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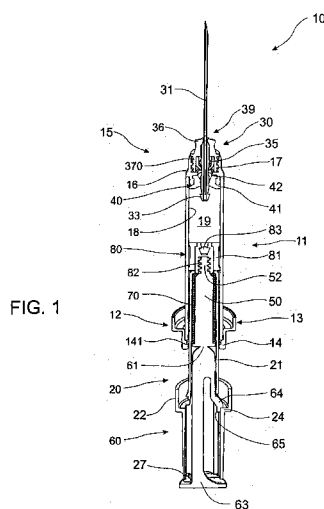
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(57) Abstract: A replaceable needle assembly is provided for a retractable, prefilled syringe comprising a barrel having a mounting member and a plunger, whereby the retractable needle can be replaced by a user without affecting the retraction mechanism. The replaceable needle assembly comprises a needle fitted to a retractable needle mount and a needle retainer. The needle mount is removably, screw-threadedly mountable to the mounting member of the barrel. The needle retainer comprises a plurality of fingers that releasably engage the retractable needle to thereby prevent inadvertent retraction of the retractable needle before engagement by the plunger. The plunger comprises a plunger seal comprising an outer member and an inner member that engages the needle for spring-driven retraction. At the end of retraction, a lock is formed between the plunger and barrel to prevent re-use of the syringe.

VACCINATION SYRINGE

FIELD

THIS INVENTION relates to syringes. More particularly, this invention relates to a
5 retractable syringe that includes a replaceable, retractable needle.

BACKGROUND

The practice of sharing syringes without adequate sterilization between successive users is a major contributor to the transfer of Human Immunodeficiency
10 Virus (HIV) and Hepatitis with subsequent severe repercussions for the sufferer and at a high cost to society for supporting and providing medical attention to sufferers. Further problems arise for health professionals administering medicines and vaccines to infected individuals, where accidental needle stick injury by a used syringe can lead to infection.

15 In response to this problem, syringes have been developed which either provide a needle sheathing mechanism or a needle retraction mechanism to prevent re-use and/or needle stick injury.

However, many such retractable syringes have fixed needles or highly specialized retractable needle assemblies that are not amenable to replacing needles
20 which have been bent or burred or for allowing a user to select an appropriate needle size.

SUMMARY

The invention is therefore, at least in part, broadly directed to a replaceable
25 needle assembly for a retractable syringe, whereby a retractable needle can be replaced by a user without affecting the retraction mechanism.

The invention is also broadly directed to a barrel suitable for mounting the replaceable needle assembly.

The invention also broadly provides an improved retraction mechanism comprising respective elements of the retractable needle assembly and/or a plunger capable of engaging and retracting a retractable needle.

5 In a first aspect, the invention provides a replaceable needle assembly for a retractable syringe comprising a plunger and a barrel having a mounting member, said replaceable needle assembly comprising: a retractable needle that is engageable by said plunger; a needle mount that is removably mountable to the mounting member of the barrel; and a needle retainer.

10 In one embodiment the needle mount comprises a male member which is receivable by a female member of said mounting member.

Preferably, the needle mount comprises a screw-thread which in use is received by a complementary screw thread of said mounting member.

15 In a preferred embodiment, the needle retainer comprises a plurality of fingers that engage said retractable needle to prevent inadvertent retraction of said retractable needle.

In a second aspect, the invention provides a barrel for a retractable syringe, said barrel comprising a mounting member to which is removably mountable a replaceable needle assembly.

20 In one embodiment, said mounting member comprises a female member that receives a male member of a needle mount of said retractable, replaceable needle assembly.

Preferably, the mounting member comprises a screw-thread which in use receives a complementary screw thread of a needle mount of said replaceable needle assembly.

25 Preferably, the barrel further comprises a needle seal coupled to the mounting member.

Preferably, the barrel comprises a releasing member.

In one embodiment, the barrel further comprises a collar.

Preferably, the collar comprises the releasing member.

30 In a third aspect, the invention provides a plunger for a retractable syringe comprising a retractable needle, said plunger comprising: a biasing means; a plunger

member releasably connected to a control rod; a plunger housing; and a plunger seal mounted to the plunger member; wherein the plunger member, control rod and plunger housing co-operate to maintain said biasing means in an initially energized state prior to retraction.

5 Suitably, the plunger comprises a needle-engaging portion that is capable of engaging the retractable needle to facilitate retraction of the retractable needle.

In one embodiment, the plunger seal comprises an inner member and an outer member. Preferably, the plunger seal comprises a stop to prevent or minimize forward travel of the inner member relative to the outer member. Suitably, according
10 to this embodiment the inner member comprises the needle-engaging portion.

Preferably, said plunger is arranged so that at the end of depression of said plunger to deliver fluid contents of said retractable syringe, said control rod disengages from said plunger housing to facilitate a release of energy from said biasing means to thereby retract said control rod and said plunger member with a
15 needle coupled thereto.

Preferably, said needle is coupled to said inner member of said seal. An advantage of this embodiment is that because the outer member of the seal remains stationary during retraction, the "glide force" required to retract the inner member and coupled needle is relatively reduced.

20 Suitably, said biasing member is any device which can store energy in a releasable form, such as a spring, elastic or the like.

Preferably, said biasing means is a spring.

In a fourth aspect, the invention provides a retractable syringe kit comprising the barrel of the second aspect prefilled with fluid contents and the plunger of the
25 third aspect in combination; and a plurality of needle assemblies according to the first aspect..

In one embodiment of the retractable syringe kit, the plurality of needle assemblies respectively comprise a 0.5 inch needle, a 1.0 inch needle and a 1.5 inch needle.

In a fifth aspect, the invention provides a retractable syringe comprising: the replaceable needle assembly of the first aspect removably mounted to the barrel of the second aspect; and/or the plunger of the third aspect.

5 In one embodiment, the retractable syringe further comprises a lock formed between said plunger housing and said collar of said barrel which prevents or hinders removal of the plunger housing from the retractable syringe after retraction of the retractable needle.

Preferably, the retractable syringe is a prefilled retractable syringe.

10 In a sixth aspect, the invention provides a method of operating a retractable syringe including the step of removably mounting a replaceable needle assembly to a barrel of a retractable syringe prefilled with fluid contents.

Preferably, the method includes the step of removing a plug from a mounting member of the barrel prior to removably mounting the replaceable needle assembly to the barrel.

15 In one embodiment, the method includes the step of screw-threadedly mounting a needle mount of the replaceable needle assembly to a mounting member of the barrel.

20 In a seventh aspect, the invention provides a method of making a pre-filled syringe including the steps of coupling a plunger and a seal in a syringe barrel, wherein the syringe barrel comprises fluid contents, a plug member mounted thereto or a replaceable needle assembly of the first aspect mounted thereto.

25 Throughout this specification, unless otherwise indicated, "comprise", "comprises" and "comprising" are used inclusively rather than exclusively, so that a stated integer or group of integers may include one or more other non-stated integers or groups of integers.

BRIEF DESCRIPTION OF THE DRAWINGS

Non-limiting embodiments of the invention are described herein with reference to the following drawings wherein:

30 FIG. 1 is a sectional view of an embodiment of a retractable syringe;
FIG. 2 is a sectional view of an embodiment of a plunger;

FIG. 3 is a sectional view of an embodiment of a replaceable needle assembly;

FIG. 4A is a sectional view of an embodiment of a barrel prior to removal of a plug and FIG. 4B is a sectional view showing mounting of a replaceable needle assembly to a barrel mounting member;

FIG. 5 is a sectional view of a plunger engaging a needle assembly prior to needle retraction;

FIG. 6 is a sectional view showing spring-driven retraction of a plunger, plunger rod and retractable needle; and

FIG. 7 is a sectional view showing an embodiment of a retractable syringe after retraction of a retractable needle.

DETAILED DESCRIPTION

Referring to FIG. 1, an embodiment of syringe 10 comprises barrel 11 and plunger 20 which is slidably, axially moveable within barrel 11, plunger 20 having plunger member 50 and plunger housing 21. Replaceable needle assembly 30 comprises retractable needle 39 that comprises cannula 31 and needle body 32 comprising plunger-engaging foot 33, needle mount 36 having screw threaded portion 370 and needle retainer 35. Seal 80 is mounted to projection 52 of plunger member 50. Barrel 11 comprises plunger end 12 at which is located collar 13 comprising release ring 14 having rim 141. Barrel 11 also comprises needle end 15 having mounting member 16 onto which can be mounted replaceable needle assembly 30. Mounting member 16 comprises screw thread 17 and is typically glued or otherwise firmly affixed inside needle end 15 of barrel 11. Needle seal 40 is also mounted inside needle end 15 of barrel 11 behind mounting member 16 (i.e proximal to the user). Sealing base 41 of needle seal 40 seals against inside wall 18 of barrel while body 42 is coupled to mounting member 16.

Referring now to FIG. 2, plunger 20 comprises plunger housing 21 with skirt 22 having flange 23 comprising inner circumferential ledge 24. Skirt 22 also comprises step 27 at an end of skirt 22 proximal to a user. Plunger housing 21 further comprises arm 28 having shoulder 29. Control rod 60 is releasably connected to

plunger member 50 by way of frangible connection 61. Control rod further comprises shaft 62, button 63 which is operable by a user and trigger 64 which comprises notch 65. In this embodiment, the biasing means is spring 70. Before retraction, trigger 64 of control rod 60 engages flange 23 of plunger housing 21 by way of notch 65
5 releasably engaging inner circumferential ledge 24. This retains spring 70 in an initially compressed state, compressed between inner shoulder 25 of plunger housing and annular base 51 of plunger member 50. In this context, "initially compressed" means that spring 70 is in a compressed (*i.e* energized) state before use of the retractable syringe.

10 Plunger member 50 further comprises projection 52, which in this embodiment is screw threaded, which is coupled to plunger seal 80. Plunger seal 80 comprises inner member 81 and outer member 82 that are releasably coupled. Stop 85 is formed between shoulder 86 of inner member 81 and ledge 87 of outer member 82 to minimize or prevent unwanted forward travel of inner member 81 relative to
15 outer member 82 (*i.e* towards needle end 15 of barrel 11), particularly when plunger 20 is initially inserted into barrel 10. Stop 85 selectively allows axial movement of inner member 81 relative to outer member 82 towards the user during retraction, as will be described in more detail hereinafter. Inner member 81 further comprises complementary mating portion 83 for receiving and engaging foot 33 of needle body
20 32 and plunger-engaging recess 84 that is screw-threadedly mounted to projection 52 of plunger member 50. Outer member 82 seals against inside wall 18 of barrel to prevent fluid leaking from fluid space 19. It is also noted that inner member 81 and outer member 82 provide a fluid-tight seal at internal interface 88. Although not shown, complementary annular ribs and grooves could be added to inner member 81
25 and outer member 82, or *vice versa*, to facilitate the fluid-tight seal.

As shown in FIG. 3, replaceable needle assembly 30 comprises retractable needle 39 comprising cannula 31, needle body 32 that comprises plunger-engaging foot 33 and shoulders 34A, 34B, needle retainer 35 and needle mount 36 having screw threaded "male" portion 370. Needle retainer 35 also comprises fingers 37A, B
30 that respectively bear against shoulders 34A, 34B of needle body 32 which retain retractable needle 39 in needle assembly 30 and prevent inadvertent retraction of

retractable needle 39. This retaining function can withstand up to a 6N force, but nevertheless allow spring-driven retraction of retractable needle 39, as will be described in more detail hereinafter. An advantage of this arrangement is that no other structure (*e.g.* an ejector member) is required to release retractable needle 39 from fingers 37A, 37B. Complementary angled faces 38A, B, C and D also assist preventing inadvertent ejection of retractable needle, if for example subjected to a “needle pull” force 39 from needle assembly 30.

Referring now to FIGS. 4A and 4B, syringe 10 is typically provided prefilled with fluid contents, such as a vaccine, although without limitation thereto. As is evident in FIG. 4A, prior to use, plug 90 comprising screw-threaded portion 91 has been fitted into complementary screw-thread 17 of mounting member 16 at needle end 15 of barrel 11 to thereby seal barrel 11. Plug 90 is then unscrewed as indicated by the arrow and removed by the user so that replaceable needle assembly 30 can be mounted by way of screw thread 35 in needle mount 36 engaging complementary screw thread 17 in mounting member 16. Replaceable needle assembly 30 may be provided with a removable cover (not shown) for cannula 31 and also a screw-threaded cover (not shown) mountable to screw thread 35 of needle mount 36. Once these covers are removed and the needle assembly mounted to barrel 11, syringe 10 is ready for use. It will be appreciated that the replaceable needle assembly 30 allows a user to replace a needle that becomes bent or burred. Furthermore, a user may select an appropriate size or gauge needle for delivery.

Referring to FIG. 5, in use plunger 20 is moved axially in the direction of the solid arrow toward needle end 15 of barrel 11 to deliver fluid contents of syringe 10. At or near the end of plunger 20 depression, complementary mating portion 83 of seal inner 81 receives and snap-lock engages foot 33 of needle body 32. This effectively couples retractable needle 39 to plunger member 50, as shown in FIG. 5. It will also be appreciated that while this embodiment describes male-female engagement between foot 33 and complementary mating portion 83, the reverse arrangement is also contemplated.

The sequence of events that occur to facilitate controlled retraction of retractable needle 39 is as follows.

Continued movement of plunger 20 in the direction of the solid arrow in FIG. 5 is allowed by seal 80 and needle seal 40, which are formed of a compressible material and allow continued movement of plunger housing 21 toward needle end 15 of barrel 11 until release ring 14 bears against arm 64 of control rod 60, thereby moving trigger 64 radially inwardly in the direction of the arrow in FIG. 5. This disengages notch 65 from inner circumferential ledge 24 which thereby triggers release of control rod 60 from plunger housing 21. This allows initially compressed spring 70 to decompress and forcibly bear against annular base 51 of plunger member 50 to thereby retract plunger member 50 and connected control rod 60. Retraction of plunger member 50 occurs with sufficient force to dislodge needle body 32 from fingers 37A, B of needle retainer 35. At this time, inner member 81 of plunger seal 80 uncouples from outer member 82, moving axially towards the user so that cannula 31 and needle body 32, which is coupled to inner sealing member 81 mounted to plunger member 50, retracts in the direction of the arrow in FIG. 6 (inside plunger housing 21 which remains stationary relative to barrel 11).

Accordingly, control rod 60 retracts, the rate of which retraction is controlled by a user relaxing pressure (such as by way of thumb pressure) against control button 63. As shown in FIG. 7, retraction is complete when base 51 of first plunger member 50 abuts step 27 in plunger housing 21 which is stationary during retraction of plunger member 50 and control rod 60. Needle seal 40, needle mount 36 and needle retainer 35 also remain stationary at needle end 15 of barrel 11.

As shown in FIG. 6 and 7, at the end of plunger 20 depression to complete injection of fluid contents of syringe 10, lock 90 is formed between lock elements in the form of shoulder 29 of arm 28 of plunger housing 21 locked onto rim 141 inside release ring 14 of collar 13 at plunger end 12 of barrel 11, to thereby prevent withdrawal of plunger housing 21 from barrel 11. This also facilitates ease of removal of control rod 60, which can be manually removed from syringe 10 by breaking control rod 60 away from plunger member 50 at frangible connection 61. Control rod 60 may then be discarded as "clean" waste, leaving syringe 10 with plunger housing 21 and plunger member 50 remaining inside barrel 11 for a more compact medical waste disposal.

In light of the foregoing it will be appreciated that the present invention provides a relatively simple, robust and inexpensive syringe that is automatically disabled with little or no assistance from the user to thereby prevent, or at least minimize the likelihood of, re-use of the syringe or needle-stick injury to the user.

5 Furthermore, the replaceable needle assembly allows a user to select a needle of appropriate size of gauge or needle length and/or to replace a needle that becomes bent or burred. Another advantage of the retractable syringe described herein is that it can accommodate and fully encapsulate on retraction, needles of varying length up to 1.5 inches (~3.8 cm) in length, thereby providing great flexibility to the user.

10 Throughout the specification, the aim has been to describe the preferred embodiments of the invention without limiting the invention to any one embodiment or specific collection of features. Various changes and modifications may be made to the embodiments described and illustrated without departing from the present invention.

15 The disclosure of each patent and scientific document, computer program and algorithm referred to in this specification is incorporated by reference in its entirety,

CLAIMS

1. A replaceable needle assembly for a retractable syringe comprising a plunger and a barrel that comprises a mounting member, said replaceable needle assembly
5 comprising: a retractable needle that is engageable by said plunger to facilitate retraction of the retractable needle; a needle mount that is removably mountable to the mounting member of the barrel; and a needle retainer to prevent inadvertent retraction of said retractable needle.
2. The replaceable needle assembly of Claim 1, wherein the needle mount
10 comprises a male member which is receivable by a female member of said mounting member.
3. The replaceable needle assembly of Claim 2, wherein the needle mount comprises a screw-thread which in use receives a complementary screw thread of said mounting member.
- 15 4. The replaceable needle assembly of any preceding claim, wherein the needle retainer comprises a plurality of fingers that releasably engage said retractable needle to thereby prevent inadvertent retraction of said retractable needle.
5. The replaceable needle assembly of Claim 4, wherein said plurality of fingers are releasable from said retractable needle upon retraction of said plunger when
20 engaged with said retractable needle.
6. A barrel for a retractable syringe, said barrel comprising a mounting member to which is removably mountable a retractable, needle mount of a replaceable needle assembly.
7. The barrel of Claim 6, wherein said mounting member comprises a female
25 member that receives a male member of the needle mount of said retractable, replaceable needle assembly.
8. The barrel of Claim 7, wherein the mounting member comprises a screw-thread which in use receives a complementary screw thread of the needle mount of said replaceable needle assembly.
- 30 9. The barrel of any one of Claims 6 to 8, wherein the barrel further comprises a needle seal coupled to the mounting member.

10. The barrel of any one of Claims 6 to 9, which further comprises a collar.
11. The barrel of Claim 10, wherein the collar comprises a releasing member.
12. The barrel of Claim 10 or Claim 11, wherein the collar comprises one or more lock elements capable of forming a lock with one or more lock elements of a plunger after retraction.
13. The barrel of any one of Claims 6-12, comprising the replaceable needle assembly according to any one of Claims 1-5 mounted thereto.
14. A plunger for a retractable syringe, said plunger comprising: a biasing means; a plunger member releasably connected to a control rod; a plunger housing; and a plunger seal mounted to the plunger member, said plunger seal comprising a releasably coupled inner member and outer member; wherein the plunger member, control rod and plunger housing co-operate to maintain said biasing means in an initially energized state prior to retraction.
15. The plunger of Claim 14, wherein the plunger seal comprises a stop to prevent or minimize forward travel of the inner member relative to the outer member.
16. The plunger of Claim 14 or Claim 15, wherein the inner member comprises a needle-engaging portion.
17. The plunger of any one of Claims 14 to 16, wherein the control rod comprises an arm that initially engages said plunger housing prior to retraction to facilitate maintaining said biasing means in an initially energized state prior to retraction.
18. The plunger of any one of Claims 14 to 17, arranged so that at the end of depression of said plunger to deliver fluid contents of said retractable syringe, said control rod is disengageable from said plunger housing to facilitate a release of energy from said biasing means to thereby retract said control rod and said plunger member with a needle coupled thereto.
19. The plunger of any one of Claims 14-18, wherein the biasing means is a spring.
20. The plunger of any one of Claims 14-19, wherein the plunger outer comprises one or more lock elements capable of forming a lock with a barrel after retraction.

21. A retractable syringe kit comprising the barrel of any one of Claims 6-13 prefilled with fluid contents and the plunger of any one of Claims 14-20 in combination; and a plurality of replaceable needle assemblies according to any one of Claims 1-5.
- 5 22. The retractable syringe kit of Claim 21, wherein the plurality of needle assemblies respectively comprise a 0.5 inch needle, a 1.0 inch needle and a 1.5 inch needle.
23. The retractable syringe kit of Claim 21 or Claim 22, which comprises a plug removably mounted to the mounting member of the barrel.
- 10 24. A retractable syringe comprising: the replaceable needle assembly of any one of Claims 1 to 5 removably mounted to the barrel of any one of Claims 6 to 13 and a plunger capable of engaging the retractable needle.
25. The retractable syringe of Claim 24, wherein the plunger is according to any one of Claim 14 to 20.
- 15 26. The retractable syringe of Claim 25, further comprising a lock formed between respective lock elements of said plunger housing and the collar of said barrel, which lock prevents or hinders removal of the plunger housing from the retractable syringe after retraction of the retractable needle.
27. The retractable syringe of Claim 25 or Claim 26, which is a prefilled retractable syringe.
- 20 28. A method of operating a retractable syringe comprising a barrel and a plunger, including the step of removably mounting a replaceable needle assembly comprising a retractable needle that is engageable by said plunger to facilitate retraction of the retractable needle; a needle mount that is removably mountable to the barrel; and a needle retainer to prevent inadvertent retraction of said retractable needle to a barrel of a retractable syringe prefilled with fluid contents.
- 25 29. The method of Claim 28, which includes the step of removing a plug from a mounting member of the barrel prior to removably mounting the replaceable needle assembly to the mounting member.

30. The method of Claim 28 or Claim 29, which includes the step of screw-threadedly mounting a needle mount of the replaceable needle assembly to a mounting member of the barrel.
31. The method of any one of Claims 28-30, wherein the replaceable needle
5 assembly is according to any one of Claims 1 to 5; the barrel is according to any one of Claims 6 to 13; and/or the plunger is as according to any one of Claims 14 to 20.
32. A method of making a pre-filled syringe including the steps of coupling a plunger and a plunger seal in a syringe barrel, wherein the syringe barrel is prefilled with fluid contents, and comprises a plug member removably mounted thereto or a
10 replaceable needle assembly removably mounted thereto.
33. The method of any one of Claims 28 to 32, wherein the replaceable needle assembly is according to any one of Claims 1 to 5; the barrel is according to any one of Claims 6 to 13; and/or the plunger is as according to any one of Claims 14 to 20.

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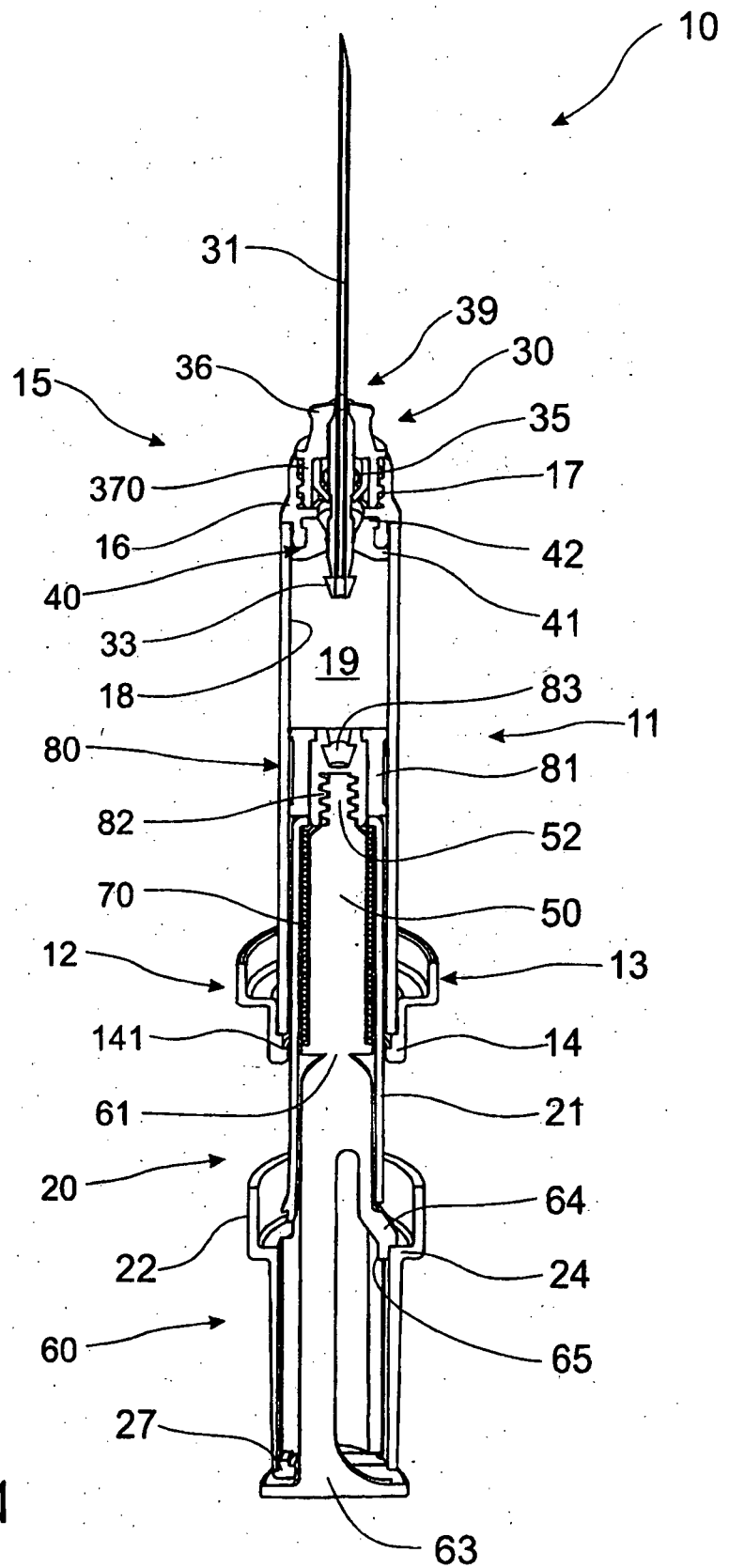


FIG. 1

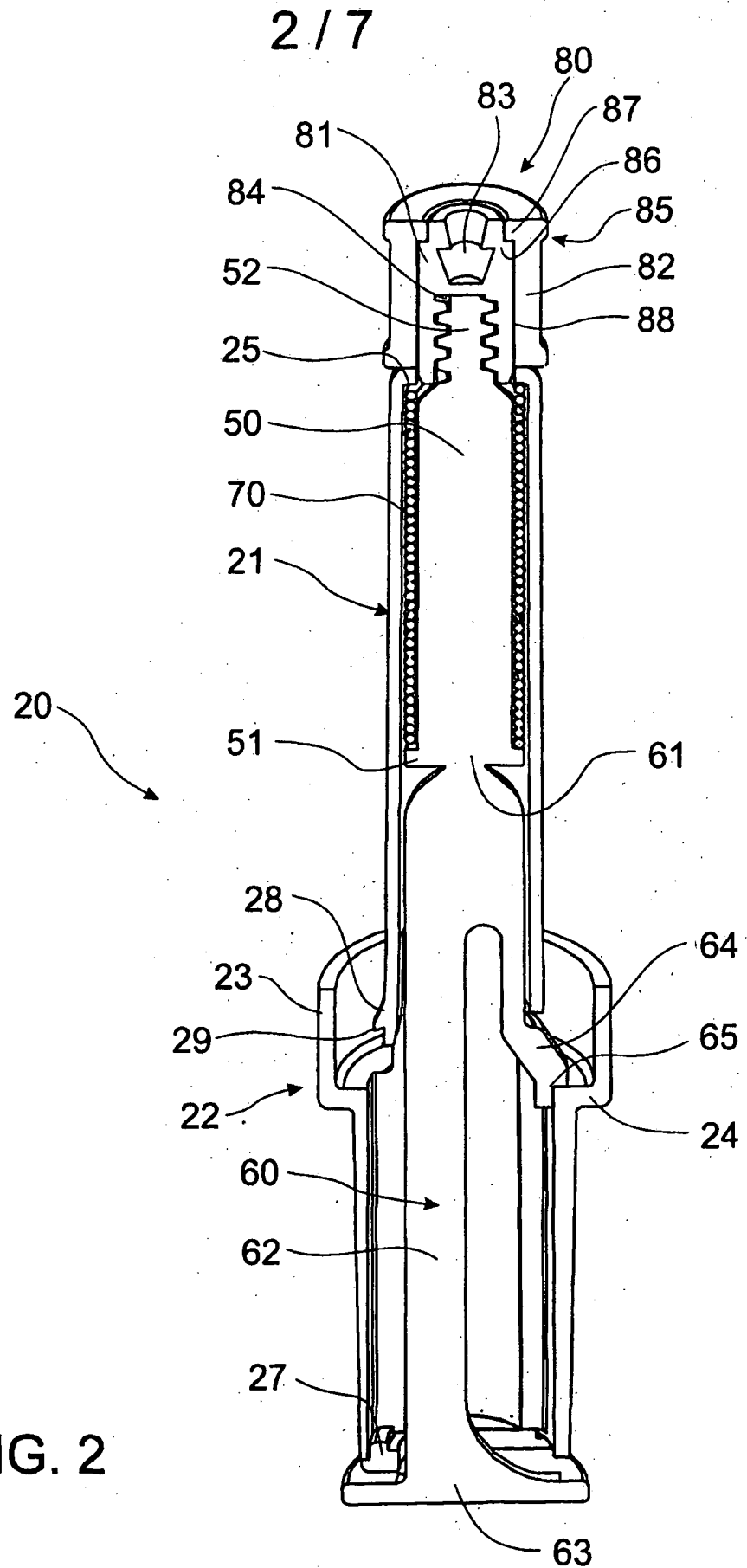


FIG. 2

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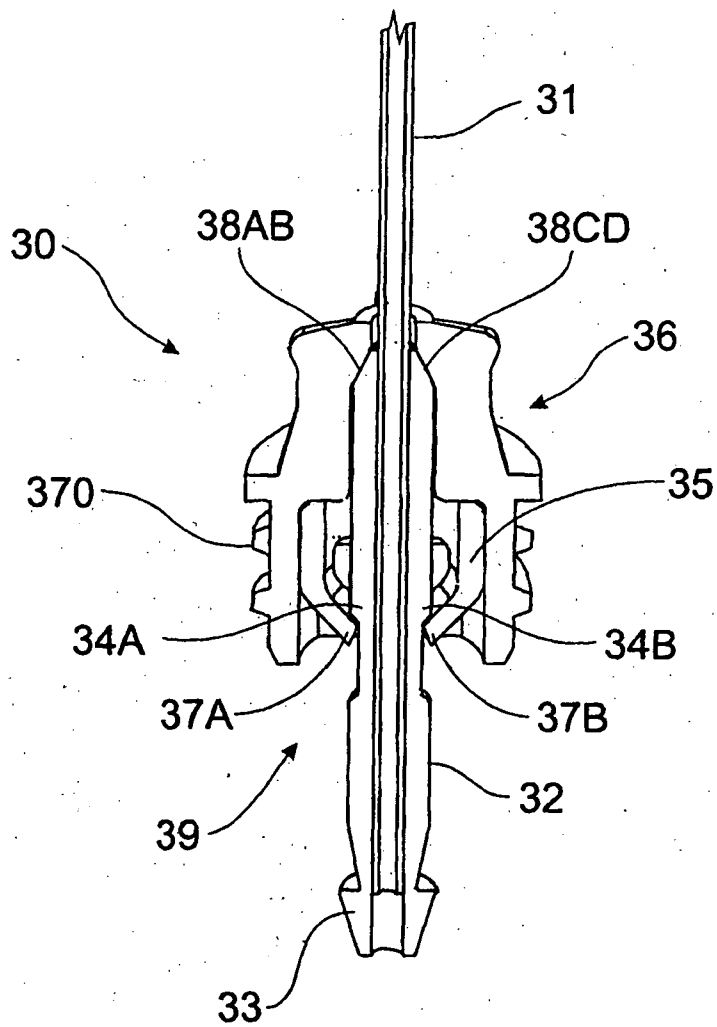


FIG. 3

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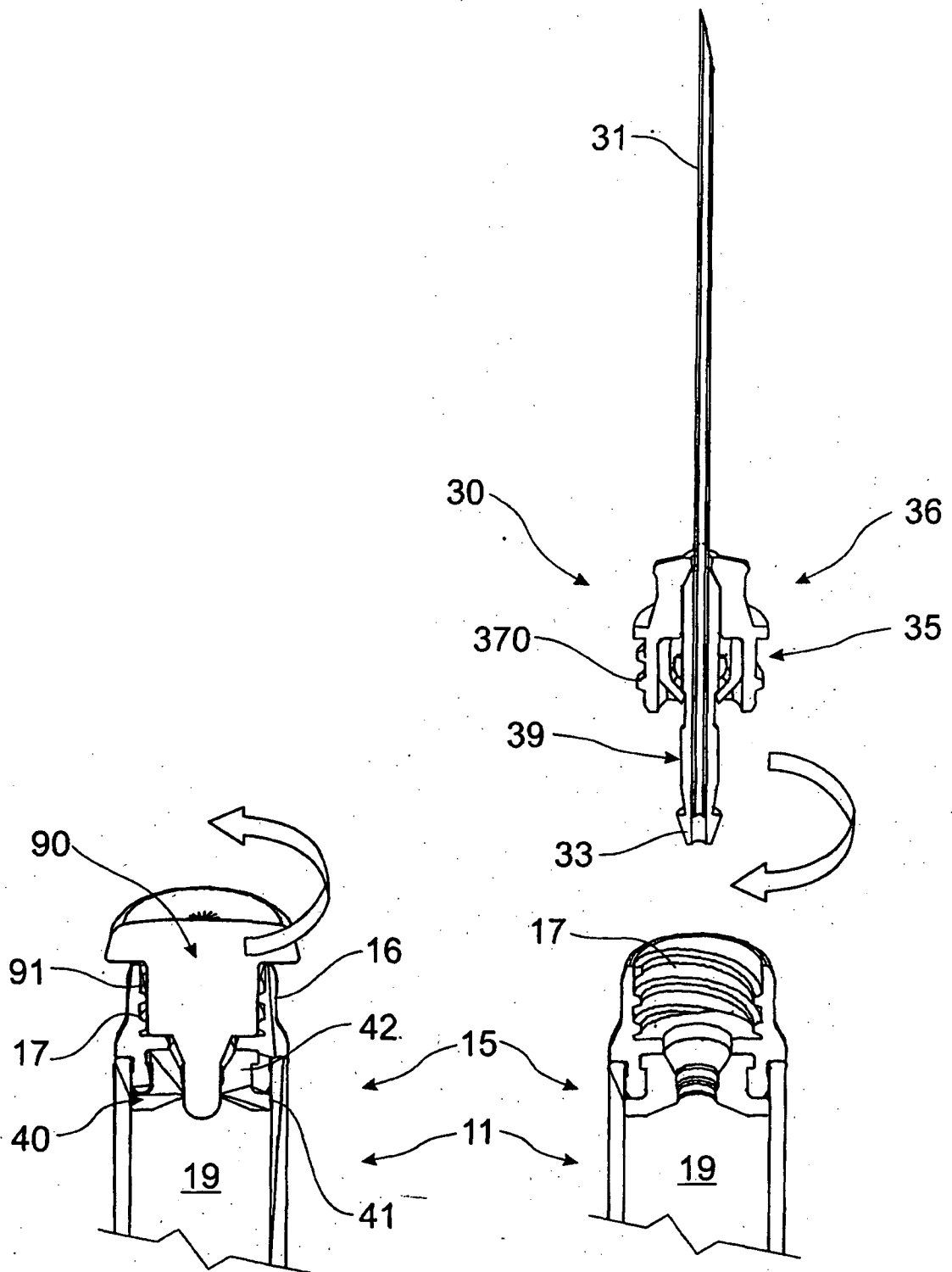
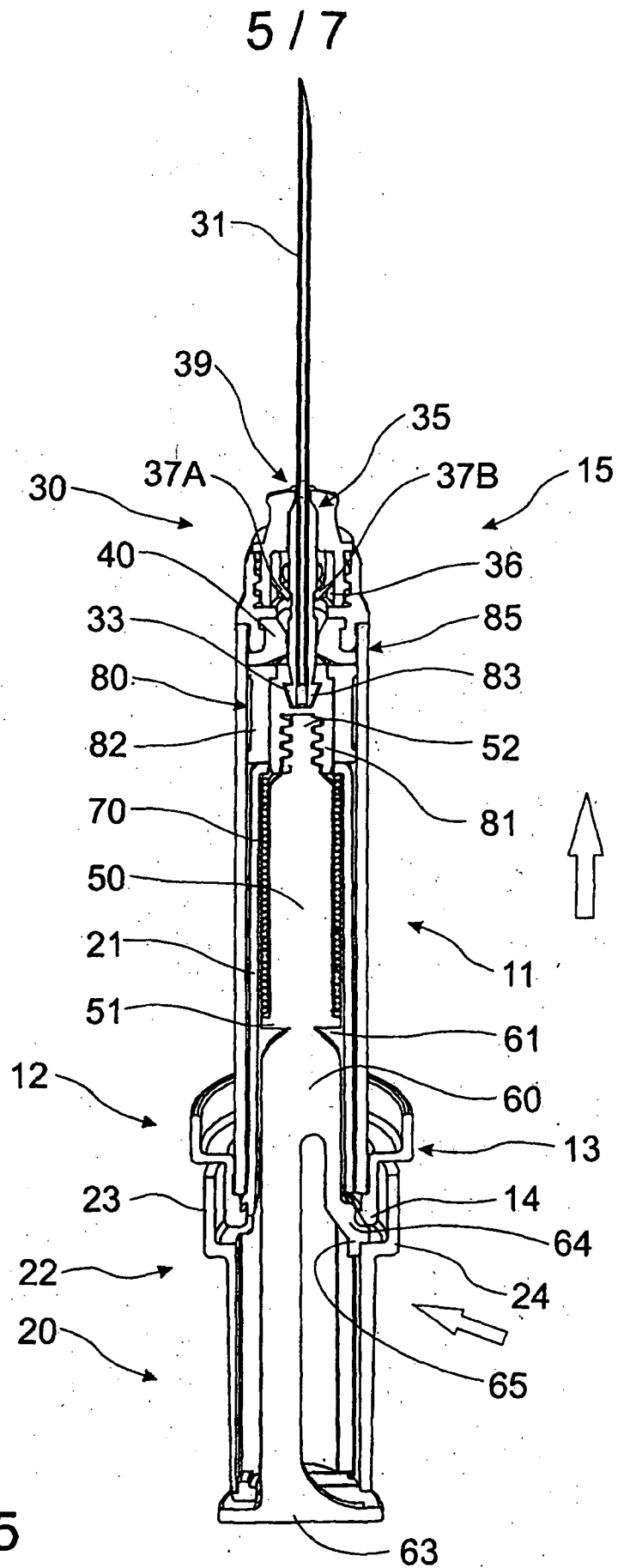


FIG. 4A

FIG. 4B



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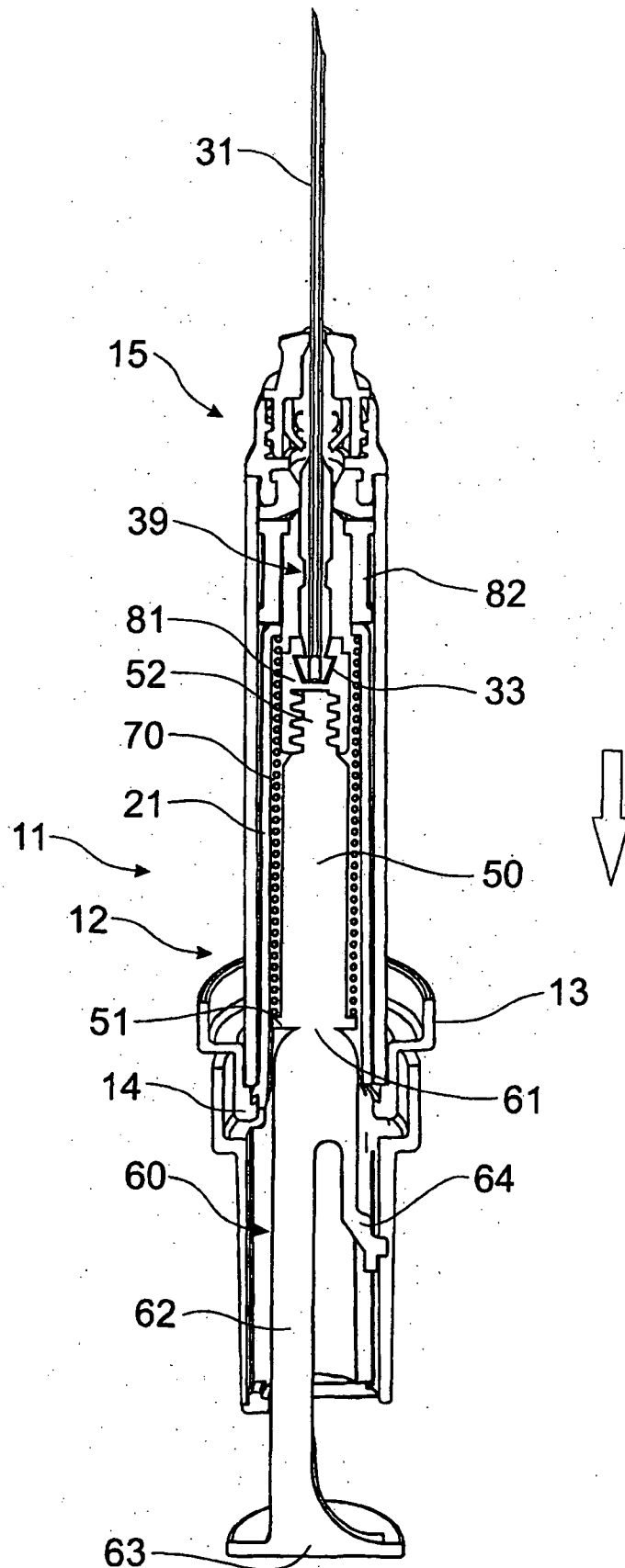


FIG. 6

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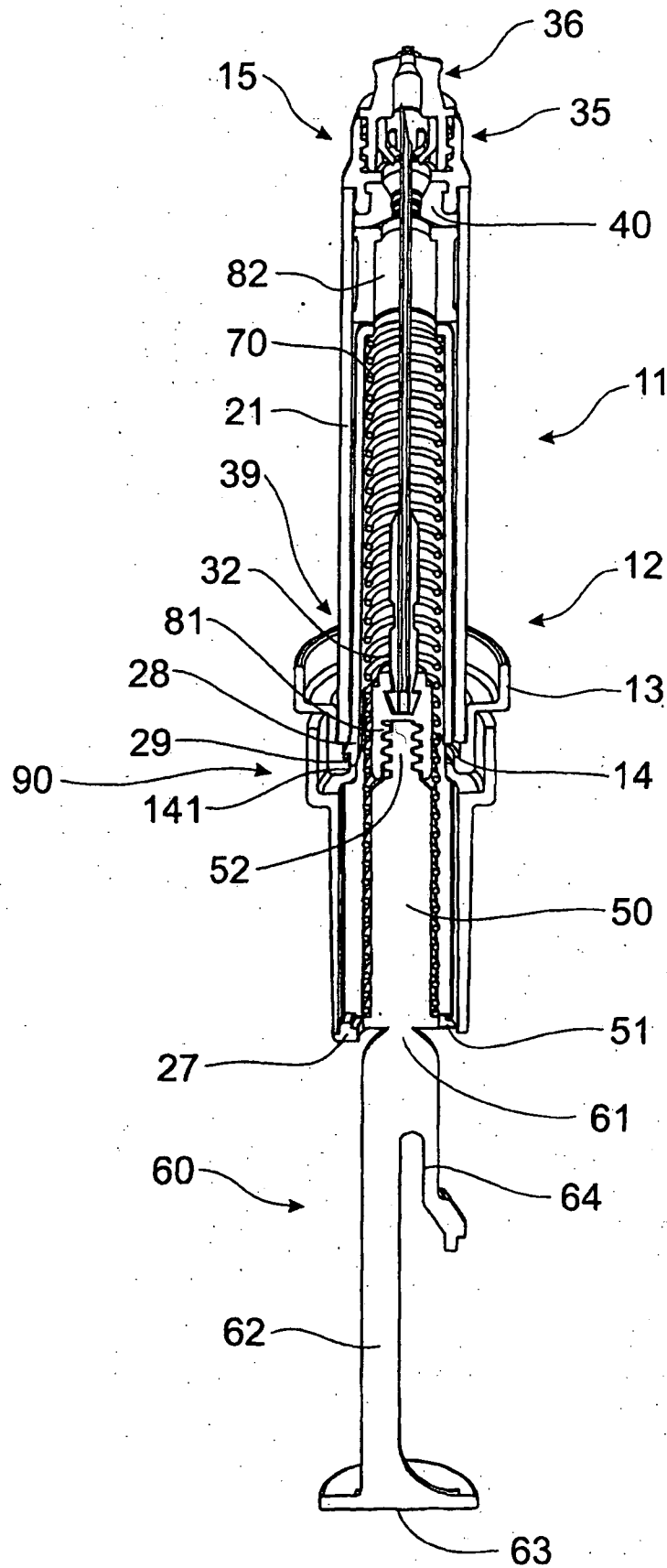


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2010/001505

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 5/32 (2006.01)

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)

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 practicable, search terms used)

EPODOC, WPI: A61M 5/- : EPODOC: A61M 5/32C2F, A61M 5/32C2F2F: Keywords; syringe, needle, replaceable, retractable, engage, plunger and like terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/136775 A2 (TENG) 13 November 2008 Figures 2a, 3a, 7, 8; Page 4, last paragraph	1-3, 6-13
X	US 5453093 A (HAINING) 26 September 1995 Column 1, lines 35-38; Column 2, line 13 to column 3, line 4	1-3, 6-10, 13, 28-31, 33
X	US 5401249 A (SHIELDS) 28 March 1995 Abstract; Column 5, lines 24-31; Column 6, lines 50-60	1-3, 6-11, 13, 28, 31, 33
X	WO 2007/028189 A1 (GLOBAL MEDISAFE HOLDINGS PTY LIMITED) 15 March 2007 Figure 6; Page 2, lines 1-8; Page 3, lines 9-15, 21-23; Page 6, lines 13-14; Page 7, lines 16-18	1-3, 6-10, 12, 13

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

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
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Date of the actual completion of the international search
16 December 2010Date of mailing of the international search report
18 JAN 2011Name and mailing address of the ISA/AU
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2010/001505

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1995/027524 A1 (ELFANDI et al.) 19 October 1995 Abstract; Figures 2a, 2b; Page 8, lines 18-21 * English machine translation used.	1, 2, 4, 6, 7, 13
X	US 5395337 A (CLEMENS et al.) 7 March 1995 Abstract; Figures 2, 3, 5-7; Column 6, lines 5-9, 23-28, 50-67; column 7, lines 23-43	1-4, 6-11, 13
X	US 5222944 A (HARRIS) 29 June 1993 Abstract; Column 4, line 47 to column 5, line 14	1-3, 6-8, 10-13
X	US 5501670 A (SAK) 26 March 1996 Abstract; Figure 3; Column 1, lines 5-11; Column 5, lines 14-23, 46-49; Column 6, lines 19-23; Column 7, lines 47-56	1-3, 6-11, 13, 28, 30, 33

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box 1, below.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-13, 28-31, 33.**

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box 1

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 13, 28 to 31 and 33 are directed to a replaceable needle assembly for a syringe comprising a retractable needle that is removably mounted to a mounting member of a syringe barrel. It is considered that a syringe comprising a retractable needle mount that is removable comprises a first distinguishing feature.
- Claims 14 to 20 are directed to a plunger for a retractable syringe, the plunger releasably connected to a control rod to maintain a biasing means in an energized state prior to retraction. It is considered that a plunger for a retractable syringe comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

- Claim 32 is directed to a method of making a pre-filled syringe, the syringe optionally comprising a removable needle assembly. It is considered that a method of making a pre-filled syringe comprising a removable needle assembly comprises a third distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to the claims 1 to 13 and 21 to 33 is a removable needle assembly, this feature further being optional in claim 32. However this common feature is generic in the art. This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

[Continued in Supplemental Box 2]

Supplemental Box 2

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: Supplemental Box 1

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2010/001505

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO	2008/136775	SG	148042		
US	5453093	NONE			
US	5401249	NONE			
WO	2007/028189	AU	2005336322	AU	2006289645
		CA	2621479	CA	2621480
		CN	101304776	EA	200800704
		EP	1931407	EP	1940492
		MX	2008003211	US	2009/0018503
		WO	2007/028190	ZA	200803045
BR	PI0520606				
		CN	101291698		
		EA	200800747		
		KR	20080068648		
		US	2009/0171287		
WO	9527524	FR	2718358		
US	5395337	AU	49077/96	AU	76827/94
		EP	0716617	US	5531694
		WO	9627403	CA	2172503
				WO	9506490
US	5222944	NONE			
US	5501670	CA	2217057	EP	0912208
				WO	9630063
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					