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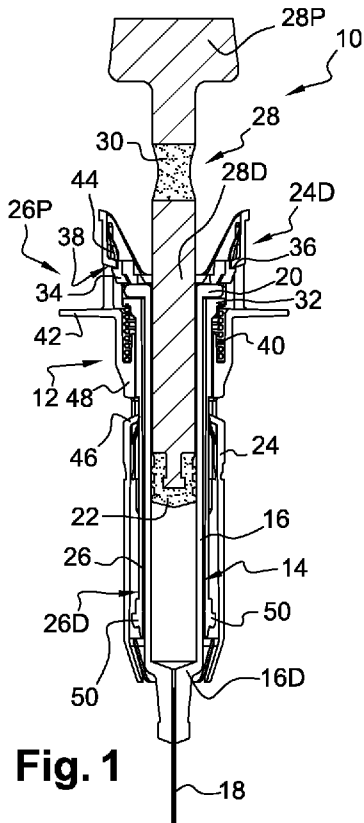
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(54) Title: SAFETY DEVICE FOR AN INJECTION SYRINGE



(57) Abstract: The invention relates to a safety device (12) for an injection syringe (14), the injection syringe comprising a body (16) having an injection needle (18) fitted thereon, the device (12) comprising a plunger rod (22, 28) including a distal plunger part (28D) slidably movable in the body (16) of the syringe, and a proximal triggering part (28P), configured to trigger the displacement of a protection sheath (24), from an injection position, wherein the needle (18) is uncovered, towards a safety position, wherein the needle (18) is covered by the sheath (24). The proximal triggering part (28P) is able to move relative to the distal plunger part (28D) once the distal plunger part is at the distal end of its stroke, to trigger the displacement of the protection sheath (24).



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Safety device for an injection syringe

The present invention relates to the field of safety device for a liquid injection syringe, in particular for a prefilled syringe.

5 A prefilled liquid injection syringe is known from the prior art. The syringe comprises a body of tubular shape forming a reservoir for the liquid and having fitted thereto at a distal end of the body a needle or a fitment for fastening a needle carrier on the syringe body. The syringe also includes a piston sealingly movable in the syringe body. Usually, the piston is a rubber part.

10 A safety device for a syringe such as the one described above is also known, for example from EP 1436026. The safety device comprises a syringe support, having a tubular shape, and being coaxial with the syringe body and a protective sheath also having a tubular shape, the protective sheath and the syringe support being axially movable relative to each other. The syringe support is housed in the protective
15 sheath and is substantially coaxial therewith. The safety device also includes a plunger rod, intended to be fastened on the piston of the syringe. The rod is configured to trigger the displacement of the protective sheath relative to the syringe support from an injection position, wherein the needle is uncovered, towards a safety position, wherein the needle is covered by the sheath. The safety device enables the
20 needle to be retracted automatically into the sheath so as to ensure that a person handling the syringe assembly cannot accidentally be pricked by the needle after the liquid has been injected into the body of a patient. This type of safety device is also called "passive" safety device.

The term "proximal" will be used to name an element or an end of an element that
25 is axially closer to the end of the plunger rod that is to be actuated by a user than a "distal" end of an element. Thus, the term "distal" will be used to name an element intended to be axially closer to the needle.

However, the displacement of the sheath relative to the support or the syringe, i.e., to the needle, always occurs when the piston is near the distal end of the body
30 of the syringe in an end-of-liquid injection position.

Yet, in some case, it can be of interest that the displacement of the sheath relative to the support does not take place automatically when the piston reaches the end-of-liquid injection position.

For example, in case of extemporaneous injection, i.e., when the liquid to be
35 injected needs first to be reconstituted by mixing a solvent contained in the prefilled syringe body with an active ingredient contained in a vial, it is of interest that at the end of the injection of the solvent in the vial, the displacement of the protective

sheath relative to the support would not be triggered. Indeed, the syringe needs to be refilled with the desired volume of the mixture before injection into the patient body. It is only at the end of this second injection that the safety device needs to be triggered so as to avoid any risk of contamination by a needle prick.

5 Moreover, especially with glass syringes, where large manufacturing tolerances are allowed, the safety device is activated near the end of the stroke of the proximal part of the plunger, generally while the plunger has not reached the distal end of the syringe body. This is detrimental to the ability to inject very small volume of liquid (in particular to inject medicine to babies or children) because when the user pushes the
10 plunger to eliminated bubbles of air or to reduce the volume of liquid contained in the syringe body, the safety device can be activated and the medicine in the syringe cannot be injected anymore.

 An object of the invention is to provide a safety device that is not always automatically triggered at the end of the piston stroke and that allows for full delivery
15 of the product contained in the syringe body.

 Accordingly, the invention provides a safety device for an injection syringe, the injection syringe comprising a body having an injection needle fitted thereon, the device being characterized in that the device comprises a plunger rod including:

 - a distal plunger part slidably movable in the body of the syringe,
20 - a proximal triggering part, configured to trigger the displacement of a protection sheath, from an injection position, wherein the needle is uncovered, towards a safety position, wherein the needle is covered by the sheath,

 wherein the proximal triggering part is able to move relative to the distal plunger part once the distal plunger part is at the distal end of its stroke in order to trigger the
25 displacement of the protection sheath.

 Thanks to the fact that once the distal plunger part has reached the distal end of the syringe body, i.e. an end-of-injection position, the proximal triggering part is still able to move relative to the distal plunger part in the injection direction, the user is capable of choosing whether or not the safety device will be triggered. It is to be
30 understood that the plunger rod may or may not comprise the piston.

 If the user does not want to activate the safety device, once the distal plunger part reaches a stop at the distal end of its stroke, i.e., when a distal surface of a piston fitted on the distal plunger part or when a distal surface of the distal plunger part reaches its final distal position, the user does not exert more pressure on the
35 proximal triggering part of the plunger. On the contrary, if the needle needs to be covered by the sheath after injection, once the piston has reached the distal end of the syringe, the user exerts more pressure on the proximal triggering part of the

plunger rod which moves relative to the distal plunger part to trigger the displacement of the protection sheath from the injection position towards the safety position. This type of safety device is also called "active" safety device.

5 An advantage of the on-demand activation of the safety device is that it allows to complete delivery of the liquid contained in the syringe body as the displacement of the sheath can only be triggered once the distal plunger part has reached the distal end of the syringe body. For example, in case of extemporaneous injection, all the solvent contained in the prefilled syringe is injected in the vial and the concentration reproducibility of the active ingredient in the solution is therefore improved.

10 This is also advantageous when injecting a very small volume of liquid. As the piston is allowed to reach the distal end of the syringe body, even when the volume to be injected is small, e.g., when the piston stroke is around few millimeters (mm), preferentially less than 5 mm, more preferably less than 3 mm, one can reliably control the delivered volume of liquid and, if needed, can trigger the safety device at
15 the end of the injection. This is particularly advantageous for the delivery medicine to a child or a baby. Indeed, one can then use a standard prefilled syringe, wherein the beginning of the dose is thrown away, so that there is only a small amount of medicine left in the syringe body. The risk to trigger the safety device during the reduction of the volume of liquid contained in the syringe body and before injecting
20 the liquid to the patient is therefore reduced. In such a case, the complete delivery of the small amount of medicine is crucial, and the proposed safety device permits to be sure that the piston on the syringe reaches the end of its stroke without automatically triggering the protection sheath of the needle.

Another advantage is that the safety device can easily be transformed from
25 "passive" to "active" by changing only the plunger rod, all the other element of the safety device remaining the same. This improves the standardization of the safety device. The choice to use a passive or an active safety device is made by the company selling the prefilled syringes.

30 It is to be noted that, usually, the plunger rod belongs to the safety device, whereas the piston, mounted on the distal plunger part of the plunger rod belongs to the prefilled syringe though, in some embodiments, the plunger rod comprises the piston. Usually also, the prefilled syringe is inserted into a syringe support, slidably mounted on or in the protection sheath. Furthermore, the piston is preferably made of rubber.

35 The safety device may also include at least one of the following characteristics, taken alone or in combination.

- The distal plunger part and the proximal triggering part are linked by deformable

means, deformable under a force that is higher than the force required to move a piston in the syringe body, when injecting the liquid contained in the syringe body. Therefore, under the force exerted to move the piston in the syringe body, the deformable means are slightly deformed but the deformation is not great enough to allow the safety device to be activated as soon as the piston is in contact with a distal end of the syringe body, i.e., when the distal plunger part has reached the end of its stroke. Thus, the force required to displace the proximal part relative to the distal part of the plunger rod on a distance allowing the triggering of the safety sheath is higher than the force required during injection to move the piston in the syringe body and the user can therefore choose if the safety device needs to be activated at the end of the distal plunger part stroke.

- The deformable means comprise elastic means. The force applied on the plunger rod can be high at the beginning of the injection, as the piston can stick to the walls of the syringe body. The force may be higher than the force requested at the end of the injection to activate the safety device. It is therefore advantageous for the deformable means to be elastic. After the beginning of the injection, when the force applied to the plunger rod decreases to a normal injection force, the deformable means can resume a shape close to their initial shape. Even if the deformable means are slightly deformed at the end of the injection, the deformation is not great enough to allow the safety device to be automatically activated as soon as the distal surface of the piston is in contact with a distal end of the syringe body.

- The elastic means comprise an elastomeric material glued, soldered, snap-fitted or overmolded on the distal plunger part and/or the proximal triggering part.

- The elastic means are integral with the piston.

- The elastic means is a spring. In such a case, the spring can be situated in the proximal part of the piston rod, the triggering part being supported by an element shaped like a cap, and the distal plunger part being supported by another tubular element.

- The distal plunger part and the proximal triggering part each form a seat for the spring.

- The distal plunger part and the proximal triggering part are snap-fastened to each other.

- The distal plunger part and the proximal triggering part each comprise complementary anti-rotational means. Thus, the proximal part and the distal part cannot rotate relative to each other. The screwing of the plunger rod on the piston is therefore easier.

- The complementary anti-rotational means comprise a lug cooperating with a

groove.

The invention also provides an assembly of a safety device according to the invention and of a liquid injection syringe. This syringe is usually prefilled.

These and additional objects, embodiments, and aspects of the invention will
5 become apparent by reference to the figures and detailed description below in which:

Figure 1 is an axial sectional view of a first embodiment of an assembly of a syringe and a safety device before injection;

Figure 2 is an axial sectional view of the assembly of Figure 1 at the end of the injection, before activation of the safety device;

10 Figure 3 is an axial sectional view of the assembly of Figure 1 during activation of the safety device;

Figure 4 is an axial sectional view of the assembly of Figure 1, the safety device being locked in safety position;

Figure 5 is an axial section view of a second embodiment of an assembly of a
15 syringe and a safety device before injection, before injection;

Figure 6 is an axial section view of the assembly of Figure 5 at the end of the injection, before activation of the safety device;

Figure 7 is an axial section view of the assembly of Figure 5 during activation of the safety device;

20 Figures 8 to 11 are axial sectional views of a third embodiment of an assembly of a syringe and a safety device, respectively before injection, before activation of the safety device, during activation of the safety device and locked in safety position;

Figures 12 to 14 are axial section views of a fourth embodiment of an assembly of a syringe and a safety device, respectively before injection, before activation of the
25 safety device and during activation of the safety device;

Figure 15 is a perspective view of a plunger rod according to a fifth embodiment;

Figure 16 is an axial section view of a plunger rod according to a sixth embodiment;

30 Figure 17 is a perspective view of a plunger rod according to a seventh embodiment;

Figures 18 and 19 are partial axial section views of an eighth embodiment of an assembly of a syringe and a safety device, respectively before activation of the safety device and during activation of the safety device.

35 The present invention will now be described with reference to the specific embodiments of the invention. This invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and

complete, and to fully convey the scope of the invention to those skilled in the art.

A preferred embodiment of an assembly 10 of a safety device 12 and a prefilled injection syringe 14 is shown in Figures 1 to 4.

In Figure 1, the syringe 14 comprises a tubular syringe body 16 forming a
5 reservoir for the liquid. The body 16 has an open proximal end 16P provided with a collar 20, and a distal end 16D, generally in the form of a cone converging away from the proximal end 16P, having an injection needle 18 fitted thereon. For example the syringe body 16 is made of glass material, it could also be made of plastic material.

The syringe 14 also includes a piston 22 mounted to be sealingly and axially
10 movable in the body 16 from a ready-to-inject position, shown in Figure 1, to an end-of-injection position, shown in Figure 2, in which the piston 22 is in contact with the distal end 16D of the body 16.

The safety device 12 comprises the first member of generally tubular shape,
15 referred to as the protective sheath 24, and a second member of generally tubular shape, referred to as the syringe support 26. The support 26 is housed inside the sheath 24, being substantially coaxial therewith. For example, the sheath 24 and the support 26 are made of plastic material.

The sheath 24 and a support 26 are movable axially relative to each other
20 between an injection position, wherein the needle 18 is uncovered, and a safety position, wherein the needle 18 is covered by the sheath 24. The sheath 24 also comprises grip means including, in this embodiment, two outer radial tabs 42. The sheath 24 is locked in the injection position thanks to complementary retaining means 36, 38 respectively carried by the support 26 and sheath 24. These retaining
25 means oppose the resilient return force of the thrust spring 40. The first retaining means 38 are formed by the free end of an axial tongue 44 provided on a proximal end 24D of the sheath 24. The tongue 44 is elastically deformable in a radial direction. The second retaining means 36 are formed on a proximal part 26P of the syringe support 26.

The safety device also has locking means for locking the sheath in the safety
30 position as shown in Figure 4. The locking means comprise at least one radial projection 50 formed on a distal end 26D of the syringe support 26 for snap-fastening between a pair of abutments 46, 48 formed on the sheath 24, to prevent axial movement of the sheath 24 relative to the support 26 and therefore to the needle 18.

The safety device 12 also comprises a plunger rod 28, for example made of
35 plastic material. The plunger rod 28 comprises a distal plunger part 28D and a proximal triggering part 28P. The distal part 28D and the proximal part 28P are linked by deformable means, which in this embodiment are elastic means comprising and

elastomeric material 30 glued, soldered, snap-fitted or overmolded on the distal part 28D and on the proximal part 28P. The proximal part 28P is configured to trigger the displacement of the sheath 26 from the injection position to the safety position.

5 In this embodiment, the elastomeric material 30 has a non-constant section along the axial axis of the plunger rod 28, the middle section being smaller than the end sections. The plunger rod 28 is mounted on the piston 22, for example by screwing the plunger rod 28 on the piston 22.

10 The body of this syringe 14 is housed in a known manner in the support 26. More particularly, the syringe body 16 is prevented from moving axially in this syringe support 26 as the collar 20 is snap-fastened between appearing seat 32 formed in the support 26 and at least one retractable locking abutment 34 secured to the support 26, in this embodiment, the support 26 has two diametrically opposite locking abutment 34.

15 With references to figures 1 to 4, the operation of the assembly 10 will be described.

Once the prefilled syringe body 16 is mounted in the safety device 12 and the plunger rod 18 is screwed on the piston 22, the assembly 10 is in the injection position and ready to use.

20 The user take the assembly 10 in one hand putting two fingers on the outer radial tabs 42 and one finger on our the proximal part 28P of the piston rod. The user then exerts on the plunger rod 18 until the distal part 28D reaches the end of its stroke and the piston 22 is in contact with the distal end 16D of the syringe body 16, as can be seen in Figure 2. In this position, the proximal part 28P of the plunger rod 18 has not yet reached the end of its stroke.

25 If the user wants to activate the safety device 12, a force higher than the force used to move the plunger in the syringe body 16 is needed to deform the elastomeric material 30, in this example axially and radially, as shown in Figure 3, and to allow proximal part 28P to cooperate with the tongue 44 deforming the tongue 44 radially and unlocking the retaining means 36 and 38. As described, the proximal part 28P of
30 the plunger rod is configured to trigger the displacement of the sheath 24 from its injection position towards its safety position, the displacement being relative to the support 26. To this end, the proximal part 28P has an external diameter that is larger than the internal diameter of the tongues 44. When the proximal part 28P reaches the tongues 44, the proximal part 28P pushes aside and deforms radially the
35 tongues 44 causing the first and second retaining means 38, 36 to disengage. There is therefore no more force opposing the spring 40 to detent. The safety device 12 is activated while the proximal part 28P of the plunger rod 28 has reached the end of

its stroke.

Driven by the spring 40, the displacement of the sheath 24 relative to the support 26 is triggered and the sheath takes its safety position, as shown in Figure 4. It can be seen that the sheath 24 and the support 26 are locked in the safety position
5 thanks to the snap-fastening of two projections 50, each between a pair of abutments 46, 48.

If the user does not want to activate the safety device 12, once the distal part 28D of the plunger rod 28 has reached the end of its stroke, the user does not apply a supplementary force on the proximal part 28P of the plunger rod, although the piston
10 22 having reached the distal end 16D of the syringe body, the safety device is not activated and the assembly the syringe can be filled, for example with a reconstituted mixture.

In the embodiment shown in Figures 8 to 11, wherein the elements common to embodiment of Figures 1 to 4 are identified by same numeral references, the plunger
15 rod 28, and more particularly the distal plunger part 28D, comprises the piston 22. In this example, the elastomeric material 30 is integral with the piston 22. It could also be glued, soldered, snap-fitted or overmolded on the distal plunger part 28D.

The operation of the assembly 10 is similar to the one described above. Once the piston 22, i.e., the distal part 28D of the plunger rod has reached the end of its
20 stroke, as shown in Figure 9, when the user wants to activate the safety device 12, a force higher than the force used to move the plunger in the syringe body 16 is needed to deform the elastomeric material 30, in this example axially and radially, as shown in Figure 10, and to allow proximal part 28P to cooperate with the tongue 44 deforming the tongue 44 radially and unlocking the retaining means 36 and 38. The
25 deformation of the elastomeric material 30 allowing for displacement of the proximal triggering part 28P relative to the distal part 28D so the proximal part 28P reaches the end of its stroke.

In another preferred embodiment shown in Figures 5 to 7, elements common to embodiment of Figures 1 to 4 are identified by same numeral references.

30 The safety device 12 and the syringe 14 are similar to the ones described in the previous embodiment except for the plunger rod 28.

In the embodiment of figures 5 to 7, the plunger rod 28 comprises the distal plunger part 28D screwed on the piston 22 and a proximal part 28P linked to the distal part by an activation spring 52.

35 The proximal triggering part 28P has a general form of a cap having an essentially flat bottom part 54 and an annular wall 70. The flat bottom part 54 carries an inner annular projection 56 helping to center the activation spring 52 within the proximal

part 28P, the flat bottom part 54 forming a seat for the activation spring 52. The external diameter of the annular wall 70 is larger than the internal diameter of the tongues 44.

5 The distal end 28D comprises, at its proximal end 58, a groove 60 for receiving the activation spring 52. The groove 60 is formed by an external annular wall 64 and an inner cylindrical projection 62, the cylindrical projection 62 being housed in sliding contact in the annular projection 56.

10 The proximal part 28P and the distal part 28D comprise complementary snap-fastening means 66, 68. The snap-fastening means are formed, on the one hand, by a bead 66 supported by an external surface of the external annular wall 64 of the proximal end 58 of the distal part 28D, and on the other hand, by lugs 68 supported by an inner surface of the annular wall 70 of the proximal part 28P. Once the activation spring 52 is placed within the cap-shaped proximal part 28P, around the inner annular projection 56, the proximal part is mounted on the distal part 28D. The activation spring 52 is in compression between the two parts 28P, 28D. The complementary snap-fastening means 66, 68, opposing the force of the activation spring 52, secure the distal part 28D and the proximal part 28P together.

15 The plunger rod 28 also comprises anti-rotational means to avoid rotation of the proximal part 28P relative to the distal part 28P. The anti-rotational means comprise, on the one hand, the lugs 68 supported by the inner surface of the annular wall 70 of the proximal part 28P and, on the other end, grooves 72 formed in the external annular wall 64. These anti-rotational 68, 72 means are complementary and cooperating with each other. It is to be noted that in this example, the lugs 68 are forming snap-fastening means as well as anti-rotational means. Thanks to these complementary anti-rotational means, screwing of the plunger rod 28 onto the piston is facilitated.

20 The operation of the assembly 10 is similar to the one described for the previous embodiment. Once the distal part 28P of the plunger rod 28 reaches the end of its stroke as shown in Figure 6, i.e., when the piston 22 is in contact with the distal end 16D of the syringe body, the user can choose whether or not he wants to activate the safety device. The proximal part 28P of the plunger rod has not yet reached the end of its stroke.

25 If the safety device 12 needs to be activated, a complementary force applied on the proximal part 28P of the piston rod 28 is required so as to further compress the activation spring 52 and to bring the proximal part 28P in its end-of-stroke position, as shown in Figure 7. Indeed, the force required to compress the activation spring 52 is greater than the force required to move the piston in the syringe body.

The external diameter of the annular wall 70 being larger than the inner diameter of the tongues 44, when the proximal part 28P reaches the tongues 44, the proximal part 28P pushes aside and deforms radially the tongues 44 causing the first and second retaining means 38, 36 to disengage. There is therefore no more force opposing the spring 40 to detent. The safety device 12 is activated while the proximal part 28P of the plunger rod 28 has reached the end of its stroke.

Driven by the spring 40, the displacement of the sheath 24 relative to the support 26 is triggered and the sheath takes its safety position, similarly to what has been previously described.

The plunger rod 28 of the embodiment shown in Figure 15 is similar to the one of Figures 5 to 7. The proximal triggering part 28P has a general form of a cap having an essentially flat bottom part 54, an annular wall 70 and an inner cylindrical projection 78. The activation spring 52 is received in a room 76 housed in the proximal end 58 of the distal part 28D of the plunger rod and the inner cylindrical projection 78 is slidably movable in the room 76, so as to compress the activation spring 52 upon activation of the safety device.

Figures 12 to 14 show another embodiment, similar to the embodiment of Figures 5 to 7 in which the needle 18 is mounted onto the syringe body 16 via a fastener end piece referred to as a Luer lock 74. Thanks to the Luer lock 74, the prefilled syringe can be stored without the needle mounted on the syringe body 16, with or without the safety device 12. Thus, during storage, the syringe is more compact.

The Luer lock also allows for changing the needle 18 carried by the syringe body 16. For example, in case of extemporaneous injection, a first needle is used to inject the solvent in the vial and to refill the syringe while a second needle, generally thinner, is used to inject the reconstituted mixture into the patient body.

In the embodiment shown in Figure 16, the elastic means comprise elastic lugs connecting the distal part 28D to the proximal part 28P of the plunger rod 28.

Elastic deformation means have been described; however, the deformation means can also be plastic, the force required to plastically deform the deformation means, on a distance allowing to trigger the displacement of the sheath, being higher than the force required to move a piston in the syringe body.

As shown in Figure 17, the proximal part 28P of the plunger rod 28 comprises a plurality of breakable links 82 between the proximal end 58 of the distal part 28D and the annular wall 70 of the proximal triggering part. When the piston 22 mounted on the distal end of the distal part 28D of the plunger rod 28 (not shown in Figure 17) is in contact with the distal end 16D of the syringe body, the user can choose whether or not he wants to activate the safety device. The proximal part 28P of the plunger

rod has not yet reached the end of its stroke. To activate the safety device, once the distal part 28D of the plunger rod 28 has reached the end of its stroke, the user needs to apply an additional force to break the breakable links to allow the proximal part 28P to reach the end of its stroke and to allow proximal part 28P to cooperate with the tongue 44 deforming the tongue 44 radially and unlocking the retaining means 36 and 38.

It is to be noted that the links 82, instead of being breakable, could also be deformable, elastically or plastically.

Figures 18 and 19 show an eighth embodiment of an assembly 10 of a syringe 14 and a safety device 12 in which the plunger rod 28 comprises a hollow cylindrical distal part 28D receiving the proximal triggering part 28P. The proximal part 28P is slidably movable in the distal part 28D. The hollow cylindrical distal part 28D carries a projection 84 on the distal end of its inner surface. In the embodiment of Figure 18, the projection 84 has a cone shape which section decreases towards the proximal end of the device. The distal end of the proximal part 28P of the plunger rod 28 carries a deformable annular projection 86 that cooperates with the projection 84 carried on the inner surface of the distal part 28D. Upon injection, the annular projection 86 pushes the projection 84, the force required for injection being smaller than the force required to deform the annular projection 86, both the proximal part 28P and the distal part 28D slide together in the body 16 of the syringe. When the piston 22 mounted on the distal end of the distal part 28D of the plunger rod 28 is in contact with the distal end 16D of the syringe body, the user can choose whether or not he wants to activate the safety device. The proximal part 28P of the plunger rod has not yet reached the end of its stroke. To activate the safety device, once the distal part 28D of the plunger rod 28 has reached the end of its stroke, the user needs to apply an additional force to deform the annular projection 86 to allow the projection 84 to be received in the annular projection 86. The proximal part 28P can therefore reach the end of its stroke and the proximal part 28P can cooperate with the tongue 44 deforming the tongue 44 radially and unlocking the retaining means 36 and 38.

It is to be noted that the elastic means can be prestressed to a given value, i.e., the elastic means will not be deformed unless a force larger than the prestressed value is exerted on the triggering proximal part 28P of the plunger rod 28.

The stiffness of the thrust spring 40 may be adapted in function of the force required to activate the safety device.

The safety device can also operate without syringe support, the sheath being mounted onto the syringe body.

Some plunger rod may also comprise a sealing bead and there is therefore no

need of a piston as described above. Thus, the end of the stroke of the plunger rod is reached when the distal plunger rod is in contact with the distal end of the syringe body.

CLAIMS

1. Safety device (12) for an injection syringe (14), the injection syringe comprising a body (16) having an injection needle (18) fitted thereon, the device (12) being characterized in that the device comprises a plunger rod (22, 28) including:
- a distal plunger part (28D) slidably movable in the body (16) of the syringe,
 - a proximal triggering part (28P), configured to trigger the displacement of a protection sheath (24), from an injection position, wherein the needle (18) is uncovered, towards a safety position, wherein the needle (18) is covered by the sheath (24),
- wherein the proximal triggering part (28P) is able to move relative to the distal plunger part (28D) once the distal plunger part is at the distal end of its stroke in order to trigger the displacement of the protection sheath (24).
2. Safety device (12) according to claim 1, wherein the distal plunger part (28D) and the proximal triggering part (28P) are linked by deformable means (30, 52, 80, 82, 86), deformable under a force that is higher than the force required to move a piston (22) in the syringe body (16) when injecting the liquid contained in the syringe body (16).
3. Safety device (12) according to claim 2, wherein the deformable means (30, 52, 80, 86) comprise elastic means.
4. Safety device (12) according to claim 3, wherein the elastic means are integral with the piston (22).
5. Safety device (12) according to claims 3 or 4, wherein the elastic means (30) comprise an elastomeric material glued, soldered, snap-fitted or overmolded on the distal plunger part and/or the proximal triggering part.
6. Safety device (12) according to claim 3, wherein the elastic means is a spring (52).
7. Safety device (12) according to claim 6, wherein the distal plunger part (28D) and the proximal triggering part (28P) each form a seat for the spring (52).
8. Safety device (12) according to claim 7, wherein the distal plunger part (28D) and the proximal triggering part (28P) are snap-fastened to each other.
9. Safety device (12) according to any of claims 1 to 8, wherein the distal plunger part (28D) and the proximal triggering part (28P) each comprise complementary anti-rotational means (68, 72).

10. Safety device (12) according to claim 9, wherein the complementary anti-rotational means (68, 72) comprise a lug (68) cooperating with a groove (72).

11. Assembly (10) of a safety device (12) according to any of claims 1 to 10 and of a liquid injection syringe (14).

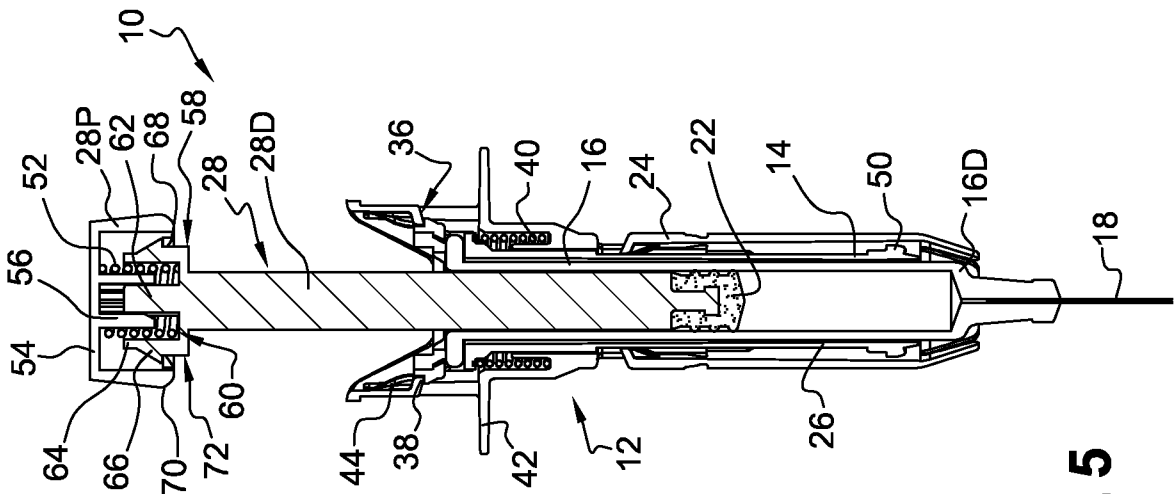


Fig. 5

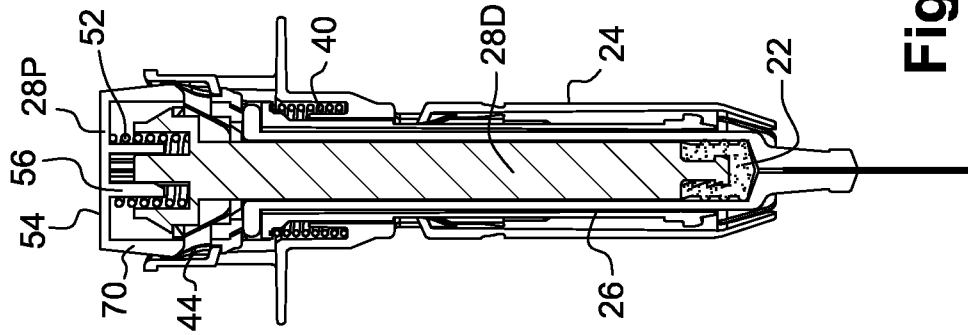


Fig. 6

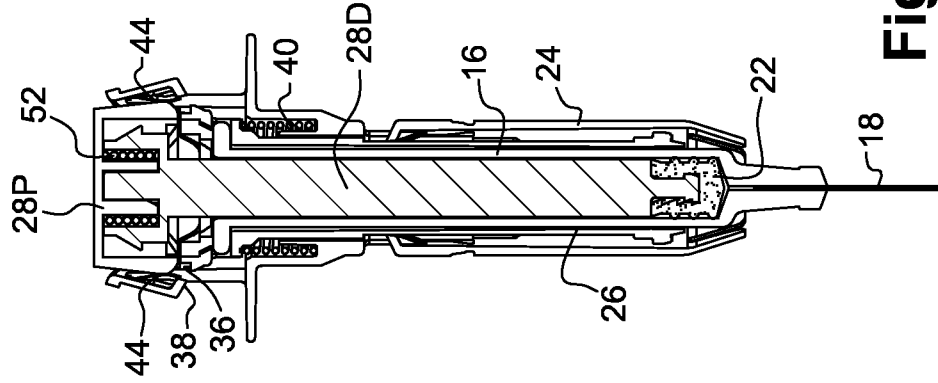


Fig. 7

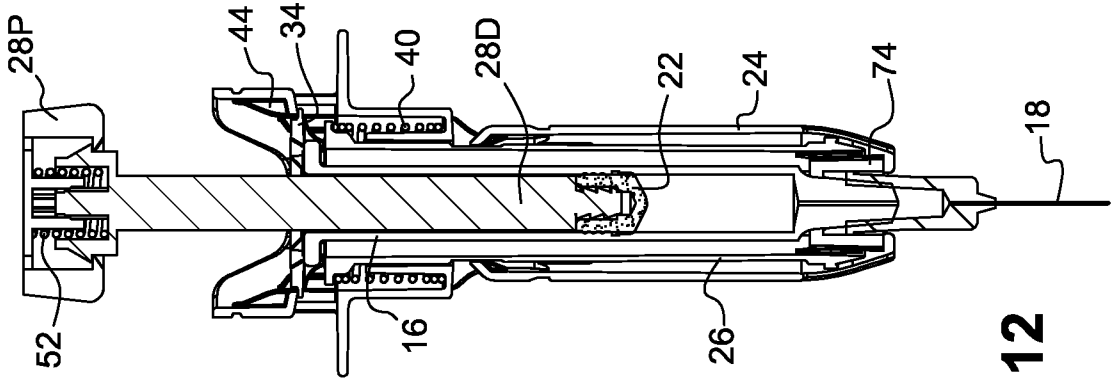


Fig. 12

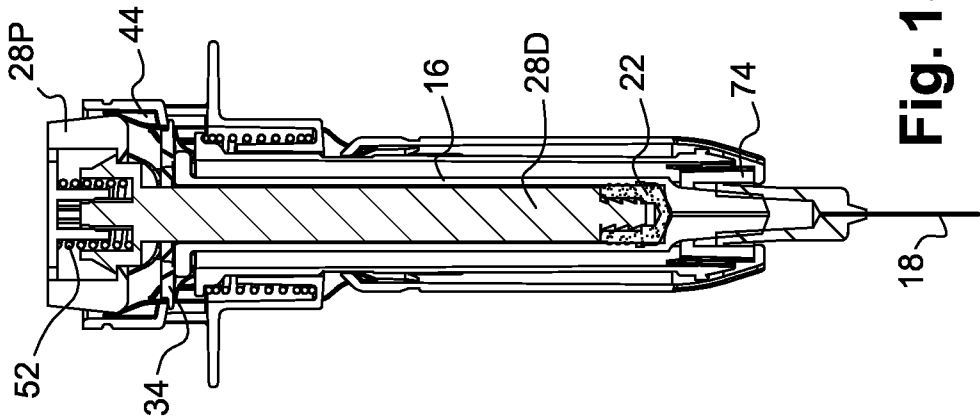


Fig. 13

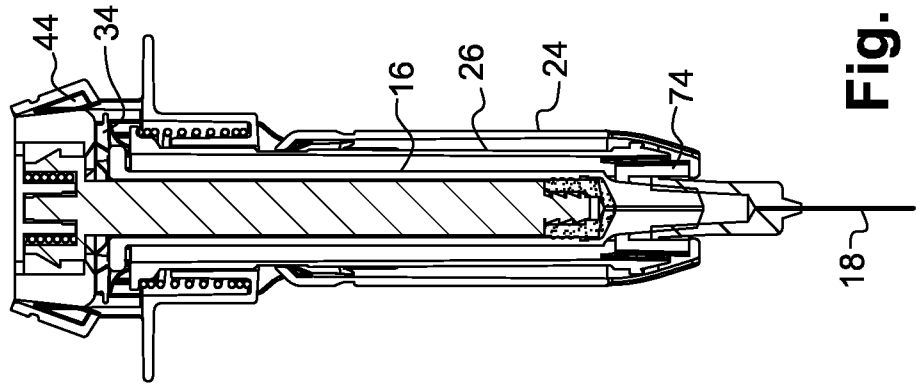


Fig. 14

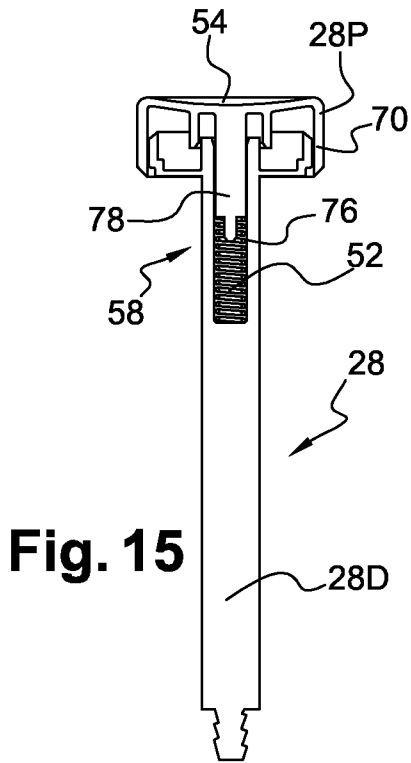


Fig. 15

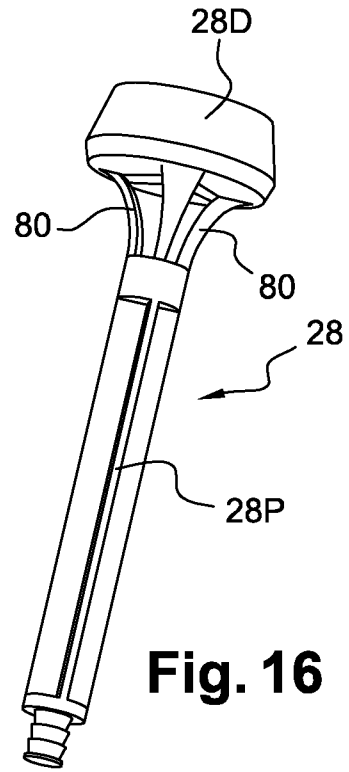


Fig. 16

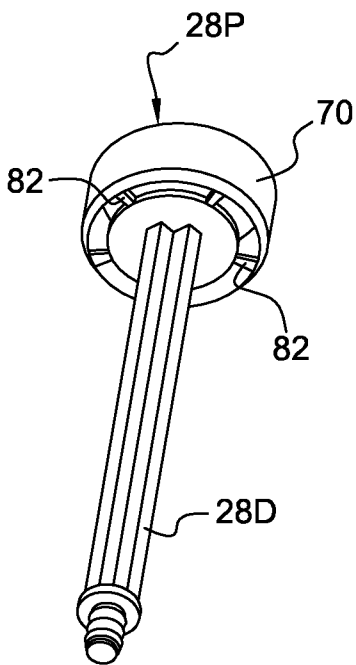


Fig. 17

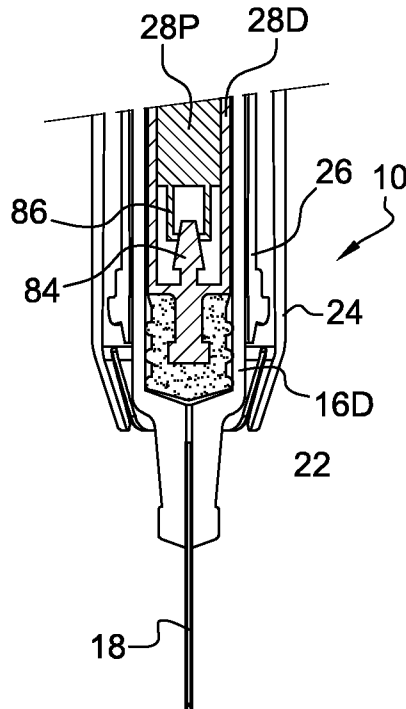


Fig. 18

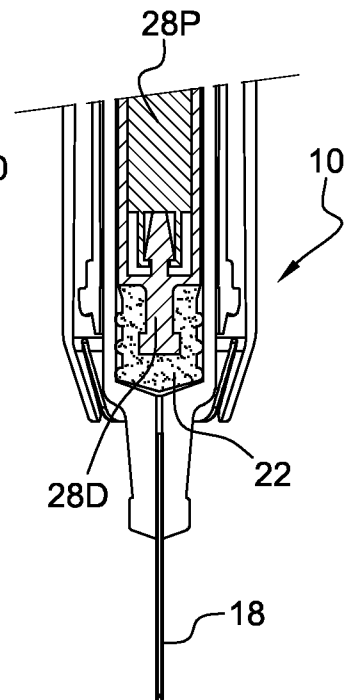


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/077826

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32 A61M5/315
ADD.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 830 765 A1 (PLASTIC OMNIUM CIE [FR]) 18 April 2003 (2003-04-18) cited in the application	1
Y	figures	2-11

X	US 5 562 626 A (SANPIETRO JOSEPH A [US]) 8 October 1996 (1996-10-08)	1
Y	figures	2-11

X	WO 2011/135269 A1 (REXAM HEALTHCARE LA VERPILLIER [FR]; DUGAND PASCAL [FR]; LANZI SYLVAIN) 3 November 2011 (2011-11-03)	1
Y	figures	2-11

Y	WO 2011/039226 A1 (SANOFI AVENTIS DEUTSCHLAND [DE]; MACDONALD CATHERINE ANNE [GB]; VEASEY) 7 April 2011 (2011-04-07) figures 4,5	2-11

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Further documents are listed in the continuation of Box C.

See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search 27 January 2014	Date of mailing of the international search report 03/02/2014
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Ehrsam, Fernand
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/077826

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 314 415 A (LIEBERT RICHARD T [US] ET AL) 24 May 1994 (1994-05-24) figures 6,7 -----	2-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2013/077826

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2830765	A1	18-04-2003	AT 491487 T 15-01-2011
			EP 1436026 A1 14-07-2004
			FR 2830765 A1 18-04-2003
			US 2006036216 A1 16-02-2006
			WO 03033059 A1 24-04-2003

US 5562626	A	08-10-1996	NONE

WO 2011135269	A1	03-11-2011	EP 2563432 A1 06-03-2013
			FR 2959419 A1 04-11-2011
			US 2013053788 A1 28-02-2013
			WO 2011135269 A1 03-11-2011

WO 2011039226	A1	07-04-2011	CA 2773844 A1 07-04-2011
			EP 2482872 A1 08-08-2012
			JP 2013506458 A 28-02-2013
			US 2012283662 A1 08-11-2012
			WO 2011039226 A1 07-04-2011

US 5314415	A	24-05-1994	AT 175127 T 15-01-1999
			AU 6759894 A 02-02-1995
			BR 9402865 A 04-04-1995
			CA 2128468 A1 22-01-1995
			CZ 9401705 A3 15-02-1995
			DE 69415596 D1 11-02-1999
			DE 69415596 T2 26-08-1999
			EP 0635278 A1 25-01-1995
			ES 2125398 T3 01-03-1999
			FI 943465 A 22-01-1995
			IL 110389 A 10-06-1997
			JP 3584060 B2 04-11-2004
			JP H07144021 A 06-06-1995
			NO 942735 A 23-01-1995
			RU 2104716 C1 20-02-1998
			SK 86094 A3 08-02-1995
			US 5314415 A 24-05-1994
