SAFETY DEVICE FOR A PRE-FILLED SYRINGE AND INJECTION DEVICE

Technical Field

The present invention relates to safety devices that provide needle safety and more particularly to safety devices for pre-filled syringes. The safety device is adapted to avoid accidental needle pricks and needle injuries before, during and after an injection of a medication or drug contained in the pre-filled syringe. In particular, the safety device provides needle safety for a subcutaneous self-administrated injection or for an injection administered by a health-care professional. The present invention further relates to injection devices comprising a safety device and a pre-filled syringe.

Background of the Invention

Pre-filled syringes that are filled with a selected dosage of a medication are well known injection devices for administering the medication to a patient. Safety devices for covering a needle of a pre-filled syringe before and after use are also well known. Typically, these devices comprise a needle shield that is either manually moved or moved by the action of a relaxing spring to surround the needle. However, there is a need for safety devices comprising a low number of components.

Summary of the Invention

It is an object of the present invention to provide an improved safety device for a pre-filled syringe.

It is a further object of the invention to provide an improved injection device comprising a pre-filled syringe that is safe to handle and in particular prevents accidental needle pricks.

The object is achieved by a safety device according to claim 1 and by an injection device according to claim 18.

Preferred embodiments are subject of the dependent claims.

In the context of this invention, the terms distal and proximal are defined from the point of view of a person performing an injection. Consequently, a distal direction refers to a direction pointing towards the body of a patient receiving an injection and a distal end defines an end of an element that is directed towards the body of the patient. Respectively, the proximal end of an element or the proximal direction is directed away from the body of the patient receiving the injection and opposite to the distal end or distal direction.

According to the invention, a safety device for a pre-filled syringe comprises a hollow support body to retain the pre-filled syringe therein, a hollow needle shield that is slidable relative to the support body and guiding means for guiding the movement of the needle shield relative to the support body. The guiding means comprise a deflectable flexible arm, a guide pin and a guide track. The deflectable flexible arm extends essentially parallel to a central axis of the safety device. The guide pin extends radially from the flexible arm. The guide track guides the guide pin within and along the guide track when the needle shield is slid relative to the support body.

The guide pin is moved within and along the guide track when the needle shield is slid relative to the support body to cover and/or to expose in particular a hypodermic needle of a pre-filled syringe inserted into the support body of the safety device. As the flexible arm is deflectable in a lateral direction, a relative rotation of any external parts like the needle shield and the support body is unnecessary to guide the guide pin along the guide track. Especially when external parts of the safety device abut the skin of a patient during the injection, friction between these rotating external parts and the skin of the patient is uncomfortable and may even cause pain to the patient, in particular while

the hypodermic needle still penetrates the skin. The safety device thus allows for a safe and convenient injection of a medication.

The guiding means of the safety device comprise a longitudinal tongue that is received in a longitudinal groove when the needle shield is moved with respect to the support body in a distal direction, whereby a relative rotation of the needle shield and the support body is prevented. This anti-rotational guiding means ensures the proper interaction of the guide pin with the guide track when the needle shield and the support body is moved axially displaced relative to each other.

The flexible arm is connected to one of the needle shield or the support body. The guide track is formed into the other of the support body or the guide track. Therefore, it is within the scope of the present invention that the safety device comprises a support body with a guide track and a needle shield with a flexible arm, or alternatively, that the flexible arm is connected to the support body and a guide track is formed into the needle shield.

Preferably, the flexible arm is integrally formed to the needle shield or to the support body. The safety device comprises only a small number of parts that are cost-efficiently mass-produced allowing the safety device to be used as a single-use disposable device that provides needle safety for disposable pre-filled syringes.

The flexible arm is deflectable and energizable by the action of a relaxing spring means, e.g. a compression spring, biasing the needle shield in the retracted position. Thus, no additional effort is required from the user performing the injection to energize the flexible arm.

According to a possible embodiment, the guide pin is located in an intermediate position in proximity of a proximal end of the guide track when the needle shield is in a retracted position and in an end position in proximity of a distal end of the guide track when the needle shield is an advanced position.

The needle shield is substantially received in the support body in the retracted position and protrudes the distal end of the support body in the advanced position. The movement of the guide pin within and along the guide track controls the extension and/or retraction of the needle shield allowing for a safe injection.

Alternatively, the substantial cylindrical needle shield comprises a radial diameter that is sized to substantially receive the support body in the retracted position. In this alternative embodiment the support body slides into the needle shield when the needle shield is moved from the advanced to the retracted position.

In a possible embodiment of the invention, the movement of the needle shield is controlled in a way as to hide the hypodermic needle from the view of a user throughout the injection. This reduces the fear of performing in particular self-administered subcutaneous injections that patients suffering from diabetes frequently have to carry out.

The guide pin in the end position is prevented from moving in a proximal direction by an interaction between the guide track and the guide pin, so that the needle shield is locked in the advanced position. The safety device is rendered non-reusable after the first use, whereby a further interaction or attention of the user is not required.

The guide pin in the start position, in the end position and in the intermediate position is non-biased in a lateral direction perpendicular to the central axis. The flexible arm is deflected to bias the guide pin during use of the safety device. The safety device is stored with the guide pin retained in the start position, wherein the flexible arm is not stressed and in an equilibrium position. This avoids material fatigue and associated mechanism failure even after prolonged periods of storage.

The guide pin in the end position is in an equilibrium position locking the needle shield in the advanced position and preventing re-usage of the safety device. As the guide pin is non-biased in the lateral direction in the intermediate position, occurring friction

between the guide pin and the guide track is minimized during the injection stroke performed by the user, so that the injection stroke can be carried out with minimal effort.

The flexible arm is deflected to bias the guide pin in the lateral direction when the guide pin moves along the guide track from the intermediate position towards the end position. As the flexible arm is typically made from a resilient plastics material that is prone to fatigue of material, it is advantageous to deflect and energize the flexible arm during use of the safety device, so that the shelf-life of the safety device is extended.

According to a possible embodiment of the invention, the needle shield protrudes the support body in an initial position and the spring mean is in a partially energized state when the needle shield is in the initial position. As the safety device is stored with the needle shield in the initial position, fatigue of material of the spring mean is avoided by only partially energizing the spring mean. This allows for a reliable use of the safety device even after prolonged periods of storage.

According to a possible embodiment, the needle shield is made from an opaque plastics material. The hypodermic needle is hidden from the view of the patient before the injection by the needle shield that is retained in the initial position. This eases a possible fear of needles of the patient. The safety device is thus particularly suited for performing self-administered injections.

According to an alternative embodiment, the needle shield is made from a transparent plastics material. A healthcare professional that uses the safety device thus can visually confirm the correct placement of the hypodermic needle penetrating the skin of the patient, even when the hypodermic needle is surrounded by the needle shield.

As the safety device is both suited for self-administered injections and injections carried out by a healthcare professional, the person referred to as the user or the patient may be one and the same person.

In a possible embodiment of the invention, the needle shield of the safety device is retained in the initial position prior to use by a resilient flexing gate element releasably retaining the guide pin in a start position located between the distal and the proximal end of the guide track. The flexing gate element serves as a simple means to releasably retain the needle shield connected to the guide pin in the initial position, whereas the needle shield protrudes the distal end of the support body to surround the hypodermic needle of the pre-filled syringe before the injection.

According to the same embodiment of the invention, the resilient flexing gate element guides the movement of the guide pin within the guide track, so that the movement of the needle shield relative to the support body is controlled in a manner that avoids a relative rotation of needle shield and support body.

According to the same embodiment, the flexing gate element is deflectable in a lateral direction as to allow the guide pin to move proximally from the start to the intermediate position. In particular, the flexing gate element is integrally formed into the support body and establishes a section of narrowed width that the guide pin has to pass to leave the start position and to activate the needle safety features of the safety device. A user typically applies a force to the needle shield in a distal direction to activate the safety features, so that the guide pin passes the section of narrowed width, whereby the flexing gate element is laterally deflected. Thus, an inadvertent activation of the needle safety features is prevented by the flexing gate element that retains the guide pin in the start position in particular during transportation of the safety device prior to use.

The flexing gate element of the same embodiment comprises a sloped section that guides the movement of the guide pin along a section of the guide track from the intermediate to the end position and prevents the guide pin from re-entering the start position. The safety device is non-reusable after a single injection has been performed and thus adapted to be used in combination with a disposable pre-filled syringe.

According to another embodiment of the invention, the needle shield further comprises at least one radial outwardly protruding retaining catch that can be engaged by a

release flap formed into the support body. The needle shield is releasably retained within the support body by the release flap and the retaining catch in the retracted position. The release flap is hinged to the support body. The release flap is engaged by an interior surface of the outer body at the end of an injection stroke, whereas the release flap presses the retaining catch inwards to release the needle shield. This mechanism prevents an unintended early release of the needle shield and makes sure that the medication has been fully delivered before the needle shield is released.

In yet another embodiment of the invention, the outer body comprises an inward projection that abuts the guide pin in the intermediate position to retain the needle shield in the retracted position. This simple mechanism allows for a secure retention of the needle shield in the retracted position.

According to the same embodiment, the guide pin and the inward projection comprise a triangular cross-section, so that upon releasing the needle shield from being retained in the retracted position, the guide pin is redirected in the lateral direction and guided within and along the guide track. This minimizes friction between the guide pin, the guide track and the inward projection allowing for a smooth use of the safety device.

The inward projection of the same embodiment moves along a section of the guide track thereby releasing the needle shield from being retained in the retracted position. The mechanism for both retaining and releasing the needle shield is integrated in existing parts having additional functionality. The safety device has a low part count that can be cost-efficiently produced.

An injection device comprises a pre-filled syringe retained in the support body of the safety device. The pre-filled syringe comprises a hypodermic needle attached to a distal end of the pre-filled syringe, a barrel with an inner cavity in fluid communication with the hypodermic needle and a piston fluid-tightly sealing a proximal end of the inner cavity. The piston is movable by actuating a piston rod protruding a proximal end of the barrel. The pre-filled syringe is retained within the support body of the safety device, so that the hypodermic needle protrudes the distal end of the support body. The hypodermic

needle of the injection device is surrounded by the needle shield in the initial position and/or in the advanced position and the hypodermic needle is exposed when the needle shield is in the retracted position. The injection device comprising the pre-filled syringe and the safety device combines the aforementioned advantages and avoids inadvertent needle sticks before, during and after an injection delivering the medication beneath the skin of patient.

The injection device is particularly suited for self-administered subcutaneous and intramuscular injections.

Details of the present invention are described hereinafter. However, it should be understood that the detailed description and the specific examples indicate possible embodiments of the invention and are given by way of illustration only. Various changes and modifications of the illustrated embodiments within the spirit and scope of the invention are appreciated by those skilled in the art.

Brief Description of the Drawings

The present invention will be better understood from the detailed description given in the following. The accompanying drawings are given for illustrative purposes only and do not limit the scope of the present invention.

Figure 1	shows a perspective view of an injection device with a safety device and a pre-filled syringe according to a first embodiment of the invention.
Figure 2	shows a perspective view of a needle shield with a laterally deflectable flexible arm.
Figure 3	shows a side view of a needle shield with a laterally deflectable flexible arm.

Figure 4 shows a sectional view of an injection device according to the first embodiment, whereas a needle shield is in an initial position.

Figure 5 shows a perspective view of a needle shield that is retracted within a support body according to the first embodiment of the invention.

Figure 6 shows a sectional view of an injection device according to the first embodiment, whereas a needle shield is in a retracted position.

Figure 7 shows a sectional view of an injection device according to the first embodiment, whereas a needle shield is in an advanced position and a support body is received in an outer body.

Figures 8A to 8D show a guide track formed into a support body and the movement of a guide pin within and along the guide track during an injection according to the first embodiment.

Figure 9 shows a perspective view of an injection device according to an alternative first embodiment of the invention.

Figure 10 shows a perspective view of an injection device according to a second embodiment of the invention.

Figure 11 shows a sectional view of an injection device according to the second embodiment, whereas a needle shield is in a retracted position.

Figure 12 shows a sectional view of an injection device according to the second embodiment, whereas a needle shield is in an advanced position.

Figure 13 shows a perspective view of a needle shield and a support body according to the second embodiment, whereas a pre-filled syringe is retained within the support body.

Figure 14 shows a perspective view of an injection device according to a third embodiment.

Figure 15 shows a perspective view of an injection device of the third embodiment, whereby an outer body is retained in a position relative to a support body, so that the support body protrudes the outer body in a distal direction.

Figures 16A to 16D show a guide track formed into a support body and the movement of a guide pin within and along the guide track during an injection according to the third embodiment.

Figure 17 shows a perspective view of an injection device according to the third embodiment, whereas the needle shield is in an advanced position.

Figure 18A to 18H show alternative embodiments, whereas a guide track is formed into one of a support body or a needle shield and a flexible arm is connected to, and in particular integral part of, the other of the support body or the needle shield.

Corresponding parts are marked with the same reference symbols in all figures.

Detailed Description of Possible Embodiments

Figure 1 shows an injection device D comprising a safety device 1 and a pre-filled syringe 2. The injection device D is in a packaged state as it would be presented to a user performing an injection. The safety device 1 comprises a substantially cylindrical and hollow needle shield 1.1. The needle shield 1.1 is received within a substantially cylindrical and hollow support body 1.2, whereas the needle shield 1.1 is slidable with respect to the support body 1.2. Prior use of the safety device 1, the needle shield 1.1 is retained in an initial position I, wherein the needle shield 1.1 protrudes the support body 1.2.

The needle shield 1.1 further comprises a circumferential skin-contact flange 1.1.1 at its distal end. The skin-contact flange 1.1.1 is adapted to be pressed against the skin of a patient and protrudes radial outwardly and perpendicular to a central axis A.

The injection device D comprises the safety device 1 with the pre-filled syringe 2 retained within the support body 1.2. In the packaged state as shown in figure 1, a hypodermic needle 2.1 is covered by a needle cap 2.2 preferably at least partially made from a plastics material like rubber. The needle cap 2.2 protrudes the skin-contact flange 1.1.1 of the safety device 1 in a distal direction, so that the user can easily remove the needle cap 2.2 from the pre-filled syringe 2.

Two diametrical opposing longitudinal tongues 1.1.2 are formed to an exterior surface of the needle shield 1.1 that protrude radial outwardly. Each longitudinal tongue 1.1.2 extends over an axial length parallel to the central axis A of the substantially cylindrical needle shield 1.1. The longitudinal tongue 1.1.2 is received in a corresponding longitudinal groove 1.2.1 formed into an interior surface of the support body 1.2 to prevent a rotation of the needle shield 1.1 relative to the support body 1.2.

Additionally, a longitudinal notch 1.2.8 is formed into an outer surface of the support body 1.2. An outer body 1.3 is slidably arranged relative to the support body 1.2. An inwardly protruding dent is formed into an inner surface of the substantially hollow outer body 1.3 that is received in the longitudinal notch 1.2.8. The outer body 1.3 is moved relative to the support body 1.2. This prevents a rotation of the outer body 1.3 relative to

the support body 1.2, so that in particular the outer body 1.3 can be slid with respect to the support body 1.2 in the distal direction to perform a linear injection stroke.

As best seen in figure 2, a guide pin 1.1.3 is integrally formed to a flexible arm 1.1.4 of the needle shield 1.1. As illustrated in figure 1, the guide pin 1.1.3 protrudes radial outwardly into a guide track 1.2.2 formed into the substantially cylindrical support body 1.2. Prior to use of the safety device 1, the guide pin 1.1.3 is retained within the guide track 1.2.2 in a start position PS located between a proximal end and a distal end of the guide track 1.2.2.

The guide pin 1.1.3 is retained in the start position PS by a flexing gate element 1.2.3 that is deflectable in a lateral direction L perpendicular to the central axis A and is formed to the support body 1.2. The flexing gate element 1.2.3 is curved towards one side to form a narrowed section that the guide pin 1.1.3 has to pass to leave the start position PS. As the guide pin 1.1.3 is integrally connected to the needle shield 1.1, the needle shield 1.1 is retained in the initial position I when the guide pin 1.1.3 is held by the flexing gate element 1.2.3 in the start position PS. The flexing gate element 1.2.3 is laterally deflectable to allow the guide pin 1.1.3 to move within the guide track 1.2.2 in a distal direction.

The safety device 1 comprises the essentially cylindrical and hollow outer body 1.3 with an open distal and a closed proximal end. The proximal end of the support body 1.2 is received within the open distal end of the outer body 1.3, whereas the outer body 1.3 is slidable with respect to the support body 1.2 in a distal direction to substantially receive the support body 1.2 inside the outer body 1.3.

A circumferential and outwardly protruding hand flange 1.3.1 is integrally formed to an exterior surface of the outer body 1.3 close to its distal end.

Two longitudinal recesses 1.3.2 are formed into the outer body 1.3 that extend over a substantial axial length of the outer body 1.3 and parallel to the central axis A.

Each longitudinal recess 1.3.2 receives a corresponding outward projection 1.2.4 integral part of the support body 1.2. The outward projection 1.2.4 moves within the longitudinal recess 1.3.2 when the outer body 1.3 is slid relative to the support body 1.2 to perform the injection stroke, whereas a relative rotation of the outer body 1.3 relative to the support body 1.2 is prevented.

The longitudinal recess 1.3.2 shown in figure 1 has the form of a slot. Alternatively, the longitudinal recess 1.3.2 is formed into an inner surface of the outer body 1.3, so that the outward projection 1.2.4 moves along the longitudinal recess 1.3.2 within the outer body 1.3 and is inaccessible from the outside.

Figures 2 and 3 show details of the essentially tubular needle shield 1.1 comprising the skin-contact flange 1.1.1 and the flexible arm 1.1.4 having the guide pin 1.1.3 formed to its proximal end. The flexible arm 1.1.4 and the guide pin 1.1.3 are integral parts of the needle shield 1.1 that is favourably made from a resilient plastics material.

Preferably, two flexible arms 1.1.4 are formed into opposite sides of the needle shield 1.1, whereas each flexible arm 1.1.4 comprises a guide pin 1.1.3. Correspondingly, two guide tracks 1.2.2 are formed into opposite sides of the support body 1.2, whereas one guide pin 1.1.3 travels within one of the guide tracks 1.2.2.

The flexible arm 1.1.4 extends over a substantial axial length of the needle shield 1.1. A wedge-shaped cut-out 1.1.5 is formed into the needle shield 1.1 to allow for a deflection of the flexible arm 1.1.4 in the lateral direction L. The flexible arm 1.1.4 extends essentially parallel to the central axis A in its equilibrium position and, as indicated in figure 3 by a dashed line, is oriented at an acute angle with respect to the central axis A when the flexible arm 1.1.4 is laterally deflected. The flexible arm 1.1.4 in the laterally deflected state is stressed and biased towards its equilibrium position. The guide pin 1.1.3 moves along an arc and on a cylindrical surface of the needle shield 1.1 when the flexible arm 1.1.4 is laterally deflected.

Figure 4 shows a sectional view of the injection device D comprising the safety device 1 and the pre-filled syringe 2 retained within the support body 1.2. The pre-filled syringe 2 has a barrel 2.3 with a collar 2.4 and an inner cavity 2.3.1 that is in fluid communication with the hypodermic needle 2.1. The medication contained in the inner cavity 2.3.1 can be distally expelled through the hollow hypodermic needle 2.1 by a distal movement of a piston 2.5, which provides a liquid-tight seal of a proximal end of the inner cavity 2.3.1. The piston 2.5 is connected to a piston rod 2.6 proximally extending from a barrel 2.3, whereas the piston 2.5 is movable within the inner cavity 2.3.1 by actuating the piston rod 2.6.

A proximal end of the piston rod 2.6 abuts the closed distal end of the outer body 1.3, so that the piston 2.5 is movable in a distal direction by the distal displacement of the outer body 1.3 with respect to the support body 1.2.

Alternatively, the piston rod 2.6 is connected to the outer body 1.3 or an integral part of the outer body 1.3. This alternative embodiment has additional advantage of a low overall part count, so that manufacturing costs are reduced.

The needle shield 1.1 is in the initial position I surrounding the hypodermic needle 2.1 of the pre-filled syringe 2. A spring mean 1.4 is arranged within the safety device 1 in a partially energized state bearing distally against an inner surface of the needle shield 1.1 and proximally against an inner surface of the support body 1.2, thereby biasing these two parts 1.1, 1.2 away from each other. The spring mean 1.4 may be provided as a compression spring, a tension spring or a torsion spring. The needle shield 1.1 is retained in the initial position I by the guide pin 1.1.3 abutting against the support body 1.2 in the start position PS.

Figure 5 shows a perspective view of the needle shield 1.1 in a retracted position R that is substantially received within the support body 1.2. The guide pin 1.1.3, that is integral part of the needle shield 1.1 is in an intermediate position PI within the guide track 1.2.2 and in proximity of a proximal end thereof. The intermediate position PI corresponds to the retracted position R of the needle shield 1.1.

The support body 1.2 further comprises two clips 1.2.5 arranged diametrical opposite to each other. The clips 1.2.5 are located near the proximal end of the support body 1.2 and clamp to the collar 2.4 of the pre-filled syringe 2 to affix the pre-filled syringe 2 to the support body 1.2, so that the pre-filled syringe 2 is firmly retained within the support body 1.2.

Figure 6 shows a sectional view of the injection device D. The needle shield 1.1 is in the retracted position R, so that the hypodermic needle 2.1 distally protrudes the skin-contact flange 1.1.1 of the needle shield 1.1. The spring mean 1.4 that is arranged within the safety device 1 between the needle shield 1.1 and the support body 1.2 is compressed and thus fully energized.

Figure 7 shows a sectional view of the injection device D according to the first embodiment after the injection of the medication. The sectional view given in figure 7 is rotated with respect to the sectional views shown in figure 4 and 6 about an angle of 90 degrees around the central axis A. The needle shield 1.1 is in an advanced position E distally protruding from the support body 1.2, whereas the hypodermic needle 2.1 is surrounded by the needle shield 1.1 to avoid needle pricks. The needle shield 1.1 is fixed to the advanced position E by the guide pin 1.1.3 being retained in an end position PE in proximity of a distal end of the guide track 1.2.2.

The piston 2.5 is fully depressed inside the barrel 2.3 of the pre-filled syringe 2. The support body 1.2 is received within the outer body 1.3 and locked to it, so that a re-usage of the safety device 1 is prevented. An inwardly protruding locking catch 1.3.3 is formed to an inner surface of the outer body 1.3 that engages a corresponding locking recess 1.2.6 formed into the support body 1.2 to irreversibly lock the support body 1.2 with respect to the outer body 1.3.

Figure 8A to 8D show in detail the form of the guide track 1.2.2 according to the first embodiment of the invention and the movement of the guide pin 1.1.3 within and along the guide track 1.2.2 during an injection.

Prior to the injection, the guide pin 1.1.3 is retained by the flexing gate element 1.2.3 in the start position PS, as shown in figure 8A, affixing the needle shield 1.1 to the initial position I. In the initial position I, the hypodermic needle 2.1 is surrounded by the needle shield 1.1.

The needle shield 1.1 is made from an opaque plastics material, so that the hypodermic needle 2.1 is hidden from view of the patient throughout the injection.

Alternatively, the needle shield 1.1 is made from a transparent plastics material, so that a healthcare professional performing the injection may visually confirm the correct placement of the hypodermic needle 2.1 before penetrating the skin of the patient.

The injection is carried out by orientating the central axis A essentially perpendicular to the skin of the patient, whereas the skin-contact flange 1.1.1 of the needle shield 1.1 rests on the skin surface of the patient and the proximal section of the outer body 1.3 proximal of the hand flange 1.3.1 is gripped by the user performing the injection. The hand flange 1.3.1 supports the hand of the user to carry out an injection stroke.

The injection is carried out in stages. In a first stage, the needle shield 1.1 is pushed inside the support body 1.2 in the proximal direction against the biasing force of the spring mean 1.4. The guide pin 1.1.3 leaves its start position PS, whereby the flexing gate element 1.2.3, as indicated by figure 8B, is laterally deflected. The guide pin 1.1.3 passes the section of narrowed width and moves proximally along the guide track 1.2.2 until it reaches the intermediate position PI.

Figure 9 shows an alternative embodiment of the safety device 1. The longitudinal recess 1.3.2 is separated by a web 1.3.6 in a distal section 1.3.2.1 and a proximal section 1.3.2.2. During the first stage of the injection, the outward projection 1.2.4 is retained in the distal section 1.3.2.1 of the longitudinal recess 1.3.2 to block a relative movement of the outer body 1.3 relative to the support body 1.2 until the needle

shield 1.1 reaches the retracted position R and the guide pin the intermediate position PI .

As soon as the guide pin 1.1.3 passes the section of narrowed width as shown in figure 8B, the needle safety features, that in particular prevent re-usage of the injection device D and the safety device 1, are activated.

When the guide pin 1.1.3 is in the intermediate position PI, the needle shield 1.1 is in the retracted position R, so that the hypodermic needle 2.1 protrudes the skin-contact flange 1.1.1 and penetrates the skin of the patient. The hypodermic needle 2.1 protrudes the skin-contact flange 1.1.1 by a length that corresponds to a penetration depth of the hypodermic needle 2.1. The spring mean 1.4 is fully energized when the needle shield 1.1 is in the retracted position R.

In the alternative embodiment of figure 9, the continued force exerted upon the outer body 1.3 in the distal direction after the pre-defined penetration depth of the hypodermic needle 2.1 has been reached, causes the outward projection 1.2.4 to pass the web 1.3.6. The outward projection 1.2.4 protrudes into the proximal section 1.3.2.2 of the longitudinal recess 1.3.2 in the following second stage of the injection. As the proximal section 1.3.2.2 of the longitudinal recess 1.3.2 extends over a substantial length of the outer body 1.3, the outer body 1.3 becomes sildable with respect to the support body 1.2.

In the second stage, the outer body 1.3 moves with respect to the support body 1.2 in the distal direction. Simultaneously, the piston rod 2.6 interacting with the outer body 1.3 is actuated to move the piston 2.5 in the distal direction, whereby the medication contained in the inner cavity 2.3.1 is delivered through the hypodermic needle 2.1 and beneath the skin of the patient.

At the end of the injection stroke, the support body 1.2 is substantially received within the outer body 1.3. The locking catch 1.3.3 engages the locking recess 1.2.6 to permanently lock the support body 1.2 to the outer body 1.3.

The injection device D comprising the safety device 1 with the pre-filled syringe 2 received therein is taken away from the skin surface. The needle shield 1.1 immediately moves distally by the action of the relaxing spring mean 1.4 thereby re-sheathing the hypodermic needle 2.1. The guide pin 1.1.3 moves with the needle shield 1.1 distally, whereby it abuts a sloped section 1.2.3.1 of the flexing gate element 1.2.3 that is curved towards one side of the guide track 1.2.2, as illustrated in figure 8C. The flexing gate element 1.2.3 is laterally deflected towards said side of the guide track 1.2.2 preventing the guide pin 1.1.3 to re-enter the start position PS. The guide pin 1.1.3 is redirected by the sloped section 1.2.3.1 of the flexing gate element 1.2.3 in a lateral direction opposite to said side of the guide track 1.2.2, so that the guide pin 1.1.3 moves further distally towards the end position PE.

As the guide pin 1.1.3 travels in the distal and in the lateral direction, the flexible arm 1.1.4 is deflected laterally thereby biasing the guide pin 1.1.3 in the lateral direction towards the end position PE.

When the guide pin 1.1.3 reaches the distal most portion of the guide track 1.2.2 the guide pin 1.1.3 is moved by the action of the relaxing flexible arm 1.1.4 until it reaches the end position PE, as shown in figure 8D.

The guide pin 1.1.3 is securely retained in the end position PE and abuts the support body 1.2 in a proximal direction thereby preventing a subsequent proximal movement of the needle shield 1.1 relative to the support body 1.2. A lateral deflection of the guide pin 1.1.3 is prevented by the form of the guide track 1.2.2 at the end position PE and by the flexible arm 1.1.4.

The needle shield 1.1 is firmly retained in the advanced position E by the guide pin 1.1.3 being retained in the end position PE, whereby a re-usage of the injection device D and/or the safety device 1 is prevented.

In a possible embodiment of the invention, the hypodermic needle 2.1 is hidden from the view of the patient throughout the injection.

The injection is carried out and the needle safety features of the safety device 1 are activated by a single linear movement of outer body 1.3 towards the skin of the patient.

Figure 10 shows a perspective view of the injection device D according to a second embodiment of the invention. The support body 1.2 of the safety device 1 comprises at least one release flap 1.2.7 hinged to the support body 1.2. The release flap 1.2.7 protrudes outwards at an acute angle relative to the central axis A and is located in a longitudinal notch 1.2.8 formed into an outer surface of the support body 1.2, whereas the longitudinal notch 1.2.8 extends over a substantial axial length of the support body 1.2.

At least one inwardly protruding dent 1.3.4 is formed to an interior surface of the outer body 1.3 that is sized to move within and along the longitudinal notch 1.2.8 and over the release flap 1.2.7 when the outer body 1.3 is slid relative to the support body 1.2.

Preferably, two longitudinal notches 1.2.8 and two release flaps 1.2.7 are formed into opposite sides of the support body 1.2.

A cylindrical needle cap remover 3 is detachably attached to a distal end of the needle cap 2.2 frictionally held on a distal end of the pre-filled syringe 2 to facilitate removal of the needle cap 2.2 when the pre-filled syringe 2 is assembled within the safety device 1. The needle cap remover 3 has a proximal end that snugly fits over and frictionally engages the distal end of the needle cap 2.2, so that the needle cap 2.2 can be pulled off the pre-filled syringe 2 arranged inside the safety device 1 by a distal movement of the needle cap remover 3. The cylindrical needle cap remover 3 has an outer diameter that allows the needle cap remover 3 to be inserted into the distal end of the needle shield 1.1, so that the needle cap 2.2 can be easily pulled off the pre-filled syringe 2 even when the distal end of the needle cap 2.2 is surrounded by the needle shield 1.1.

As illustrated in figure 11, the needle shield 1.1 of the second embodiment comprises a retaining catch 1.1.6 that protrudes outwards into a recess formed by the release flap 1.2.7 to retain the needle shield 1.1 in the initial position I, in which the needle shield 1.1 protrudes the support body 1.2 in the retracted position R. Therefore, the recess formed by the release flap 1.2.7 extends over a length of the support body 1.2. The retaining catch 1.1.6 is slidable within the recess formed by the release flap 1.2.7 over a length of the support body 1.2.

The inwardly protruding dent 1.3.4 engages the release flap 1.2.7 when the support body 1.2 is substantially received within the outer body 1.3 at the end of the injection stroke. The release flap 1.2.7 pivots inwards and presses the retaining catch 1.1.6 in an inward direction to release the retaining catch 1.1.6 from engagement with the recess formed by the release flap 1.2.7. The needle shield 1.1 is moved by the action of the relaxing spring mean 1.4 from the retracted position R to the advanced position E that is shown in figure 12.

The needle shield 1.1 locks to the support body 1.2 in the advanced position E, whereas a subsequent proximal movement of the needle shield 1.1 with respect to the support body 1.2 is prevented by the retaining catch 1.1.6 protruding outwards into a distal indent 1.2.9 formed into the distal end of the support body 1.2. A distal movement of the needle shield 1.1 in the advanced position E is prevented by the guide pin 1.1.3 abutting the support body 1.2 in the end position PE, as best seen in figure 13.

Figure 13 shows the needle shield 1.1, the support body 1.2 and a pre-filled syringe 2 retained with the support body 1.2 according to the second embodiment of the invention. The needle shield 1.2 is in the advanced position E that corresponds to the end position PE of the guide pin 1.1.3 within the guide track 1.2.2.

Details of the guide track 1.2.2 according to the second embodiment can be seen in figure 13. The guide track 1.2.2 of second embodiment does not comprise the flexing gate element 1.2.3 of the first embodiment, as the needle shield 1.2 is retained in the initial position I by an interaction of the retaining catch 1.1.6 and the recess formed by

the release flap 1.2.7, as described herein above. The guide track 1.2.2 of the second embodiment is designed as a single continuous track. When the needle shield 1.1 is in the initial position I, the guide pin 1.1.3 is located in the start position PS within the guide track 1.2.2. The guide pin 1.1.3 is located in the intermediate position PI, when the needle shield 1.1 is in the retracted position R.

Figure 14 shows a perspective view of the injection device D according to a third embodiment of the invention. Prior to use of the safety device 1 or the injection device D comprising the safety device 1 and the pre-filled syringe 2 received therein, the needle shield 1.1 is in the retracted position R and retained within the support body 1.2. The hypodermic needle 2.1 of the pre-filled syringe 2 is exposed before the injection.

Furthermore, the support body 1.2 of the third embodiment may comprise a skin-contact surface 1.2.11 that is designed to rest on the skin of the patient receiving the injection similar to the skin-contact flange 1.1.1 of the needle shield 1.1 previously described herein before.

An axial tongue 1.2.12 is formed into the outer surface of the support body 1.2. The axial tongue 1.2.12 is received in a correspondingly formed groove when the outer body 1.3 is slid with respect to the support body 1.2 in the distal direction, whereby a relative rotation of the parts 1.2, 1.3 is prevented.

The outer body 1.3 comprises an inwardly protruding dent 1.3.4 that protrudes into a retaining notch 1.2.10 formed into the support body 1.2 to retain the outer body 1.3 relative to the support body 1.2 in a position, in which the support body 1.2 protrudes distally from the distal end of the outer body 1.3. The inwardly protruding dent 1.3.4 is outwardly deflectable when a sufficient force is exerted upon the outer body 1.3 in the distal direction, whereby the inwardly protruding dent 1.3.4 disengages the retaining notch 1.2.10 at the beginning of the injection stroke.

As illustrated in figure 15, an inward projection 1.3.5 is formed into an inner surface of the outer body 1.3. The inward projection 1.3.5 protrudes inwardly adjacent to the guide

track 1.2.2 and abuts the guide pin 1.1.3 to retain the guide pin 1.1.3 in the start position PS, thereby retaining the needle shield 1.1 in the retracted position R. In the third embodiment, the start position PS of the guide pin 1.1.3 is located in proximity of a proximal end of the guide track 1.2.2.

The inward projection 1.3.5 moves within and along a section of the guide track 1.2.2 during the injection stroke, as best seen in figure 16A to 16D.

Figure 16A shows the relative position of the inward projection 1.3.5 and the guide pin 1.1.3 within the guide track 1.2.2 when the needle shield 1.1 is in the retracted position R. The guide pin 1.1.3 is retained in the start position PS by an engagement with the inward projection 1.3.5, so that the needle shield 1.1 is retained in the retracted position R prior to use of the safety device 1.

Both the guide pin 1.1.3 and the inward projection 1.3.5 comprise substantially triangular cross-sections.

After the inwardly protruding dent 1.3.4 disengaged the retaining notch 1.2.10, the inward projection 1.3.5 is free to move along a proximal section of the guide track 1.2.2. The guide pin 1.1.3 follows the distal movement of the inward projection 1.3.5, as the spring mean 1.4 urges the needle shield 1.1 towards the advanced position E.

Figure 16B shows the position of the inward projection 1.3.5 and the guide pin 1.1.3 at the start of the drug delivery. The triangular shape of the inward projection 1.3.5 urges and redirects the guide pin 1.1.3 laterally into a section of the guide track 1.2.2 that is oriented relative to the central axis A at an acute angle. The safety features of the safety device 1 are activated when the guide pin 1.1.3 reaches the first position P1 shown in figure 16B and starts to move further along the guide track 1.2.2 in the distal direction, whereby the guide pin 1.1.3 is urged distally by the spring mean 1.4.

The flexible arm 1.1.4 is laterally deflected when the guide pin 1.1.3 moves along the section oriented at an acute angle relative to the central axis A, whereby the flexible arm 1.1.4 is stressed to bias the guide pin 1.1.3 in a lateral direction.

When the needle shield 1.1 abuts the skin of the patient, the guide pin 1.1.3 stops at a second position P2, as shown in figure 16C, and is prevented from moving further distally until the injection device D and/or safety device 1 is taken away from the injection site.

Figure 16D shows the guide pin 1.1.3 when it reached the end position PE. The guide pin 1.1.3 in the end position PE locks the needle shield 1.1 in the advanced position E. A lateral deflection of the guide pin 1.1.3 is prevented by both the form of the guide track 1.2.2 at the end position PE and by the flexible arm 1.1.4.

Figure 17 shows the safety device 1 of the third embodiment, whereas the needle shield 1.1 is locked in the advanced position E. The inwardly protruding dent 1.3.4 protrudes inwardly into the distal indent 1.2.9 to lock the outer body 1.3 with respect to the support body 1.2, whereby a relative movement of outer and support body 1.3, 1.2 is prevented.

Figures 18A to 18H illustrate alternative embodiments of the invention. The guide track 1.2.2 is formed into one of the support body 1.2 or the needle shield 1.1 and the flexible arm 1.1.4 is connected to, and in particular integral part of, the other of the support body 1.2 or the needle shield 1.1. Possible different orientations of the guide track 1.2, of the flexible arm 1.1.4 and of the cut-out 1.1.5 that are within the scope of the present invention are also shown. The flexible arm 1.1.4 has a bias to one of the lateral sides of the safety device 1.

Figure 18A shows an orientation of the guide track 1.2.2, of the flexible arm 1.1.4 and of the cut-out 1.1.5 according to the first embodiment described herein before.

Figure 18B shows an alternative embodiment, whereas the flexible arm 1.1.4 extends into the cut-out 1.1.5 from a proximal direction.

Figure 18C and 18D show other alternative embodiments, in which the guide track 1.2.2 is formed into the needle shield 1.1 and the flexible arm 1.1.4 is connected to the support body 1.2.

Figure 18E to 18H illustrate alternative embodiments of the invention, wherein the support body 1.2 is received within the needle shield 1.1 when the support body 1.2 and needle shield 1.1 are slid relative to each other.

List of References

1	safety device
1.1	needle shield
1.1.1	skin-contact flange
1.1.2	longitudinal tongue
1.1.3	guide pin
1.1.4	flexible arm
1.1.5	wedge-shaped cut-out
1.1.6	retaining catch
1.2	support body
1.2.1	longitudinal groove
1.2.2	guide track
1.2.3	flexing gate element
1.2.3.1	sloped section
1.2.4	outward projection
1.2.5	clip
1.2.6	locking recess
1.2.7	release flap
1.2.8	longitudinal notch
1.2.9	distal indent
1.2.10	retaining notch
1.2.11	skin-contact surface
1.2.12	axial tongue
1.3	outer body
1.3.1	hand flange
1.3.2	longitudinal recess
1.3.2.1	distal section
1.3.2.2	proximal section
1.3.3	locking catch
1.3.4	inwardly protruding dent

1.3.5	inward projection
1.3.6	web
1.4	spring mean
2	pre-filled syringe
2.1	hypodermic needle
2.2	needle cap
2.3	barrel
2.3.1	inner cavity
2.4	collar
2.5	piston
2.6	piston rod
3	needle cap remover
D	injection device
A	central axis
L	lateral direction
I	initial position
R	retracted position
E	advanced position
PS	start position
PI	intermediate position
PE	end position
P1	first position
P2	second position

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A safety device for a pre-filled syringe, comprising:

- a hollow support body to retain the pre-filled syringe therein,

- a piston rod for moving a piston within an inner cavity of the pre-filled syringe,

- a longitudinal notch formed into an outer surface of the support body,

- an outer body slidably arranged relative to the support body, wherein an inwardly protruding dent is formed into an inner surface of the substantially hollow outer body that is received in the longitudinal notch, wherein a proximal end of the piston rod abuts with or is an integral part of the outer body,

- a hollow needle shield that slidable relative to the support body and

- guiding means for guiding the movement of the needle shield relative to the support body, wherein the guiding means comprise

- a deflectable flexible arm with a guide pin radial extending therefrom, the flexible arm extending essentially parallel to a central axis of the safety device and

- a guide track that guides the guide pin within and along the guide track so that the guide pin follows the guide track when the needle shield is slid relative to the support body,

- whereby the flexible arm is laterally deflected as the guide pin moves along a section of the guide track oriented at an acute angle relative to the central axis,

- whereby the flexible arm is connected to or is integrally formed to the needle shield or the support body and the guide track is formed into the other of the needle shield or the support body,

wherein the guiding means further comprise a longitudinal tongue that is received in a longitudinal groove when the needle shield is moved with respect to the support body in a distal direction, whereby a relative rotation of the needle shield and the support body is prevented.

2. A safety device according to one of the previous claims, characterized in that the flexible arm is deflectable and energizable by the action of a relaxing spring mean.

3. A safety device according to one of the previous claims, characterized in that the guide pin is located in an intermediate position in proximity of a proximal end of the guide track, when the needle shield is in a retracted position, and in an end position in proximity of a distal end of the guide track, when the needle shield is an advanced position, whereas the needle shield is substantially received in the support body in the retracted position and protrudes the distal end of the support body in the advanced position.

4. A safety device according to one of the previous claims, characterized in that the guide pin in a start position, in the end position and in the intermediate position is non-biased in a lateral direction perpendicular to the central axis.

5. A safety device according to one of the previous claims, characterized in that the flexible arm is deflected to bias the guide pin in the lateral direction when the guide pin moves along the guide track from the intermediate position towards the end position.

6. A safety device according to one of the previous claims, characterized in that the needle shield protrudes the support body in an initial position and that the spring mean is in a partially energized state when the needle shield is in the initial position.

7. A safety device according to one of the previous claims, characterized in that the needle shield is retained in an initial position by a flexing gate element retaining the guide pin in a start position between the distal and the proximal end of the guide track.

8. A safety device according to claim 7,
characterized in that the flexing gate element guides the movement of the guide pin within the guide track.

9. A safety device according to claim 7 or 8,
characterized in that the flexing gate element is deflectable in a lateral direction as to allow the guide pin to move from the start position towards the intermediate position.

10. A safety device according to claims 7 to 9,
characterized in that a sloped section of the flexing gate element guides the movement of the guide pin along a section of the guide track and prevents the guide pin from re-entering the start position.

11. A safety device according to one of the previous claims,
characterized in that the needle shield further comprises at least one radial outwardly protruding retaining catch to releasably retain the needle shield in the retracted position and the support body further comprises at least one release flap hinged to the support body, whereas an interior surface of an outer body engages the release flap that presses the retaining catch inwardly to release the needle shield.

12. A safety device according to one of the previous claims,
characterized in that the outer body comprises an inward projection that abuts the guide pin in an intermediate position to retain the needle shield in a retracted position.

13. A safety device according to claim 12,
characterized that the guide pin and the inward projection comprise a substantially triangular cross-section.

14. A safety device according to claim 12 or 13,
characterized in that the inward projection moves along a section of the guide track thereby releasing the needle shield from being retained in the retracted position.

15. An injection device comprising a safety device according to one of the previous claims and a pre-filled syringe, wherein the pre-filled syringe is retained within the support body of the safety device, so that the hypodermic needle protrudes the distal end of the support body, whereas the hypodermic needle is surrounded by the needle shield in the initial position and/or in the advanced position and the hypodermic needle is exposed when the needle shield is in the retracted position.