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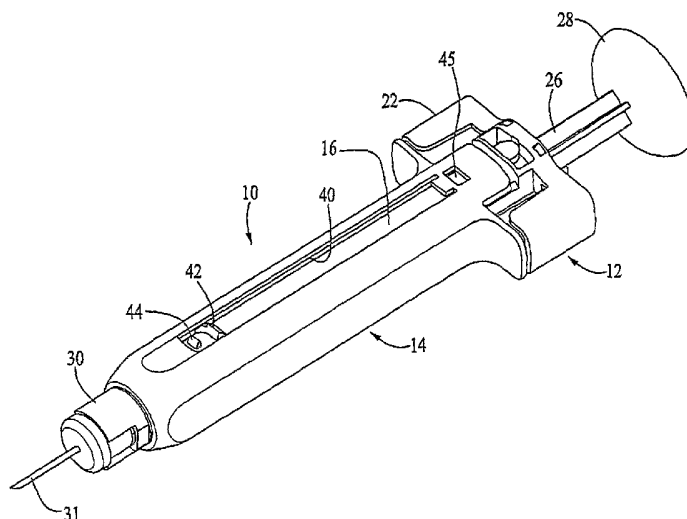
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

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[Continued on next page]

(54) Title: INJECTION DEVICE COMPRISING A SYRINGE WITH NEEDLE GUARD



(57) Abstract: The present invention provides an injection device including a syringe (12) having a distal end for receiving a needle, and a plunger inserted into the proximal end. A guard (14) is slidable on the syringe, has a proximal end, a distal end, and is biased from a first position wherein the needle is exposed toward a second position wherein the guard covers the needle. The syringe includes a body having a central cylindrical opening for receiving medicine and the plunger, and further includes a pair of longitudinally extending members (18) on opposite sides of the body. The guard has an interior configuration for mating with the longitudinal members and sliding thereon.



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FIELD OF THE INVENTION

The present invention relates generally to injection devices for administering therapeutic agents to patients, particularly to safety devices for syringes, and more particularly to syringe devices that include a needle guard slidably coupled to a syringe for covering a
5 needle of the syringe after use.

BACKGROUND

Medication is often dispensed using a medicine cartridge, such as a syringe, having a barrel with a needle extending from one end and a plunger slidably inserted into the other end.
10 Such cartridges are often referred to as "pre-filled syringes" because they may contain a specific dosage or volume of medication when they are initially provided, as compared to conventional syringes that are furnished empty and filled by the user before making an injection.

Alternatively, a medicine cartridge may be used, such as an ampoule or vial, that
15 includes a penetrable seal instead of a needle on one end of the barrel, and/or a piston rather than a plunger on the other end. Such medicine cartridges are generally inserted into an adapter that includes a hollow body adapted to hold the cartridge, a plunger to engage and move the piston in the cartridge, and a double-ended needle to penetrate the seal and communicate with the interior of the barrel.

Because of the risk of communicable diseases, a number of syringes and adapters have
20 been developed that are intended to prevent accidental needle sticks and/or inadvertent reuse of a syringe. Retractable needle devices have been suggested for this purpose that include a cartridge that allows a needle of the cartridge to be withdrawn into the barrel after medication is dispensed from it. For example, U.S. Patent No. 4,973,316 discloses a syringe including a
25 barrel having a needle assembly that is slidable within the barrel between an exposed position such that a needle on the assembly extends from the barrel and a retracted position wherein the needle assembly is withdrawn into the barrel. The needle assembly is initially locked in the exposed position, but may be disengaged upon depression of the plunger, whereupon a spring biases the assembly towards the retracted position, thereby withdrawing the needle into the
30 barrel.

Alternatively, syringe holders have been suggested that include a body within which a conventional syringe or cartridge may be received, and a shield that is manually slidable with respect to the body to cover the needle. For example, U.S. Patent No. 6,030,366 which is assigned to the assignee of the present application, discloses a self-shielding guard that

includes a body having an open proximal end for inserting a syringe into a cavity within the body, and a distal end with an opening through which a needle on the syringe may extend once received in the body. A shield is slidable over the body between retracted and extended positions to expose and cover the needle, respectively. With the shield in the retracted position and the needle exposed, an injection may be made, and then the shield may be manually advanced to the extended position. In the extended position, cooperating detents and detent pockets on the body and shield substantially permanently lock together, thereby preventing reuse of the needle, reducing the risk of accidental needle sticks, and/or facilitating disposal of the syringe.

As an alternative to requiring manual extension of a shield to cover a needle, spring-loaded devices have also been developed. These devices often include a body and slidable shield, similar to the manual devices described above, but also may include a spring element to bias the shield to advance and cover the needle. An actuator, such as a button or lever, may be activated by the user to release the shield, thereby allowing the spring element to advance the shield to cover the needle. For example, U.S. Patent No. 5,695,475 and U.S. Patent No. 4,923,447 disclose spring-loaded syringe devices that include inner and outer sliding sleeves that include a button slidable in a longitudinal slot to selectively expose and cover a needle on the devices. A spring in the devices biases one of the sleeves to extend and cover the needle, but this bias may be manually overcome to expose the needle. Thus, these devices may not lock the extending sleeve in a covered position, and therefore may risk accidental needle exposure and/or reuse of the needle. In addition, although these devices are spring-driven, their shields may not extend unless they are manually activated by using a button, and therefore are not truly "passive," but require an affirmative decision by a user to activate their safety feature.

Improved automatic syringe and guard assemblies have been developed comprising a body for receiving a syringe, and a guard or shield slideably disposed on the body, and further including detents for maintaining the shield in a first position in which a needle of the syringe is exposed for use, and in a second position covering the needle after use. A suitable spring is disposed between the body and guard to bias the guard and body to the second position. Several examples are Patent Number 6,623,459 and 6,613,022.

SUMMARY OF THE INVENTION

The present invention is directed to injection devices incorporating both a syringe, such as a pre-filled syringe, or a medicine cartridge, and a guard that covers a needle of the syringe after a medication in the syringe is injected into a patient. More particularly, the present

invention is directed to a syringe design which requires no separate body, and a guard disposed on the syringe, and wherein the syringe and guard are each formed of one piece from plastic. The guard includes one or more latch members forming a detent or detents for retaining the guard in a position on the syringe for exposing a needle of the syringe, and wherein the detent or detents may be released upon predetermined depression of a plunger of the syringe to cause the needle of the syringe to be covered by the guard.

In accordance with one aspect of the present invention, an injection device is provided that includes a syringe having a proximal end, a distal end, and a plunger extending from the proximal end. The injection device also includes a guard having a proximal end, a distal end, and a cavity therebetween. The guard is slidably mounted onto the syringe, and includes a latch member that extends proximally from the guard. A needle may extend from the distal end of the syringe. The guard is biased from a first or retracted position wherein the needle of the syringe is exposed, toward a second or extended position wherein the guard covers the needle. The guard may be biased by a spring element between the syringe and guard, such as located in the distal portion of the guard between the guard and the syringe.

First cooperating detents on the syringe and the guard act to retain the guard in the first position. The first cooperating detents preferably include a ledge on the proximal end of the syringe and a catch on a latch member extending from the guard. Here, the ledge and catch engage one another to retain the guard in the first position. As the plunger is advanced within the syringe, the plunger engages the latch member and releases the first cooperating detents, whereupon the guard slides toward the second position. Second cooperating detents are provided on the syringe and guard to retain the guard in the second position. The second cooperating detents preferably include a detent pocket on the guard and a corresponding tab on the syringe.

More particularly, the syringe comprises a central body having a cylindrical opening for containing medicine and a plunger, and one or more elongated rectangular members or rails disposed on opposite sides of the body and which rails are configured to fit and slide within the guard. The proximal end of the syringe can include suitable gripping surfaces, and the distal end includes a hub to which a needle may be attached such as by threads or a luer lock.

Optionally, the guard may also include a window or slot that extends axially along the guard. When the slot is present on the guard, the syringe may include a stop tab configured to travel within the slot. The stop tab and slot may be configured to limit the proximal and distal movement of the syringe relative to the guard. For example, the stop tab may abut the distal edge of the window when the guard is in the first position to prevent further distal movement

of the syringe (or proximal movement of the guard). Similarly, the stop tab may abut the proximal edge of the window when the guard is in the second position to prevent further proximal movement of the syringe (or distal movement of the guard). In addition, the guard may also include a set of finger flanges or grips usable for controlling the movement and speed of advancement or sliding of the guard between the first and second positions with respect to the syringe.

Other advantages and features of the present invention will become apparent from consideration of the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a syringe and guard of the present invention with the guard in a retracted position exposing a needle of the syringe.

Figure 2 is another perspective view, but illustrating the guard in an extended position with respect to the syringe for covering the needle thereof.

Figure 3a is a prospective view of the syringe.

Figure 3b is a top plan view of the syringe.

Figure 3c is a side elevational view.

Figure 3d is a cross-sectional view taken along line 3d-3d of Figure 3c.

Figure 3e is a proximal end view of the syringe.

Figure 4a is a top plan view of the guard.

Figure 4b is a side elevational view.

Figure 4c is a cross-sectional view taken along a line 4c-4c of Figure 4b.

Figure 4d is an enlarged proximal end elevational view.

DETAIL DESCRIPTION

Turning now to the drawings, and first to Figures 1 and 2, a syringe and guard assembly 10 is illustrated and comprises a syringe 12 and guard 14. The syringe 12 includes a central body 16 which is a hollow cylinder on the inside and may be cylindrical on the outside as seen in Figure 2. The syringe 12 includes a pair of longitudinally extending members or rails 18 which are integrally formed on opposite sides of the body 16 as seen in Figure 2. The proximal end of the syringe 12 includes a gripping member 22. The syringe 12 further includes a conventional plunger 26 with a thumb pad 28. The plunger 26 includes the usual flexible or rubber piston (not shown) on the distal end thereof which slides within the smooth wall interior cylindrical surface of the barrel 16 to dispense medication from the distal end 30 of the syringe

12 through a needle. A needle 31 is attached to the distal end 30. Tab or stop 44 limits distal movement.

The guard 14 is configured to slide between the retracted position shown in Figure 1 and the extended position shown in Figure 2, and has elongated rectangular interior sides, only side 36 being seen in Figure 2, to appropriately mate with the elongated rails 18 of the syringe 12. The guard 14 includes finger grips 38, and preferably includes a window 40 within which a tab 42 from the barrel 16 of the syringe 12 forming a detent may lie. The tab 42 on the syringe limits distal motion of the guard 14 as best seen in Figure 2. The guard includes a cross-member 43 defining a slot 45. When the guard is in the fully extended position as seen in Figure 2, the tab 42 of the syringe snaps into the slot 45 to maintain the guard and syringe in the needle protected position seen in Figure 2.

Reference is now made to the drawings of the syringe and guard in Figs. 3 and 4. The guard 14 further includes one or more latches 48 having respective flanges or catches 50 forming detents on the proximal end of the guard 14 for engaging cooperating detent surfaces or ledges in the proximal end of the syringe as described below. Turning to Fig. 3c, the proximal end of the syringe 12 is illustrated particularly showing slots 56 on opposite sides of the barrel 16 into which the arms of the latches 48 can rest with the flanges 50 hooked on the rear proximal surface 58 of the proximal end of the syringe 12 when the guard 14 is fully retracted onto the syringe 12 as seen in Figure 1. The flanges 50 of the latches 48 have inwardly extending fingers 62 (see Figs. 4a & 4d) which extend further proximally and are engageable by a rounded outer surface of the thumb pad 28 as the plunger approaches its far distal position in dispensing medicine. By the pad 28 engaging the fingers 62, the latches 48 are deflected outwardly, thereby releasing the flanges 50 from the surface 58 and out of the slots 56 to allow the guard 14 to automatically move to the extended position with respect to the syringe as seen in Figure 2 under the bias of a coil spring which is described below.

Turning more specifically to the syringe Figures 3a-3e, the same show the structure of the syringe in more detail, particularly the tab 42, stop 44, and slots 56 which the arms of latches 48 (Fig. 4) hook on as seen in Figures 4a and 4d. At the proximal end of the syringe, these slots 56 allow the latches 48 to move inwardly so that the flanges 50 can readily hook on the rear proximal surface 58 of the proximal end of the syringe 12 when the guard 14 is fully retracted onto the syringe as seen in Figure 1.

After an injection is made, the guard and syringe move, preferably via spring action from a spring (not shown) between the distal ends of the syringe and guard, to the relative positions shown in Figure 2. The tab 42 locks in the slot 45 to fully lock the guard 14 in the

position covering the needle of the syringe. Stop 44 and cross member 43 limit the distal movement.

While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail.

- 5 It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

WHAT IS CLAIMED IS

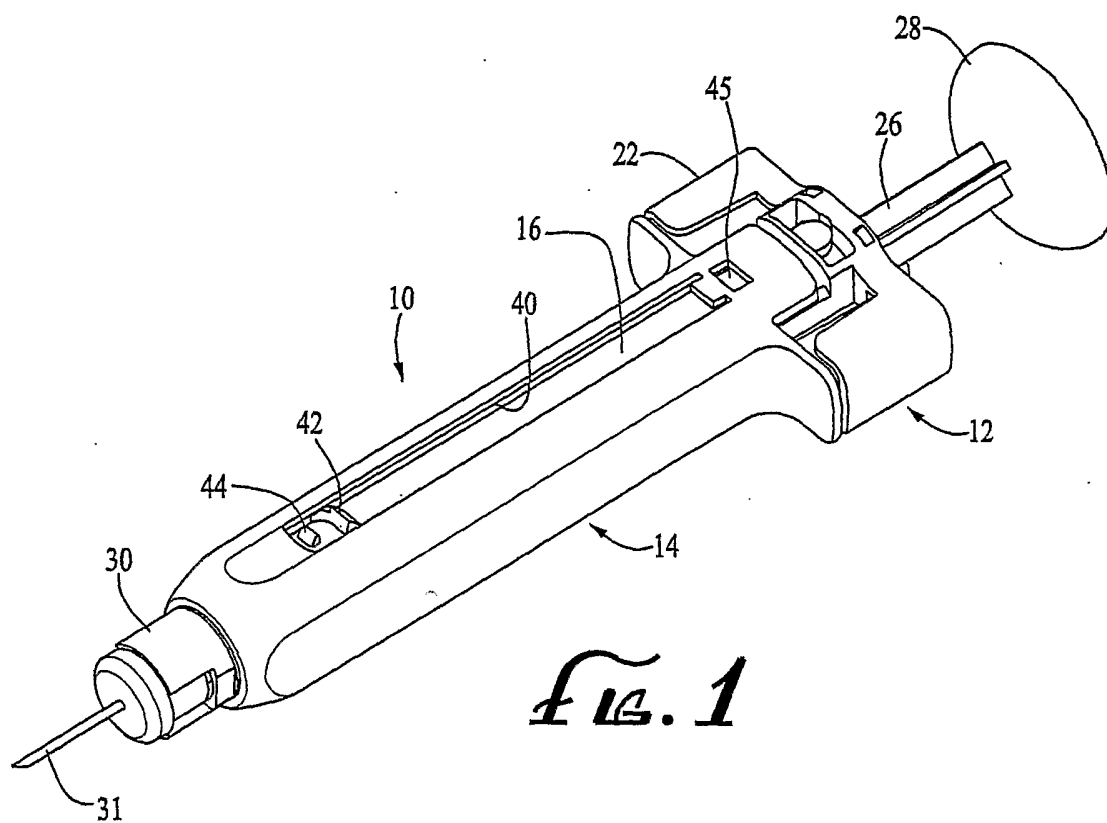
1. An injection device, comprising:
 - a plastic syringe comprising a proximal end, a distal end, and a plunger extending from the proximal end, the syringe comprising a body having a hollow cylindrical interior for receiving medicine and the plunger, and a pair of longitudinal members on opposite sides of the body,
 - a plastic guard slidably attached to the syringe and having a proximal end and a distal end, the guard being biased from a first position wherein the distal end of the syringe is exposed toward a second position wherein the guard covers the distal end of the syringe, the guard having an interior configuration for mating with the longitudinal members of the syringe and being slideable thereon,
 - cooperating detents on the syringe and guard for retaining the guard in the first position and in the second position, and
 - a latch member extending proximally from the guard, the latch member being engageable by the plunger as the plunger is advanced into the syringe for releasing cooperating detents of the syringe and guard whereupon the guard may slide toward the second position.
2. The device of claim 1, further comprising a spring coupled to the guard and the syringe for biasing the guard toward the second position.
3. The device of claim 1, wherein the guard further comprises a window extending along the guard, and wherein the syringe further comprises a tab configured to travel within the window.
4. The device of claim 3, wherein the guard includes an opening forming a pocket in the proximal end thereof separated from the window, and wherein the tab of the syringe engages the opening when the guard is in the second position, the tab and pocket at least partially comprising second cooperating detents.
5. The device of claim 4, wherein the tab and a proximal edge of the window prevent the guard from advancing distally beyond the second position.
6. The device of claim 4, wherein the tab and a distal edge prevent the guard from moving proximally beyond the second position.
7. The device of claim 1, wherein the first cooperating detents comprise a ledge on the proximal end of the syringe and a catch on the latch member, and wherein the guard is retained in the first position when the catch engages the ledge.
8. The device of claim 7, wherein the latch member further comprises a proximal

finger for engaging the plunger, and the finger is located distally from the proximal end of the latch member.

9. The device of claim 1, wherein second cooperating detents comprise a pocket on the guard and tab on the syringe for preventing the guard from being moved from the second position toward the first position.

10. The device of claim 1, wherein the guard further comprises a set of finger flanges for facilitating controlling movement of the guard from the first position toward the second position.

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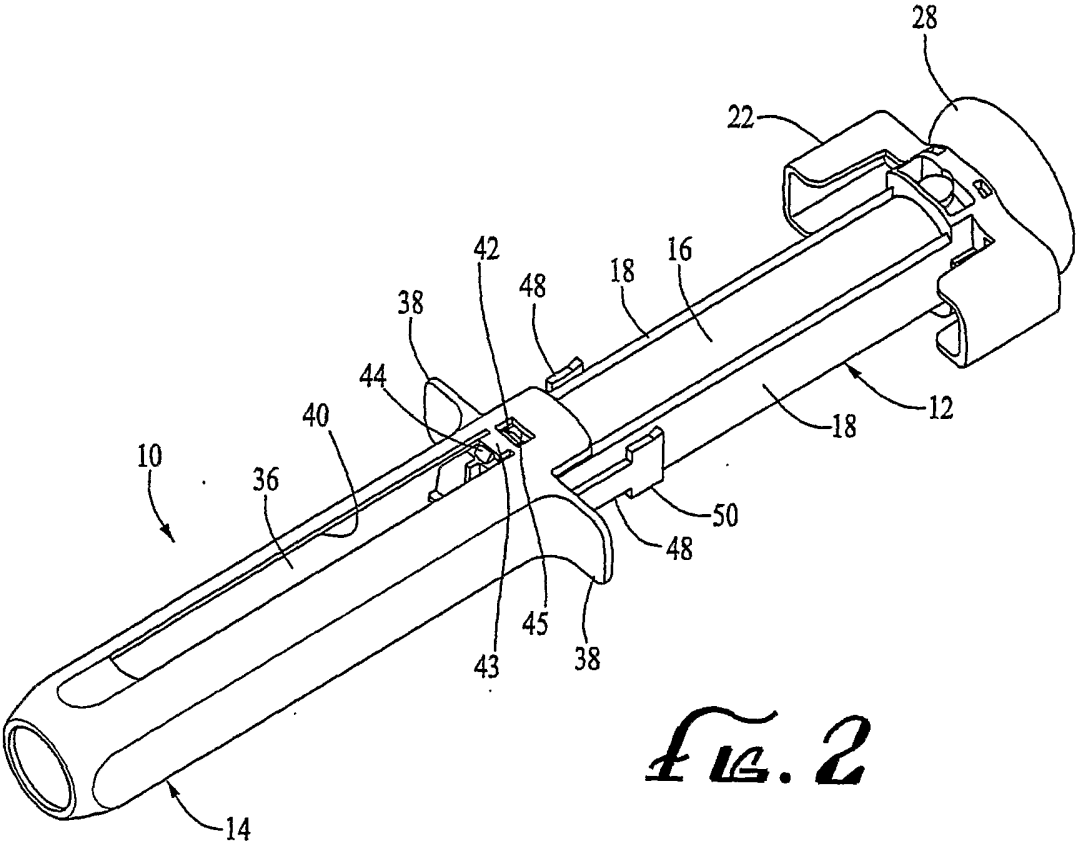
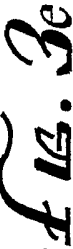
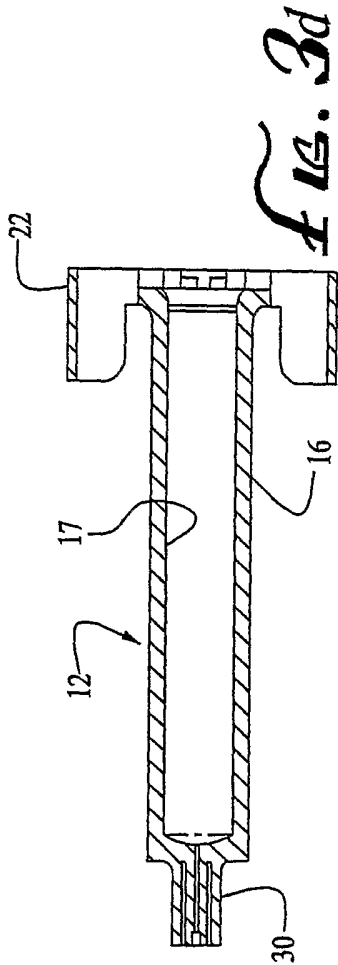
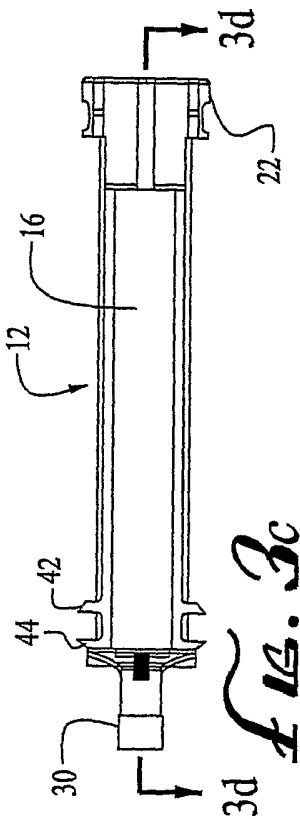
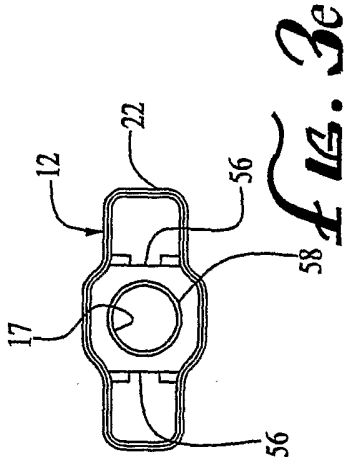
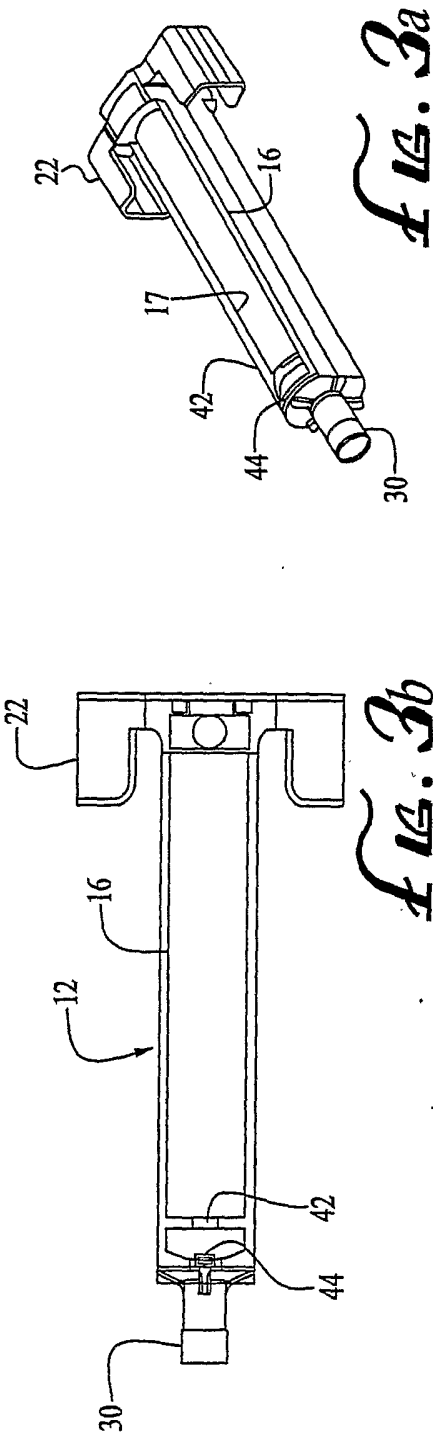


Fig. 2



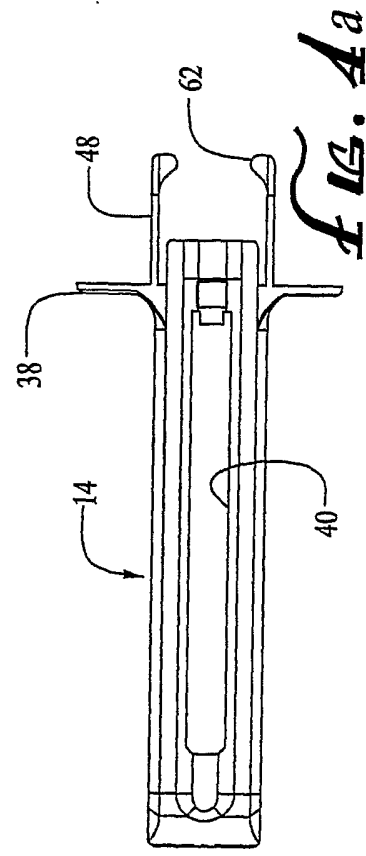


FIG. 4a

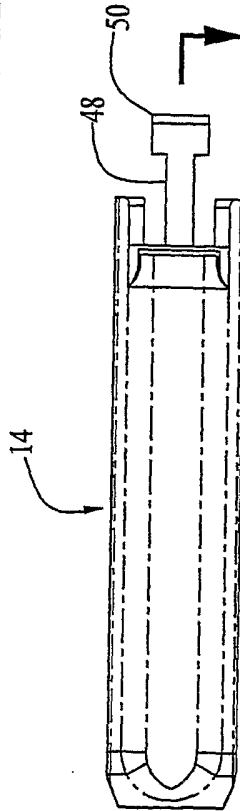


FIG. 4b

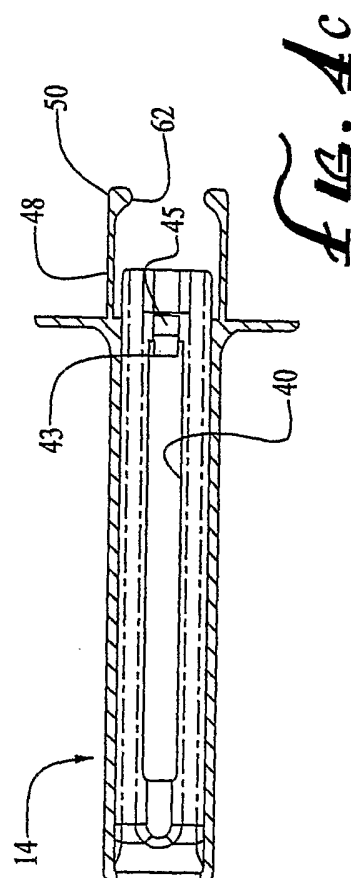


FIG. 4c

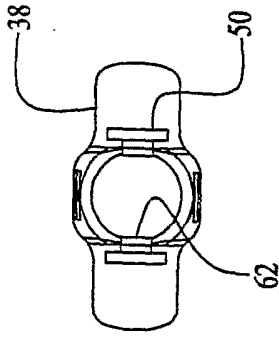


FIG. 4d

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/019508

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/082386 A (SAFETY SYRINGES, INC; DOYLE, MARK, CHRISTOPHER) 9 October 2003 (2003-10-09) page 6, line 1 - page 11, line 35; claims 1-15; figures 1A-9C	1-10
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

13 September 2006

Date of mailing of the international search report

26/09/2006

Name and mailing address of the ISA/

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Björklund, Andreas

INTERNATIONAL SEARCH REPORT

International application No

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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