) at a distal end of said barrel (14), said luer tip (51) including a coupling opening (50) extending therethrough, characterized by a distal end of said luer tip (51) being expandable from a constricted position, wherein at least a distal portion of the coupling opening (50) is smaller than a portion of said needle (16, 43 and 44) attached to said barrel (14), to an expanded position, wherein the coupling opening (50) is larger than said needle (16, 43 and 44) attached to said barrel (14).

26. The syringe (lO) of claim 25, further characterized by an extractor (26) moveable within said barrel (14), said extractor (26) including at a distal end (52) thereof a release face (42) to expand said luer tip (51) of said barrel (14).

27. The syringe (10) of one of claims 25 or 26, characterized in that the expandable distal end of said luer tip (51) is segmented.

28. The syringe (10) of claim 25, further characterized by an extractor (26) moveable within said barrel (14), a distal tip (52) of said extractor (26) having a release face (42) smaller in diameter than said coupling opening (50) and larger in diameter than any portion of said needle (16, 43 and 44) and a needle coupling (42) at said distal tip (52) to connect said needle (16, 43 and 44) to said extractor (26).

29. The syringe (10) of claim 28, characterized in that said needle coupling (42) is disposed on said extractor (26) with respect to said release face (42) such that when said needle (16, 43 and 44) is coupled to said extractor (26), a portion of said needle (16, 43 and 44) that is larger than the coupling opening (50), when said luer tip (51) is in the constricted position, is sufficiently proximate said release face (42) that said expandable distal end of said luer tip

* C L M S *

This is the replacement sheet

Date: 20 NOV 1998

(51) will not engage any removable portion of the needle (16, 43 and 44) as the needle (16, 43 and 44) is withdrawn through the coupling opening (50).

30. The syringe (10) of claim 29, characterized in that the expandable distal end of said luer tip (51) is segmented.

31. The syringe (10) of claim 1, further characterized in that said barrel (14) has a generally cylindrical cavity (37) extending inward from a proximal end thereof, and said luer tip (51) and an attachment portion (20) define a needle attachment coupling (20, 51) at a distal end of said barrel (14) for attaching said needle (16) to said barrel (14); said needle attachment coupling (20, 51) including a coupling opening (50) extending from said cavity (37); said luer tip (51) defining a releasable abutment (51); said needle hub (18) including a mating portion (46) attached to said attachment portion (20) of said needle attachment coupling (20, 51), a proximal abutment surface (45), and a needle receiving hole (45a) extending therethrough from said proximal abutment surface (45) to a distal end of said hub (18); said needle (16) and said needle flange (44) defining a needle subassembly (16, 44); said needle flange (44) being mounted between a distal portion of said needle (16) and a proximal portion of said needle subassembly (16, 44), said proximal portion of said needle subassembly (16, 44) extending into said coupling opening (50), and said needle flange (44) extending outward between said proximal abutment surface (45) of said needle hub (18) and said releasable abutment portion (51) of said needle attachment coupling (20, 51); and by: a plunger (12) mounted to slide within said cavity (37), including a slide (22) extending outward from said cavity (37), a piston (28) forming a sealing engagement with said cavity (37), a needle extractor (26) extending from a distal end of said plunger (12), said needle extractor (26) including gripping means (42) for engaging said proximal portion of said needle subassembly (16, 44) when said plunger (12) is moved to a distal end of said cavity (37), said needle extractor (26) including release means (42) for moving said releasable abutment (51) from a

This is the replacement sheet

* C L M S *

Date: 20 NOV 1998

blocking configuration, in which motion of said needle flange (44) past said releasable abutment (51) is prevented, to a released configuration, in which motion of said needle flange (44) past said releasable abutment (51) is permitted.

32. The syringe (10) of Claim 31 characterized in that said releasable abutment (51) includes a plurality of segments (58) arranged around said coupling opening (50), forming a restriction of said coupling opening (50) to prevent passage therethrough of said needle flange (44); and in that a distal extractor tip (52) of said needle extractor (26) includes a tubular portion (42) having an inner surface forming said gripping means (42), and an outer surface forming said release means (42) by deflecting said segments (58) outward to permit passage of said needle flange (44) through said coupling opening (50).

33. The syringe (10) of Claim 32 characterized in that said segments (58) are formed as integral portions of said barrel (14); in that said segments (58) are separated by slots (56) extending inward from distal surfaces of said segments (58), in a longitudinal direction along said barrel (14); and in that said segments (58) are formed to block passage of said needle flange (44) in an undeflected state.

34. The syringe (10) of one of Claims 32 or 33 characterized in that said plunger (12) includes elastic means (31) for holding said distal extractor tip (52) disposed at an acute angle relative to a central axis of said cavity (37); in that said cavity (37) is of sufficient length to enclose said needle subassembly (16, 44) when said proximal end of said needle subassembly (16, 44) is held by said gripping means (42); and in that said cavity (37) includes, at a distal end, a funnel shaped surface (54) extending inward to said coupling opening (50).

35. The syringe (10) of Claim 34 characterized in that said needle extractor (26) includes a proximal extractor surface (31) defined by said elastic means (31) opposite said distal extractor tip (52), said proximal extractor surface (31) being inclined relative to an axis of said distal tip (52); in that said plunger (12) includes a plunger surface (30) extending perpendicularly to said central axis of said cavity (37); and in that said elastic means (31) holds said proximal extractor surface (31) against said plunger surface (30).

36. The syringe (10) of Claim 35 characterized in that said needle extractor (26) further includes an extractor hub (42) defined by said gripping means (42) and an extractor flange (31) defined by said elastic means (31), said extractor hub (42) extending between said distal extractor tip (52) and said extractor flange (31), said proximal extractor surface (31) being formed as part of said extractor flange (31); and in that said piston (28) includes an elastic distal piston portion (28) extending around said extractor flange (31), with said extractor hub (42) extending through an aperture in said distal piston portion (28), with said distal piston portion (28) holding said proximal extractor surface (31) against said plunger surface (30).

37. The syringe (10) of one of Claims 31, 32 or 33 characterized in that said needle flange (44) is formed as part of a collar (42a) secured in place on said needle (16); and in that a hub (43) extending from a proximal side of said needle flange (44) is additionally part of said collar (42a), said hub (43) forming said proximal portion of said needle assembly (17).

38. The syringe (10) of one of Claims 31, 32 or 33 characterized in that said needle flange (44) is formed as part of a collar (42a) secured in place on said needle (16), with a distal portion of said needle (16) extending from a distal side of said collar (42a), and with a proximal portion of said needle (16) extending from a proximal side of said collar (42a), said proximal portion of said needle (16) forming said proximal portion of said needle subassembly

* C L M S *

This is the replacement sheet

Date: 20 NOV 1998

(16, 44); and in that a hub (43) extending from a distal side of said needle flange (44) is additionally part of said collar (42a).

39. The syringe (10) of one of Claims 31, 32, or 33 characterized in that said proximal portion of said needle subassembly (16, 44) includes a ridge (64) formed to resist slippage when a tensile force is applied to said proximal portion of said needle (16).

40. The syringe (10) of one of Claims 31, 32 or 33 characterized in that a sealant is applied within an annular space between said needle (16) and said needle hub (18).

41. The syringe (10) of Claim 31 characterized in that said attachment portion (20) of said needle attachment coupling (20, 51) and said mating portion (46) of said needle hub (18) are engageable by relative rotation in a first direction and disengageable by relative rotation in a direction opposite said first direction; and in that said needle (16) and said needle hub (18) are together attachable and removable from a distal end of said needle attachment coupling (20, 51), from outside said barrel (14).

42. The syringe (10) of Claim 31 further characterized by plunger travel limiting means (72, 74) for stopping outward motion of said plunger (12) beyond said distal end of said barrel (14).

43. The syringe (100) of claim 1, further characterized by expanding means (106) radially held within said barrel (14, 102) while said needle assembly (12 and 17, 104) is positioned within said barrel (14, 102), said expanding means (106) being expanded over a proximal end (108) of said barrel (14, 102) upon withdrawal after a certain distance of said needle assembly (12 and 17, 104) from said barrel (14, 102), thereby inhibiting re-positioning of said needle assembly (12 and 17, 104) within said barrel (14, 102).

This is the replacement sheet

* C L M S *

Date: 20 NOV 1998

44. The syringe (100) of claim 43 characterized by means (120) to limit the withdrawal of said needle assembly (12 and 17, 104) from said barrel (14, 102) to said certain distance.

45. The syringe of claim 1 further characterized by an extractor (26, 126) moveable within said barrel (14, 122) to be connected with said needle assembly (17, 128) and to withdraw said needle assembly (17, 128) into said barrel (14, 122), and by means (132, 134) to indicate the approaching connection between said extractor (26, 126) and needle assembly (17, 128) as said extractor (26, 126) moves towards said needle assembly (17, 128).

* C L M S *

This is the replacement sheet

Date: 20 NOV 1998