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(54) **REMOVAL OF NEEDLE SHIELD FROM SYRINGES AND AUTOMATIC INJECTION DEVICES**

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(21) Appl. No.: **17/237,362**

(22) Filed: **Apr. 22, 2021**

Related U.S. Application Data

(63) Continuation of application No. 16/022,399, filed on Jun. 28, 2018, now abandoned, which is a continuation of application No. 15/094,364, filed on Apr. 8, 2016, now Pat. No. 10,022,503, which is a continuation of application No. 14/253,348, filed on Apr. 15, 2014, now Pat. No. 9,339,610, which is a continuation of application No. 13/357,508, filed on Jan. 24, 2012, now Pat. No. 8,708,968.

(60) Provisional application No. 61/435,467, filed on Jan. 24, 2011.

Publication Classification

(51) **Int. Cl.**

A61M 5/32 (2006.01)

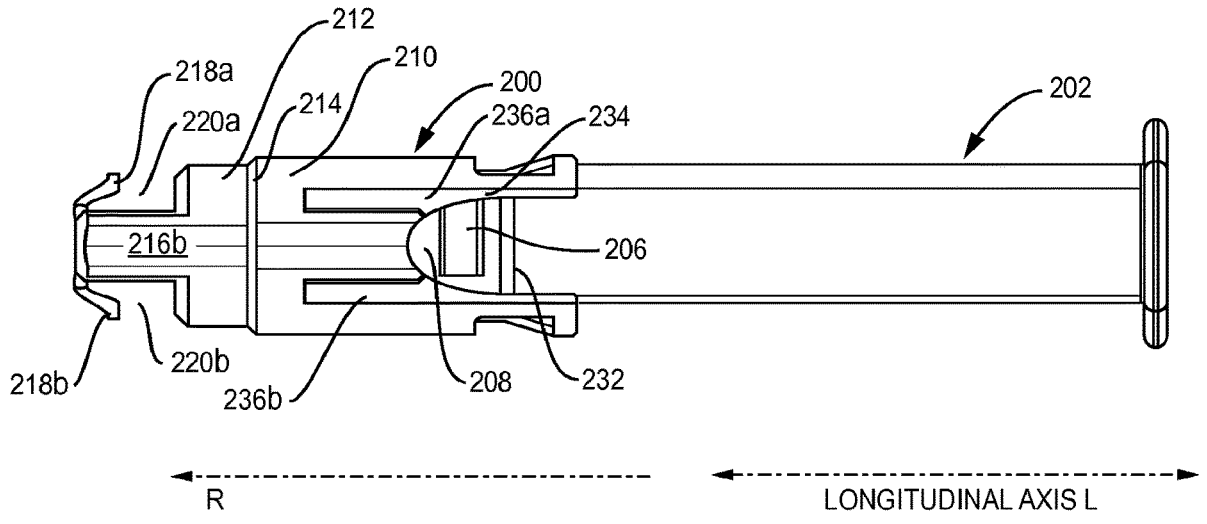
A61M 5/20 (2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/3204*** (2013.01); ***A61M 5/32*** (2013.01); ***A61M 5/321*** (2013.01); ***A61M 5/20*** (2013.01); *A61M 2207/00* (2013.01); *Y10T 29/49826* (2015.01); *Y10T 29/53* (2015.01); *A61M 2205/581* (2013.01); ***A61M 5/3202*** (2013.01)

(57) **ABSTRACT**

Exemplary embodiments provide a needle shield remover that reliably engages with a distal cap of an automatic injection device and with one or more needle shields coupled to a syringe of the device. When a user removes the distal cap, the needle shield remover reliably removes the needle shields (e.g., a soft needle shield and a rigid needle shield) from the syringe, thereby exposing the injection needle for performing an injection. In an exemplary assembly method, a needle shield remover is engaged to a needle shield coupled to a syringe, prior to insertion of the syringe and needle shield remover assembly into a housing of the device. This exemplary assembly method allows visual inspection, outside the housing of the device, to ensure that the needle shield remover is correctly and reliably engaged to the needle shield before the syringe and needle shield remover assembly is inserted into the housing.



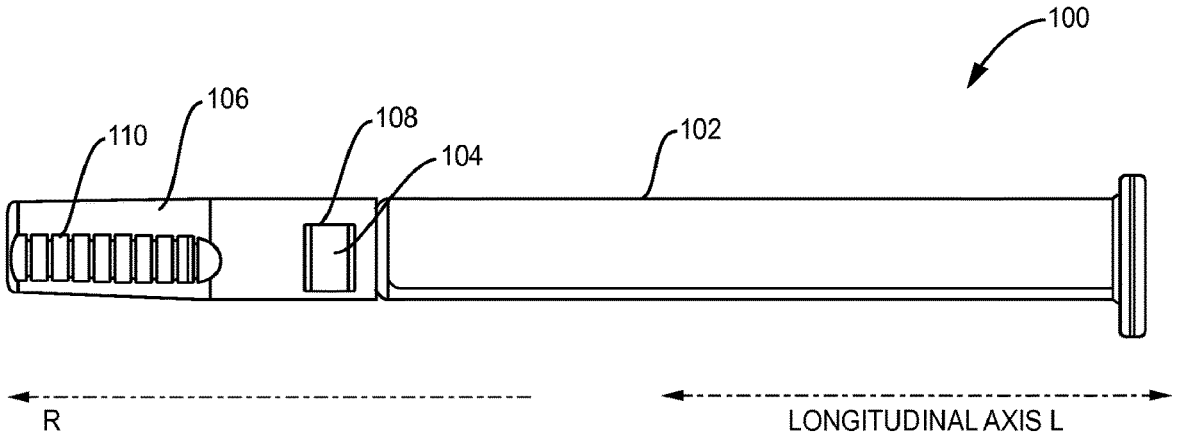

100
106
110
108
104
102
R
LONGITUDINAL AXIS L

FIG. 1A

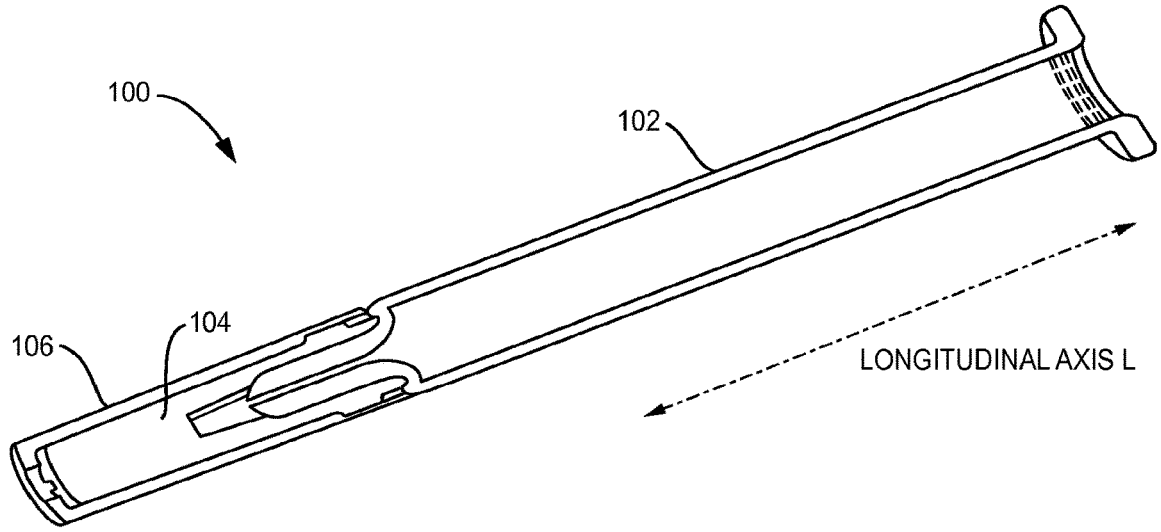

100
102
106
104
LONGITUDINAL AXIS L

FIG. 1B

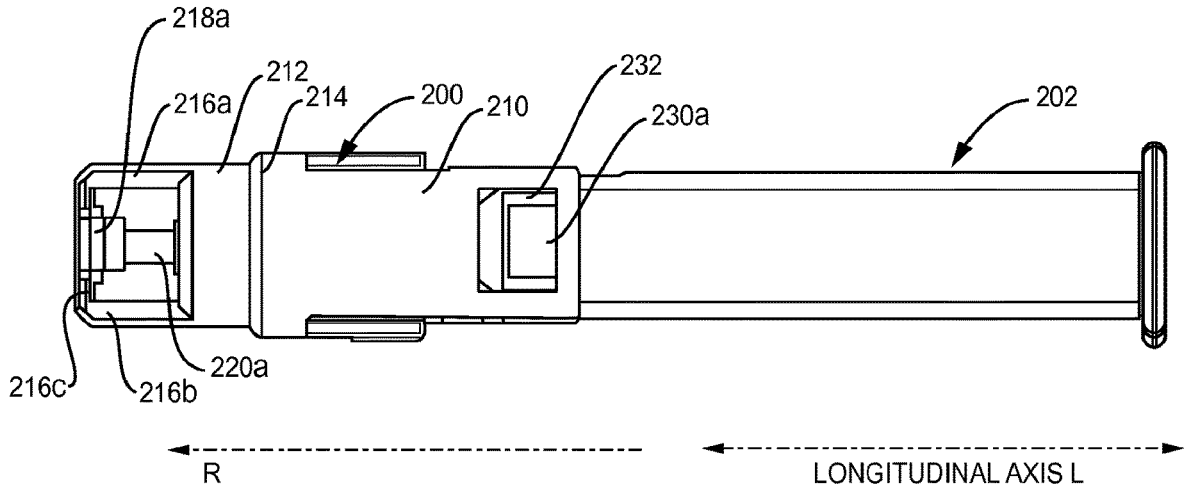

218a
212
216a
214
200
210
232
230a
202
216c
216b
220a
R
LONGITUDINAL AXIS L

FIG. 2A

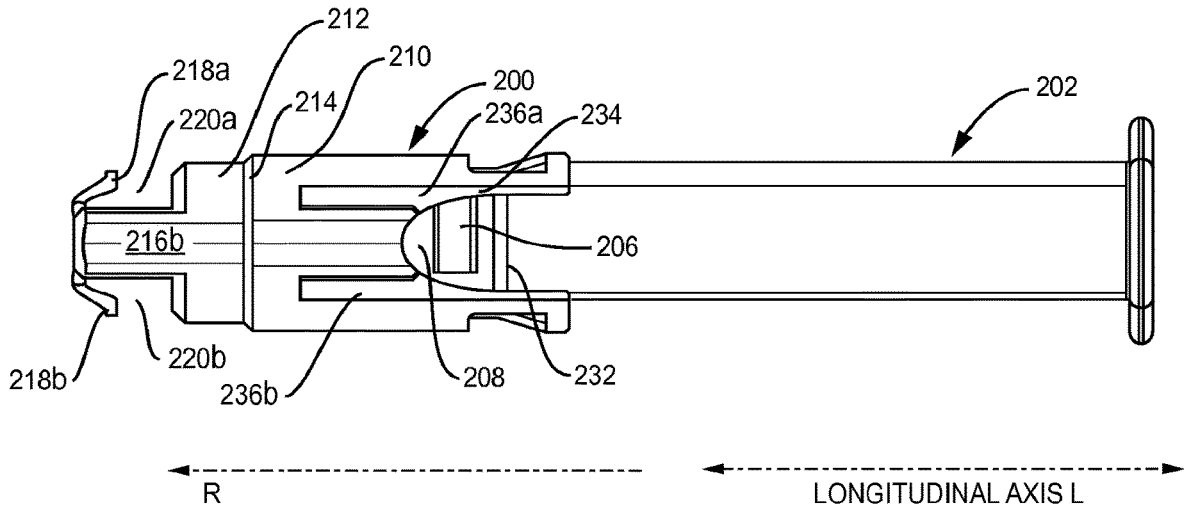

212
218a
210
200
220a
214
236a
234
202
216b
206
218b
220b
236b
208
232
R
LONGITUDINAL AXIS L

FIG. 2B

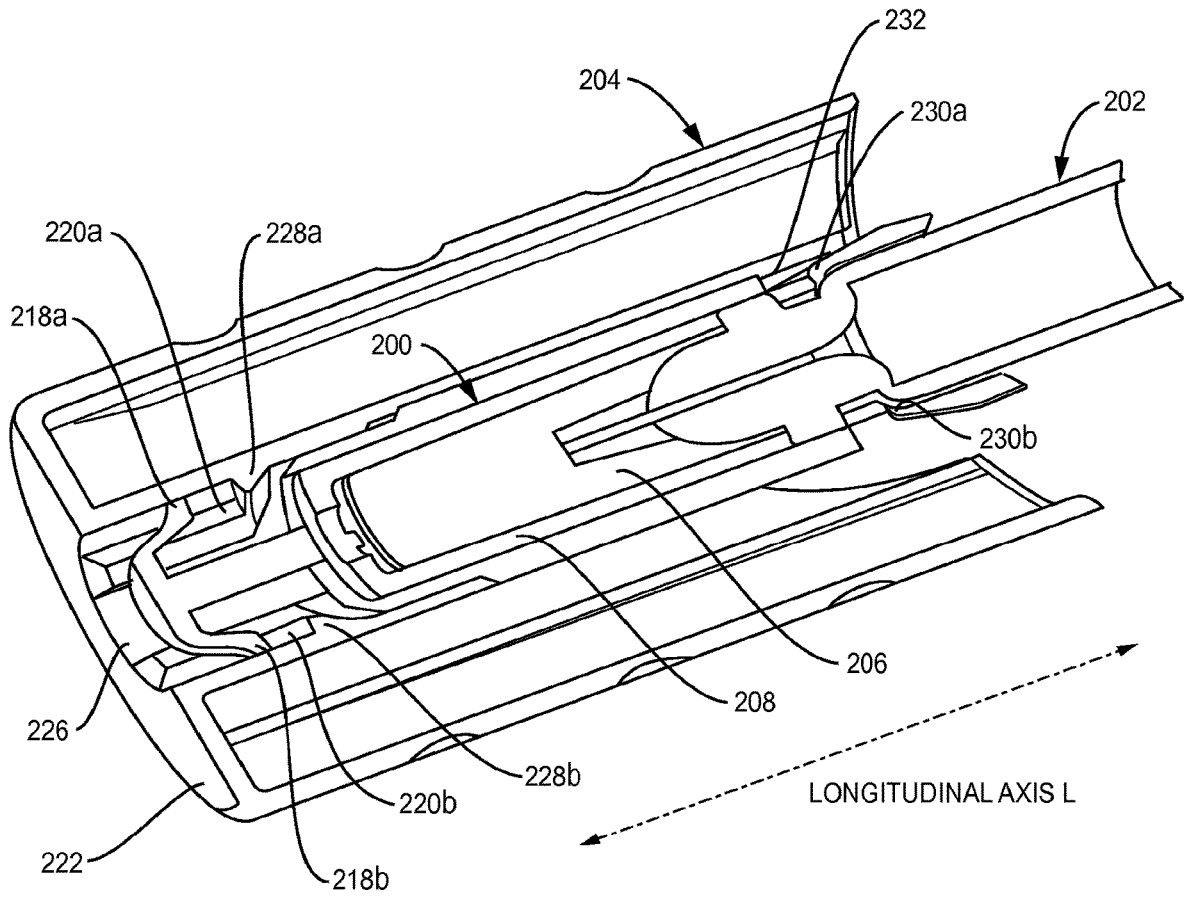

232
204
230a
202
220a
228a
218a
200
230b
206
208
226
228b
220b
LONGITUDINAL AXIS L
222
218b

FIG. 2C

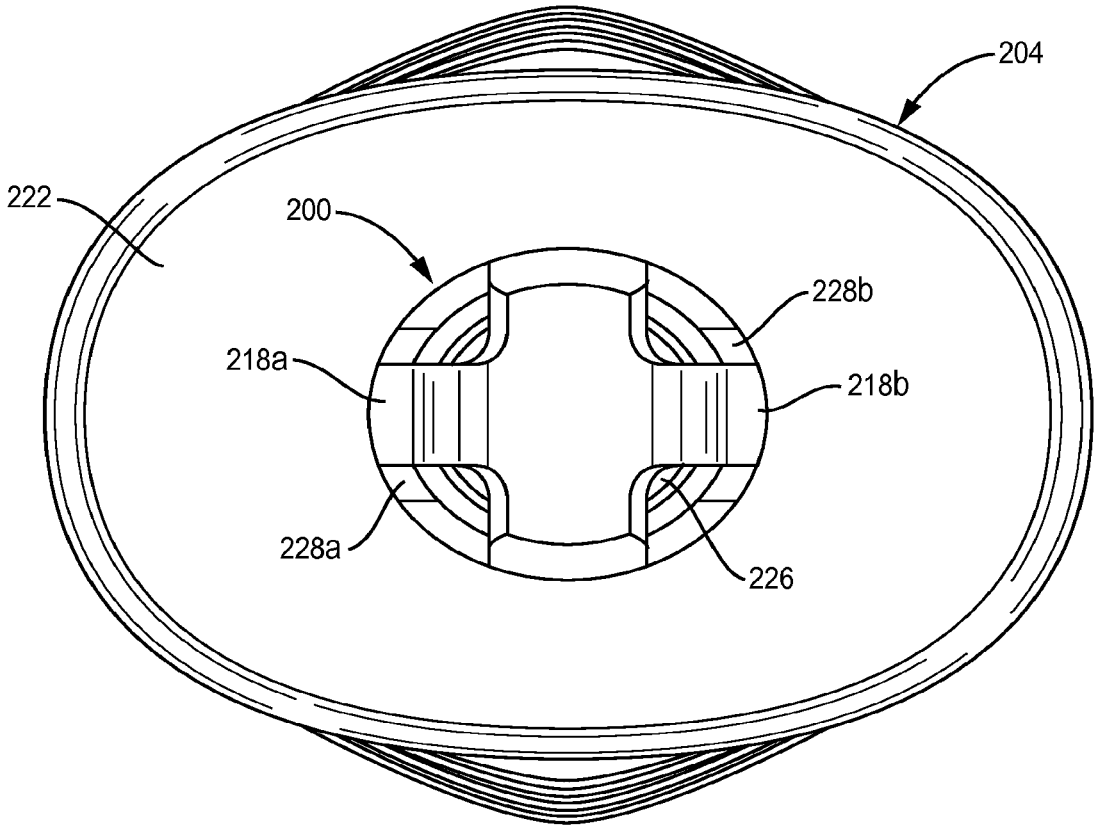


FIG. 2D

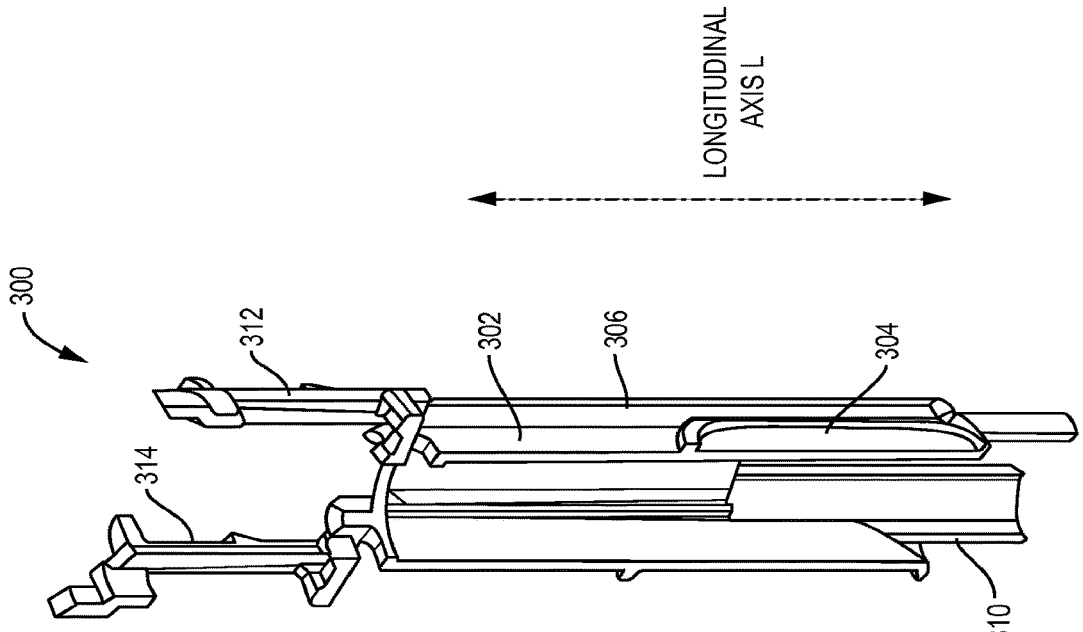

LONGITUDINAL AXIS L
300
312
302
306
304
314
310

FIG. 3B

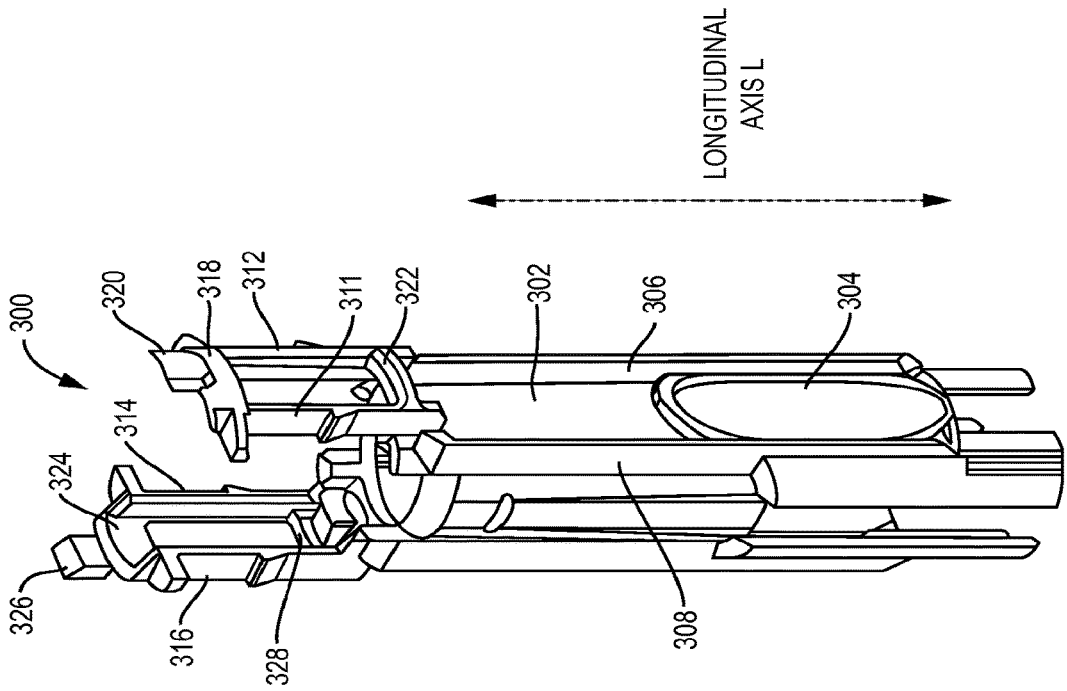

LONGITUDINAL AXIS L
300
320
318
312
311
322
302
306
304
314
324
326
316
328
308

FIG. 3A

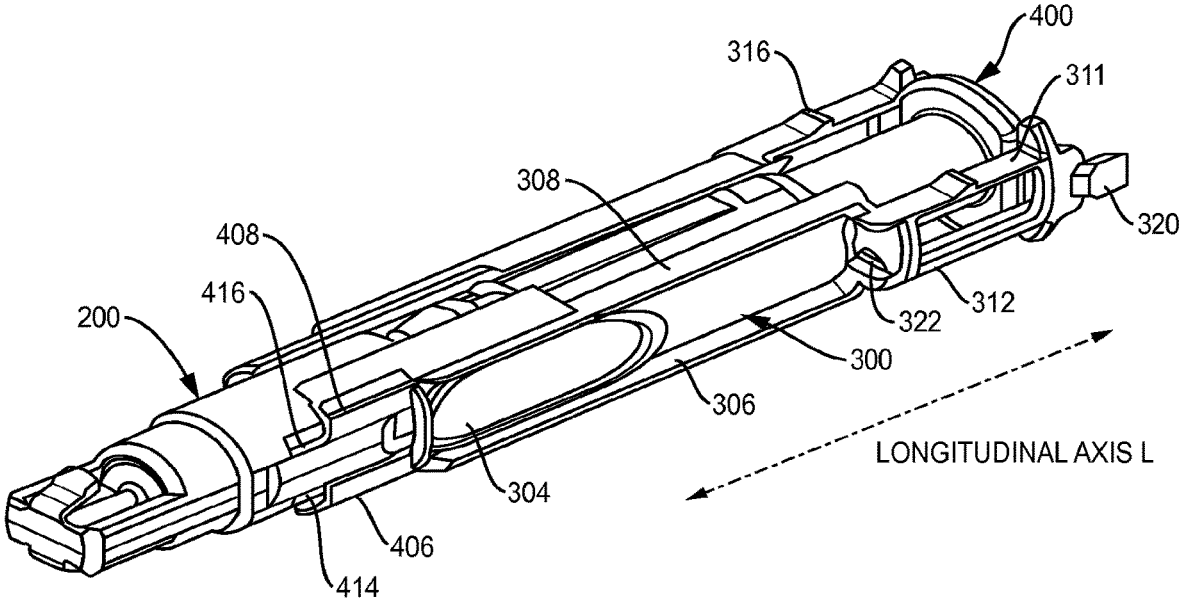

400
316
311
308
320
408
416
312
322
200
300
306
LONGITUDINAL AXIS L
304
406
414

FIG. 4A

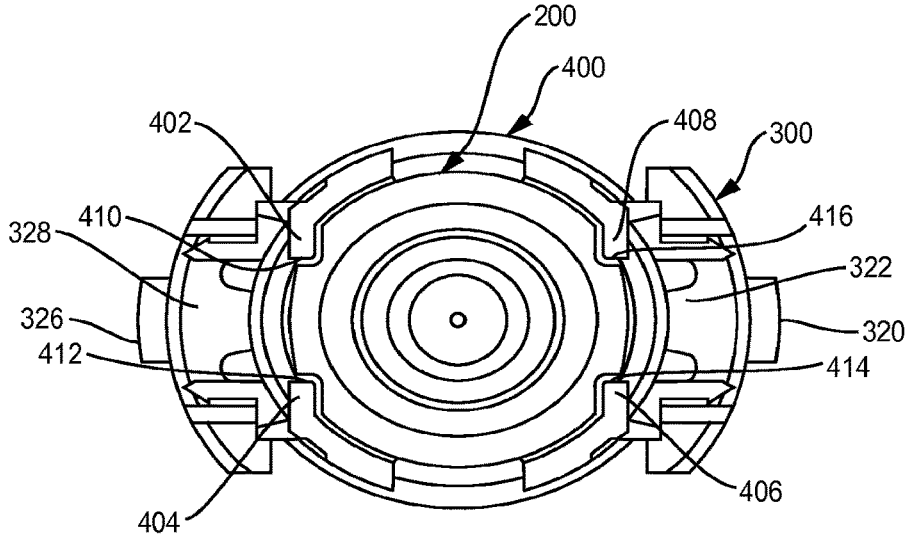

200
400
402
408
300
410
416
328
322
326
320
412
414
406
404

FIG. 4B

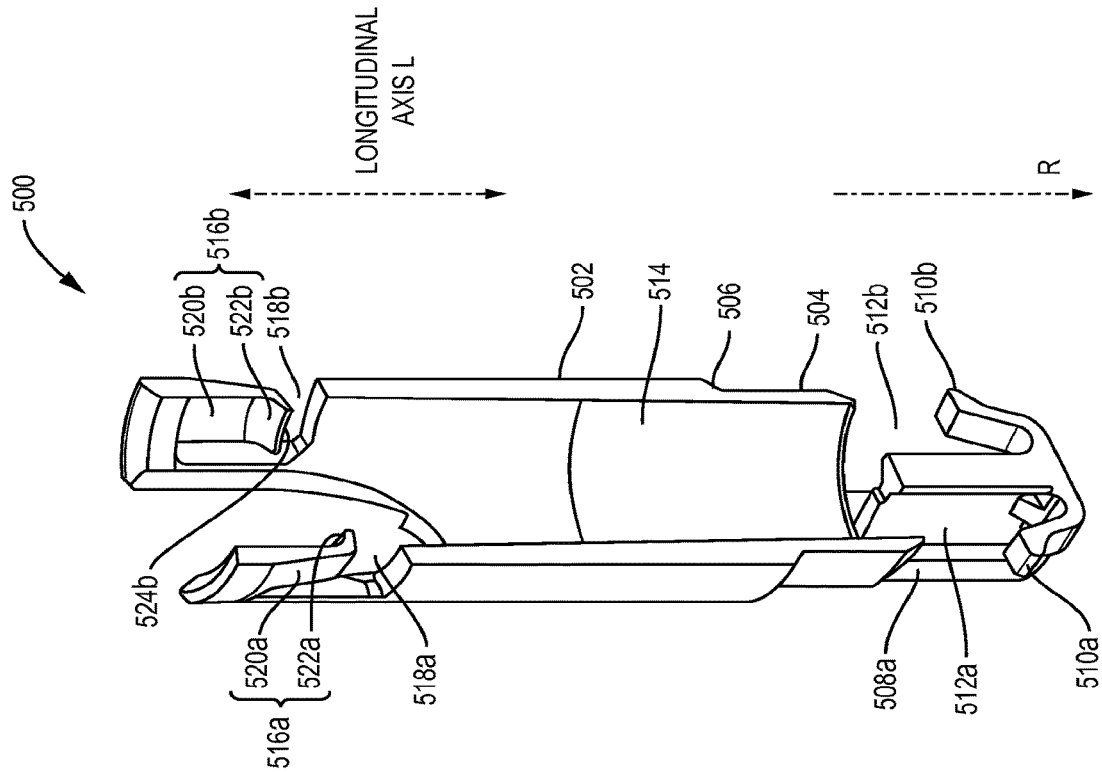

500
LONGITUDINAL AXIS L
R
516b
520b
522b
518b
502
514
506
504
512b
510b
524b
520a
522a
518a
516a
508a
512a
510a

FIG. 5B

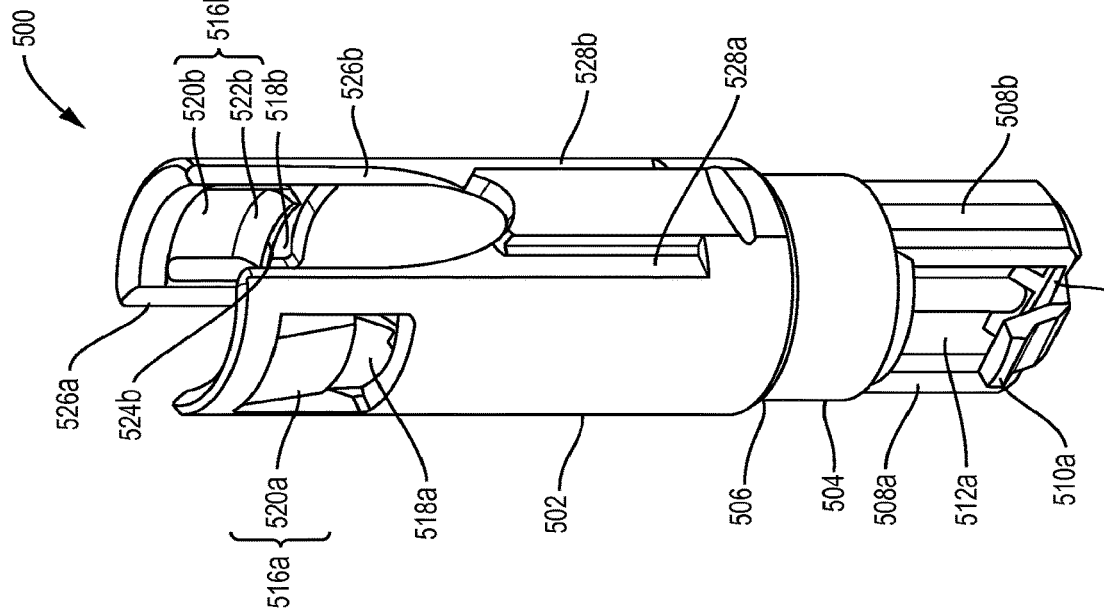

500
LONGITUDINAL AXIS L
R
516b
520b
522b
518b
526b
528b
528a
508b
526a
524b
520a
516a
518a
502
506
504
508a
512a
510a
508c

FIG. 5A

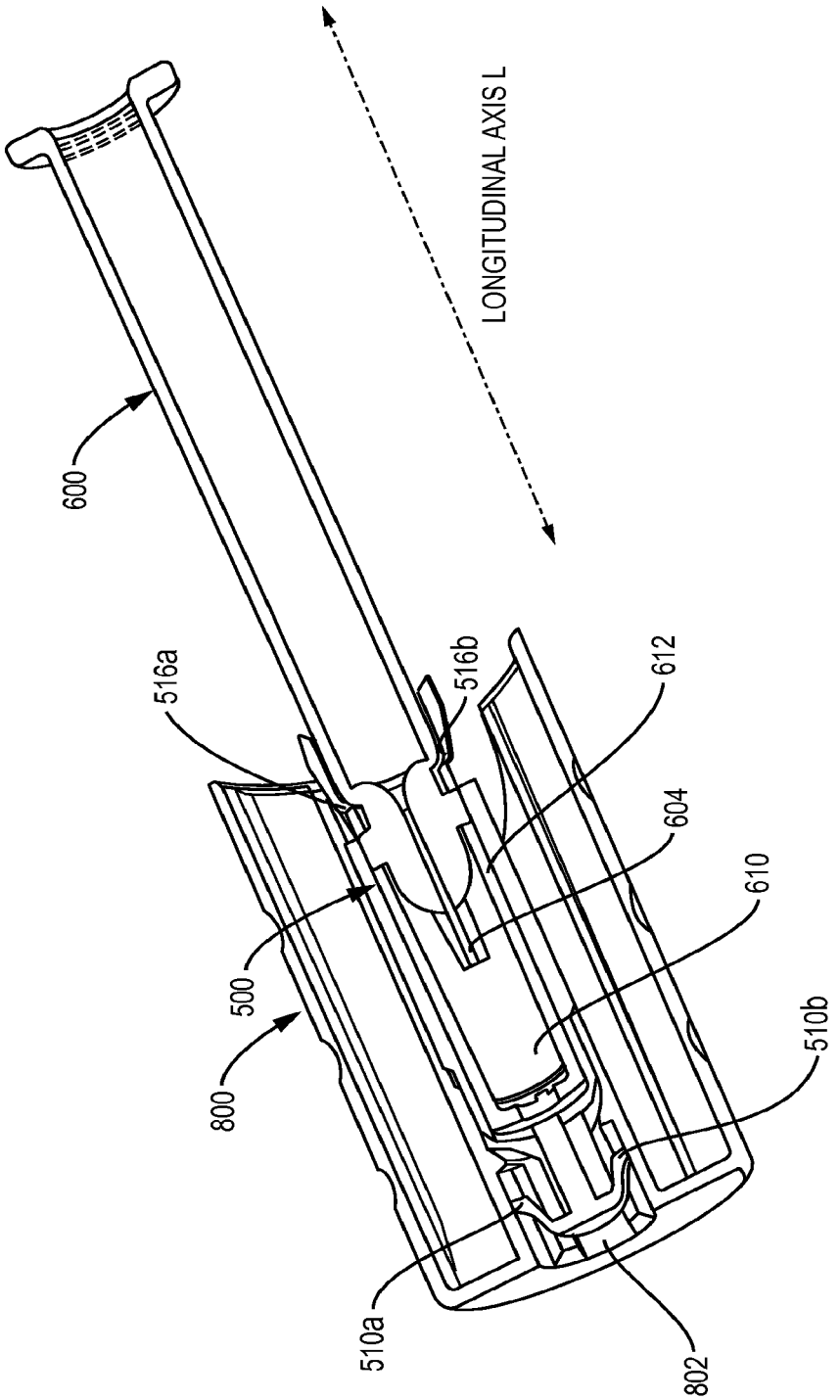

LONGITUDINAL AXIS L
600
516a
516b
612
604
610
500
800
510b
510a
802

FIG. 6

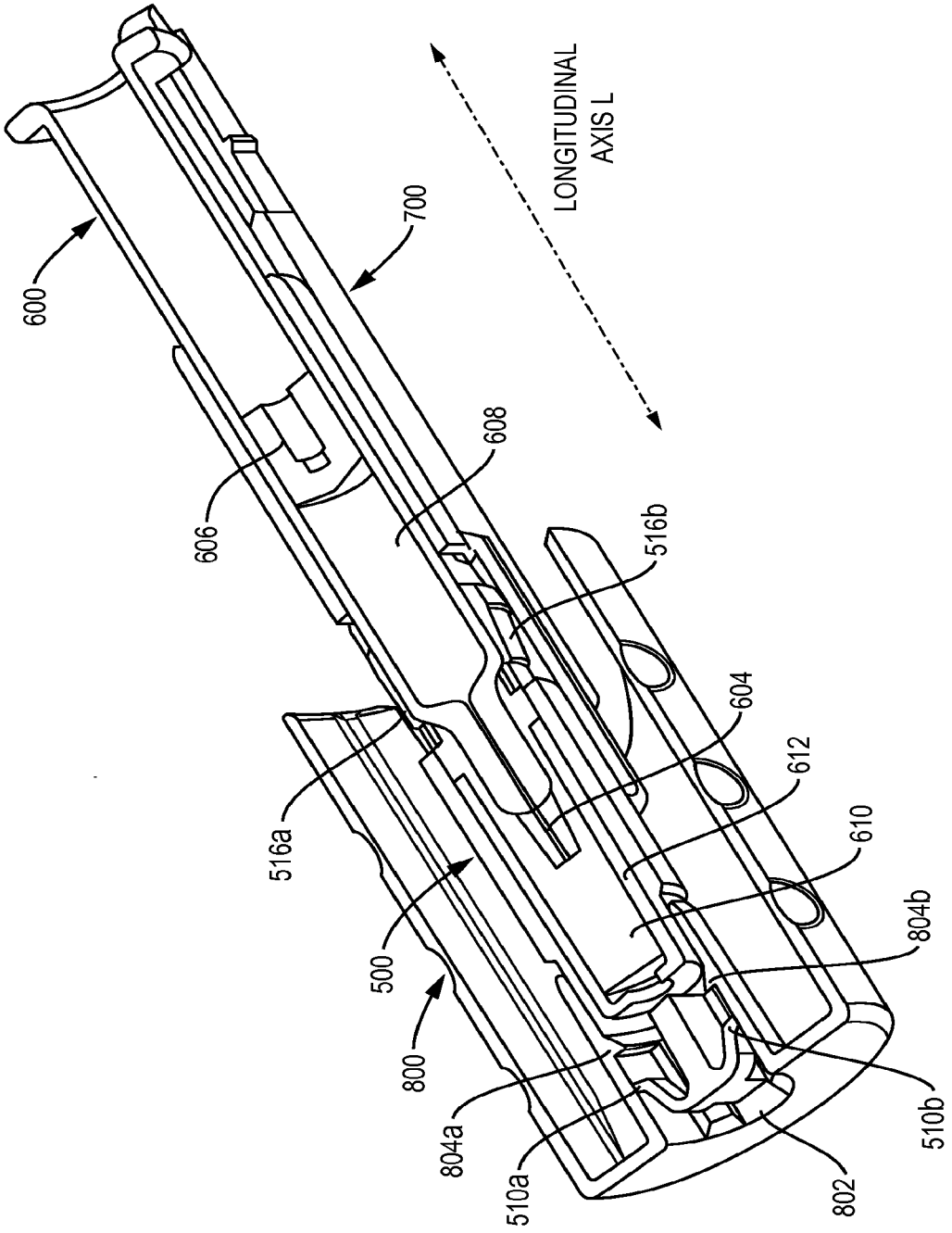

LONGITUDINAL AXIS L
600
700
606
608
516b
604
612
610
804b
516a
500
800
804a
510a
802
510b

FIG. 7

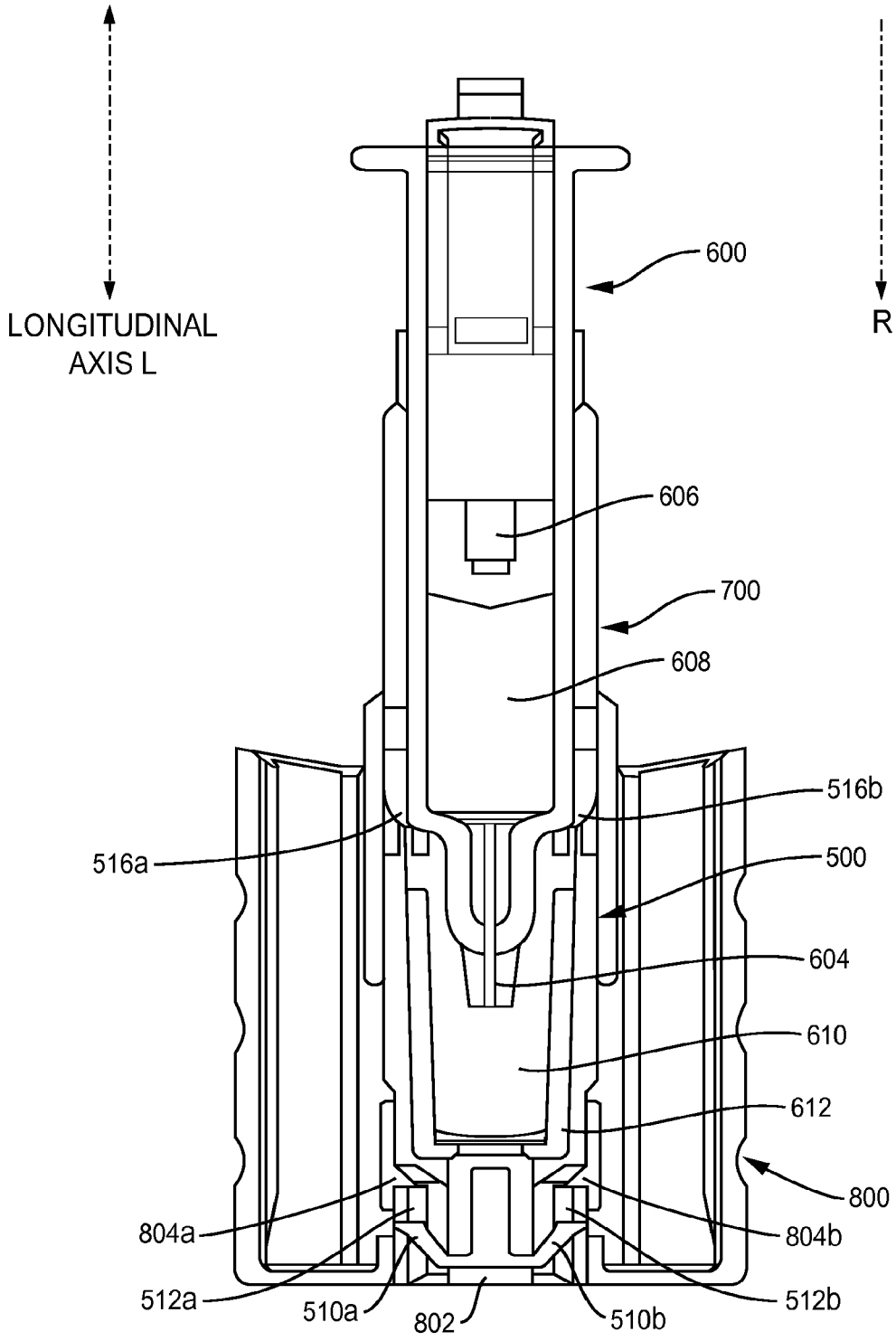

LONGITUDINAL
AXIS L
R
600
606
700
608
516b
516a
500
604
610
612
800
804a
804b
512a
510a
802
510b
512b

FIG. 8

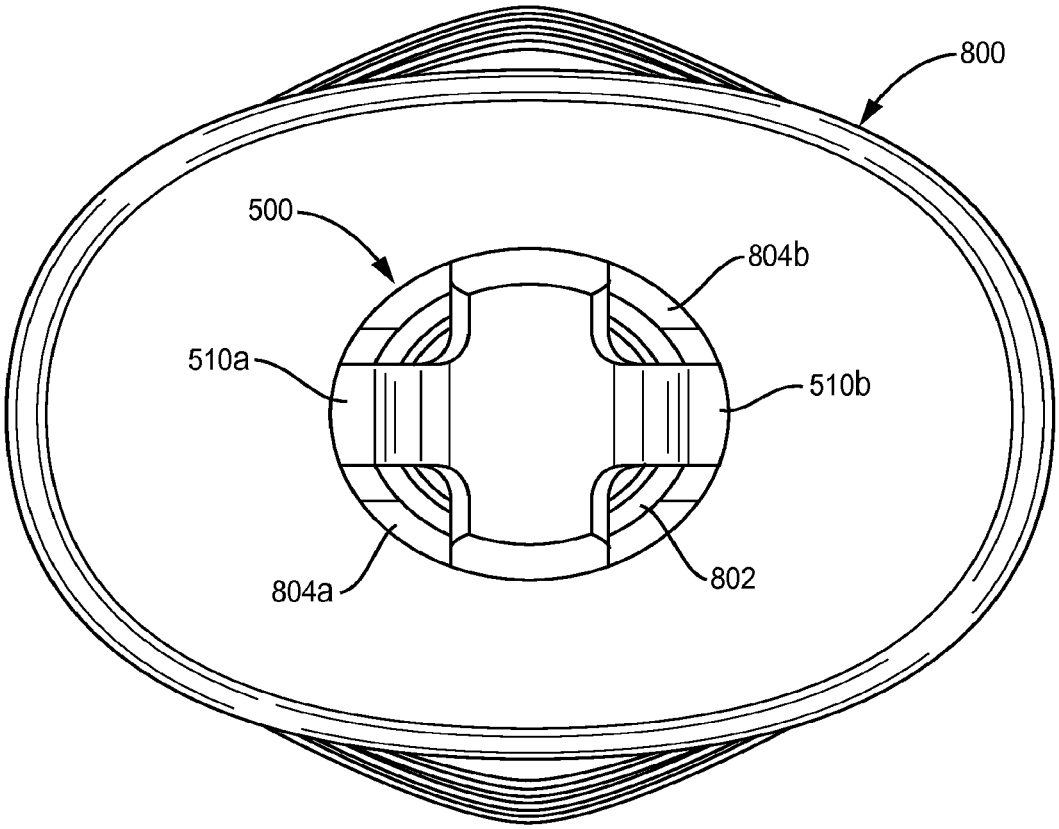


FIG. 9

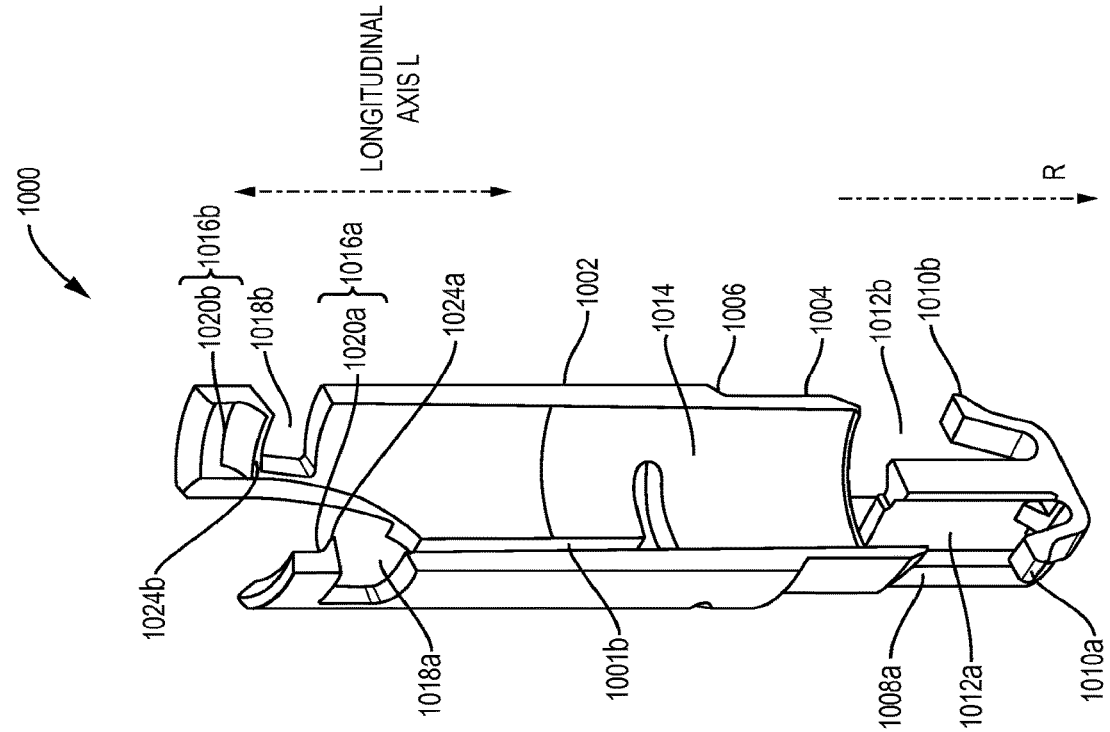


FIG. 10A

FIG. 10B

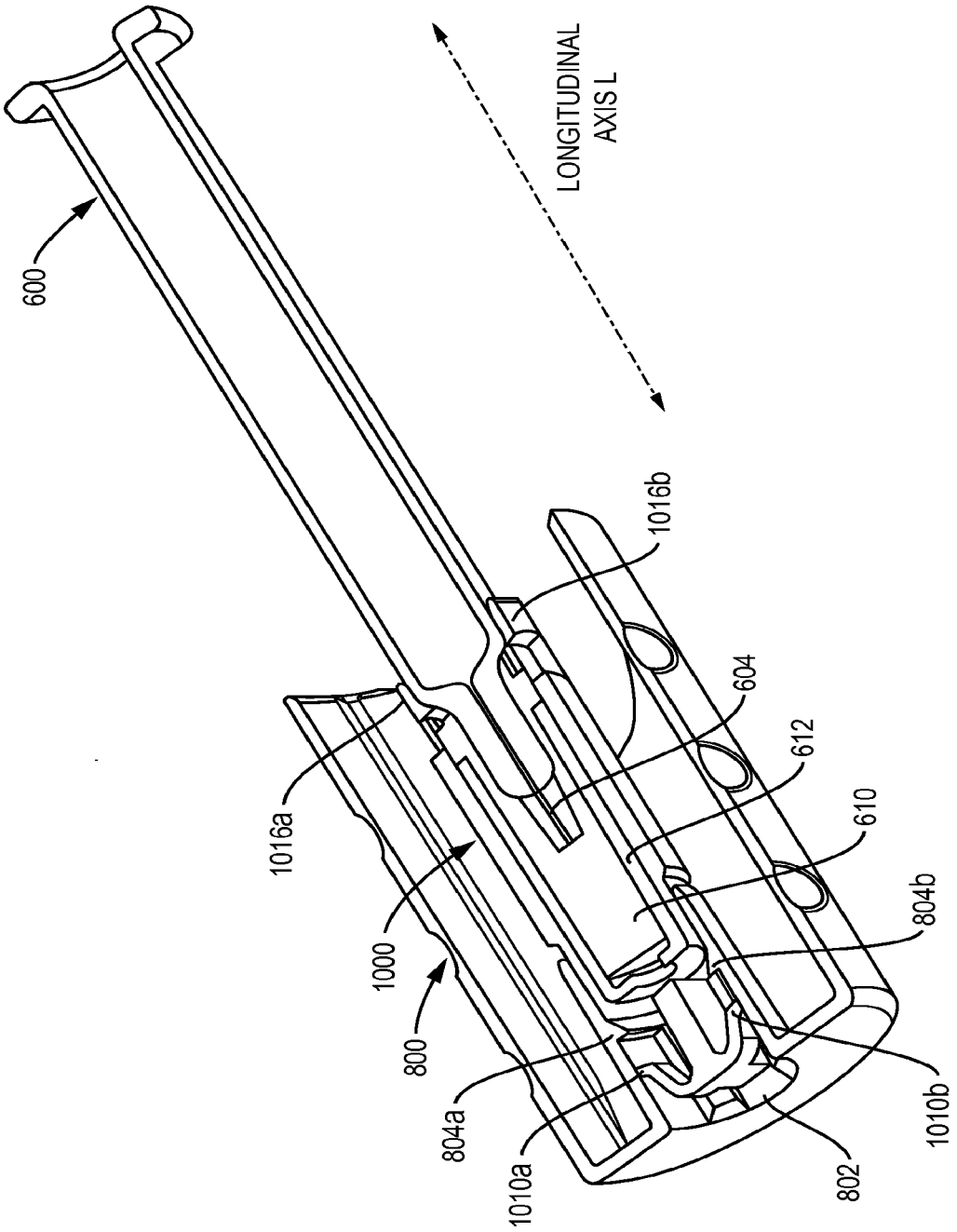

600
LONGITUDINAL AXIS L
1016b
604
612
610
804b
1016a
1000
800
804a
1010a
802
1010b

FIG. 11

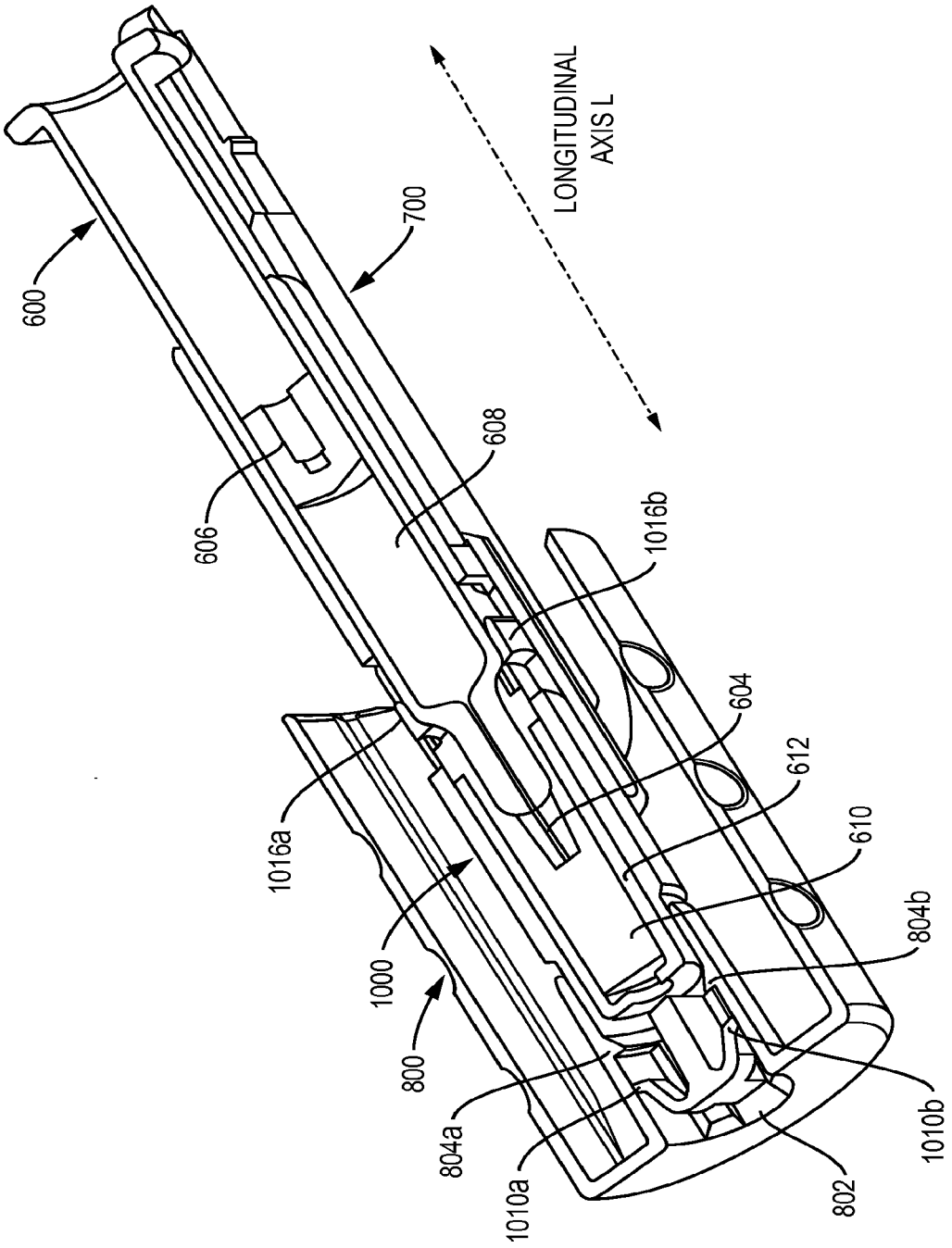

600
700
LONGITUDINAL AXIS L
606
608
1016b
604
612
610
804b
1016a
1000
800
804a
1010a
802
1010b

FIG. 12

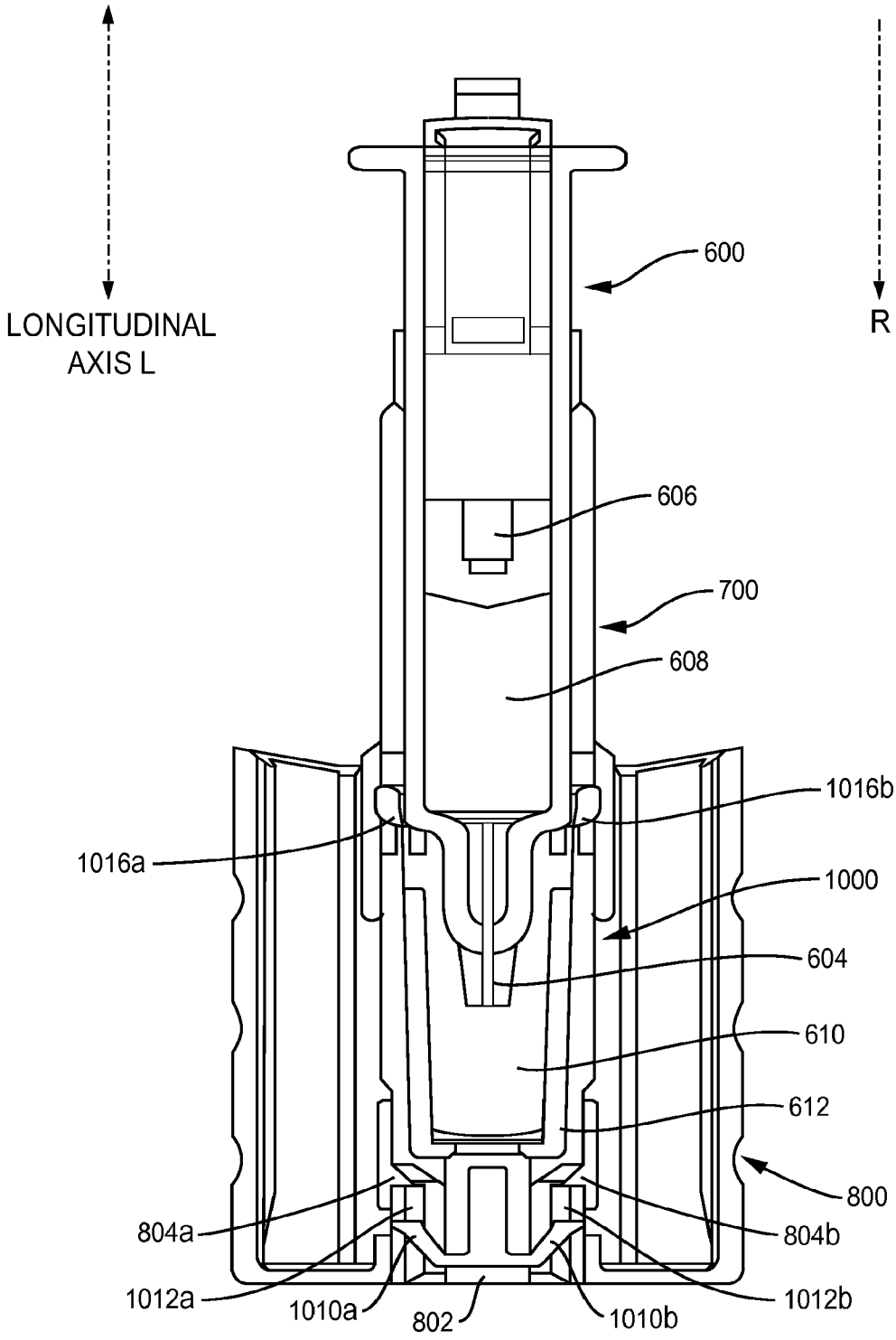

LONGITUDINAL
AXIS L
R
600
606
700
608
1016b
1016a
1000
604
610
612
800
804a
804b
1012a
1010a
802
1010b
1012b

FIG. 13

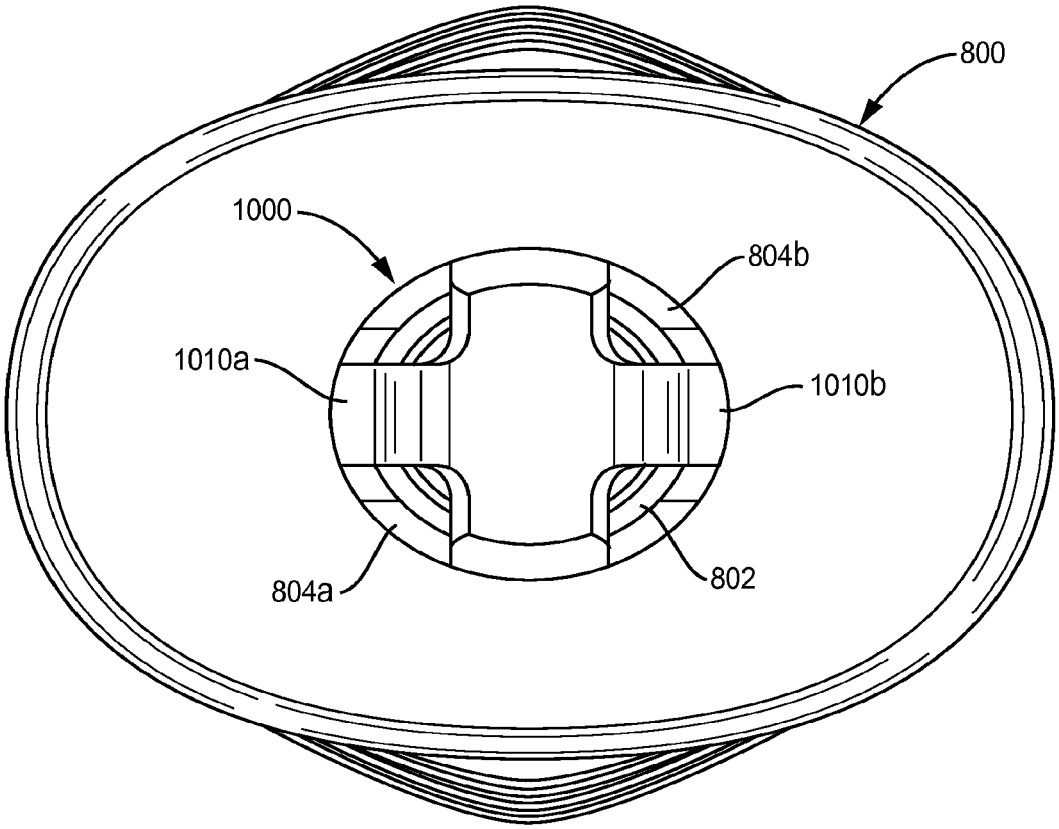


FIG. 14

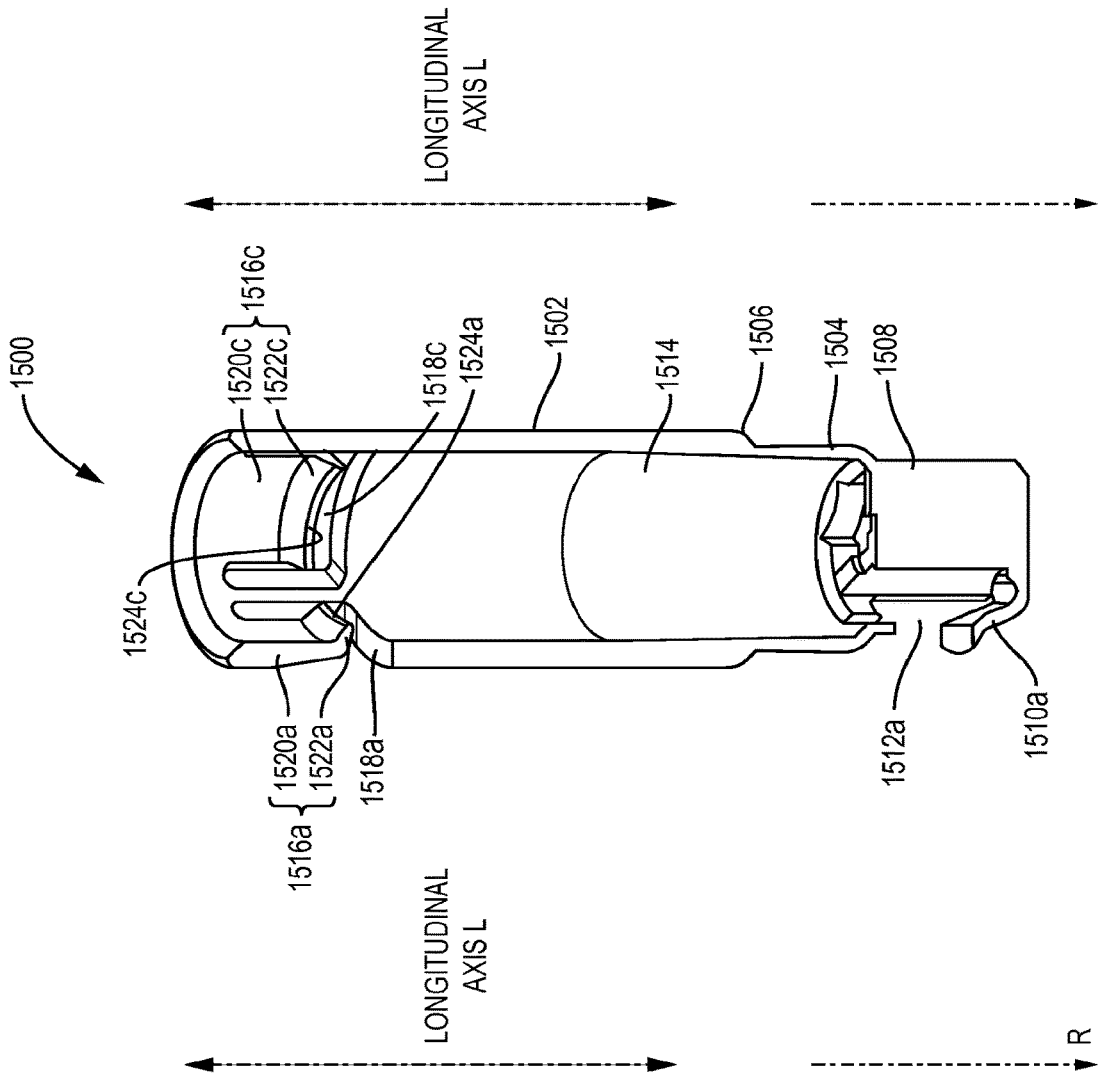


FIG. 15B

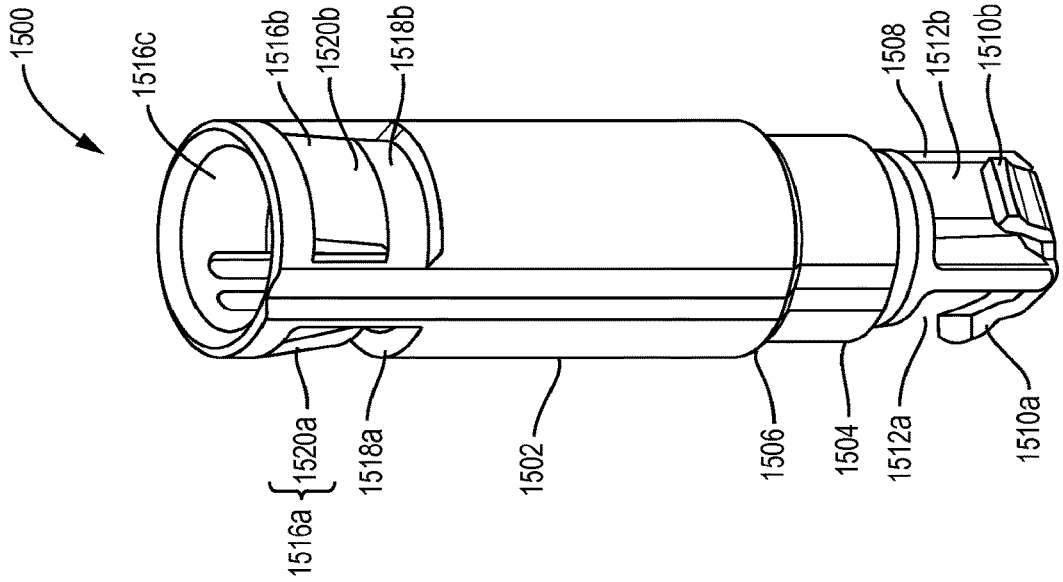


FIG. 15A

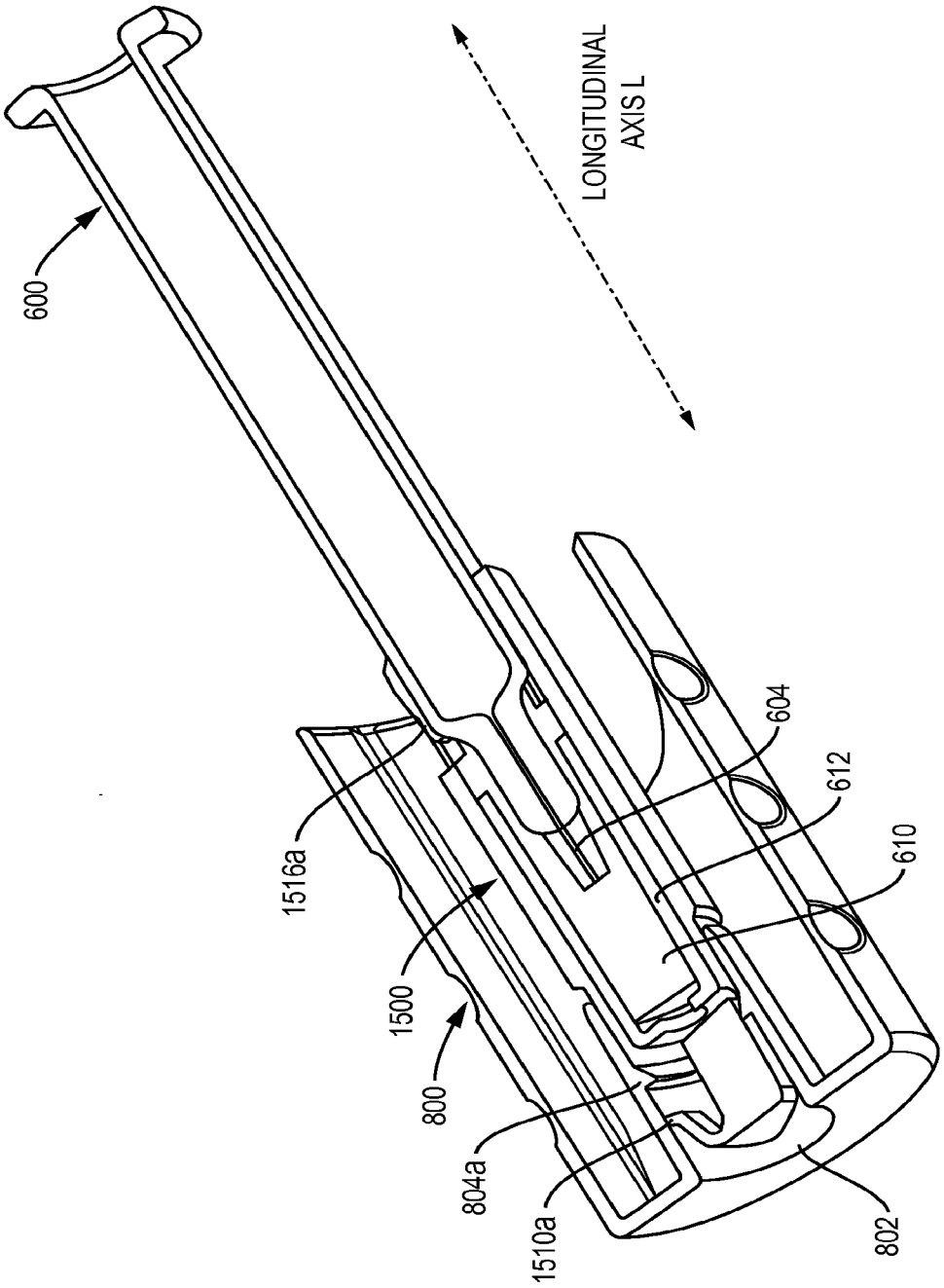

600
LONGITUDINAL AXIS L
1516a
1500
800
804a
1510a
802
604
612
610

FIG. 16

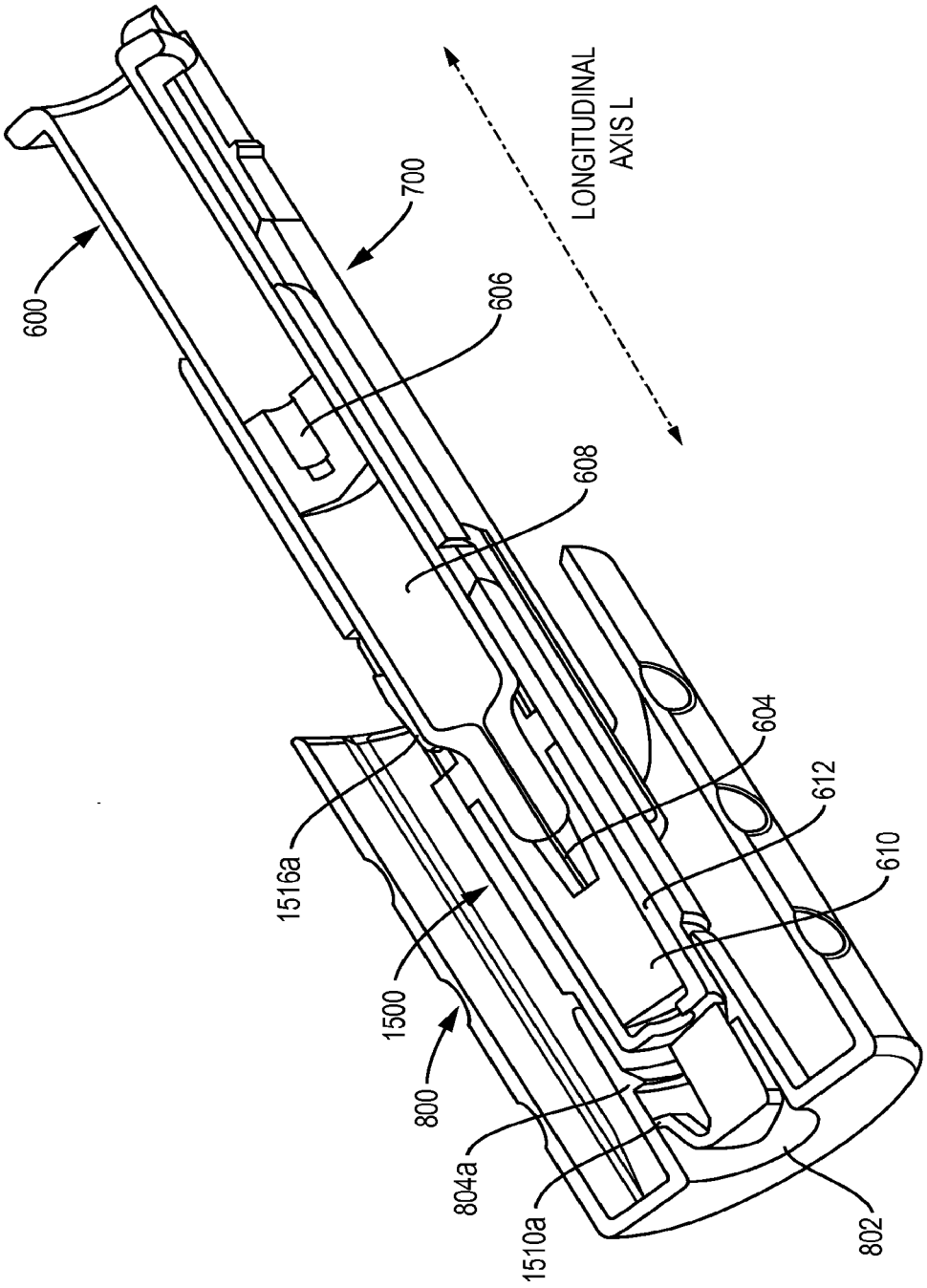

600
700
606
608
LONGITUDINAL AXIS L
604
612
610
1516a
1500
800
804a
1510a
802

FIG. 17

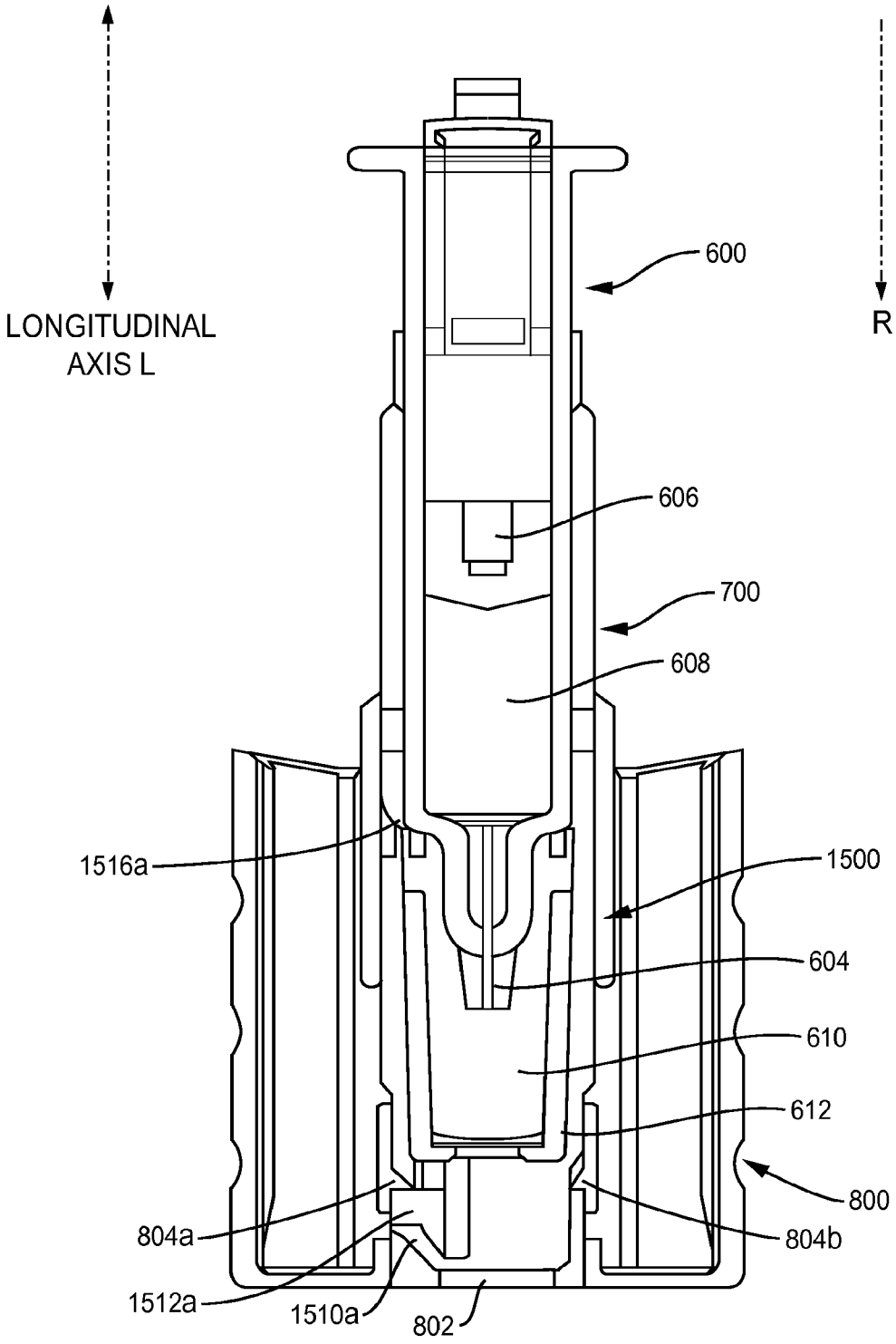

LONGITUDINAL
AXIS L
R
600
606
700
608
1516a
1500
604
610
612
800
804a
804b
1512a
1510a
802

FIG. 18

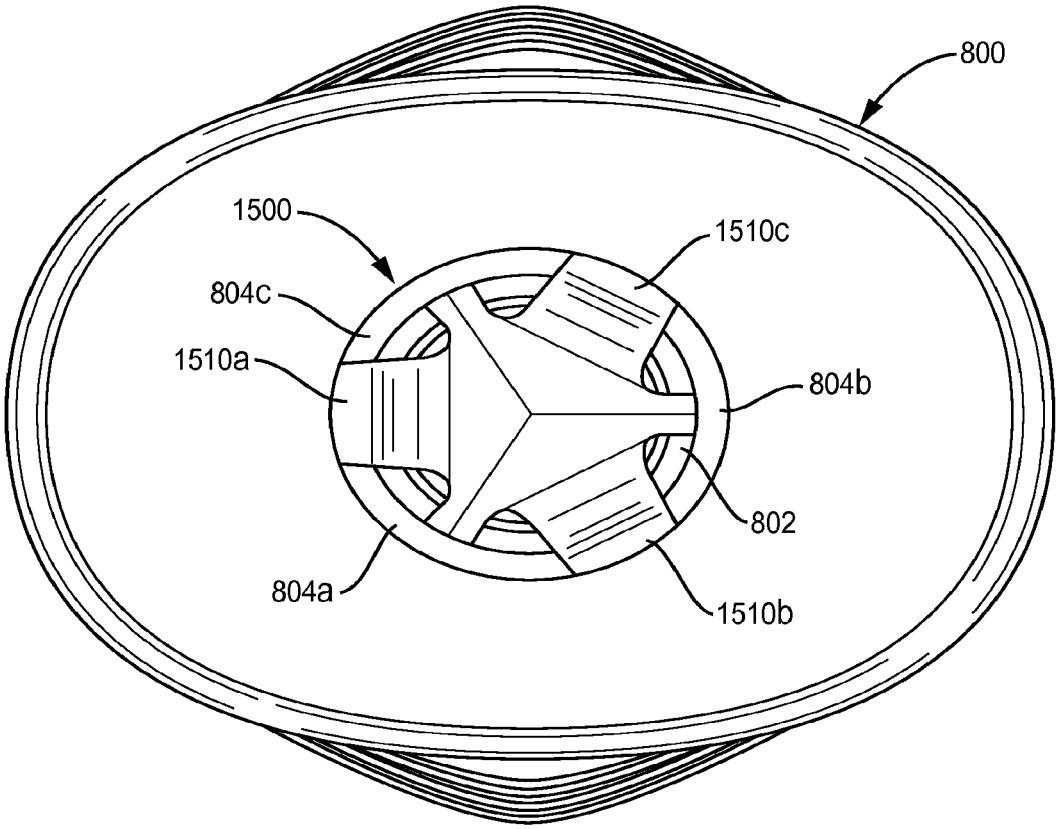


FIG. 19

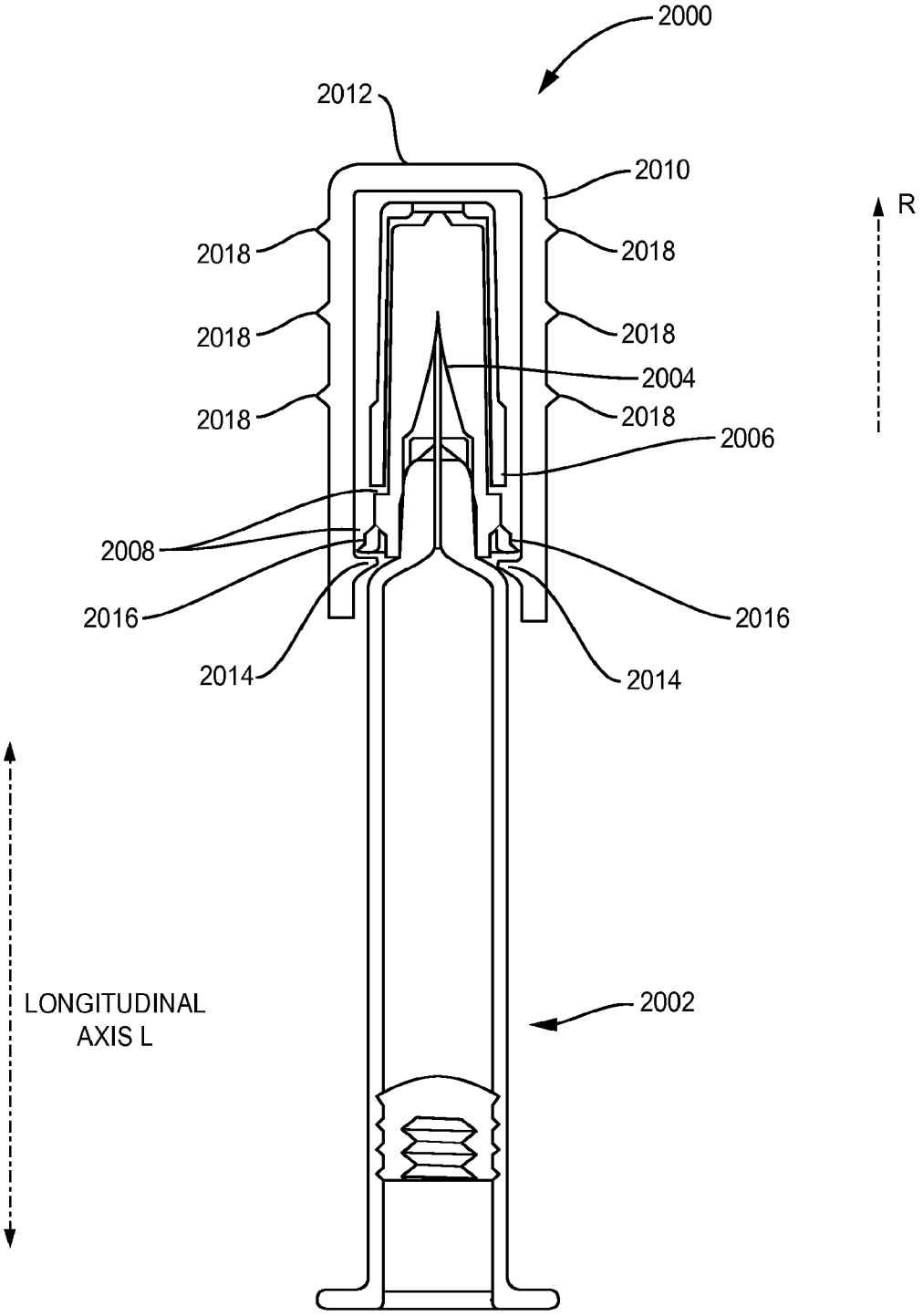

2000
2012
2010
R
2018
2018
2018
2018
2004
2018
2006
2008
2016
2016
2014
2014
LONGITUDINAL
AXIS L
2002

FIG. 20

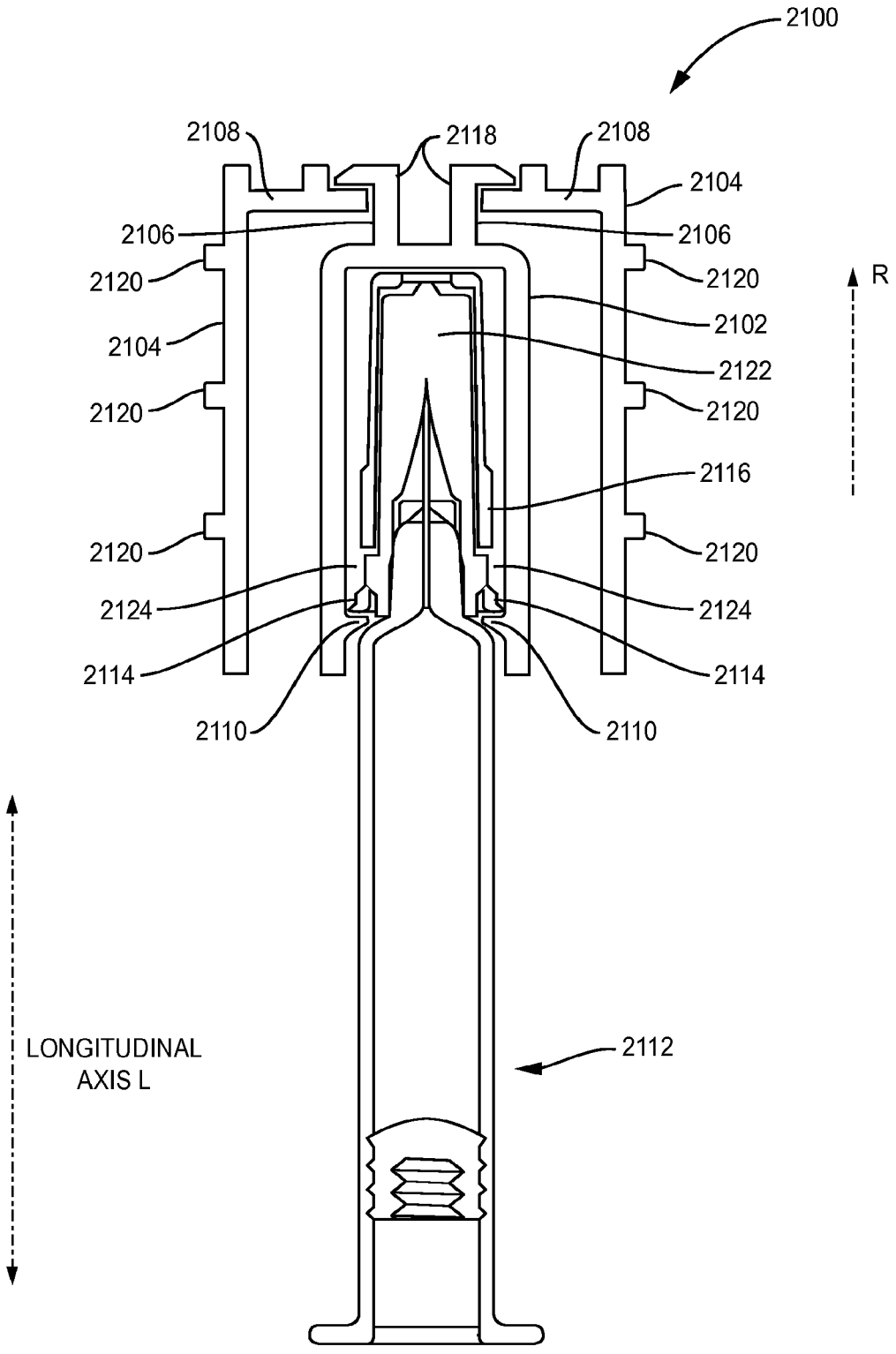

2100
2108
2118
2108
2104
2106
2106
2120
2120
R
2102
2104
2122
2120
2120
2116
2120
2120
2124
2124
2114
2114
2110
2110
LONGITUDINAL
AXIS L
2112

FIG. 21

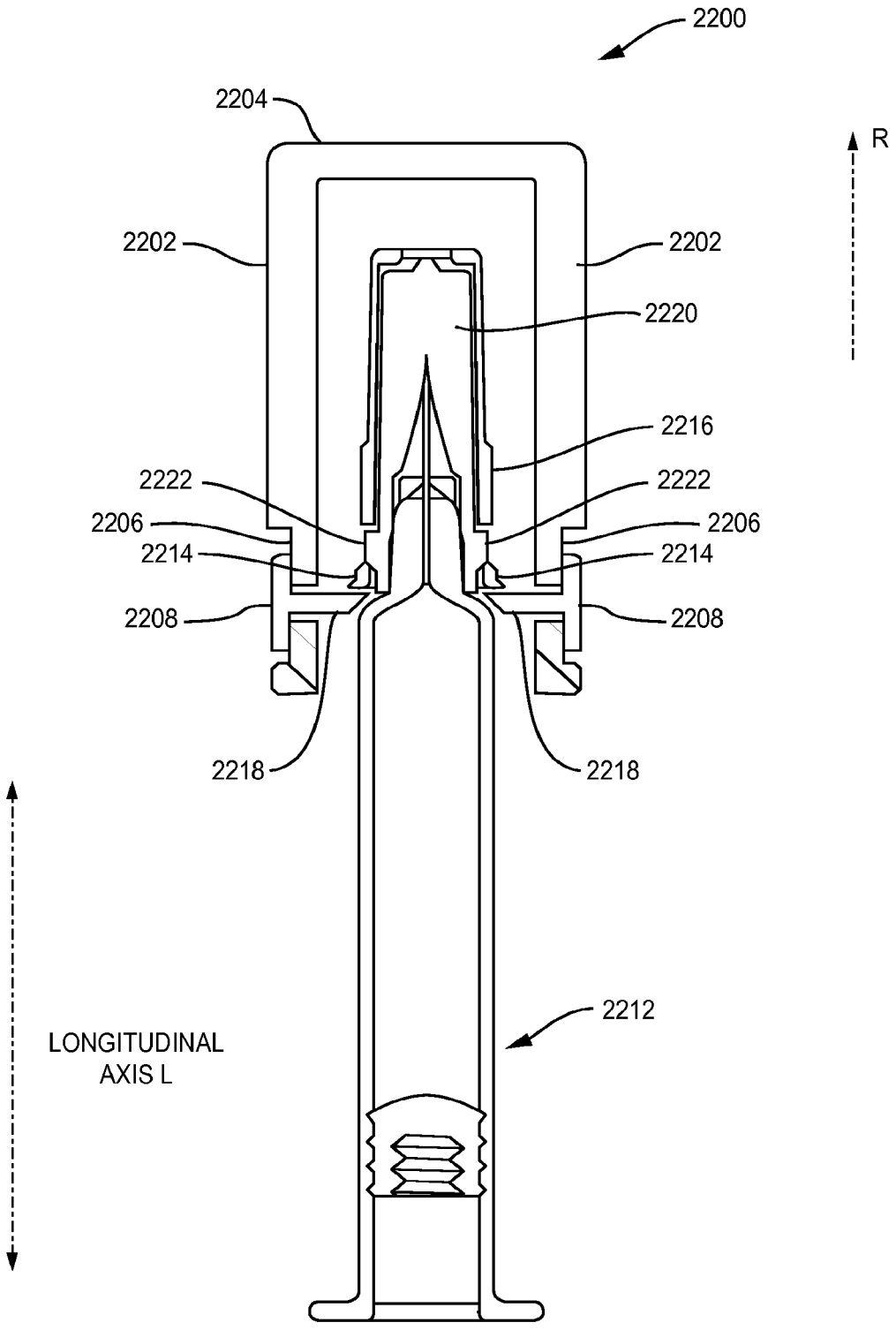

2200
2204
R
2202
2202
2220
2216
2222
2222
2206
2206
2214
2214
2208
2208
2218
2218
2212
LONGITUDINAL
AXIS L

FIG. 22

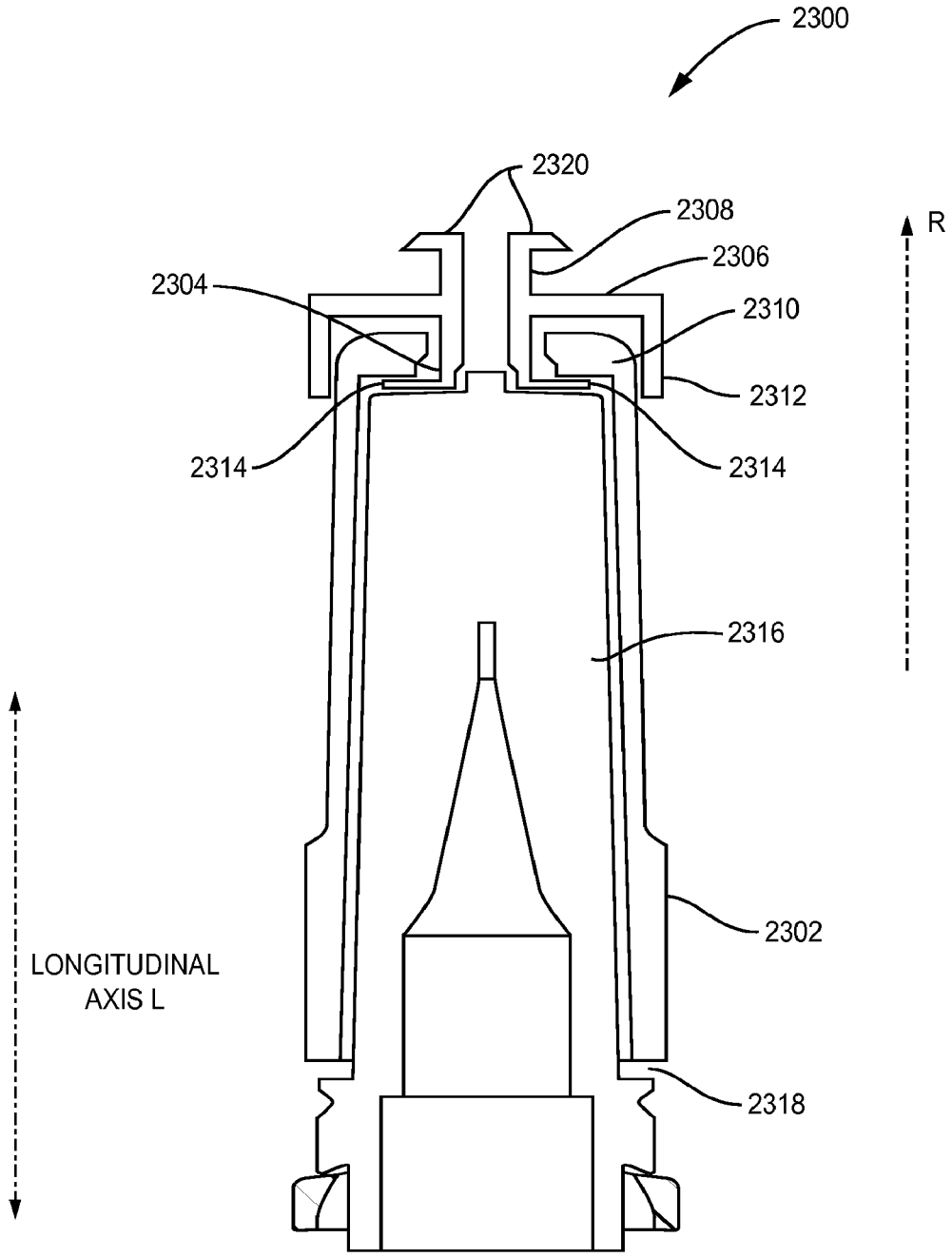

2300
2320
2308
2306
2304
2310
2312
2314
2314
R
2316
LONGITUDINAL
AXIS L
2302
2318

FIG. 23

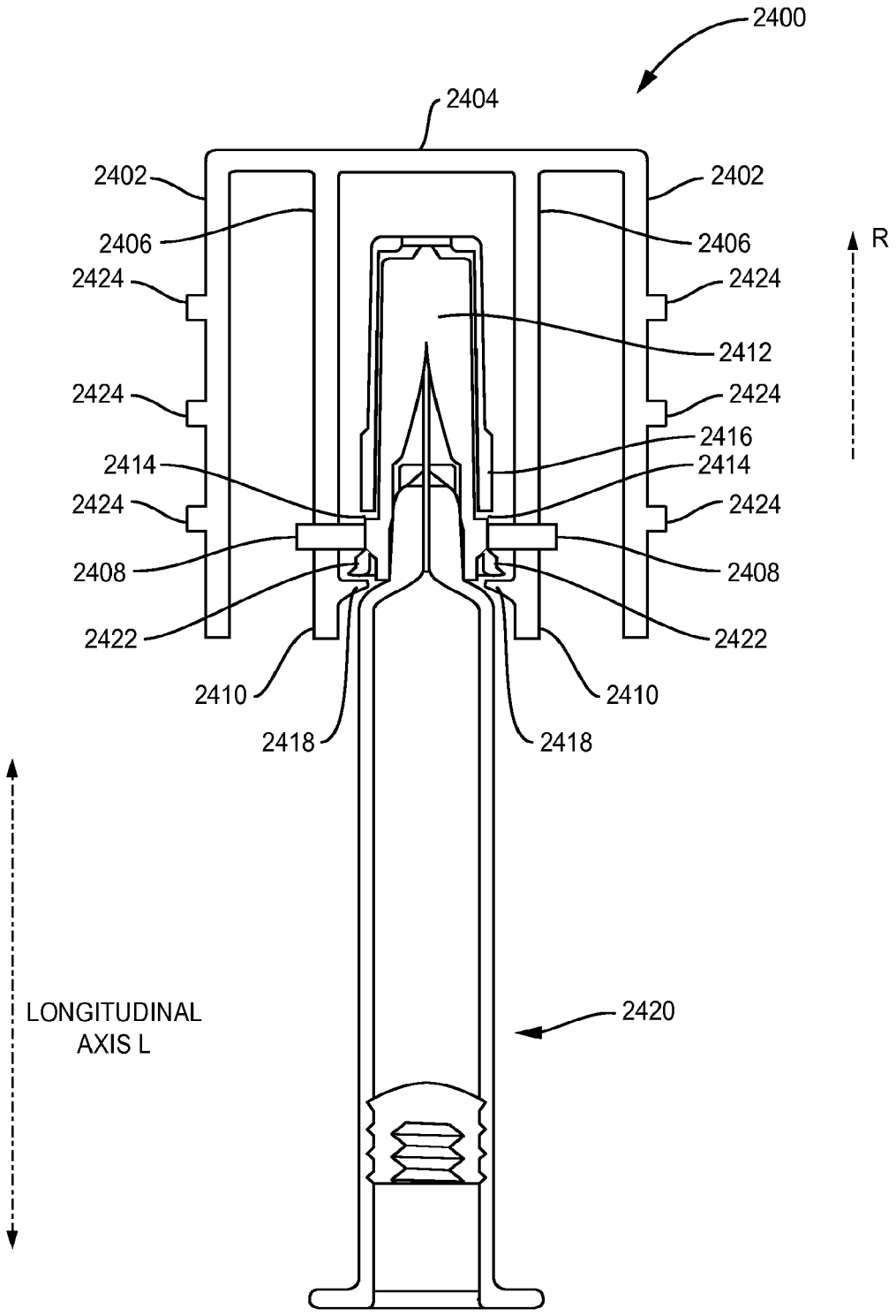

2400
2404
2402
2402
2406
2406
2424
2424
2412
2424
2424
2416
2414
2414
2424
2424
2408
2408
2422
2422
2410
2410
2418
2418
R
LONGITUDINAL
AXIS L
2420

FIG. 24

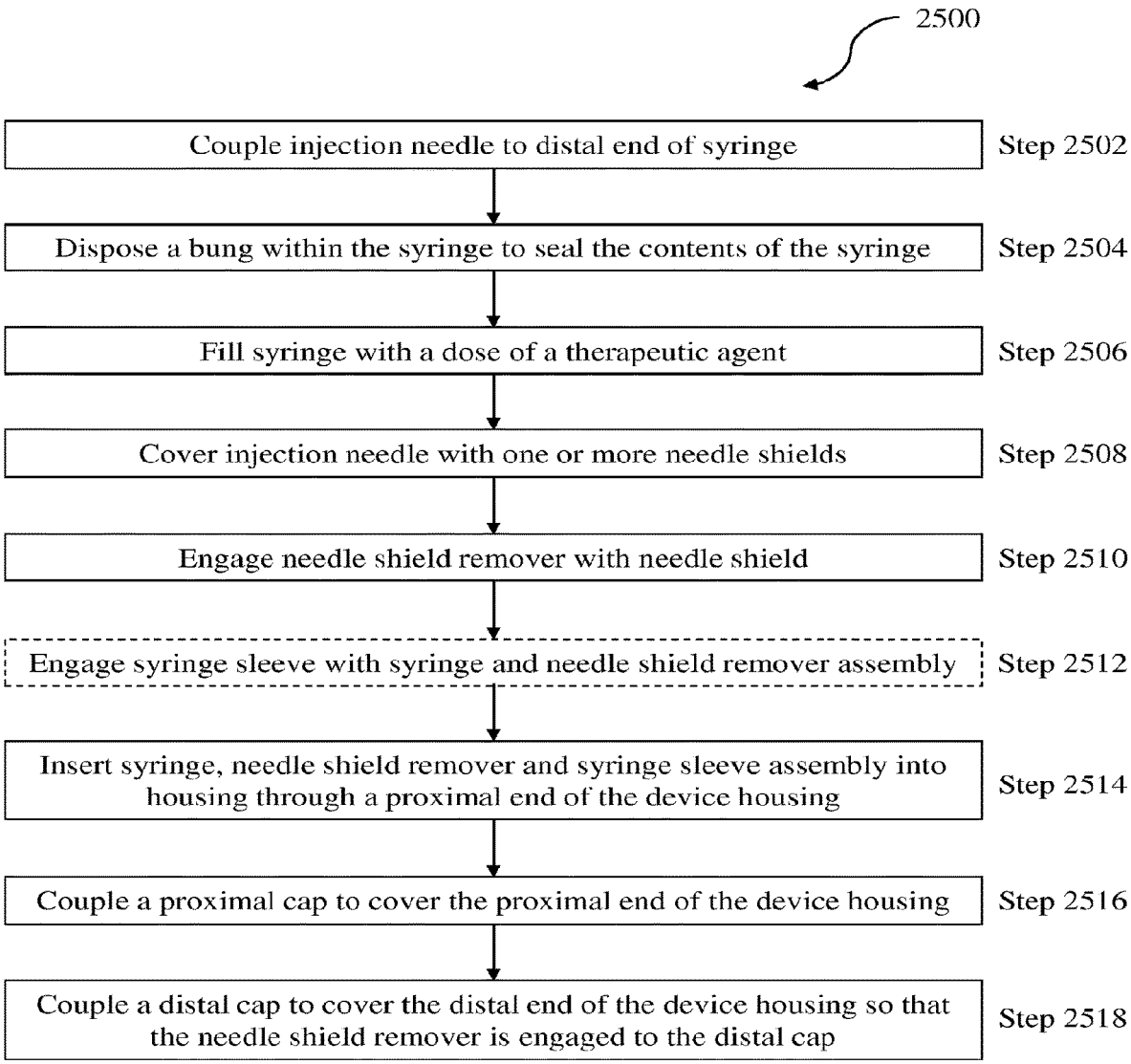

2500
Couple injection needle to distal end of syringe
Step 2502
Dispose a bung within the syringe to seal the contents of the syringe
Step 2504
Fill syringe with a dose of a therapeutic agent
Step 2506
Cover injection needle with one or more needle shields
Step 2508
Engage needle shield remover with needle shield
Step 2510
Engage syringe sleeve with syringe and needle shield remover assembly
Step 2512
Insert syringe, needle shield remover and syringe sleeve assembly into housing through a proximal end of the device housing
Step 2514
Couple a proximal cap to cover the proximal end of the device housing
Step 2516
Couple a distal cap to cover the distal end of the device housing so that the needle shield remover is engaged to the distal cap
Step 2518

FIG. 25

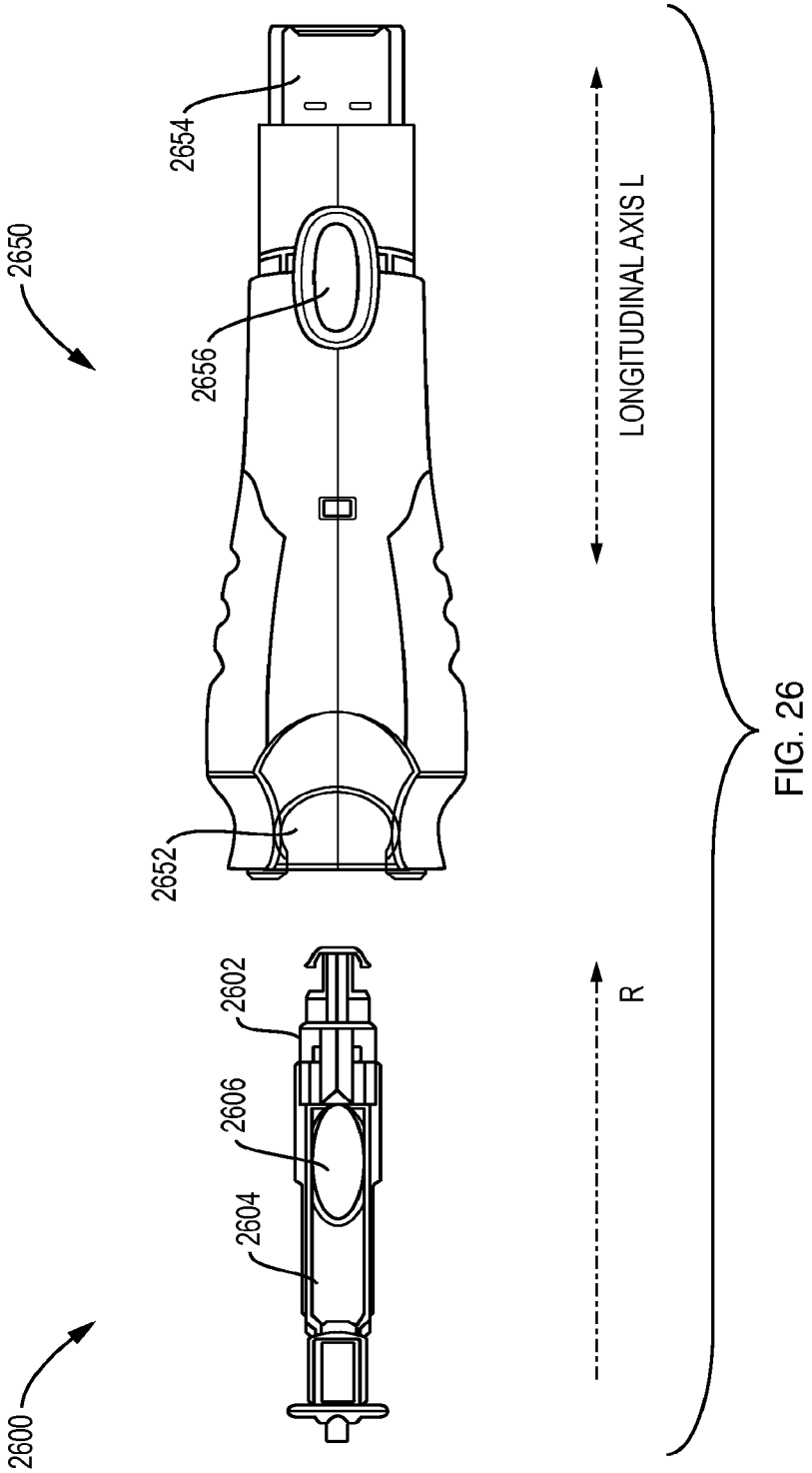

2650
2654
2656
2652
LONGITUDINAL AXIS L
2600
2602
2606
2604
R

FIG. 26

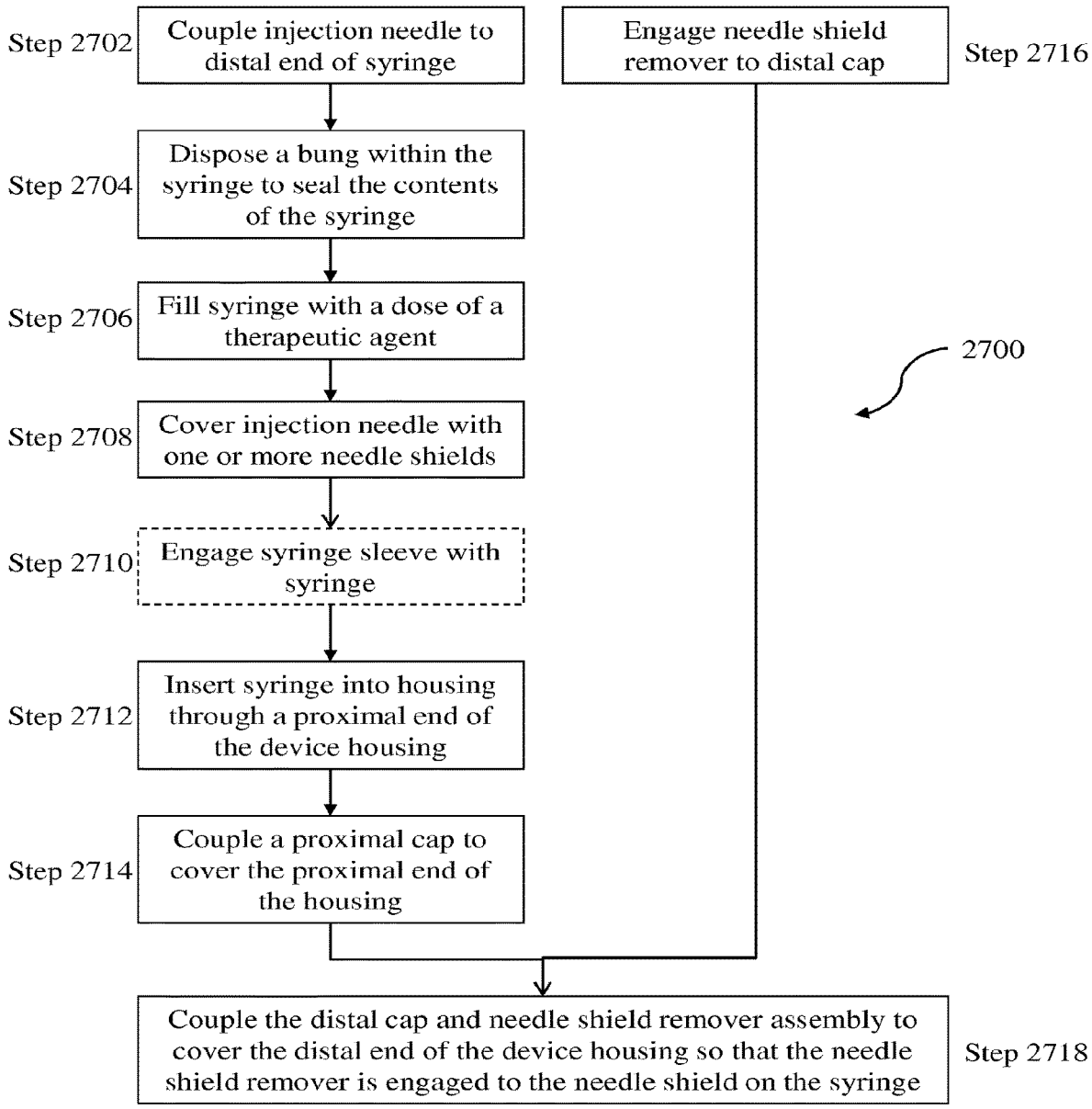

Step 2702
Couple injection needle to distal end of syringe
Step 2704
Dispose a bung within the syringe to seal the contents of the syringe
Step 2706
Fill syringe with a dose of a therapeutic agent
Step 2708
Cover injection needle with one or more needle shields
Step 2710
Engage syringe sleeve with syringe
Step 2712
Insert syringe into housing through a proximal end of the device housing
Step 2714
Couple a proximal cap to cover the proximal end of the housing
Step 2716
Engage needle shield remover to distal cap
2700
Couple the distal cap and needle shield remover assembly to cover the distal end of the device housing so that the needle shield remover is engaged to the needle shield on the syringe
Step 2718

FIG. 27

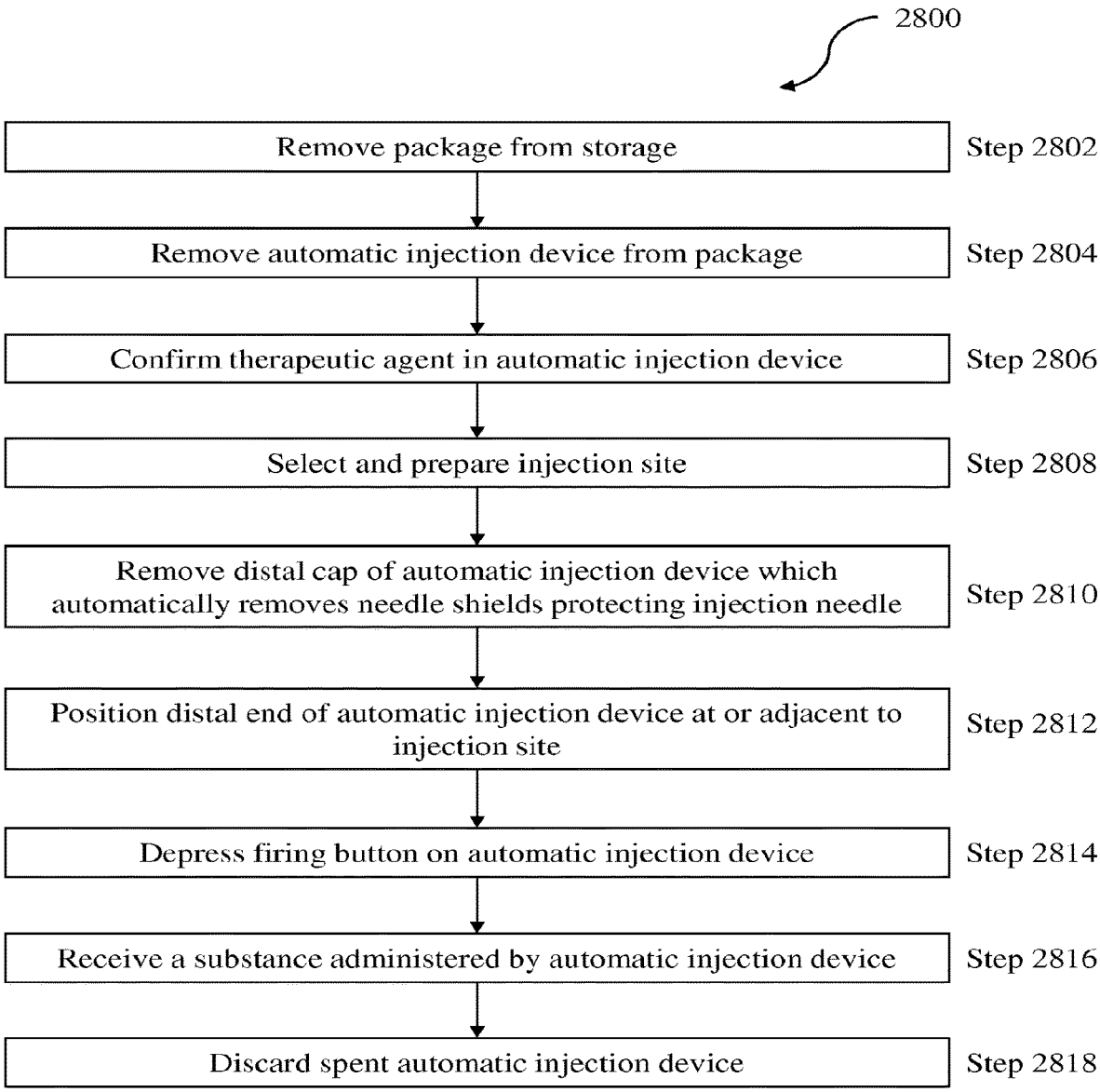

2800
Remove package from storage
Step 2802
Remove automatic injection device from package
Step 2804
Confirm therapeutic agent in automatic injection device
Step 2806
Select and prepare injection site
Step 2808
Remove distal cap of automatic injection device which automatically removes needle shields protecting injection needle
Step 2810
Position distal end of automatic injection device at or adjacent to injection site
Step 2812
Depress firing button on automatic injection device
Step 2814
Receive a substance administered by automatic injection device
Step 2816
Discard spent automatic injection device
Step 2818

FIG. 28

REMOVAL OF NEEDLE SHIELD FROM SYRINGES AND AUTOMATIC INJECTION DEVICES

RELATED APPLICATIONS

[0001] This application is a continuation of and claims the benefits of priority to U.S. Ser. No. 15/094,364 filed on Apr. 8, 2016, which is a continuation of and claims benefits of priority to U.S. Ser. No. 14/253,348, filed on Apr. 15, 2014, which is a continuation of and claims benefit of priority to U.S. Ser. No. 13/357,508, filed on Jan. 24, 2012, which claims the benefit of priority to U.S. Provisional Patent Application No. 61/435,467, filed Jan. 24, 2011, the entire contents of each application are incorporated herein by reference.

BACKGROUND

[0002] Automatic injection devices offer an alternative to manually-operated syringes for administering therapeutic agents into patients' bodies and allowing patients to self-administer therapeutic agents. Automatic injection devices may be used to administer 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, for example, U.S. Pat. Nos. 3,910,260; 4,004,577; 4,689,042; 4,755,169; and 4,795,433, the entire contents of which are incorporated herein in their entirety by reference. Various types of automatic injection devices are also described in, for example, U.S. Pat. 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, the entire contents of which are incorporated herein in their entirety by reference.

[0003] 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 injected into a patient's body.

[0004] A conventional automatic injection may include one or more needle shields to protect the syringe needle from damage and accidental contact and to maintain sterility of the injection needle. Needle shields include a soft needle shield that is formed of a flexible material, and a rigid needle shield that is formed of a rigid, inflexible material and that provide greater mechanical protection to the injection needle. Conventional automatic injection devices may also include a removable cap covering the needle shields to provide mechanical protection for the needle shields and to facilitate removal of the needle shields before an injection may be performed.

[0005] FIGS. **1**A and **1**B illustrate an exemplary syringe **100** including a substantially tubular syringe body **102** for holding a therapeutic agent. FIG. **1**A illustrates a side view of the exemplary syringe **100**. FIG. **1**B illustrates a cross-sectional view of the exemplary syringe **100** bisected along the longitudinal axis L. An injection needle may be coupled at a distal end of the syringe body **102**. The injection needle may be covered and protected by a soft needle shield **104** and a rigid needle shield **106** that surrounds the soft needle shield **104**. One or more apertures **108** may be provided in a side wall of the rigid needle shield **106** to allow a portion of the soft needle shield **104** to extend through the apertures **108**. This permits the soft needle shield **104** and the rigid needle shield **106** to latch together which, in turn, permits removal of both the soft needle shield **104** and the rigid needle shield **106** when the rigid needle shield **106** is pulled away from the syringe body **102** in the distal direction (represented by arrow R), thereby exposing the injection needle for use in performing an injection. In an exemplary embodiment, a ridged portion **110** may be provided in the exterior surface of the rigid needle shield **106**. The ridged portion **110** may include one or more alternating outwardly-projecting ridges interspaced with grooves, and may thereby provide a region of higher friction contact for removal of the rigid needle shield **106** from the syringe.

SUMMARY

[0006] Exemplary embodiments provide a needle shield remover that reliably engages with a distal cap of an automatic injection device and with one or more needle shields coupled to a syringe of the device. An exemplary needle shield remover includes one or more inwardly-projecting shield engagement mechanisms that reliably engage with the needle shields, and one or more cap engagement mechanisms that reliably engage with the distal cap. When a user removes the distal cap, the needle shield remover reliably removes the needle shields (e.g., a soft needle shield and a rigid needle shield) from the syringe, thereby exposing the injection needle for performing an injection. In an exemplary assembly method, an exemplary needle shield remover is engaged to a needle shield coupled to a syringe, prior to insertion of the syringe and needle shield remover assembly into a housing of the automatic injection device. This exemplary assembly method allows visual inspection, outside the housing of the device, to ensure that the needle shield remover is correctly and reliably engaged to the needle shield before the syringe and needle shield remover assembly is inserted into the housing.

[0007] In accordance with one exemplary embodiment, an apparatus is provided for removing a needle shield from a syringe. The apparatus includes a tubular member for enclosing the needle shield coupled to the syringe. The apparatus also includes one or more cap engagement mechanisms provided at a distal end of the tubular member and configured for engagement with a distal cap provided for covering a distal end of the syringe. The apparatus also includes one or more shield engagement mechanisms provided at a proximal end of the tubular member and configured for engagement with the needle shield. When the apparatus is pulled away from the syringe, the one or more shield engagement mechanisms exert force against the needle shield to remove the needle shield from the syringe.

[0008] In accordance with another exemplary embodiment, an automatic injection device is provided. The automatic injection device includes a syringe, a needle shield coupled to a distal end of the syringe, and a distal cap for covering the needle shield. The automatic injection device also includes a needle shield remover disposed between the needle shield and the distal cap. The needle shield includes a tubular member for enclosing the needle shield coupled to the syringe, one or more cap engagement mechanisms provided at a distal end of the tubular member and engaged with the distal cap, and one or more shield engagement mechanisms provided at a proximal end of the tubular

member and engaged with the needle shield. When the needle shield remover is pulled away from the syringe, the one or more shield engagement mechanisms exert force against the needle shield to remove the needle shield from the syringe.

[0009] In accordance with another exemplary embodiment, a method is provided for assembling an automatic injection device. The method includes coupling a needle shield to a distal end of a syringe. The method also includes engaging one or more shield engagement mechanisms of a needle shield remover to the needle shield. The method further includes inserting an assembly comprising the syringe, the needle shield and the needle shield remover into a housing of the automatic injection device.

BRIEF DESCRIPTION TO THE DRAWINGS

[0010] The foregoing and other objects, aspects, features, and advantages of exemplary embodiments will become more apparent and may be better understood by referring to the following description taken in conjunction with the accompanying drawings, in which:

[0011] FIG. **1**A illustrates a side view of an exemplary syringe.

[0012] FIG. **1**B illustrates a cross-sectional view of the exemplary syringe of FIG. **1**A bisected along the longitudinal axis L.

[0013] FIG. **2**A illustrates a side view of an exemplary needle shield remover engaged to a syringe.

[0014] FIG. **2**B illustrates another side view of the exemplary needle shield remover of FIG. **2**A rotated by about 90 degrees.

[0015] FIG. **2**C illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **2**A and **2**B engaged to a syringe and a distal cap.

[0016] FIG. **2**D is a bottom view of the exemplary distal cap of FIG. **2**C showing engagement of the needle shield remover to the distal cap.

[0017] FIG. **3**A illustrates a perspective view of an exemplary syringe sleeve.

[0018] FIG. **3**B illustrates a cross-sectional perspective view of the exemplary syringe sleeve of FIG. **3**A bisected along a longitudinal axis L.

[0019] FIG. **4**A illustrates a perspective view of an assembly of an exemplary syringe sleeve housing an exemplary syringe that is fitted with an exemplary needle shield remover.

[0020] FIG. **4**B illustrates a transverse cross-sectional view of the exemplary assembly of FIG. **4**A.

[0021] FIG. **5**A illustrates a perspective view of an exemplary needle shield remover.

[0022] FIG. **5**B illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIG. **5**A bisected along a longitudinal axis L.

[0023] FIG. **6** illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **5**A and **5**B assembled with a syringe and a distal cap.

[0024] FIG. **7** illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **5**A and **5**B assembled with a syringe, a distal cap and a syringe sleeve.

[0025] FIG. **8** illustrates a front cross-sectional view of the exemplary assembly of FIG. **7**.

[0026] FIG. **9** illustrates a bottom view of an exemplary distal cap that is applicable to FIGS. **6-8**.

[0027] FIG. **10**A illustrates a perspective view of an exemplary needle shield remover.

[0028] FIG. **10**B illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIG. **10**A bisected along a longitudinal axis L.

[0029] FIG. **11** illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **10**A and **10**B assembled with a syringe and a distal cap.

[0030] FIG. **12** illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **10**A and **10**B assembled with a syringe, a distal cap and a syringe sleeve.

[0031] FIG. **13** illustrates a front cross-sectional view of the exemplary assembly of FIG. **12**.

[0032] FIG. **14** illustrates a bottom view of an exemplary distal cap that is applicable to FIGS. **11-13**.

[0033] FIG. **15**A illustrates a perspective view of an exemplary needle shield remover.

[0034] FIG. **15**B illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIG. **15**A bisected along a longitudinal axis L.

[0035] FIG. **16** illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **15**A and **15**B assembled with a syringe and a distal cap.

[0036] FIG. **17** illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **15**A and **15**B assembled with a syringe, a distal cap and a syringe sleeve.

[0037] FIG. **18** illustrates a front cross-sectional view of the exemplary assembly of FIG. **17**.

[0038] FIG. **19** illustrates a bottom view of an exemplary distal cap that is applicable to FIGS. **16-18**.

[0039] FIG. **20** illustrates a cross-sectional view of another exemplary needle shield remover bisected along the longitudinal axis L.

[0040] FIG. **21** illustrates a cross-sectional view of another exemplary needle shield remover bisected along the longitudinal axis L.

[0041] FIG. **22** illustrates a cross-sectional view of another exemplary needle shield remover bisected along the longitudinal axis L.

[0042] FIG. **23** illustrates a cross-sectional view of another exemplary needle shield remover bisected along the longitudinal axis L.

[0043] FIG. **24** illustrates a cross-sectional view of another exemplary needle shield remover bisected along the longitudinal axis L.

[0044] FIG. **25** is a flowchart of an exemplary method for assembling an exemplary needle shield remover with a syringe and a distal cap of an automatic injection device, in which the needle shield remover is assembled with a syringe prior to insertion of the syringe into the housing of the device.

[0045] FIG. **26** illustrates a device view of the exemplary method of FIG. **25** by which an exemplary automatic injection device may be assembled.

[0046] FIG. **27** is a flowchart of an exemplary method for assembling an exemplary needle shield remover with a syringe and a distal cap of an automatic injection device, in which the needle shield remover is assembled with a syringe after insertion of the syringe into the housing of the device.

[0047] FIG. **28** is a flowchart of an exemplary method for using an exemplary automatic injection device to administer an injection.

DETAILED DESCRIPTION

[0048] One difficulty in the design of conventional automatic injection devices lies in providing a mechanism that reliably engages a soft needle shield and/or a rigid needle shield to remove it from the syringe. For example, in certain conventional automatic injection devices, a removable distal cap includes a mechanism that snaps into position in a gap formed between the syringe body and the needle shield. When the removable distal cap is removed, the mechanism in the cap allows the needle shield to be removed as well because of its engagement with the cap. However, due to component tolerances and other component variations that arise during the manufacturing process, it is difficult to achieve, in a conventional automatic injection device, a needle shield removal mechanism that consistently fits within the gap formed between the syringe body and the needle shield. For the same reasons, it is difficult to ensure, in a conventional automatic injection device, that the needle shield removal mechanism is maintained in engagement with the needle shield, and that the needle shield removal mechanism applies an appropriate level of force to the needle shield when the user removes the cap in order to remove the needle shield.

[0049] Exemplary embodiments address the deficiencies in conventional automatic injection devices by providing a needle shield remover that reliably engages and removes one or more needle shields when a removable distal cap is removed from a distal end of the device. An exemplary needle shield remover may be provided separately from one or more needle shields and from a removable distal cap covering the distal end of the device. The needle shield remover may include one or more inwardly-projecting shield engagement mechanisms that reliably engage with one or more needle shields, and one or more cap engagement mechanisms that reliably engage with the removable distal cap. When a user removes the removable distal cap covering the distal end of the device, the exemplary needle shield remover reliably removes the needle shields from the syringe, thereby exposing the injection needle for performing an injection.

[0050] U.S. Provisional Patent Application No. 61/435,467, filed Jan. 24, 2011, to which the present application claims priority, teaches some exemplary needle shield removers that employ the concept of "float" relative to a removable distal cap and a needle shield remover attached thereto prior to placement of the removable distal cap onto an automatic injection device. U.S. Provisional Patent Application No. 61/435,467, filed Jan. 24, 2011, also teaches some exemplary needle shield removers that are "floatless" and do not employ the concept of "float" relative to a removable distal cap and a needle shield remover attached to an automatic injection device.

[0051] The concept of "float" refers to the structure, function and operation of a needle shield remover and a removable distal cap that form a single assembly and, as part of the assembly, slide relative to each other along a longitudinal axis during attachment to an automatic injection device, where the relative movement exceeds acceptable tolerances that account for manufacturing variations in the assembled components. The employment of "float" refers to a single assembly formed of a needle shield remover and a removable distal cap that are pre-assembled before the needle shield remover is engaged to a needle shield. That is, in an automatic injection device that employs "float," the pre-assembled removable distal cap and needle shield remover form a one-piece assembly that is engaged to the needle shield and the automatic injection device after the syringe is loaded into the automatic injection device. The pre-assembled removable distal cap and needle shield remover are engaged to the automatic injection device in at least two steps in which the distal cap is first engaged to the automatic injection device, and subsequently the needle shield remover is engaged to the needle shield by sliding along a longitudinal axis from a first position to an second engaged position while the distal cap remains engaged to the automatic injection device.

[0052] Other exemplary needle shield removers and distal caps taught in the present application are "floatless" and do not rely on the concept of "float" for correctly and reliably assembling a needle shield remover and a removable distal cap in an automatic injection device. The concept of "floatless" or "floatlessness" refers to the structure, function and operation of an exemplary needle shield remover and a removable distal cap that are not pre-assembled as a single assembly and that are not configured to slide relative to each other along a longitudinal axis during attachment to an automatic injection device in order to engage the needle shield remover to the needle shield, where the relative movement exceeds acceptable tolerances that account for manufacturing variations in the assembled components. That is, in an automatic injection device that does not employ "float" (i.e., "floatless") the removable distal cap and the exemplary needle shield remover are not pre-assembled and do not form a one-piece assembly. That is, in exemplary "floatless" embodiments an exemplary needle shield remover is an assembly engaged to a needle shield attached to a syringe prior to insertion of the syringe and needle shield remover assembly into a housing of the automatic injection device. In turn, the removable distal cap is then engaged to the device in a one-step process in which coupling the distal cap to the distal end of the device housing also engages the distal cap with the needle shield remover. The structure, function and operation of the removable distal cap and the needle shield remover in "floatless" embodiments do not accommodate pre-assembly as a one piece assembly and do not accommodate movement of the needle shield remover attached to the removable distal cap from a first position to an engaged position along a longitudinal axis.

[0053] Automatic injection devices that do not rely on the concept of "float" to assemble an exemplary needle shield remover and a distal cap are advantageous over automatic injection devices that rely on the "float" concept. This is because reliance on the relative movement between the needle shield remover and the distal cap in automatic injection devices that use "float" increases the risk of unreliable and incorrect engagement of the needle shield remover with the needle shield, and thereby reduces robustness of the assembly.

[0054] Furthermore, the ability, in exemplary embodiments, to assemble the exemplary needle shield remover with the needle shield outside the device housing and outside the distal cap allows visual inspection of the assembly process to ensure that the needle shield remover is correctly and reliably engaged with a gap between the syringe body and the needle shield.

I. DEFINITIONS

[0055] Certain terms are defined in this section to facilitate understanding of exemplary embodiments.

[0056] The terms "automatic injection device" and "auto-injector," as used herein, refer to a device that enables a patient to self-administer a therapeutically effective dose of a therapeutic agent, wherein the device differs from a conventional syringe by the inclusion of a mechanism for automatically delivering the therapeutic agent to the patient by injection when the mechanism is engaged.

[0057] The terms "vessel" and "container," as used herein, refer to a syringe or cartridge that may be used in an exemplary automatic injection device for holding a dose of a therapeutic agent.

[0058] The terms "syringe" and "cartridge," as used herein, refer to a sterile barrel portion of an automatic injection device that is filled with a dose of a therapeutic agent prior to distribution or sale of the device to a patient or other non-medical professional for administration of the therapeutic agent to a patient. In an exemplary embodiment, a distal end of the barrel portion of a syringe may be coupled to a sterile hypodermic injection needle. In an exemplary embodiment, a distal end of the barrel portion of a cartridge may not be coupled to an injection needle. That is, in exemplary embodiments, a syringe may be a cartridge with a pre-attached injection needle coupled to its barrel portion.

[0059] Exemplary embodiments described herein with reference to a syringe assembly may also be implemented using a cartridge assembly. Similarly, exemplary embodiments described herein with reference to a cartridge assembly may also be implemented using a syringe assembly.

[0060] The term "pre-filled syringe," as used herein, refers to a syringe that is filled with a therapeutic agent immediately prior to administration of the therapeutic agent to a patient, and a syringe that is filled with a therapeutic agent and stored in this pre-filled form for a period of time before administration of the therapeutic agent to a patient.

[0061] The terms "injection needle" and "needle," as used herein, refer to a needle in an automatic injection device that is inserted into a patient's body to deliver a dose of a therapeutic agent into the patient's body. In an exemplary embodiment, the injection needle may be directly coupled to or may otherwise be in contact with a syringe assembly or a cartridge assembly that holds a dose of the therapeutic agent. In another exemplary embodiment, the injection needle may be indirectly coupled to the syringe or cartridge assembly, for example, via a syringe needle and/or a transfer mechanism that provides fluid communication between the syringe or cartridge assembly and the injection needle.

[0062] The term "thermoplastic material," as used herein, refers to a material that has the property of softening or fusing when heated and of hardening and becoming rigid again when cooled. Thermoplastic materials can be re-melted and cooled repeatedly without undergoing any appreciable chemical change. A thermoplastic is a polymer that turns to a liquid when heated and freezes to a very glassy state when cooled sufficiently. Most thermoplastics are high-molecular-weight polymers whose chains associate through weak Van der Waals forces (polyethylene); stronger dipole-dipole interactions and hydrogen bonding (nylon); or even stacking of aromatic rings (polystyrene). Thermoplastic polymers differ from thermosetting polymers (vulcanized rubber) as they can, unlike thermosetting polymers, be re-melted and re-molded. Many thermoplastic materials are addition polymers; e.g., vinyl chain-growth polymers such as polyethylene and polypropylene.

[0063] The term "pre-injection state," as used herein, refers to a state of an automatic injection device prior to activation of the device, i.e., prior to the start of delivery of a therapeutic agent contained in the device.

[0064] The term "injection state," as used herein, refers to one or more states of an automatic injection device during the delivery of a therapeutic agent contained in the device.

[0065] The term "post-injection state," as used herein, refers to completion of delivery of a therapeutically effective dose of a therapeutic agent contained in the device, or removal of the device from the patient prior to completion of delivery of a therapeutically effective dose of the therapeutic agent.

[0066] The term "patient" or "user," as used herein, refers to any type of animal, human or non-human, that may be administered a substance using exemplary automatic injection devices.

[0067] The term "proximal," as used herein, refers to a portion, end or component of an exemplary automatic injection device that is farthest from an injection site on a patient's body when the device is held against the patient for an injection or for mimicking an injection.

[0068] The term "distal," as used herein, refers to a portion, end or component of an exemplary automatic injection device that is closest to an injection site on a patient's body when the device is held against the patient for an injection or for mimicking an injection.

[0069] The term "planar" is used herein, in a broad lay sense, to mean exactly planar or approximately planar within some tolerance from the exactly planar.

[0070] The term "concave" is used herein, in a broad lay sense, to mean exactly concave or approximately concave within some tolerance from the exactly concave.

[0071] The term "convex" is used herein, in a broad lay sense, to mean exactly convex or approximately convex within some tolerance from the exactly convex.

[0072] The term "elliptical" is used herein, in a broad lay sense, to mean exactly elliptical or approximately elliptical within some tolerance from the exactly elliptical.

[0073] The term "oval" is used herein, in a broad lay sense, to mean exactly oval or approximately oval within some tolerance from the exactly oval.

[0074] The term "rectangular" is used herein, in a broad lay sense, to mean exactly rectangular or approximately rectangular within some tolerance from the exactly rectangular.

[0075] The term "parallel" is used herein, in a broad lay sense, to mean exactly parallel or approximately parallel within some tolerance from the exactly parallel.

[0076] The term "straight" is used herein, in a broad lay sense, to mean exactly straight or approximately straight within some tolerance from the exactly straight.

[0077] The term "equal" is used herein, in a broad lay sense, to mean exactly equal or approximately equal within some tolerance.

[0078] The term "adjacent" is used herein, in a broad lay sense, to mean immediately adjacent or approximately adjacent within some tolerance.

[0079] The term "transverse axis" is used herein to refer to an axis substantially perpendicular to a longitudinal axis.

[0080] The term "inwardly-projecting" is used herein to refer to one or more tabs or teeth on a needle shield remover

extending length wise along a longitudinal axis and having a proximal end attached to a tubular structure of the needle shield remover and a distal end detached from the tubular structure of the needle shield remover and projecting inwardly into an inner cavity of the tubular structure.

II. EXEMPLARY NEEDLE SHIELD REMOVERS

[0081] In an exemplary embodiment, a needle shield remover may be provided as a separate component from a needle shield for covering an injection needle and from a removable distal cap for covering a distal end of an automatic injection device. The needle shield remover may include one or more cap engagement mechanisms configured for engagement with the removable distal cap so that removal of the distal cap from the device housing automatically removes the needle shield remover as well. The needle shield remover may include one or more inwardly-projecting shield engagement mechanisms configured for directly or indirect engagement with a rigid needle shield (in a device that includes a rigid needle shield) and/or a soft needle shield (in a device that includes a soft needle shield but lacks a rigid needle shield). Since the needle shield remover is engaged to the needle shield, when the needle shield remover is removed from the device housing (e.g., by removal of the distal cap engaged to the needle shield remover), this results in the removal of the needle shield engaged to the needle shield remover.

[0082] Exemplary needle shield removers are configured and designed for quick, easy and reliable engagement to both the distal cap and to a needle shield. One or more exemplary methods may be used to assemble an exemplary needle shield remover to a needle shield coupled to a syringe. In an exemplary method, an exemplary needle shield remover may be assembled with a needle shield coupled to a syringe after the syringe has been inserted into the housing of the device. In another exemplary method, an exemplary needle shield remover—that is provided as a separate component from a distal cap and a syringe—may be assembled with a needle shield coupled to a syringe prior to insertion of the syringe into the housing of the device. The ability to assemble the needle shield remover to the needle shield outside the device housing allows visual inspection of the assembly process to ensure that the needle shield remover reliably engages the needle shield on the syringe before the syringe assembly is inserted into the device housing. Thus, assembly of the exemplary needle shield remover in the automatic injection device allows one to be certain that, when the syringe assembly is inserted into the device housing, the needle shield remover is engaged reliably and correctly with the needle shield, thereby resolving the issue of unreliable positioning of needle shield removal mechanisms in conventional automatic injection devices.

[0083] FIGS. **2**A-**2**D illustrate an exemplary needle shield remover **200** engaged to a syringe **202** and to a distal cap **204**. FIG. **2**A illustrates a side view of an exemplary needle shield remover engaged to a syringe. FIG. **2**B illustrates another side view of the exemplary needle shield remover of FIG. **2**A rotated by about 90 degrees. FIG. **2**C illustrates a cross-sectional perspective view of the exemplary needle shield remover of FIGS. **2**A and **2**B engaged to a syringe and a distal cap. FIG. **2**D is a bottom view of the exemplary distal cap of FIG. **2**C showing engagement of the needle shield remover to the distal cap. The length of an exemplary needle shield remover **200** may range from about 10 mm to about 50 mm, but is not limited to this exemplary range.

[0084] FIGS. **2**A-**2**D are presented for the purpose of generally describing the structure, function and operation of an exemplary needle shield remover. Certain specific but non-limiting exemplary embodiments of needle shield removers are described in connection with FIGS. **5**-**24**.

[0085] In the exemplary embodiment of FIGS. **2**A-**2**D, an injection needle (not pictured) is coupled to the distal end of the syringe **202**. The needle is covered with a soft needle shield **206** that is, in turn, positioned within and covered by a rigid needle shield **208**. Portions of the soft needle shield **206** may extend through one or more apertures in the rigid needle shield **208** as shown in FIG. **2**B. The exemplary needle shield remover **200** is positioned over the rigid needle shield **208**. The needle shield remover **200** may be used to remove all of the needle shields when the needle shield remover **200** is removed from its engagement to the syringe **202**.

[0086] The exemplary needle shield remover **200** may include a single tubular member. In other exemplary embodiments, the needle shield remover **200** may include two, three or more tubular members. In the exemplary embodiment illustrated in FIGS. **2**A-**2**D, the exemplary needle shield remover **200** may include a proximal tubular member **210** that, at its distal edge, is integrally coupled to a distal tubular member **212** in some exemplary embodiments. The distal tubular member **212** may have a smaller outer diameter and a shorter length than the proximal tubular member **210**, and may extend along a shorter length of the needle shield remover **200** along the longitudinal axis L than the proximal tubular member **210**. A transition portion **214** may extend between the proximal tubular member **210** and the distal tubular member **212**. An exemplary transition portion **214** may be a stepped transition, a ramped transition, or a combination of both.

[0087] The distal tubular member **212** may be substantially cylindrical in shape with a substantially circular or oval cross-section. At its distal end, the side wall of the distal tubular member **212** may include one or more platform structures that project longitudinally from the face of the distal tubular member **212** toward a removable distal cap. In an exemplary embodiment, a platform structure may include a first longitudinally-projecting portion **216***a*, a second longitudinally-projecting portion **216***b*, and a transverse portion **216***c* that extends between the longitudinally-projecting portions **216***a*, **216***b* at a distal end of the platform structure. The transverse portion **216***c* may support one or more cap engagement mechanisms in one exemplary embodiment.

[0088] At its distal end, an exemplary platform structure may support or define or provide one or more cap engagement mechanisms **218***a*, **218***b* that project radially outwardly from the platform structure. Exemplary cap engagement mechanisms may take the form of protrusions, teeth, clips, and other suitable engagement mechanisms. Exemplary cap engagement mechanisms **218***a*, **218***b* may have any suitable dimensions and structure. Exemplary lengths of the cap engagement mechanisms may include, but are not limited to, about 1, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.5, 7 mm, all intermediate numbers, and the like.

[0089] In the exemplary embodiment illustrated in FIGS. **2**A and **2**B, a first cap engagement mechanism **218***a* and a

second cap engagement mechanism **218***b* are provided at opposite sides of the platform structure, i.e., separated from each other by about 180 degrees. In the exemplary embodiment illustrated in FIGS. **2**A and **2**B, the cap engagement mechanisms are provided separately and spaced from each other. In another exemplary embodiment, a single cap engagement mechanism may be provided to extend in an annular manner around the platform structure. One of ordinary skill in the art will recognize that exemplary needle shield removers may include any suitable number of cap engagement mechanisms extending from the platform structure including, but not limited to, one, two, three, four, five, six, seven, and the like.

[0090] A first end of each cap engagement mechanism **218***a*, **218***b* may be coupled to or may be provided integrally with the platform structure, and a second end of each cap engagement mechanism **218***a*, **218***b* may be suspended over a corresponding gap **220***a*, **220***b* between the second end of the cap engagement mechanism and the distal tubular member **212**. During assembly of the needle shield remover **200** with a removable distal cap **204**, provided to cover the needle shield remover, the cap engagement mechanisms **218***a*, **218***b* may be coupled to the cap **204** so that removal of the cap also automatically removes the needle shield remover **200**.

[0091] FIG. **2**C illustrates a cross-sectional perspective view of the removable distal cap **204** in which a central aperture **226** is provided along longitudinal axis L. FIG. **2**D is a bottom view of a distal face **222** of the distal cap **204** showing engagement of the needle shield remover **200** to the distal cap **204**. One or more inwardly-projecting stop portions **228***a*, **228***b* (e.g., flanges or raised edges) may be provided at the interior surface of the central aperture **226** of the distal cap **204**. In the exemplary embodiment of FIGS. **2**C and **2**D, the inwardly-projecting stop portions **228***a*, **228***b* may not extend along the entire periphery of the central aperture **226**. In another exemplary embodiment, the inwardly-projecting stop portions may extend along the entire periphery of the central aperture **226**.

[0092] As shown in FIG. **2**C, the one or more cap engagement mechanisms **218***a*, **218***b* of the needle shield remover **200** may be made to fit through the aperture **226** of the distal cap **204**. In this assembled configuration of the needle shield remover **200** and the distal cap **204**, inwardly-projecting stop portions **228***a*, **228***b* (e.g., flanges or raised edges) provided in the aperture **226** of the distal cap **204** may be positioned reliably within the gap **220***a*, **220***b* of the needle shield remover **200**. This allows the needle shield remover **200** to be reliably engaged to the distal cap **204** upon assembly and during removal of the cap **204** from the device housing, thus causing removal of the distal cap **204** from the device housing to automatically remove the needle shield remover **200** as well. Since the needle shield remover **200** is reliably engaged to one or more needle shields **206**, **208**, removal of the needle shield remover, in turn, automatically removes the needle shields as well.

[0093] The cap engagement mechanisms **218***a*, **218***b* may snap into place in the aperture **226** of the distal cap **204** so that the inwardly-projecting stop portions **228***a*, **228***b* are positioned within the gap **220***a*, **220***b* of the needle shield remover **200**. In an exemplary embodiment, when the cap engagement mechanisms **218***a*, **218***b* are engaged with the distal cap **204**, there may be a decrease in the force experienced against insertion of the distal cap **204** over the needle shield remover **200**. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting stop portions **228***a*, **228***b* of the distal cap **204** have been reliably positioned within the gap **220***a*, **220***b* of the needle shield remover **200**. In an exemplary embodiment, when the cap engagement mechanisms **218***a*, **218***b* are engaged with the distal cap **204**, an audible "click" sound may be emitted to provide an audible indication that the distal cap **204** has been successfully engaged with the needle shield remover **200**.

[0094] The proximal tubular member **210** of the needle shield remover **200** may be substantially cylindrical in shape with a substantially circular or oval cross-section. The side wall of the first tubular member **210** may enclose and define a substantially cylindrical cavity for housing the injection needle covered by the soft needle shield **206** and the rigid needle shield **208**.

[0095] At or near its proximal edge, the side wall of the proximal tubular member **210** may define and/or include one or more inwardly-projecting shield engagement mechanisms **230***a*, **230***b* that are biased by the side wall to reliably remain positioned within a gap **232** formed between the body of the syringe **202** and the proximal edge of the rigid needle shield **208**. In the exemplary embodiment of FIGS. **2**A and **2**B, a first inwardly-projecting shield engagement mechanism **230***a* and a second inwardly-projecting shield engagement mechanism **230***b* are provided at opposite sides of the needle shield remover **200**, i.e., separated from each other by about 180 degrees.

[0096] The inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be positioned in the gap **232** during the assembly process and may reliably be positioned in the gap during the use of the device. When the removable distal cap covering the injection needle is removed before performing an injection (by pulling in the direction indicated by arrow R), the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* exert force in the direction R against the peripheral edge of the rigid needle shield **208**, thereby pulling the rigid needle shield **208** and the soft needle shield **206** away from the syringe body **202** in the direction R and exposing the injection needle for performing an injection.

[0097] Exemplary inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be configured to bias against the gap **232** with a sufficient force to ensure that when the needle shield remover is removed from the device, the needle shield remover **200** remains engaged with the rigid needle shield **208** and thereby reliably removes the rigid needle shield **208** from the body of the syringe **202**. Exemplary inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be configured to interface with the gap **232** over a sufficient area or width to apply a sufficient force to remove the rigid needle shield when the needle shield remover is pulled away from the syringe. In exemplary embodiments, a width of an exemplary inwardly-projecting shield engagement mechanism **230***a*, **230***b* that interfaces with the gap **232** may range from about 3 mm to about 7 mm, but is not limited to this exemplary range. In an exemplary embodiment, the edge of the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* that interfaces with the gap **232** may be substantially straight. In another exemplary embodiment, the edge of the inwardly-projecting

shield engagement mechanisms **230***a*, **230***b* that interfaces with the gap **232** may be serrated.

[0098] In an exemplary embodiment, the inner diameter of the needle shield remover **200** at the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be less than the outer diameter of the rigid needle shield **208**. The inner diameter of the needle shield remover **200** at the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may also be less than the outer diameter of the syringe body **202**. The inner diameter of the needle shield remover **200** at the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be substantially equal to the outer diameter of the gap **232** formed between the syringe body and the proximal end of the rigid needle shield **208**. This configuration of the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* allows the shield engagement mechanisms to snap into place at the gap **232** in a reliable and tight manner so that disengagement requires a minimal threshold level of force. This configuration also prevents creep of the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* out of the gap **232** before the needle shield remover **200** is pulled away from the syringe body.

[0099] An exemplary inner diameter of the needle shield remover **200** may range from about 5 mm to about 20 mm, but is not limited to this exemplary range. An exemplary inner diameter of the needle shield remover **200** may range from about 8 mm to about 11 mm in some exemplary embodiments. An exemplary inner diameter of the needle shield remover **200** may be about 8.5 mm in an exemplary embodiment. An exemplary inner diameter of the needle shield remover **200** may be about 11 mm in another exemplary embodiment.

[0100] The inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may snap into place at the gap **232** as the needle shield remover **200** is inserted over the rigid needle shield **208**. When the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* snap into place at the gap **232**, there may be a decrease in the force experienced against insertion of the needle shield remover **200** over the rigid needle shield **208**. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* have been successfully engaged to the gap **232**. In an exemplary embodiment, the positioning of the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* in the gap **232** may emit an audible "click" sound that provides an audible indication that the needle shield remover **200** has been successfully engaged with the rigid needle shield **208**.

[0101] One of ordinary skill in the art will recognize that exemplary needle shield removers may include any suitable number of inwardly-projecting shield engagement mechanisms **230***a*, **230***b* including, but not limited to, one, two, three, four, five, six, seven, and the like. Exemplary inwardly-projecting shield engagement mechanisms may take the form of protrusions, teeth, clips, and other suitable engagement mechanisms.

[0102] In the exemplary embodiment illustrated in FIGS. **2**A and **2**B, the one or more inwardly-projecting shield engagement mechanisms **230***a*, **230***b* are configured and positioned to consistently and reliably fit within the gap **232** formed between the body of the syringe **202** and the proximal edge of the rigid needle shield **208**. In another exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be configured and positioned to consistently and reliably engage with an aperture in the rigid needle shield **208** (for example, exemplary aperture **108** illustrated in FIG. **1**A). This allows automatic removal of the rigid needle shield **208** (and an associated soft needle shield **206**) by the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* of the needle shield remover **200**, when the needle shield remover **200** is removed from the device housing by its engagement with a distal cap **204** that is removed by a user.

[0103] In another exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be configured and positioned to consistently and reliably engage with a ridged portion in the rigid needle shield **208** (for example, exemplary ridged portion **110** illustrated in FIG. **1**A). This allows automatic removal of the rigid needle shield **208** (and an associated soft needle shield **206**) by the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* of the needle shield remover **200**, when the needle shield remover **200** is removed from the device housing by engagement of the needle shield remover **200** with a distal cap **204** that is removed by a user. In another exemplary embodiment in which the injection needle is covered by a soft needle shield **206** and lacks a rigid needle shield **208**, one or more inwardly-projecting shield engagement mechanisms **230***a*, **230***b* of the needle shield remover **200** may be configured and positioned to consistently and reliably engage with the soft needle shield **206**. One of ordinary skill in the art will recognize that the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* may be configured and positioned to engage any other suitable component on the rigid needle shield **208** and/or the soft needle shield **206**.

[0104] In the exemplary embodiment illustrated in FIGS. **2**A and **2**B, the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* are provided in a component separate from the rigid needle shield **208** (i.e., in the needle shield remover **200**), and the shield engagement mechanisms **230***a*, **230***b* are not permanently engaged with the rigid needle shield **208**. In another exemplary embodiment, the inwardly-projecting shield engagement mechanisms **230***a*, **230***b* of the needle shield remover **200** may be permanently engaged with the rigid needle shield **208**, for example, using glue or epoxy.

[0105] At or near its proximal edge, the side wall of the proximal tubular member **210** of the needle shield remover **200** may also define one or more cutout portions **234** for allowing a user to view the contents of the syringe **202** and/or to view an end-of-injection indicator from outside the device housing. That is, the cutout portions **234** of the proximal tubular member **210** may align with a transparent inspection window or inspection aperture provided in the device housing to allow a user to view the contents of the syringe **202** and/or to view an end-of-injection indicator from outside the device. In an exemplary embodiment, two exemplary cutout portions may be provided at opposite sides of the needle shield remover **200**, i.e., separated from each other by about 180 degrees. In an exemplary embodiment, the cutout portions **234** may be provided in an alternating manner with the inwardly-projecting shield engagement mechanisms **230***a*, **230***b*, all of which may be provided at or near the proximal edge of the proximal tubular member **210**. In an exemplary embodiment, each cutout portion **234** may

have a substantially concave shape or a semicircular shape, but is not limited to these exemplary shapes.

[0106] An exemplary width of the cutout portions may range from about 3 mm to about 7 mm, but is not limited to this exemplary range. Exemplary widths of the cutout portions may include, but are not limited to, about 4.0, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.0, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6.0 mm, and the like.

[0107] One or more additional protrusions and/or grooves may be provided in the exterior surface of the proximal tubular member **210** and/or the distal tubular member **212** in order to facilitate engagement of the needle shield remover **200** with another component of the automatic injection device, e.g., a syringe sleeve that cooperatively engages with and covers a proximal portion of the needle shield remover **200**, a removable cap **204** that covers a distal portion of the needle shield remover **200**, and the like. For example, one or more longitudinally-extending grooves **236***a*, **236***b* may be provided in the exterior surface of the needle shield remover **200** to movably engage with a syringe sleeve. In an exemplary embodiment, the syringe sleeve may allow relative movement of the syringe sleeve and/or the needle shield remover **200** along the longitudinal axis L, but may hold the needle shield remover **200** in a substantially fixed axial orientation relative to the syringe sleeve. This ensures that the cutout portions **234** of the needle shield remover **200** are maintained in alignment with a transparent inspection window or inspection aperture provided in the syringe sleeve and with a transparent inspection window or inspection aperture provided in the device housing, thus allowing a user to view the contents of the syringe **202** and/or to view an end-of-injection indicator through the inspection windows or apertures. Certain exemplary embodiments of syringe sleeves are described in connection with FIGS. **3** and **4**.

[0108] In the exemplary embodiment illustrated in FIGS. **2**A-**2**C, the needle shield remover **200** may be provided as a separate component from the distal cap **204** of the automatic injection device. In another exemplary embodiment, a needle shield remover **200** may be provided integrally with the distal cap **204**, for example, by integrally coupling the cap engagement mechanisms **218***a*, **218***b* of the needle shield remover **200** with the distal cap **204** of the device.

III. EXEMPLARY SYRINGE SLEEVES FOR USE IN AUTOMATIC INJECTION DEVICES

[0109] An exemplary automatic injection device may include a syringe sleeve that is a structural member for enveloping a portion of a syringe fitted with a needle shield remover. The syringe sleeve may be configured to hold and guide the syringe fitted with a needle shield remover, so that the syringe may move forwardly within and relative to the housing of the device from a retracted position (i.e., farther away from the injection site) to an injection position (i.e., closer to the injection site in which the injection needle projects from an open end of the device housing). The syringe may rest within the syringe sleeve, and both may be housed within the housing of the automatic injection device.

[0110] Other exemplary automatic injection devices may not provide a syringe sleeve.

[0111] An exemplary syringe sleeve may include a transparent inspection window or inspection aperture that may be aligned with both a cutout portion of the needle shield remover and an inspection window or inspection aperture provided the device housing, so that the contents of the syringe may be reliably viewed from outside the device housing. The syringe sleeve may maintain the needle shield remover in a substantially fixed axial orientation so that the cutout portion of the needle shield remover is aligned with the inspection window or inspection aperture of the syringe sleeve and the device housing. This ensures that movement of the needle shield remover within the device does not lead to obscuration of the inspection window or inspection aperture of the device housing.

[0112] The syringe sleeve may have any suitable configuration, shape and size suitable for accommodating the syringe fitted with the needle shield remover, and for axially orienting the cutout portion of the needle shield remover in alignment with the inspection window or inspection aperture of the device housing. The syringe sleeve may be formed of any suitable material including, but not limited to, thermoplastic polymers, e.g., polycarbonates.

[0113] FIG. **3**A illustrates a perspective view of an exemplary syringe sleeve **300**. FIG. **3**B illustrates a cross-sectional perspective view of the exemplary syringe sleeve **300** bisected along a longitudinal axis L. The exemplary syringe sleeve **300** may include a tubular member **302** that may be substantially cylindrical in shape with a substantially circular or oval cross-section. The side wall of the tubular member **302** may enclose and define a substantially cylindrical cavity for housing a syringe fitted with a needle shield remover.

[0114] The side wall of the tubular member **302** may define and/or include one or more transparent inspection windows or inspection apertures **304** for allowing a user of the device to view the contents of the syringe and/or an indicator. The inspection window or inspection aperture of the tubular member **302** may be aligned with the cutout portion of the needle shield remover and with the inspection window or inspection aperture of the automatic injection device housing to provide a clear unobstructed view of the syringe contents and/or an indicator. The inspection window or inspection aperture **304** may have any suitable configuration, size and shape for allowing viewing of the contents of the syringe. Exemplary shapes of the inspection window or inspection aperture **304** may include, but are not limited to, a substantially elongated oval or elliptical shape, a substantially elongated rectangular shape, and the like. In an exemplary embodiment, the inspection window or inspection aperture **304** may have a longer length along the longitudinal axis L than a width along a transverse axis.

[0115] In an exemplary embodiment, the entire syringe sleeve **300** may be formed of a transparent material. In another exemplary embodiment, the inspection window or inspection aperture **304** may be the only component of the syringe sleeve **300** that is formed of a transparent material or is an aperture in the tubular member **302**.

[0116] An exterior surface of the tubular member **302** may include one or more raised structures and/or grooves to engage with one or more other components of the automatic injection device. An exemplary raised structure may be one or more longitudinally-extending rails **306**, **308** that may fit movably along internal longitudinally-extending grooves and/or protrusions (not pictured) provided on an interior surface of the device housing. The rails **306**, **308** may allow the syringe sleeve **300** to move longitudinally relative to the device housing, and may allow the syringe sleeve **300** to be held in a fixed axial orientation relative to the device housing. In an exemplary embodiment, the rails **306**, **308**

may extend along the entire length of the tubular member **302**. In exemplary embodiments, one, two, three, four, five, six rails may be provided in the exterior surface of the tubular member **302**, but the number of rails is not limited to these exemplary numbers. Exemplary lengths of the rails **306**, **308** or grooves and/or protrusions in the exterior surface of the tubular member **302** may range from about 1 mm to about 6 mm, but are not limited to this exemplary range.

[0117] An interior surface of the tubular member **302** may include one or more raised structures and/or grooves to engage with one or more other components of the automatic injection device. An exemplary raised structure may be one or more longitudinally-extending rails **310** that may fit movably along internal longitudinally-extending grooves and/or protrusions provided on an exterior surface of a needle shield remover. The rails **310** may allow the syringe sleeve **300** to move longitudinally relative to the needle shield remover and to allow the needle shield remover to move longitudinally relative to the syringe sleeve **300**. The rails **310** may also allow the needle shield remover to be held in a fixed axial orientation relative to the syringe sleeve **300**. The fixed axial orientation between the needle shield remover and the syringe sleeve **300** allows the cutout portion of the needle shield remover to be aligned with the inspection window or inspection aperture of the syringe sleeve **300** and with the inspection window or inspection aperture of the device housing. This ensures that the contents of the syringe may be reliably viewed at any time from the outside of the device through the inspection window or inspection aperture in the device housing. Exemplary lengths of the rails **310** or grooves on the interior surface of the tubular member **302** may range from about 1 mm to about 6 mm, but are not limited to this exemplary range.

[0118] A proximal portion of the tubular member **302** (farthest from the injection site) may be coupled to one or more longitudinally-extending syringe alignment guides **311**, **312**, **314**, **316** for aligning a syringe in a substantially fixed axial orientation relative to the syringe sleeve **300**. This ensures that the inspection window or inspection aperture **304** of the tubular member **302** is reliably aligned with a corresponding cutout portion of an exemplary needle shield remover attached to the syringe. One of ordinary skill in the art will recognize that any number of syringe alignment guides may be used in exemplary syringe sleeves.

[0119] In an exemplary embodiment, two pairs of syringe alignment guides may be provided so that the pairs are provided on opposite sides of the tubular member **302**. In an exemplary embodiment, a first pair of guides may include a first syringe alignment guide **311** and a second syringe alignment guide **312**. A second pair of guides may be provided on an opposite side of the tubular member **302** (i.e., offset from the first pair of guides by about 180 degrees), and may include a third syringe alignment guide **314** and a fourth syringe alignment guide **316**.

[0120] At a proximal end of the alignment guides, the alignment guides **311** and **312** may be coupled to each other by a first beam **318** extending along a transverse axis between the alignment guides **311** and **312**. In an exemplary embodiment, a tabbed foot **320** may extend outwardly from the first beam **318** to engage with the device housing. At a distal end of the alignment guides, the alignment guides **311** and **312** may be coupled together by a second flexible beam **322** extending along a transverse axis between the alignment guides **311** and **312**. In an exemplary embodiment, the second flexible beam **322** may provide a stopping position for the proximal end of the syringe. That is, when a flanged proximal end of the syringe reaches the second flexible beam **322**, the syringe may be prevented from farther movement toward the injection site as it has already achieved its injection position.

[0121] Similarly, at a proximal end of the alignment guides, the alignment guides **314** and **316** may be coupled to each other by a first beam **324** extending along a transverse axis between the alignment guides **314** and **316**. In an exemplary embodiment, a tabbed foot **326** may extend outwardly from the first beam **324** to engage with the device housing. At a distal end of the alignment guides, the alignment guides **314** and **316** may be coupled together by a second flexible beam **328** extending along a transverse axis between the alignment guides **314** and **316**. In an exemplary embodiment, the second flexible beam **328** may provide a stopping position for the proximal end of the syringe. That is, when a flanged proximal end of the syringe reaches the second flexible beam **328**, the syringe may be prevented from farther movement toward the injection site as it has already achieved its injection position.

[0122] FIG. **4**A illustrates a perspective view of an assembly of an exemplary syringe sleeve **300** housing an exemplary syringe **400** that is fitted with an exemplary needle shield remover **200** at its distal end. The syringe alignment guides **311**, **312**, **314**, **316** provided at the proximal portion of the syringe sleeve **300** may align the syringe **400** and hold it in a substantially fixed axial orientation relative to the syringe sleeve **300**. As shown in FIG. **4**A, the needle shield remover **200** and the syringe sleeve **300** overlap each other at some portions, such that the inspection window or inspection aperture **304** of the syringe sleeve **300** overlaps and is aligned with a cutout portion of the needle shield remover **200**.

[0123] FIG. **4**B illustrates a transverse cross-sectional view of an exemplary assembly in which an exemplary syringe sleeve **300** that houses an exemplary syringe **400** fitted with an exemplary needle shield remover **200**. The exemplary syringe sleeve **300** includes four exemplary longitudinally-extending rails **402**, **404**, **406**, **408** on an interior surface of the exemplary syringe sleeve **300**. The syringe sleeve **300** partially encloses an exemplary needle shield remover **200** including four corresponding longitudinal grooves **410**, **412**, **414**, **416**, respectively. Each rail of the syringe sleeve **300** may engage with a corresponding groove of the needle shield remover **200**, so that the needle shield remover **200** is held in a substantially fixed axial orientation relative to the syringe sleeve **300**.

[0124] Exemplary components illustrated in FIGS. **4**A and **4**B that are common to the components illustrated in FIGS. **3**A and **3**B are described in connection with FIGS. **3**A and **3**B.

[0125] One of ordinary skill in the art will recognize that syringe sleeves other than the exemplary syringe sleeve illustrated in FIGS. **3**A, **3**B, **4**A and **4**B may be used in exemplary automatic injection devices.

IV. FIRST NON-LIMITING EXEMPLARY EMBODIMENT OF A NEEDLE SHIELD REMOVER

[0126] FIGS. **5**A and **5**B illustrate an exemplary needle shield remover **500** having two exemplary inwardly-project-

ing shield engagement mechanisms for engagement with a rigid needle shield. FIG. **5**A illustrates a perspective view of the exemplary needle shield remover **500**. FIG. **5**B illustrates a cross-sectional perspective view of the exemplary needle shield remover **500** of FIG. **5**A bisected along a longitudinal axis L.

[0127] The exemplary needle shield remover **500** may include a proximal tubular member **502** that, at its distal edge, is integrally coupled to a distal tubular member **504** in some exemplary embodiments. The distal tubular member **504** may have a smaller diameter and a shorter length than the proximal tubular member **502**, and may extend along a shorter length of the needle shield remover **500** along the longitudinal axis L than the proximal tubular member **502**. A transition portion **506** may extend between the proximal tubular member **502** and the distal tubular member **504**. An exemplary transition portion **506** may be a stepped transition, a ramped transition, or a combination of both.

[0128] The distal tubular member **504** of the needle shield remover **500** may be substantially cylindrical in shape with a substantially circular or oval cross-section. At its distal end, the side wall of the distal tubular member **504** may include one or more platform structures that project longitudinally from the face of the distal tubular member **504** toward a removable distal cap. In an exemplary embodiment, a platform structure may include a first longitudinally-projecting portion **508***a*, a second longitudinally-projecting portion **508***b*, and a transverse portion **508***c* that extends between the longitudinally-projecting portions **508***a*, **508***b* at a distal end of the platform structure. The transverse portion **508***c* may support one or more cap engagement mechanisms in one exemplary embodiment.

[0129] At its distal end, an exemplary platform structure may support or define or provide a first outwardly-projecting flexible cap engagement mechanism **510***a* and a second outwardly-projecting flexible cap engagement mechanism **510***b* that project radially outwardly from the platform structure. Exemplary cap engagement mechanisms may be any suitable protrusion, projection, teeth, and the like. In the exemplary embodiment of FIGS. **5**A and **5**B, the cap engagement mechanisms **510***a*, **510***b* are provided at opposite sides of the platform structure, i.e., separated from each other by about 180 degrees. One of ordinary skill in the art will recognize that exemplary needle shield removers may include any suitable number of cap engagement mechanisms extending from the platform structure including, but not limited to, one, two, three, four, five, six, seven, and the like.

[0130] A first end of each cap engagement mechanisms **510***a*, **510***b* may be coupled to or may be provided integrally with the platform structure, and a second end of each cap engagement mechanism **510***a*, **510***b* may be suspended over a gap **512***a*, **512***b* between the cap engagement mechanisms **510***a*, **510***b* and the distal tubular member **504**. During assembly of the needle shield remover **500** with a distal cap of the automatic injection device (not pictured) provided to cover the needle shield remover, the cap engagement mechanisms **510***a*, **510***b* may be coupled to the distal cap so that removal of the cap also automatically removes the needle shield remover **500**. In an exemplary embodiment, the cap engagement mechanisms **510***a*, **510***b* of the needle shield remover **500** may be inserted to fit within a central aperture provided in the distal cap such that one or more inwardly-projecting stop portions (e.g., flanges or raised edges) provided in the central aperture of the distal cap reliably engage the gaps **512***a*, **512***b* of the needle shield remover **500**. This engagement allows the needle shield remover **500** to be reliably engaged to the distal cap after assembly and during removal of the distal cap from the device housing, thus causing removal of the distal cap from the device housing to automatically remove the needle shield remover **500** as well. Since the needle shield remover **500** is reliably engaged to one or more needle shields, removal of the needle shield remover, in turn, automatically removes the needle shields coupled to a syringe.

[0131] In the exemplary embodiment illustrated in FIGS. **5**A and **5**B, the needle shield remover **500** may be provided as a separate component from a distal cap of the automatic injection device. In another exemplary embodiment, a needle shield remover may be provided integrally with the distal cap, for example, by integrally coupling the cap engagement mechanisms **510***a*, **510***b* of the needle shield remover **500** with the distal cap of the device.

[0132] The proximal tubular member **502** of the needle shield remover **500** may be substantially cylindrical in shape with a substantially circular or oval cross-section. The side wall of the proximal tubular member **502** may enclose and define a substantially cylindrical cavity **514** for housing the injection needle covered by a soft needle shield and/or a rigid needle shield coupled to a syringe.

[0133] At or near its proximal edge, the side wall of the proximal tubular member **502** may define and/or include a first inwardly-projecting shield engagement mechanisms **516***a* and a second inwardly-projecting shield engagement mechanism **516***b*. The first and second inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may be biased by the side wall to reliably remain positioned within a gap formed between the body of a syringe and the proximal edge of a rigid needle shield. Exemplary inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may be any suitable protrusion, projection, teeth, and the like. In the exemplary embodiment of FIGS. **5**A and **5**B, the exemplary inwardly-projecting shield engagement mechanisms **516***a*, **516***b* are provided at opposite sides of the needle shield remover **500**, i.e., separated from each other by about 180 degrees. The inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may be positioned in a gap formed between a syringe body and a rigid needle shield during the assembly process, and may reliably be positioned in the gap during the use of the device. When a distal cap covering the injection needle is removed before performing an injection (by pulling in the direction indicated by arrow R), the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* exert force in the direction R against the peripheral edge of the rigid needle shield, thereby pulling the rigid needle shield and the soft needle shield away from the syringe body in the direction R and exposing the injection needle for performing an injection.

[0134] In an exemplary configuration, each inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may be situated at an aperture **518***a*, **518***b* in the proximal tubular member **502**. Each inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may include a first inclined or radial wall **520***a*, **520***b* that extends from a proximal base wall of the aperture **518***a*, **518***b* and projects inwardly into the cavity **514** at a first angle relative to the longitudinal axis L. The first inclined or radial wall **520***a*, **520***b* may be coupled to or may be integrally formed with an inwardly-projecting second inclined or radial wall **522***a*, **522***b*. The second inclined

or radial wall **522***a*, **522***b* may extend from the first inclined or radial wall inwardly into the cavity **514** at a second angle relative to the longitudinal axis L.

[0135] In an exemplary embodiment, the second angle corresponding to the second inclined or radial wall **522***a*, **522***b* may be substantially greater than the first angle corresponding to the first inclined or radial wall **520***a*, **520***b*, so that the first inclined or radial wall **520***a*, **520***b* extends substantially along the longitudinal axis L and the second inclined or radial wall **522***a*, **522***b* extends substantially orthogonally to the longitudinal axis L. An exemplary first angle may range from about 0 degree to about 20 degrees relative to the longitudinal axis L toward the cavity **514**. An exemplary second angle may range from about 30 degrees to about 60 degrees relative to the longitudinal axis L toward the cavity **514**.

[0136] Providing the shield engagement mechanisms **516***a*, **516***b* as part of the proximal tubular member **502** facilitates robust assembly of the needle shield remover **500** in the automatic injection device. Projection of the inclined or radial walls of the shield engagement mechanisms **516***a*, **516***b* from the proximal base wall of the aperture **518***a*, **518***b* inwardly into the cavity **514** also facilitates robust assembly of the needle shield remover **500** in the device. These structural features, for example, allow the inclined or radial walls of the needle shield remover **500** to move radially outwardly with respect to the proximal tubular member **502**, while minimizing a radially outward movement of the proximal tubular member **502** at the shield engagement mechanisms **516***a*, **516***b*, as the needle shield remover **500** is inserted coaxially over a needle shield during assembly. That is, expansion of the outer diameter of the needle shield remover **500** is minimized during assembly in order to minimize the risk of the shield engagement mechanisms **516***a*, **516***b* not being positioned at the gap between the needle shield and the syringe body and to minimize the risk of the shield engagement mechanisms **516***a*, **516***b* from becoming disengaged from the gap between the needle shield and the syringe body.

[0137] Certain conventional needle shield removers include shield engagement mechanisms that are not formed as a part of a tubular member. In addition, in certain conventional needle shield removers, the shield engagement mechanisms do not extend from a proximal base edge of an aperture or support mechanism. These conventional needle shield removers do not minimize a radially outward movement needle shield removers at the shield engagement mechanisms. This radially outward movement of the conventional needle shield removers reduces the robustness of the assembly process as it increases the risk of positioning the shield engagement mechanisms outside a gap formed between the syringe body and the needle shield.

[0138] Exemplary first and second inclined or radial walls may have any suitable dimension and structure. Exemplary lengths and widths of the first and second inclined or radial walls may include, but are not limited to, about 1, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.5, 7 mm, all intermediate numbers, and the like.

[0139] The second inclined or radial walls **522***a*, **522***b* of the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may be configured to be positioned within a gap formed between a syringe body and a proximal edge of a rigid needle shield. Each second inclined or radial wall **522***a*, **522***b* may have a peripheral edge **524***a*, **524***b* with a width that provides a sufficiently large interface with the rigid needle shield. In exemplary embodiments, the width of the peripheral edge **524***a*, **524***b* may range from about 3 mm to about 7 mm, but is not limited to this exemplary range. In an exemplary embodiment, the width is about 4.00 mm.

[0140] In an exemplary embodiment, the inwardly-projecting first and second inclined or radial walls **520***a*, **520***b*, **522***a*, **522***b* cause the inner diameter of the needle shield remover **500** at the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* to be less than the outer diameter of the proximal end of the rigid needle shield. In an exemplary embodiment, the inwardly-projecting first and second inclined or radial walls **520***a*, **520***b*, **522***a*, **522***b* cause the inner diameter of the needle shield remover **500** at the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* to be less than the outer diameter of the syringe body. The inner diameter of the needle shield remover **500** at the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may be substantially equal to the outer diameter of the gap formed between the syringe body and the proximal end of the rigid needle shield. This configuration of the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* thereby allows the second inclined or radial walls **522***a*, **522***b* to snap into place at the gap in a reliable and tight manner so that disengagement requires at least a minimal threshold level of force. This configuration also prevents creep of the second inclined or radial walls **522***a*, **522***b* out of the gap after assembly but before removal by a user.

[0141] The inwardly-projecting shield engagement mechanisms **516***a*, **516***b* may snap into place at the gap formed between the rigid needle shield and the syringe body, as the needle shield remover **500** is inserted over the rigid needle shield. When the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* snap into place at the gap, there may be a decrease in the force experienced against insertion of the needle shield remover **500** over the rigid needle shield. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* have been successfully engaged to the gap formed between the rigid needle shield and the syringe body. In an exemplary embodiment, the positioning of the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* in the gap may emit an audible "click" sound that provides an audible indication that the needle shield remover **500** has been successfully engaged with the rigid needle shield.

[0142] In the exemplary embodiment illustrated in FIGS. **5**A and **5**B, the needle shield remover **500** may be provided as a separate component from a needle shield of the automatic injection device. In another exemplary embodiment, a needle shield remover may be provided integrally with the rigid needle shield, for example, by integrally coupling the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* of the needle shield remover **500** with the rigid needle shield.

[0143] At or near its proximal edge, the side wall of the proximal tubular member **502** may also define one or more cutout portions **526***a*, **526***b* for allowing a user to view of the contents of the syringe and/or to view an indicator from outside the device housing. That is, the cutout portions **526***a*,

526*b* of the proximal tubular member **502** align with a transparent inspection window or inspection aperture of the device housing to allow a user to view the syringe contents and/or to view an indicator from outside the device. In the exemplary embodiment of FIGS. **5**A and **5**B, a first cutout portion **526***a* and a second cutout portion **526***b* are provided at opposite sides of the needle shield remover **500**, i.e., separated from each other by about 180 degrees. In an exemplary embodiment, the cutout portions **526***a*, **526***b* may be provided in an alternating manner with the inwardly-projecting shield engagement mechanisms **516***a*, **516***b*, all of which are provided at or near the proximal edge of the proximal tubular member **502**. In an exemplary embodiment, each cutout portion **526***a*, **526***b* may take a substantially concave shape or a semicircular shape, but is not limited to these exemplary shapes.

[0144] In an exemplary embodiment, one or more additional protrusions and/or grooves may be provided in the exterior surface of the proximal tubular member **502** and/or the distal tubular member **504** in order to facilitate engagement of the needle shield remover **500** with another component of the automatic injection device, e.g., a syringe sleeve that cooperatively engages with and covers a proximal portion of the needle shield remover, a removable cap that covers a distal portion of the needle shield remover, and the like. For example, one or more longitudinally-extending grooves **528***a*, **528***b* may be provided in the exterior surface of the needle shield remover **500** to movably engage with a syringe sleeve. In an exemplary embodiment, the syringe sleeve may allow relative movement of the syringe sleeve and/or the needle shield remover along the longitudinal axis L, but may hold the needle shield remover in a substantially fixed axial orientation relative to the syringe sleeve. This ensures that the cutout portions **526***a*, **526***b* of the needle shield remover **500** are maintained in alignment with a transparent inspection window or inspection aperture of the syringe sleeve and with a transparent inspection window or inspection aperture of the device housing, thus allowing a user to view the contents of the syringe and/or to view an indicator through the inspection windows or inspection apertures.

[0145] FIG. **6** illustrates a cross-sectional perspective view of the exemplary needle shield remover **500** of FIGS. **5**A and **5**B assembled with a syringe **600** and a distal cap **800**. In the exemplary embodiment of FIG. **6**, the assembly lacks a syringe sleeve. FIG. **7** illustrates a cross-sectional perspective view of the exemplary needle shield remover **500** of FIGS. **5**A and **5**B assembled with a syringe **600** and a distal cap **800**. In the exemplary embodiment of FIG. **7**, the assembly includes a syringe sleeve **700**. FIG. **8** illustrates a front cross-sectional view of the exemplary assembly of FIG. **7** including a syringe sleeve **700**. FIG. **9** illustrates a bottom view of an exemplary distal cap **800** that is applicable to FIGS. **6**-**8**.

[0146] An injection needle **604** may be affixed to a distal end of the syringe **600**, a bung **606** may be disposed within the syringe **600**, and a dose of a therapeutic agent **608** may be provided to fill the syringe **600**. The injection needle **604** may be covered with a soft needle shield **610** and a rigid needle shield **612** disposed over the soft needle shield **610**. The exemplary needle shield remover **500** may be disposed over the rigid needle shield **612** so that the inwardly-projecting shield engagement mechanisms **516***a*, **516***b* of the needle shield remover **500** fit within a gap between the rigid needle shield **612** and the body of the syringe **600**. The cap engagement mechanisms **510***a*, **510***b* of the needle shield remover **500** may engage with a distal cap **800** provided to cover the distal portion of the device. In an exemplary embodiment, the cap engagement mechanisms **510***a*, **510***b* may be accommodated within a central aperture **802** provided in the distal cap **800**, so that one or more inwardly-projecting stop portions **804***a*, **804***b* (e.g., flanges or raised edges) provided in the central apertures **802** of the distal cap **800** are positioned reliably within gaps **512***a*, **512***b* proximal to the cap engagement mechanisms **510***a*, **510***b*. In an exemplary embodiment, a single stop portion may extend radially around the periphery of the central aperture **802**.

[0147] In the exemplary embodiment illustrated in FIGS. **7** and **8**, a syringe sleeve **700** may be provided over the syringe **600** and the needle shield remover **500** to maintain the needle shield remover **500** in a substantially fixed axial orientation with the device housing.

[0148] Exemplary components illustrated in FIGS. **6**-**9** that are common to the components illustrated in FIGS. **2**-**3** are described in connection with FIGS. **2**-**3**.

V. SECOND NON-LIMITING EXEMPLARY EMBODIMENT OF A NEEDLE SHIELD REMOVER

[0149] FIGS. **10**A and **10**B illustrate an exemplary needle shield remover **1000** having two exemplary inwardly-projecting shield engagement mechanisms for engagement with a rigid needle shield. FIG. **10**A illustrates a perspective view of the exemplary needle shield remover **1000**. FIG. **10**B illustrates a cross-sectional perspective view of the exemplary needle shield remover **1000** bisected along a longitudinal axis L.

[0150] The exemplary needle shield remover **1000** may include a proximal tubular member **1002** that, at its distal edge, is integrally coupled to a distal tubular member **1004** in some exemplary embodiments. The distal tubular member **1004** may have a smaller diameter and a shorter length than the proximal tubular member **1002**, and may extend along a shorter length of the needle shield remover **1000** along the longitudinal axis L than the proximal tubular member **1002**. A transition portion **1006** may extend between the proximal tubular member **1002** and the distal tubular member **1004**. An exemplary transition portion **1006** may be a stepped transition, a ramped transition, or a combination of both.

[0151] The distal tubular member **1004** of the needle shield remover **1000** may be substantially cylindrical in shape with a substantially circular or oval cross-section. At its distal end, the side wall of the distal tubular member **1004** may include one or more platform structures that project longitudinally from the face of the distal tubular member **1004** toward a removable distal cap. In an exemplary embodiment, a platform structure may include a first longitudinally-projecting portion **1008***a*, a second longitudinally-projecting portion **1008***b*, and a transverse portion **1008***c* that extends between the first and second longitudinally-projecting portions **1008***a*, **1008***b* at the distal end of the platform structure. The transverse portion **1008***c* may support one or more cap engagement mechanisms in one exemplary embodiment.

[0152] At its distal end, an exemplary platform structure may support or define or provide a first outwardly-projecting flexible cap engagement mechanism **1010***a* and a second outwardly-projecting flexible cap engagement mechanism

1010*b* that project radially outwardly from the platform structure. Exemplary cap engagement mechanisms may be any suitable protrusion, projection, teeth, and the like. In the exemplary embodiment of FIGS. **10**A and **10**B, the cap engagement mechanisms **1010***a*, **1010***b* are provided at opposite sides of the platform structure, i.e., separated from each other by about 180 degrees. One of ordinary skill in the art will recognize that exemplary needle shield removers may include any suitable number of cap engagement mechanisms extending from the platform structure including, but not limited to, one, two, three, four, five, six, seven, and the like.

[0153] A first end of each cap engagement mechanisms **1010***a*, **1010***b* may be coupled to or may be provided integrally with the platform structure, and a second end of each cap engagement mechanism **1010***a*, **1010***b* may be suspended over a gap **1012***a*, **1012***b* between the cap engagement mechanisms **1010***a*, **1010***b* and the distal tubular member **1004**. During assembly of the needle shield remover **1000** with a distal cap of the automatic injection device (not pictured) provided to cover the needle shield remover, the cap engagement mechanisms **1010***a*, **1010***b* may be coupled to the distal cap so that removal of the cap also automatically removes the needle shield remover **1000**.

[0154] In an exemplary embodiment, the cap engagement mechanisms **1010***a*, **1010***b* of the needle shield remover **1000** may be inserted to fit within a central aperture provided in the distal cap such that one or more inwardly-projecting stop portions (e.g., flanges or raised edges) provided in the central aperture of the distal cap reliably engage the gap **1012***a*, **1012***b* of the needle shield remover **1000**. This engagement allows the needle shield remover **1000** to be reliably engaged to the distal cap after assembly and during removal of the distal cap from the device housing, thus causing removal of the distal cap from the device housing to automatically remove the needle shield remover **1000** as well. Since the needle shield remover **1000** is reliably engaged to one or more needle shields, removal of the needle shield remover, in turn, automatically removes the needle shields coupled to the syringe.

[0155] In the exemplary embodiment illustrated in FIGS. **10**A and **10**B, the needle shield remover **1000** may be provided as a separate component from a distal cap of the automatic injection device. In another exemplary embodiment, a needle shield remover may be provided integrally with the distal cap, for example, by integrally coupling the cap engagement mechanisms **1010***a*, **1010***b* of the needle shield remover **1000** with the distal cap of the device.

[0156] The proximal tubular member **1002** of the needle shield remover **1000** may be substantially cylindrical in shape with a substantially circular or oval cross-section. The side wall of the proximal tubular member **1002** may enclose and define a substantially cylindrical cavity **1014** for housing the injection needle covered by a soft needle shield and/or a rigid needle shield coupled to the syringe.

[0157] At or near its proximal edge, the side wall of the proximal tubular member **1002** may define and/or include a first inwardly-projecting shield engagement mechanism **1016***a* and a second inwardly-projecting shield engagement mechanism **1016***b*. The first and second inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may be biased by the side wall to reliably remain positioned within a gap formed between the body of a syringe and the proximal edge of a rigid needle shield. Exemplary inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may be any suitable protrusion, projection, teeth, and the like. In the exemplary embodiment of FIGS. **10**A and **10**B, the exemplary inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* are provided at opposite sides of the needle shield remover **1000**, i.e., separated from each other by about 180 degrees. The inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may be positioned in a gap formed between a syringe body and a rigid needle shield during the assembly process, and may reliably be positioned in the gap during the use of the device. When the distal cap covering the injection needle is removed before performing an injection (by pulling in the direction indicated by arrow R), the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* exert force in the direction R against the peripheral edge of the rigid needle shield, thereby pulling the rigid needle shield and the soft needle shield away from the syringe body in the direction R and exposing the injection needle for performing an injection.

[0158] In an exemplary configuration, each inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may be situated at an aperture **1018***a*, **1018***b* that provides an opening in the side wall of the proximal tubular member **1002**. Each inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may include an inwardly-projecting inclined or radial wall **1020***a*, **1020***b* that extends from a proximal base wall of the aperture **1018***a*, **1018***b* and projects inwardly into the cavity **1014** at an angle relative to the longitudinal axis L. An exemplary angle may range from about 30 degrees to about 60 degrees relative to the longitudinal axis L toward the cavity. Providing the shield engagement mechanisms **1016***a*, **1016***b* as part of the proximal tubular member **1002** facilitates robust assembly of the needle shield remover **1000** in the automatic injection device. Projection of the inclined or radial walls of the shield engagement mechanisms **1016***a*, **1016***b* from the proximal base wall of the aperture **1018***a*, **1018***b* inwardly into the cavity **1014** also facilitates robust assembly of the needle shield remover **1000** in the device. These structural features, for example, allow the inclined or radial walls of the needle shield remover **1000** to move radially outwardly with respect to the proximal tubular member **1002**, while minimizing a radially outward movement of the proximal tubular member **1002** at the shield engagement mechanisms **1016***a*, **1016***b*, as the needle shield remover **1000** is inserted coaxially over a needle shield during assembly. That is, expansion of the outer diameter of the needle shield remover **1000** is minimized during assembly in order to minimize the risk of the shield engagement mechanisms **1016***a*, **1016***b* not being positioned at the gap between the needle shield and the syringe body and to minimize the risk of the shield engagement mechanisms **1016***a*, **1016***b* from becoming disengaged from the gap between the needle shield and the syringe body.

[0159] Certain conventional needle shield removers include shield engagement mechanisms that are not formed as a part of a tubular member. In addition, in certain conventional needle shield removers, the shield engagement mechanisms do not extend from a proximal base edge of an aperture or support mechanism. These conventional needle shield removers do not minimize a radially outward movement needle shield removers at the shield engagement mechanisms. This radially outward movement of the conventional needle shield removers reduces the robustness of the assembly process as it increases the risk of positioning

the shield engagement mechanisms outside a gap formed between the syringe body and the needle shield.

[0160] In an exemplary embodiment, the proximal tubular member **1002** may be dissected by one or more slots **1001***a*, **1001***b* that extend substantially parallel to the longitudinal axis L at radial locations between the shield engagement mechanisms **1016***a*, **1016***b*. In an exemplary embodiment, two exemplary slots **1001***a*, **1001***b* may be separated from each other on the proximal tubular member **1002** by about 180 degrees. In an exemplary embodiment, the slots **1001***a*, **1001***b* may facilitate in engaging the shield engagement mechanisms **1016***a*, **1016***b* of the needle shield remover **1000** with a rigid needle shield.

[0161] In this exemplary embodiment, the slots **1001***a*, **1001***b* may allow the shield engagement mechanisms **1016***a*, **1016***b* to move radially outwardly as the needle shield remover **1000** is inserted coaxially over a needle shield during assembly, which advantageously allows the needle shield remover **1000** to be engaged to the needle shield without requiring the application of a large amount of force opposite to the direction indicated by arrow R. Application to a large amount force during assembly can result in damage to the needle shields and the syringe, thereby adversely affecting the reliability of the assembled needle shield remover.

[0162] Exemplary inclined or radial walls may have any suitable dimension and structure. Exemplary lengths and widths of the inclined or radial walls may include, but are not limited to, about 1, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.5, 7 mm, all intermediate numbers, and the like.

[0163] The inclined or radial walls **1020***a*, **1020***b* of the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may be configured to be positioned within a gap formed between a syringe body and a proximal edge of a rigid needle shield. The inclined or radial wall **1020***a*, **1020***b* may have a peripheral edge **1024***a*, **1024***b* with a width that provides a sufficiently large interface with the rigid needle shield. In exemplary embodiments, the width of the peripheral edge **1024***a*, **1024***b* may range from about 3 mm to about 7 mm, but is not limited to this exemplary range. In an exemplary embodiment, the width is about 5.3 mm.

[0164] In an exemplary embodiment, the inwardly-projecting inclined or radial walls **1020***a*, **1020***b* cause the inner diameter of the needle shield remover **1000** at the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* to be less than the outer diameter of the proximal end of the rigid needle shield. In an exemplary embodiment, the inwardly-projecting inclined or radial walls **1020***a*, **1020***b* cause the inner diameter of the needle shield remover **1000** at the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* to be less than the outer diameter of the syringe body. The inner diameter of the needle shield remover **1000** at the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may be substantially equal to the outer diameter of the gap formed between the syringe body and the proximal end of the rigid needle shield. This configuration of the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* thereby allows the inclined or radial walls **1020***a*, **1020***b* to snap into place at the gap in a reliable and tight manner so that disengagement requires at least a minimal threshold level of force. This configuration also prevents creep of the inclined or radial walls **1020***a*, **1020***b* out of the gap after assembly but before removal by a user.

[0165] The inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* may snap into place at the gap formed between the rigid needle shield and the syringe body, as the needle shield remover **1000** is inserted over the rigid needle shield. When the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* snap into place at the gap, there may be a decrease in the force experienced against insertion of the needle shield remover **1000** over the rigid needle shield. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* have been successfully engaged to the gap formed between the rigid needle shield and the syringe body. In an exemplary embodiment, the positioning of the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* in the gap may emit an audible "click" sound that provides an audible indication that the needle shield remover **1000** has been successfully engaged with the rigid needle shield.

[0166] In the exemplary embodiment illustrated in FIGS. **10**A and **10**B, the needle shield remover **1000** may be provided as a separate component from a needle shield of the automatic injection device. In another exemplary embodiment, a needle shield remover may be provided integrally with the rigid needle shield, for example, by integrally coupling the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* of the needle shield remover **1000** with the rigid needle shield.

[0167] At or near its proximal edge, the side wall of the proximal tubular member **1002** may also define one or more cutout portions **1026***a*, **1026***b* for allowing a user to view of the contents of the syringe and/or to view an indicator from outside the device housing. That is, the cutout portions **1026***a*, **1026***b* of the proximal tubular member **1002** align with a transparent inspection window or inspection aperture of the device housing to allow a user to view the syringe contents and/or to view an indicator from outside the device. In the exemplary embodiment of FIGS. **10**A and **10**B, a first cutout portion **1026***a* and a second cutout portion **1026***b* are provided at opposite sides of the needle shield remover **1000**, i.e., separated from each other by about 180 degrees. In an exemplary embodiment, the cutout portions **1026***a*, **1026***b* may be provided in an alternating manner with the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b*, all of which are provided at or near the proximal edge of the proximal tubular member **1002**. In an exemplary embodiment, each cutout portion **1026***a*, **1026***b* may take a substantially concave shape or a semicircular shape, but is not limited to these exemplary shapes. In an exemplary embodiment, the distal ends of the cutout portions **1026***a*, **1026***b* may contiguously join with the dissection slots **1001***a*, **1001***b*.

[0168] In an exemplary embodiment, one or more additional protrusions and/or grooves may be provided in the exterior surface of the proximal tubular member **1002** and/or the distal tubular member **1004** in order to facilitate engagement of the needle shield remover **1000** with another component of the automatic injection device, e.g., a syringe sleeve that cooperatively engages with and covers a proximal portion of the needle shield remover, a removable cap that covers a distal portion of the needle shield remover, and

the like. For example, one or more longitudinally-extending grooves **1028***a*, **1028***b* may be provided in the exterior surface of the needle shield remover **1000** to movably engage with a syringe sleeve. In an exemplary embodiment, the syringe sleeve may allow relative movement of the syringe sleeve and/or the needle shield remover along the longitudinal axis L, but may hold the needle shield remover in a substantially fixed axial orientation relative to the syringe sleeve. This ensures that the cutout portions **1026***a*, **1026***b* of the needle shield remover **1000** are maintained in alignment with a transparent inspection window or inspection aperture of the syringe sleeve and with a transparent inspection window or inspection aperture of the device housing, thus allowing a user to view the contents of the syringe and/or to view an indicator through the inspection windows or inspection apertures.

[0169] FIG. **11** illustrates a perspective cross-sectional view of the exemplary needle shield remover **1000** of FIGS. **10**A and **10**B assembled with a syringe **600** and a distal cap **800**. In the exemplary embodiment of FIG. **11**, the assembly lacks a syringe sleeve. FIG. **12** illustrates a perspective cross-sectional view of the exemplary needle shield remover **1000** of FIGS. **10**A and **10**B assembled with a syringe **600** and a distal cap **800**. In the exemplary embodiment of FIG. **12**, the assembly includes a syringe sleeve **700**. FIG. **13** illustrates a front cross-sectional view of the exemplary assembly of FIG. **12** including a syringe sleeve **700**. FIG. **14** illustrates a bottom view of an exemplary distal cap **800** that is applicable to FIGS. **11-13**.

[0170] An injection needle **604** may be affixed to a distal end of the syringe **600**, a bung **606** may be disposed within the syringe **600**, and a dose of a therapeutic agent **608** may be provided to fill the syringe **600**. The injection needle **604** may be covered with a soft needle shield **610** and a rigid needle shield **612** disposed over the soft needle shield **610**. The exemplary needle shield remover **1000** may be disposed over the rigid needle shield **612** so that the inwardly-projecting shield engagement mechanisms **1016***a*, **1016***b* of the needle shield remover **1000** fit within a gap between the rigid needle shield **612** and the body of the syringe **600**. The cap engagement mechanisms **1010***a*, **1010***b* of the needle shield remover **1000** may engage with a distal cap **800** provided to cover the distal portion of the device. In an exemplary embodiment, the cap engagement mechanisms **1010***a*, **1010***b* may be accommodated within a central aperture **802** provided in the distal cap **800**, so that inwardly-projecting stop portions **804***a*, **804***b* (e.g., flanges or raised edges) provided in the central aperture of the distal cap are positioned reliably within gaps **1012***a*, **1012***b* proximal to the cap engagement mechanisms **1010***a*, **1010***b*.

[0171] In the exemplary embodiment illustrated in FIGS. **12** and **13**, a syringe sleeve **700** may be provided over the syringe **600** and the needle shield remover **1000** to maintain the needle shield remover **1000** in a substantially fixed axial orientation with the device housing.

[0172] Exemplary components illustrated in FIGS. **11-14** that are common to the components illustrated in FIGS. **2-3** are described in connection with FIGS. **2-3**.

VI. THIRD NON-LIMITING EXEMPLARY EMBODIMENT OF A NEEDLE SHIELD REMOVER

[0173] FIGS. **15**A and **15**B illustrate an exemplary needle shield remover **1500** having three exemplary inwardly-projecting shield engagement mechanisms for engagement with a rigid needle shield. FIG. **15**A illustrates a perspective view of the exemplary needle shield remover **1500**. FIG. **15**B illustrates a cross-sectional perspective view of the exemplary needle shield remover **1500** bisected along a longitudinal axis L.

[0174] The exemplary needle shield remover **1500** may include a proximal tubular member **1502** that, at its distal edge, is integrally coupled to a distal tubular member **1504** in some exemplary embodiments. The distal tubular member **1504** may have a smaller diameter and a shorter length than the proximal tubular member **1502**, and may extend along a shorter length of the needle shield remover **1500** along the longitudinal axis L than the proximal tubular member **1502**. A transition portion **1506** may extend between the proximal tubular member **1502** and the distal tubular member **1504**. An exemplary transition portion **1506** may be a stepped transition, a ramped transition, or a combination of both.

[0175] The distal tubular member **1504** of the needle shield remover **1500** may be substantially cylindrical in shape with a substantially circular or oval cross-section. At its distal end, the side wall of the distal tubular member **1504** may include one or more platform structures **1508** that project longitudinally from the face of the distal tubular member **1504** toward a removable distal cap. In an exemplary embodiment, a platform structure **1508** may include one or more longitudinally-projecting portions and a transverse portion that extends between the longitudinally-projecting portions at the distal end of the platform structure **1508**.

[0176] At its distal end, one or more platform structures **1508** may support or define or provide a first outwardly-projecting flexible cap engagement mechanism **1510***a*, a second outwardly-projecting flexible cap engagement mechanism **1510***b* and a third outwardly-projecting flexible cap engagement mechanism **1510***c*, that project radially outwardly from the platform structure **1508**. Providing three cap engagement mechanisms in this exemplary embodiment provides a larger surface of the needle shield remover that engages with the distal cap than embodiments that include one or two cap engagement mechanism. The exemplary needle shield remover **1500** thereby allows reliably removal of the needle shield remover from the syringe when the distal cap is removed before administration of an injection.

[0177] Exemplary cap engagement mechanisms may be any suitable protrusion, projection, teeth, and the like. In the exemplary embodiment of FIGS. **15**A and **15**B, the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* are spaced from one another around the platform structure **1508**, i.e., separated by about 120 degrees. One of ordinary skill in the art will recognize that exemplary needle shield removers may include any suitable number of cap engagement mechanisms extending from the platform structure **1508** including, but not limited to, one, two, three, four, five, six, seven, and the like.

[0178] A first end of each cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* may be coupled to or may be provided integrally with the platform structure **1508**, and a second end of each cap engagement mechanism **1510***a*, **1510***b*, **1510***c* may be suspended over a gap (e.g., gap **1512***a*, **1512***b*, **1512***c*) between the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* and the distal tubular member **1504**. During assembly of the needle shield remover **1500** with a distal cap of the automatic injection device (not pictured) provided to

cover the needle shield remover, the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* may be coupled to the distal cap so that removal of the cap also automatically removes the needle shield remover **1500**.

[0179] In an exemplary embodiment, the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* of the needle shield remover **1500** may be inserted to fit within a central aperture provided in the distal cap such that one or more inwardly-projecting stop portions (e.g., flanges or raised edges) provided in the central aperture of the distal cap reliably engage the gaps **1512***a*, **1512***b*, **1512***c* of the needle shield remover **1500**. This engagement allows the needle shield remover **1500** to be reliably engaged to the distal cap after assembly and during removal of the distal cap from the device housing, thus causing removal of the distal cap from the device housing to automatically remove the needle shield remover **1500** as well. Since the needle shield remover **1500** is reliably engaged to one or more needle shields, removal of the needle shield remover, in turn, automatically removes the needle shields.

[0180] In the exemplary embodiment illustrated in FIGS. **15**A and **15**B, the needle shield remover **1500** may be provided as a separate component from a distal cap of the automatic injection device. In another exemplary embodiment, a needle shield remover may be provided integrally with the distal cap, for example, by integrally coupling the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* of the needle shield remover **1500** with the distal cap of the device.

[0181] The proximal tubular member **1502** of the needle shield remover **1500** may be substantially cylindrical in shape with a substantially circular or oval cross-section. The side wall of the proximal tubular member **1502** may enclose and define a substantially cylindrical cavity **1514** for housing the injection needle covered by a soft needle shield and/or a rigid needle shield.

[0182] At or near its proximal edge, the side wall of the proximal tubular member **1502** may define and/or include a first inwardly-projecting shield engagement mechanism **1516***a*, a second inwardly-projecting shield engagement mechanism **1516***b*, and a third inwardly-projecting shield engagement mechanism **1516***c*. The first, second and third inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may be biased by the side wall to reliably remain positioned within a gap formed between the body of a syringe and the proximal edge of a rigid needle shield. Exemplary inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may be any suitable protrusion, projection, teeth, and the like. In the exemplary embodiment of FIGS. **15**A and **15**B, the exemplary inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may be spaced from one another around the needle shield remover **1500**, i.e., separated from each other by about 120 degrees.

[0183] The inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may be positioned in a gap formed between a syringe body and a rigid needle shield during the assembly process, and may reliably be positioned in the gap during the use of the device. When the distal cap covering the injection needle is removed before performing an injection (by pulling in the direction indicated by arrow R), the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* exert force in the direction R against the peripheral edge of the rigid needle shield, thereby pulling the rigid needle shield and the soft needle shield away from the syringe body in the direction R and exposing the injection needle for performing an injection.

[0184] In an exemplary configuration, each inwardly-projecting shield engagement mechanism **1516***a*, **1516***b*, **1516***c* may be situated at an aperture **1518***a*, **1518***b*, **1518***c* that provides an opening in the side wall of the proximal tubular member **1502**. Each inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may include a first inclined or radial wall **1520***a*, **1520***b*, **1520***c* that extends from a proximal wall of the aperture **1518***a*, **1518***b*, **1518***c* into the cavity **1514** at a first angle relative to the longitudinal axis L. The first inclined or radial wall **1520***a*, **1520***b*, **1520***c* may be coupled to or may be integrally formed with an inwardly-projecting second inclined or radial wall **1522***a*, **1522***b*, **1522***c*. The second inclined or radial wall **1522***a*, **1522***b*, **1522***c* may extend from the first inclined or radial wall into the cavity **1514** at a second angle relative to the longitudinal axis L.

[0185] The second angle corresponding to the second inclined or radial wall **1522***a*, **1522***b*, **1522***c* may be substantially greater than the first angle corresponding to the first inclined or radial wall **1520***a*, **1520***b*, **1520***c*, so that the first inclined or radial wall **1520***a*, **1520***b*, **1520***c* extends substantially along the longitudinal axis L and the second inclined or radial wall **1522***a*, **1522***b*, **1522***c* extends substantially orthogonally to the longitudinal axis L. An exemplary first angle may range from about 0 degree to about 20 degrees relative to the longitudinal axis L toward the cavity **1514**. An exemplary second angle may range from about 30 degrees to about 60 degrees relative to the longitudinal axis L toward the cavity **1514**.

[0186] Providing the shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* as part of the proximal tubular member **1502** facilitates robust assembly of the needle shield remover **1500** in the automatic injection device. Projection of the inclined or radial walls of the shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* from the proximal base wall of the aperture **1518***a*, **1518***b*, **1518***c* inwardly into the cavity **1514** also facilitates robust assembly of the needle shield remover **1500** in the device. These structural features, for example, allow the inclined or radial walls of the needle shield remover **1500** to move radially outwardly with respect to the proximal tubular member **1502**, while minimizing a radially outward movement of the proximal tubular member **1502** at the shield engagement mechanisms **1516***a*, **516***b*, **1516***c*, as the needle shield remover **1500** is inserted coaxially over a needle shield during assembly. That is, expansion of the outer diameter of the needle shield remover **1500** is minimized during assembly in order to minimize the risk of the shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* not being positioned at the gap between the needle shield and the syringe body and to minimize the risk of the shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* from becoming disengaged from the gap between the needle shield and the syringe body.

[0187] Certain conventional needle shield removers include shield engagement mechanisms that are not formed as a part of a tubular member. In addition, in certain conventional needle shield removers, the shield engagement mechanisms do not extend from a proximal base edge of an aperture or support mechanism. These conventional needle shield removers do not minimize a radially outward movement needle shield removers at the shield engagement mechanisms. This radially outward movement of the con-

ventional needle shield removers reduces the robustness of the assembly process as it increases the risk of positioning the shield engagement mechanisms outside a gap formed between the syringe body and the needle shield.

[0188] Exemplary first and second inclined or radial walls may have any suitable dimension and structure. Exemplary lengths and widths of the first and second inclined or radial walls may include, but are not limited to, about 1, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.5, 7 mm, all intermediate numbers, and the like.

[0189] The second inclined or radial wall **1522***a*, **1522***b*, **1522***c* of the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may be configured to be positioned within a gap formed between a syringe body and a proximal edge of a rigid needle shield. Providing three inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* in this exemplary embodiment provides a larger surface of the needle shield remover that engages with the rigid needle shield than embodiments that include one or two inwardly-projecting shield engagement mechanism. The exemplary needle shield remover **1500** thereby allows reliably removal of the needle shields from the syringe when the needle shield remover is removed before administration of an injection. The second inclined or radial wall **1522***a*, **1522***b*, **1522***c* may have a peripheral edge **1524***a*, **1524***b*, **1524***c* with a width that provides a sufficiently large interface with the rigid needle shield. In exemplary embodiments, the width of the peripheral edge **1524***a*, **1524***b*, **1524***c* may range from about 3 mm to about 7 mm, but is not limited to this exemplary range. In an exemplary embodiment, the width is about 5.4 mm. The greater width of the peripheral edge of the second inclined or radial wall **1522***a*, **1522***b*, **1522***c* also provides a larger surface of the needle shield remover that engages with the rigid needle shield than embodiments that include one or two inwardly-projecting shield engagement mechanism, allowing reliable removal of the needle shields from the syringe when the needle shield remover is removed before administration of an injection

[0190] In an exemplary embodiment, the inwardly-projecting first and second inclined or radial walls cause the inner diameter of the needle shield remover **1500** at the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* to be less than the outer diameter of the proximal end of the rigid needle shield. In an exemplary embodiment, the inwardly-projecting first and second inclined or radial walls cause the inner diameter of the needle shield remover **1500** at the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* to be less than the outer diameter of the syringe body. The inner diameter of the needle shield remover **1500** at the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may be substantially equal to the outer diameter of the gap formed between the syringe body and the proximal end of the rigid needle shield. This configuration of the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* thereby allows the second inclined or radial walls **1522***a*, **1522***b*, **1522***c* to snap into place at the gap in a reliable and tight manner so that disengagement requires at least a minimal threshold level of force. This configuration also prevents creep of the second inclined or radial walls **1522***a*, **1522***b*, **1522***c* out of the gap after assembly but before removal by a user.

[0191] The inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* may snap into place at the gap formed between the rigid needle shield and the syringe body, as the needle shield remover **1500** is inserted over the rigid needle shield. When the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* snap into place at the gap, there may be a decrease in the force experienced against insertion of the needle shield remover **1500** over the rigid needle shield. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* have been successfully engaged to the gap formed between the rigid needle shield and the syringe body. In an exemplary embodiment, the positioning of the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* in the gap may emit an audible "click" sound that provides an audible indication that the needle shield remover **1500** has been successfully engaged with the rigid needle shield.

[0192] In the exemplary embodiment illustrated in FIGS. **15**A and **15**B, the needle shield remover **1500** may be provided as a separate component from a distal cap of the automatic injection device. In another exemplary embodiment, a needle shield remover may be provided integrally with the distal cap, for example, by integrally coupling the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* of the needle shield remover **1500** with the distal cap of the device.

[0193] In an exemplary embodiment, one or more additional protrusions and/or grooves may be provided in the exterior surface of the proximal tubular member **1502** and/or the distal tubular member **1504** in order to facilitate engagement of the needle shield remover **1500** with another component of the automatic injection device, e.g., a syringe sleeve that cooperative engages with and covers a proximal portion of the needle shield remover, a removable cap that covers a distal portion of the needle shield remover, and the like.

[0194] FIG. **16** illustrates a perspective cross-sectional view of the exemplary needle shield remover **1500** of FIGS. **15**A and **15**B assembled with a syringe **600** and a distal cap **800**. In the exemplary embodiment of FIG. **16**, the assembly lacks a syringe sleeve. FIG. **17** illustrates a perspective cross-sectional view of the exemplary needle shield remover **1500** of FIGS. **15**A and **15**B assembled with a syringe **600** and a distal cap **800**. In the exemplary embodiment of FIG. **17**, the assembly includes a syringe sleeve **700**. FIG. **18** illustrates a front cross-sectional view of the exemplary assembly of FIG. **17** including a syringe sleeve **700**. FIG. **19** illustrates a bottom view of an exemplary distal cap **800** that is applicable to FIGS. **16**-**18**.

[0195] An injection needle **604** may be affixed to a distal end of the syringe **600**, a bung **606** may be disposed within the syringe **600**, and a dose of a therapeutic agent **608** may be provided to fill the syringe **600**. The injection needle **604** may be covered with a soft needle shield **610** and a rigid needle shield **612** disposed over the soft needle shield **610**. The exemplary needle shield remover **1500** may be disposed over the rigid needle shield **612** so that the inwardly-projecting shield engagement mechanisms **1516***a*, **1516***b*, **1516***c* of the needle shield remover **1500** fit within a gap between the rigid needle shield **612** and the body of the syringe **600**. The cap engagement mechanisms **1510***a*,

1510*b*, **1510***c* of the needle shield remover **1500** may engage with a distal cap **800** provided to cover the distal portion of the device. In an exemplary embodiment, the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c* may be accommodated within a central aperture **802** provided in the distal cap **800**, so that inwardly-projecting stop portions **804***a*, **804***b*, **804***c* (e.g., flanges or raised edges) provided in the central aperture of the distal cap are positioned reliably within gaps **1512***a*, **1512***b*, **1512***c* proximal to the cap engagement mechanisms **1510***a*, **1510***b*, **1510***c*.

[0196] In an exemplary embodiment illustrated in FIGS. **17** and **18**, a syringe sleeve **700** may be provided over the syringe **600** and the needle shield remover **1500** to maintain the needle shield remover **1500** in a substantially fixed axial orientation with the device housing.

[0197] Exemplary components illustrated in FIGS. **16-19** that are common to the components illustrated in FIGS. **2-3** are described in connection with FIGS. **2-3**.

VII. CERTAIN OTHER NON-LIMITING EXEMPLARY EMBODIMENTS OF NEEDLE SHIELD REMOVERS

[0198] FIG. **20** illustrates a cross-sectional view of an exemplary needle shield remover **2000** bisected along the longitudinal axis L. The needle shield remover **2000** is configured for removing needle shields from a syringe **2002** or an automatic injection device. The syringe **2002** may include any type of syringe typically utilized with an automatic injection device having one or more needle shields, such as a soft needle shield **2004** and a rigid needle shield **2006**. As discussed above, the soft needle shield **2004** is positioned within the rigid needle shield **2006**, and portions of the soft needle shield **2004** extend through apertures **2008** formed in the rigid needle shield **2006**.

[0199] The needle shield remover **2000** includes a outer wall **2010** which is attached to and depends from (or is formed integrally with) the periphery of an base wall **2012**, and one or more inwardly-facing protrusions or teeth **2014** which are biased by the outer wall **2010** in position within a gap formed between the body of the syringe **2002** and the periphery **2016** of the rigid needle shield **2006**. The outer wall **2010** and base wall **2012** may have any desired shape or size (e.g., the needle shield remover **2000** may be cylindrical or other shape), and a plurality of outer walls **2010** may be provided (e.g., if the needle shield remover **2000** is square or rectangular in shape). The needle shield remover **2000** defines a cavity that receives the soft needle shield **2004** and the rigid needle shield **2006**. A plurality of outer protrusions **2018** may be provided on the outer surface of the outer wall **2010**, to facilitate fixed engagement of the needle shield remover **2000** within a removable cap of an automatic injection device to provide a gripping surface to the removable cap. In this manner the removable cap cooperatively engages with the gripping surface defined by the plurality of protrusions **2018** and the plurality of valleys to reliably remove the rigid needle shield **2006** and the soft needle shield **2004** from the syringe or the automatic injection device.

[0200] When the needle shield remover **2000** is pulled away from the syringe body **2002** (as shown by arrow R), the protrusions **2014** exert force against the periphery **2016** of the rigid needle shield **2006**, thereby pulling the rigid needle shield **2006** and the soft needle shield **2004** away from the syringe body **2002** and exposing the needle of the syringe **2002** for use. It is noted that the protrusions **2014** may also be configured to fit within the apertures **2008** of the rigid needle shield **2006**, or to otherwise contact the rigid needle shield **2006** (e.g., to fit within corresponding recesses formed in the rigid needle shield **2006**).

[0201] FIG. **21** illustrates a cross-sectional view of another exemplary needle shield remover **2100** bisected along the longitudinal axis L. In this embodiment, the needle shield remover **2100** includes an inner (first) wall **2102** which is positioned coaxially within an outer (second) wall **2104**, and which is coupled to the outer wall **2104** by a hollow projection **2106** extending through an aperture formed in a base wall **2108** that is joined at its periphery to the outer wall **2104** (or formed integrally therewith). Similar to the embodiment shown and discussed above in connection with FIG. **20**, the inner wall **2102** includes one or more protrusions **2110** extending therefrom which are biased in a gap formed between the syringe body **2112** and the lower periphery **2114** of the rigid needle shield **2116**. The inner wall **2102** may be fixedly or rotatably coupled to the outer wall **2104**. One or more protrusions **2118**, for example a flange or collar, may be formed at a base end of the hollow projection **2106**, so as to couple the base wall **2108** and the outer wall **2104**. The inner wall **2102** and the outer wall **2104** may have a circular cross section, an elongated cross section, square cross section, rectangular cross section or any other suitable cross section. The outer wall **2104** may be fixedly coupled to inner surfaces of a removable cap of an automatic injection device, and, as shown in FIG. **21**, may include one or more protrusions **2120** to facilitate such coupling and to provide a gripping surface for the removable cap. The protrusions may be rings, collars, flanges or other type of protrusion.

[0202] When the outer wall **2104** is pulled away from the syringe body **2112** (as indicated by arrow R), it pulls the inner wall **2102** away from the syringe body **2112**, thereby causing the protrusions **2110** to exert force against the lower periphery **2114** of the rigid needle shield **2116** and to pull the rigid needle shield **2116** and the soft needle shield **2122** away from the syringe **2112** to expose the needle for use. As with prior embodiments, it is noted that the protrusions **2110** may be positioned at other locations, e.g., they may be positioned to extend into the apertures **2124** in the rigid needle shield **2116** or to contact other locations (e.g., corresponding recesses) on the rigid needle shield **2116**.

[0203] FIG. **22** illustrates a cross-sectional view of an exemplary needle shield remover **2200** bisected along the longitudinal axis L. The needle shield remover **2200** includes an outer wall **2202** that depends from and is connected to the periphery of a base wall **2204** (or, formed integrally therewith). As mentioned in connection with earlier embodiments, the needle shield remover **2200** may have any shape (e.g., cylindrical or other shape). An annular recess **2206** with an annular opening or a plurality of apertures radially spaced circumferentially about the annular recess is provided along one end of the outer wall **2202**, and receives removal element **2208**, for example, an annular washer, ring or pins having one or more protrusions **2218** extending through corresponding apertures formed in the recess **2206**. Ends of the protrusions **2218** are positioned in a gap formed between the syringe body **2212** and the lower periphery **2214** of the rigid needle shield **2216**. The needle shield remover **2200** may be fixedly coupled to inner surfaces of a removable cap of an automatic injection device.

[0204] When the needle shield remover **2200** is pulled away from the syringe **2212** (as indicated by arrow R), the protrusions **2218** exert force against the lower periphery **2214** of the rigid needle shield **2216** and pull the rigid needle shield **2216** and the soft needle shield **2220** away from the syringe **2212**, thereby exposing the needle for use. It is noted that the removal element **2208** may be positioned so that the protrusions contact other locations, e.g., they may be positioned to extend into the apertures **2222** of the rigid needle shield **2216** or contact other locations of the rigid needle shield **2216** (e.g., they may contact corresponding recesses formed in the rigid needle shield **2216**).

[0205] FIG. **23** illustrates a cross-sectional view of an exemplary needle shield remover **2300** bisected along the longitudinal axis L. The needle shield remover **2300** includes a modified rigid needle shield **2302** having a top aperture **2304**, and a captive component **2306** which is coupled to the rigid needle shield **2302**. The captive component **2306** includes a hollow axle **2308** that extends through the aperture **2304**. Shoulders **2310** of the rigid needle shield **2302** are captured between a peripheral wall **2312** of the captive component **2306** and a transverse annular wall **2314** formed at a lower end of the axle **2308** and positioned between the shoulders **2310** and the soft needle shield **2316**. Portions of the soft needle shield **2316** extend through apertures **2318** formed in the rigid needle shield **2302**. Protrusions **2320** are provided at a base end of the axle **2308** for coupling (e.g., by way of snap fit) the captive component **2306** to a removable cap of an automatic injection device. When the captive component **2306** is pulled away from a syringe (as indicated by arrow R), the transverse annular wall **2314** exerts force against the shoulders **2310**, thereby pulling the rigid needle shield **2302** and the soft needle shield **2316** away from a syringe and exposing the needle for use.

[0206] FIG. **24** illustrates a cross-sectional view of an exemplary needle shield remover **2400** bisected along the longitudinal axis L. The needle shield remover **2400** includes an outer wall **2402** extending from and connected to (or formed integrally with) a base wall **2404**, and an inner wall **2406** extending from and connected to (or formed integrally with) the base wall **2404**. The outer wall **2402** and the inner wall **2406** may be annularly aligned about a central longitudinal axis of the syringe. The outer wall **2402** and the inner wall **2406** may have a circular cross section, an elongated cross section, square cross section, rectangular cross section or any other suitable cross section.

[0207] A collar or spring clip **2408** extends through apertures formed in one end **2410** of the inner wall **2406**, and contact the soft needle shield **2412** through the apertures **2414** of the rigid needle shield **2416**. One or more protrusions **2418** are formed at the lower end **2410** of the inner wall **2406** and are positioned in a gap formed between the syringe body **2420** and the lower periphery **2422** of the rigid needle shield **2416**. The collar/spring clip **2408** stabilizes the protrusions **2418** to prevent them from creeping out of the gap between the syringe body **2420** and the lower periphery **2422** of the rigid needle shield **2416**. It is noted that the outer wall **2402** may be fixedly coupled to inner surfaces of a removable cap of an automatic injection device, and, as shown in FIG. **24**, may include one or more protrusions **2424** to facilitate such coupling and to provide a gripping surface for the removable cap. The protrusions may be rings, collars, flanges or other type of protrusion.

[0208] When the needle shield remover **2400** is pulled away from the syringe **2420** (as indicated by arrow R), the collar **2408** and the protrusions **2418** exert force against the rigid needle shield **2416**, thereby pulling the rigid needle shield **2416** and the soft needle shield **2412** away from the syringe **2420** and exposing the needle for use. It is noted that the collar/spring clip **2408**, and/or the protrusions **2418**, may be positioned to contact other locations of the rigid needle shield **2416** and/or the soft needle shield **2412**. The needle shield remover **2400** may be fixedly coupled to inner surfaces of a removable cap of an automatic injection device.

[0209] It is noted that, in each of the embodiments discussed herein, the various protrusions which contact the rigid needle shield to remove it from the syringe may be permanently attached to the rigid needle shield, e.g., by way of gluing/epoxy. Of course, such a feature is entirely optional, and the protrusions need not be permanently attached to the rigid needle shield.

VIII. EXEMPLARY METHODS OF ASSEMBLING AND USING AUTOMATIC INJECTION DEVICES

[0210] Exemplary needle shield removers are configured and designed for quick, easy and reliable engagement to both a distal cap of an automatic injection device and to one or more needle shields covering an injection needle of the device. One or more exemplary methods may be used to assemble an exemplary needle shield remover with the other components of the device.

[0211] In an exemplary method, an exemplary needle shield remover may be assembled with a syringe after the syringe has been inserted into the housing of the device.

[0212] In another exemplary method, an exemplary needle shield remover—that is provided as a separate component from a distal cap and from a needle shield—may be assembled with a syringe prior to insertion of the syringe into the housing of the device. The ability to assemble the exemplary needle shield remover with the syringe outside the device housing allows visual inspection of the assembly process to ensure that the needle shield remover is correctly and reliably engaged with the needle shield on the syringe before the syringe and needle shield remover assembly is inserted into the device housing. Thus, assembly of the exemplary needle shield remover in the automatic injection device allows one to be certain that, when the syringe assembly is inserted into the device housing, the needle shield remover is engaged reliably and consistently with the needle shield. This resolves the issue of component tolerance and unreliable positioning of needle shield removal mechanisms in conventional automatic injection devices.

[0213] FIG. **25** is a flowchart of an exemplary method **2500** for assembling an exemplary needle shield remover with a syringe and a distal cap of an automatic injection device, in which the needle shield remover is assembled with the syringe prior to insertion of the syringe into the housing of an automatic injection device.

[0214] In step **2502**, a suitable injection needle may be coupled to a distal end of the syringe. In step **2504**, a bung may be disposed within the syringe to seal the contents of the syringe. In step **2506**, the syringe may be filled with a dose of a therapeutic agent. In step **2508**, the injection needle may be covered by one or more soft needle shields and/or one or more rigid needle shields.

[0215] In step **2510**, a needle shield remover may be engaged to the rigid needle shield attached to the syringe prior to insertion of the syringe into the housing of the device. The ability to assemble the exemplary needle shield remover to the syringe outside the device housing allows visual inspection of the assembly process to ensure that the needle shield remover reliably engages the needle shield on the syringe before the syringe assembly is inserted into the device housing.

[0216] In an exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms of the needle shield remover may be engaged to a gap formed between the proximal end of the rigid needle shield and the syringe body. In an exemplary embodiment, as the needle shield remover is positioned surrounding the rigid needle shield, the shield engagement mechanisms may snap into place at the gap and may not be disengaged during the assembly process. When the inwardly-projecting shield engagement mechanisms snap into place at the gap, there may be a decrease in the force experienced against insertion of the needle shield remover over the rigid needle shield. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting shield engagement mechanisms have been successfully engaged to the needle shield at the gap. In an exemplary embodiment, positioning of the shield engagement components at the gap may emit an audible "click" sound that provides an audible indication that the needle shield remover has been successfully engaged with the rigid needle shield.

[0217] In another exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms of the needle shield remover may be engaged to one or more apertures defined in a rigid needle shield. In another exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms of the needle shield remover may be engaged to one or more ridged portions in the exterior surface of the rigid needle shield.

[0218] In step **2512**, in an exemplary embodiment, a syringe sleeve may be engaged with the syringe and needle shield remover. The syringe sleeve may be maintained in a substantially fixed axial orientation relative to the device housing. The syringe sleeve may, in turn, maintain the needle shield remover in a substantially fixed axial orientation relative to the syringe sleeve. This assembly aligns the cutout portions of the needle shield remover with the inspection window or inspection aperture of the syringe sleeve and with the inspection window or inspection aperture of the device housing. This allows a user to view the contents of the syringe and/or an end-of-injection indicator through the inspection window or inspection aperture of the device housing.

[0219] In another exemplary embodiment, a syringe sleeve may be absent in the automatic injection device and step **2512** may be skipped. In this exemplary embodiment, the axial orientation of the needle shield remover may be manually or automatically adjusted relative to the device housing so that the cutout portions of the needle shield remover are aligned with the inspection window or inspection aperture of the device housing. This allows a user to view the contents of the syringe and/or to view an indicator through the inspection window or inspection aperture of the device housing.

[0220] In step **2514**, the syringe, needle shield remover and syringe sleeve assembly may be inserted into the device housing through a proximal end of the device housing.

[0221] In step **2516**, a proximal cap may be coupled to the proximal end of the device housing to seal the proximal end.

[0222] In step **2518**, a distal cap may be coupled to the distal end of the device housing so that the distal cap is engaged to both the distal end of the housing and to the needle shield remover in one step. In an exemplary embodiment, as the distal cap is inserted over the needle shield remover disposed at the distal end of the device housing, one or more cap engagement mechanisms of the needle shield remover may fit within a central aperture provided in the distal cap. One or more inwardly-projecting stop portions (e.g., flanges or raised edges) provided in the central aperture of the distal cap may snap into place within a gap formed under the cap engagement mechanisms. When the cap engagement mechanisms snap into place at the gap over the inwardly-projecting stop portions in the central aperture of the distal cap, there may be a decrease in the force experienced against insertion of the distal cap over the needle shield remover. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the cap engagement mechanisms have been successfully engaged to the distal cap. In an exemplary embodiment, the engagement of the cap engagement mechanisms with the distal cap may emit an audible "click" sound that provides an audible indication that the needle shield remover has been successfully engaged with the distal cap.

[0223] FIG. **26** illustrates a device view of the exemplary method **2500** of FIG. **25** by which an exemplary automatic injection device may be assembled. A syringe assembly **2600** may include a syringe, a needle shield remover **2602** coupled to the syringe, and a syringe sleeve **2604** coupled to the syringe and the needle shield remover **2602**. A side wall of the syringe sleeve **2604** may define or include a transparent inspection window or inspection aperture **2606**. The syringe assembly **2600** may be assembled before its insertion into a housing **2650** of the automatic injection device. The housing **2650** may have a proximal end **2652** that is open during assembly and that may be covered by a proximal cap (not pictured) after the syringe assembly is inserted into the housing **2650**. The housing **2650** may have a distal end **2654** that is open during assembly and that may be covered by a distal cap (not pictured) after the syringe assembly is inserted into the housing **2650**. A side wall of the housing **2650** may define or include a transparent inspection window or inspection aperture **2656** through which a user may view the contents of the syringe.

[0224] The assembled syringe **2600** may be inserted into the device housing **2650** at the proximal end **2652** in the direction represented by arrow R, so that the distal end of the needle shield remover **2602** is disposed at the distal end **2654** of the device housing **2650**. Once the syringe assembly **2600** is inserted in the housing **2650**, the inspection window or inspection aperture **2656** of the housing **2650** is aligned with the inspection window or inspection aperture **2606** of the syringe sleeve **2604**. The transparent inspection window or inspection aperture **2606** of the syringe sleeve **2604** is, in turn, aligned with a cutout portion on the needle shield remover **2602**, thus allowing a user of the device to view the contents of the syringe and/or to view an end-of-injection

indicator through the inspection window or inspection aperture **2656** of the device housing **2650**.

[0225] FIG. **27** is a flowchart of an exemplary method **2700** for assembling an exemplary needle shield remover with a syringe and a distal cap of an automatic injection device, in which the needle shield remover is assembled with the syringe after insertion of the syringe into the housing of the device.

[0226] In step **2702**, a suitable injection needle may be coupled to a distal end of the syringe. In step **2704**, a bung may be disposed within the syringe to seal the contents of the syringe. In step **2706**, the syringe may be filled with a dose of a therapeutic agent. In step **2708**, the injection needle may be covered by one or more soft needle shields and/or one or more rigid needle shields.

[0227] In step **2710**, in an exemplary embodiment, a syringe sleeve may be engaged to the syringe. The syringe sleeve may be maintained in a substantially fixed axial orientation relative to the device housing. The syringe sleeve may, in turn, maintain a needle shield remover in a substantially fixed axial orientation relative to the syringe sleeve. This assembly aligns the cutout portions of the needle shield remover with the inspection window or inspection aperture of the syringe sleeve and with the inspection window or inspection aperture of the device housing. This allows a user to view the contents of the syringe and/or to view an end-of-injection indicator through the inspection window or inspection aperture of the device housing.

[0228] In another exemplary embodiment, a syringe sleeve may be absent in the automatic injection device and step **2710** may be skipped. In this exemplary embodiment, the axial orientation of the needle shield remover may be manually or automatically adjusted relative to the device housing so that the cutout portions of the needle shield remover are aligned with the inspection window or inspection aperture of the device housing. This allows a user to view the contents of the syringe and/or to view an end-of-injection indicator through the inspection window or inspection aperture of the device housing.

[0229] In step **2712**, the syringe and syringe sleeve assembly may be inserted into the device housing through a proximal end of the device housing.

[0230] In step **2714**, a proximal cap may be coupled to the proximal end of the device housing to seal the proximal end.

[0231] In step **2716**, a needle shield remover may be engaged to a distal cap of the automatic injection device. In an exemplary embodiment, as the distal cap is inserted over the needle shield remover, the distal end of the needle shield remover may fit within a central aperture provided in the distal cap. One or more inwardly-projecting stop portions (e.g., flanges or raised edges) provided in the central aperture of the distal cap may snap into place within a gap formed under the cap engagement mechanisms provided at the distal end of the needle shield remover. When the cap engagement mechanisms snap into place at the gap over the inwardly-projecting stop portions in the central aperture of the distal cap, there may be a decrease in the force experienced against insertion of the distal cap over the needle shield remover. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the cap engagement mechanisms have been successfully engaged to the distal cap. In an exemplary embodiment, the engagement of the cap engagement mechanisms with the distal cap may emit an audible "click" sound that provides an audible indication that the needle shield remover has been successfully engaged with the distal cap.

[0232] In step **2718**, the distal cap and needle shield assembly may be coupled to the distal end of the device housing to cover the distal end, so that the needle shield remover is engaged to the needle shield on the syringe. In an exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms of the needle shield remover are engaged to a gap formed between the rigid needle shield and the syringe body. In an exemplary embodiment, as the needle shield remover is inserted over the rigid needle shield, the inwardly-projecting shield engagement mechanisms may snap into place at the gap and may not be disengaged during the assembly process. When the inwardly-projecting shield engagement mechanisms snap into place at the gap, there may be a decrease in the force experienced against insertion of the needle shield remover over the rigid needle shield. In an exemplary embodiment, this decrease in the force may be sensed by a user or automatically by an assembly machine to determine that the inwardly-projecting shield engagement mechanisms have been successfully engaged to the needle shield at the gap. In an exemplary embodiment, positioning of the shield engagement components at the gap may emit an audible "click" sound that provides an audible indication that the needle shield remover has been successfully engaged with the rigid needle shield.

[0233] In another exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms of the needle shield remover may be engaged to one or more apertures defined in a rigid needle shield. In another exemplary embodiment, one or more inwardly-projecting shield engagement mechanisms of the needle shield remover may engaged to one or more ridged portions in the exterior surface of the rigid needle shield.

[0234] FIG. **28** is a flowchart of an exemplary method **2800** for using an exemplary automatic injection device to administer an injection. An exemplary automatic injection device may be packaged and pre-filled with a therapeutic agent and may be stored in refrigerated storage before use. In step **2802**, the packaged automatic injection device may be removed from storage. In step **2804**, the automatic injection device may be removed from its packaging and any over-wrap and warmed to room temperature, for example, by leaving the device outside the packaging at room temperature or by warming the device. In step **2806**, the user may view the contents of the device through a transparent inspection window or inspection aperture provided in the device housing to ensure that the device contains a volume of the therapeutic agent and to confirm the clarity of the therapeutic agent, if necessary. In step **2808**, the injection site on a patient's body may be selected and prepared for the delivery of the therapeutic agent.

[0235] In step **2810**, the user of the automatic injection device may remove the distal cap of the automatic injection device that protects the injection needle and any needle shields protecting the needle. A needle shield remover provided in the device automatically removes all of the needle shields when the user removes the distal cap. In step **2812**, the user of the device may position the automatic injection device so that the distal end of the device is positioned at or adjacent to the injection site on the patient's body. In step **2814**, a firing button on the device may be

depressed or otherwise activated to cause the device to perform an injection at the injection site. In step **2816**, the injection site on the patient's body may receive a therapeutically effective dose of the therapeutic agent administered by the device. In an exemplary embodiment, activating the firing button may cause a syringe to advance within and relative to the device housing so that the injection needle protrudes from an open distal end of the housing, and may cause a bung to move within the syringe to expel the therapeutic agent out of the syringe through the injection needle and into the injection site.

[0236] In step **2818**, after administration of the therapeutic agent, the automatic injection device may be removed from the injection site on the patient's body and discarded in an appropriate manner.

IX. INCORPORATION BY REFERENCE

[0237] The entire contents of all references, including patents and patent applications, cited throughout this application are hereby incorporated herein by reference in their entirety. The appropriate components and methods of those references may be selected for the invention and embodiments thereof. Still further, the components and methods identified in the Background section are integral to this disclosure and may be used in conjunction with or substituted for components and methods described elsewhere in the disclosure within the scope of the invention.

X. EQUIVALENTS

[0238] In describing exemplary embodiments, specific terminology is used for the sake of clarity. For purposes of description, each specific term is intended to, at least, include all technical and functional equivalents that operate in a similar manner to accomplish a similar purpose. Additionally, in some instances where a particular exemplary embodiment includes a plurality of system elements or method steps, those elements or steps may be replaced with a single element or step. Likewise, a single element or step may be replaced with a plurality of elements or steps that serve the same purpose. Further, where parameters for various properties are specified herein for exemplary embodiments, those parameters may be adjusted up or down by ½0th, ⅒th, ⅕th, ⅓rd, ½nd, and the like, or by rounded-off approximations thereof, unless otherwise specified. Moreover, while exemplary embodiments have been shown and described with references to particular embodiments thereof, those of ordinary skill in the art will understand that various substitutions and alterations in form and details may be made therein without departing from the scope of the invention. Further still, other aspects, functions and advantages are also within the scope of the invention.

[0239] Exemplary flowcharts are provided herein for illustrative purposes and are non-limiting examples of methods. One of ordinary skill in the art will recognize that exemplary methods may include more or fewer steps than those illustrated in the exemplary flowcharts, and that the steps in the exemplary flowcharts may be performed in a different order than shown.

What is claimed is:

1. An apparatus for removing a needle shield from a syringe, comprising:

a tubular member for enclosing the needle shield coupled to the syringe;

one or more cap engagement mechanisms provided at a distal end of the tubular member and configured for engagement with a distal cap provided for covering a distal end of the syringe; and

one or more shield engagement mechanisms provided at a proximal end of the tubular member and configured for engagement with the needle shield;

wherein, when the apparatus is pulled away from the syringe, the one or more shield engagement mechanisms exert force against the needle shield to remove the needle shield from the syringe.

2. The apparatus of claim **1**, wherein the distal cap comprises an aperture and a flanged portion provided in the aperture, and wherein the one or more cap engagement mechanisms are configured to fit within the aperture in the distal cap and wherein the flanged portion of the distal cap is accommodated in a gap under the one or more cap engagement mechanisms.

3. The apparatus of claim **1**, wherein the tubular member comprises two apertures, and wherein two shield engagement mechanisms are provided in the apertures.

4. The apparatus of claim **1**, wherein the tubular member comprises three apertures, and wherein three shield engagement mechanisms are provided in the apertures.

5. The apparatus of claim **1**, wherein the one or more shield engagement mechanisms are configured for engagement with a gap between the needle shield and the syringe.

6. The apparatus of claim **1**, wherein the needle shield comprises a soft inner portion and a rigid outer portion.

7. The apparatus of claim **1**, wherein the apparatus is configured for engagement with the needle shield coupled to the syringe before the syringe is inserted into a housing of an automatic injection device.

8. An automatic injection device, comprising:

a syringe;

a needle shield coupled to a distal end of the syringe;

a distal cap for covering the needle shield; and

a needle shield remover disposed between the needle shield and the distal cap, the needle shield comprising:

a tubular member for enclosing the needle shield coupled to the syringe,

one or more cap engagement mechanisms provided at a distal end of the tubular member and engaged with the distal cap, and

one or more shield engagement mechanisms provided at a proximal end of the tubular member and engaged with the needle shield;

wherein, when the needle shield remover is pulled away from the syringe, the one or more shield engagement mechanisms exert force against the needle shield to remove the needle shield from the syringe.

9. The automatic injection device of claim **8**, wherein the distal cap comprises an aperture and a flanged portion provided in the aperture, and wherein the one or more cap engagement mechanisms are configured to fit within the aperture in the distal cap and wherein the flanged portion of the distal cap is accommodated in a gap under the one or more cap engagement mechanisms.

10. The automatic injection device of claim **8**, wherein the tubular member comprises two apertures, and wherein two shield engagement mechanisms are provided in the apertures.

11. The automatic injection device of claim **8**, wherein the tubular member comprises three apertures, and wherein three shield engagement mechanisms are provided in the apertures.

12. The automatic injection device of claim **8**, wherein the one or more shield engagement mechanisms are for engagement with a gap between the needle shield and the syringe.

13. The automatic injection device of claim **8**, wherein the needle shield comprises a soft inner portion and a rigid outer portion.

14. The automatic injection device of claim **8**, wherein the needle shield remover is configured for engagement with the needle shield coupled to the syringe before the syringe is inserted into a housing of the automatic injection device.

15. A method for assembling an automatic injection device, comprising:

coupling a needle shield to a distal end of a syringe;

engaging one or more shield engagement mechanisms of a needle shield remover to the needle shield; and

inserting an assembly comprising the syringe, the needle shield and the needle shield remover into a housing of the automatic injection device.

16. The method of claim **15**, further comprising:

coupling a distal cap to a distal end of the housing of the automatic injection device; and

engaging one or more cap engagement mechanisms of the needle shield remover to the distal cap.

17. The method of claim **16**, further comprising:

when the needle shield remover is pulled away from the syringe, exerting force against the needle shield using the shield engagement mechanisms of the needle shield remover to remove the needle shield from the syringe.

18. The method of claim **16**, wherein the distal cap comprises an aperture and a flanged portion provided in the aperture, and wherein the one or more cap engagement mechanisms are configured to fit within the aperture in the distal cap and wherein the flanged portion of the distal cap is accommodated in a gap under the one or more cap engagement mechanisms.

19. The method of claim **15**, wherein the needle shield remover comprises a tubular member, and wherein the one or more shield engagement mechanisms are provided at a proximal end of the tubular member and the one or more cap engagement mechanisms are provided at a distal end of the tubular member.

20. The method of claim **19**, wherein the tubular member comprises two apertures, and wherein two shield engagement mechanisms are provided in the apertures.

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