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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
INVENTARIO

PCT

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EXPEDIENTE No.

08-34639

Contiene los documentos relativos a la solicitud de registro de:

Titulo : **JERINGA DE SEGURIDAD DE USO UNICO
CON AGUJA RETRÁCTIL.**

Clase : **de la Clasificación Internacional de Niza**

Solicitante : **GLOBAL MEDISAFE HOLDINGS
LIMITED.**

De : **AUSTRALIA**

Apoderado : **MAURICIO JARAMILLO**

Bogotá, D.C., Abril de 2008

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Act. 411 PRESENTACION Folios: 90

**FORMULARIO UNICO DE SOLICITUD DE PATENTE
PCT**

ENTRADA EN FASE NACIONAL

6 abril 2008

①

SOLICITUD DE :☒ Patente de Invención.☐ Patente de Modelo de Utilidad☐

Capítulo I

☒

Capítulo II

②

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⑤

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⑥

TITULO (54)**JERINGA DE SEGURIDAD DE USO UNICO CON AGUJA RETRÁCTIL**

⑦

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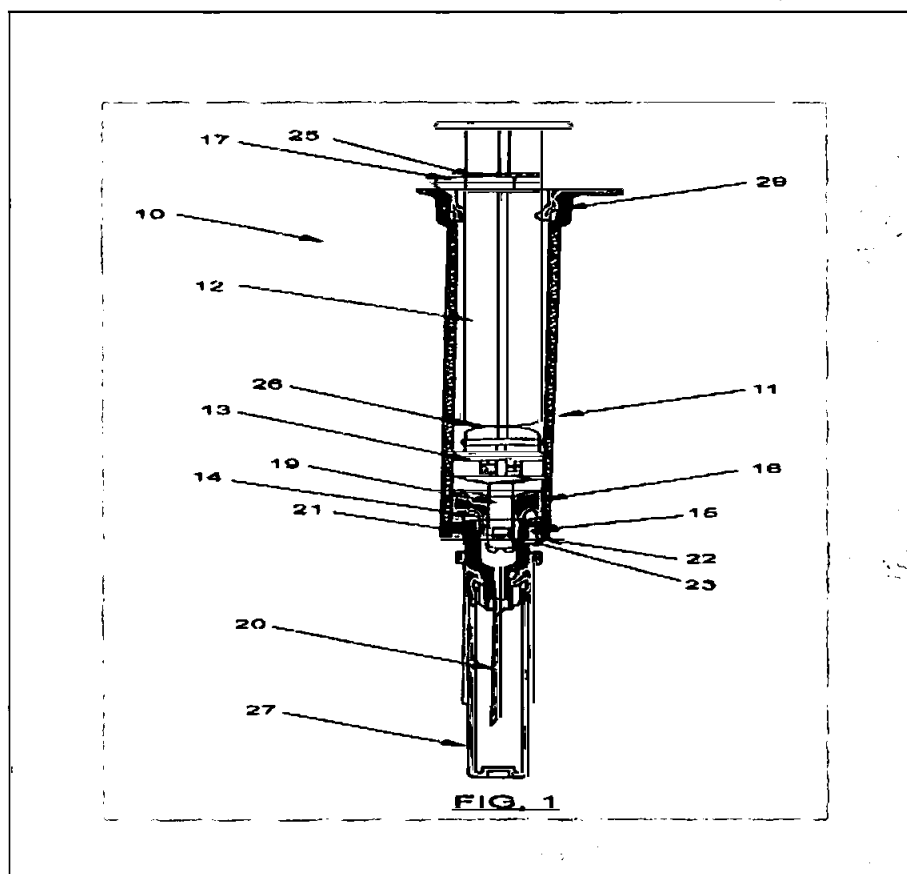
Instrucciones para el diligenciamiento del presente formulario, ver reverso de esta página.

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Anexos

- ☒ Comprobante de pago de la tasa de presentación de la solicitud
- ☐ Documento que acredite la existencia y representación legal cuando el solicitante sea persona jurídica
- ☐ Poderes, si fuere el caso
- ☐ Documento de cesión del inventor al solicitante o a su causante
- ☐ Declaraciones
- ☒ Copia de la solicitud internacional (resumen, descripción, reivindicaciones, dibujos)
- ☒ Traducción simple de la primera solicitud, si se reivindica prioridad
- ☒ Copia del examen preliminar internacional efectuado por la Autoridad Internacional de Examen Preliminar (IPEA)
- ☐ Traducción del examen preliminar internacional efectuado por la IPEA
- ☐ De ser el caso, copia del contrato de acceso
- ☐ De ser el caso, documento que acredite la licencia o autorización de uso de conocimientos tradicionales de las comunidades indígenas
- ☐ De ser el caso, certificado de depósito del material biológico
- ☒ Arte final 12 x 12
- ☒ De ser el caso, información sobre otras solicitudes de patente o títulos en el extranjero por el mismo titular o su causante, relacionadas parcial o totalmente con la invención de esta solicitud
- ☐ De ser el caso, modificaciones efectuadas a la solicitud internacional

⑪

FIGURA CARACTERISTICA:

⑫

solicito la concesión de la patente

NOMBRE: MAURICIO JARAMILLO CAMPUZANO

FIRMA:

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***** CONCEPTO *****

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1		TRAMITES DE SOL. DE PATENTE DE IN	501,000.00
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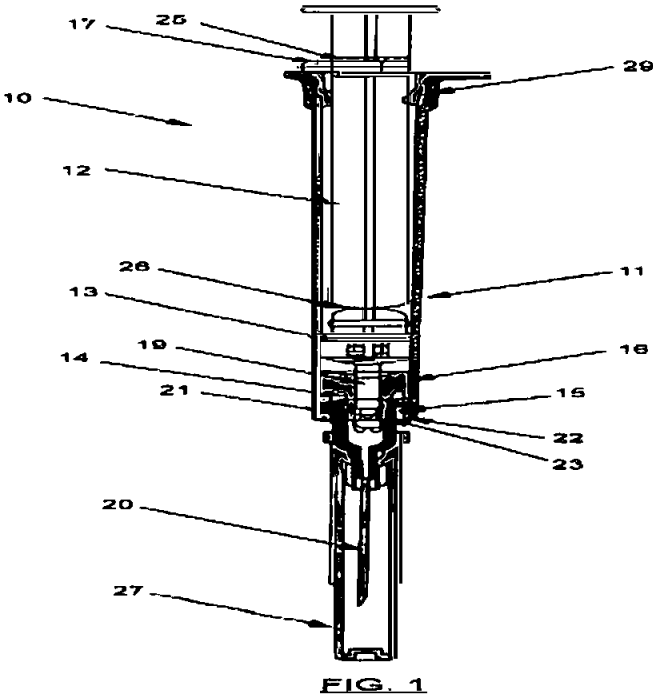
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(54) Título: JERINGA DE SEGURIDAD DE USO UNICO CON AGUJA RETRÁCTIL	

RESUMEN

Se describe una jeringa retráctil de seguridad de uso único (10) que tiene una aguja retráctil (20). La jeringa incluye un barril hueco (11), un émbolo (13) que se ajusta de manera deslizante en el barril y un pistón (13) que se ajusta sobre la parte anterior del émbolo. La jeringa también incluye un mecanismo accionador (14) que se localiza en la parte anterior del barril. El accionador es capaz de ajustarse a través del extremo abierto de la parte anterior del barril hueco. El mecanismo accionador tiene un vástago (18) para soportar la cabeza (15) de la aguja. Se proporcionan los medios (24) sobre el extremo del émbolo para embragar el accionador y hacerlo reaccionar con la aguja al término de la inyección.



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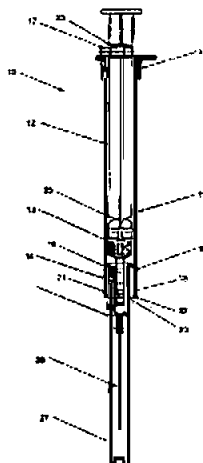
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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: SINGLE USE SAFETY SYRINGE HAVING A RETRACTABLE NEEDLE



(57) Abstract: A single use safety retractable syringe (10) having a retractable needle (20) is disclosed. The syringe includes a hollow barrel (11), a plunger (13) which slideably fits in the barrel, and a piston (13) which fits on the forepart of the plunger. The syringe also includes an actuator mechanism (14), which is located in the forepart of the barrel. The actuator is able to be fitted through the open end of that forepart of the hollow barrel. The actuator mechanism has a stem (18) for supporting a needle hub (15). Means (24) are provided on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection.

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SINGLE USE SAFETY SYRINGE HAVING A RETRACTABLE NEEDLE

Technical Field

This invention relates to a single use safety syringe. In particular it relates to a retractable needle for use in a single-use safety syringe, whereby the syringe user
5 might be protected from injury by the needle after its use.

Background

The danger of injury and possible infection from the HIV or hepatitis B virus to medical practitioners using needles in the normal course of their business is well documented.

10 Further, persons who are in the habit of administering drugs to themselves run a severe risk of contacting either of the specified viruses, or indeed contacting other viruses if a needle, once used, is reused in an unsterilised form.

There have been many proposals aimed at reducing the number of so-called needle-stick injuries and various attempts have been made to provide a safe system for
15 disposal of such needles once used, but such prior proposals have had deficiencies.

Object of the Invention

It is therefore an object of the present invention to provide a single use safety syringe which employs a retractable surgical needle and for permanently storing that surgical needle, once used, in a substantially safe manner, so as to reduce needle stick injuries
20 as well as preventing re-usage of the syringe thereby preventing cross infections of diseases.

It is a particular object of the invention to ameliorate against some or all of the known disadvantages of prior art syringes and to provide a simple safety syringe having a retractable needle which renders the syringe unable to be re-used. At the
25 very least, the invention provides an alternate means for accommodating the needle of a used syringe to protect against accidental injury arising from unwanted contact with the exposed needle once the syringe has been used.

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Disclosure of the Invention

The invention in one broad form provides a single-use safety syringe having a retractable needle, the syringe including a hollow barrel, a plunger which slideably fits in the barrel, a piston which fits on the forepart of the plunger, and an actuator mechanism, which is located in the forepart of the barrel and which is able to be fitted therein through the open end of that forepart of the hollow barrel, the actuator mechanism having a stem for supporting a needle hub, and means located on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection.

Where the actuator is located in the barrel, there is provided an inner flange on the barrel and a corresponding flange on the actuator mechanism, for fitment of the actuator from that open end of the barrel. The flanges are preferably shaped, for example having bevel surfaces on one side and right angled surfaces on the other, so that when the plunger is depressed (ie after the actuator has been thus fitted), the flange of the actuator mechanism locks against the corresponding inner flange of the barrel, for example by virtue of the opposing right angled surfaces coming into contact, so that in normal use the actuator will not be dislodged. Preferably a force of at least 98N may be endured. In this way, the actuator can not be dislodged from the barrel when the piston is depressed during an injection.

On the other hand the flanges need only withstand a lesser force than 98N in order to prevent the actuator from being withdrawn into the barrel when the needle of the syringe is inserted into the patient. Such force is preferably 49N. Indeed, in order that the actuator may be withdrawn into the barrel at the completion of the injection however, it is preferable that these opposing flange surfaces are bevelled so that only a lesser force is needed, ie a force preferably between 49N and 98N.

At the point of contact between the actuator and the barrel there is preferably provided at least one "O" type piston seal, sufficient that there is no leakage between the actuator and the barrel during use.

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It will be appreciated that the actuator will be hollow so that fluid contained in the barrel may pass through it and hence through the needle which it supports. The end of the stem of the actuator is preferably provided with at least one flexible finger member. The plunger is preferably provided with a solid stem having a shaped head
5 so that when the injection is completed, the head of the plunger stem enters into the hollow stem of the actuator and passes through the end thereof and is thereby engaged with the actuator, the one or more fingers retaining the head of the plunger stem beyond the stem of the actuator. When the plunger is pulled back, exerting a force preferably between 49 and 98N pull force, the one or more fingers can not
10 break off, and the actuator will be successfully pulled into the barrel.

In order to prevent premature engagement of the head of the plunger stem with the fingers of the actuator stem, a depth stop is preferably provided to prevent the plunger from thus engaging with the actuator before retraction of the needle is required. Preferably such depth stop is provided in the form of a pin located in a hole
15 located transverse the shaft of the plunger and located thereon so as to prevent the plunger coming into contact with the actuator until the pin is depressed, thereby avoiding early unwarranted destruction of the syringe.

The present invention is therefore a single use safety syringe which includes the following components: a hollow barrel, one plunger which fits the barrel and one
20 piston which fits the forepart of the plunger. There is an actuator which fits the forepart of the barrel. Preferably on the actuator there is located a standard 6:100 luer taper. This taper is designed to receive the hub of a needle utilising interference fit. Alternatively, in order to provide a more positive interconnection between the actuator and the needle hub, a screw thread including so-called luer-lock thread may
25 be employed with advantage.

Between the barrel and the outer actuator surface, there is fitted at least one seal. At the end of the barrel there is located at least one means for preventing complete depression of the plunger until the injection is complete and the syringe is to be

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rendered useless. At the forepart of the plunger there is located a pull back lock, preferably in the form of a head element for engagement with the forepart of the actuator's inner hole which is provided with flexible fingers, claws or the like, so that when the plunger is moved towards the actuator, the pull back hook in the forepart
5 will enter into the actuator's engagement means easily. When the plunger is withdrawn, the actuator is pulled into the barrel, to realise the safe destruction thereof.

The safety syringe according to the preferred embodiments of the invention has the following advantages when compared with those of the existing market: firstly, it is
10 provided with corresponding a flanges on the barrel and actuator to ensure that the actuator can not be dislodged and move back, an "O" type piston being provided between the actuator and the barrel, to make sure no liquid leaks out, and after injection, when the plunger is withdrawn the actuator can be pulled into the barrel easily, it can not be reused, achieving a truly safe syringe which is effectively
15 destroyed; second, only need a minimal force to have the stem of the plunger enter into the flexible fingers of the stem of the actuator, thereby reducing the patient's pain which has been caused in injection in more recent times; third, the depth stop at the back-end of the plunger prevents the syringe being destroyed before it is used to give an injection through mis-operation causing premature destruction of the syringe.

20 Preferably the plunger is provided with a break point. Snapping off the plunger also renders the syringe both ineffective for subsequent use as well as providing additional safety in that there is no means by which the needle can be caused to re-emerge or extend from the syringe body.

Furthermore, it is preferable to provide means whereby the plunger can in fact be
25 locked in position prior to being snapped off. This maybe achieved by utilising a sleeve or collar inserted in the end of the barrel, for example either by interference fit or by screwing it in place. A protrusion or lug may be provided on the plunger adjacent the break point and a passage for example like a thread may be provide in

the sleeve or collar so that the plunger may be wound out through the collar or sleeve and locked by suitable means, eg flange or ratchet means so that when plunger is broken off at the break point there is no means by which it can be caused to re-enter the barrel as it is retained in the collar or sleeve.

5 Brief Description of the Drawings

The invention may be better understood from the following non-limiting description of preferred embodiments, in which:

Figure 1 is an exploded view of a single-use safety syringe according to one embodiment of the invention;

- 10 Figure 2 is a cross-sectional view of the assembled syringe of Figure 1, showing the syringe prior to use with a cap covering and protecting the needle;

Figure 3 is a cross-sectional view of the syringe of Figure 2, showing the plunger drawn back, the barrel having been filled with injectable solution;

- 15 Figure 4 is a cross-sectional view of the syringe of the previous figures, at the completion of injection, the plunger having engaged the actuator;

Figure 5 is a cross-sectional view of the syringe of the previous figures, the plunger having been withdrawn so that the actuator and needle are safely withdrawn into the barrel of the syringe; and

- 20 Figure 6 is a cross section of the syringe of the earlier figures, the plunger having been locked in the sleeve at the end of the barrel and broken off at the break point rendering the syringe safely destroyed.

Detailed Description of the Drawings

Referring to Figure 1 there is shown an exploded view of a syringe, generally referenced 10, according to a preferred embodiment of the invention.

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The syringe includes a barrel 11, plunger 12, piston 13, actuator 14, needle hub 15 supporting a needle 20, "O" type piston 16, and depth stop 17. A cap 29 is provide to protect the needle prior to use.

An inner flange 21 is located in the foremost part of the barrel 11. A corresponding
5 flange 22 is located on the actuator 14, for engagement of the actuator 14 when it is inserted into the barrel 11 from the open end of that foremost part of the barrel 11.

The advantages of inserting the actuator 14 from that end of the barrel 11 lie in ease of assembly and less damage in situations where a needle hub 15 of a needle 20 is already fitted to the actuator 11; than would occur if the actuator were assembled by
10 inserting it from the other (ie plunger) end of the syringe barrel 11.

Flexible spring fingers 23 are located on the end of the hollow stem 18 of the actuator 14. The solid stem 19 at the end of the plunger 13 is provided with a locking head 24. A hole 25 is located in the plunger 13 to accommodate the pin 7 which functions as a depth stop.

15 Break point 26 is provided on the plunger 13. The plunger also has flanges 28 which allow the plunger 13 to be twist locked in the twist lock sleeve 29 located in the end of the barrel 11.

Referring generally to Figures 2 to 6, there is shown a syringe 10 which has the various parts illustrated as in Figure 1, the same reference numerals being utilised
20 throughout.

The safety syringe 10 according to the invention possesses the following characters:

At the junction between the actuator 14 and barrel 11 there is located a sealing member 16 in the form of an "O" ring or the like. There is also located corresponding flanges 22, 21 on the actuator 14 and on the inner surface of the barrel
25 11 respectively. At each edge of the actuator flange 22 there is formed a bevel and a right angle respectively, the bevel and right angle correspond with a bevel and a right angle located on the flange 21 inside the barrel 11. In essence the orientation of the respective shapes of the two flanges 21, 22 means that in use, normal pressure as

exerted during an injection will not cause the actuator to be dislodged outwardly or indeed inwardly. Indeed the use of the depth stop 17, prior to its being pressed in will ensure that this can't happen accidentally either. However, the use of the locking head 24 which engages the fingers 23 is in fact sufficient to easily draw the actuator 14 back, once the locking head 24 of the plunger 13 has been allowed to engage the actuator 14 by pressing in stop 17.

On the plunger 13 there is provided a break point 26, so that the plunger 13 can be broken off easily along the break point 26. At the back-end of plunger 13 there is located a depth stop 17 which can be pushed in, but which contacts the end of the barrel 11, until such time as it is pushed in so as to prevent the plunger 13 from being fully depressed and hence engaging with the actuator 14.

In Figure 2, the needle is protected by a cap 27 prior to use. The plunger 13 is prevented from engaging with actuator 14 by virtue of depth stop 17 which is in the out position.

In use the cap 27 is removed to reveal the needle 20 and the needle 20 is inserted into the fluid to be used for the injection (such as in a vial - not shown). The plunger 13 is then withdrawn as in Figure 3 to take fluid into the barrel 11.

The injection is then performed after the depth stop 17 has been pushed in so that the plunger 13 now engages with the actuator 14 as in Figure 4.

At the end of the injection, the locking head 24 will have entered the hollow stem 18 of the actuator 14 and beyond into the flexible fingers 23 so that it is retained therein.

Upon withdrawing the plunger 13 once more, the actuator 14 and needle hub/needle assembly 15, 20 are caused to be withdrawn into the barrel 11 of the syringe 10 as shown in Figure 5.

As shown in Figure 6, the flanges 28 located on the plunger 13 are twisted through the twist lock sleeve 29 fitted in the end of the barrel. Breaking off the plunger 13 at the break point 26 renders the syringe 10 totally safe and useless.

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It will be appreciated by those skilled in the art that many modifications and variations may be made to the embodiments described herein without departing from the spirit or scope of the invention.

Throughout the specification the word "comprise" and its derivatives are intended to have an inclusive rather than exclusive meaning unless the context requires otherwise.

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Claims

1. A single use safety retractable syringe having a retractable needle, the syringe including a hollow barrel, a plunger which slideably fits in the barrel, a piston which fits on the forepart of the plunger, and an actuator mechanism, which is
5 located in the forepart of the barrel and which is able to be fitted therein through the open end of that forepart of the hollow barrel, the actuator mechanism having a stem for supporting a needle hub, and means located on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection.
- 10 2. A single use safety retractable syringe according to claim 1, wherein at the point where the actuator is located in the barrel, there is provided an inner flange on the barrel and a corresponding flange on the actuator mechanism.
3. A single use safety retractable syringe according to claim 2, wherein the
15 respective flanges are shaped, having bevel surfaces on one side and right angled surfaces on the other, so that when the plunger is depressed, the flange of the actuator mechanism locks against the corresponding inner flange of the barrel, by virtue of the opposing right angled surfaces coming into contact, so that in normal use the actuator will not be dislodged.
4. A single use safety retractable syringe according to claim 3, wherein a force of at
20 least 98N may be endured, so that the actuator can not be dislodged from the barrel when the piston is depressed during an injection under normal use conditions.
5. A single use safety retractable syringe according to either claim 3 or claim 4,
25 wherein the flanges need only withstand a lesser force than 98N in order to prevent the actuator from being withdrawn into the barrel when the needle of the syringe is inserted into the patient.
6. A single use safety retractable syringe according to claim 5, wherein the lesser force is preferably 49N.

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7. A single use safety retractable syringe according to any one of claims 5 to 6 wherein the opposing flange surfaces are bevelled so that only a lesser force is needed, ie a force preferably between 49N and 98N.
8. A single use safety retractable syringe according to any one of the preceding
5 claims wherein at the point of contact between the actuator and the barrel there is provided at least one "O" type piston, sufficient that there is no leakage between the actuator and the barrel during use.
9. A single use safety retractable syringe according to any one of the preceding claims in which the stem of the actuator being hollow is preferably provided with
10 at least one flexible finger member.
10. A single use safety retractable syringe according to claim 9 wherein the plunger is provided with a solid stem having a shaped head so that when the injection is completed, the head of the plunger stem enters into the hollow stem of the actuator and passes through the end thereof and is thereby engaged with the
15 actuator, the one or more fingers retaining the head of the plunger stem beyond the stem of the actuator..
11. A single use safety retractable syringe according to claim 10, wherein when the plunger is pulled back, exerting a force between 49 and 98N pull force, the one or more fingers can not break off, and the actuator will be successfully pulled
20 into the barrel.
12. A single use safety retractable syringe according to any one of claims 9 to 11, wherein in order to prevent premature engagement of the head of the plunger stem with the fingers of the actuator stem, a depth stop is preferably provided to prevent the plunger from thus engaging with the actuator before retraction of the
25 needle is required.
13. A single use safety retractable syringe according to claim 12 wherein the depth stop is provided in the form of a pin located in a hole located transverse the shaft of the plunger and located thereon so as to prevent the plunger coming into

contact with the actuator until the pin is depressed, thereby avoiding early unwarranted destruction of the syringe.

14. A single use safety retractable syringe including: a hollow barrel, a plunger which fits the barrel and a piston which fits the forepart of the plunger, and an actuator which fits the forepart of the barrel.

15. A single use safety retractable syringe according to any one of the preceding claims wherein on the actuator there is located a standard 6:100 luer taper to receive the hub of a needle utilising interference fit.

16. A single use safety retractable syringe according to any one of claims 1 to 14, wherein in order to provide a more positive interconnection between the actuator and the needle hub, a screw thread including a so-called luer-lock thread is employed.

17. A single use safety retractable syringe according to any one of the preceding claims wherein the plunger is provided with a break point, so that the plunger is snapped off at completion of the injection rendering the syringe both ineffective for subsequent use as well as providing additional safety in that there is no means by which the needle can be caused to re-emerge or extend from the syringe body.

18. A single use safety retractable syringe according to claim 17 wherein means are provided whereby the plunger can be locked in position prior to being snapped off.

19. A single use safety retractable syringe according to claim 18 wherein a sleeve or collar is inserted in the end of the barrel by interference fit or by screwing it in place and one or more protrusions or lugs are provided on the plunger adjacent the break point and a passage like a thread is provided in the sleeve or collar so that the plunger may be twisted or wound out through the collar or sleeve and locked by suitable means, including flange or ratchet means so that when plunger is broken off at the break point there is no means by which it can be caused to enter the barrel again as it is retained in the collar or sleeve.

(7)

20. A retractable syringe substantially as herein described with reference to the drawings.

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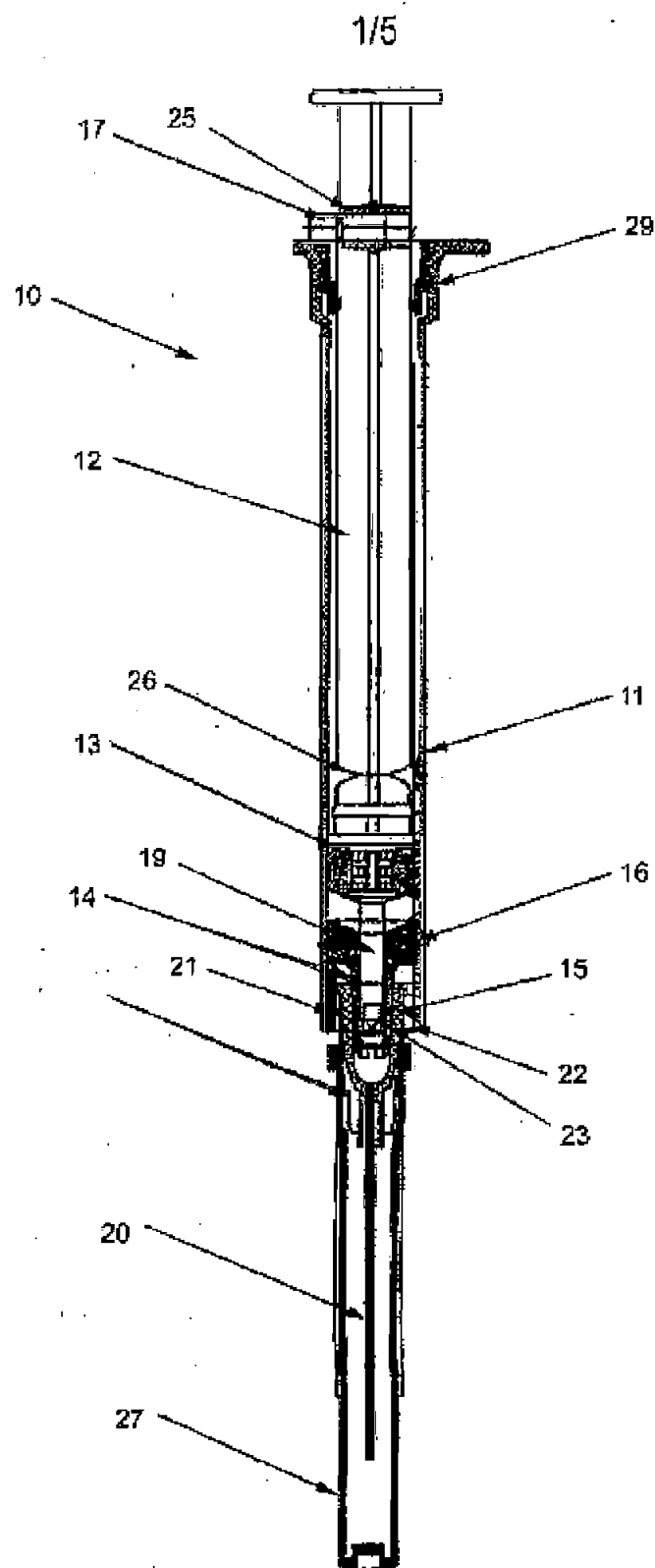
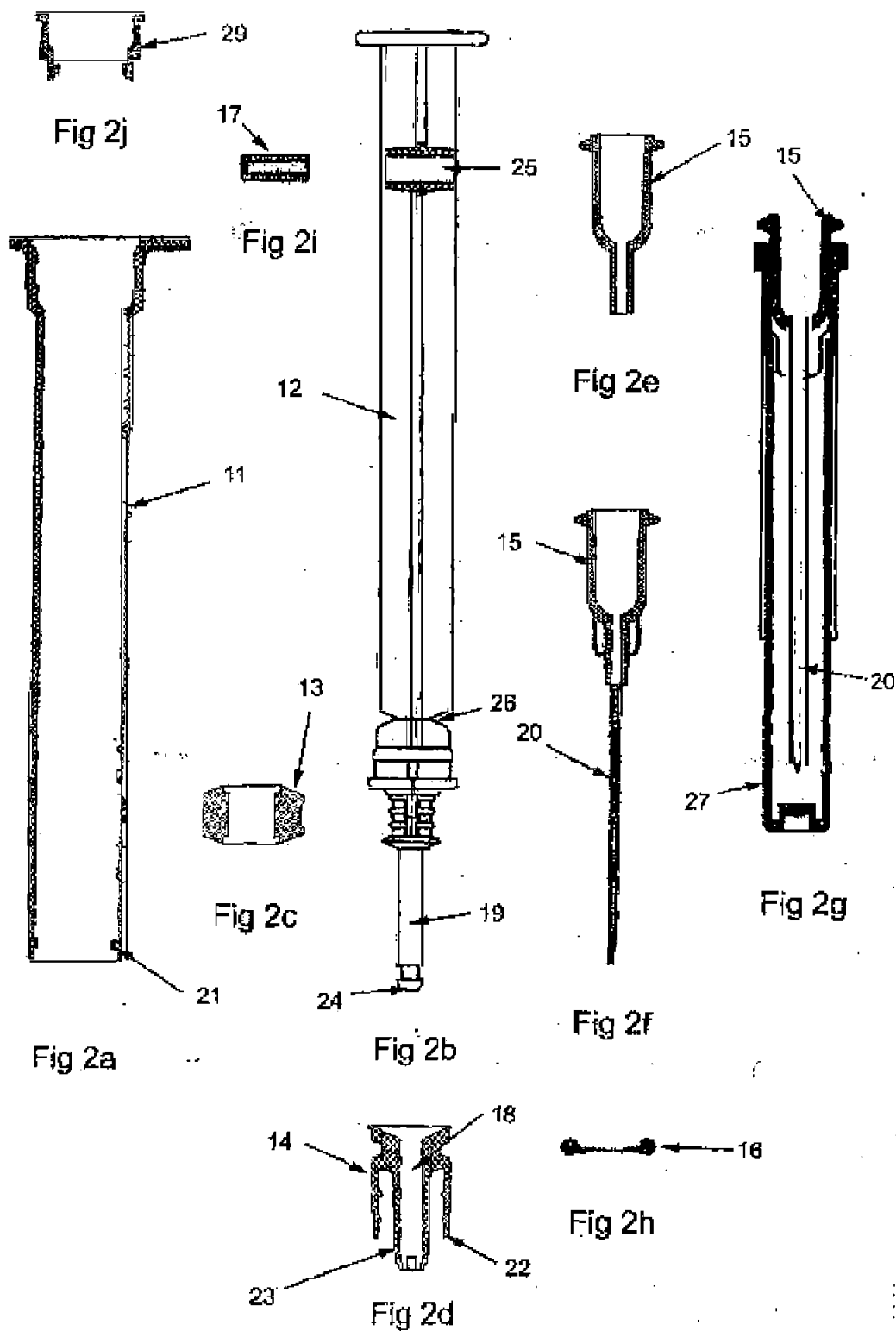


Fig 1

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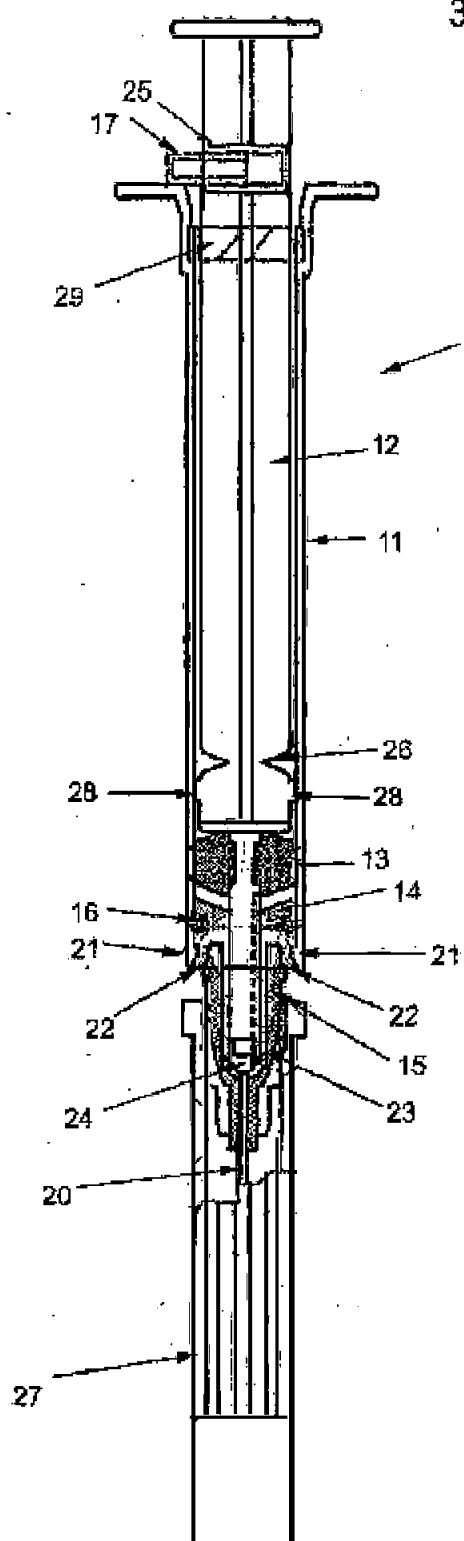


Fig 3

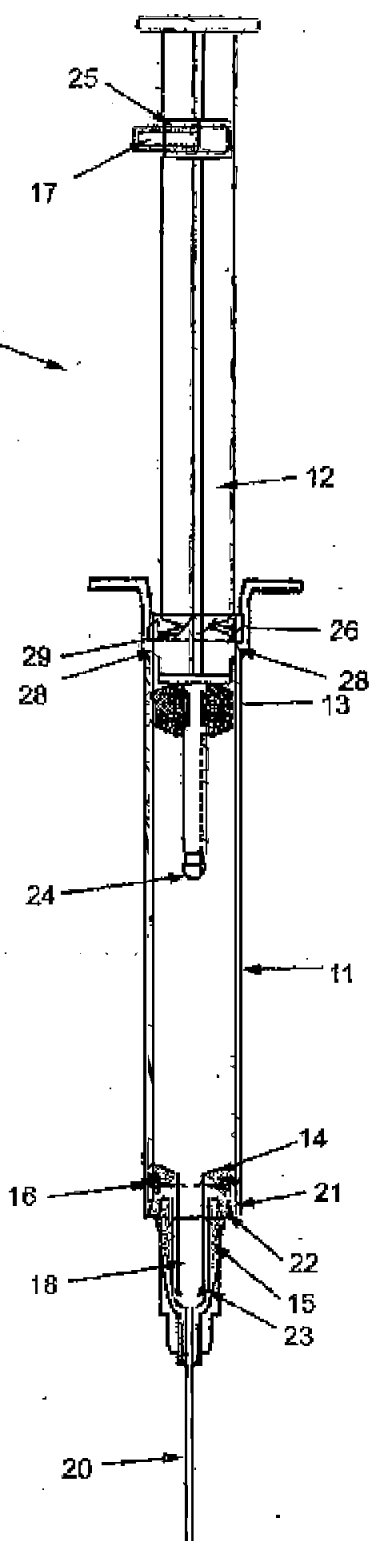


Fig 4

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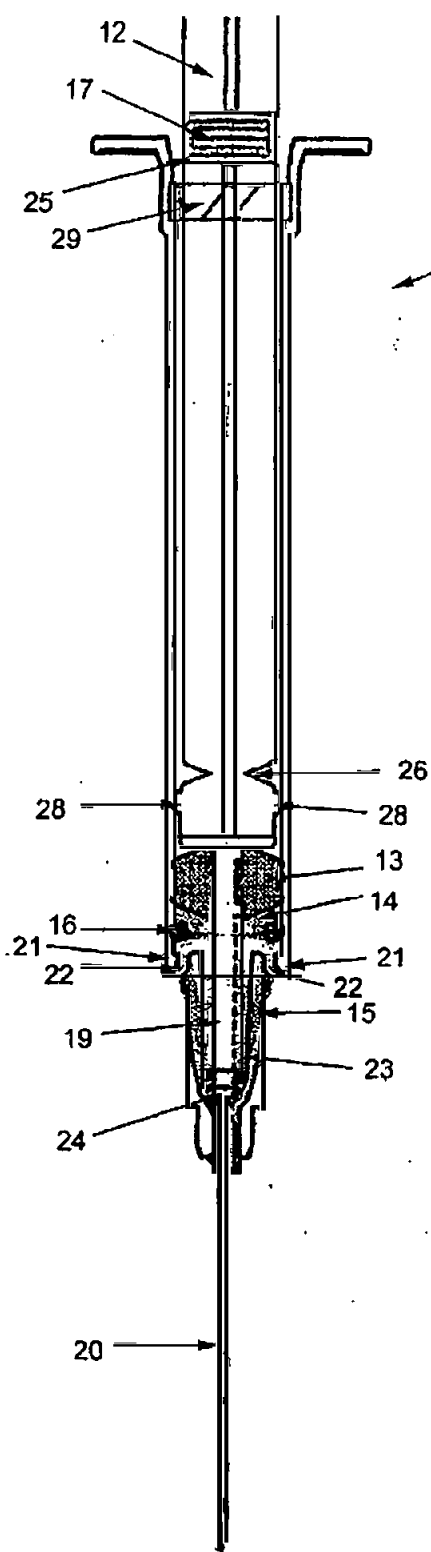


Fig 5

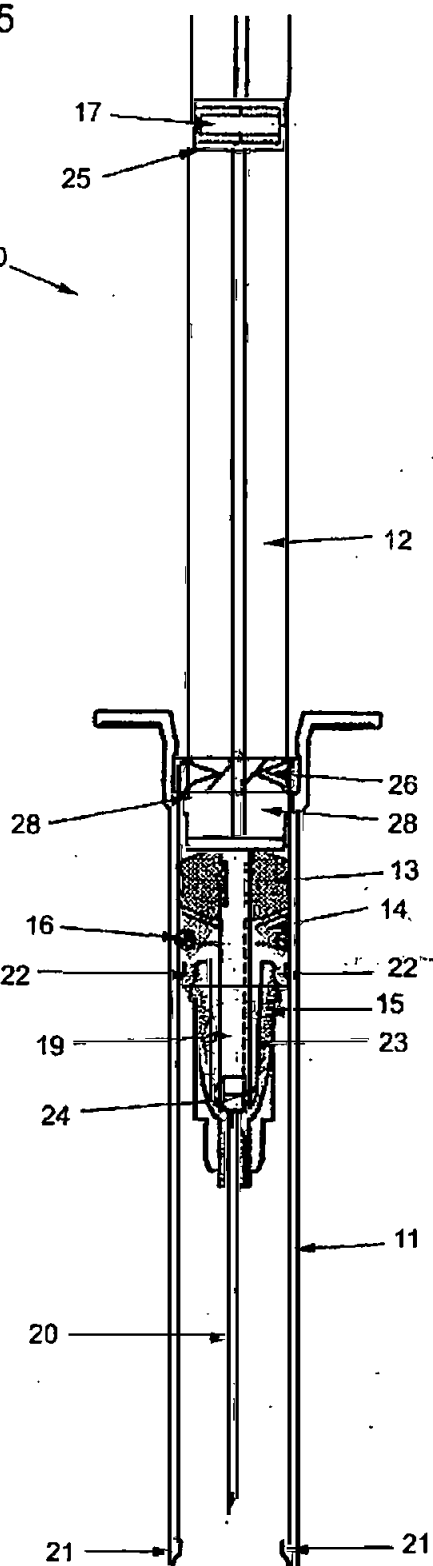


Fig 6

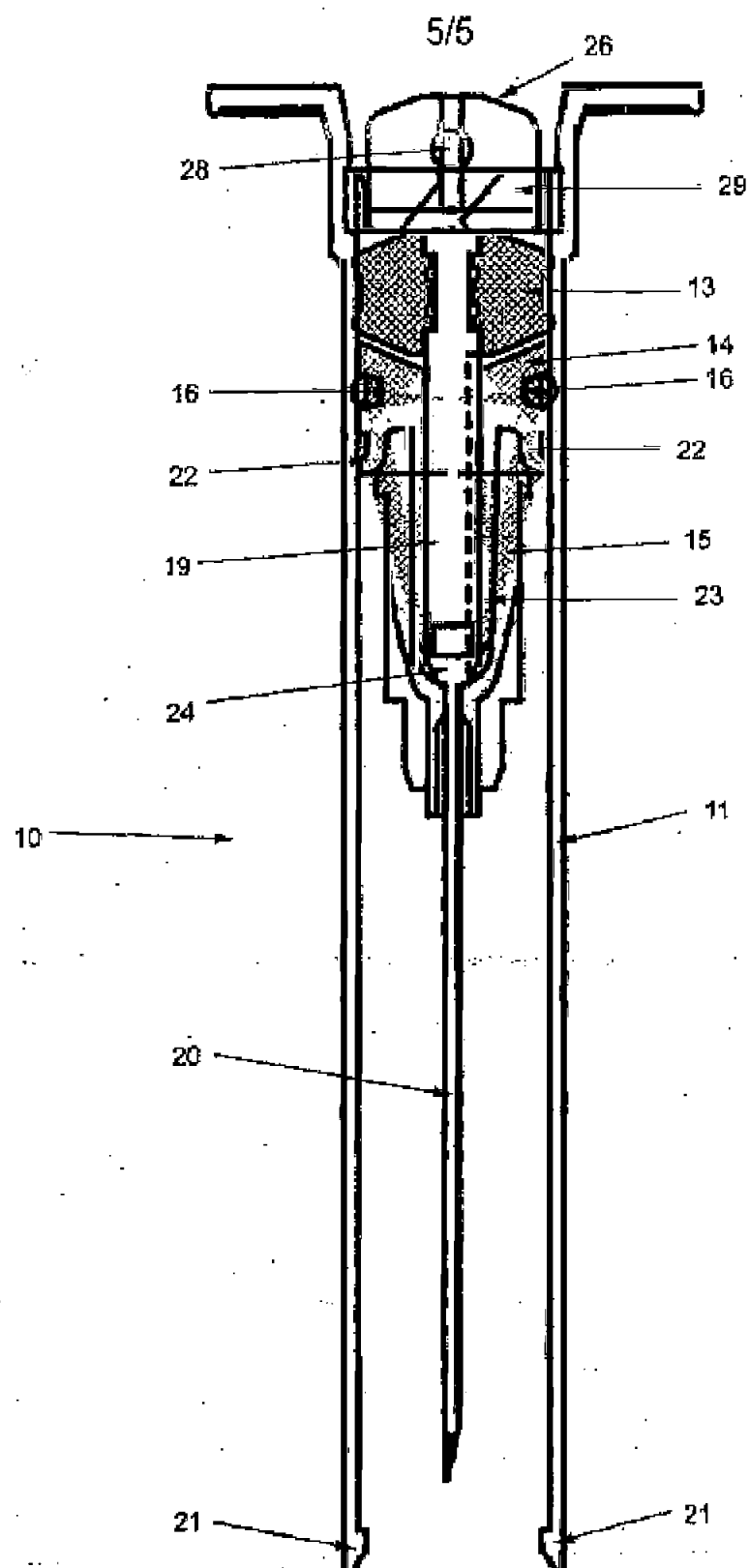


Fig 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/000372

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 5/50 (2006.01) 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)

DWPI IPC A61-005/50 and Keywords (syringe, withdraw, needle, barrel, front, open, push, fit, inner, flange, seat) 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 Y	CA 2183823 A1 (CHEN) 22 February 1998 Whole document	1-7, 15-17 8-12, 18
X Y	EP 1421963 A1 (LIFE-SHIELDS PRODUCTS INC) 26 May 2004 Whole document	1, 2, 15-17 8-12, 18
X Y	CA 2444988 A1 (LIFE-SHIELD PRODUCTS INC) 16 April 2004 Whole document	1, 2, 15-17 8-12, 18

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

* "A" Special categories of cited documents: 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
"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"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
"O" document referring to an oral disclosure, use, exhibition or other means	"Z" document member of the same patent family
"I" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
19 April 2006Date of mailing of the international search report
27 APR 2006Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
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Telephone No : (02) 6283 2064

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2006/000372

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2004/0210198 A1 (SHIH) 21 October 2004 Whole document	1, 2, 15-17 8-12, 18
X Y	CA 2459795 A1 (LIFE-SHIELD PRODUCTS INC) 17 September 2004 Whole document	1, 2, 15-17 8-12, 18
Y	US 2004/0254529 A1 (FITZGERALD) 16 December 2004 items 9 & 16 of Fig. 7	9-11
Y	US 2004/0236283 A1 (TANG) 25 November 2004 item 3 of Fig. 1, item 54 of Fig. 8	8, 12
Y	EP 0498376 A1 (MEGA-TECH GMBH) 12 August 1992 item 37 of Fig. 7	18

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2006/000372

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		
CA	2183823				
EP	1421963	EP	1550476	US	2004102737
		US	2005107747	US	2004153035
CA	2444988	AU	2003248445	JP	2004136088
US	2004/0210198	EP	1576977	US	2005203458
CA	2459795	BR	0400210	ZA	200401615
US	2004/0254529				
US	2004/0236283	CN	1453049	JP	2004344666
EP	0498376	ES	2031754		
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.					
END OF ANNEX					

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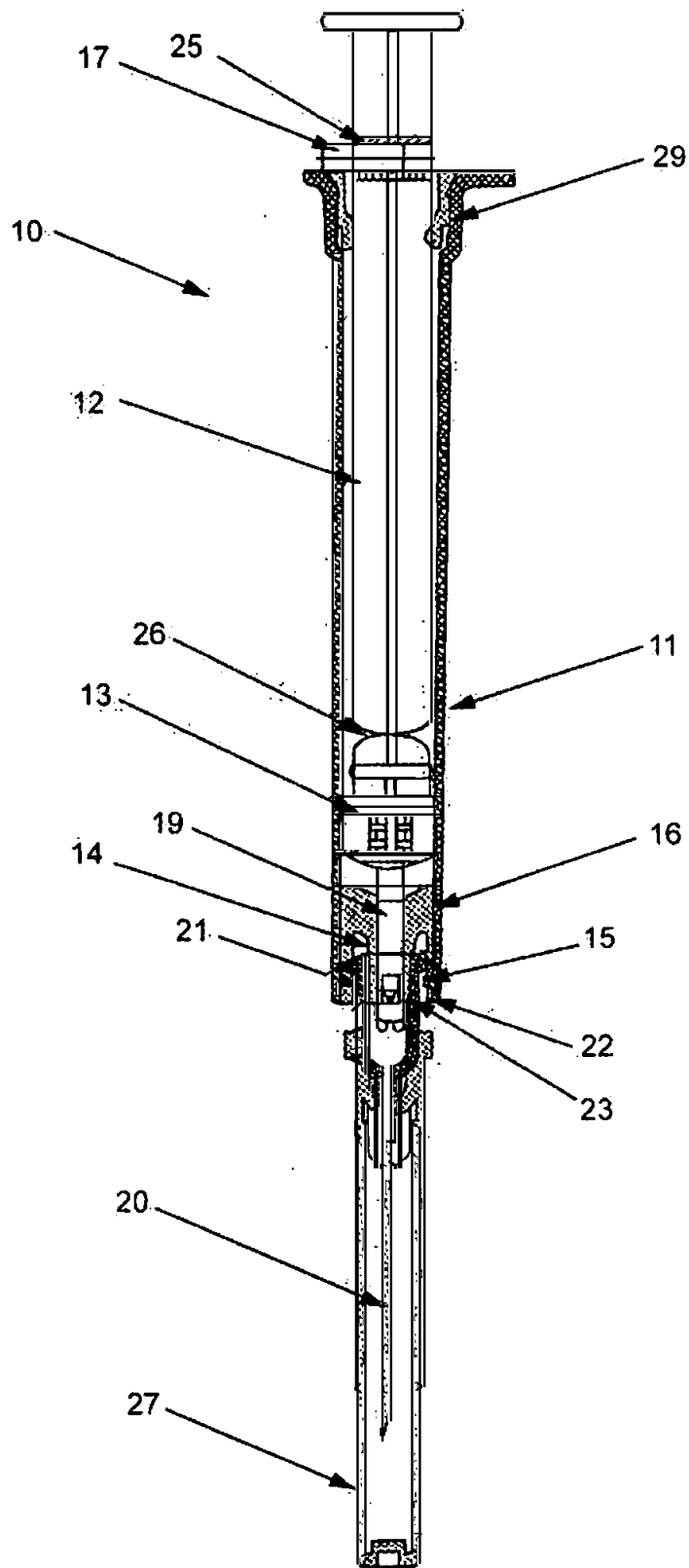
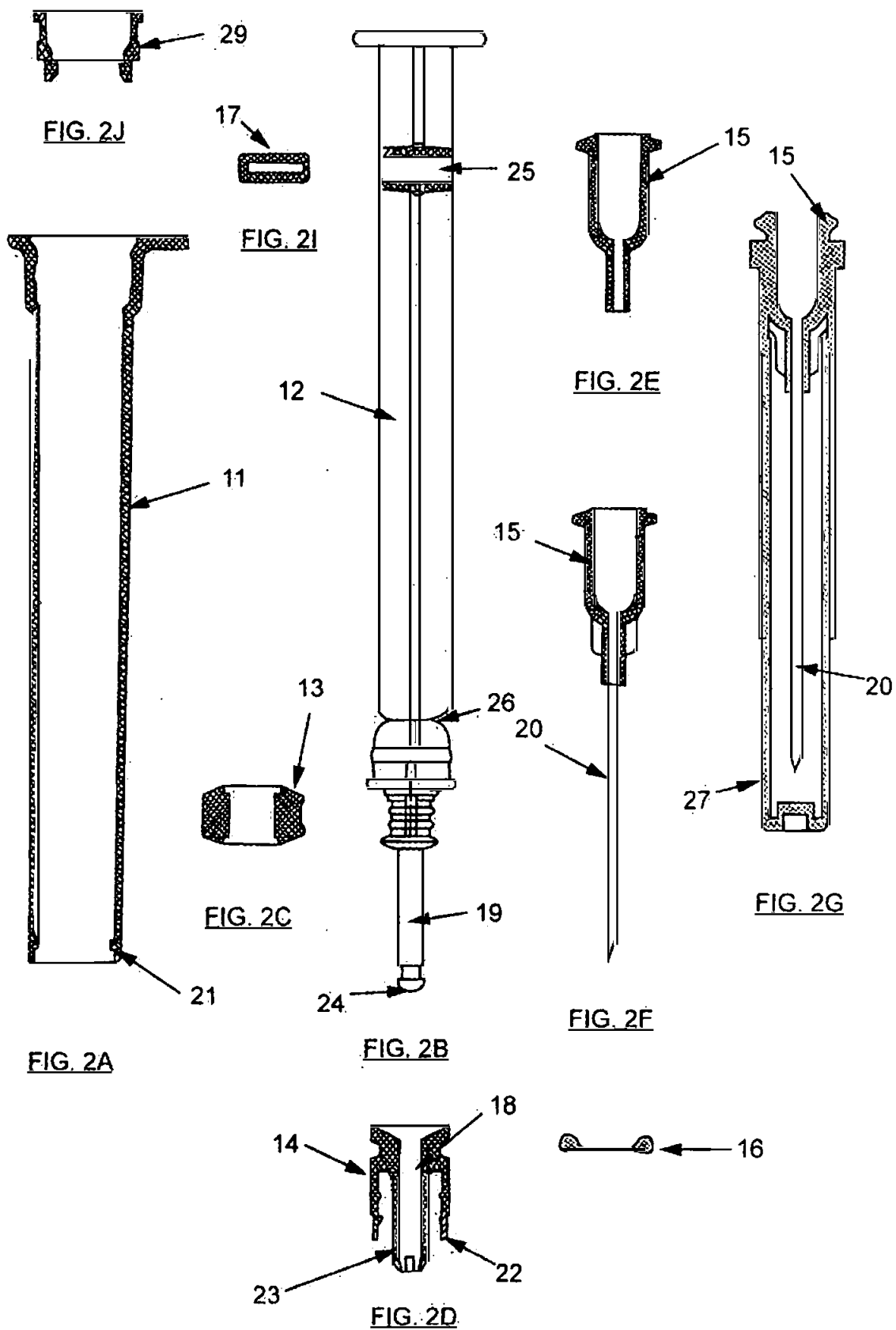
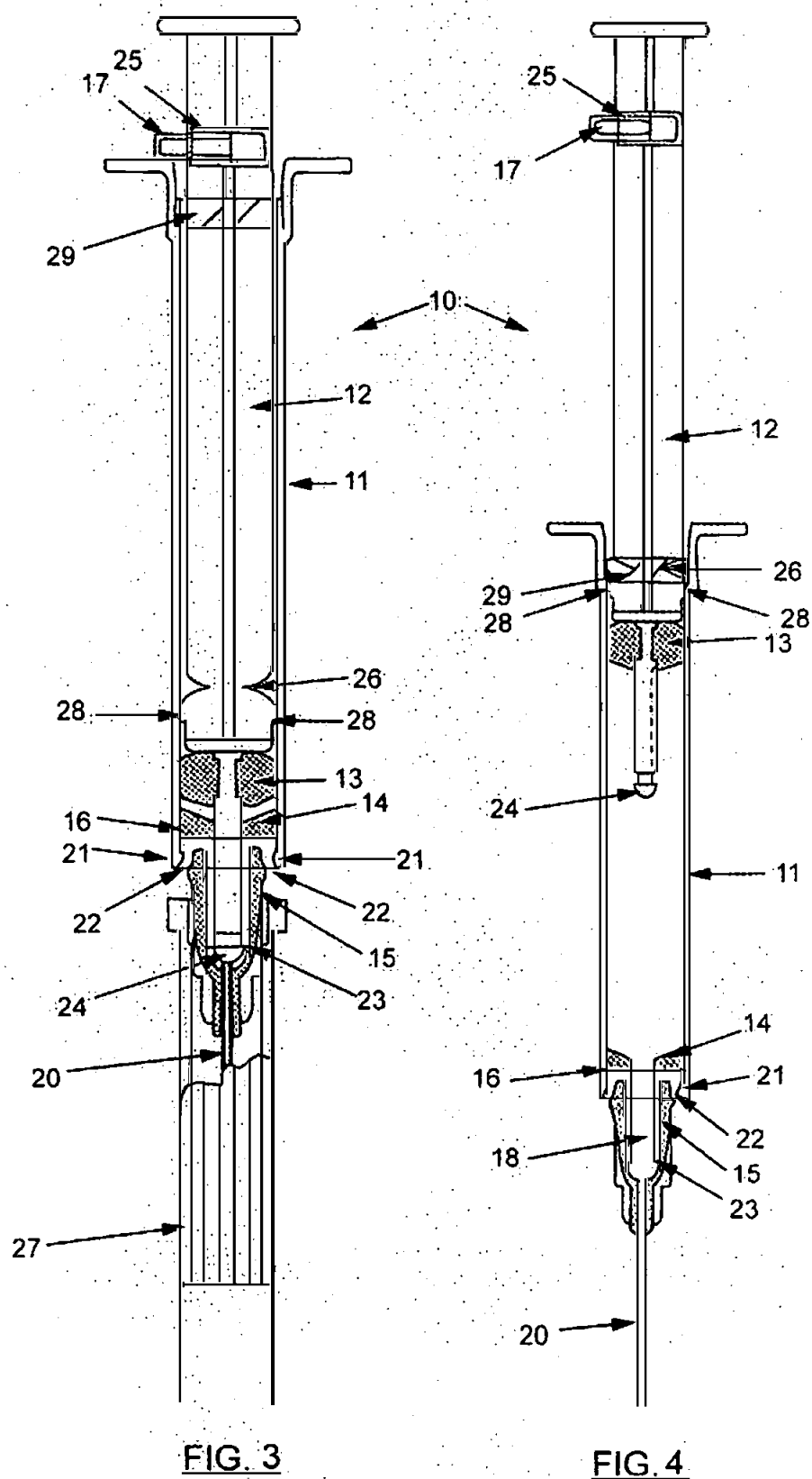


FIG. 1

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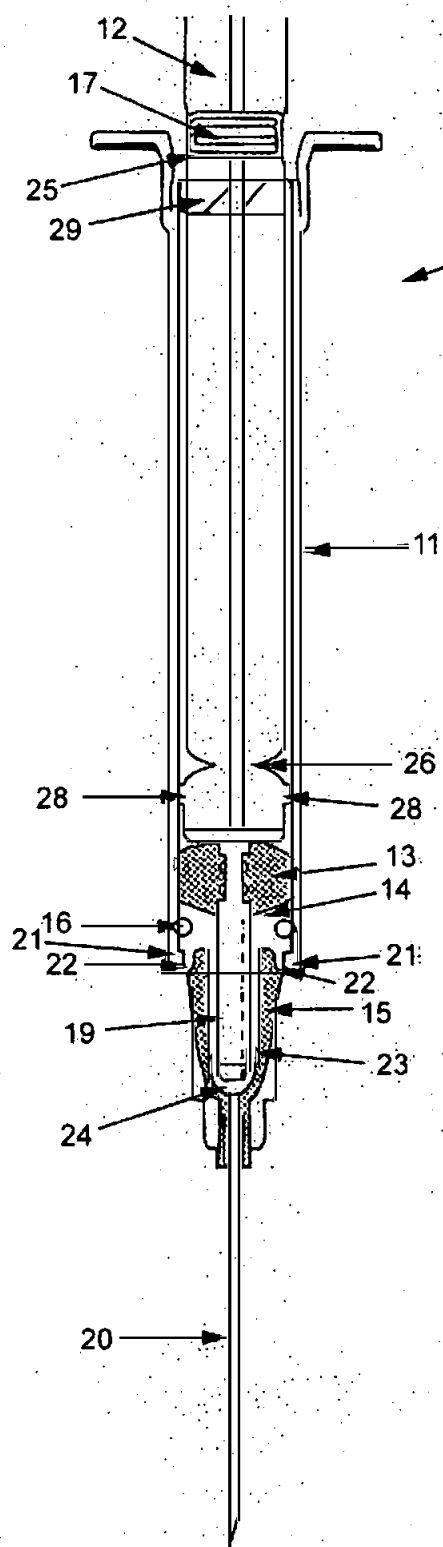


FIG. 5

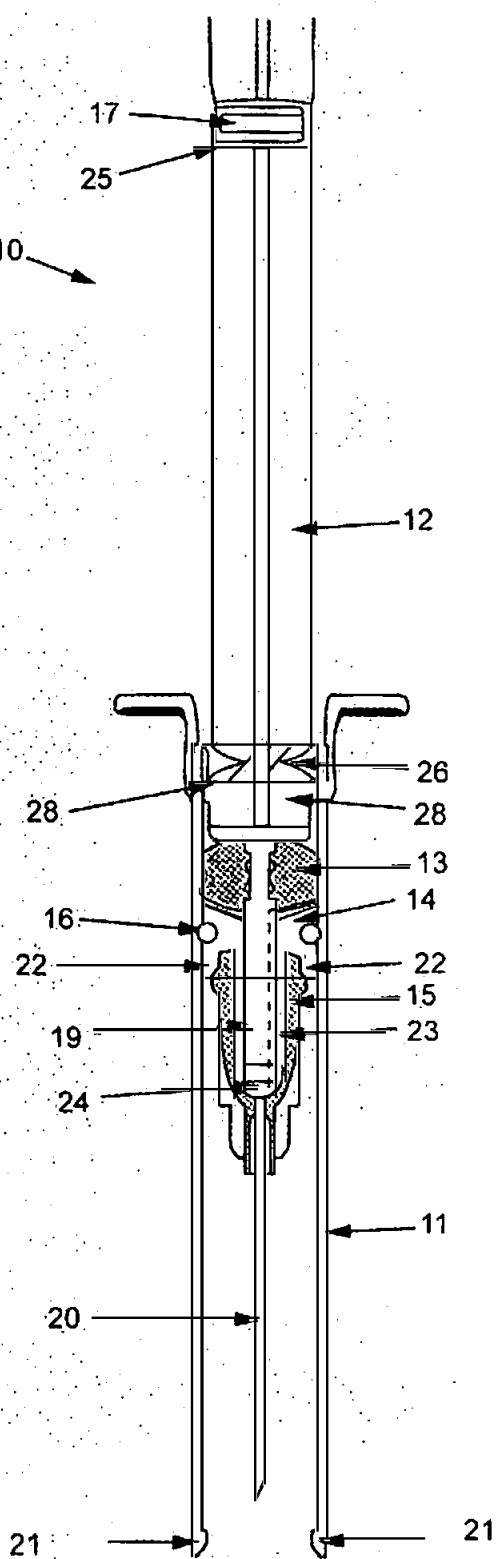


FIG. 6

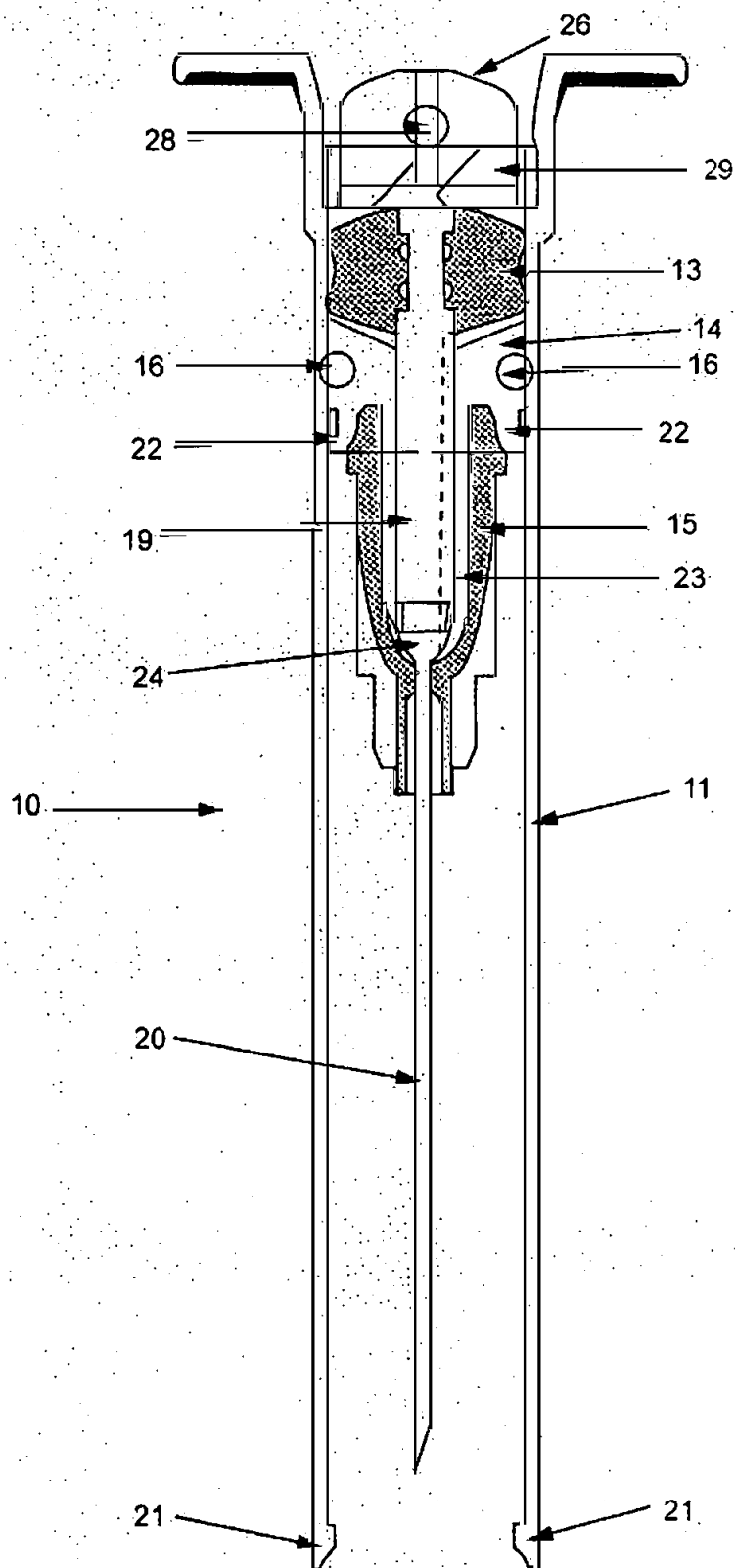


FIG. 7

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Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/AU2006/000372

International filing date: 20 March 2006 (20.03.2006)

Document type: Certified copy of priority document

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Number: PCT/AU2005001343
Filing date: 06 September 2005 (06.09.2005)

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Remark: Priority document submitted or transmitted to the International Bureau in
compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

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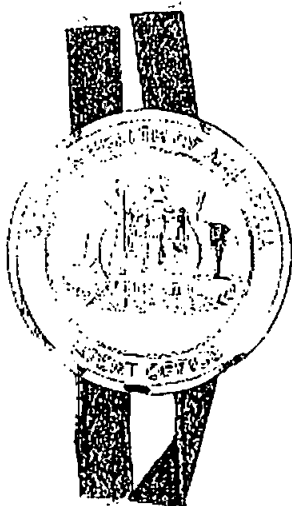
PCT/AU2006/000372



Australian Government

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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of International Application No. PCT/AU2005/001343 filed at the Australian receiving Office on 6 September 2005.



WITNESS my hand this
Twenty-ninth day of March 2006

A handwritten signature in dark ink, appearing to be 'A' or 'L' with a flourish.

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT
AND SALES

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SINGLE USE SAFETY SYRINGE HAVING A RETRACTABLE NEEDLE

Technical Field

This invention relates to a single use safety syringe. In particular it relates to a retractable needle for use in a single-use safety syringe, whereby the syringe user
5 might be protected from injury by the needle after its use.

Background

The danger of injury and possible infection from the HIV or hepatitis B virus to medical practitioners using needles in the normal course of their business is well documented.

10 Further, persons who are in the habit of administering drugs to themselves run a severe risk of contacting either of the specified viruses, or indeed contacting other viruses if a needle, once used, is reused in an unsterilised form.

There have been many proposals aimed at reducing the number of so-called needle-stick injuries and various attempts have been made to provide a safe system for
15 disposal of such needles once used, but such prior proposals have had deficiencies.

Object of the Invention

It is therefore an object of the present invention to provide a single use safety syringe which employs a retractable surgical needle and for permanently storing that surgical needle, once used, in a substantially safe manner, so as to reduce needle stick injuries
20 as well as preventing re-usage of the syringe thereby preventing cross infections of diseases.

It is a particular object of the invention to ameliorate against some or all of the known disadvantages of prior art syringes and to provide a simple safety syringe having a retractable needle which renders the syringe unable to be re-used. At the
25 very least, the invention provides an alternate means for accommodating the needle of a used syringe to protect against accidental injury arising from unwanted contact with the exposed needle once the syringe has been used.

Disclosure of the Invention

The invention in one broad form provides a single-use safety syringe having a retractable needle, the syringe including a hollow barrel, a plunger which slideably fits in the barrel, a piston which fits on the forepart of the plunger, and an actuator mechanism, which is located in the forepart of the barrel, the actuator mechanism
5 having a stem for supporting a needle hub, and means located on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection.

Where the actuator is located in the barrel, there is provided an inner flange on the
10 barrel and a corresponding flange on the actuator mechanism. The flanges are preferably shaped, for example having bevel surfaces on one side and right angled surfaces on the other, so that when the plunger is depressed, the flange of the actuator mechanism locks against the corresponding inner flange of the barrel, for example by virtue of the opposing right angled surfaces coming into contact, so that in normal
15 use the actuator will not be dislodged. Preferably a force of at least 98N may be endured. In this way, the actuator can not be dislodged from the barrel when the piston is depressed during an injection.

On the other hand the flanges need only withstand a lesser of force in order to prevent the actuator from being withdrawn into the barrel when the needle of the
20 syringe is inserted into the patient. Such force is preferably 49N. Indeed, in order that the actuator may be withdrawn into the barrel at the completion of the injection----- however, it is preferable that these opposing flange surfaces are bevelled so that only a lesser force is needed, ie a force preferably between 49N and 98N.

At the point of contact between the actuator and the barrel there is preferably
25 provided at least one "O" type piston, sufficient that there is no leakage between the actuator and the barrel during use.

It will be appreciated that the actuator will be hollow so that fluid contained in the barrel may pass through it and hence through the needle which it supports. The end

of the stem of the actuator is preferably provided with at least one flexible finger member. The plunger is preferably provided with a solid stem having a shaped head so that when the injection is completed, the head of the plunger stem enters into the hollow stem of the actuator and passes through the end thereof and is thereby
5 engaged with the actuator, the one or more fingers retaining the head of the plunger stem beyond the stem of the actuator. When the plunger is pulled back, exerting a force preferably between 49 and 98N pull force, the one or more fingers can not break off, and the actuator will be successfully pulled into the barrel.

In order to prevent premature engagement of the head of the plunger stem with the
10 fingers of the actuator stem, a depth stop is preferably provided to prevent the plunger from thus engaging with the actuator before retraction of the needle is required. Preferably such depth stop is provided in the form of a pin located in a hole located transverse the shaft of the plunger and located thereon so as to prevent the plunger coming into contact with the actuator until the pin is depressed, thereby
15 avoiding early unwarranted destruction of the syringe.

The present invention is therefore a single use safety syringe which includes the following components: a hollow barrel, one plunger which fits the barrel and one piston which fits the forepart of the plunger. There is an actuator which fits the forepart of the barrel. Preferably on the actuator there is located a standard 6:100
20 luer taper. This taper is designed to receive the hub of a needle utilising interference fit. Alternatively, in order to provide a more positive interconnection between the actuator and the needle hub, a screw thread including so-called luer-lock thread may be employed with advantage.

Between the barrel and the outer actuator surface, there is fitted at least one seal. At
25 the end of the barrel there is located at least one means for preventing complete depression of the plunger until the injection is complete and the syringe is to be rendered useless. At the forepart of the plunger there is located a pull back lock, preferably in the form of a head element for engagement with the forepart of the

actuator's inner hole which is provided with flexible fingers, claws or the like, so that when the plunger is moved towards the actuator, the pull back hook in the forepart will enter into the actuator's engagement means easily. When the plunger is withdrawn, the actuator is pulled into the barrel, to realise the safe destruction
5 thereof.

The safety syringe according to the preferred embodiments of the invention has the following advantages when compared with those of the existing market: firstly, it is provided with corresponding a flanges on the barrel and actuator to ensure that the actuator can not be dislodged and move back, an "O" type piston being provided
10 between the actuator and the barrel, to make sure no liquid leaks out, and after injection, when the plunger is withdrawn the actuator can be pulled into the barrel easily, it can not be reused, achieving a truly safe syringe which is effectively destroyed; second, only need a minimal force to have the stem of the plunger enter into the flexible fingers of the stem of the actuator, thereby reducing the patient's pain
15 which has been caused in injection in more recent times; third, the depth stop at the back-end of the plunger prevents the syringe being destroyed before it is used to give an injection through mis-operation causing premature destruction of the syringe.

Preferably the plunger is provide with a break point. Snapping off the plunger also renders the syringe both ineffective for subsequent use as well as providing
20 additional safety in that there is no means by which the needle can be caused to re-emerge or extend from the syringe body.

Furthermore, it is preferable to provide means whereby the plunger can in fact be locked in position prior to being snapped off. This maybe achieved by utilising a sleeve or collar inserted in the end of the barrel, for example either by interference fit
25 or by screwing it in place. A protrusion or lug may be provided on the plunger adjacent the break point and a passage for example like a thread may be provide in the sleeve or collar so that the plunger may be wound out through the collar or sleeve and locked by suitable means, eg flange or ratchet means so that when plunger is

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broken off at the break point there is no means by which it can be caused to re-enter the barrel as it is retained in the collar or sleeve.

Brief Description of the Drawings

The invention may be better understood from the following non-limiting description
5 of preferred embodiments, in which:

Figure 1 is an exploded view of a single-use safety syringe according to one embodiment of the invention;

Figure 2 is a cross-sectional view of the assembled syringe of Figure 1, showing the syringe prior to use with a cap covering and protecting the needle;

10 Figure 3 is a cross-sectional view of the syringe of Figure 2, showing the plunger drawn back, the barrel having been filled with injectable solution;

Figure 4 is a cross-sectional view of the syringe of the previous figures, at the completion of injection, the plunger having engaged the actuator;

Figure 5 is a cross-sectional view of the syringe of the previous figures, the plunger
15 having been withdrawn so that the actuator and needle are safely withdrawn into the barrel of the syringe; and

Figure 6 is a cross section of the syringe of the earlier figures, the plunger having been locked in the sleeve at the end of the barrel and broken off at the break point rendering the syringe safely destroyed.

20 Detailed Description of the Drawings

Referring to Figure 1 there is shown an exploded view of a syringe, generally referenced 10, according to a preferred embodiment of the invention.

The syringe includes a barrel 11, plunger 12, piston 13, actuator 14, needle hub 15 supporting a needle 20, "O" type piston 16, and depth stop 17. A cap 29 is provide to
25 protect the needle prior to use.

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An inner flange 21 is located in the foremost part of the barrel 11. A corresponding flange 22 is located on the actuator 14. Flexible spring fingers 23 are located on the end of the hollow stem 18 of the actuator 14. The solid stem 19 at the end of the plunger 13 is provided with a locking head 24. A hole 25 is located in the plunger 13 to accommodate the pin 7 which functions as a depth stop.

Break point 26 is provided on the plunger 13. The plunger also has flanges 28 which allow the plunger 13 to be twist locked in the twist lock sleeve 29 located in the end of the barrel 11.

Referring generally to Figures 2 to 6, there is shown a syringe 10 which has the various parts illustrated as in Figure 1, the same reference numerals being utilised throughout.

The safety syringe 10 according to the invention possesses the following characters:

At the junction between the actuator 14 and barrel 11 there is located a sealing member 16 in the form of an "O" ring or the like. There is also located corresponding flanges 22, 21 on the actuator 14 and on the inner surface of the barrel 11 respectively. At each edge of the actuator flange 22 there is formed a bevel and a right angle respectively, the bevel and right angle correspond with a bevel and a right angle located on the flange 21 inside the barrel 11. In essence the orientation of the respective shapes of the two flanges 21, 22 means that in use, normal pressure as exerted during an injection will not cause the actuator to be dislodged outwardly or indeed inwardly. Indeed the use of the depth stop 17, prior to its being pressed in will ensure that this can't happen accidentally either. However, the use of the locking head 24 which engages the fingers 23 is in fact sufficient to easily draw the actuator 14 back, once the locking head 24 of the plunger 13 has been allowed to engage the actuator 14 by pressing in stop 17.

On the plunger 13 there is provided a break point 26, so that the plunger 13 can be broken off easily along the break point 26. At the back-end of plunger 13 there is located a depth stop 17 which can be pushed in, but which contacts the end of the

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barrel 11, until such time as it is pushed in so as to prevent the plunger 13 from being fully depressed and hence engaging with the actuator 14.

In Figure 2, the needle is protected by a cap 27 prior to use. The plunger 13 is prevented from engaging with actuator 14 by virtue of depth stop 17 which is in the
5 out position.

In use the cap 27 is removed to reveal the needle 20 and the needle 20 is inserted into the fluid to be used for the injection (such as in a vial - not shown). The plunger 13 is then withdrawn as in Figure 3 to take fluid into the barrel 11.

The injection is then performed after the depth stop 17 has been pushed in so that the
10 plunger 13 now engages with the actuator 14 as in Figure 4.

At the end of the injection, the locking head 24 will have entered the hollow stem 18 of the actuator 14 and beyond into the flexible fingers 23 so that it is retained therein.

Upon withdrawing the plunger 13 once more, the actuator 14 and needle hub/needle assembly 15,20 are caused to be withdrawn into the barrel 11 of the syringe 10 as
15 shown in Figure 5.

As shown in Figure 6, the flanges 28 located on the plunger 13 are twisted through the twist lock sleeve 29 fitted in the end of the barrel. Breaking off the plunger 13 at the break point 26 renders the syringe 10 totally safe and useless.

It will be appreciated by those skilled in the art that many modifications and
20 variations may be made to the embodiments described herein without departing from the spirit or scope of the invention.

Throughout the specification the word "comprise" and its derivatives are intended to have an inclusive rather than exclusive meaning unless the context requires otherwise.

Claims

1. A single use safety retractable syringe having a retractable needle, the syringe including a hollow barrel, a plunger which slideably fits in the barrel, a piston which fits on the forepart of the plunger, and an actuator mechanism, which is located in the forepart of the barrel, the actuator mechanism having a stem for supporting a needle hub, and means located on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection.
2. A single use safety retractable syringe according to claim 1, wherein at the point where the actuator is located in the barrel, there is provided an inner flange on the barrel and a corresponding flange on the actuator mechanism.
3. A single use safety retractable syringe according to claim 2, wherein the respective flanges are shaped, having bevel surfaces on one side and right angled surfaces on the other, so that when the plunger is depressed, the flange of the actuator mechanism locks against the corresponding inner flange of the barrel, by virtue of the opposing right angled surfaces coming into contact, so that in normal use the actuator will not be dislodged.
4. A single use safety retractable syringe according to claim , wherein a force of at least 98N may be endured, so that the actuator can not be dislodged from the barrel when the piston is depressed during an injection under normal use conditions.
5. A single use safety retractable syringe according to either claim 3 or claim 4, wherein the flanges need only withstand a lesser of force in order to prevent the actuator from being withdrawn into the barrel when the needle of the syringe is inserted into the patient.
6. A single use safety retractable syringe according to claim 5, wherein the lesser force is preferably 49N.

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7. A single use safety retractable syringe according to any one of claims 5 to 6 wherein the opposing flange surfaces are bevelled so that only a lesser force is needed, ie a force preferably between 49N and 98N.
8. A single use safety retractable syringe according to any one of the preceding
5 claims wherein at the point of contact between the actuator and the barrel there is provided at least one "O" type piston, sufficient that there is no leakage between the actuator and the barrel during use.
9. A single use safety retractable syringe according to any one of the preceding claims in which the stem of the actuator being hollow is preferably provided with
10 at least one flexible finger member.
10. A single use safety retractable syringe according to claim 9 wherein the plunger is provided with a solid stem having a shaped head so that when the injection is completed, the head of the plunger stem enters into the hollow stem of the actuator and passes through the end thereof and is thereby engaged with the
15 actuator, the one or more fingers retaining the head of the plunger stem beyond the stem of the actuator..
11. A single use safety retractable syringe according to claim 10, wherein when the plunger is pulled back, exerting a force between 49 and 98N pull force, the one or more fingers can not break off, and the actuator will be successfully pulled
20 into the barrel.
12. A single use safety retractable syringe according to any one of claims 9 to 11, wherein in order to prevent premature engagement of the head of the plunger stem with the fingers of the actuator stem, a depth stop is preferably provided to prevent the plunger from thus engaging with the actuator before retraction of the
25 needle is required.
13. A single use safety retractable syringe according to claim 12 wherein the depth stop is provided in the form of a pin located in a hole located transverse the shaft of the plunger and located thereon so as to prevent the plunger coming into

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contact with the actuator until the pin is depressed, thereby avoiding early unwarranted destruction of the syringe.

14. A single use safety retractable syringe including: a hollow barrel, a plunger which fits the barrel and a piston which fits the forepart of the plunger, and an actuator which fits the forepart of the barrel.
15. A single use safety retractable syringe according to any one of the preceding claims wherein on the actuator there is located a standard 6:100 luer taper to receive the hub of a needle utilising interference fit.
16. A single use safety retractable syringe according to any one of claims 1 to 14, wherein in order to provide a more positive interconnection between the actuator and the needle hub, a screw thread including a so-called luer-lock thread is employed.
17. A single use safety retractable syringe according to any one of the preceding claims wherein the plunger is provided with a break point, so that the plunger is snapped off at completion of the injection rendering the syringe both ineffective for subsequent use as well as providing additional safety in that there is no means by which the needle can be caused to re-emerge or extend from the syringe body.
18. A single use safety retractable syringe according to claim 17 wherein means are provided whereby the plunger can be locked in position prior to being snapped off.
19. A single use safety retractable syringe according to claim 18 wherein a sleeve or collar is inserted in the end of the barrel by interference fit or by screwing it in place and one or more protrusions or lugs are provided on the plunger adjacent the break point and a passage like a thread is provided in the sleeve or collar so that the plunger may be twisted or wound out through the collar or sleeve and locked by suitable means, including flange or ratchet means so that when plunger is broken off at the break point there is no means by which it can be caused to enter the barrel again as it is retained in the collar or sleeve.

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20. A retractable syringe substantially as herein described with reference to the drawings.

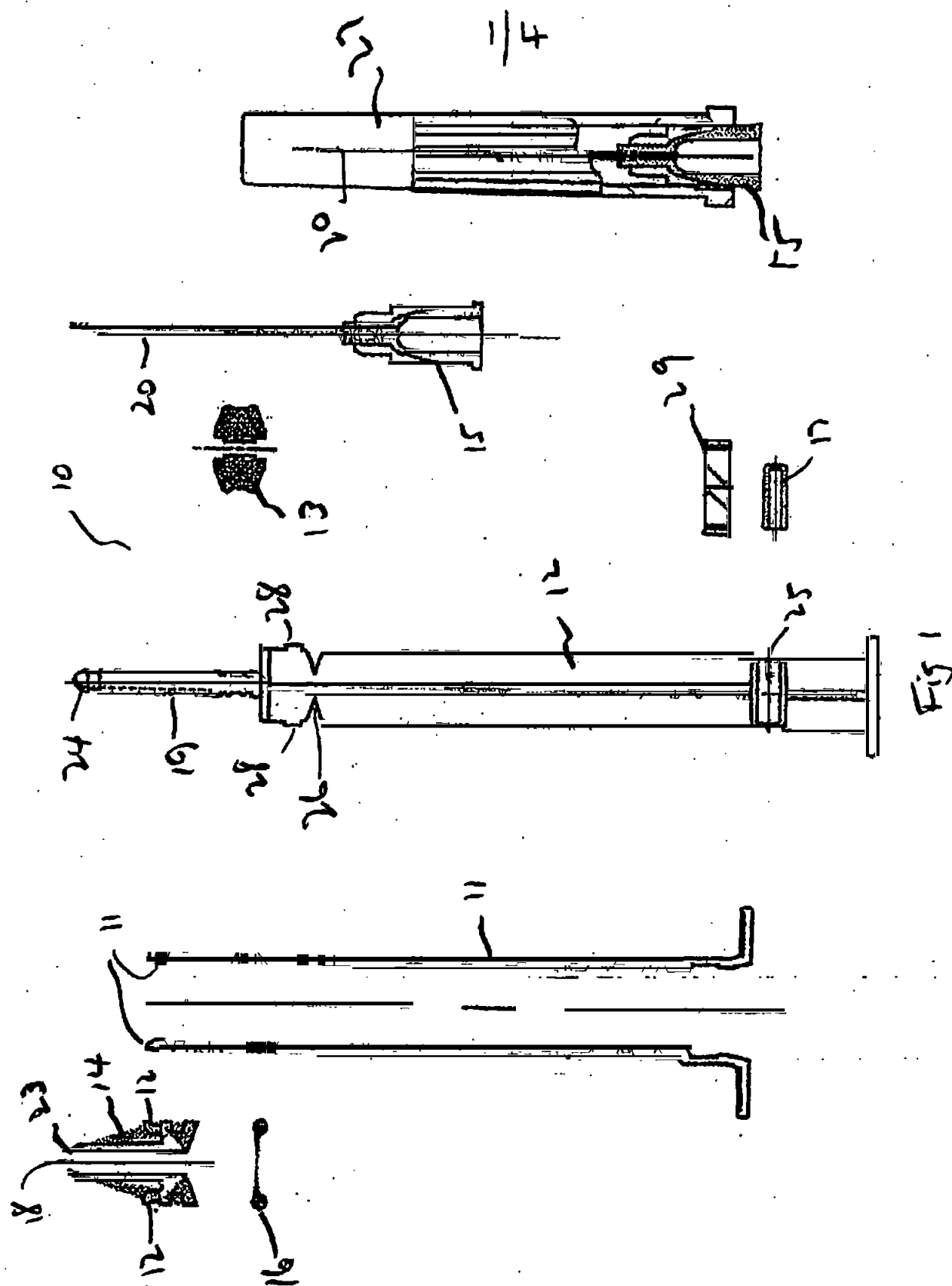
ABSTRACT

SINGLE USE SYRINGE HAVING A RETRACTABLE NEEDLE

A single use safety retractable syringe (10) having a retractable needle (20) is disclosed. The syringe includes a hollow barrel (11), a plunger (13) which slideably
5 fits in the barrel, and a piston (13) which fits on the forepart of the plunger. The syringe also includes an actuator mechanism (14), which is located in the forepart of the barrel. The actuator mechanism has a stem (18) for supporting a needle hub (15). Means (24) are provided on the end of the plunger to engage the actuator and cause it
to retract with the needle upon completion of the injection.

10

Fig 2



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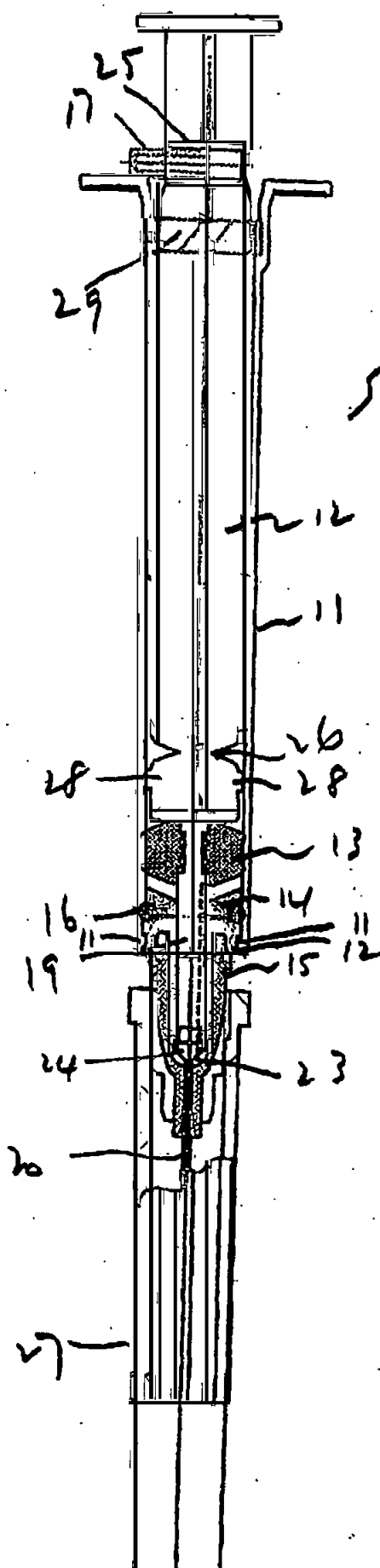


Fig 2

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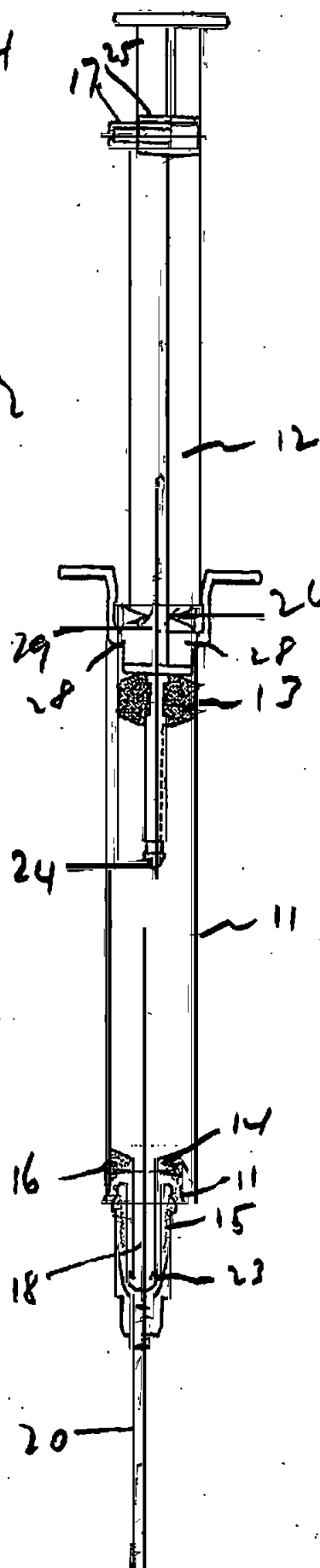


Fig 3

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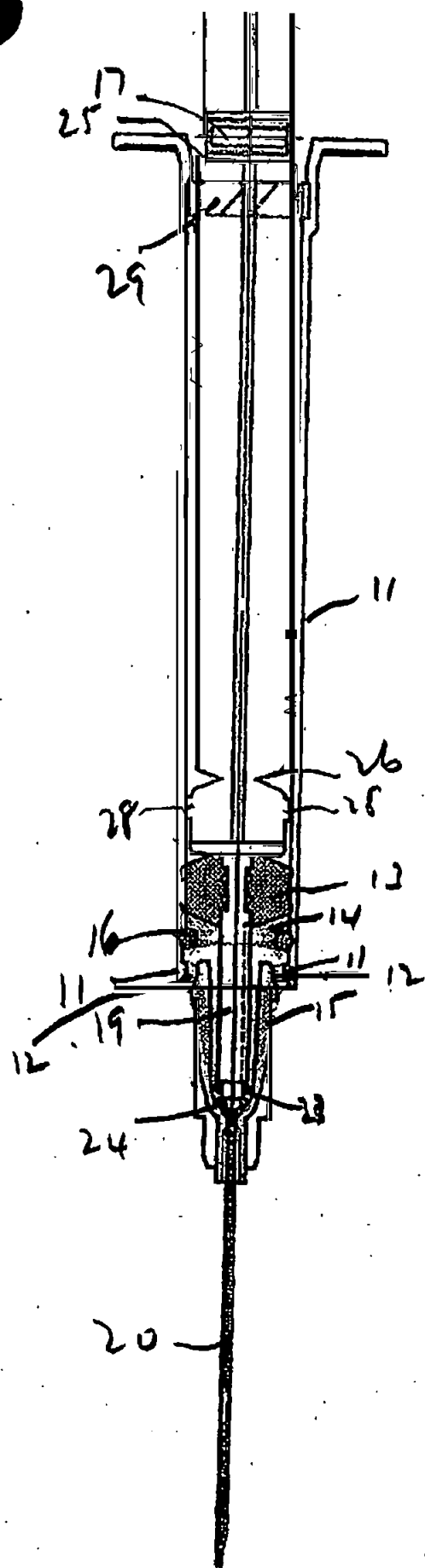


Fig 4

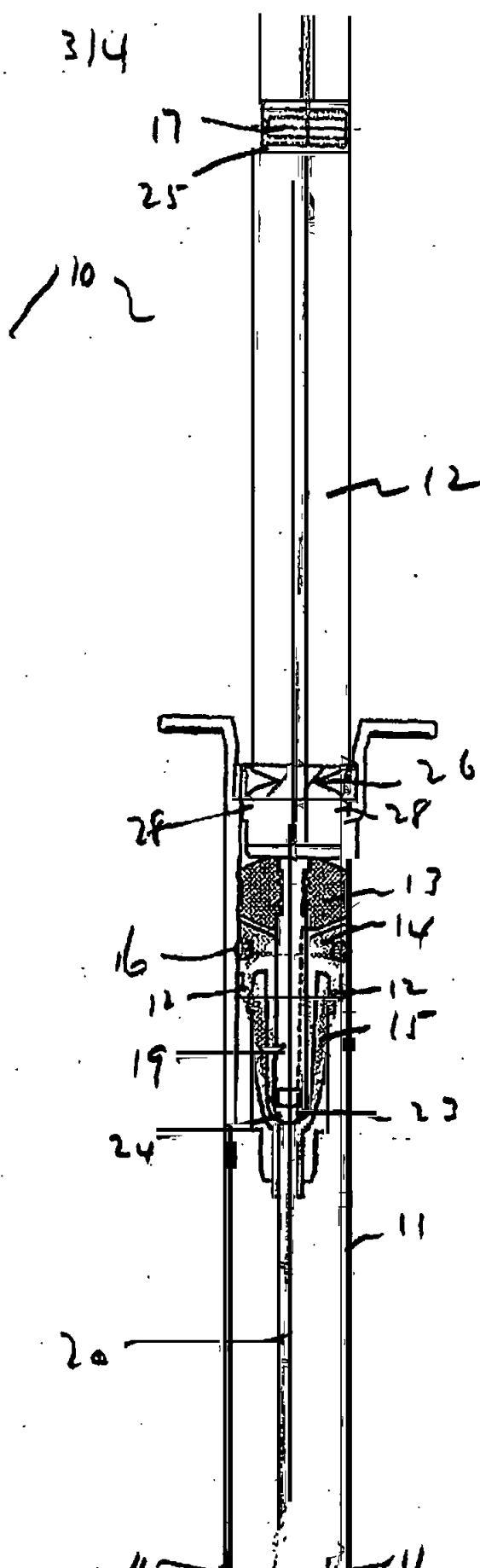


Fig 5

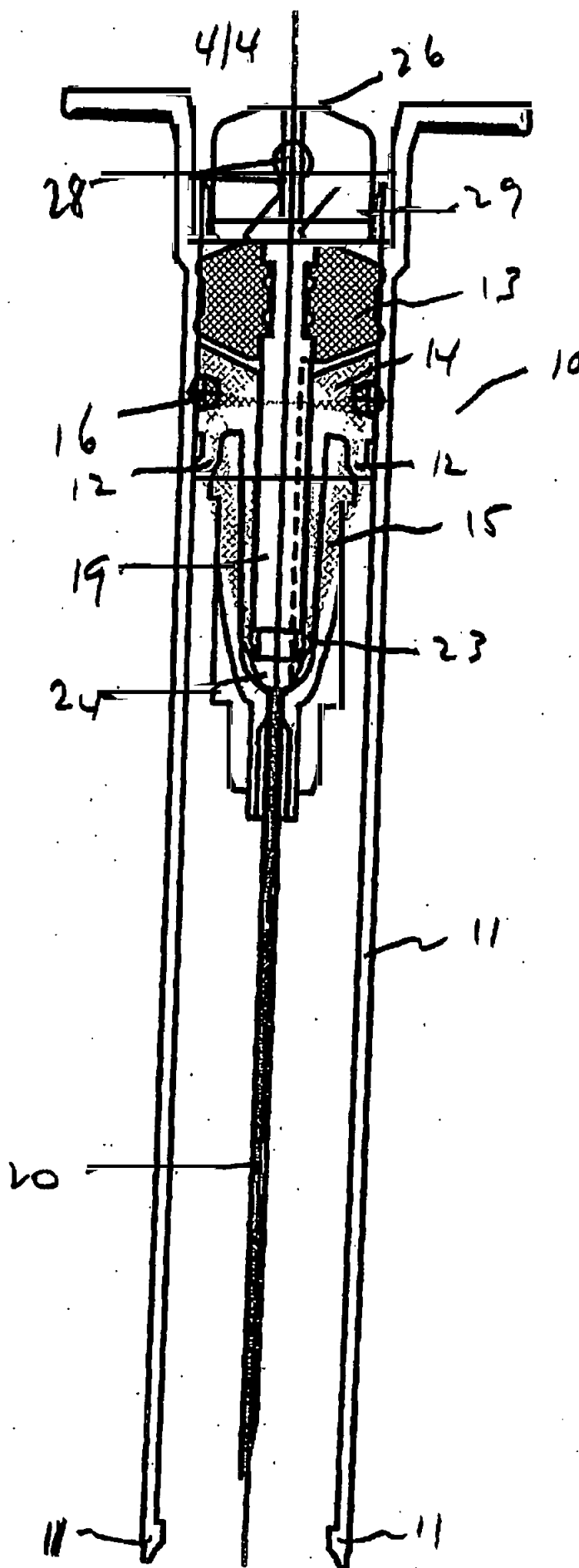


Fig 6

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Se describe una jeringa retráctil de seguridad de uso único (10) que tiene una aguja retráctil (20). La jeringa incluye un barril hueco (11), un émbolo (13) que se ajusta de manera deslizable en el barril y un pistón (13) que se ajusta sobre la parte anterior del émbolo. La jeringa también incluye un mecanismo accionador (14) que se localiza en la parte anterior del barril. El accionador es capaz de ajustarse a través del extremo abierto de la parte anterior del barril hueco. El mecanismo accionador tiene un vástago (18) para soportar la cabeza (15) de la aguja. Se proporcionan los medios (24) sobre el extremo del émbolo para embragar el accionador y hacerlo reaccionar con la aguja al término de la inyección.

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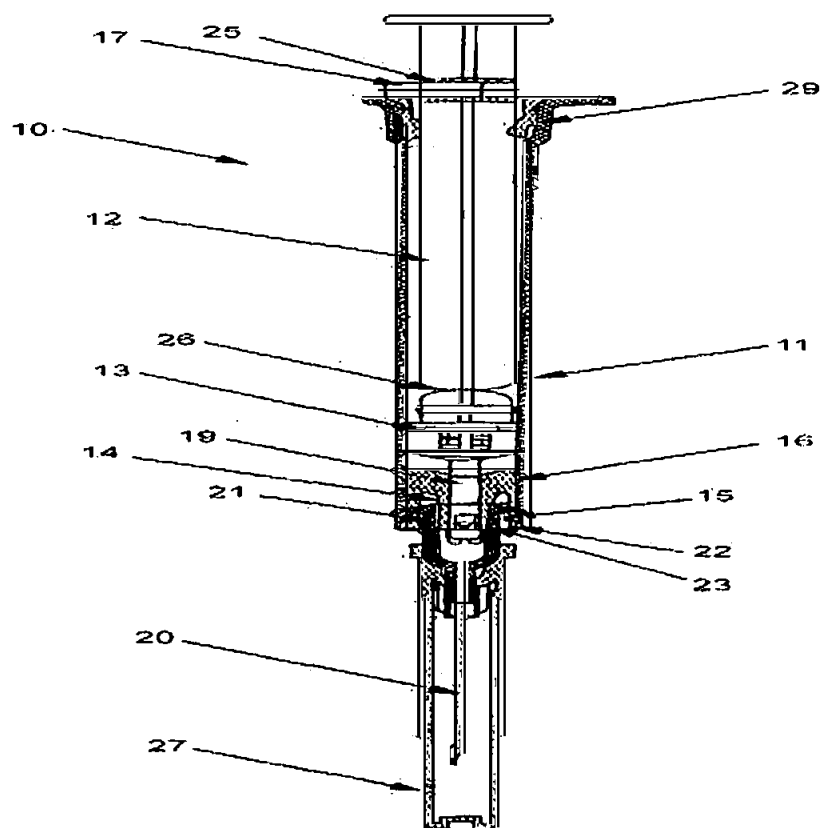


FIG. 1

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JERINGA DE SEGURIDAD DE USO ÚNICO CON AGUJA RETRÁCTIL

Campo Técnico

Esta invención se refiere a una jeringa de seguridad de uso único. En particular se refiere a una aguja retráctil para utilizarse en una jeringa de seguridad de uso único, mediante lo cual el usuario de la jeringa puede protegerse de daño por la aguja después de su uso.

Antecedentes

Se encuentra bien documentado el peligro de daño y posible infección por virus de VIH o hepatitis B a practicantes de la medicina utilizando agujas en el curso normal de su trabajo.

Además, las personas que tienen el hábito de administrarse fármacos por si mismas, corren un severo riesgo de contraer cualquiera de los virus especificados o efectivamente hacer contacto con otros virus si la aguja, una vez utilizada, se re-utiliza en una forma no esterilizada.

Han existido muchas propuestas dirigidas a reducir el número de las así llamadas lesiones por picadura con aguja y se han hecho diversos intentos para proporcionar un sistema seguro para la eliminación de tales agujas una vez utilizadas, pero tales propuestas anteriores han tenido deficiencias.

Objetivo de la Invención

Es por lo tanto un objetivo de la presente

invención proporcionar una jeringa de seguridad de uso único que emplea una aguja quirúrgica retráctil y para almacenar de manera permanente esa aguja quirúrgica, una vez utilizada, en una manera sustancialmente segura, a fin de reducir las
5 lesiones por picadura con aguja así como el evitar el re-uso de la jeringa evitando mediante esto las infecciones cruzadas de enfermedades.

Es un objetivo particular de la invención mejorar algunas o todas las desventajas conocidas de las jeringas de
10 la técnica anterior y proporcionar una jeringa de seguridad sencilla que tenga una aguja retráctil la cual haga a la jeringa incapaz de re-utilizarse. Por último, la invención proporciona un medio alternativo para acomodar la aguja de una jeringa utilizada para protegerse contra una lesión
15 accidental que surja del contacto no deseado con la aguja expuesta una vez que la jeringa se ha utilizado.

Sumario de la Invención

La invención en forma amplia proporciona una jeringa de seguridad de uso único que tiene una aguja
20 retráctil, incluyendo la jeringa un barril hueco, un émbolo que se ajusta de manera deslizable en el barril, un pistón que se ajusta sobre la parte anterior del émbolo y un mecanismo accionador, que se ubica en la parte anterior del barril y que es capaz de ajustarse en el mismo a través del
25 extremo abierto de la parte anterior del barril hueco,

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teniendo el mecanismo accionador un vástago para soportar la cabeza de la aguja y medios ubicados sobre el extremo del émbolo para embragar el accionador y hacerlo que se retraiga con la aguja al finalizar la inyección.

5 Cuando el accionador se ubica en el barril, se proporciona una saliente interior sobre el barril y una saliente correspondiente sobre el mecanismo accionador, para el ajuste del accionador desde ese extremo abierto del barril. Las salientes se forman preferentemente, por ejemplo
10 teniendo superficies en bisel sobre un lado y superficies anguladas rectas en el otro, de manera que cuando el émbolo se oprime (i.e., después de que el accionador se ha ajustado de este modo), la saliente del mecanismo accionador se asegura contra la saliente interior correspondiente del
15 barril, por ejemplo en virtud de las superficies anguladas rectas opuestas que entran en contacto, de manera que en el uso normal el accionador no se soltará. Preferentemente puede soportar una fuerza de al menos 98 N. En esta forma, el accionador no puede soltarse del barril cuando el pistón
20 se oprime durante una inyección.

 Por otro lado las salientes solo necesitan soportar una fuerza menor de 98 N a fin de evitar que el accionador se extraiga hacia el barril cuando la aguja de la jeringa se inserte en el paciente. Tal fuerza es preferentemente de 49
25 N. Sin embargo, verdaderamente y a fin de que el accionador

pueda extraerse hacia el barril al finalizar la inyección, es preferible que estas superficies de saliente opuestas se biselen de manera que solo sea necesaria una fuerza menor, i.e., una fuerza preferentemente entre 49 N y 98 N.

5 En el punto de contacto entre el accionador y el barril se proporciona preferentemente al menos un cierre hermético de pistón tipo "O" suficiente para que no exista filtración entre el accionador y el barril durante el uso.

Se apreciará que el accionador será hueco a fin de
10 que el fluido contenido en el barril pueda pasar a través de éste y por lo tanto a través de la aguja que soporta. El extremo del vástago del accionador se proporciona preferentemente con al menos un miembro de linguete flexible. El émbolo se proporciona preferentemente con un vástago
15 sólido que tiene una cabeza conformada de manera que cuando se termina la inyección, la cabeza del vástago del émbolo entre en el vástago hueco del accionador y pase a través del extremo del mismo y se embrague mediante esto con el accionador, reteniendo el uno o más linguetes la cabeza del
20 vástago del émbolo mas allá del vástago del accionador. Cuando el émbolo se retrae, ejerciendo preferentemente una fuerza entre 49 y 98 N de fuerza de tracción, el uno o más linguetes no pueden romperse y el accionador se atraerá exitosamente hacia el barril.

25 A fin de evitar el embrague prematuro de la cabeza

del vástago del émbolo con los linguetes del vástago del accionador, se proporciona preferentemente un tope de profundidad para evitar que el émbolo se embrague así con el accionador antes de que se requiera la retracción de la
5 aguja. Preferentemente tal tope de profundidad se proporciona en la forma de un pasador ubicado en el orificio localizado transverso al eje del émbolo y ubicado sobre el mismo a fin de evitar que el émbolo entre en contacto con el accionador hasta que el pasador se oprima, evitando mediante
10 esto la destrucción temprana injustificada de la jeringa.

Por lo tanto, la presente invención es una jeringa de seguridad de uso único que incluye los siguientes componentes: un barril hueco, un émbolo que se ajusta al barril y un pistón que se ajusta a la parte anterior del
15 émbolo. Existe un accionador que se ajusta a la parte anterior del barril. Preferentemente sobre el accionador se ubica un ahusamiento luer estándar de 6:100. Este ahusamiento se diseña para recibir la cabeza de una aguja utilizando el ajuste con apriete. De manera alternativa, a fin de
20 proporcionar una interconexión más positiva entre el accionador y la cabeza de la aguja, puede emplearse con ventaja una rosca de tornillo incluyendo la así llamada rosca de seguridad luer.

Entre el barril y la superficie exterior del
25 accionador, se encuentra adaptado al menos un cierre

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hermético. En el extremo del barril se localiza al menos un medio para evitar que se oprima completamente el émbolo hasta que se termina la inyección y la jeringa se vuelva inservible. En la parte anterior del émbolo se encuentra
5 localizado un seguro retráctil, preferentemente en la forma de un elemento de cabeza para embragarse con la parte anterior del orificio interno del accionador el cual se proporciona con linguetas flexibles, ganchos o lo similar, de manera que cuando se mueve el émbolo hacia el accionador, el
10 gancho retráctil en la parte anterior entrará fácilmente en los medios de embrague del accionador. Cuando el émbolo se extrae, el accionador se atrae hacia el barril, para realizar la destrucción segura del mismo.

La jeringa de seguridad de acuerdo con las
15 modalidades preferidas de la invención tiene las siguientes ventajas cuando se comparan con las del mercado existente: primero, se proporciona con salientes correspondientes sobre el barril y el accionador para asegurar que el accionador no se suelte y se mueva hacia atrás, se proporciona un pistón
20 tipo "O" entre el accionador y el barril, para asegurar que no se filtre líquido y después de la inyección, cuando el émbolo se extrae del accionador pueda atraerse fácilmente hacia el barril, no puede re-utilizarse, logrando una jeringa verdaderamente segura que se destruye de manera efectiva;
25 segundo, solo se necesita una fuerza mínima para que el

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vástago del émbolo entre hacia los linguetes flexibles del
vástago del accionador, reduciendo mediante esto el dolor del
paciente que se ha ocasionado por la inyección en ocasiones
más recientes; tercero, el tope de profundidad en el extremo
5 posterior del émbolo evita que la jeringa se destruya antes
de que se utilice para dar una inyección, a través de un mal
funcionamiento ocasionando la destrucción prematura de la
jeringa.

Preferentemente se proporciona el émbolo con un
10 punto de ruptura. La ruptura brusca del émbolo también
vuelve la jeringa tanto inefectiva para uso subsecuente como
proporciona seguridad adicional ya que no existen medios por
los cuales pueda ocasionarse que la aguja re-emerja o se
extienda desde el cuerpo de la jeringa.

15 Además, es preferible proporcionar medios por los
cuales el émbolo puede de hecho bloquearse en su posición
antes de romperse bruscamente. Esto puede lograrse
utilizando un manguito o collar insertado en el extremo del
barril, por ejemplo ya sea mediante el ajuste con apriete o
20 al enroscarlo en su lugar. Puede proporcionarse una
protusión o proyección sobre el émbolo adyacente al punto de
ruptura y puede proporcionarse un pasaje por ejemplo similar
a una rosca en el manguito o collar de manera que el émbolo
puede enrollarse a través del collar o manguito y asegurarse
25 por medios adecuados, e.g., medios de saliente o de retén de

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manera que cuando se rompe el émbolo en el punto de ruptura no existe ningún medio por el cual pueda hacerse que se reintroduzca al barril ya que se retiene en el collar o manguito.

5 **Breve Descripción de los Dibujos**

La invención puede entenderse mejor a partir de la siguiente descripción no limitante de las modalidades preferidas, en las cuales:

La Figura 1 es una vista despiezada de una jeringa de seguridad de uso único de acuerdo con una modalidad de la invención;

La Figura 2 es una vista en sección transversal de la jeringa ensamblada de la Figura 1, mostrando la jeringa antes de utilizarse con un tapa que cubre y protege la aguja;

La Figura 3 es una vista en sección transversal de la jeringa de la Figura 2, mostrando el émbolo retraído, teniendo el barril lleno con solución inyectable;

La Figura 4 es una vista en sección transversal de la jeringa de las figuras anteriores al finalizar la inyección, teniendo el émbolo embragado el accionador;

La Figura 5 es una vista en sección transversal de la jeringa de las figuras anteriores, teniendo el émbolo extraído de manera que el accionador y la aguja se retiran de manera segura hacia el barril de la jeringa; y

La Figura 6 es una vista en sección transversal de

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la jeringa de las figuras anteriores, estando el émbolo asegurado en el manguito en el extremo del barril y roto en el punto de ruptura destruyendo la jeringa de manera segura.

Descripción Detallada de los Dibujos

5 Refiriéndose a la Figura 1 se muestra una vista despiezada de una jeringa, generalmente referida 10, de acuerdo con una modalidad preferida de la invención.

La jeringa incluye un barril 11, émbolo 12, pistón 13, accionador 14, cabeza de la aguja 15 que soporta una
10 aguja 20, pistón tipo "O" 16 y un tope de profundidad 17. Se proporciona una tapa 29 para proteger la aguja antes de utilizarse.

Una saliente interior 21 se ubica en la parte principal del barril 11. Una saliente 22 correspondiente se
15 ubica sobre el accionador 14, para embragar el accionador 14 cuando se inserta en el barril 11 desde el extremo abierto de esa parte principal del barril 11. Las ventajas de insertar el accionador 14 desde ese extremo del barril 11 se encuentran en la facilidad para ensamblar y disminuir el daño
20 en situaciones en donde la cabeza 15 de la aguja 20 ya se encuentra ajustada en el accionador 11; que lo que ocurriría si el accionador se ensamblara al insertarlo desde el otro extremo (i.e., émbolo) del barril 11 de la jeringa.

Los linguetes de resorte flexibles 23 se ubican al
25 final del vástago hueco 18 del accionador 14. Se proporciona

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el vástago sólido 19 en el extremo del émbolo 13 con una cabeza de aseguramiento 24. Se ubica un orificio 25 en el émbolo 13 para acomodar el pasador 7 que funciona como un tope de profundidad.

5 Se proporciona el punto de ruptura 26 sobre el émbolo 13. El émbolo también tiene salientes 28 que permiten que el émbolo 13 se asegure por giro en el manguito 29 de aseguramiento por giro localizado en el extremo del barril 11.

10 Refiriéndose en general a las Figuras 2 a 6, se muestra una jeringa 10 que tiene diversas partes ilustradas como en la Figura 1, utilizándose los mismos numerales de referencia en todas partes.

15 La jeringa de seguridad 10 de acuerdo con la invención posee las siguientes características:

20 En la unión entre el accionador 14 y el barril 11 se ubica un miembro de cierre hermético 16 en la forma de una "junta tórica" o lo similar. También se ubican salientes 22, 21 correspondientes sobre el accionador 14 y sobre la superficie interior del barril 11 respectivamente. En cada borde de la saliente 22 del accionador se forma un bisel y un ángulo recto respectivamente, correspondiendo el bisel y el ángulo recto con un bisel y un ángulo recto ubicados sobre la saliente 21 dentro del barril 11. En esencia la orientación
25 de las formas respectivas de las dos salientes 21, 22 se

entiende que en uso, la presión normal como se ejerce durante una inyección no hará que el accionador se mueva hacia fuera o efectivamente hacia dentro. En realidad el uso del tope de profundidad 17, antes de que se presione, asegurará que esto
5 tampoco pueda ocurrir accidentalmente. Sin embargo, el uso de la cabeza de aseguramiento 24 que embraga las salientes 23 es de hecho suficiente para retirar fácilmente el accionador 14, una vez que la cabeza de aseguramiento 24 del émbolo 13 haya embragado el accionador 14 al presionar el tope 17.

10 Se proporciona un punto de ruptura 26 sobre el émbolo 13, de manera que el émbolo 13 puede romperse fácilmente a lo largo del punto de ruptura 26. En el extremo posterior del émbolo 13 se ubica un tope de profundidad 17 que puede presionarse, pero el cual hace contacto con el
15 extremo del barril 11, hasta tal momento que se presiona a fin de evitar que el émbolo 13 se oprima completamente y en consecuencia embrague con el accionador 14.

En la Figura 2, la aguja se protege mediante una tapa 27 antes de utilizarse. El émbolo 13 se evita que
20 embrague con el accionador 14 en virtud del tope de profundidad 17 que se encuentra en la posición exterior.

Al utilizarse, la tapa 27 se retira para descubrir la aguja 20 y la aguja 20 se inserta en el fluido para utilizarse para la inyección (tal como en un recipiente - no
25 mostrado). El émbolo 13 se extrae entonces como en la Figura

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3 para tomar el fluido en el barril 11.

La inyección se lleva a cabo entonces después que el tope de profundidad 17 se ha presionado a fin de que el émbolo 13 ahora se embrague con el accionador 14 como en la 5 Figura 4.

Al final de la inyección, la cabeza de aseguramiento 24 entrará al vástago hueco 18 del accionador 14 y más allá en los linguetes flexibles 23 de manera que se retiene en el mismo.

10 Al retirar el émbolo 13 una vez más, el accionador 14 y la cabeza de la aguja/instalación de aguja 15, 20 se hace que se retire hacia el barril 11 de la jeringa 10 como se muestra en la Figura 5.

Como se muestra en la Figura 6, las salientes 28 15 ubicadas sobre el émbolo 13 se tuercen a través del manguito 29 de aseguramiento por giro adaptado en el extremo del barril. El rompimiento del émbolo 13 en el punto de ruptura 26 vuelve la jeringa 10 totalmente segura e inútil.

Se apreciará por los expertos en la materia que 20 pueden hacerse muchas modificaciones y variaciones a las modalidades descritas en la presente sin apartarse del espíritu o alcance de la invención.

A través de toda la especificación la palabra "comprende" y sus derivados se propone para tener un 25 significado inclusivo más que exclusivo a menos que el

contexto lo requiera de otro modo.

REIVINDICACIONES

1. Una jeringa retráctil de seguridad de uso único que tiene una aguja retráctil, incluyendo la jeringa un barril hueco, un émbolo que se ajusta deslizablemente en el
5 barril, un pistón que se ajusta sobre la parte anterior del émbolo y un mecanismo accionador, que se ubica en la parte anterior del barril, y que es capaz de ajustarse en el mismo a través del extremo abierto de esa parte anterior del barril hueco, teniendo el mecanismo accionador un vástago para
10 soportar una cabeza de aguja y medios ubicados en el extremo del émbolo para embragar el accionador y hacerlo que se retraiga con la aguja al término de la inyección.

2. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 1, en donde en el
15 punto en donde el accionador se ubica en el barril, se proporciona una saliente interior sobre el barril y una saliente correspondiente sobre el mecanismo accionador.

3. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 2, en donde las
20 salientes respectivas se forman, teniendo superficies de bisel sobre un lado y superficies anguladas rectas sobre el otro, de manera que cuando se oprime el émbolo, la saliente del mecanismo accionador se asegura contra la saliente interior correspondiente del barril, en virtud de que las
25 superficies anguladas rectas opuestas entran en contacto, de

manera que en uso normal el accionador no se soltará.

4. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 3, en donde puede soportarse una fuerza de al menos 98 N, de manera que el accionador no puede soltarse del barril cuando el pistón se oprime durante una inyección bajo condiciones de uso normales.

5. Una jeringa retráctil de seguridad de uso único de acuerdo con ya sea la reivindicación 3 o la reivindicación 4, en donde las salientes necesitan solo soportar una fuerza menor de 98 N a fin de evitar que el accionador se retire hacia el barril cuando la aguja de la jeringa se inserta en el paciente.

6. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 5, en donde la fuerza menor es preferentemente de 49 N.

7. Una jeringa retráctil de seguridad de uso único de acuerdo con cualquiera de las reivindicaciones 5 a 6, en donde las superficies de saliente opuestas se biselan a fin de que solo se necesite una fuerza menor, i.e., una fuerza preferentemente entre 49 N y 98 N.

8. Una jeringa retráctil de seguridad de uso único de acuerdo con cualquiera de las reivindicaciones precedentes, en donde en el punto de contacto entre el accionador y el barril se proporciona al menos un pistón tipo

"O" suficiente para que no exista filtración entre el accionador y el barril durante el uso.

9. Una jeringa retráctil de seguridad de uso único de acuerdo con cualquiera de las reivindicaciones precedentes, en la cual el vástago del accionador siendo hueco se proporciona preferentemente con al menos un miembro de linguete flexible.

10. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 9, en donde se proporciona el émbolo con un vástago sólido que tiene una cabeza formada de manera que cuando se termina la inyección, la cabeza del vástago del émbolo entra en el vástago hueco del accionador y pasa a través del extremo del mismo y se embraga mediante esto con el accionador, reteniendo el uno o más linguetes la cabeza del vástago del émbolo más allá del vástago del accionador.

11. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 10, en donde cuando el émbolo se retrae, ejerciendo una fuerza entre 49 y 98 N de fuerza de tracción, el uno o más linguetes no pueden romperse y el accionador se atraerá exitosamente hacia el barril.

12. Una jeringa retráctil de seguridad de uso único de acuerdo con cualquiera de las reivindicaciones 9 a 11, en donde a fin de evitar el embrague prematuro de la cabeza del vástago del émbolo con los linguetes del vástago

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del accionador, se proporciona preferentemente un tope de profundidad para evitar que el émbolo se embrague así con el accionador antes que se requiera la retracción de la aguja.

13. Una jeringa retráctil de seguridad de uso
5 único de acuerdo con la reivindicación 12, en donde se proporciona el tope de profundidad en la forma de un pasador ubicado en un orificio localizado transversal al eje del émbolo y localizado en el mismo a fin de evitar que el émbolo entre en contacto con el accionador hasta que se oprime el
10 pasador, evitando mediante esto la destrucción temprana injustificada de la jeringa.

14. Una jeringa retráctil de seguridad de uso
único que incluye: un barril hueco, un émbolo que se ajusta al barril y un pistón que se ajusta a la parte anterior del
15 émbolo y un accionador que se ajusta a la parte anterior del barril.

15. Una jeringa retráctil de seguridad de uso
único de acuerdo con cualquiera de las reivindicaciones precedentes, en donde sobre el accionador se ubica un
20 ahusamiento luer estándar de 6:100 para recibir la cabeza de una aguja utilizando el ajuste con apriete.

16. Una jeringa retráctil de seguridad de uso
único de acuerdo con cualquiera de las reivindicaciones 1 a 14, en donde a fin de proporcionar una interconexión más
25 positiva entre el accionador y la cabeza de aguja, se emplea

un rosca de tornillo incluyendo la así llamada rosca de seguridad luer.

17. Una jeringa retráctil de seguridad de uso único de acuerdo con cualquiera de las reivindicaciones precedentes, en donde se proporciona el émbolo con un punto de ruptura, de manera que el émbolo se rompe bruscamente al finalizar la inyección volviendo la jeringa tanto inefectiva para uso subsecuente como proporcionando seguridad adicional en que no existen medios por los cuales la aguja pueda re-emerger o extenderse desde el cuerpo de la jeringa.

18. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 17, en donde se proporcionan medios por los cuales el émbolo puede asegurarse en su posición antes de romperse bruscamente.

19. Una jeringa retráctil de seguridad de uso único de acuerdo con la reivindicación 18, en donde un manguito o collar se inserta en el extremo del barril mediante ajuste con apriete o al enroscarlo en su lugar y se proporcionan una o más protusiones o proyecciones sobre el émbolo adyacentes al punto de ruptura y se proporciona un pasaje similar a una rosca en el manguito o collar de manera que el émbolo puede torcerse o enrollarse a través del collar o manguito y asegurarse por medios adecuados, incluyendo medios de saliente o retén de manera que cuando se rompe el émbolo en el punto de ruptura no existe ningún medio por el

cual pueda hacerse que entre de nuevo al barril ya que se retiene en el collar o manguito.

20. Una jeringa retráctil sustancialmente como se describe en la presente con referencia a los dibujos.

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RESUMEN

Se describe una jeringa retráctil de seguridad de uso único (10) que tiene una aguja retráctil (20). La jeringa incluye un barril hueco (11), un émbolo (13) que se
5 ajusta de manera deslizable en el barril y un pistón (13) que se ajusta sobre la parte anterior del émbolo. La jeringa también incluye un mecanismo accionador (14) que se localiza en la parte anterior del barril. El accionador es capaz de ajustarse a través del extremo abierto de la parte anterior
10 del barril hueco. El mecanismo accionador tiene un vástago (18) para soportar la cabeza (15) de la aguja. Se proporcionan los medios (24) sobre el extremo del émbolo para embragar el accionador y hacerlo reaccionar con la aguja al término de la inyección.

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

WILSON, Garry, Adrian
Chysiliou Law
15-19 Parraween Street
Cremorne, NSW 2090
AUSTRALIE

Date of mailing (day/month/year) 15 November 2006 (15.11.2006)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 15010	
International application No. PCT/AU2006/000372	International filing date (day/month/year) 20 March 2006 (20.03.2006)

1. The following indications appeared on record concerning:

☒ the applicant ☒ the inventor ☐ the agent ☐ the common representative

Name and Address WALTON, Graeme, Francis 1/29 Nesca Parade Newcastle, NSW 2300	State of Nationality AU	State of Residence AU
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☒ the name ☒ the address ☒ the nationality ☒ the residence

Name and Address GLOBAL MEDISAFE HOLDINGS PTY LIMITED Unit 1, 29 Nesca Parade The Hill, NSW 2300 Australia	State of Nationality AU	State of Residence AU
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:
An assignment. The person shown in Box 1 remains an applicant and inventor for US only.

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☐ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Singh Ram Kishan
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 87 40 Telephone No. +41 22 338 84 50

PATENT COOPERATION TREATY

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From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Chrysiliou Law
15-19 Parraween Street
CREMORNE NSW 2090

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)	27 APR 2006
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Applicant's or agent's file reference
15010/GW

FOR FURTHER ACTION
See paragraph 2 below

International application No. PCT/AU2006/000372	International filing date (day/month/year) 20 March 2006	Priority date (day/month/year) 6 September 2005
---	--	---

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

INT. CL.

A61M 5/50 (2006.01) A61M 5/32 (2006.01)

Applicant
WALTON, Graeme Francis et al

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application
2. **FURTHER ACTION**
 If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.
 If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
 For further options, see Form PCT/ISA/220.
3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Date of completion of this opinion 19 April 2006	Authorized Officer XAVIER GISZ Telephone No. (02) 6283 2064
--	--	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/000372

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/000372

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: 14

because:

☐ the said international application, or the said claim Nos.

relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.

are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos.

are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 14

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/000372

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-13, 18-20	YES
	Claims 1, 2, 15-17	NO
Inventive step (IS)	Claims 13, 19, 20	YES
	Claims 1-12, 15-18	NO
Industrial applicability (IA)	Claims 1-13, 15-20	YES
	Claims	NO

2. Citations and explanations:

- D1 CA 2183823
- D2 EP 1421963
- D3 CA 2444988
- D4 US 2004/0210198
- D5 CA 2459795
- D6 US 2004/0254529
- D7 US 2004/0236283
- D8 EP 0498376

Novelty (N) Claims 1-3, 15-17

Claims 1, 2, 15, 16

D1 to D5 individually discloses all the features of claims 1, 2, 15 and 16. For example, D1 discloses a retractable syringe comprising a barrel (10), a plunger (40), a piston (41), and an actuator mechanism (30) located in the forepart of the barrel which is able to be fitted therein through the open end of the forepart of the barrel (see page 3, lines 5-10), the actuator mechanism having a stem (33) for supporting a needle hub (20), and means (42) located on the end of the plunger to engage the actuator and cause it to retract with the needle, wherein the point where the actuator is located in the barrel is provided with an inner flange (11) on the barrel and corresponding flange on the actuator mechanism, wherein the interconnection between the actuator mechanism and the needle hub is provided with a screw thread (32). The feature of a 6:100 luer taper on the actuator mechanism to receive the needle hub is considered an inessential difference when compared with D1 to D5 since this does not materially affect the way the invention works and, as such, is not an essential feature of the invention.

Claim 3

D1 discloses all the features of claim 3. For example, D1 discloses the respective flanges are shaped having a front sloping wall (111) of smaller slope than a rear sloping wall (112) (see page 3, lines 5-10). The feature of the rear sloping wall being *right angled* is considered an inessential difference when compared with D1 since this does not materially affect the way the invention works and, as such, is not an essential feature of the invention.

Claim 17

D1 to D3 individually discloses all the features of claim 17. For example, D1 discloses the plunger is provided with a break point (401).

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International Application No.

PCT/AU2006/000372

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V

Inventive Step (IS) Claims 1-12, 15-18

Claims 1-3, 15-17

As above. Furthermore, the feature added by claim 17 of the plunger having a break point merely amounts to common general knowledge and does not involve an inventive step in light of either D4 or D5.

Claims 4-7

Although the amount of force required at various stages of operation of the syringe is not stated, the claimed values would be obvious to select to a person skilled in the art and consequently lack an inventive step in light of D1.

Claim 8

D1 to D5 does not individually disclose the feature of providing at least one "O" type piston between the actuator and barrel. However, this feature is disclosed when any one of D1 to D5 is combined with D7, as would be obvious to a person skilled in the art to do.

Claims 9, 10

D1 to D5 does not individually disclose the features of providing at least one flexible finger member on the stem of the actuator which is hollow and providing the plunger with a solid stem having a shaped head such that the plunger engages with the actuator mechanism. However, this feature is disclosed when any one of D1 to D5 is combined with D6, as would be obvious to a person skilled in the art to do.

Claim 11

Although the amount of force required at various stages of operation of the syringe is not stated, the claimed values would be obvious to select to a person skilled in the art and consequently lack an inventive step in light of any one of D1 to D5 when combined with D6, as would be obvious to a person skilled in the art to do.

Claim 12

D1 to D5 does not individually disclose the feature of providing a depth stop to prevent the plunger from engaging with the actuator mechanism. However, this feature is disclosed when any one of D1 to D5 is combined with D6 and D7, as would be obvious to a person skilled in the art to do.

Claim 18

D1 to D5 does not individually disclose the feature of providing a means to lock the plunger into position. However, this feature is disclosed when any one of D1 to D5 is combined with D8, as would be obvious to a person skilled in the art to do.

Industrial Applicability (IA) Claims 1-13, 15-20

The claims are related to products capable of commercial application.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2006/000372

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

- Claim 14 is not fully supported by the description since the claim is wholly silent of locating the actuator mechanism in the forepart of the barrel by fitting it through the open end of the forepart of the barrel which, from reading the specification at page 2, lines 5 and 6, appears to be an essential feature of the invention.

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From the INTERNATIONAL BUREAU

PCT**NOTIFICATION OF THE RECORDING
OF A CHANGE**(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

GLOBAL MEDISAFE HOLDINGS PTY LIMITED
Unit 1, 29 Nesca Parade
The Hill, NSW 2300
AUSTRALIE

Date of mailing (day/month/year)

18 April 2007 (18.04.2007)

Applicant's or agent's file reference

IMPORTANT NOTIFICATION

International application No.

PCT/AU2006/000372

International filing date (day/month/year)

20 March 2006 (20.03.2006)

1. The following indications appeared on record concerning:

☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address

WILSON, Garry, Adrian
Chysiliou Law
15-19 Parraween Street
Cremorne, NSW 2090
Australia

State of Nationality

AU

State of Residence

AU

Telephone No.

(02) 9953 4222

Facsimile No.

(02) 9953 4755

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address

State of Nationality

State of Residence

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

Deleted.

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Mena Ana

Facsimile No. +41 22 338 82 70

Facsimile No. +41 22 338 87 40

Telephone No. +41 22 338 86 65

JB

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

WILSON & YOUNG
488 Botany Road
Alexandria NSW 2015
AUSTRALIE

Date of mailing (day/month/year) 16 January 2008 (16.01.2008)	IMPORTANT NOTIFICATION International filing date (day/month/year) 20 March 2006 (20.03.2006)
Applicant's or agent's file reference	
International application No. PCT/AU2006/000372	

1. The following indications appeared on record concerning:	
☐ the applicant ☐ the inventor ☒ the agent ☐ the common representative	
Name and Address	State of Nationality State of Residence
	Telephone No.
	Facsimile No.
	Teleprinter No.
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:	
☐ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence	
Name and Address WILSON & YOUNG 488 Botany Road Alexandria NSW 2015 Australia	State of Nationality State of Residence
	Telephone No.
	Facsimile No.
	Teleprinter No.
3. Further observations, if necessary: The person identified in Box 2 is now recorded as agent.	
4. A copy of this notification has been sent to:	
☒ the receiving Office ☐ the designated Offices concerned ☐ the International Searching Authority ☒ the elected Offices concerned ☐ the International Preliminary Examining Authority ☐ other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 87 40	Authorized officer Ben-Mansour Naceur e-mail pt01.pct@wipo.int Telephone No. +41 22 338 74 01
---	--

21

From the INTERNATIONAL BUREAU

PCT**NOTIFICATION OF THE RECORDING
OF A CHANGE**(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

WILSON, Garry, Adrian
Chysiliou Law
15-19 Parraween Street
Cremorne, NSW 2090
AUSTRALIE

Date of mailing (day/month/year) 15 November 2006 (15.11.2006)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 15010	
International application No. PCT/AU2006/000372	International filing date (day/month/year) 20 March 2006 (20.03.2006)

1. The following indications appeared on record concerning:

☒ the applicant

 ☒ the inventor

 ☐ the agent

 ☐ the common representative

Name and Address

LIN, Zuo, Qian
317500 Wanquanju
Taiping Street
Wenling City
Zhejiang Province
China

State of Nationality

CN

State of Residence

CN

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person

 ☒ the name

 ☒ the address

 ☒ the nationality

 ☒ the residence

Name and Address

WALSH, Allan
14 Sassan Crescent
Medowie, NSW 2318

State of Nationality

AU

State of Residence

AU

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

The person shown in Box 1 remains as an applicant and inventor for US only.

4. A copy of this notification has been sent to:

☒ the receiving Office	☐ the designated Offices concerned
☐ the International Searching Authority	☐ the elected Offices concerned
☒ the International Preliminary Examining Authority	☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Singh Ram Kishan

Facsimile No. +41 22 338 82 70

Facsimile No. +41 22 338 87 40

Telephone No. +41 22 338 84 50

80

From the INTERNATIONAL BUREAU

PCTNOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

WILSON, Garry, Adrian
Chysiliou Law
15-19 Parraween Street
Cremorne, NSW 2090
AUSTRALIE

Date of mailing (day/month/year) 15 November 2006 (15.11.2006)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 15010	
International application No. PCT/AU2006/000372	
International filing date (day/month/year) 20 March 2006 (20.03.2006)	

1. The following indications appeared on record concerning:		
☒ the applicant	☒ the inventor	☐ the agent
☐ the common representative		
Name and Address WALSH, Allan 14 Sassin Crescent Medowie, NSW 2318 Australia	State of Nationality AU	State of Residence AU
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
☐ the person	☒ the name	☒ the address
☐ the nationality		
☐ the residence		
Name and Address GLOBAL MEDISAFE HOLDINGS PTY LIMITED Unit 1, 29 Nesca Parade The Hill, NSW 2300 Australia	State of Nationality AU	State of Residence AU
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary: An assignment. The person shown in Box 1 remains as applicant and inventor for US only.		
4. A copy of this notification has been sent to:		
☒ the receiving Office	☐ the designated Offices concerned	
☐ the International Searching Authority	☐ the elected Offices concerned	
☒ the International Preliminary Examining Authority	☐ other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Singh Ram Kishan
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 87 40
	Telephone No. +41 22 338 84 50

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From the INTERNATIONAL BUREAU

PCT**NOTIFICATION OF THE RECORDING
OF A CHANGE**(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

GLOBAL MEDISAFE HOLDINGS LIMITED
First Floor
805 Hunter Street
Newcastle NSW 2300
AUSTRALIEDate of mailing (day/month/year)
16 January 2008 (16.01.2008)

Applicant's or agent's file reference:

IMPORTANT NOTIFICATIONInternational application No.
PCT/AU2006/000372International filing date (day/month/year)
20 March 2006 (20.03.2006)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

Name and Address

GLOBAL MEDISAFE HOLDINGS PTY LIMITED
Unit 1, 29 Nesca Parade
The Hill, NSW 2300
Australia

State of Nationality

AU

State of Residence

AU

Telephone No.

Facsimile No.

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☒ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address

GLOBAL MEDISAFE HOLDINGS LIMITED
First Floor
805 Hunter Street
Newcastle NSW 2300
Australia

State of Nationality

AU

State of Residence

AU

Telephone No.

Facsimile No.

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☐ the International Preliminary Examining Authority ☐ other:The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Ben-Mansour Naceur

Facsimile No. +41 22 338 87 40

e-mail pct01.pct@wipo.int

Telephone No. +41 22 338 74 01

From the INTERNATIONAL BUREAU

PCTNOTIFICATION CONCERNING
SUBMISSION OR TRANSMITTAL
OF PRIORITY DOCUMENT

To:

WILSON, Garry, Adrian
Chysiliou Law
15-19 Parraween Street
Cremorne, NSW 2090
AUSTRALIE

(PCT Administrative Instructions, Section 411)

Date of mailing (day/month/year) 05 May 2006 (05.05.2006)	
Applicant's or agent's file reference 15010	IMPORTANT NOTIFICATION
International application No. PCT/AU2006/000372	International filing date (day/month/year) 20 March 2006 (20.03.2006)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 06 September 2005 (06.09.2005)
Applicant WALTON, Graeme, Francis et al	

- By means of this Form, which replaces any previously issued notification concerning submission or transmittal of priority documents, the applicant is hereby notified of the date of receipt by the International Bureau of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to a date of receipt, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- (If applicable)* The letters "NR" appearing in the right-hand column denote a priority document which, on the date of mailing of this Form, had not yet been received by the International Bureau under Rule 17.1(a) or (b). Where, under Rule 17.1(a), the priority document must be submitted by the applicant to the receiving Office or the International Bureau, but the applicant fails to submit the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- (If applicable)* An asterisk (*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b) (the priority document was received after the time limit prescribed in Rule 17.1(a) or the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b)). Even though the priority document was not furnished in compliance with Rule 17.1(a) or (b), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
06 September 2005 (06.09.2005)	PCT/AU2005001343	AU	04 April 2006 (04.04.2006)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Gijsbertus Beijer

Facsimile No. +41 22 338 82 70

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Telephone No. +41 22 338 95 61

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15010/GW	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/AU2006/000372	International filing date (<i>day/month/year</i>) 20 March 2006	Priority date (<i>day/month/year</i>) 6 September 2005
International Patent Classification (IPC) or national classification and IPC Int. Cl. A61M 5/50 (2006.01) A61M 5/32 (2006.01)		
Applicant WALTON, Graeme Francis et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ (sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 8 September 2006	Date of completion of this report 06 August 2007
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer A. ALI AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2607

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2006/000372

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

- ☐ the international application as originally filed/furnished
- ☒ the description:
 pages 1, 4-8 as originally filed/furnished
 pages 2, 3 received by this Authority on 13 September 2006 with the letter of 13 September 2006
 pages* received by this Authority on _____ with the letter of _____
- ☒ the claims:
 pages _____ as originally filed/furnished
 pages* as amended (together with any statement) under Article 19
 pages 9-11 received by this Authority on 13 September 2006 with the letter of 13 September 2006
 pages* received by this Authority on _____ with the letter of _____
- ☒ the drawings:
 pages 1/5-5/5 as originally filed/furnished
 pages* received by this Authority on _____ with the letter of _____
 pages* received by this Authority on _____ with the letter of _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

5. ☐ This report has been established taking into account the rectification of an obvious mistake authorized by or notified to the Authority under Rule 91 (Rule 70.2(e)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2006/000372

85

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-16	YES
	Claims	NO
Inventive step (IS)	Claims 1-16	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-16	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)**Novelty (N)**

Independent claim 1 has been amended to further include the features of:

- (i) the stem of the actuator being hollow is provided with at least one flexible finger member;
- (ii) in order to prevent premature engagement of the head of the plunger stem with the fingers of the actuator stem, a depth stop is provided to prevent the plunger from thus engaging with the actuator before retraction of the needle is required;
- (iii) the depth stop is provided in the form of a pin located in a hole located transverse of the shaft of the plunger and located thereon so as to prevent the plunger coming into contact with the actuator until the pin is depressed, thereby avoiding early unwarranted destruction of the syringe.

These features are neither explicitly nor implicitly disclosed in any of the prior art documents previously cited.

Therefore the subject matter of claim 1 (and its dependent claims 2-16) is new and meets the requirements of Article 33(2) of the PCT with regard to novelty.

Inventive Step (IS)

The claimed invention is not obvious in the light of any of the cited documents nor is it disclosed in any obvious combination of them. It is also considered that it would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.

Therefore the subject matter of claims 1-16 is not obvious and meets the requirements of Article 33(3) of the PCT with regard to inventive step.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

Disclosure of the Invention

The invention in one broad form provides a single-use safety syringe having a retractable needle, the syringe including a hollow barrel, a plunger which slideably fits in the barrel, a piston which fits on the forepart of the plunger, and an actuator mechanism, which is located in the forepart of the barrel and which is able to be fitted therein through the open end of that forepart of the hollow barrel, the actuator mechanism having a stem for supporting a needle hub, and means located on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection, wherein the stem of the actuator is hollow and provided with at least one flexible finger member and wherein in order to prevent premature engagement of the head of the plunger stem with the fingers of the actuator stem, a depth stop is provided to prevent the plunger from thus engaging with the actuator before retraction of the needle is required, the depth stop being provided in the form of a pin located in a hole located transverse the shaft of the plunger and located thereon so as to prevent the plunger coming into contact with the actuator until the pin is depressed, thereby avoiding early unwarranted destruction of the syringe.

Where the actuator is located in the barrel, there is provided an inner flange on the barrel and a corresponding flange on the actuator mechanism, for fitment of the actuator from that open end of the barrel. The flanges are preferably shaped, for example having bevel surfaces on one side and right angled surfaces on the other, so that when the plunger is depressed (ie after the actuator has been thus fitted), the flange of the actuator mechanism locks against the corresponding inner flange of the barrel, for example by virtue of the opposing right angled surfaces coming into contact, so that in normal use the actuator will not be dislodged. Preferably a force of at least 98N may be endured. In this way, the actuator can not be dislodged from the barrel when the piston is depressed during an injection.

On the other hand the flanges need only withstand a lesser force than 98N in order to prevent the actuator from being withdrawn into the barrel when the needle of the

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syringe is inserted into the patient. Such force is preferably 49N. Indeed, in order that the actuator may be withdrawn into the barrel at the completion of the injection, however, it is preferable that these opposing flange surfaces are bevelled so that only a lesser force is needed, ie a force preferably between 49N and 98N.

- 5 At the point of contact between the actuator and the barrel there is preferably provided at least one "O" type piston seal, sufficient that there is no leakage between the actuator and the barrel during use.

It will be appreciated that the actuator will be hollow so that fluid contained in the barrel may pass through it and hence through the needle which it supports. The end
10 of the stem of the actuator is preferably provided with at least one flexible finger member. The plunger is preferably provided with a solid stem having a shaped head so that when the injection is completed, the head of the plunger stem enters into the hollow stem of the actuator and passes through the end thereof and is thereby
engaged with the actuator, the one or more fingers retaining the head of the plunger
15 stem beyond the stem of the actuator. When the plunger is pulled back, exerting a force preferably between 49 and 98N pull force, the one or more fingers can not break off, and the actuator will be successfully pulled into the barrel.

The present invention is therefore a single use safety syringe which includes the following components: a hollow barrel, one plunger which fits the barrel and one
20 piston which fits the forepart of the plunger. There is an actuator which fits the forepart of the barrel. Preferably on the actuator there is located a standard 6:100 luer taper. This taper is designed to receive the hub of a needle utilising interference fit. Alternatively, in order to provide a more positive interconnection between the actuator and the needle hub, a screw thread including so-called luer-lock thread may
25 be employed with advantage.

Between the barrel and the outer actuator surface, there is fitted at least one seal. At the end of the barrel there is located at least one means for preventing complete depression of the plunger until the injection is complete and the syringe is to be

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Claims

1. A single use safety retractable syringe having a retractable needle, the syringe including a hollow barrel, a plunger which slideably fits in the barrel, a piston which fits on the forepart of the plunger, and an actuator mechanism, which is located in the forepart of the barrel and which is able to be fitted therein through the open end of that forepart of the hollow barrel, the actuator mechanism having a stem for supporting a needle hub, and means located on the end of the plunger to engage the actuator and cause it to retract with the needle upon completion of the injection, wherein the stem of the actuator is hollow and provided with at least one flexible finger member and wherein in order to prevent premature engagement of the head of the plunger stem with the fingers of the actuator stem, a depth stop is provided to prevent the plunger from thus engaging with the actuator before retraction of the needle is required, the depth stop being provided in the form of a pin located in a hole located transverse the shaft of the plunger and located thereon so as to prevent the plunger coming into contact with the actuator until the pin is depressed, thereby avoiding early unwarranted destruction of the syringe.
2. A single use safety retractable syringe according to claim 1, wherein at the point where the actuator is located in the barrel, there is provided an inner flange on the barrel and a corresponding flange on the actuator mechanism.
3. A single use safety retractable syringe according to claim 2, wherein the respective flanges are shaped, having bevel surfaces on one side and right angled surfaces on the other, so that when the plunger is depressed, the flange of the actuator mechanism locks against the corresponding inner flange of the barrel, by virtue of the opposing right angled surfaces coming into contact, so that in normal use the actuator will not be dislodged.
4. A single use safety retractable syringe according to claim 3, wherein a force of at least 98N may be endured, so that the actuator can not be dislodged from the

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barrel when the piston is depressed during an injection under normal use conditions.

5. A single use safety retractable syringe according to either claim 3 or claim 4, wherein the flanges need only withstand a lesser force than 98N in order to prevent the actuator from being withdrawn into the barrel when the needle of the syringe is inserted into the patient.
6. A single use safety retractable syringe according to claim 5, wherein the lesser force is preferably 49N.
7. A single use safety retractable syringe according to any one of claims 5 to 6 wherein the opposing flange surfaces are bevelled so that only a lesser force is needed, ie a force preferably between 49N and 98N.
8. A single use safety retractable syringe according to any one of the preceding claims wherein at the point of contact between the actuator and the barrel there is provided at least one "O" type piston, sufficient that there is no leakage between the actuator and the barrel during use.
9. A single use safety retractable syringe according to any one of the preceding claims wherein the plunger is provided with a solid stem having a shaped head so that when the injection is completed, the head of the plunger stem enters into the hollow stem of the actuator and passes through the end thereof and is thereby engaged with the actuator, the one or more fingers retaining the head of the plunger stem beyond the stem of the actuator..
10. A single use safety retractable syringe according to claim 9, wherein when the plunger is pulled back, exerting a force between 49 and 98N pull force, the one or more fingers can not break off, and the actuator will be successfully pulled into the barrel.

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11. A single use safety retractable syringe according to any one of the preceding claims wherein on the actuator there is located a standard 6:100 luer taper to receive the hub of a needle utilising interference fit.
12. A single use safety retractable syringe according to any one of claims 1 to 10,
5 wherein in order to provide a more positive interconnection between the actuator and the needle hub, a screw thread including a so-called luer-lock thread is employed.
13. A single use safety retractable syringe according to any one of the preceding claims wherein the plunger is provided with a break point, so that the plunger is
10 snapped off at completion of the injection rendering the syringe both ineffective for subsequent use as well as providing additional safety in that there is no means by which the needle can be caused to re-emerge or extend from the syringe body.
14. A single use safety retractable syringe according to claim 13 wherein means are provided whereby the plunger can be locked in position prior to being snapped
15 off.
15. A single use safety retractable syringe according to claim 14 wherein a sleeve or collar is inserted in the end of the barrel by interference fit or by screwing it in place and one or more protrusions or lugs are provided on the plunger adjacent the break point and a passage like a thread is provided in the sleeve or collar so
20 that the plunger may be twisted or wound out through the collar or sleeve and locked by suitable means, including flange or ratchet means so that when plunger is broken off at the break point there is no means by which it can be caused to enter the barrel again as it is retained in the collar or sleeve.
16. A retractable syringe substantially as herein described with reference to the
25 drawings.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 08-034639- -00000-0000

Fecha: 2008-04-07 16:53:25 Dep: 2020 NUECREACION
Tra: 11 PATENTE IYII Evt: 379 FASE NACIONAL II
Act: 411 PRESENTACION Folios: 90



Industria y Comercio
SUPERINTENDENCIA

REQUISITOS MINIMOS PARA ADMISION A TRAMITE
PCT

PATENTE DE INVENCION

☒

MODELO DE UTILIDAD

☐

- ◆ Indicación de que se solicita la concesión de una patente ☒
- ◆ Datos de identificación del solicitante o de la persona que presenta la solicitud ☒
- ◆ Descripción de la invención ☒
- ◆ Dibujos de ser estos pertinentes ☒
- ◆ Comprobante de pago de las tasas establecidas ☒

COMPLETA ☐

INCOMPLETA ☐

DISEÑO INDUSTRIAL ☐

- ◆ Indicación de que se solicita el registro de Diseño Industrial ☐
- ◆ Datos de identificación del solicitante o de la persona que presenta la solicitud ☐
- ◆ Representación gráfica y fotográfica del Diseño Industrial o muestra del material que incorpora el diseño ☐
- ◆ Comprobante de pago de las tasas establecidas ☐

COMPLETA ☐

INCOMPLETA ☐

ESQUEMA DE TRAZADO ☐

- ◆ Indicación de que se solicita el registro de un Esquema de Trazado ☐
- ◆ Datos de identificación del solicitante o de la persona que presenta la solicitud ☐
- ◆ Representación gráfica del esquema trazado ☐
- ◆ Comprobante de pago de las tasas establecidas ☐

COMPLETA ☐

INCOMPLETA ☐

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Firma Responsable

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REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Bogotá,
2020

Doctor(a)
JARAMILLO CAMPUZANO MAURICIO

REFERENCIA	Radicación No.	08 34639
	Solicitud internacional	PCT/AU2006/000372
	Fecha inicio fase nacional	06/04/2005
	Trámite	11
	Evento	379
	Actuación	430
	Oficio No.	6755

Como resultado del examen de forma, realizado con fundamento en el artículo 38 de la Decisión 486 de la Comisión de la Comunidad Andina, artículo 27 del Tratado de Cooperación en Materia de Patentes (PCT), regla 51 bis del Reglamento y Circular Única de la Superintendencia de Industria y Comercio, se le comunica que:

1. La solicitud no contiene la traducción de los anexos del reporte de examen preliminar internacional (Art. 36.2.b) del tratado PCT.
2. La traducción de los capítulos descriptivo y reivindicatorio debe ir acompañada de los respectivos dibujos.
3. La solicitud no contiene la copia del documento en que consta la cesión del derecho a la patente del inventor al solicitante o a su causante. (Art. 26-k) Decisión 486.
4. La solicitud no contiene el poder debidamente otorgado, con el lleno de los requisitos exigidos por los artículos 63 y subsiguientes del Código de Procedimiento Civil. Adicionalmente, deberá presentar el documento que acredita la existencia y representación legal de la sociedad solicitante, cuando ésta fuere persona jurídica.

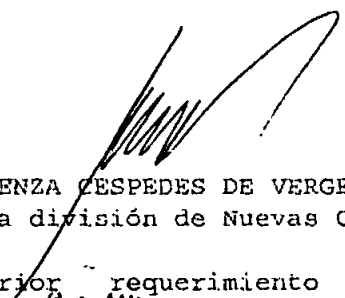
En cumplimiento de lo dispuesto por el artículo 39 de la Decisión 486, se le requiere para que dentro del término de dos meses siguientes a la fecha de notificación del presente oficio, complete los requisitos anteriormente enunciados. En caso de no dar cumplimiento al presente requerimiento, la solicitud se considerará abandonada y perderá su prelación.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No.10 de 2001.

Continúa en la página siguiente...

REPUBLICA DE COLOMBIA
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

Radicación No.: 8 34639



ALIX CARMENZA CESPEDES DE VERGEL
Jefe de la división de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista de
fecha 29 MAYO 2008
jfernand