# SYRINGE WITH SAFETY SHEATH

## FIELD OF THE INVENTION

The present invention relates to a syringe having a sheath. Embodiments of the present invention find application, though not exclusively, in the medical industry for use in administering drugs and other substances to patients.

## BACKGROUND OF THE INVENTION

The risk of needle stick injury is a potential issue associated with the use of syringes for drug delivery. This risk is of particular concern due to the possibility that the syringe needle may be contaminated with infectious material after use. One means provided in the prior art for minimizing this risk is the provision of a sheath which is slidable from an retracted position in which the syringe needle is exposed to an extended position in which the syringe needle is housed within the sheath such that the user is substantially protected from inadvertent contact with the needle tip. Examples of such prior art are disclosed in United States Patent Nos. 4693708, 4702738, 4976702, 5222945, 6093170, and the International Application having Publication Number WO93/00122. It has been appreciated by the inventor of the present application that each of these prior art syringes require the user to manually displace the sheath to the extended position so as to derive the desired safety benefit.

Another potential issue that may be associated with the use of syringes is a fear response experienced by some patients upon catching sight of the sharp needle. The use of a sheath as disclosed in the prior art mentioned in the preceding paragraph may assist in this regard by obscuring the patient's view of the needle. However, immediately prior to injecting such prior art syringes, it is typically necessary to displace the sheath into the retracted position, thereby visually exposing the needle to the patient, even if only briefly. Additionally, the patient may catch sight of the needle when it is being withdrawn after use.

Yet another issue associated with many or all the prior art syringes mentioned above is that the sheath is typically affixed onto the syringe at the time of manufacture such that the sheath is not readily detachable. This may limit the flexibility of usage of the syringe.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in this specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia or elsewhere before the priority date of this application.

## SUMMARY OF THE INVENTION

It is an object of the present invention to overcome, or substantially ameliorate, one or more of the disadvantages of the prior art, or to provide a useful alternative.

In one aspect of the present invention there is provided a syringe including:

at least one substance storage chamber;

a hypodermic needle in fluid communication with the substance storage chamber, the hypodermic needle defining a needle tip;

a sheath slidably disposed for displacement between a retracted position in which at least the needle tip is exposed and an extended position in which the needle tip is shrouded; and

biasing means adapted to bias the sheath toward the extended position.

Preferably the biasing means is resilient and it may be in the form of a spring.

In one embodiment the substance storage chamber defines a proximal end having an aperture for receipt of a plunger and a flange is disposed at or adjacent to the proximal end of the substance storage chamber. In such an embodiment the biasing means typically extends between the flange and the sheath.

A distal end of the biasing means may abut a proximal end of the sheath.

In an embodiment the biasing means is a coil spring and at least part of the substance storage chamber is disposed internally of the coil spring.

Preferably the coil spring, substance storage chamber and sheath are all substantially cylindrical.

In an embodiment a guide slot is defined in one of the substance storage chamber or the sheath and a follower element adapted for displacement along the slot is provided upon the other of the substance storage chamber or the sheath. In this embodiment the guide slot defines a first position for locking of the sheath in the retracted position and the guide slot defines a second position for locking of the sheath in the extended position.

The guide slot may have an open end adapted for passage of the follower element into and out of the slot such that the sheath is selectively attachable and detachable from the substance storage chamber. Preferably the needle is disposed on a needle assembly which is selectively detachable from the substance storage chamber to allow for attachment of a connector to the substance storage chamber. The connector may be any one of: a catheter; an intravenous feeding tube; a Luer lock or a Luer slip, for example.

In an embodiment the sheath has a side wall thickness of greater than or equal to 0.5mm, and more preferably greater than or equal to 1mm.

Preferably the syringe is a single-use syringe.

An embodiment of the syringe further includes an automatically operable locking means adapted to lock the sheath in the extended position. The automatically operable locking means may include an arcuate portion of the guide slot leading to the

second position, such that extension of the sheath displaces the follower element along the arcuate portion and into the second position. In one such embodiment the slot defines a recess adjacent the second position such that the recess contacts and halts the follower element in response to retraction forces applied to the sheath whilst locked in the extended position.

According to another aspect of the invention there is provided a method of using a syringe including the steps of:

providing a syringe as described above;

positioning a distal end of the sheath on a patient whilst allowing the biasing means to retain the sheath in the extended position;

displacing the syringe toward the patient so as to simultaneously retract the sheath and insert the needle into the patient.

Preferably the method further includes the step of displacing the syringe away from the patient so as to simultaneously withdraw the needle from the patient and allow the biasing means to displace the sheath toward the extended position, thereby retaining the distal end of the sheath in contact with the patient until the sheath reaches the extended position. The method may further include the step of locking the sheath in the extended position.

The features and advantages of the present invention will become further apparent from the following detailed description of preferred embodiments, provided by way of example only, together with the accompanying drawings.

## BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

**Figures 1A and 1B** are side partially cross sectional views of a first embodiment of the invention, with the sheath depicted in the extended position on Fig. 1A and the sheath depicted in the retracted position on Fig. 1B;

**Figure 2** is an enlarged cross sectional view of the substance storage chamber and a part of the sheath of the first embodiment;

**Figure 3** is a perspective view of the first embodiment;

**Figures 4A and 4B** are side partially cross sectional views of a second embodiment of the invention, with the sheath depicted in the extended position on Fig. 4A and the sheath depicted in the retracted position on Fig. 4B;

**Figures 5A and 5B** are side views of a third embodiment of the invention, with the sheath depicted in the extended position on Fig. 5A and the sheath depicted in the retracted position on Fig. 5B;

**Figure 6** is a perspective view of the third embodiment; and

**Figure 7** is a side view of a fourth embodiment of the invention.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

With reference to Figs. 1A to 3, the syringe 31 has a substance storage chamber 10 in the form of a substantially cylindrical barrel portion. The substance storage chamber 10 defines a proximal end 24 having an aperture for receipt of a plunger 36. A flange 38 is disposed at or adjacent to the proximal end 24 of the substance storage chamber 10. A hypodermic needle 18, defining a needle tip 19, is in fluid communication with the substance storage chamber 10, such that movement of the plunger 36 can selectively force fluid through the needle 18, either into, or out of, the substance storage chamber 10.

The outer surface of the substance storage chamber 10 is provided with a guide slot 12 for a retractable safety sheath 14. The guide slot 12 comprises a linear guide section 16 extending at least sufficiently along the length of the barrel portion 10 for the safety sheath 14 to slide between a fully retracted position, and an extended position. The sheath 14 is a substantially cylindrical hollow member that is arranged so as to prevent inadvertent needle-stick injuries. The thickness of the sidewall of the sheath 14 is preferably approximately 0.5mm to 1mm, although in some embodiments the thickness may fall outside this range.

In the extended position the safety sheath 14 extends beyond the needle tip 19 of

the needle 18 so as to shroud the needle tip 19 and thereby render the needle tip 19 generally incapable of contact with the skin of a patient or user. The extended position is shown on the syringe depicted in Fig. 1A. In the retracted position the needle tip 19 is exposed, as may be seen on the syringe depicted in Fig. 1B.

Resilient biasing means, in the form of a substantially cylindrical coil spring 33, is adapted to bias the sheath 14 toward the extended position. As best shown in figure 2, the coil spring 33 extends such that the proximal end of the coil spring 33 abuts the flange 38 and the distal end of the coil spring 33 abuts the proximal end of the sheath 14. Part of the substance storage chamber 10 is disposed internally of the coil spring 33.

The coil spring 33 resiliently urges the sheath 14 toward the extended position, thus relieving the user of the responsibility to do so manually. Due to the biasing, an effort is required to retract the sheath 14 against the force exerted by the spring 33. Hence, unless locked in the retracted position (as described in more detail below) the natural resting position of the sheath is in the extended position. This promotes improved safety as in normal use the sheath 14 is more likely to be positioned in the extended position.

The guide slot 12 is provided with a retracted locking segment 20 and an extended locking segment 22. Both segments are a continuation of the guide slot 16 but are disposed transverse to it so as to extend a short distance around the circumference of the barrel portion 10, with the retracted locking segment 20 close to the proximal end 24 of barrel portion 10.

As may best be seen in the enlarged part sectioned view of the barrel portion 10 in Fig. 2, sheath 14 is provided with a generally cylindrical follower element 26 that is adapted for displacement along the guide slot 12. The cylindrical follower element protrudes radially from the inside surface of the sheath 14 and is dimensioned to slide in the linear guide section 16 and locking segments 20 and 22 of the barrel portion 10. Further, the follower element 26 is disposed near the proximal end 30 of the sheath 14 and is arranged so that when the sheath is fully retracted, the sheath may be rotated

relative to the barrel 10 so that the follower element 26 enters locking segment 20, thereby retaining the sheath 14 in the retracted position despite the biasing force exerted by the coil spring 33. Hence, the retracted locking segment 20 defines a first position in the guide slot 12 for disposition of the follower element 26 so as to lock of the sheath 14 in the retracted position. Similarly, the extended locking segment 22 defines a second position in the guide slot 12 for disposition of the follower element 26 so as to lock the sheath 14 in the extended position.

Typically, the user of the syringe 31 may choose to lock the sheath 14 into the retracted position immediately prior to charging a substance, such as a drug for example, into the substance storage chamber 10 and/or immediately prior to injecting the hypodermic needle into a patient. However, as outlined in more detail later in this specification, the invention also encompasses alternative methodologies for injecting the needle 18 into a patient which do not require the user to manually retract the sheath 14.

As best seen in Fig. 3, when fully extended, the sheath 14 may be rotated to enter the follower element 26 into the extended locking segment 22, thereby locking the sheath in the extended position. When the follower element 26 is so engaged in the locking segment 22, the sheath 14 is prevented from axial movement relative to the barrel portion 10. The protruding follower element 26 and guide and locking segments 20 and 22 of the channel 12 are so sized that, particularly when in the locked extended position, the sheath 14 resists accidental dislodgement by the typical accidental end impacts encountered when manipulating a syringe in use. In other words, the facility to lock the sheath 14 in the extended position provides further resistance to retraction of the sheath in addition to that provided by the biasing force applied to the sheath by the coil spring 33.

In at least one preferred embodiment of the sheath as shown in Fig. 4A and Fig. 4B, the distal end 32 of the sheath 14 is extended and tapered, narrowing towards its distal end, so that when extended in the safety position, it resists accident insertion of a finger into the sheath opening.

In the embodiment illustrated in figures 5A, 5B and 6 the guide slot 12 is

defined on the internal surface of the sheath 14 and the follower element 26 is provided upon the outer surface of the substance storage chamber 10. Additionally, the guide slot 12 has an open end 40 adapted for passage of the follower element 26 into and out of the slot 12. This allows the sheath 14 to be selectively attachable and detachable from the substance storage chamber 10. Additionally, the needle 18 is disposed on a needle assembly 42, which is selectively detachable from the substance storage chamber 10. Hence, the sheath 14 may be attached to the syringe if required to protect against hypodermic needle injuries. Alternatively, if it is desired to use the syringe in a non-hypodermic needle mode, then the sheath 14 may be detached. This allows for detachment of the needle assembly 42, which in turn allows for attachment of another type of connector to the substance storage chamber 10. A non-limiting list of examples of such other types of connectors includes catheters, intravenous feeding tubes, Luer locks and Luer slips. It will be appreciated that this facility to utilise other types of connectors advantageously enhances the usage flexibility offered by some embodiments of the syringe.

In some embodiments of the invention the syringe 31 is a single use syringe. This may be achieved with the use of a one way valve, or other similar arrangement. Examples of some single use syringes are provided by International Patent Application No. PCT/AU2005/001939 (Publication No. WO 2006/066336, dated 26 June 2006), the contents of which are hereby incorporated in their entirely by way of reference.

As illustrated in figure 7, an embodiment of the invention has an automatically operable locking means 44 adapted to automatically lock the sheath in the extended position. The automatically operable locking means 44 includes an arcuate portion 46 disposed at the proximal end of the guide slot 12, which leads to second position 48. The automatically operable locking means 44 functions in the following manner. If the sheath 14 is initially retracted and is ready to be extended by the biasing force exerted by the coil spring 33, then follower element 26 is initially positioned at the distal end of the linear guide section 16. Displacement of the sheath 14 towards the extended position caused by the biasing force causes relative movement between the guide slot 12 and the follower element 26 such that the follower element 26 draws closer to the proximal end of the

guide slot 12. By the time the relative movement causes follower element 26 to enter the arcuate portion 46, the combination of extension momentum and the continually exerted biasing force continues the relative movement such that the follower element 26 tracks around the arcuate portion 46 and seats into the second position 48, as illustrated in figure 7. When the follower element 26 is in the second position 48, the sheath 14 is prevented from retracting. The second position 48 is defined at the proximal end of the guide slot 12 and includes a first recess 50 on the proximal side of the guide slot 12 and a second recess 52 on the distal side of the guide slot 12. The biasing force exerted by the coil spring 33 forces the follower element into the first recess 50. This acts as a detent by providing a degree of mechanical resistance so as to retain the follower element 26 in the second position and thereby retain the sheath 14 in the extended position. This detent must be overcome by a user to displace the follower element out of the first recess and into the arcuate portion 46 so as to allow for retraction of the sheath 14.

If the sheath 14 of the embodiment shown in figure 7 is locked in the extended position (i.e. when the follower element 26 is seated within the first recess 50) an inadvertent retractive force, such as an accidental bumping of the end of the sheath, which is significant enough to overcome the biasing force of the coil spring 33, will tend to displace the sheath 14 toward the substance storage chamber 10. However, this inadvertent retraction of the sheath 14 is unlikely to guide the follower element 26 into the arcuate portion 46 to allow for full retraction of the sheath because the arcuate portion 46 of the slot 12 extends away from the second position 48 in a direction that is roughly at right angles to the direction of retraction of the sheath 14. Rather, it is likely that the inadvertent retraction will be halted once the follower element 26 makes contact with the second recess 52. The minimal amount of retraction of the sheath 14 required for the follower element 26 to make contact with the second recess 52 is not sufficient for the needle tip 19 to clear the distal end of the sheath 14. Hence, at all times during any such inadvertent retraction of the sheath 14, this embodiment helps to address the risk of needle stick injury.

One methodology for using an embodiment of the syringe 31 commences with the step of positioning a distal end of the sheath 14 at an appropriate site on a patient

whilst allowing the biasing means to retain the sheath in the extended position. Hence the needle 18 is visually obscured from the patient both whilst the syringe 31 is being brought into the patient's proximity and whilst the syringe is being held against the patient's skin. The next step in this methodology involves inserting the hypodermic needle 18 into the patient. To achieve this, the user displaces the syringe 31 toward the patient whilst allowing the patient's skin to remain in contact with the distal end of the sheath 14. This retracts the sheath 14 whilst inserting the needle 18 into the patient. Once the needle 18 has been inserted, the user operates the plunger 36 so as to inject or withdraw fluid, as required. The user then displaces the syringe 31 away from the patient so as to simultaneously withdraw the needle 18 from the patient and allow the biasing means 33 to displace the sheath 14 toward the extended position. This retains the distal end of the sheath 14 in contact with the patient's skin until the sheath 14 reaches the fully extended position. Once the sheath 14 is fully extended, if one of the embodiments shown in figures 1A to 6 is being utilized, the user manually locks the sheath in the extended position in the manner discussed above. Alternatively, if the embodiment shown in figure 7 is being utilized, the automatic locking means automatically locks the sheath 14 once it reaches the fully extended position.

Throughout the methodology described in the preceding paragraph the needle 18 remains obscured from the patient's sight. This may help nervous patients to avoid additional stress associated with the sight of a sharp needle. Additionally, throughout this process the only point at which the sheath 14 is retracted sufficiently for the needle tip 19 to clear the end of the sheath is whilst the end of the sheath is being held against the patient's skin. Hence, there is little or no risk that anyone other than the intended patient will come into contact with the needle tip 19 when properly executing this methodology.

While a number of preferred embodiments have been described, it will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS

1. A syringe including:

at least one substance storage chamber;

a hypodermic needle in fluid communication with the substance storage chamber, the hypodermic needle defining a needle tip;

a sheath slidably disposed for displacement between a retracted position in which at least the needle tip is exposed and an extended position in which the needle tip is shrouded; and

biasing means adapted to bias the sheath toward the extended position,

wherein a guide slot is defined in one of the substance storage chamber or the sheath and wherein a follower element adapted for displacement along said slot is provided upon the other of the substance storage chamber or the sheath,

wherein the guide slot defines a first position for locking of the sheath in the retracted position and wherein the guide slot defines a second position for locking of the sheath in the extended position,

wherein the syringe further includes an automatically operable locking means adapted to lock the sheath in the extended position, the automatically operable locking means including an arcuate portion of the guide slot leading to the second position, such that extension of the sheath displaces the follower element along the arcuate portion and into the second position, and

wherein the slot defines a recess adjacent the second position such that the recess contacts and halts the follower element in response to retraction forces applied to the sheath whilst locked in the extended position.

2. A syringe according to claim 1 wherein the biasing means is resilient.

3. A syringe according to claim 2 wherein the resilient biasing means is a spring.

4. A syringe according to any one of the preceding claims wherein the substance storage chamber defines a proximal end having an aperture for receipt of a plunger and wherein a flange is disposed at or adjacent to the proximal end of the substance storage

chamber.

5. A syringe according to claim 4 wherein the biasing means extends between the flange and the sheath.

6. A syringe according to claim 5 wherein a distal end of the biasing means abuts a proximal end of the sheath.

7. A syringe according to claim 5 or 6 wherein the biasing means is a coil spring and wherein at least part of the substance storage chamber is disposed internally of the coil spring.

8. A syringe according to claim 7 wherein the coil spring, substance storage chamber and sheath are all substantially cylindrical.

9. A syringe according to any one of the preceding claims wherein the guide slot has an open end adapted for passage of the follower element into and out of the slot such that the sheath is selectively attachable and detachable from the substance storage chamber.

10. A syringe according to claim 9 wherein the needle is disposed on a needle assembly which is selectively detachable from the substance storage chamber to allow for attachment of a connector to the substance storage chamber.

11. A syringe according to claim 10 wherein the connector is any one of:
a catheter; an intravenous feeding tube; a Luer lock or a Luer slip.

12. A syringe according to any one of the preceding claims wherein the sheath has a side wall thickness of greater than or equal to 0.5mm.

13. A syringe according to any one of the preceding claims wherein the sheath has a

side wall thickness of greater than or equal to 1mm.

14. A syringe according to any one of the preceding claims wherein the syringe is a single-use syringe.