The invention provides a drug delivery device comprising: a drug container, a needle coupled to the drug container, having a front end for insertion into a patient and a rear end for receiving drug from the drug container, a rupturable needle cover covering the front end of the needle, wherein, in use, the front end of the needle ruptures the needle cover prior to insertion into a patient, and a venting element, the venting element configured to allow air to escape from within the needle cover following rupture of the needle cover by the needle.
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NEEDLE INSERTION SYSTEM FOR AN AUTOINJECTOR

Field of the Invention

The present invention relates to autoinjectors and in particular to a sterile needle assembly for an autoinjector that is safe for the patient being injected.

Background to the Invention

An autoinjector is a drug delivery device which contains a medical, therapeutic, diagnostic, pharmaceutical or cosmetic compound (drug) before it is administered, and which is used to administer the compound through the skin of the patient via a hollow needle.

Autoinjectors may be used by the patient themselves or by a different user, and are also used to administer drugs to animals.

Autoinjectors are typically used because they reduce the amount of training and effort needed by a user compared with that needed for a syringe, by automating either or both processes of inserting the needle into the patient and expelling the drug through the needle. They can also reduce the fear of injection by hiding the needle from the patient.

Autoinjectors typically include a housing containing a drug and a plunger that is driven by an automatic mechanism to move the plunger within the housing to eject the drug through a hypodermic needle. The automatic mechanism may also move the needle relative to the housing to insert the needle into a patient. Motive power for the mechanism may come from one or more metal springs or other power sources such as compressed gas.

The needle needs to be kept sterile until the autoinjector is used, in order to prevent infection of the patient. Autoinjectors typically take one of two approaches to achieve this, either by having a separate rubber needle cover that needs to be manually removed just before the autoinjector is used, or by having a fixed needle cover which the needle pierces during use of the autoinjector, just prior to insertion of the needle into the patient.

Autoinjectors are used to deliver so-called crisis drugs such as epinephrine for the treatment of anaphylactic shock. Accordingly, patients, including children, may carry around autoinjectors with them over long periods of time in case they are needed. There is a risk that where manual removal of the needle cover is possible, users may remove the cover, i.e. before the autoinjector is intended to be used, out of curiosity or by accident. This compromises the sterility of the needle. Either the autoinjector must then be thrown...
away or the patient risks becoming infected at a later date through use of the non-sterile needle. A fixed needle cover has the advantage over a removable needle cover in that it is harder for the user to erroneously compromise the sterility of the needle before use.

However, for a fixed needle cover which is pierced by the needle, when the autoinjector is used, problems can arise following rupture of the needle cover, as the ruptured needle cover can interfere with subsequent movement of the needle during insertion of the needle into a patient body. This is particularly true of close fitting covers. Loose fitting covers that enclose a larger volume of air between the needle and the cover provide less mechanical interference than tight fitting covers, but there can be a problem with gas trapped in the cover following puncture. This gas can interfere with needle insertion, can produce disconcerting noises during needle insertion and can potentially be forced into the patient's body or back into the drug container.

It is an object of the invention to address the above described problems with fixed needle covers.

**Summary of the Invention**

Aspects of the present invention are defined in the appended independent claims, to which reference should be made. Features described in relation to one aspect of the invention may be provided in one or more of the other aspects. Preferred features of the invention are defined in the dependent claims.

The present invention relates to a system and method of venting the gas inside a needle cover of an autoinjector. In particular, it relates to a venting mechanism for an autoinjector that provides a passage for gas during and after the process of insertion of the needle to a patient.

In one aspect, the invention provides a drug delivery device comprising:

a drug container;

a needle coupled to the drug container, having a front end for insertion into a patient and a rear end for receiving drug from the drug container;

a rupturable needle cover covering the front end of the needle, wherein, in use, the front end of the needle ruptures the needle cover prior to insertion into a patient; and
a venting element, the venting element configured to allow air to escape from within the needle cover following rupture of the needle cover by the needle.

The venting element may be directly coupled to the needle, directly coupled to the drug container or directly coupled to both the needle and the drug container. Alternatively, the venting element may be coupled to another part of the drug delivery device. The venting element may be integrally formed with the drug container or with another part of the drug delivery device.

Preferably, the venting element is tapered towards the front end of the needle. The venting element may have a generally conical or pyramidal shape, at least at a front end. Preferably, the venting element includes at least one channel extending in the direction of a longitudinal extent of the needle. Preferably, a front end of the channel opens onto the needle. The tapering of the venting element ensures that a front end of the venting element engages the opening formed in the needle cover by the needle as the needle pushes through the cover. By forming a channel in the venting element which opens onto the needle at the front end of the venting element, air from within the cover can pass through the channel and escape from the cover out of the front end of the channel.

Preferably, the venting element includes a plurality of channels extending in the direction of a longitudinal extent of the needle, a front end of each channel opening onto the needle. The provision of a plurality of channel reduces the likelihood of blockage and allows for a more rapid escape of air.

The venting element may comprise a plurality of components spaced around a circumference of the needle, the plurality of components defining at least one channel between them through which air can escape. The channel or channels can be of any width and may occupy a greater volume that the venting element, so that, for example, the venting element may take the form of one or more walls or fins arranged around the needle.

In use, the venting element may engage with an aperture in the needle cover formed by the front end of the needle during rupture. The venting element maintains one or more airflow passages providing fluid communication from within the needle cover to the exterior of the needle cover.
Preferably, the needle cover is formed from rubber or another flexible material. Preferably, an air space is provided between the needle cover and the needle prior to rupture of the needle cover.

Preferably, the needle cover is coupled to the drug container and encloses the needle within a space defined by the needle cover and the drug container.

The drug delivery device may include a front end housing against which the needle cover is pressed during a needle insertion operation, the front end housing comprising an aperture through which the needle can pass. The venting element is preferably coupled to or surrounds a rear portion of the needle so that a front end of the venting element is within or has passed through the aperture when the needle is in a forward or insertion position. The needle cover is preferably configured to engage the aperture, and may include a front surface configured to match the shape of the aperture.

As an alternative, or in addition, to a venting element coupled to the needle or to the drug container, a venting element may be coupled to, or part of, the front end housing. A venting element coupled to the front end housing may be configured to engage the needle cover as the needle cover is pressed against the front end housing. The venting element may comprise one or more piercing elements that pierce the needle cover as the needle cover is pressed against the front end housing. In particular a surface provided around a rear end of the needle may be configured to press the needle cover into contact with the piercing elements as the needle is moved to a forward position.

In another aspect the invention provides a drug container for use in a drug delivery device, the drug container comprising:

- a housing portion containing a drug;
- a needle coupled to the housing portion, having a front end for insertion into a patient and a rear end for receiving drug from the housing portion;
- a rupturable needle cover covering the front end of the needle, wherein, in use, the front end of the needle ruptures the needle cover prior to insertion into a patient; and
- a venting element coupled to the needle or to the housing portion, the venting element configured to allow air to escape from within the needle cover following rupture of the needle cover by the needle.
Preferably, the venting element is tapered towards the front end of the needle. Preferably the venting element includes at least one channel extending in the direction of the longitudinal extent of the needle. Preferably a front end of the channel opens onto the needle.

Preferably, the venting element comprises a plurality of components spaced around a circumference of the needle, the plurality of components defining a least one channel between them through which air can escape from within the needle cover.

The invention provides a mechanism for allowing air to escape from within a ruptured needle cover quickly and quietly without interfering with the operation of the drug delivery device.

**Brief Description of the Drawings**

Embodiments of the invention will now be described in detail, by way of example only, with reference to the accompanying drawings, in which:

- Figure 1a is cross section through a drug delivery device in accordance with a first embodiment of the invention;
- Figure 1b is a perspective horizontal section through the device of Figure 1a;
- Figure 1c is a perspective vertical section through the device of Figure 1a;
- Figure 2 is an enlarged view of the front end of Figure 1b;
- Figure 3a is a perspective view of the front end of the drug container of Figure 1a;
- Figure 3b is a perspective, cut away view of the drug container of Figure 1a;
- Figure 4a is a perspective view of the needle cover of Figure 1a;
- Figure 4b is a perspective sectional view of the needle cover of Figure 1a;
- Figure 5 shows the device of Figure 1a with the safety cap removed;
Figure 6 shows the device of Figure 5 with the drug container and needle in a forward position;

Figure 7 shows the device of Figure 6 with the sealing element ruptured, so that drug can be delivered to a patient;

Figure 8 illustrates a first alternative design for the drug container and venting element;

Figure 9 illustrates a second alternative design for the drug container and venting element;

Figure 10 illustrates a further alternative type of venting element provided on a front housing of the device; and

Figure 11 is an enlarged view of the front end of Figure 10.

**Detailed Description**

Figures 1a, 1b and 1c illustrate a drug delivery device in accordance with one example of the invention, before use. Figure 1a is a cross sectional view and Figures 1b and 1c are respectively a perspective horizontal and a perspective vertical section of the device shown in Figure 1a.

The drug delivery device shown in Figure 1a is an autoinjector containing a drug for delivery to a patient. The autoinjector comprises a drug container 10 in which a dose of drug 12 is contained. A hollow hypodermic needle 14 is fixed to a front end of the drug container 10 and a plunger 16 provided within the drug container 10. The needle 14 is separated from the drug 12 by a sealing element 18. Movement of the plunger 16 towards the needle 14 causes the drug to push the sealing element onto a rear end of the needle. The rear end of the needle pierces the sealing element 18 allowing the drug to be expelled from the drug container 10 through the needle 14.

As used herein "front" refers to the end of the drug container or autoinjector closest to the patient in use, i.e. the end through which the drug is delivered to the patient, and "rear" refers to the end of the drug container or autoinjector furthest from the patient in use.
The needle 14 is surrounded by a needle cover 20. The needle cover comprises a flexible sheath typically formed from rubber, and which is fixed to the drug container 10 and encloses the needle within a space between the cover and the drug container. A volume of air is trapped between the needle 14 and the needle cover 20. The needle cover is provided to keep the needle sterile prior to use.

This drug container assembly is housed within a housing 22 that contains a drive mechanism for inserting the needle 14 into a subject and for moving the plunger 16 within the drug container 10 to expel the drug 12. The housing also contains a skin sensing mechanism 24 for activating the drive mechanism on contact with the skin of a subject. The drive mechanism comprises a helical spring 26 that stores energy for driving needle insertion and drug delivery operations, as is described in detail with reference to Figures 5 to 7. A safety cap 28 is provided to cover the front end of the autoinjector and prevent accidental activation of the drive mechanism.

The drug container 10 may be formed of any suitable drug compatible material, but in this example is formed by injection moulding from cyclic olefin copolymer. The housing 22 and safety cap 28 are formed by injection moulding from polyester thermoplastic. The spring 26 is a helical metal spring. The plunger 16 is formed from styrene butadiene rubber.

Figure 2 is an enlarged view of the needle cover and front end of the drug container of Figure 1b. The needle cover 20 is coupled to the drug container 10 using adhesive. However, welding, an interference fit or any another suitable sealing means may be used. A front end of the needle cover 20 abuts a front end housing 30, which is part of the autoinjector housing and is fixed relative to housing 22. Front end housing includes an opening 34 through which the needle passes during operation of the autoinjector. The front end of the needle cover 20 includes a flange portion 32 that engages a rearward facing surface of the front end housing surrounding the opening 34. Flange portion 32 ensures that the needle cover is retained behind the opening 34 and is not squeezed into the aperture, which might interfere with the needle insertion operation.

The needle 14 is fixed relative to the drug container 10 and is held in a needle holding portion 36. In the embodiment of Figure 2, the needle holding portion 36 is formed integrally with the drug container 10. The needle holding portion 36 also acts as a venting element that allows air to escape from within the needle cover 20 during operation of the autoinjector.
The needle holding portion is tapered towards a front end and has a generally conical shape. The needle is engaged in a central bore 37 and fixed in the bore using adhesive. Venting channels or grooves 38 are formed in the needle holding portion. The channels 38 extend from a front end of the needle holding portion, adjacent to the needle, rearward towards a main body of the drug container 10. Only one channel 38 is visible in Figure 2 but any number of channels 38 may be provided around the needle holding portion.

The needle holding portion 36 is shown separately in Figures 3a and 3b. Figure 3a is a perspective view showing multiple channels 38 formed in the needle holding portion. Figure 3b is a cut away perspective view of the complete drug container 10, including the needle holding portion 36. Bore 37 can be clearly seen as well as channel 38.

Figure 4a is a perspective view of the needle cover 20, clearly showing that the needle cover has a substantially circular cross section and, in conjunction with the drug container, is able to fully enclose the needle. Figure 4b is a perspective sectional view of Figure 4a.

Figure 5 to 7 illustrate the drug delivery device of Figures 1a, 1b and 1c at different stages during its use. Figure 5 shows the drug delivery device with the safety cap removed but prior to activation. In Figure 5 the needle 14 has not ruptured the needle cover 20 or the sealing element 18. The compressed spring 26 is applying force on pusher 54. The pusher 54 transfers that force through coupling component 56 to the rear end of the drug container 10. The drug container is prevented from moving forward through the housing 22 by resilient arms 50, and in particular by latch portions 52 on the resilient arms. The resilient arms are part of the housing 22 of the autoinjector. The latch portions 52 engage the front end of the drug container 10. The spring 26 is therefore retained in a compressed state until the latch portions 52 disengage from the drug container 10.

The resilient arms are prevented from disengaging from the drug container by the skin sensor element 24. However, skin sensor element 24 includes windows 58. In use, the skin sensor element 24 is pushed rearward by a patient's skin relative to the housing 22 until the windows 58 align with latch portions 52. At that point the resilient arms are flexed radially outward by the force exerted to the latch portions by the drug container 10 under the action of the spring 26. The drug container can then move forward through the housing 22 and the needle extends beyond the front end of the skin sensor element and penetrates the patient.
Figure 6 shows the needle and drug container in the most forward position, but prior to the ejection of drug 12 from the container 10.

During the needle insertion movement the needle cover is retained with the front end housing 30 and is ruptured by the needle 14. As shown in Figure 6, the needle cover is compressed with the space between the drug container 10 and the front end housing 30. During this compression, a large proportion of the volume of air held within the needle cover 20 must escape from the needle cover. As the needle reaches its forward position, the tapered front end of the needle holding portion engages the hole formed in the needle cover by the needle 14 and opens it up. The front end of the needle holding portion enters into the opening 34 in the front end housing. The front ends of channels 38 are then exposed to the external environment and so the channels provide a fluid path between the interior of the needle cover to the external environment. This allows air to escape rapidly and reliably without interfering or hampering needle insertion or making disconcerting noises.

The length of the channels is at least the thickness of the needle cover and is preferably many times the thickness of the needle cover 20 to minimise the possibility of the ruptured needle cover sealing a channel from the rest of the interior of the needle cover.

As the drug container moves towards its forward position, the coupling component 56 moves into a region of the housing 22 of increased internal diameter. This allows the coupling component 56 to flex outwardly and the pusher 54 to pass through the coupling component to engage the rear end of plunger 16. The force required to move the plunger through the drug container 10 to eject the drug 12 is greater than that required to move the drug container 10 through the housing 22. So the action of the spring is still move the drug container forward.

After the drug container 10 has reached its most forward position, as shown in Figure 6, the plunger 16 is moved within the drug container. The pressure exerted by the plunger on the drug 12 causes the drug to push on the sealing element 18 until it contacts the rear end of the needle 14 and ruptures. This is illustrated in Figure 7. Continued movement of the plunger under the pressure of the spring 26 forces the drug out of the drug container 10, through the needle 14 and into the patient.
In the embodiment described with reference to Figures 1 to 7, the venting element is
formed as part of the drug container. Figures 8 and 9 illustrate alternative designs.

In Figure 8 the drug container 80 is formed to receive a separate venting element and
needle holder 82. The venting element holds the needle 14 within a central bore and the
needle is glued in place. The front surface of the venting element 82 has the same shape
as needle holding portion 36 shown in Figure 2. Channels 84 are formed in venting element
82 in the same manner as in needle holding portion 36. The venting element is then
received in a front end opening in the drug container 80 and fixed by welding adhesive or
by a mechanical fixing, such as a snap fitting or a screw fixing. Needle cover 20 can then
be attached over the needle in the same manner as for the embodiment described with
reference to Figure 1 to 7.

In Figure 9 the needle 14 is fixed to the drug container 90 and a separate venting element
92 is provided on a front of the housing which need not be fixed to the needle 14. The
venting element can be secured to the drug container using a mechanical fixing such as a
screw fitting on a snap fitting, or may be glued or welded in position. The front surface of
the venting element 92 has the same shape as needle holding portion 36 shown in Figure
2. Channels 84 are formed in venting element 92 in the same manner as in needle holding
portion 36. Needle cover 20 can then be attached over the needle in the same manner as
for the embodiment described with reference to Figure 1 to 7.

Figure 10 shows another embodiment of the design where venting elements 94 are
attached to, or integrally formed with, the front end housing 30, and are forced to pierce the
needle cover 20 separately to allow the air inside to be vented when the needle cover 20 is
driven onto them by a surface 93 around the base of the needle 14 during insertion of the
needle 14 into the patient. Further venting channels 95 are shown on the surface of the
front end housing 30. These assist in venting the air away from the area around the
opening 34 through which the needle passes during operation of the autoinjector, and
could alternatively be formed in the opposing surface of the skin sensor 24 or elsewhere.
The venting elements 94 could be provided as an alternative to or in addition to the venting
channels 38, 84 described with reference to Figures 1 to 9.

Figure 11 shows a detail of Figure 10 at a greater scale for clarity.
Claims

1. A drug delivery device comprising:

   a drug container;

   a needle coupled to the drug container, having a front end for insertion into a patient and a rear end for receiving drug from the drug container;

   a rupturable needle cover covering the front end of the needle, wherein, in use, the front end of the needle ruptures the needle cover prior to insertion into a patient; and

   a venting element, the venting element configured to allow air to escape from within the needle cover following rupture of the needle cover by the needle.

2. A drug delivery device according to claim 1, wherein the venting element is coupled to the needle or to the drug container, or to both the needle and to the drug container.

3. A drug delivery device according to claim 1 or 2, wherein the venting element is tapered towards the front end of the needle.

4. A drug delivery device according to any preceding claim, wherein the venting element includes at least one channel extending in the direction of a longitudinal extent of the needle.

5. A drug delivery device according to claim 4, wherein a front end of the channel opens onto the needle.

6. A drug delivery device according to claim 4 or 5, wherein the venting element includes a plurality of channels extending in the direction of a longitudinal extent of the needle, a front end of each channel opening onto the needle.

7. A drug delivery device according to any preceding claim, wherein the venting element comprises a plurality of components spaced around the needle, the plurality of components defining a least one channel between them through which air can escape.
8. A drug delivery device according to any preceding claim, wherein an air space is provided between the needle cover and the needle prior to rupture of the needle cover.

9. A drug delivery device according to any preceding claim, wherein the needle cover is coupled to the drug container and encloses the needle within a space defined by the needle cover and the drug container.

10. A drug delivery device according to any preceding claim, further comprising a front end housing against which the needle cover is pressed during a needle insertion operation, the front end housing comprising an aperture through which the needle can pass.

11. A drug delivery device according to claim 10, wherein the venting element is coupled to, or part of, the front end housing.

12. A drug delivery device according to claim 10, wherein the venting element is coupled to the needle so that a front end of the venting element is within or has passed through the aperture when the needle is in a forward position.

13. A drug delivery device according to any one of claims 10 to 12, comprising one venting element coupled to or forming part of the front end housing and another venting element coupled to or forming part of the drug container.

14. A drug container for use in a drug delivery device, the drug container comprising:

   a housing portion containing a drug;

   a needle coupled to the housing portion, having a front end for insertion into a patient and a rear end for receiving drug from the housing portion;

   a rupturable needle cover covering the front end of the needle, wherein, in use, the front end of the needle ruptures the needle cover prior to insertion into a patient; and

   a venting element, the venting element configured to allow air to escape from within the needle cover following rupture of the needle cover by the needle.
15. A drug delivery device according to claim 14, where the venting element is directly coupled to the needle.

16. A drug delivery device according to claim 14 or 15, where the venting element is directly coupled to the housing portion.

17. A drug container according to claim 14, 15 or 16, wherein the venting element is tapered towards the front end of the needle.

18. A drug container according to any one of claims 14 to 17, wherein the venting element includes at least one channel extending in the direction of the longitudinal extent of the needle.

19. A drug container according to claim 18, wherein a front end of the channel opens onto the needle.

20. A drug container according to any one of claims 14 to 19, wherein the venting element comprises a plurality of components spaced around a circumference of the needle, the plurality of components defining a least one channel between them through which air can escape.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/20 A61M5/32

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Date of the actual completion of the international search
28 February 2012

Date of mailing of the international search report
06/03/2012
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