

FLUID TRANSFER ASSEMBLY

Field of the Invention

The present invention relates to a fluid transfer assembly, a fluid transfer system, an injection kit comprising the fluid transfer system and a method of assembling an
5 injection device.

Background of the Invention

Subcutaneous drugs can be supplied to patients in a vial for home injection. The current method is for the patient to draw the drug from the vial into a syringe and perform a manual injection. The market is moving towards auto-injectors to carry out home
10 injection. Auto-injectors which are manufactured and assembled including a pre-filled syringe of drug are known, for example from international patent application publication no. 2006/106295, which is incorporated herein by reference. There is currently no easy way for a patient to transfer a subcutaneous drug from a vial into an auto-injector.

Summary of the Invention

15 The present invention aims to solve the aforementioned problems.

In a first aspect of the invention, there is provided a fluid transfer assembly having a means for connection to a syringe, means for receiving a vial having a closure element where the receiving means is adapted to engage and open the closure element and permit fluid to be transferred from the vial to the syringe.

20 This fluid transfer system can be used with a delivery device having a delivery sub-assembly and a reusable drive sub-assembly which are both adapted to be attached to the syringe and operate together to deliver fluid from the syringe. The fluid transfer assembly thus permits a conventional syringe to be used in conjunction with a vial and an injection device.

Preferably, the receiving means comprises a needle to pierce the closure element and extend into the vial. The needle may also form part of a fluid pathway which extends in use between the vial and the syringe. Thus, a fluid pathway between the syringe and vial can be readily achieved without substantial user intervention.

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In one embodiment of the invention, the receiving means is a cylinder open at a first end which is dimensioned to receive the vial. Preferably, the connection means and receiving means are integrally formed with each other.

10 Advantageously, the connection means may comprise a second end which is open and dimensioned to fit over or in an open end of the syringe which is opposite the needle end of the syringe. This provides a stable, secure and sealed connection between the inside of the vial and the inside of the syringe.

15 Preferably, the fluid is transferred in use from the vial to the syringe under the force of gravity acting on the fluid, when the connection means is located above the receiving means. This means that limited input from a user of the injection device is required to fill the syringe and the transfer

20 In a second aspect of the invention, there is provided a fluid transfer system comprising: the fluid transfer assembly of any one of the preceding claims; and a syringe.

In a third aspect of the invention, there is provided an injection kit, comprising:

the fluid transfer system described above; and

25 a delivery device including a delivery sub-assembly and a drive sub-assembly, which are both adapted to be attached to the syringe, and operate together to deliver the fluid from the syringe.

Preferably, the delivery sub-assembly is adapted to support the syringe; and the drive
30 sub-assembly comprises a drive adapted on activation to act on the syringe to advance it from a retracted position in which a discharge nozzle of the syringe is contained within

the delivery sub-assembly to an extended position in which the discharge nozzle extends from the delivery sub-assembly.

In one embodiment of the invention, the delivery sub-assembly comprises: a syringe
5 carrier adapted to support the syringe between its retracted and extended positions; and a retraction element adapted to move the syringe after fluid delivery from the extended position to the retracted position.

Preferably, the drive sub-assembly comprises a release mechanism to release the drive to
10 act on the syringe to cause it to move from the retracted position to the extended position, wherein the drive is in a first position when the syringe is in its retracted position and the drive is in a second position when the syringe is in its extended position.

In one embodiment of the present invention, there is provided a base-station which is
15 adapted to receive the drive sub-assembly and reset the drive by moving it from its second position to its first position and reset the release mechanism such that when actuated again it releases the drive. Preferably, the base station comprises an attachment to hold the delivery sub-assembly whilst it is being reset. The attachment may simply be a port, for example a cylindrical support that is dimensioned to surround the . The base-
20 station may comprises a protrusion within the port which acts on the drive to force it into the housing, into its retracted position, when the injection device is inserted into the port.

Advantageously, the syringe may be disposable.

25 In a fourth aspect of the present invention, there is provided a method of assembling an injection device, comprising:

inserting fluid into a syringe through a vial via the fluid transfer assembly described above;

inserting a syringe having a piston into a delivery sub-assembly;

30 attaching a drive sub-assembly comprising a drive to the delivery sub-assembly;
and

assembling the drive sub-assembly and delivery sub-assembly together.

The method may further comprise the step of resetting the drive assembly after activation of the drive. Advantageously, the transfer of the content of the vial to the
5 syringe assembly can occur while the delivery assembly is on a base station.

Brief Description of Drawings

One or more embodiments of the present invention are described below with reference to the accompanying drawings, in which:-

10 Fig. 1 shows a perspective view of sub-assemblies of the injection device according to the present invention;

Fig. 2 shows an exploded view of components of the injection device according to the present invention;

Figs. 3a to 3c show perspective views of a fluid transfer assembly according to the
15 present invention; and

Fig. 4 shows a perspective view of a fluid transfer system according to the present invention.

Detailed Description of the Drawings

20 Figs. 1 and 2 show a delivery device 110 according to the present invention, having a delivery device housing 112 with a proximal end 110a and a distal end 110b. A distal end 110a of the housing 112 has an exit aperture 128, through which the end of a sleeve 119 can emerge.

The delivery device 110 is assembled from two sub-assemblies as shown in Fig. 1. A delivery sub-assembly 210 comprises a syringe carrier 150, an interchangeable release element 155, sleeve 119 and spring 126, as well as an end-cap 101.

A drive sub-assembly 220 comprises the housing 112 and drive elements and actuators of the injection device 110 as will be discussed below. Upon assembly of the two sub-assemblies 220, 210 to form the injection device 110, the drive assembly 220 is able to actuate the syringe 114 held by the delivery sub-assembly 210. After actuation, the two sub-assemblies can be separated and the drive elements and actuators of the drive assembly 220 reset for further use.

10 The housing 112 is adapted to receive a hypodermic syringe 114 of conventional type, including a syringe body 116 defining a reservoir and terminating at one end in a hypodermic needle 118 and at the other in a flange 120. The syringe body 116 is of substantially constant diameter along the length of the reservoir, and is of significantly smaller diameter close to the end of the syringe 114 which terminates in the hypodermic
15 needle. A drive coupling 134 acts through the bung of the syringe 114 to discharge the contents of the syringe 114 through the needle 118. This drive coupling 134 constrains a drug to be administered within the reservoir defined by syringe body 116. Whilst the syringe 114 illustrated is of hypodermic type, this need not necessarily be so. Transcutaneous or ballistic dermal and subcutaneous syringes may also be used with the
20 injection device of the present invention.

As illustrated, the syringe 114 is housed in the syringe carrier 150 within the delivery sub-assembly 210. The syringe carrier 150 has a proximal end 151 through which the needle 118 of the syringe protrudes. The return spring 126, via the return spring support 160 and the syringe carrier 150 biases the syringe 114 from an extended position in
25 which the needle 118 extends from the aperture 128 in the housing 112 to a retracted position in which the needle 118 is contained within the housing 112.

The syringe carrier 150 comprises a sheath (not shown) into which the syringe 114 can be inserted from a distal end 170. The syringe 114 is provided with a boot (not shown). If the syringe were to fail or break, the sheath, which surrounds the syringe 114 along its

length, would contain the broken pieces of syringe and reduce the likelihood of them from escaping from the injection device 110.

The housing of the drive assembly also includes an actuator, and a drive which here takes the form of a compression drive spring 130. Drive from the drive spring 130 is transmitted via a multi-component drive to the piston of the syringe 114 to advance the syringe 114 from its retracted position to its extended position and discharge its contents through the needle 118. The drive accomplishes this task by acting directly on the drug and the syringe 114. Static friction between the drive coupling 134 and the syringe body 116 initially ensures that they advance together, until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion.

The multi-component drive between the drive spring 130 and the syringe 114 consists of three principal components. A drive sleeve 131 takes drive from the drive spring 130 and transmits it to a drive element 132. This in turn transmits drive to the drive coupling 134 already mentioned.

A trigger 214 is provided on the housing 112 remote from the exit aperture 128. The trigger, when operated, serves to decouple the drive sleeve 131 from the housing 112, allowing it to move relative to the housing 112 under the influence of the drive spring 130. The operation of the device is then as follows.

The actuator is then depressed and the drive spring 130 is released. The drive spring 130 moves the drive sleeve 131, the drive sleeve 131 moves the drive element 132 and the drive element 132 moves the drive coupling 134. The drive coupling 134 moves and, by virtue of static friction and hydrostatic forces acting through the drug to be administered, moves the syringe body 114 against the action of the return spring 126. The syringe body 114 moves the syringe carrier 150, which in turn moves the return spring support 160 and compresses the return spring 126. The hypodermic needle 118 emerges from the exit aperture 128 of the housing 112. This continues until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion. Because the static friction between the drive coupling 134

and the syringe body 116 and the hydrostatic forces acting through the drug to be administered are not sufficient to resist the full drive force developed by the drive spring 130, at this point the drive coupling 134 begins to move within the syringe body 116 and the drug begins to be discharged. Dynamic friction between the drive coupling 134 and the syringe body 116 and hydrostatic and hydrodynamic forces now acting through the drug to be administered are, however, sufficient to retain the return spring 126 in its compressed state, so the hypodermic needle 118 remains extended.

Before the drive coupling 134 reaches the end of its travel within the syringe body 116, so before the contents of the syringe have fully discharged, flexible latch arms linking the first and drive couplings 132, 134 reach an interchangeable release element 155 connected to the distal end of the syringe carrier 150.

The interchangeable release element 155 is essentially a constriction which moves the flexible latch arms to a position so that they no longer couple the drive element 132 to the drive coupling 134. Once this happens, the drive element 132 acts no longer on the drive coupling 134, allowing the drive element 132 to move relative to the drive coupling 134. Consequently, the drive coupling 134 continues to move within the syringe body 116 and the drug continues to be discharged. Thus, the return spring 126 remains compressed and the hypodermic needle remains extended.

After a time, the drive coupling 134 completes its travel within the syringe body 116 and can go no further. At this point, the contents of the syringe 114 are completely discharged and the force exerted by the drive spring 130 acts to retain the drive coupling 134 in its terminal position, allowing the drive element 132 to continue its movement.

Flexible latch arms linking the drive sleeve 131 with the drive element 132 reach another constriction within the housing 112. The constriction moves the flexible latch arms so that they no longer couple the drive sleeve 131 to the drive element 132. Once this happens, the drive sleeve 131 acts no longer on the drive element 132, allowing them to move relative each other. At this point, the forces developed by the drive spring 130 are no longer being transmitted to the syringe 114. The only force acting on the syringe will be the return force from the return spring 126 which acts on the end of the syringe 114

nearest to the needle 118 via the return spring support 160 and the syringe carrier 150. Consequently, the syringe is returned to its retracted position and the injection cycle is complete.

5 The interchangeable release element 155 is provided with flexible arms 271 for connecting the interchangeable release element 155 to the syringe carrier 150 at cut-outs 281 on the syringe carrier 150.

10 Figs. 3a to 3c show a fluid transfer assembly 10 having a first open end 11 which is adapted to receive a vial 14 containing fluid. The fluid transfer assembly 10 also has a second open end 12 which is adapted to be attached to delivery assembly 210 without interchangeable release element 155 connected to the syringe carrier 150. The second open end 12 has a diameter smaller than the first open end 11. The fluid transfer assembly can be cylindrical in shape and formed from a plastic type material.

15 The first open end 11 also comprises a hollow needle 13, which, when a vial is attached to the first open end 11, acts to pierce a seal 14a on the vial. The needle 13 forms the fluid pathway between the two ends 11, 12. The seal, as on most types of vial, is formed from breachable material, one type of material that could be used is metallic foil.

20 The vial can be attached to the first open end 11 and held by the cylindrical walls of the fluid transfer system. The second open end 12 can be attached to the delivery assembly 210, as shown in Fig. 3c, with the first open end 11 above the second open end 12 with respect to ground, the fluid can then flow from the vial under the force of gravity into the syringe body 116 through the fluid pathway formed by the needle 13 and the second open end 12.

25 Fig. 4 shows a base station 20 for use in conjunction with the injection device 110 and transfer assembly 10 and vial 14 of the present invention. The base station 20 comprises two sections 20a and 20b. Section 20a of the base station 20 is sized and dimensioned to support the delivery sub-assembly 210 and section 20b is adapted to reset the drive sub-assembly 220. The section 20b comprises a protrusion (not shown) which acts on the extended drive of the injection device (after use) to force it to retract and be reset. The

transfer assembly 10 described above is placed on the open end of the delivery subassembly 210 whilst it is held in place on the base station 20. Once the fluid from the vial 14 has been transferred to the syringe, the fluid transfer assembly is removed from the delivery assembly 210, the interchangeable release element 155 is attached to the top
5 of the syringe carrier 150 on the delivery assembly 210 and the reusable drive assembly 220 is inserted over the delivery assembly 210 to form a delivery device 110 which can then be removed from the base station 20.

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
10 the invention.

Claims

1. A fluid transfer assembly comprising:
means for connection to a syringe;
5 means for receiving a vial having a closure element,
wherein the receiving means is adapted to engage and open the closure element
and permit fluid in the vial to be transferred to the syringe from the vial.
2. The fluid transfer assembly of claim 1, wherein the receiving means comprises a
10 needle to pierce the closure element and extend into the vial.
3. The fluid transfer assembly of claim 2, wherein the needle forms part of a fluid
pathway which extends in use between the vial and the syringe.
- 15 4. The fluid transfer assembly of any one of the preceding claims, wherein the
receiving means is a cylinder open at a first end which is dimensioned to receive the vial.
5. The fluid transfer assembly of claim 4, wherein the connection means and
receiving means are integrally formed with each other.
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6. The fluid transfer assembly of claim 5 wherein the connection means comprises a
second end which is open and dimensioned to fit over or in an open end of the syringe.
7. The fluid transfer assembly of any one of the preceding claims, wherein the fluid
25 transfers in use from the vial to the syringe under the force of gravity, when the
connection means is located above the receiving means.
8. A fluid transfer system comprising:
the fluid transfer assembly of any one of the preceding claims; and
30 a syringe.

9. An injection kit comprising:
the fluid transfer system of claim 8; and
a delivery device including a delivery sub-assembly and a drive sub-assembly,
which are both adapted to be attached to the syringe, and operate together to deliver the
5 fluid from the syringe.
10. The kit of claim 8, wherein the delivery sub-assembly is adapted to support the
syringe; and
the drive sub-assembly comprises a drive adapted on activation to act on the
10 syringe to advance it from a retracted position in which a discharge nozzle of the syringe
is contained within the delivery sub-assembly to an extended position in which the
discharge nozzle extends from the delivery sub-assembly.
11. The kit of claim 10 wherein the delivery sub-assembly comprises;
15 a syringe carrier adapted to support the syringe between its retracted and
extended positions; and
a retraction element adapted to move the syringe after fluid delivery from the
extended position to the retracted position.
- 20 12. The kit of claim 11 wherein the drive sub-assembly comprises a release
mechanism to release the drive to act on the syringe to cause it to move from the
retracted position to the extended position,
wherein the drive is in a first position when the syringe is in its retracted position
and the drive is in a second position when the syringe is in its extended position.
- 25 13. The kit of any of the preceding claims further comprising a base station which is
adapted to receive the drive sub-assembly and reset the drive by moving it from its
second position to its first position and reset the release mechanism such that when
actuated again it releases the drive.

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14. The kit of claim 13 wherein the base station comprises an attachment to hold the delivery sub-assembly

15. The kit of claim any one of claims 9 to 14, wherein the syringe is disposable.

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16. A method of assembling an injection device, comprising:

inserting fluid into a syringe through a vial via the fluid transfer assembly of any one of claims 1 to 7;

inserting a syringe having a piston into a delivery sub-assembly;

10 attaching a sub-assembly comprising a drive to the delivery sub-assembly; and assembling the drive sub-assembly and delivery sub-assembly together.

17. The method of claim 15 further comprising the step of resetting the drive assembly after activation of the drive.

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18. The method of claim 1 wherein transfer of the content of the vial to the syringe assembly occurs while the delivery assembly is on the base station.

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