

CLAIMS

1. A needle adaptor for forming an injection device for administering a fluid to a subject comprising:

5 a housing formed from a first housing portion and a second housing portion, the housing having a proximal end and a distal end;

a needle unit fixedly mounted within the housing, wherein the needle unit comprises:

a needle shaft comprising a first end for penetrating the subject's skin and a second end connected to a needle hub,

10 the needle hub comprising a distal end connected to the second end of the needle shaft and a proximal end comprising a pair of radially extending diametrically opposing flanges;

wherein each of the first housing portion and the second housing portion comprises at least two consecutive transverse walls or projections extending from an inner surface thereof,

15 wherein the at least two consecutive transverse walls or projections form a gap therebetween for receiving at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit to fixedly mount the needle unit within the housing;

20 wherein the proximal end of the housing together with the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion define a channel for receiving a syringe tip for engagement with the needle hub;

wherein the distal end of the housing comprises a first contact surface adapted to be placed on a skin of the subject and a second contact surface, wherein the first end of the needle shaft extends out of the second contact surface by a predefined distance for limiting a penetration depth of the needle shaft.

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2. The needle adaptor of claim 1, wherein the gap formed by the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion is configured to receive the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit in one of a first orientation and a second orientation of mounting of the needle unit,

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wherein:

the predefined distance by which the first end of the needle shaft extends out of the second contact surface is a first predefined distance when the needle unit is mounted in the first orientation, and

the predefined distance by which the first end of the needle shaft extends out of the second contact surface is a second predefined distance when the needle unit is mounted in the second orientation,
wherein the first predefined distance is different from the second predefined distance.

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3. The needle adaptor of claim 1 or 2, wherein the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit has a frictional engagement with opposing surfaces of the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion when received in the gap therebetween.

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4. The needle adaptor of any one of claims 1-3, wherein the first housing portion and the second housing portion are configured for snap-fit engagement with one another to form the housing.

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5. The needle adaptor of any one of claims 1-4, wherein each of the first housing portion and the second housing portion further comprises a plurality of projections extending from the inner surface of a distal end thereof to form a needle guide configured to hold the needle shaft in place.

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6. The needle adaptor of claim 5, wherein the plurality of projections comprises at least two needle-stabilizing projections disposed on either side of the needle shaft and offset from one another along a longitudinal axis of the needle shaft, each of the at least two needle-stabilizing projections having a sloped surface abutting the needle shaft.

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7. The needle adaptor of any one of claims 1-6, wherein the first contact surface is disposed along the perimeter of the distal end of the housing, and the second contact surface is substantially centrally disposed at the distal end of the housing.

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8. The needle adaptor of any one of claims 1-7, wherein the first housing portion and the second housing portion are of at least substantially similar or identical construction.

9. The needle adaptor of any one of claims 1-8, wherein the housing is generally cylindrical in shape.

10. The needle adaptor of any one of claims 1-9, wherein each of the first housing portion
5 and the second housing portion is generally semi-cylindrical in shape.

11. An assembly for forming an injection device for administering a fluid to a subject, the assembly comprising:

10 a foot comprising a first contact surface adapted to be placed on a skin of the subject, the foot having a tubular shape for receiving a needle adaptor body;

a needle adaptor body comprising:

a housing formed from a first housing portion and a second housing portion, the housing having a proximal end and a distal end;

15 a needle unit fixedly mounted within the housing, wherein the needle unit comprises:

a needle shaft comprising a first end for penetrating the subject's skin and a second end connected to a needle hub, the needle hub comprising a distal end connected to the second end of the needle shaft and a proximal end comprising a pair of
20 radially extending diametrically opposing flanges;

wherein each of the first housing portion and the second housing portion comprises at least two consecutive transverse walls or projections extending from an inner surface thereof, wherein the at least two consecutive transverse walls or projections form a gap therebetween for receiving at least
25 a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit to fixedly mount the needle unit within the housing;

wherein the proximal end of the housing together with the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion define a channel for receiving a syringe tip for engagement with the needle hub; and
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wherein the distal end of the housing comprises a second contact surface, wherein the first end of the needle shaft extends out of the second

contact surface by a predefined distance for limiting a penetration depth of the needle shaft;

the needle adaptor body being movably mounted to the foot for allowing movement of the needle adaptor body from a first position to a second position, wherein:

5 when the needle adaptor body is in the first position, the needle shaft is in a retracted position such that the first end of the needle shaft does not extend beyond the first contact surface, and

 when the needle adaptor body is in the second position, the first end of the needle shaft extends beyond the first contact surface and out of the second
10 contact surface by the predefined distance for limiting the penetration depth of the needle shaft;

 the assembly further comprising a friction means for inhibiting movement of the needle adaptor body relative to the foot when the needle adaptor body is in the first position, until a predefined static friction force is overcome, and for causing or allowing a sudden acceleration
15 of the needle adaptor body towards the foot for increasing a speed of the needle shaft for increasing chance of penetration of the skin.

12. The assembly of claim 11, wherein the gap formed by the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing
20 portion is configured to receive the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit in one of a first orientation and a second orientation of mounting of the needle unit,

 wherein:

 the predefined distance by which the first end of the needle shaft extends out
25 of the second contact surface is a first predefined distance when the needle unit is mounted in the first orientation, and

 the predefined distance by which the first end of the needle shaft extends out of the second contact surface is a second predefined distance when the needle unit is mounted in the second orientation,

30 wherein the first predefined distance is different from the second predefined distance.

13. The assembly of claim 11 or 12, wherein the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit has a frictional

engagement with opposing surfaces of the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion when received in the gap therebetween.

- 5 14. The assembly of any one of claims 11-13, wherein the first housing portion and the second housing portion are configured for snap-fit engagement with one another to form the housing.
- 10 15. The assembly of any one of claims 11-14, wherein each of the first housing portion and the second housing portion further comprises a plurality of projections extending from the inner surface of a distal end thereof to form a needle guide configured to hold the needle shaft in place.
- 15 16. The assembly of claim 15, wherein the plurality of projections comprises at least two needle-stabilizing projections disposed on either side of the needle shaft and offset from one another along a longitudinal axis of the needle shaft, each of the at least two needle-stabilizing projections having a sloped surface abutting the needle shaft.
- 20 17. The assembly of any one of claims 11-16, wherein the first contact surface is disposed along the perimeter of a distal end of the foot, and the second contact surface is substantially centrally disposed at the distal end of the housing.
- 25 18. The assembly of any one of claims 11-17, wherein the first housing portion and the second housing portion are of at least substantially similar or identical construction.
19. The assembly of any one of claims 11-18, wherein the housing is generally cylindrical in shape.
- 30 20. The assembly of any one of claims 11-19, wherein each of the first housing portion and the second housing portion is generally semi-cylindrical in shape.
21. The assembly of any one of claims 11-20, wherein the friction means comprises at least two protrusions extending from an inner surface of a proximal end of the foot being in

contact with at least two corresponding grooves located on an outer surface of the distal end of the housing of the needle adaptor body, wherein a radial dimension defined by the at least two protrusions before assembly of the needle adaptor body and the foot, is smaller than a radial dimension defined by the at least two corresponding grooves, the static friction being provided by radial clamping.

22. The assembly of claim 21, wherein the at least two corresponding grooves are configured to prevent disengagement of the foot from the needle adaptor body by limiting movement of the foot away from the needle adaptor body following engagement of the at least two protrusions extending from the inner surface of the proximal end of the foot with the at least two corresponding grooves.

23. The assembly of claim 21 or 22, wherein the at least two corresponding grooves are oriented generally parallel to a longitudinal axis of the housing.

24. The assembly of claim 23, further comprising at least two deactivation grooves located on the outer surface of the distal end of the housing of the needle adaptor body,

wherein each of the at least two deactivation grooves intersects one of the at least two corresponding grooves at an angle relative to the longitudinal axis of the housing, such that axial movement of the foot away from the needle adaptor body and rotation of the foot relative to the needle adaptor body engages the at least two protrusions with the at least two deactivation grooves,

wherein each of the at least two deactivation grooves comprises an indentation complementary to a shape of each of the at least two protrusions to fixedly engage each of the at least two protrusions, such that the needle adaptor body is held in a fixed, deactivated position relative to the foot,

wherein the first end of the needle shaft does not extend beyond the first contact surface when the needle adaptor body is in the fixed, deactivated position relative to the foot.

25. The assembly of any one of claims 11-24, further comprising a locking mechanism for providing a locked mode and an unlocked mode of the device,

the locked mode being a mode of the assembly, wherein the needle adaptor body is prevented from moving axially towards the foot, even when an axial force larger than the predefined static friction is exerted on the needle adaptor body relative to the foot;

the unlocked mode being a mode of the assembly wherein the needle adaptor body is
5 allowed to move towards the foot, when an axial force larger than the predefined static friction is applied to the needle adaptor body relative to the foot.

26. The assembly of claim 25, wherein the locking mechanism comprises a removable safety clip configured to engage with a portion of the outer surface of the housing to maintain
10 the foot and needle adaptor body spaced apart from one another to prevent the needle adaptor body from moving axially towards the foot.

27. A method for assembling the needle adaptor of claim 1, the method comprising:
obtaining the first housing portion and the second housing portion;
15 obtaining the needle unit;
optionally, measuring a length of the needle shaft, and removing a preselected portion of a distal end of each of the first housing portion and the second housing portion based on the length of the needle shaft;
mounting the needle unit in one of the first housing portion and the second housing
20 portion by inserting the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit into the gap formed between the at least two consecutive transverse walls or projections; and
engaging the first housing portion and the second housing portion with one another to form the housing.

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28. A method for assembling the needle adaptor of claim 2, the method comprising:
obtaining the first housing portion and the second housing portion;
obtaining the needle unit;
measuring a length of the needle shaft;
30 determining whether the needle unit is to be mounted in the first orientation or the second orientation based on the length of the needle shaft;

optionally, removing a preselected portion of a distal end of each of the first housing portion and the second housing portion based on the length of the needle shaft and based on whether the needle unit is to be mounted in the first orientation or the second orientation;

mounting the needle unit in one of the first housing portion and the second housing
5 portion in the first orientation or the second orientation by inserting the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit into the gap formed between the at least two consecutive transverse walls or projections; and
engaging the first housing portion and the second housing portion with one another to
form the housing.

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29. The method of claim 27 or 28, wherein the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit has a frictional engagement with opposing surfaces of the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion when received
15 in the gap therebetween.

30. The method of any one of claims 27-29, wherein the first housing portion and the second housing portion are configured for snap-fit engagement with one another to form the housing.

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31. The method of any one of claims 27-30, wherein each of the first housing portion and the second housing portion further comprises a plurality of projections extending from the inner surface of a distal end thereof to form a needle guide configured to hold the needle shaft in place.

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32. The method of claim 31, wherein the plurality of projections comprises at least two needle-stabilizing projections disposed on either side of the needle shaft and offset from one another along a longitudinal axis of the needle shaft, each of the at least two needle-stabilizing projections having a sloped surface that abuts the needle shaft when the needle unit is
30 mounted in one of the first housing portion and the second housing portion.

33. The method of any one of claims 27-32, wherein the first contact surface is disposed along the perimeter of the distal end of the housing, and the second contact surface is substantially centrally disposed at the distal end of the housing.

5 34. The method of any one of claims 27-33, wherein the first housing portion and the second housing portion are of at least substantially similar or identical construction.

35. The method of any one of claims 27-34, wherein the housing is generally cylindrical in shape.

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36. The method of any one of claims 27-35, wherein each of the first housing portion and the second housing portion is generally semi-cylindrical in shape.

37. The method of any one of claims 27-36, wherein removing the preselected portion of the distal end of each of the first housing portion and the second housing portion comprising cutting the preselected portion of the distal end of each of the first housing portion and the second housing portion, such as by laser cutting.

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38. The method of any one of claims 27-37, wherein the method is automated.

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39. A method for assembling the assembly of claim 11, wherein the assembly optionally further comprises a locking mechanism comprising a removable safety clip configured to engage with a portion of the outer surface of the housing to maintain the foot and needle adaptor body spaced apart from one another to prevent the needle adaptor body from moving axially towards the foot, the method comprising:

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obtaining the foot;

obtaining the first housing portion and the second housing portion forming the housing of the needle adaptor body;

obtaining the needle unit;

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optionally, obtaining the removable safety clip;

optionally, measuring a length of the needle shaft, and removing a preselected portion of a distal end of each of the first housing portion and the second housing portion based on the length of the needle shaft;

mounting the needle unit in one of the first housing portion and the second housing portion by inserting the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit into the gap formed between the at least two consecutive transverse walls or projections;

5 engaging the first housing portion and the second housing portion with one another to form the housing of the needle adaptor body;

 engaging the removable safety clip, if present, with the portion of the outer surface of the housing; and

 engaging the foot and the needle adaptor body.

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40. A method for assembling the assembly of claim 12, wherein the assembly optionally further comprises a locking mechanism comprising a removable safety clip configured to engage with a portion of the outer surface of the housing to maintain the foot and needle adaptor body spaced apart from one another to prevent the needle adaptor body from moving axially towards the foot, the method comprising:

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 obtaining the foot;

 obtaining the first housing portion and the second housing portion forming the housing of the needle adaptor body;

 obtaining the needle unit;

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 optionally, obtaining the removable safety clip;

 measuring a length of the needle shaft;

 determining whether the needle unit is to be mounted in the first orientation or the second orientation based on the length of the needle shaft;

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 optionally, removing a preselected portion of a distal end of each of the first housing portion and the second housing portion based on the length of the needle shaft and based on whether the needle unit is to be mounted in the first orientation or the second orientation;

 mounting the needle unit in one of the first housing portion and the second housing portion in the first orientation or the second orientation by inserting the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit into the gap formed between the at least two consecutive transverse walls or projections; and

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 engaging the first housing portion and the second housing portion with one another to form the housing of the needle adaptor body;

engaging the removable safety clip, if present, with the portion of the outer surface of the housing; and

engaging the foot and the needle adaptor body.

- 5 41. The method of claim 39 or 40, wherein the at least a portion of one or both of the pair of radially extending diametrically opposing flanges of the needle unit has a frictional engagement with opposing surfaces of the at least two consecutive transverse walls or projections of each of the first housing portion and the second housing portion when received in the gap therebetween.
- 10 42. The method of any one of claims 39-41, wherein the first housing portion and the second housing portion are configured for snap-fit engagement with one another to form the housing.
- 15 43. The method of any one of claims 39-42, wherein each of the first housing portion and the second housing portion further comprises a plurality of projections extending from the inner surface of a distal end thereof to form a needle guide configured to hold the needle shaft in place.
- 20 44. The method of claim 43, wherein the plurality of projections comprises at least two needle-stabilizing projections disposed on either side of the needle shaft and offset from one another along a longitudinal axis of the needle shaft, each of the at least two needle-stabilizing projections having a sloped surface abutting the needle shaft.
- 25 45. The method of any one of claims 39-44, wherein the first contact surface is disposed along the perimeter of a distal end of the foot, and the second contact surface is substantially centrally disposed at the distal end of the housing.
- 30 46. The method of any one of claims 39-45, wherein the first housing portion and the second housing portion are of at least substantially similar or identical construction.
47. The method of any one of claims 39-46, wherein the housing is generally cylindrical in shape.

48. The method of any one of claims 39-47, wherein each of the first housing portion and the second housing portion is generally semi-cylindrical in shape.

5 49. The method of any one of claims 39-48, wherein the friction means comprises at least two protrusions extending from an inner surface of a proximal end of the foot being in contact with at least two corresponding grooves located on an outer surface of the distal end of the housing of the needle adaptor body, wherein a radial dimension defined by the at least two protrusions before assembly of the needle adaptor body and the foot, is smaller than a radial
10 dimension defined by the at least two corresponding grooves, the static friction being provided by radial clamping;

wherein engaging the foot and the needle adaptor body comprises engaging the at least two protrusions extending from the inner surface of the proximal end of the foot with the at least two corresponding grooves located on the outer surface of the distal end of the
15 housing of the needle adaptor body.

50. The method of claim 49, wherein the at least two corresponding grooves are configured to prevent disengagement of the foot from the needle adaptor body by limiting movement of the foot away from the needle adaptor body following engagement of the at least
20 two protrusions extending from the inner surface of the proximal end of the foot with the at least two corresponding grooves.

51. The method of claim 49 or 50, wherein the at least two corresponding grooves are oriented generally parallel to a longitudinal axis of the housing.

25 52. The method of claim 51, wherein the assembly further comprises at least two deactivation grooves located on the outer surface of the distal end of the housing of the needle adaptor body,

wherein each of the at least two deactivation grooves intersects one of the at least two
30 corresponding grooves at an angle relative to the longitudinal axis of the housing, such that axial movement of the foot away from the needle adaptor body and rotation of the foot relative to the needle adaptor body engages the at least two protrusions with the at least two deactivation grooves,

wherein each of the at least two deactivation grooves comprises an indentation complementary to a shape of each of the at least two protrusions to fixedly engage each of the at least two protrusions, such that the needle adaptor body is held in a fixed, deactivated position relative to the foot,

- 5 wherein the first end of the needle shaft does not extend beyond the first contact surface when the needle adaptor body is in the fixed, deactivated position relative to the foot.53.

The method of any one of claims 39-52, wherein removing the preselected portion of the distal end of each of the first housing portion and the second housing portion comprising cutting the preselected portion of the distal end of each of the first housing portion and the
10 second housing portion, such as by laser cutting.

54. The method of any one of claims 39-53, wherein the method is automated.

55. A method of administering a fluid to a subject via injection, the method comprising:
15 (a) obtaining the needle adaptor of any one of claims 1-10;
(b) obtaining a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip,
wherein the syringe or the other dosing device is loaded with the fluid to be administered to the subject;
20 (c) inserting the tip of the syringe or the other dosing device into the channel disposed at the proximal end of the housing so as to engage the tip with the needle hub;
(d) engaging the first contact surface with the skin of the subject;
(e) pushing the housing against the skin to allow the first end of the needle shaft to penetrate the skin;
25 (f) expelling the fluid from the syringe or the other dosing device through the needle shaft into the subject; and
(g) optionally, engaging the needle adaptor with a safety holder, wherein the safety holder has an open end for receiving at least the distal end of the needle adaptor housing and a closed end, the closed end comprising opposed wings for stabilizing the safety holder
30 on a horizontal surface.

56. A method of administering a fluid to a subject via injection, the method comprising:

(a) obtaining the assembly of any one of claims 11-26, wherein the needle adaptor body is in the first position;

(b) obtaining a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip,

5 wherein the syringe or the other dosing device is loaded with the fluid to be administered to the subject;

(c) inserting the tip of the syringe or the other dosing device into the channel disposed at the proximal end of the needle adaptor housing so as to engage the tip with the needle hub;

10 (d) engaging the first contact surface of the foot with the skin of the subject;

(e) pushing the housing of the needle adaptor body towards the foot to move the needle adaptor body from the first position to the second position, thus causing the first end of the needle shaft to penetrate the skin; and

(f) expelling the fluid from the syringe or the other dosing device through the needle shaft into the subject.

57. A method of administering a fluid to a subject via injection, the method comprising:

(a) obtaining the assembly of claim 24, wherein the needle adaptor body is in the first position;

20 (b) obtaining a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip,

 wherein the syringe or the other dosing device is loaded with the fluid to be administered to the subject;

(c) inserting the tip of the syringe or the other dosing device into the channel disposed at the proximal end of the needle adaptor housing so as to engage the tip with the needle hub;

(d) engaging the first contact surface of the foot with the skin of the subject;

(e) pushing the housing of the needle adaptor body towards the foot in an axial direction to move the needle adaptor body from the first position to the second position, thus causing the first end of the needle shaft to penetrate the skin;

30 (f) expelling the fluid from the syringe or the other dosing device through the needle shaft into the subject; and

(g) pulling the housing of the needle adaptor body away from the foot in an axial direction and rotating the foot relative to the needle adaptor body to engage the at least two protrusions with the at least two deactivation grooves and to fixedly engage each of the at least two protrusions in the indentation in each of the at least two deactivation grooves, such
5 that the needle adaptor body is held in the fixed, deactivated position relative to the foot.

58. A method of administering a fluid to a subject via injection, the method comprising:
(a) obtaining the assembly of claim 26, wherein the needle adaptor body is in the first
10 position;
(b) obtaining a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip, wherein the syringe or the other dosing device is loaded with the fluid to be administered to the subject;
15 (c) inserting the tip of the syringe or the other dosing device into the channel disposed at the proximal end of the needle adaptor housing so as to engage the tip with the needle hub;
(d) engaging the first contact surface of the foot with the skin of the subject;
(e) pushing the housing of the needle adaptor body towards the foot in an axial
20 direction to move the needle adaptor body from the first position to the second position, thus causing the first end of the needle shaft to penetrate the skin;
(f) expelling the fluid from the syringe or the other dosing device through the needle shaft into the subject; and
(g) pulling the housing of the needle adaptor body away from the foot in an axial
25 direction and rotating the foot relative to the needle adaptor body to engage the at least two protrusions with the at least two deactivation grooves and to fixedly engage each of the at least two protrusions in the indentation in each of the at least two deactivation grooves, such that the needle adaptor body is held in the fixed, deactivated position relative to the foot;
the method further comprising removing the safety clip from the outer surface of the
30 housing after step (c) and prior to step (d), or after step (d) and prior to step (e).

59. A kit comprising:
the needle adaptor of any one of claims 1-10;

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a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip, wherein the syringe or the other dosing device is optionally loaded with the fluid to be administered to the subject;

optionally, a vial containing the fluid to be administered to the subject;

5 optionally, a removable needle unit or other means for extracting the fluid from the optional vial into the syringe or the other dosing device, the removable needle unit being removable for allowing the tip of the syringe or the other dosing device to be inserted into the channel of the housing;

10 optionally, a safety holder, wherein the safety holder has an open end for receiving at least the distal end of the needle adaptor housing and a closed end, the closed end comprising opposed wings for stabilizing the safety holder on a horizontal surface; and optionally, instructions for use.

60. A kit comprising:

15 the assembly of any one of claims 11-26;

a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip, wherein the syringe or the other dosing device is optionally loaded with the fluid to be administered to the subject;

optionally, a vial containing the fluid to be administered to the subject;

20 optionally, a removable needle unit or other means for extracting the fluid from the optional vial into the syringe or the other dosing device, the removable needle unit being removable for allowing the tip of the syringe or the other dosing device to be inserted into the channel of the housing; and

optionally, instructions for use.

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61. An injection device comprising:

the needle adaptor of any one of claims 1-10; and

a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip, wherein the syringe or the
30 other dosing device is optionally loaded with a fluid to be administered to a subject.

62. An injection device comprising:

the assembly of any one of claims 11-26; and

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a syringe or other dosing device, wherein the other dosing device comprises a dispensing tip that is similar in size and shape to a syringe tip, wherein the syringe or the other dosing device is optionally loaded with a fluid to be administered to a subject.