WEARABLE AUTOMATIC INJECTION DEVICE FOR CONTROLLED DELIVERY OF THERAPEUTIC AGENTS

Related Applications

This application is related to and claims priority to U.S. Provisional Application Serial No. 61/326,637, filed April 21, 2010, the entire contents of which are expressly incorporated herein by reference in their entirety.

Background

Automatic injection devices offer an alternative to manually-operated syringes for delivering therapeutic agents into patients' bodies and allowing patients to self-administer injections. Automatic injection devices have been used to deliver medications under emergency conditions, for example, to administer epinephrine to counteract the effects of a severe allergic reaction. Automatic injection devices have also been described for use in administering anti-arrhythmic medications and selective thrombolytic agents during a heart attack (*See*, e.g., U.S. Patent Nos. 3,910,260; 4,004,577; 4,689,042; 4,755,169; and 4,795,433). Various types of automatic injection devices are also described in, for example, U.S. Patent Nos. 3,941,130; 4,261,358; 5,085,642; 5,092,843; 5,102,393; 5,267,963; 6,149,626; 6,270,479; and 6,371,939; and International Patent Publication No. WO/2008/005315.

Conventionally, an automatic injection device houses a syringe and, when operated, causes the syringe to move forwardly and a needle to project from the housing so that a therapeutic agent contained in the syringe is ejected into a patient's skin. An automatic injection device typically includes a bung disposed within the syringe that, when actuated, moves within the syringe to expel the therapeutic agent from the syringe and into the patient's skin.

Summary

Exemplary examples provide wearable automatic injection devices that may adhere to the skin or clothing of a patient and deliver a therapeutic agent into the patient's body by subcutaneous injection at slow, controlled injection rates, e.g., in a single slow bolus. Exemplary examples provide methods of assembling exemplary wearable automatic injection devices. Exemplary examples also provide methods of

using wearable automatic injection devices worn by a patient for slow, controlled therapeutic agent delivery. Exemplary wearable automatic injection devices reduce or eliminate a burning sensation often felt or perceived by patients who use a conventional automatic injection device. Exemplary wearable automatic injection devices maintain the sterility of the therapeutic agent container (e.g., syringe), are easy to use, pre-fill capable, easy to manufacture, and/or do not require aseptic assembly. The wearable automatic injection devices provided by exemplary examples may adhere to the skin or clothing of the patient to deliver any therapeutic agent subcutaneously including, but not limited to, a biologic drug, such as, for example, an antibody, insulin, etc.

In accordance with an exemplary example, a wearable automatic injection device is provided for providing a subcutaneous injection of a therapeutic agent into a patient. The device includes a housing comprising a patient contact portion securable to the patient. The device also includes an injection assembly moveably disposed in the housing holding a hypodermic injection needle for insertion into the patient, the injection assembly moveable between a retracted position in which the injection needle does not protrude outside the housing and an extended position in which the injection needle protrudes outside the housing. The device also includes a vessel provided in the housing for holding the therapeutic agent, a plunger moveably disposed in the vessel for ejecting the therapeutic agent from the vessel into the injection assembly, and a plunger actuation mechanism for actuating the plunger within the vessel. The device also includes a retraction trigger responsive to a change of state of the wearable automatic injection device from an injection state to a post-injection state, and a retraction mechanism for automatically retracting the injection assembly from the extended position in the injection state to the retracted position in the post-injection state upon triggering by the retraction trigger.

In one aspect, the present disclosure refers to a wearable automatic injection device for injecting a therapeutic agent into a patient, the wearable automatic injection device comprising:

a housing having a patient contact portion securable to a patient;

a vessel in the housing for holding a therapeutic agent;

a bung disposed in the vessel;

a syringe needle fluidically couplable to the vessel;

an injection assembly moveably disposed in the housing having an injection needle for insertion into the patient and fluidically couplable with the syringe needle;

a fluid-based plunger actuation mechanism having a pressure element providing a hydraulic pressure to an incompressible working fluid held therein, and one or more fluid circuits to transport the incompressible working fluid from the pressure element into fluid communication with the bung to provide a force thereto to eject the therapeutic agent from the vessel; and

a delivery trigger that when activated releases the working fluid into fluid communication with the bung and generates a fluid pressure to advance the bung within the vessel.

In another aspect, the present disclosure refers to a wearable automatic injection device for injecting a therapeutic agent into a patient, the wearable automatic injection device comprising:

a housing having a patient contact portion securable to the patient;

a vessel in the housing for holding the therapeutic agent;

a bung disposed in the vessel;

a syringe needle fluidically couplable to the vessel;

an injection assembly moveably disposed in the housing having an injection needle for insertion into the patient and fluidically couplable with the syringe needle; and

a mechanical-based plunger actuation mechanism for actuating the bung within the vessel, wherein the plunger actuation mechanism comprises:

a biasing mechanism;

a fusee; and

a tether coupling the biasing mechanism to the fuse.

In accordance with another exemplary example, a method is provided for subcutaneously injecting a therapeutic agent into a patient. The method includes providing a wearable automatic injection device including a housing comprising a patient contact portion securable to the patient. The device also includes an injection assembly moveably disposed in the housing holding a hypodermic injection needle for insertion into the patient, the injection assembly moveable between a retracted position

in which the injection needle does not protrude outside the housing and an extended position in which the injection needle protrudes outside the housing. The device also includes a vessel provided in the housing for holding the therapeutic agent, a plunger moveably disposed in the vessel for ejecting the therapeutic agent from the vessel into the injection assembly, and a plunger actuation mechanism for actuating the plunger within the vessel. The device also includes a retraction trigger responsive to a change of state of the wearable automatic injection device from an injection state to a post-injection state, and a retraction mechanism for automatically retracting the injection assembly from the extended position in the injection state to the retracted position in the post-injection state upon triggering by the retraction trigger. The method includes securing the wearable automatic injection device to the skin of the patient or an article of clothing on the patient using the patient contact of the housing. The method also includes administering the therapeutic agent into the skin of the patient using the wearable automatic injection device.

In accordance with another exemplary example, a wearable automatic injection device is provided for subcutaneously injecting a therapeutic agent into a patient. The device includes a housing and a cartridge assembly movably disposed within the housing. The cartridge includes a barrel portion for holding the therapeutic agent, and a hollow needle in fluid communication with the barrel portion for ejecting the therapeutic agent from the barrel portion. The cartridge also includes a bung for sealing the barrel portion and selectively applying pressure to the therapeutic agent to force the therapeutic agent through the hollow needle. The cartridge further includes a plunger actuator for applying pressure to the bung, and a trigger mechanism that actuates the plunger actuator to apply pressure to the bung when the cartridge is depressed from a ready position (in a pre-injection state) to a depressed position (in an injection state) inside the housing. The trigger mechanism actuates the plunger actuator such that the therapeutic agent is ejected from the barrel portion and into the patient at a controlled, slow rate with little or no burning sensation felt or perceived by the patient. The device also includes a fastener layer disposed on a patient contact surface to fasten the device to the skin or clothing of the patient or to an article of clothing of the patient. The fastener layer may include an adhesive for temporarily securing the wearable automatic injection device to the patient at least during the controlled injection of the therapeutic agent.

The wearable automatic injection device includes a retraction mechanism that retracts the cartridge from the depressed position to a retracted position (in a post-injection state). The wearable automatic injection device also includes a retraction trigger that activates the retraction mechanism, the retraction trigger trips when delivery of the therapeutic agent completes, or times out due an elapsed period of time, or when the wearable automatic injection device is removed from the patient, for example, before delivery of the therapeutic agent is completed. The wearable automatic injection device operates and functions entirely on mechanical principles or in combination with a controlled reaction to transition from any state (i.e., a pre-injection state, an injection state, a post-injection state), and controls the injection rate of the therapeutic agent over a time period that is selected for patient comfort, convenience or preference, or exceeds a time period for injection by a conventional automatic handheld device. In an exemplary example, the time period of the injection by an exemplary wearable automatic injection device may range between about ten seconds and about twelve hours. In a preferred example, the time period may range between about five minutes and about thirty minutes.

In another exemplary example, a method is provided for subcutaneously injecting a therapeutic agent into a patient. The method includes providing a wearable automatic injection device comprising a housing and a cartridge assembly movably disposed within the housing. The cartridge includes a barrel portion for holding a therapeutic agent, and a hollow needle in fluid communication with the barrel portion for ejecting the therapeutic agent from the barrel portion. The cartridge also includes a bung for sealing the barrel portion and selectively applying pressure to the therapeutic agent to force the therapeutic agent through the hollow needle. The cartridge further includes a plunger actuator for applying pressure to the bung, and a trigger mechanism that actuates the plunger actuator to apply pressure to the bung when the cartridge is depressed from a ready position (in a pre-injection state) to a depressed position (in an injection state) inside the housing. The trigger mechanism actuates the plunger actuator such that the therapeutic agent is ejected from the barrel portion and into the patient at a controlled, slow rate and substantially free of any burning sensation.

The method also includes depressing the cartridge from the ready position to a depressed position within the housing. Depressing the cartridge automatically causes the injection needle that is used to pierce the patient's skin to project from an opening in the housing to penetrate the skin of the patient, and actuates the plunger actuator to apply pressure to the bung such that the therapeutic agent is delivered into the patient at a controlled, slow rate and substantially free of any burning sensation.

The method further includes automatically retracting the cartridge from the depressed to a retracted position (in a post-injection state) in the housing when delivery of the therapeutic agent is completed, or times out due to an elapsed period of time, or when the wearable automatic injection device is removed from the skin or clothing of the patient, for example, before delivery of the therapeutic agent is completed.

In an exemplary example, a wearable automatic injection device is provided. The wearable automatic injection device provides a subcutaneous injection of a therapeutic agent into a patient. The wearable automatic injection device includes a housing having a patient contact portion securable to the patient and an interior portion defined by a plurality of walls and defining at least one open end opposing the patient contact portion. The wearable automatic injection device also includes a cartridge assembly movably disposed within the interior portion of the housing and movable from any of a ready position, an injection position, and a retraction position. The wearable automatic injection device further includes a trigger mechanism responsive to a change in state of the wearable automatic injection device from a pre-injection state to an injection state to actuate a plunger actuator disposed in the cartridge assembly to begin ejection of a therapeutic agent from the cartridge assembly, and a retraction trigger responsive to a change of state of the wearable automatic injection device from the injection state to a post-injection state. The wearable automatic injection device also includes a retraction mechanism responsive to the retraction trigger to automatically retract the cartridge assembly from the patient when the automatic injection device enters the post-injection state.

In another exemplary example, a method of subcutaneously injecting a therapeutic agent into a patient is provided. The method includes securing to a patient a wearable automatic injection device comprising a housing having a patient contact

CLAIMS

What is claimed is:

1. A wearable automatic injection device for injecting a therapeutic agent into a patient, the wearable automatic injection device comprising:

a housing having a patient contact portion securable to a patient;

a vessel in the housing for holding a therapeutic agent;

a bung disposed in the vessel;

a syringe needle fluidically couplable to the vessel;

an injection assembly moveably disposed in the housing having an injection needle for insertion into the patient and fluidically couplable with the syringe needle;

a fluid-based plunger actuation mechanism having a pressure element providing a hydraulic pressure to an incompressible working fluid held therein, and one or more fluid circuits to transport the incompressible working fluid from the pressure element into fluid communication with the bung to provide a force thereto to eject the therapeutic agent from the vessel; and

a delivery trigger that when activated releases the working fluid into fluid communication with the bung and generates a fluid pressure to advance the bung within the vessel.

2. The wearable automatic injection device of claim 1, wherein the plunger actuation mechanism further comprises:

a fluid conduit provided between the pressure element and the plunger.

3. The wearable automatic injection device of claim 2, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the vessel and the pressure element to regulate the ejection of the therapeutic agent from the vessel.

4. The wearable automatic injection device of claim 3, wherein the damping mechanism comprises a flow restrictor for maintaining the hydraulic pressure downstream of the flow restrictor toward the vessel at a lower pressure that the hydraulic pressure upstream of the flow restrictor toward the source of the working fluid.

5. The wearable automatic injection device of claim 5, wherein the pressure element is coupled to the flow restrictor using a tubing.

6. The wearable automatic injection device of claim 1, wherein the working fluid includes one of water or oil.

7. The wearable automatic injection device of claim 1, wherein the pressure element includes one of an elastic bladder, a master cylinder, or a spring-loaded syringe.

8. A wearable automatic injection device for injecting a therapeutic agent into a patient, the wearable automatic injection device comprising:

a housing having a patient contact portion securable to the patient;

a vessel in the housing for holding the therapeutic agent;

a bung disposed in the vessel;

a syringe needle fluidically couplable to the vessel;

an injection assembly moveably disposed in the housing having an injection needle for insertion into the patient and fluidically couplable with the syringe needle; and

a mechanical-based plunger actuation mechanism for actuating the bung within the vessel, wherein the plunger actuation mechanism comprises:

a biasing mechanism;

a fusee; and

a tether coupling the biasing mechanism to the fusee.

9. The wearable automatic injection device of claim 8, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the fusee for regulating the movement of the fusee; and

a gear train including one or more gears for coupling the fusee to the damping mechanism.

10. The wearable automatic injection device of claim 9, wherein the damping mechanism comprises a viscous damper.

11. The wearable automatic injection device of claim 9, wherein the damping mechanism comprises an escapement mechanism.

12. The wearable automatic injection device of claim 11, wherein the escapement mechanism is a swiss lever escapement.

13. The wearable automatic injection device of claim 11, wherein the escapement mechanism is a runaway escapement.

14. The wearable automatic injection device of any one of claims 1 or 8, wherein the vessel is moveably disposed within the housing, and further comprises a vessel actuator for automatically actuating the vessel from a first position in the pre-injection state to a second position in the injection state.

15. The wearable automatic injection device of any one of claims 1 or 8, further comprising:

a pierceable septum separating the syringe needle from the sterile fluid conduit in a pre-injection state, wherein the vessel moves in an injection state causing the syringe needle to pierce the septum and establishing fluid communication between the syringe needle and the injection needle.

16. The wearable automatic injection device of any one of claims 1 or 8, wherein the plunger actuation mechanism and the patient contact portion are non-sterile.

17. The wearable automatic injection device of any one of claims 1 or 8, wherein the housing is non-sterile.

18. The wearable automatic injection device of any one of claims 1 or 8, wherein the plunger actuation mechanism includes a flow restrictor to regulate a rate of delivery of the therapeutic agent into the patient.

19. The wearable automatic injection device of any one of claims 1 or 8, further comprising:

a needle locking mechanism for automatically locking the injection needle in a retracted position within the housing in a post-injection state.

20. The wearable automatic injection device of claim 19, wherein the needle locking mechanism comprises:

a barrier mechanism moveably disposed over an injection needle aperture in the housing;

wherein the injection needle aperture is open and allows the injection needle to protrude outside the housing when the barrier mechanism is in a first position; and

wherein the injection needle aperture is closed and prevents the injection needle from protruding outside the housing when the barrier mechanism is in a second position.

21. The wearable automatic injection device of claim 19, wherein the needle locking mechanism comprises:

a needle lock release mechanism responsive to retraction of the injection assembly from an extended position in the injection state to a retracted position in the post-injection state; and

a pivoting member coupled to the injection needle and to the needle lock release mechanism;

wherein activation of the needle lock release mechanism causes the pivoting member to pivot the injection needle away from an injection needle aperture in the housing.

22. The wearable automatic injection device of any one of claims 1 or 8, further comprising a transfer mechanism defining a sterile fluid conduit between the syringe needle and the injection needle.

23. The wearable automatic injection device of claim 22, wherein the transfer mechanism comprises an adapter coupled to the syringe needle and the injection needle establishing the sterile fluid conduit between the syringe needle and the injection needle.

24. The wearable automatic injection device of claim 23, wherein the first portion of the adapter substantially envelopes a distal end of the vessel.

25. The wearable automatic injection device of claim 22, wherein the sterile fluid conduit comprises raised wall portions extending along the edges of the centrally extending channel to constrain the therapeutic agent to the channel.

26. The wearable automatic injection device of any one of claims 1 or 8, wherein the wearable automatic injection device is operable without electrical power.

27. The wearable automatic injection device of any one of claims 1 or 8, wherein the therapeutic agent is delivered in a linear delivery profile at a constant linear flow rate.