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

In one aspect, there is provided a wearable automatic injection device free of a battery for providing a subcutaneous injection of a therapeutic agent into a patient, the wearable automatic injection device comprising:

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

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;

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;

a plunger actuation mechanism for actuating the plunger using a mechanical or hydraulic mechanism within the vessel;

a retraction trigger responsive to a change of state of the wearable automatic injection device from an injection state to a post-injection state, wherein the wearable automatic injection device enters the post-injection state upon completion of delivery of a therapeutically effective dose of the therapeutic agent and enters the post-injection state upon removal of the wearable automatic injection device from the patient prior to completion of delivery of the therapeutically effective dose of the therapeutic agent; 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.

Exemplary embodiments 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 embodiments provide methods of assembling exemplary wearable automatic injection devices. Exemplary embodiments also provide methods of

CLAIMS

What is claimed is:

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

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

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;

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;

a plunger actuation mechanism for actuating the plunger within the vessel;

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.

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

an interior portion defined by a plurality of walls and defining at least one open end opposing the patient contact portion.

3. The wearable automatic injection device of claim 1, further comprising:

a cover portion covering the open end of the housing.

4. The wearable automatic injection device of claim 1, wherein the housing is provided as a unitary cover coupled to a base that forms the patient contact portion.

5. The wearable automatic injective device of claim 1, wherein the housing is provided as a plurality of walls defining at least one open end opposing the patient contact portion.

6. The wearable automatic injection device of claim 1, further comprising:

an adhesive layer provided on the patient contact portion of the housing for attaching the housing to the patient.

7. The wearable automatic injection device of claim 1, further comprising:

an inspection window disposed in the housing that allows the user to inspect the therapeutic agent held by the vessel from outside the housing.

8. The wearable automatic injection device of claim 1, wherein the vessel comprises a syringe.

9. The wearable automatic injection device of claim 8, wherein the syringe comprises:

a barrel portion for holding the therapeutic agent; and

a syringe needle coupled to a distal end of the barrel portion for establishing fluid communication between the barrel portion of the syringe and the injection needle.

10. The wearable automatic injection device of claim 9, wherein the injection assembly comprises:

a septum that is pierceable by the syringe needle of the syringe; and

a fluid conduit extending between the injection needle and the septum, wherein piercing of the septum by the syringe needle of the syringe couples the barrel portion of the syringe and the injection needle.

11. The wearable automatic injection device of claim 10, wherein the syringe needle of the syringe is spaced from the septum when the device is in a pre-injection state, and wherein the syringe needle pierces the septum when the device is in the injection state.

12. The wearable automatic injection device of claim 1, wherein the vessel comprises a cartridge.

13. The wearable automatic injection device of claim 12, wherein the cartridge comprises:

a barrel portion for holding the therapeutic agent; and

a septum that is pierceable by a piercing needle.

14. The wearable automatic injection device of claim 13, wherein the injection assembly comprises:

the piercing needle for establishing fluid communication between the barrel portion of the cartridge and the injection needle; and

a fluid conduit provided between the injection needle and the piercing needle for establishing fluid communication between the injection needle and the barrel portion of the cartridge.

15. The wearable automatic injection device of claim 14, wherein piercing of the septum by the piercing needle of the injection assembly establishes fluid communication between the barrel portion of the cartridge and the injection needle.

16. The wearable automatic injection device of claim 15, wherein the septum of the cartridge is spaced from the piercing needle of the injection assembly when the device is in a pre-injection state, and wherein the piercing needle pierces the septum when the device is in the injection state.

17. The wearable automatic injection device of claim 1, wherein the vessel is moveably disposed within the housing.

18. The wearable automatic injection device of claim 17, wherein the vessel is moveable between a first position in a pre-injection state and a second position in the injection state.

19. The wearable automatic injection device of claim 18, further comprising:

a vessel actuator for automatically actuating the vessel from the first position to the second position.

20. The wearable automatic injection device of claim 19, wherein a fluid pathway is established between the injection needle and the vessel when the injection assembly is in the extended position and the vessel is in the second position in the injection state.

21. The wearable automatic injection device of claim 1, wherein the plunger actuation mechanism ejects the therapeutic agent into the patient at a controlled rate.

22. The wearable automatic injection device of claim 1, wherein the plunger actuation mechanism comprises a biasing mechanism.

23. The wearable automatic injection device of claim 22, wherein the plunger actuation mechanism further comprises:

a fusee; and

a tether coupling the biasing mechanism to the fusee and the plunger.

24. The wearable automatic injection device of claim 23, 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.

25. The wearable automatic injection device of claim 24, wherein the damping mechanism comprises a viscous damper.

26. The wearable automatic injection device of claim 24, wherein the damping mechanism comprises an escapement mechanism.

27. The wearable automatic injection device of claim 26, wherein the escapement mechanism is a swiss lever escapement.

28. The wearable automatic injection device of claim 26, wherein the escapement mechanism is a runaway escapement.

29. The wearable automatic injection device of claim 22, wherein the plunger actuation mechanism further comprises:

one or more ball bearings for coupling the biasing mechanism to the plunger.

30. The wearable automatic injection device of claim 29, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the biasing mechanism and the ball bearings for regulating the movement of the ball bearings.

31. The wearable automatic injection device of claim 30, wherein the damping mechanism comprises a viscous damper.

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

a source of a working fluid for providing a hydraulic pressure to eject the therapeutic agent from the vessel; and

a fluid conduit provided between the source of the working fluid and the plunger.

33. The wearable automatic injection device of claim 32, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the vessel and the source of the working fluid to regulate the ejection of the therapeutic agent from the vessel.

34. The wearable automatic injection device of claim 33, 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.

35. The wearable automatic injection device of claim 34, wherein the flow restrictor is coupled to the retraction trigger and wherein delivery of the therapeutic agent in the vessel causes the flow restrictor to activate the retraction trigger.

36. The wearable automatic injection device of claim 1, further comprising:

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

37. The wearable automatic injection device of claim 36, 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.

38. The wearable automatic injection device of claim 36, wherein the needle locking mechanism comprises:

a needle lock release mechanism responsive to retraction of the injection assembly from the extended position in the injection state to the retraction 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.

39. The wearable automatic injection device of claim 1, wherein the post-injection state comprises completion of delivery of a therapeutically effective dose of the therapeutic agent and removal of the wearable automatic injection device from the patient prior to completion of delivery of a therapeutically effective dose of the therapeutic agent.

40. The wearable automatic injection device of claim 1, wherein the therapeutic agent comprises a protein in a solution.

41. The wearable automatic injection device of claim 40, wherein the protein comprises any of a fusion protein, an enzyme, an antibody, or an antigen-binding fragment thereof in a solution.

42. The wearable automatic injection device of claim 41, wherein the antibody is a dual specificity antibody.

43. A method for subcutaneously injecting a therapeutic agent into a patient, the method comprising:

providing a wearable automatic injection device, comprising:

a housing comprising a patient contact portion securable to the patient,

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,

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,

a plunger actuation mechanism for actuating the plunger within the vessel,

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;

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; and

administering the therapeutic agent into the skin of the patient using the wearable automatic injection device.

44. The method of claim 43, wherein the vessel comprises a syringe.

45. The method of claim 44, wherein the syringe comprises:

a barrel portion for holding the therapeutic agent; and

a syringe needle coupled to a distal end of the barrel portion for establishing fluid communication between the barrel portion of the syringe and the injection needle.

46. The method of claim 45, wherein the injection assembly comprises:

a septum that is pierceable by the syringe needle of the syringe; and

a fluid conduit extending between the injection needle and the septum, wherein piercing of the septum by the syringe needle of the syringe couples the barrel portion of the syringe and the injection needle.

47. The method of claim 46, wherein the syringe needle of the syringe is spaced from the septum when the device is in a pre-injection state, and wherein the syringe needle pierces the septum when the device is in the injection state.

48. The method of claim 43, wherein the vessel comprises a cartridge.

49. The method of claim 48, wherein the cartridge comprises:

a barrel portion for holding the therapeutic agent; and

a septum that is pierceable by a piercing needle.

50. The method of claim 49, wherein the injection assembly comprises:

the piercing needle for establishing fluid communication between the barrel portion of the cartridge and the injection needle; and

a fluid conduit provided between the injection needle and the piercing needle for establishing fluid communication between the injection needle and the barrel portion of the cartridge.

51. The method of claim 50, wherein piercing of the septum by the piercing needle of the injection assembly establishes fluid communication between the barrel portion of the cartridge and the injection needle.

52. The method of claim 51, wherein the septum of the cartridge is spaced from the piercing needle of the injection assembly when the device is in a pre-injection state, and wherein the piercing needle pierces the septum when the device is in the injection state.

53. The method of claim 43, wherein the vessel is moveably disposed within the housing.

54. The method of claim 53, wherein the vessel is moveable between a first position in a pre-injection state and a second position in the injection state.

55. The method of claim 54, wherein the wearable automatic injection device further comprises:

a vessel actuator for automatically actuating the vessel from the first position to the second position.

56. The method of claim 55, wherein a fluid pathway is established between the injection needle and the vessel when the injection assembly is in the extended position and the vessel is in the second position in the injection state.

57. The method of claim 43, wherein the plunger actuation mechanism ejects the therapeutic agent into the patient at a controlled rate.

58. The method of claim 43, wherein the plunger actuation mechanism comprises a biasing mechanism.

59. The method of claim 58, wherein the plunger actuation mechanism further comprises:

a fusee; and

a tether coupling the biasing mechanism to the fusee and the plunger.

60. The method of claim 59, 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.

61. The method of claim 60, wherein the damping mechanism comprises a viscous damper.

62. The method of claim 60, wherein the damping mechanism comprises an escapement mechanism.

63. The method of claim 62, wherein the escapement mechanism is a swiss lever escapement.

64. The method of claim 62, wherein the escapement mechanism is a runaway escapement.

65. The method of claim 59, wherein the plunger actuation mechanism further comprises:

one or more ball bearings for coupling the biasing mechanism to the plunger.

66. The method of claim 65, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the biasing mechanism and the ball bearings for regulating the movement of the ball bearings.

67. The method of claim 66, wherein the damping mechanism comprises a viscous damper.

68. The method of claim 43, wherein the plunger actuation mechanism further comprises:

a source of a working fluid for providing a hydraulic pressure to eject the therapeutic agent from the vessel; and

a fluid conduit provided between the source of the working fluid and the plunger.

69. The method of claim 68, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the vessel and the source of the working fluid to regulate the ejection of the therapeutic agent from the vessel.

70. The method of claim 69, 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.

71. The method of claim 70, wherein the flow restrictor is coupled to the retraction trigger and wherein delivery of the therapeutic agent in the vessel causes the flow restrictor to activate the retraction trigger.

72. The method of claim 43, wherein the wearable automatic injection device further comprises:

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

73. The method of claim 72, 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.

74. The method of claim 72, wherein the needle locking mechanism comprises:

a needle lock release mechanism responsive to retraction of the injection assembly from the extended position in the injection state to the retraction 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.

75. The method of claim 43, wherein the post-injection state comprises completion of delivery of a therapeutically effective dose of the therapeutic agent and removal of the wearable automatic injection device from the patient prior to completion of delivery of a therapeutically effective dose of the therapeutic agent.

76. The method of claim 43, wherein the therapeutic agent comprises a protein in a solution.

77. The method of claim 76, wherein the protein comprises any of a fusion protein, an enzyme, an antibody, or an antigen-binding fragment thereof in a solution.

78. The method of claim 77, wherein the antibody is a dual specificity antibody.

CLAIMS

What is claimed is:

1. A wearable automatic injection device free of a battery for providing a subcutaneous injection of a therapeutic agent into a patient, the wearable automatic injection device comprising:

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

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;

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;

a plunger actuation mechanism for actuating the plunger using a mechanical or hydraulic mechanism within the vessel;

a retraction trigger responsive to a change of state of the wearable automatic injection device from an injection state to a post-injection state, wherein the wearable automatic injection device enters the post-injection state upon completion of delivery of a therapeutically effective dose of the therapeutic agent and enters the post-injection state upon removal of the wearable automatic injection device from the patient prior to completion of delivery of the therapeutically effective dose of the therapeutic agent; 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.

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

an interior portion defined by a plurality of walls and defining at least one open end opposing the patient contact portion.

3. The wearable automatic injection device of claim 1, further comprising:

a cover portion covering the open end of the housing.

4. The wearable automatic injection device of claim 1, wherein the housing is provided as a unitary cover coupled to a base that forms the patient contact portion.

5. The wearable automatic injective device of claim 1, wherein the housing is provided as a plurality of walls defining at least one open end opposing the patient contact portion.

6. The wearable automatic injection device of claim 1, further comprising:
an adhesive layer provided on the patient contact portion of the housing for attaching the housing to the patient.

7. The wearable automatic injection device of claim 1, further comprising:
an inspection window disposed in the housing that allows the user to inspect the therapeutic agent held by the vessel from outside the housing.

8. The wearable automatic injection device of claim 1, wherein the vessel comprises a syringe.

9. The wearable automatic injection device of claim 8, wherein the syringe comprises:
a barrel portion for holding the therapeutic agent; and
a syringe needle coupled to a distal end of the barrel portion for establishing fluid communication between the barrel portion of the syringe and the injection needle.

10. The wearable automatic injection device of claim 9, wherein the injection assembly comprises:
a septum that is pierceable by the syringe needle of the syringe; and
a fluid conduit extending between the injection needle and the septum, wherein piercing of the septum by the syringe needle of the syringe couples the barrel portion of the syringe and the injection needle.

11. The wearable automatic injection device of claim 10, wherein the syringe needle of the syringe is spaced from the septum when the device is in a pre-injection state, and wherein the syringe needle pierces the septum when the device is in the injection state.

12. The wearable automatic injection device of claim 1, wherein the vessel comprises a cartridge.

13. The wearable automatic injection device of claim 12, wherein the cartridge comprises:

a barrel portion for holding the therapeutic agent; and

a septum that is pierceable by a piercing needle.

14. The wearable automatic injection device of claim 13, wherein the injection assembly comprises:

the piercing needle for establishing fluid communication between the barrel portion of the cartridge and the injection needle; and

a fluid conduit provided between the injection needle and the piercing needle for establishing fluid communication between the injection needle and the barrel portion of the cartridge.

15. The wearable automatic injection device of claim 14, wherein piercing of the septum by the piercing needle of the injection assembly establishes fluid communication between the barrel portion of the cartridge and the injection needle.

16. The wearable automatic injection device of claim 15, wherein the septum of the cartridge is spaced from the piercing needle of the injection assembly when the device is in a pre-injection state, and wherein the piercing needle pierces the septum when the device is in the injection state.

17. The wearable automatic injection device of claim 1, wherein the vessel is moveably disposed within the housing.

18. The wearable automatic injection device of claim 17, wherein the vessel is moveable between a first position in a pre-injection state and a second position in the injection state.

19. The wearable automatic injection device of claim 18, further comprising:
a vessel actuator for automatically actuating the vessel from the first position to the second position.

20. The wearable automatic injection device of claim 19, wherein a fluid pathway is established between the injection needle and the vessel when the injection assembly is in the extended position and the vessel is in the second position in the injection state.

21. The wearable automatic injection device of claim 1, wherein the plunger actuation mechanism ejects the therapeutic agent into the patient at a controlled rate.

22. The wearable automatic injection device of claim 1, wherein the plunger actuation mechanism comprises a biasing mechanism.

23. The wearable automatic injection device of claim 22, wherein the plunger actuation mechanism further comprises:

a fusee; and

a tether coupling the biasing mechanism to the fusee and the plunger.

24. The wearable automatic injection device of claim 23, 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.

25. The wearable automatic injection device of claim 24, wherein the damping mechanism comprises a viscous damper.

26. The wearable automatic injection device of claim 24, wherein the damping mechanism comprises an escapement mechanism.

27. The wearable automatic injection device of claim 26, wherein the escapement mechanism is a swiss lever escapement.

28. The wearable automatic injection device of claim 26, wherein the escapement mechanism is a runaway escapement.

29. The wearable automatic injection device of claim 22, wherein the plunger actuation mechanism further comprises:

one or more ball bearings for coupling the biasing mechanism to the plunger.

30. The wearable automatic injection device of claim 29, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the biasing mechanism and the ball bearings for regulating the movement of the ball bearings.

31. The wearable automatic injection device of claim 30, wherein the damping mechanism comprises a viscous damper.

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

a source of a working fluid for providing a hydraulic pressure to eject the therapeutic agent from the vessel; and

a fluid conduit provided between the source of the working fluid and the plunger.

33. The wearable automatic injection device of claim 32, wherein the plunger actuation mechanism further comprises:

a damping mechanism coupled to the vessel and the source of the working fluid to regulate the ejection of the therapeutic agent from the vessel.

34. The wearable automatic injection device of claim 33, 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.

35. The wearable automatic injection device of claim 34, wherein the flow restrictor is coupled to the retraction trigger and wherein delivery of the therapeutic agent in the vessel causes the flow restrictor to activate the retraction trigger.

36. The wearable automatic injection device of claim 1, further comprising:

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

37. The wearable automatic injection device of claim 36, 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.

38. The wearable automatic injection device of claim 36, wherein the needle locking mechanism comprises:

a needle lock release mechanism responsive to retraction of the injection assembly from the extended position in the injection state to the retraction 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.

39. The wearable automatic injection device of claim 1, wherein the post-injection state comprises completion of delivery of a therapeutically effective dose of the therapeutic agent and removal of the wearable automatic injection device from the patient prior to completion of delivery of a therapeutically effective dose of the therapeutic agent.

40. The wearable automatic injection device of claim 1, wherein the therapeutic agent comprises a protein in a solution.

41. The wearable automatic injection device of claim 40, wherein the protein comprises any of a fusion protein, an enzyme, an antibody, or an antigen-binding fragment thereof in a solution.

42. The wearable automatic injection device of claim 41, wherein the antibody is a dual specificity antibody.

43. The wearable automatic injection device of claim 1, wherein the injection state comprises one or more states of the wearable automatic injection device during the delivery of the therapeutic agent.