

Guide For An Injection Device

Field of the invention

5 The present invention relates to a guide for the housing of an injection device that receives a syringe, extends the syringe and discharges its contents, commonly known as an auto-injector and a kit comprising the injection device.

Background of the Invention

10

Auto-injectors are known from WO 95/35126 and EP-A-0 516 473 and tend to employ a drive spring and some form of release mechanism that releases the syringe from the influence of the drive spring once its contents are supposed to have been discharged, to allow it to be retracted by a return spring.

15

An auto-injector is known from WO 2007/036676 which has a locking mechanism which must be disengaged before the release mechanism can be activated. In its locked position, the locking mechanism also prevents forward movement of the syringe out of the injection device against the bias of the return spring, for example when a cap gripping a boot covering the syringe needle, is removed. In the injection device described in WO 2007/036676, the locking mechanism comprises a sleeve which protrudes from an open end of the injection device. The sleeve is biased into its extended position by a resilient spring mechanism which must be overcome to disengage the locking mechanism. The locking mechanism can be disengaged by, for example, moving the sliding sleeve inwardly into the injection device. This can be done by forcing the end of the sliding sleeve against tissue and then activating the release mechanism.

25

It can be difficult for a user to position the sliding sleeve at the correct angle against the tissue and maintain it in that position as the locking mechanism is disengaged. Ensuring the sliding sleeve is forced against tissue at the correct angle and held sufficiently stable on the tissue as the locking mechanism is overcome is important to ensure reliable operation of the device as it is activated.

30

Summary of the Invention

The injection device and kit of the present invention is designed to deal with the aforementioned problems.

35

In a first aspect of the invention, there is provided a guide for contacting an injection device with a user; the guide having a first end adapted to engage a housing of the injection device and a second end adapted to engage the surface of a user's skin, wherein the guide permits movement of the housing towards the user's skin.

5

The guide ensures that the housing moves towards the user's skin at the correct angle since it is engaged with the skin and directs the housing of the injection device towards it. It can be dimensioned for use with existing injection devices so that modification of the injection device is unnecessary. The guide could also be used to hold the auto-injector in position during long (high viscosity) or intramuscular injections.

10

The first end of the guide may be open. By 'open' it is meant that at least a portion of the injection device may pass through the first end.

15

This allows the guide to be placed on the skin and a discharge nozzle of the injection device to pass through it towards the user's skin.

The second end of the guide may be open, thereby providing a straightforward way for the user to insert the injection device into the guide. Again, by 'open' it is meant that at least a portion of the injection device may pass through the second end.

20

The guide may be cylindrical. Typically, injection devices are cylindrical, and so this shape of guide conforms well with most kinds of injection devices. A cylindrical guide is also found to be easily to grasp, and to be most comfortable when placed on the user's skin because it lacks sharp corners. Moreover, the shape provides a linear path for the injection device to travel down and holds the housing of the injection device securely. Of course, other shapes are also possible.

25

The guide may be flared towards the second end. The flared end stabilises the guide on the skin so that its position does not change as the housing is moved towards the skin.

30

The guide may be formed as a frame (rather than a solid tube structure, for example). In this case, the user can see the passage of the injection device towards the skin, which is found to be particularly reassuring since the user can anticipate when the injection device will contact the skin.

35

Alternatively, the guide may be formed with a continuous external surface. This provides a more secure guide since the user cannot access the distal end of the injection device as it is advanced towards the skin.

The guide may comprise at least one stabilising element at its second end which is adapted to project from the guide and stabilise the guide on the skin. This helps to improve the stability of the guide on the skin during use. In a preferred embodiment, the guide may comprise three stabilising elements at its second end. Additional stabilising elements provide additional stability to the guide on the skin.

The guide may comprise a first component and a second component moveable relative to the first component. The second component can be used to engage the housing and move it towards the skin while the first component remains fixed on the skin. In this way, the guide is capable of exerting some control over the progress of the injection device through the guide.

The second component may be adapted for indexed movement relative to the first component. This allows the user to more accurately control the movement of the injection device.

For example, the guide may further comprise a ratchet disposed on its inner surface such that the housing moves towards the user's skin incrementally. The ratchet may exist between the first and second components, or between the first component and the housing itself. This second arrangement allows the user to control the movement of the injection device without the need for a second component. In any case, the ratchet prevents the injection device being removed from the guide once it has been advanced towards the user's skin, which provides improved safety.

The second end may be configured to draw the user's skin up into the second end. For example, the second end may comprise an aperture of a particular shape which causes the skin therein to be pinched, and thus raised towards the distal end of the injection device. This configuration of the skin is advantageous for subcutaneous injections.

The second end may comprise a resilient portion which is biased inwards. This acts to pinch the skin together when the second end is placed on the skin. The resilient portion may comprise at least two resilient arms biased towards each other, which is particularly effective for pinching the skin together.

In a second aspect of the invention, there is provided a kit comprising the guide of any preceding embodiment and an automatic injection device having a housing.

The first end of the guide may be adapted to engage the housing at its distal end. The guide can be dimensioned to fit pre-existing injection devices ensuring that it is readily compatible.

The housing may have a first diameter and the first end may be dimensioned to surround the first diameter. The housing is then easily inserted into the first end of the housing. Preferably, the first end is dimensioned such that there is an interference fit between the housing and the guide.

5

The internal surface of the guide may be dimensioned to be in contacting juxtaposition with an external surface of the housing. This ensures that the housing remains aligned with the wall of the guide as the housing is advanced through the guide.

10

A portion of the housing may have a second diameter which is larger than the first diameter and the first end may be dimensioned to engage the portion of the housing having a second diameter. The second diameter portion prevents the housing being advanced towards the skin further than is necessary.

15

The second diameter portion may comprise a ridge, for example to act as a stop for the housing relative to the guide.

The first end may be integral to the housing of the injection device. Thus, the injection device and housing may be provided in one piece.

20

In a third aspect of the invention, there is provided an injection device comprising a housing adapted to receive a syringe having a discharge nozzle, the syringe being moveable in the housing on actuation of the injection device along a longitudinal axis from a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharge nozzle of the syringe extends from the housing through an exit aperture at a distal end of the device, a sliding component which extends, when in a first position, from the aperture, and is movable towards the housing into a second, retracted, position; and a guide for contacting an injection device with a user; the guide having a first end adapted to engage the housing and a second end adapted to engage the surface of a user's skin, wherein the guide permits movement of the housing towards the user's skin.

25

30

The injection device may further comprise an actuator; and a drive adapted to be acted upon by the actuator and in turn act upon the syringe to advance it from its retracted position to its extended position and discharge its contents through the discharge nozzle.

35

The sliding component may be part of a locking mechanism moveable from an engaged position, when the sliding component is in its first position, to a disengaged position, when the sliding

component is in its second position, and adapted to prevent actuation of the device when it is in its engaged position and permit actuation of the device when it is in its disengaged position.

5 The sliding sleeve can be moved into its disengaged position as the housing is moved against the skin. The guide ensures that the injection device is at the correct angle for this movement to take place.

10 The injection device or injection kit of any of the above embodiments may contain a substance selected from the group consisting of: golimumab, hormones, antitoxins, substances for the control of pain, substances for the control of thrombosis, substances for the control or elimination of infection, peptides, proteins, human insulin or a human insulin analogue or derivative, polysaccharide, DNA, RNA, enzymes, antibodies, oligonucleotide, antiallergics, antihistamines, anti-inflammatories, corticosteroids, disease modifying anti-rheumatic drugs, erythropoietin, or vaccines, for use in the treatment or prevention of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, hormone deficiency, toxicity, pain, thrombosis, infection, diabetes mellitus, diabetic retinopathy, acute coronary syndrome, angina, myocardial infarction, atherosclerosis, cancer, macular degeneration, allergy, hay fever, inflammation, anaemia, or myelodysplasia, or in the expression of protective immunity.

20 By 'the injection device or injection kit may contain a substance' it is meant that the substance may be contained within a suitable medicament container, such as a vial or syringe, within the injection device, or within the syringe of the injection kit. Such medicament container may contain other substances, such as further active or inactive ingredients.

25 In a further aspect of the invention, a substance is provided, the substance being selected from the group consisting of: golimumab, hormones, antitoxins, substances for the control of pain, substances for the control of thrombosis, substances for the control or elimination of infection, peptides, proteins, human insulin or a human insulin analogue or derivative, polysaccharide, DNA, RNA, enzymes, antibodies, oligonucleotide, antiallergics, antihistamines, anti-inflammatories, corticosteroids, disease modifying anti-rheumatic drugs, erythropoietin, or vaccines, for use in the treatment or prevention of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, hormone deficiency, toxicity, pain, thrombosis, infection, diabetes mellitus, diabetic retinopathy, acute coronary syndrome, angina, myocardial infarction, atherosclerosis, cancer, macular degeneration, allergy, hay fever, inflammation, anaemia, or myelodysplasia, or in the expression of protective immunity, by delivery of said substance to a human subject using an injection device or injection kit according to any of the above embodiments.

30

35

In yet another aspect of the invention, an injection device is provided for use in the treatment or prevention of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, hormone deficiency, toxicity, pain, thrombosis, infection, diabetes mellitus, diabetic retinopathy, acute coronary syndrome, angina, myocardial infarction, atherosclerosis, cancer, macular
5 degeneration, allergy, hay fever, inflammation, anaemia, or myelodysplasia, or in the expression of protective immunity, by delivery of a substance selected from the group consisting of: golimumab, hormones, antitoxins, substances for the control of pain, substances for the control of thrombosis, substances for the control or elimination of infection, peptides, proteins, human insulin or a human
10 insulin analogue or derivative, polysaccharide, DNA, RNA, enzymes, antibodies, oligonucleotide, antiallergics, antihistamines, anti-inflammatories, corticosteroids, disease modifying anti-rheumatic drugs, erythropoietin, or vaccines, to a human subject by using the injection device, where the injection device is an injection device or injection kit of any of the above embodiments.

By 'delivery of a substance' it is meant that the injection device is used to inject said substance into
15 the human subject, for example by subcutaneous, intradermal or intramuscular injection. Said substance may be administered in combination with other substances, such as further active or inactive ingredients.

Brief description of the drawings

20 The present invention will now be described with reference to the accompanying drawings, in which: -

Figure 1 shows a perspective view of an injection device having a locking mechanism including a
25 sliding sleeve;

Figure 2 shows a cutaway side view of an injection device having a locking mechanism including a sliding sleeve;

30 Figure 3 show a side view of an injection device having a locking mechanism including a sliding sleeve;

Figure 4a shows a perspective view of a guide and an injection device of the present invention;

35 Figure 4b shows a perspective view of an alternative guide in accordance with the present invention;

Figure 5a shows a cross-section view of an alternative guide in accordance with the present invention;

Figure 5b shows a cross-section view of an alternative guide in accordance with the present invention; and

Figure 6 shows a cross-section view of a guide in accordance with the present invention.

Detailed description of the drawings

Figures 1 to 3 show an injection device 110. The injection device 110 has an injection device housing 112 and a longitudinal axis 101.

A syringe (figure 3) is contained in the housing 112. The injection device 110 comprises trigger 114 (actuator) and a releasable locking mechanism 116. The trigger 114 has a first end 114a and a second end 114b. The trigger 114 is rotatable about a pivot 115 from a rest position (as shown in Figure 2) to an active position. The second end 114b of the trigger 114 connects with a drive coupling 121 which is acted upon by a drive spring 120. The drive coupling 121 is in communication with the syringe 122.

Rotation of the trigger 114 about the pivot 115 in a direction R (i.e. downwards into the housing 112 at its first end 114a) causes the second end 114b of the trigger 114 to disengage from the drive coupling 121, thereby letting the drive spring 120 drive the syringe 122 (via the drive coupling 121) along the longitudinal axis 101 and out of an aperture 118 in the housing 112.

The releasable locking mechanism 116 is in communication with sliding sleeve 126 which protrudes, when in a first position, from the aperture 118 in the housing 112. The locking mechanism 116 is deactivated by movement of the sliding sleeve 126 along the longitudinal axis 101 into the housing 112 into a second position.

A first end 126a of the sliding sleeve 126 can be placed against a body into which drug is being delivered, thereby deactivating the releasable locking mechanism 116 and allowing the trigger 114 to rotate in direction R from its rest position to its active position.

The trigger 114 is provided at its first end 114a with a first portion having a cut-out. The first portion extends from the first end 114a of the trigger 114a in a direction substantially parallel to the longitudinal axis 101.

The releasable locking mechanism 116 includes a protrusion 154 which projects in a direction along a perpendicular axis 181 which is perpendicular to the longitudinal axis 101. The cut-out is dimensioned to receive the protrusion.

5

When the releasable locking mechanism 116 is in its first position, an end of the protrusion abuts an under-surface of the first portion 150, thereby preventing rotation of the trigger 114.

10

When the releasable locking mechanism 116 is in its second position (not shown) following movement of the sliding sleeve 126 into the housing 112, the cut-out is positioned above the end of the protrusion 154 allowing it to pass over the protrusion 154 when a downwards force is applied the trigger 114. Hence, the trigger 114 is no longer prevented from rotating and disengages itself from the drive coupling 121, thereby extending the syringe.

15

Figure 4a shows a guide 200 in accordance with the present invention. The guide comprises a cylindrical portion which is open at both its first 210 end and second end 220. The guide is flared towards the second end. Alternatively, as shown in figure 4b, the second end 220 of the guide 200 may be cylindrical. The first end 210 is dimensioned to receive the housing 112 of an injection device such as the shown in figures 1 to 3. The first end 210 of the guide 200 may be dimensioned such a first portion 130 of the housing 112 having a second diameter which is larger than a second portion 140 of the housing 112 cannot pass through the guide. The first portion engages the first end 210 of the housing 112 as the injection device is advanced through the guide 200. This provides a stop for the housing as it is advanced so that it cannot be pushed further against the skin than is necessary. Alternatively, a ridge may be provided on the housing 112 which engages the first end 210 of the guide 200 once the injection device 110 has been sufficiently advanced.

20

25

In use, the second end 220 of the guide 200 is attached to the user's skin as shown in figure 4a. The flared shape of the second end 220 acts to position the guide 200 at the correct angle to the user's skin and ensure that the guide is stable in this position. The injection device 110 is inserted into the first open end 210 of the guide. The guide 200 acts to direct the injection device 110 towards the user's skin at the correct angle such that when the sliding sleeve 126 contacts the user's skin, force is applied equally about its circumference and it is moved to its retracted position correctly, thereby enabling the user to actuate the injection device 110.

30

35

In figure 4a, the guide has a continuous external surface 230. Alternatively, the guide may be formed from a frame such that the user can see the movement of the sliding sleeve as the injection device is moved towards the skin.

As an alternative to the flared end, as shown in figure 4b, protrusions 250 may be provided at the second end 220 of the guide 200 which stabilise the guide 200 once it has been placed on the skin. The protrusions 250 may act as a tripod and prevent the guide tilting as the injection device is operated.

Figure 5a shows an alternative embodiment of the guide 300, comprising a ratchet mechanism 350 on the inner surface of the guide. The ratchet 350 engages the surface of the housing 112 of the injection device 110 as it is inserted into the first open end 310 and moved towards the skin. The injection device 110 can then be moved incrementally towards the user's skin as the sliding sleeve 126 contacts the skin and moves from its extended to its retracted position. This allows the user to accurately judge how far the injection device 110 has been advanced. The injection device 110 can then not be removed from the guide 300, and thus the skin, once the locking mechanism has been deactivated.

Alternatively, as shown in figure 5b the ratchet mechanism may be a two-part mechanism, comprising a second moveable component which engages the housing and moves with respect to the first component of the guide in an indexed fashion. The second component may be an annular component which engages the housing by a frictional fit. In another embodiment, not shown, the ratchet may be omitted such that the second component may slide relative to the first component.

Figure 6 shows an alternative embodiment of the guide in which the second open end 410 comprises two arms 440. The arms 440 are resiliently biased towards the centre of the guide such that they act to pinch tissue between them when they are placed on the user's skin. This secures the guide 400 to the user's skin and ensures it cannot shift position as the injection device is advanced through the drive and towards the skin and subsequently operated. In addition, pinching of the skin towards the aperture 118 of the device 110 from which the discharge nozzle extends is desirable when a substance is to be injected subcutaneously.

A kit may be provided which includes the injection device and the guide which is attached to the user prior to injection. Alternatively, the injection device may be supplied with the guide pre-affixed to the distal end.

In use, such an injection device as described above might be used to deliver substances such as: golimumab, hormones, antitoxins, substances for the control of pain, substances for the control of thrombosis, substances for the control or elimination of infection, peptides, proteins, human insulin or a human insulin analogue or derivative, polysaccharide, DNA, RNA, enzymes, antibodies,

oligonucleotide, antiallergics, antihistamines, anti-inflammatories, corticosteroids, disease modifying anti-rheumatic drugs, erythropoietin, or vaccines, for use in the treatment or prevention of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, hormone deficiency, toxicity, pain, thrombosis, infection, diabetes mellitus, diabetic retinopathy, acute coronary syndrome, angina, myocardial infarction, atherosclerosis, cancer, macular degeneration, allergy, hay fever, inflammation, anaemia, or myelodysplasia, or in the expression of protective immunity. In addition to these substances, any medicament contained within the injection device may also include other substances, such as inactive ingredients, as a skilled person would appreciate.

It will of course be understood by the person skilled in the art that particular substances are efficacious for use in the treatment or prevention of particular conditions, as is well known in the art. For instance, it is known that antiallergics are efficacious for use in the treatment or prevention of allergies; antihistamines are efficacious for use in the treatment or prevention of hay fever; anti-inflammatories are efficacious for use in the treatment or prevention of inflammation; and so on. Accordingly, any selection of one or more substances listed herein or in the claims for use in the treatment or prevention of one or more conditions for which those substance(s) are known to be efficacious is envisaged.

In a particular example, however, golimumab is known to be efficacious for use in the treatment or prevention of one or more of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or ulcerative colitis, or any combination of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis, or all of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

Golimumab may optionally be used in combination with one or more inactive ingredients such as any or all of L-histidine, L-histidine monohydrochloride monohydrate, sorbitol, polysorbate 80, and water. Golimumab may present in a composition in which golimumab is the only active ingredient. For example, golimumab may administered as SIMPONI®.

It will of course be understood that the present invention has been described above purely by way of example and modifications of detail can be made within the scope of the invention.

Claims

- 5 1. A guide (200,300,400) for contacting an injection device (110) with a user; the guide having a first end (210,310) adapted to engage a housing (112) of the injection device and a second end (220,320) adapted to engage the surface of a user's skin, wherein the guide permits movement of the housing towards the user's skin, characterised in that the guide further comprises a ratchet (350) disposed on its inner surface such that the housing moves towards the user's skin incrementally.
- 10 2. The guide of claim 1, wherein the first end and/or second end is open.
3. The guide of claim 1, wherein the guide is cylindrical.
- 15 4. The guide of claim 1, wherein the guide is flared towards the second end.
5. The guide of any preceding claim, wherein in the guide is formed as a frame.
6. The guide of any preceding claim, wherein the guide is formed with a continuous external surface.
- 20 7. The guide of any preceding claim, wherein the guide comprises at least one stabilising element (250) at its second end which is adapted to project from the guide and stabilise the guide on the skin, optionally wherein the guide comprises three stabilising elements at its second end.
- 25 8. The guide of any preceding claim, comprising a first component and a second component moveable relative to the first component.
- 30 9. The guide of claim 10, wherein the second component is adapted for indexed movement relative to the first component.
10. The guide of any preceding claim, wherein the second end is configured to draw the user's skin up into the second end.

11. The guide of claim 13, wherein the second end comprises a resilient portion which is biased inwards, optionally wherein the resilient portion comprises at least two resilient arms (440) biased towards each other.
- 5 12. A kit comprising the guide of any preceding claim and an automatic injection device having a housing, optionally wherein the first end is adapted to engage the housing at its distal end.
- 10 13. The kit of claim 12, wherein the housing has a first diameter and the first end is dimensioned to surround the first diameter.
14. The kit of claim 13 wherein the internal surface of the guide is dimensioned to be in contacting juxtaposition with an external surface of the housing.
- 15 15. The kit of claim 12 or 13, wherein a portion (130) of the housing has a second diameter which is larger than the first diameter and the first end is dimensioned to engage the portion of the housing having a second diameter.
- 20 16. The kit of claim 15, wherein the second diameter portion comprises a ridge.
17. The kit of any one of claims 12 to 16, wherein the first end is integral to the housing of the injection device.
- 25 18. An injection device comprising:
a housing (112) adapted to receive a syringe (122) having a discharge nozzle, the syringe being moveable in the housing on actuation of the injection device along a longitudinal axis from a retracted position in which the discharge nozzle is contained within the housing and an extended position in which the discharge nozzle of the syringe extends from the housing through an exit aperture (118) at a distal end of the device;
30 a sliding component (126) which extends, when in a first position, from the aperture, and is movable towards the housing into a second, retracted, position; and
a guide according to claim 1.
- 35 19. A device according to claim 18, further comprising:
an actuator (114); and
a drive (120,121) adapted to be acted upon by the actuator and in turn act upon the syringe to advance it from its retracted position to its extended position and discharge its contents

through the discharge nozzle, and/or wherein the sliding component is part of a locking mechanism moveable from an engaged position, when the sliding component is in its first position, to a disengaged position, when the sliding component is in its second position, and adapted to prevent actuation of the device when it is in its engaged position and permit actuation of the device when it is in its disengaged position.

5

20. A kit according to any one of claims 12 to 17 or an injection device according to any one of claim 18 or claim 19, wherein the injection device contains a substance selected from the group consisting of:

10

golimumab, hormones, antitoxins, substances for the control of pain, substances for the control of thrombosis, substances for the control or elimination of infection, peptides, proteins, human insulin or a human insulin analogue or derivative, polysaccharide, DNA, RNA, enzymes, antibodies, oligonucleotide, antiallergics, antihistamines, anti-inflammatories, corticosteroids, disease modifying anti-rheumatic drugs, erythropoietin, or vaccines,

15

for use in the treatment or prevention of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, hormone deficiency, toxicity, pain, thrombosis, infection, diabetes mellitus, diabetic retinopathy, acute coronary syndrome, angina, myocardial infarction, atherosclerosis, cancer, macular degeneration, allergy, hay fever, inflammation, anaemia, or myelodysplasia, or in the expression of protective immunity.

20