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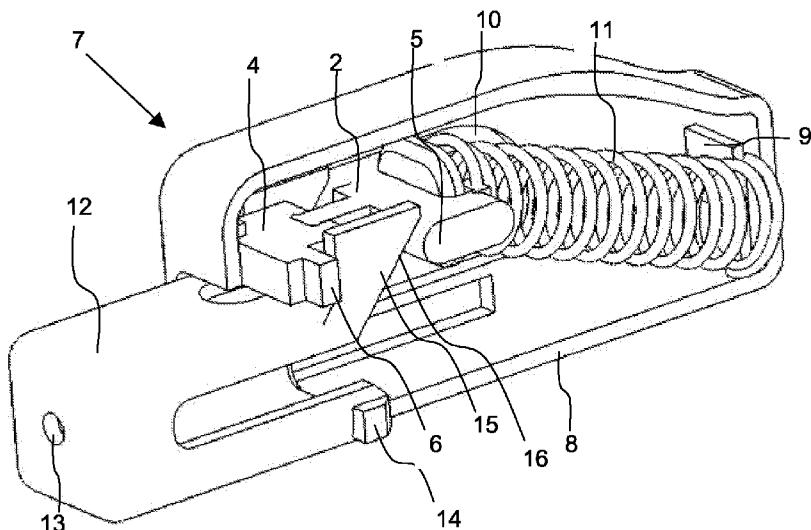
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SINGLE-USE SKIN PRICKING DEVICE



WO 2007/088394 A1

(57) Abstract: A single-use skin pricking device (7) comprising a housing (8), a lancet (1) disposed within the housing (8), biasing means (11) coupled between the housing (8) and the lancet (1), and a trigger (12) mounted to the housing (8) for relative movement therewith. The trigger (8) is releasably coupled to the lancet (1) such that movement of the trigger (8) in a first direction moves the lancet (1) in a direction to compress the biasing means (11), and then causes release of the lancet (1) from (10) the trigger (8) whereby the biasing means (11) drives the lancet (1) in a second direction substantially opposite to said first direction.

Single-use Skin Pricking Device

The present invention relates to single-use skin prickling devices.

5 Skin prickling devices are well known in the art. Typically, skin prickling devices have a lancet comprising a needle having a sharp tip at one end and being embedded in a plastics body at the opposite end, with the tip of the needle protruding from the body. Often the tip is enclosed within a cap to prevent accidental finger prickling and to maintain sterility of the needle, and the cap is
10 removed before use of the lancet. Such lancets are used to obtain a small blood sample for analysis. Many single-use skin prickling devices have been devised to make the procedure of skin prickling as simple and safe as possible. Such single-use skin prickling devices typically include a holder for holding the lancet body, and a firing mechanism. The firing mechanism is configured to
15 push the needle of the lancet into the skin for a predetermined distance or using a predetermined force. An example of such a firing device is described in EP1204371.

20 Known skin prickling devices typically require that the user performs several operations in order to safely fire the device. These include removing packaging from the device, removing the safety cap from the device, and pressing a trigger to fire the device. Some skin prickling devices also require cocking the lancet before firing, and some require recapping of the needle after firing, although most retract the needle into the device to avoid accidental skin prickling.

25 This number of steps is inconvenient and requires the user to use both hands when removing or replacing a cap, or removing packaging. It is realised that a device that requires fewer steps to fire would be more convenient to use, and furthermore a device that can be fired using only one hand would be
30 advantageous, especially to users who may have limited use of their hands.

According to a first aspect of the invention there is provided a single-use skin prickling device comprising:

a housing;
a lancet disposed within the housing;
biasing means coupled between the housing and the lancet;
a trigger mounted to the housing for relative movement therewith, the
5 trigger being releasably coupled to the lancet such that movement of the trigger
in a first direction moves the lancet in a direction to compress the biasing
means, and then causes release of the lancet from the trigger whereby the
biasing means drives the lancet in a second direction substantially opposite to
the first direction.

10

Preferably, the lancet comprises a cap covering an end of a needle, wherein the movement of the trigger in the first direction first causes the cap to be removed from the lancet to expose the needle. The cap is preferably substantially fixed relative to the housing.

15

It is preferred that the device comprises one or more guide tracks disposed within the housing for guiding movement of the lancet within the housing. The guide track may be substantially U-shaped.

20

It is preferred that the trigger is coupled to the lancet by slip means, the slip means allowing the trigger to disengage from the lancet at some predefined point of travel in the first direction. In one embodiment of the invention, the slip means comprises trigger wedges formed on the trigger and wedge engaging formations formed on the lancet, the trigger wedges engaging the formations as
25 the trigger moves in the first direction up to a point of travel where the lancet moves to disengage the wedges from the formations to release the lancet.

30

Preferably, the biasing means is arranged to retract the lancet fully within the housing once the device has been fired. The biasing means may be formed integrally with the housing. In one embodiment of the present invention, the biasing means is partially preloaded prior to depressing the trigger.

It is preferred that the biasing means comprises a helical spring.

Preferably, the trigger comprises an opening through a lancet needle projects when the device is fired. It is also preferred that the trigger is actuated by pressing it directly against an area of skin to be pricked.

5

In one embodiment of the invention, the trigger and the housing may be moulded integrally with a weakened portion disposed at an interface between the trigger and the housing, the weakened portion configured to be broken when the trigger is pressed.

10

The device preferably comprises a locking mechanism arranged to lock the trigger relative to the housing in a predetermined position once the trigger has been pressed.

15 The device may also comprise a window provided in the housing to allow a user to view the lancet.

According to a second aspect of the invention, there is provided a single-use skin pricking device comprising:

20 a housing;
a lancet disposed within the housing;
a spring coupled between the housing and the lancet;
a guide track within the housing, the lancet being mounted in the guide track; and
25 a trigger releasably coupled to the lancet and having an opening formed therein through which a needle of the lancet can project.

Preferably, the track is substantially U-shaped.

30 It is preferred that the trigger is telescopically mounted in the housing.

Preferably, the legs of the U-shaped track lie substantially parallel to the direction of movement of the trigger.

An advantage of this single use skin pricking device is that the device can be operated with one hand, and that a single movement of the trigger effects uncapping the lancet, moving the lancet into a cocked position and firing the
5 lancet.

For a better understanding of the present invention and in order to show how the same may be carried into effect reference will now be made by way of example to the accompanying drawings in which:

- 10 Figure 1 is a perspective view of a lancet for use in a single-use skin pricking device;
- Figure 2 is a perspective view of a single-use skin-pricking device with one side of a housing removed;
- Figure 3 is an exploded perspective view of the single-use skin pricking device
15 of Figure 2;
- Figure 4 is a flow diagram illustrating the stages in using the single-use skin pricking device;
- Figure 5 is a perspective view and a side elevation view of the single-use skin pricking device with one side of the housing removed with a trigger partially
20 depressed;
- Figure 6 is a perspective view and a side elevation view of the single-use skin pricking device with one side of the housing removed with the trigger further depressed;
- Figure 7 is a perspective view and a side elevation view of the single-use skin
25 pricking device with one side of the housing removed with the trigger fully depressed;
- Figure 8 is a perspective view and a side elevation view of the single-use skin pricking device with one side of a housing removed with the trigger fully depressed and the lancet needle exposed from the single-use skin pricking
30 device; and
- Figure 9 is a perspective view and a side elevation view of the single-use skin pricking device with one side of the housing removed with the trigger fully

depressed and the lancet needle retracted into the single-use skin pricking device.

Referring to Figure 1, a lancet 1 comprises a moulded plastics lancet body 2 with a needle 3 partially embedded in the lancet body 2. A tip of the needle 3 projects from the lancet body 2. A cap 4 covers the tip of the needle 3 to maintain sterility prior to use. The cap 4 may be over-moulded onto the needle tip provided that the needle 3 is embedded more firmly in the body 2 than the cap 4.

10

The lancet body further comprises a pair of shaped guide portions 5 extending either side of the lancet body. The lancet cap 4 comprises a pair of fixing projections 6 disposed either side of the lancet cap 4.

15 The single-use skin pricking device 7 comprises a housing 8. The housing is moulded as two separate symmetrical halves that may be pressed, snapped, welded or glued together to form the complete housing 8. Figure 2 shows one half of the housing removed to show the interior cavity formed by the housing 8. Each half of the housing 8 comprises a spring holder 9 disposed at a rearward 20 portion of the housing 8, and each half further comprises a lancet body guide track 10 moulded on the housing 8. The guide track 10 follows a substantially 'U'-shaped path along the inner surface of the housing 8, with the bight of the 'U' disposed towards the spring holder 9.

25 A spring 11 is disposed within the interior of the housing 8, and is held at one end of the spring 10 by the spring holder 9, and at the other end to the lancet body 2. The spring 11 is made of any suitable material such as metal or plastics. In particular, where the spring 11 is made of a plastics material, it may be integrally moulded as part of the housing 8. However, it is preferred to use a 30 metal helical spring.

Once inserted, the lancet body 2 and the lancet cap 4 are both disposed within the housing 8. The lancet body guide portions 5 are configured to cooperate on

each side with the lancet body guide track 10. The lancet cap fixing projections 6 are held in place by the housing 8 such that the lancet cap 4 does not move relative to the housing 8 following assembly. Alternatively, the lancet cap 4 may be moulded integrally with the housing 8, although this is not preferred as the 5 lancet cap 4 must be sterile, and moulding the lancet cap 4 integrally with the housing 8 necessitates the manufacturing and assembly process to be carried out in a sterile environment.

The single-use skin pricking device further comprises a trigger 12. The trigger 10 12 is connected to the housing 8 and can telescope into an opening in the housing 8 when pressure is applied to the trigger 12. The trigger 10 comprises an opening 13 through which the lancet needle 3 can project. The trigger 12 further comprises guide lugs 14 to cooperate with the housing 8 and ensure that the trigger moves linearly along the main axis of the single-use skin pricking 15 device 7 relative to the housing 8. The trigger 12 further comprises a pair of trigger wedges 15. The trigger wedges 15 each have an angled surface 16 with respect to a longitudinal axis of the single-use skin pricking device 7. The angled surfaces 16 are configured, in use, to contact the guide portions 5 of the lancet body 2.

20 The trigger 12 may be moulded separately from the housing 8, or may be moulded integrally with the housing 8 with a weakened area connecting the housing 8 and the trigger 12 to allow the trigger to "break free" of the housing 8 to allow movement of the trigger 12 relative to the housing 8.

25 When a user receives the single-use skin pricking device 7, it is in the configuration shown in Figure 2, with the trigger 12 extending from the housing 8 and the lancet cap 4 in place over the lancet needle 3. To fire the device, the user presses the trigger 12 against the skin. The steps illustrated in Figure 3 30 are then followed. When the trigger is pressed against the skin (step 17), the angled surfaces 16 of the trigger wedges 15 contact the guide portions 2 of the lancet body 2. This pushes the lancet body 2 away from the lancet cap 4, thereby removing the cap 4 from the lancet needle 3, as illustrated in Figure 5.

As the trigger 12 is further pressed, it moves into the interior of the housing 8, as shown in Figure 6. The spring 11 compresses (step 18) and the angled surfaces 16 of the trigger projections 15 push the lancet body 4 further away 5 from the cap 4. Owing to the cooperation between the each guide portion 5 of the lancet body 2 and the guide track 10, the lancet body 6 moves in a first direction down one leg of the 'U' towards the spring holder 9 at the rear of the housing 8. As the trigger wedges 15 comprise angled surfaces 16, the lancet body 2 slips down the angled surfaces 16 as the body 2 is pushed by the trigger 10 12.

Once the lancet body 4 has reached its rearward maximum travel (step 19) in the housing 8, it has reached the apex of the U-shaped guide tracks 10 and can no longer move back towards the cap 4. The angled surfaces 16 of the trigger 15 wedges 15 cause the guide portions 5 of the lancet body 2 to slip entirely away from the trigger wedges 15 such the lancet body 2 is no longer held by the trigger wedges 15. At this point, the spring 11 is at maximum compression and the trigger 12 is fully retracted into the housing 8.

20 The spring 11 pushes the lancet body 2 down over the guide portions 5 until the body 2 is free of the wedges 15. The lancet body 4 is then fired forward (step 20) by the rapid expansion of the spring 11. The lancet body 4 is pushed in a second direction determined by a co-operation between each lancet guide portion 5 and the lower legs of the guide track 10. The lancet body 4 moves 25 such that the needle tip 3 of the lancet projects from the opening 13 in the trigger 12 and pricks the skin. The lancet body 4 contacts the front face of the trigger 12. This limits the distance that the needle 3 can protrude from the opening 13, thereby preventing the needle 3 from penetrating the skin too deeply.

30

At this point the spring 11 is overextended, so the spring 11 retracts (step 21) to pull the needle 3 back through the opening 13, thereby holding the needle 3 within the interior of the single-use skin pricking device 7 to prevent any skin

pricking accidents being caused by the needle 20. Once the single-use skin pricking device 7 has been used, it cannot be reset without completely disassembling the device.

- 5 A clip or lock may be provided to lock the trigger 12 inside the housing 8 once the device has been fired to indicate to the user that the device has been used and should be disposed of.

As the needle 3 is sterile when it is embedded in the cap 4, and does not 10 contact any other part of the single-use skin pricking device 7 before it pricks the skin, there is no need to sterilize or seal the housing 8 or the parts contained within the housing 8, other than the needle 3 and the surrounding cap 4.

- 15 In order to ensure that the spring 11 fires the lancet with sufficient force to project from the opening 13 in the trigger 12, the spring 11 may be partially pre-loaded prior to assembly of the device 7.

It will be appreciated by those of skill in the art that various modifications may 20 be made to the above described embodiment without departing from the scope of the present invention. For example, a window may be provided in the wall of the housing 8 to allow the user to observe the lancet contained within the housing prior to use. This is enables the user to ensure that the cap 4 and lancet body 2 have not been separated prior to use.

CLAIMS:

1. A single-use skin pricking device comprising:
 - a housing;
 - 5 a lancet disposed within the housing;
 - biasing means coupled between the housing and the lancet;
 - a trigger mounted to the housing for relative movement therewith, the trigger being releasably coupled to the lancet such that movement of the trigger in a first direction moves the lancet in a direction to compress said biasing means, and then causes release of the lancet from the trigger whereby said biasing means drives the lancet in a second direction substantially opposite to said first direction.
- 10 2. A device according to claim 1, the lancet comprising a cap covering an end of a needle, wherein said movement of the trigger in the first direction first causes the cap to be removed from the lancet to expose the needle.
- 15 3. A device according to claim 2, wherein said cap is substantially fixed relative to said housing.
- 20 4. A device as claimed in any preceding claim and comprising one or more guide tracks disposed within the housing for guiding movement of the lancet within the housing.
- 25 5. A device as claimed in claim 4, wherein said track is substantially U-shaped.
- 30 6. A device as claimed in any preceding claim, wherein the trigger is coupled to the lancet by slip means, the slip means allowing the trigger to disengage from the lancet at some predefined point of travel in said first direction.

7. A device according to claim 6, said slip means comprising trigger wedges formed on the trigger and wedge engaging formations formed on the lancet, the trigger wedges engaging said formations as the trigger moves in said first direction up to a point of travel where the lancet moves to disengage the 5 wedges from the formations to release the lancet.

8. A device as claimed in any preceding claim, wherein the biasing means is arranged to retract the lancet fully within the housing once the device has been fired.

10

9. A device as claimed in any preceding claim, wherein the biasing means is formed integrally with the housing.

15

10. A device as claimed in any preceding claim, wherein the biasing means is partially preloaded prior to depressing the trigger.

11. A device as claimed in preceding claim, wherein the biasing means comprises a helical spring.

20

12. A device as claimed in any preceding claim wherein the trigger comprises an opening through a lancet needle projects when the device is fired.

13. A device as claimed in any preceding claim, wherein the trigger is actuated by pressing it directly against an area of skin to be pricked.

25

14. A device as claimed in any preceding claim, wherein the trigger and the housing are moulded integrally with a weakened portion disposed at an interface between the trigger and the housing, the weakened portion configured to be broken when the trigger is pressed.

30

15. A device as claimed in any preceding claim, further comprising a locking mechanism arranged to lock the trigger relative to the housing in a predetermined position once the trigger has been pressed.

16. A device as claimed in any preceding claim, further comprising a window provided in the housing to allow a user to view the lancet.

5 17. A single-use skin pricking device comprising:
a housing;
a lancet disposed within the housing;
a spring coupled between said housing and said lancet;
a guide track within the housing, the lancet being mounted in the guide
10 track; and
a trigger releasably coupled to the lancet and having an opening formed
therein through which a needle of the lancet can project.

18. A device according to claim 17, wherein said track is substantially U-
15 shaped

19. A device according to claim 17 or 18, wherein said trigger is
telescopically mounted in the housing.

20 20. A device according to claim 19 when appended to claim 18, said legs of
the U-shaped track lying substantially parallel to the direction of movement of
the trigger.

21. A single-use skin pricking device substantially as hereinbefore described
25 with reference to the accompanying drawings.

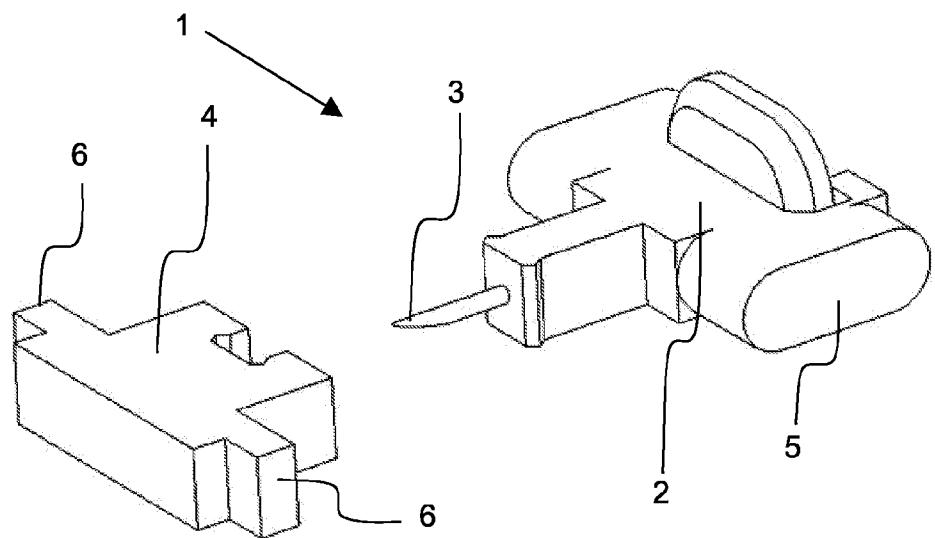


Figure 1

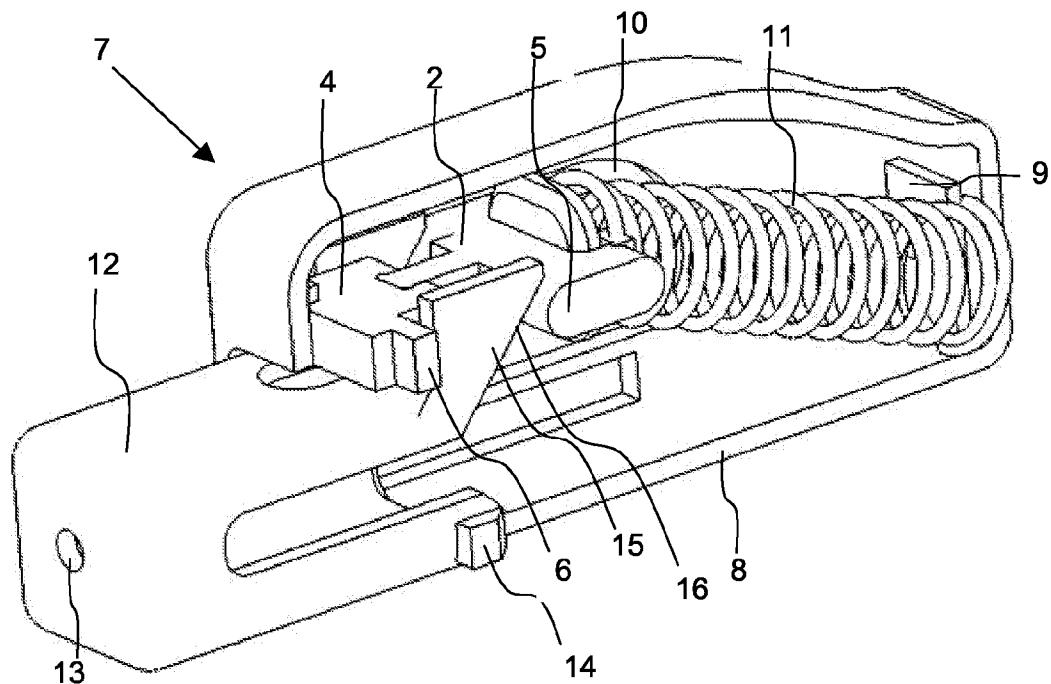


Figure 2

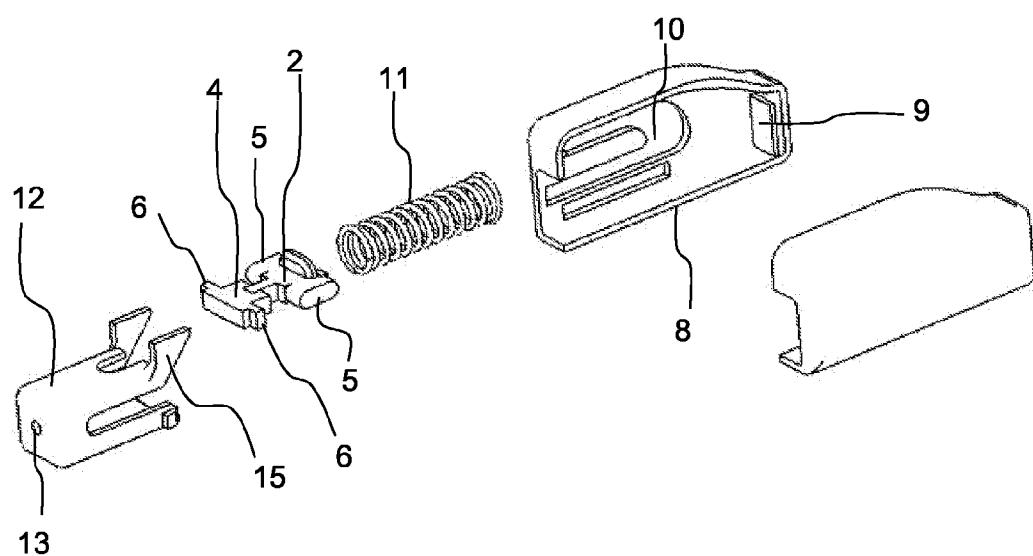


Figure 3

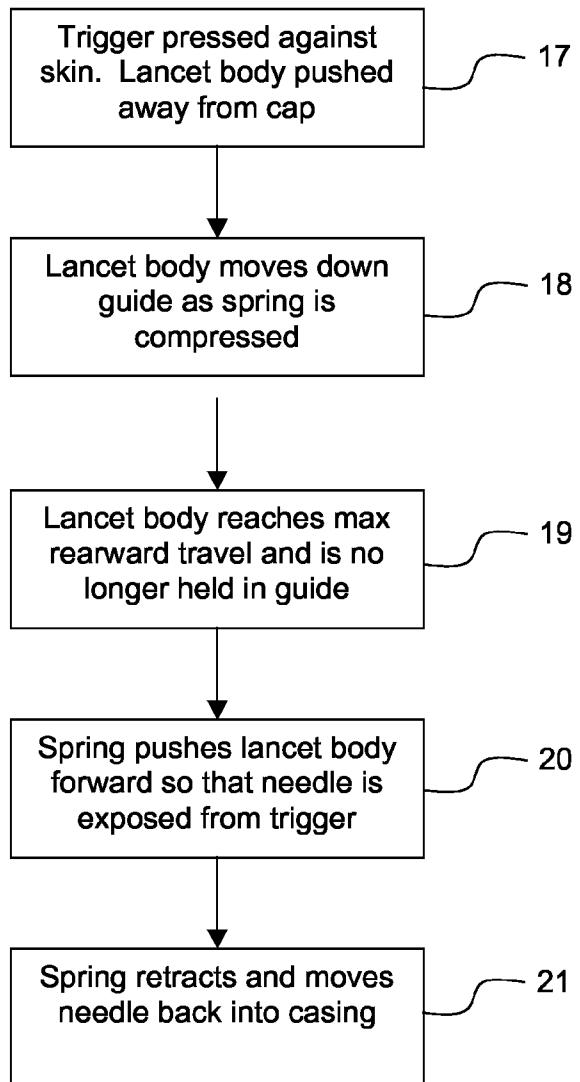


Figure 4

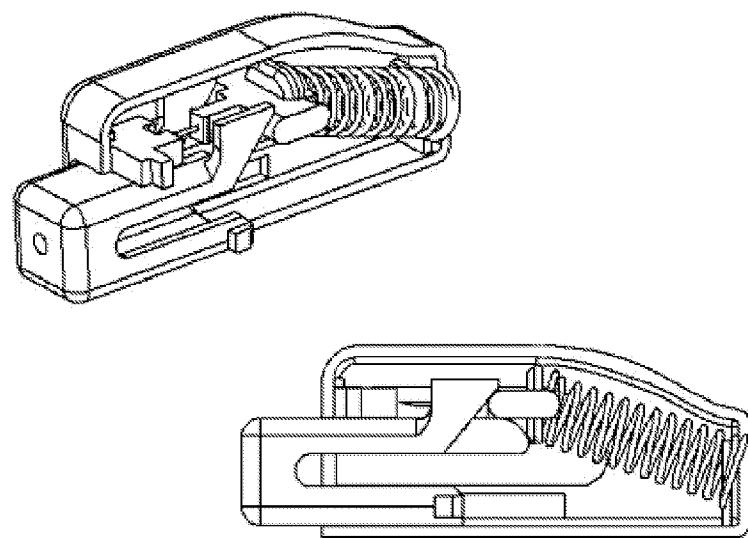


Figure 5

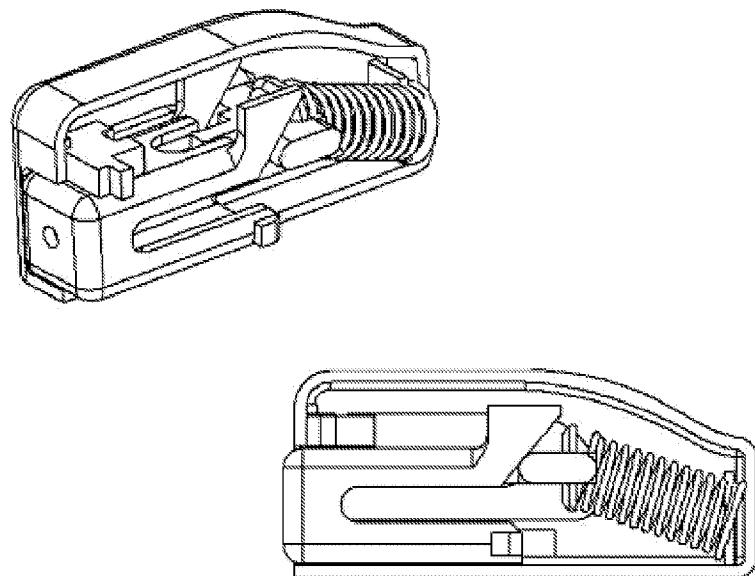


Figure 6

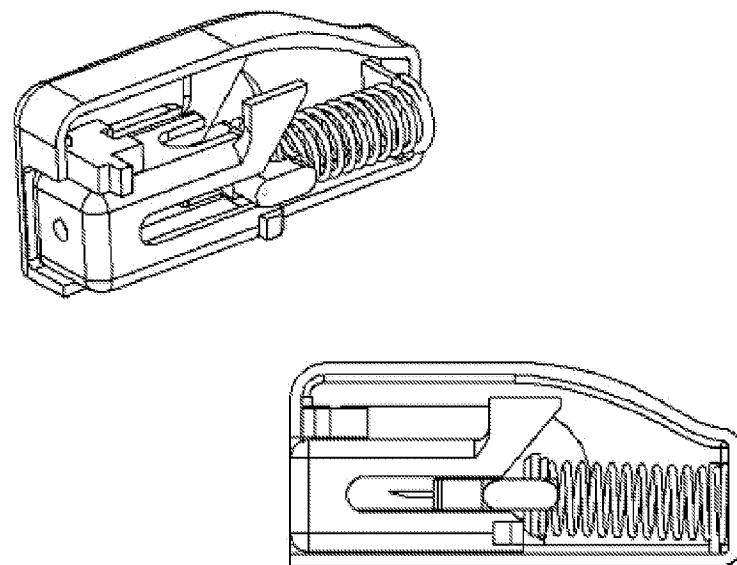


Figure 7

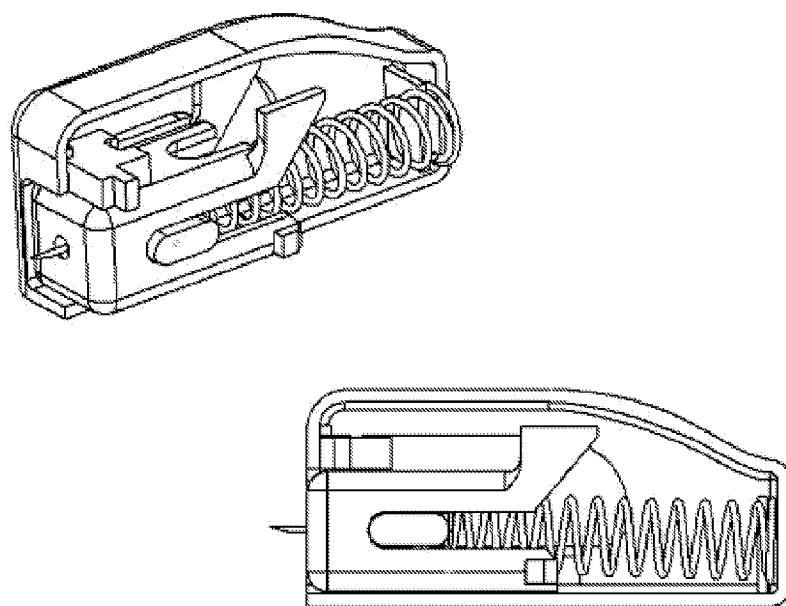


Figure 8

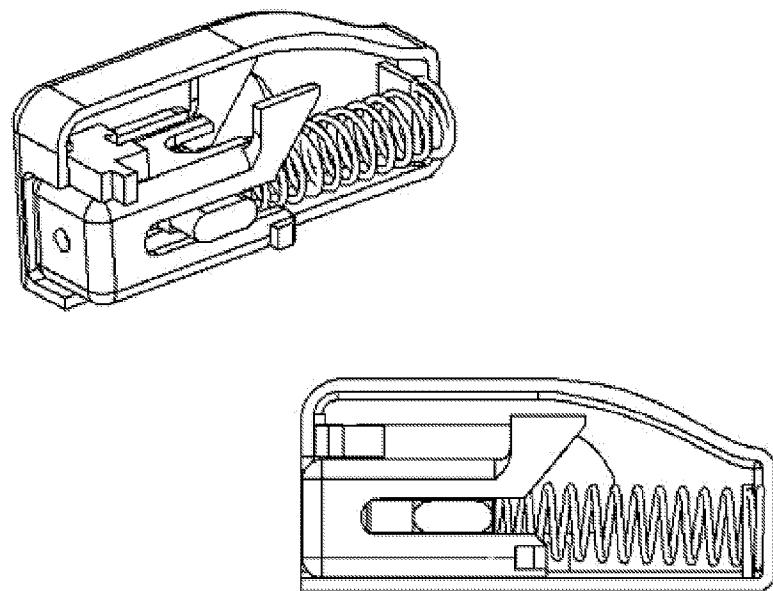


Figure 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/050010

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/151

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)
A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 747 006 A1 (APLS CO LTD [JP] ASAHI POLYSLIDER CO LTD [JP]) 11 December 1996 (1996-12-11)	1, 6-9, 12,13
A	column 2, line 36 – column 5, line 46; figures 8-10	2-4,17, 19
X	EP 1 247 489 A (PZ HTL S A [PL]) 9 October 2002 (2002-10-09) paragraphs [0011] – [0013]	1,11-13
X	US 2005/085840 A1 (YI PATRICK [SG] ET AL) 21 April 2005 (2005-04-21) paragraphs [0026] – [0033]	1,4,17
A	US 2003/050656 A1 (SCHRAGA STEVEN [US]) 13 March 2003 (2003-03-13) paragraphs [0027] – [0034]	1,4,8, 11,15, 17,19
		-/-

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

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

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

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

*& document member of the same patent family

Date of the actual completion of the international search

10 April 2007

Date of mailing of the international search report

18/04/2007

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

Manschot, Jan

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2007/050010

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/071940 A1 (FACET TECHNOLOGIES LLC [US]; LEVAUGHN RICHARD W [US]; KENNEDY GWENN E) 4 September 2003 (2003-09-04) claims 1-7 -----	2,3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2007/050010

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2007/050010

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