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# An injection device

## Field of the invention

The present invention relates to an injection device for injecting a medicament to a subject, wherein the device is capable of retracting the needle within the device after use.

## Background of the invention

The conventional syringe and needle arrangement is dangerous and requires trained personnel to use the device. For example, delivering drug formulations via subcutaneous or intramuscular injection with a needle and syringe requires trained medical personnel. Further, needle-stick injury is a grave concern due to the prevalence of diseases such as AIDS, Hepatitis A and B. Other hazards of the conventional syringes are their disposal and the possibility of re-use.

There have been several redesigns of the conventional needle and syringe to incorporate automatic or semi-automatic covering of the needle after use or retraction of the needle by rubber bands, springs or vacuum into the body of the syringe as described in US patent Nos. 5782804, 6015438 and 6050977, or modifications that destroy the functionality of the syringe mechanism after one use, for example the Becton Dickinson "Soloshot™" syringes. However, these safety syringes are more expensive than the conventional syringes and require skilled personnel to administer medicament using the safety syringes.

An inexpensive, single use, pre-filled device that has been introduced is the "Uniject™" made by Becton Dickinson. This is a plastic blister (holding the vaccine) with an attached needle. However, the problem with the "Uniject™" is that it requires training and skill to use the device. Further, it has an exposed needle, therefore still posing a risk of needle-stick injury, both before and after injection.

Another example is shown in US Patent Application No. 2003/0093036, the contents of which are incorporated herein by reference. Here the insertion of the needle is activated automatically on triggering the device. The design however is flawed in that on activating the trigger, a force is immediately applied to the plunger, with only the static friction of the plunger preventing premature ejection of the medicament. Should the resistance of a forward spring be greater than this static friction, then there is a possibility of some premature leakage of the medicament.

In fact, it is likely, given the different lubricating effects of different medicaments, and variations in ambient temperature that, static friction will need to be much greater than the resistance due to the spring in order to be certain in all reasonable applications of the syringe. The disclosure of US Patent Application No. 2003/0093036 makes no reference to this limitation.

It is therefore an object of the present invention to provide a safe syringe that doesn't lead to premature ejection of medicament.

## Summary of the invention

The present invention seeks to address the problems above. In general, the invention provides an injection device which is capable of delivering a pre-determined dose of medicament to a subject and which provides a mechanism to retract the needle after use. The present invention also seeks to provide a device with any one, or a combination of, the following attributes:

- safe disposal of contaminated needles;
- prevention of needle-stick injury;
- prevent cross-infection;
- prevent re-use of device;

- capable of being used without need for trained personnel; and
- low cost of manufacturing.

Therefore, in a first aspect the present invention provides a syringe comprising; an elongate outer housing having an aperture at an injecting end through which a needle may selectively project permitting penetration of a subject; an assembly in sliding engagement within the outer housing; said assembly comprising a barrel, a container for containing an injectable medicament, the needle being mounted to the container, a plunger sealing an open portion of the container and in sliding engagement within the barrel, such that on biasing the plunger, using a first biasing means, in a direction directed towards the injecting end, the medicament is released from the container, through the needle, to the subject; wherein said syringe further includes a first engagement means; said first engagement means adapted to permit relative movement of the plunger and the container when the assembly is at a first position within the outer housing, said engagement means preventing relative sliding engagement at all other locations.

Accordingly, the invention provides a means to prevent the premature release of medicament from the syringe by preventing the relative movement between the plunger and container, until the needle has penetrated the subject to the desired depth.

In a preferred embodiment, the first engagement means may include at least one resilient cantilever located on the barrel and a corresponding slot located on the outer housing, wherein the first position is defined by the alignment of the at least one cantilever and the slot. Thus by aligning the cantilever and slot, the cantilever may resiliently spring into the slot, and so

provide a positive action, locking into oplace. In a more preferred embodiment, there may be a pair of such cantilevers on diametrically opposed sides of the barrel, with corresponding slots in the outer housing. This may have the advantage of both providing a symmetrical locking action and a greater locking force, further securing the syringe after subsequent use.

In a preferred embodiment, the second engagement means may include a second resilient cantilever located on the barrel and a second slot located on the outer housing, said second cantilever and second slot aligning at the first position. In a more preferred embodiment, the second cantilever may in fact be a second pair of cantilevers, providing similar advantages of symmetry and additional resisting force.

In a preferred embodiment, the activation of the syringe and/or insertion of the needle is, in a first instance, may be through operator control by depressing the assembly. In this embodiment, the assembly may then project the needle to the desired distance, and on arriving at this distance, automatically begin the release of medicament and then subsequent retraction of the needle.

This embodiment has the advantage of controlling the painful initial insertion of the needle which may be best done by a professional and not automatically. It may also prevent the inadvertent activation of the syringe prior to correct position at the injection site.

In a second aspect the present invention provides a method of injecting a medicament into a subject, the method comprising the steps of: providing an assembly slidably engaged within an outer housing, said assembly comprising a barrel, a plunger slidably engaged within the barrel, said plunger sealing an open first end of a container, said container containing the medicament, a needle mounted to the container at a second end opposed to the first end and a first engagement means selectively preventing relative movement of the plunger and container; depressing the assembly and consequently sliding said assembly, within the outer housing, from an initial position to a first position, said movement progressively projecting the needle from an injecting end of the outer housing; positioning the assembly at the first position consequently releasing the first engagement means, so as to permit relative movement of the plunger and the container; biasing the plunger, using a first biasing means, and consequently releasing the medicament contained in the container.

Brief description of the figures

It will be convenient to further describe the present invention with respect to the accompanying drawings that illustrate possible arrangements of the invention. Other arrangements of the invention are possible, and consequently the particularity of the accompanying drawings is not intended to be limiting of the present invention.

Figure 1A is a cross sectional view of the syringe according to one embodiment of the present invention;

Figure 1B is an isometric view of the syringe of Figure 1A

Figure 2A is an isometric view of a portion of the assembly of the syringe of Figure 1A;

Figure 2B is a cross-sectional view of the portion of the assembly of Figure 2A;

Figure 2C is a sequence of detail views of the portion of Figure 2B;

Figure 3A is an isometric view of the assembly prior to installation within the syringe of Figure 1A;

Figure 3B is a cross sectional view of the assembly of Figure 3A;

Figure 3C is a detail view of a first part of the assembly of Figure 3B;

Figure 4A is a detail view of a second part of the assembly of Figure 3B;

Figure 4B is a detail view of a second part of the assembly of Figure 3B;

Figure 4C is a detail view of a second part of the assembly of Figure 3B;

Figure 5A is a cross-sectional view of the device according to one embodiment of the present invention;

Figure 5B is a detail view of a portion of Figure 5A;

Figure 6A is a cross-sectional view of the device according to one embodiment of the present invention when medicament is injected into a subject;

Figure 6B is a detail view of a part of Figure 6A;

Figure 6C is a detail view of a part of Figure 6B.

Figure 7A is a cross-sectional view of the device according to one embodiment of the present invention when the needle is retracted;

Figure 7B is a detail view of a part of Figure 7A.

Detailed description of the invention

Figures 1A and 1B show a disposable syringe 100 according to one embodiment of the present invention. The isometric view of the syringe 100 shown in Figure 1B shows the syringe ready for operation i.e. with the cap 120 removed exposing the depression portion 90 in an uncovered state. Figure 1A shows a cross sectional view of the disposable syringe. Here the cap 120 covers the depression portion 90 for transport and storage so as not to activate the syringe prematurely. The syringe comprises an outer housing 102 to which the cap 120 fits. Within the outer housing is an assembly comprising a barrel 116, a plunger 104 having a retention portion at one end and a seal 118 at an opposed end. The spring retention portion in the assembled state retains a spring 112 against an upper portion of barrel 116. The seal is in sealing contact with a container 106, said container 106 containing a quantity of medicament 110. The container 106 has a needle 108 attached thereto which in this unused state is fully retracted within the outer housing 102. Within a lower cavity of the outer housing 102 and in contact with the container is a spring 114 the function of which will be described later. The needle 108 is aligned with an aperture 95 in the outer housing in anticipation of activation of the syringe 100. On activation the needle 108 will project from the outer housing 102 in order to penetrate a subject for injection of the medicament 110. The barrel 116 includes two pairs of resilient cantilevers 122, 124 having ridges on both sides on extreme ends of the cantilevers 122, 124 the function of which will be described later. The outer housing 102 further includes slots 126 and 128 which are arranged in spaced relation to each other at a distance equivalent to the distance between the extreme ends of the cantilever 122, 124.

Figures 2A and 2B show a portion of the internal assembly in more detail. Here the barrel 116 can be seen encompassing the spring 112 as an upper boundary and the plunger 104 as a lower boundary in particular the retention portion 91 of the plunger 104 retains the spring within the cavity

defined by the barrel 116 and plunger 104. Assembling the internal assembly involves having the spring 112 in a partial compressed state so as to provide sufficient spring energy for later in the process.

The plunger 104 as described earlier includes the retention portion 91, the seal 118 for contacting the container and an extension member 92 between the retention portion 91 and the seal 118 so as to transmit the applied force during the process from the retention portion to the seal. Not shown as part of the assembly is the container 106 and the needle 108 mounted to said container.

Important features of the barrel 116 are the two pairs of cantilevers 122, 124 mounted to the barrel and which are able to flex laterally outwards from a longitudinal axis of the assembly 98.

Figure 2C shows a detailed view of the first cantilever pair located closest to the depression portion 90. The first cantilever 122, as previously described has at an extreme end of the cantilever, ridges comprising an outer ridge 80 and an inner ridge 81, said inner ridge 81 having a portion 82 shaped to engage the retention portion 91. The cantilevers 122 are arranged such that in a rest position i.e. unstrained, the inner ridges 81 do not interfere with the retention portion 91. However, whilst the assembly 98 is located within the outer housing 102, the outer housing 102 bears against the cantilevers 122 pushing them inwards so as to block the passage of the retention portion 91, and so maintains the plunger 104 and container 106 fixed relative to each other. Thus, in this state, no medicament 110 can be released prematurely.

Figures 3A and 3B show the complete assembly 98 including the container 106 and needle 108 prior to installation within the outer housing 102. Figure 3C shows a detailed view of the seal 118 within the container 106. In this embodiment to ensure the seal 118 does not withdraw from the container retaining a lug 302 has been included in an upper portion of the container to prevent removal of the seal 118 from said container 106.

Figures 4A, B and C show the second pair of cantilevers 124 located on the needle side of the barrel. The extreme end of the cantilever 124 includes an outer ridge 83 and an inner ridge 84. The outer ridge 83 further includes a stop portion 86 with the inner ridge 84 including a stop portion 88 and a contact surface 85. It should be noted that the contact surface 85 is inclined for subsequent contact with the retention portion 91 of the plunger 104.

In its rest state, the second cantilever 124 is arranged such that the stop portion 88 prevents the movement of the container 106. The second cantilever 124 is also arranged so that it may flex laterally outwards on application of an applied load and in fact, as will be described later, said applied force is provided by the retention portion 91 contacting the inclined surface 85 resulting in an outward force and so flexing the second cantilever 124 outwards at the appropriate time.

Figures 5A and 5B show the initial stages of use of the syringe 100. The syringe 100 is located at the injection site 502 and a downward force 70 applied at the depression portion 90 of the assembly 98. This has the effect of inserting the needle 108 into the subject until the first and second cantilevers 122, 124 align themselves with slots 126, 128 in the outer housing. This defines the

desired depth of injection which in one embodiment may be 15mm. Once the cantilevers 122, 124 are aligned with the slots 126, 128, the first cantilevers 122 spring outwards towards their rest position, from a confined state within the outer housing to a released state within the slot 126. On expanding outward into the slot 126, the cantilever 122 releases the retention portion 91 of the plunger 104. The spring 112 which was installed within the assembly 98, in compression, is now free to move the plunger downwards as relative movement formally prevented by the cantilever 122 is now no longer so prevented. Consequently, the seal 118 also moves downward relative to the container 106 and so releasing the medicament 110 through the needle 108 into the subject. It should be noted that as the second cantilever 124 has its normal rest position such that it blocks the container 106 from moving upwards, the plunger 104 is free to continue moving downwards with the container 114 maintaining a relatively static position against the spring 114. It should be noted that the spring 114 is also in a compressed state due to compression from the initial activation on applying the force 70 downwards. Thus, not only is the needle 108 inserted into the subject but also the spring 114 placed in a compressive state ready for the next stage.

As shown in Figure 6A, the plunger 104 is directed downwards with the sealed 118 having released the medicament 110 into the subject. The first spring 112 is at a fully extended or substantially extended phase corresponding to the plunger in reaching an end position defined by the seal 118 either reaching the bottom of the container 106 or at least to a point whereby the desired quantity of medicament 110 is injected into the subject. As shown in Figures 6B and 6C, the end position, not only defined by the seal 118 reaching substantially the end of the container, but also the retention portion 91 coming into contact with the second cantilever 124 at the contact surface 85. The downward movement of the retention portion 91, because of contact with the

inclined contact surface 85, applies a lateral force 89 to the second cantilever 124 pushing the cantilever outward. The extent of movement of the cantilever 124 is such so as to release the container 106 which was previously stopped by portion 88, but is no longer restrained and so free to move upwards now that the second cantilever 124 has been laterally moved outwards.

Figures 7A and 7B show the result of the container moving under the applied force of spring 114 after release of the second cantilever 124. The compression of spring 114 is such that the container is pushed upwards and so automatically retracting the needle out of the subject and back within the outer housing 102. In one preferred embodiment, the spring 114 may have an additional compression applied on assembly of the syringe 100 such that there is a slight over compression in addition to the compression due to force 70. This additional force may assist further in ensuring both a rapid and complete retraction of the needle into the outer housing. Thus with the needle fully retracted within the outer housing, the syringe 100 can no longer be used. It may now be safely disposed of without the risk of needle stick due to later handling or for the inadvertent transmission of disease by reuse of the needle.

Claims

1. A syringe comprising;

an elongate outer housing having an aperture at an injecting end through which a needle may selectively project permitting penetration of a subject;
an assembly in sliding engagement within the outer housing;
said assembly comprising a barrel, a container for containing an injectable medicament, the needle being mounted to the container, a plunger sealing an open portion of the container and in sliding engagement within the barrel, such that on biasing the plunger, using a first biasing means, in a direction directed towards the injecting end, the medicament is released from the container, through the needle, to the subject;
wherein said syringe further includes a first engagement means;
said first engagement means adapted to permit relative movement of the plunger and the container when the assembly is at a first position within the outer housing, said engagement means preventing relative sliding engagement at all other locations.

2. The syringe according to claim 1, wherein said first engagement means comprises at least one resilient cantilever located on the barrel and a corresponding slot located on the outer housing, wherein the first position is defined by the alignment of the at least one cantilever and the slot.

3. The syringe according to claim 2, wherein the resilient cantilever is confined in a retracted position by the outer housing and resiliently

expanded outwards to an extended position to fit within the slot when the barrel is located in the first position.

4. The syringe according to claim 3, wherein the cantilever member includes at least one ridge on an internal portion, said at least one ridge abutting the plunger whilst in the retracted position, said at least one ridge sized so as to permit clearance of the plunger passed said at least one ridge when in the extended position.

5. The syringe according to any one of the preceding claims, wherein the first biasing means includes a spring acting on the plunger to move the plunger to an end position to release the medicament from the container.

6. The syringe according to any one of the preceding claims, further comprising a second engagement means, said second engagement means movable from a rest position to a deflected position, the second engagement means abutting the container such that movement of the container is prevented in a direction directed away from the injecting end in the rest position, and releasing the container and allowing said movement in the deflected position, wherein the second engagement means is moved from the rest position to the deflected position on contact with the plunger when in the end position.

7. The syringe according to claim 6, further comprising a second biasing means acting on the container to move said container on release by the second engagement means.

8. The syringe according to claim 7, wherein said second engagement means comprises a second resilient cantilever located on the barrel

and a second slot located on the outer housing, said second cantilever and second slot aligning at the first position.

9. The syringe according to claim 7 or 8, wherein the second biasing means is adapted to move the container sufficiently to retract the needle completely within the outer housing.

10. The syringe according to any one of the preceding claims, wherein the needle projects a pre-determined distance from the injecting end of the outer housing when the assembly is in the first position.

11. The syringe according to claim 10, wherein the predetermined distance is at least 15 mm.

12. The syringe according to any one of the preceding claims, wherein the plunger comprises a retention portion for retaining the first biasing means, a seal for sealing the open portion of the container and an extension member intermediate the retention portion and the seal for transferring load from the first biasing means to the seal.

13. The syringe according to any one of claims 6 to 12, wherein the end position is defined as the point at which the seal moves to a point within the container such that a pre-determined quantity of the medicament is released from the container.

14. The syringe according to any one of claims 8 to 13, wherein the plunger contacts the second engagement means at an inclined surface of the second cantilever, the angle of inclination of the bevelled surface such that contact by the plunger leads to outward movement of the second cantilever.

15. The syringe according to claim 14, wherein the plunger contacts the second cantilever at the retention portion.

16. A method of injecting a medicament into a subject, the method comprising the steps of:

providing an assembly slidably engaged within an outer housing, said assembly comprising a barrel, a plunger slidably engaged within the barrel, said plunger sealing an open first end of a container, said container containing the medicament, a needle mounted to the container at a second end opposed to the first end and a first engagement means selectively preventing relative movement of the plunger and container;

depressing the assembly and consequently sliding said assembly, within the outer housing, from an initial position to a first position, said movement progressively projecting the needle from an injecting end of the outer housing;

positioning the assembly at the first position consequently releasing the first engagement means, so as to permit relative movement of the plunger and the container;

biasing the plunger, using a first biasing means, and consequently releasing the medicament contained in the container.

17. The method according to claim 16, further comprising the step of releasing a second resilient engagement means, and consequently retracting the needle into the outer housing.