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(54) Title: RETRACTABLE NEEDLE SYRINGE WITH UNITARY PROPELLANT RELEASE MODULE

(57) Abstract: A modular retractable needle assembly having a unitary propellant release structure is provided. The modular retractable needle assembly can be coupled to a suitable syringe. A modular filler needle can be provided that is engageable to the syringe. Kits comprising the modular retractable needle assembly, one or more syringes, and a modular filler needle are provided.

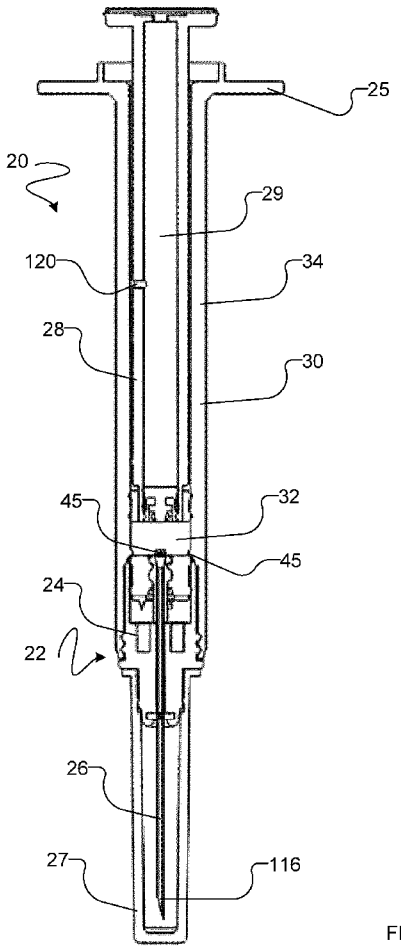

FIGURE 1

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RETRACTABLE NEEDLE SYRINGE WITH UNITARY PROPELLANT RELEASE MODULE

Cross-Reference to Related Applications

[0001] This application claims priority to, and the benefit of, United States provisional patent application No. 62/105,624 filed 20 January 2015, which is incorporated by reference herein in its entirety.

Technical Field

[0002] Some embodiments of the present invention pertain to propellant release devices for use in pneumatically actuated medical devices. Some embodiments of the present invention pertain to modular needle assemblies that include a propellant release device for use in pneumatically actuated medical devices.

Background

[0003] It is well known that many dangerous communicable diseases are spread through contacting the body fluids of an infected person. After use of a sharps-containing medical device, residual body fluids are likely to remain on or within the sharp element of the medical device, for example needles or blades. After use, the sharp element should be covered, to prevent it from accidentally stabbing the person who is using the medical device, thereby potentially releasing residual bodily fluids into such a person. While caps can be used to cover sharps elements after use, there remains a risk that persons attempting to cap the sharp element may misapply the cap and accidentally pierce their skin with the used sharp element, resulting in potential exposure to communicable diseases.

[0004] Accordingly, it is desirable to provide for retraction of a sharps element inside of a medical device after the medical device has been used. For example, syringes having retractable needles are known, and syringes having pneumatically actuated retractable needles have been developed, as exemplified by U.S. Patent Nos. 5,868,713 and 7,811,259, and Patent Cooperation Treaty patent application No. PCT/CA2015/051113, each of which is incorporated by reference herein. Often, such retractable needle syringes are provided as prefilled syringes. Modular needle assemblies designed to work with such retractable needles have also been developed,

wherein the modular needle assembly can be fitted to a syringe of any desired size, for example as described in Patent Cooperation Treaty publication No. WO 2012/162821, which is incorporated by reference herein.

[0005] There remains a need to provide pneumatically actuated medical devices that are easier and/or less expensive to construct.

[0006] The foregoing examples of the related art and limitations related thereto are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

Summary

[0007] The following embodiments and aspects thereof are described and illustrated in conjunction with systems, tools and methods which are meant to be exemplary and illustrative, not limiting in scope. In various embodiments, one or more of the above-described problems have been reduced or eliminated, while other embodiments are directed to other improvements.

[0008] In one aspect, a modular retractable needle assembly for engagement with a barrel of a retractable needle syringe having a plunger is provided. The modular retractable needle assembly has a body having an upper chamber at a proximal end thereof, a propellant chamber defined within the body, a seal sealingly engaged over the propellant chamber to seal a propellant in the propellant chamber, a retention member initially engaged within the upper chamber, the retention member being moveable in a distal direction in response to the application of a post-injection force to the plunger by a user, a needle hub initially engaged within the retention member, the needle hub being engageable with a retractable locking tip of the plunger upon the application of the post-injection force to the plunger by the user, a needle for injecting medicament into a patient engaged with the needle hub and projecting distally from the body, and a rupturing member projecting in the distal direction, the rupturing member being moveable in the distal direction in response to the application of the post-injection force to the plunger by the user to rupture the seal and thereby release propellant into the upper chamber. The outer surface of the body of the modular retractable needle assembly can be provided with engagement members for engaging the body with the barrel.

[0009] In one aspect, a modular filler needle assembly for engagement with a barrel of a syringe

is provided. The modular filler needle assembly has a base engageable with the barrel, a support disc spaced apart from the base and positioned to provide a sealing engagement with the barrel, and a needle supported on the support disc for loading medicament into the syringe, the needle projecting distally from the base. The base can have engagement members on an outer surface thereof for engaging with the barrel. The support disc can be spaced apart from the base by a sufficient distance to allow the modular filler needle assembly to be secured on a syringe having a distal cavity for receiving a modular retractable needle assembly as described in this specification.

[0010] In one aspect, a syringe for use with a modular retractable needle assembly as described in this specification, or with a modular filler needle assembly as described in this specification, is provided. The syringe has a barrel, a plunger slideable within the barrel for loading or injecting medicament from a medicament chamber of the barrel, the plunger having a retraction lumen therein for receiving a needle retracted from the modular retractable needle assembly, a locking tip initially engaged within the retraction lumen, the locking tip being engageable with a needle hub of the modular retractable needle assembly upon application of a post-injection force by a user, the locking tip being retractable into the retraction lumen when a propellant chamber of the modular retractable needle assembly is ruptured, and a recess at a distal end of the barrel for receiving a modular needle assembly or a modular filler needle assembly as described in this specification.

[0011] In other aspects, kits having one or more syringes as described in this specification and at least one modular retractable needle assembly as described in this specification are provided. The kit can contain a modular filler needle assembly as described in this specification.

[0012] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the drawings and by study of the following detailed descriptions.

Brief Description of the Drawings

[0013] Exemplary embodiments are illustrated in referenced figures of the drawings. It is intended that the embodiments and figures disclosed herein are to be considered illustrative rather than restrictive.

[0014] Figure 1 is a cross-sectional view of a pneumatically-actuated retractable needle syringe having a modular needle assembly according to one example embodiment.

[0015] Figure 2 is a partial cross-sectional view of the modular needle assembly of the example embodiment of Figure 1, with the needle and needle hub omitted for clarity.

[0016] Figure 3A is a perspective view of a syringe body that is engageable with a modular needle assembly, shown in cross-section.

[0017] Figure 3B is a fully cross-sectional view of the embodiment illustrated in Figure 3A.

[0018] Figure 4 is a partial cross-sectional view of the modular needle assembly of the example embodiment of Figure 1, with the needle secured in its initial position.

[0019] Figure 5 is a perspective view of a modular needle assembly of one example embodiment secured on the body of a syringe.

[0020] Figure 6 is a partial perspective view showing an example embodiment of a cap for capping the needle of the modular needle assembly of the example embodiment of Figure 5.

[0021] Figure 7 is a partial cross-sectional view the embodiment of Figure 1 showing the engagement between the plunger and the syringe barrel.

[0022] Figure 8 is a cross-sectional view of the embodiment of Figure 1 after a user has applied a post-injection force to the device to engage the locking tip with the needle hub and rupture the seal covering the unitary propellant release structure.

[0023] Figure 9 is a cross-sectional view of the embodiment of Figure 1 after the needle has been fully retracted.

[0024] Figures 10A and 10B are cross-sectional views of example embodiments of different channel structures that can be used to provide a unitary propellant release structure.

[0025] Figure 11 is a cross-sectional view of an example embodiment of a non-retractable filler needle module coupled to a syringe body.

[0026] Figure 12 is a perspective view of an example embodiment of a non-retractable filler needle module.

[0027] Figure 13 is a partial cross-sectional view of the example embodiment of a non-retractable filler needle module as shown in Figure 11 coupled to a syringe body.

[0028] Figure 14 is a partial cross-sectional view of a further example embodiment of a modular retractable needle assembly.

Description

[0029] Throughout the following description specific details are set forth in order to provide a more thorough understanding to persons skilled in the art. However, well known elements may not have been shown or described in detail to avoid unnecessarily obscuring the disclosure. Accordingly, the description and drawings are to be regarded in an illustrative, rather than a restrictive, sense.

[0030] In this specification, "seals" or "sealingly engages" means that two elements are engaged with sufficient sealing capability that the function for which the sealing is provided can be effectively performed.

[0031] "Distal" means the direction towards the tip of the needle when the syringe assembly is in the assembled state. "Proximal" means the direction opposite of distal, i.e. the direction away from the tip of the needle when the syringe assembly is in the assembled state.

[0032] "Downstream" means a direction in the distal direction, i.e. towards the tip of the needle, referring to the conventional direction of injection of medicament into a patient. "Upstream" means a direction opposite to downstream, i.e. in the proximal direction, e.g. in the direction of fluid flow when medicament is being drawn from a supply vial into the syringe for subsequent injection.

[0033] "Inwardly" means in a direction towards the axial centerline of the syringe. "Outwardly" means in a direction towards the outside of the syringe, i.e. away from the axial centerline of the syringe.

[0034] "Injection force" means a force that would typically be applied by a user to the plunger of a syringe to inject a medicament into a patient.

[0035] "Post-injection force" means a force that is applied to activate the propellant-actuated retraction mechanism described below after a user has completed injection of the medicament. In some embodiments, the post-injection force is greater than the injection force.

[0036] "Loading force" means a force typically applied by a user when drawing medicament into a syringe in preparation for administering that medicament to a patient.

[0037] With reference to Figure 1, an example embodiment of a retractable needle syringe **20** having a modular needle assembly **22** containing a unitary propellant release structure **24** is illustrated. Retractable needle syringe **20** has a hypodermic needle **26** at its distal end for use in

administration of a medicament to a patient. A plunger **28** is slideably engaged within the barrel **30** of the syringe, to force medicament from a medicament chamber **32** (defined within syringe barrel **30** downstream of plunger **28** and upstream of needle **26**) through needle **26** and into a patient.

[0038] A retraction lumen **29** is provided within plunger **28** for receiving the needle **26** following needle retraction. A cap **27** is provided for initially covering needle **26** prior to use. In some embodiments, cap **27** is provided with a roughened surface, a plurality of longitudinally extending ridges, or other surface features that make it easier for a user to twist modular needle assembly **22** onto syringe body **34**. Syringe body **34** is provided with a flange **25** formed therewith or attached thereto at its proximal end, to facilitate grasping and usage of syringe assembly **20** by a user.

[0039] Figure 2 shows the modular needle assembly **22** in more detail, with needle **26** and the needle hub **70** (described below) omitted for clarity. The surface of modular needle assembly **22** is provided with engagement members for engaging modular needle assembly **22** with the body **34** of syringe barrel **30**. The distal surface of syringe body **34** is provided with corresponding engagement members, to allow a user to securely couple modular needle assembly **22** with syringe body **34**. In the illustrated embodiment, modular needle assembly **22** is provided with outwardly projecting threads **36** on its external surface. Threads **36** are engageable with a corresponding set of threaded grooves **38** (Figure 3A) provided on the distal internal surface of the distal cavity **37** of syringe body **34**, to secure modular needle assembly **22** to syringe body **34**. In alternative embodiments, the engagement of threads **36** and threaded grooves **38** could be replaced by a Luer lock fitting, which is a commonly used mechanism for sealingly engaging two components of a medical fluid delivery system. In some embodiments, including the illustrated embodiment, recessed threaded grooves **38** are used on the distal internal surface of syringe body **34** rather than inwardly projecting threads to minimize any interference that might be caused by inward projections on the distal internal surface of syringe body **34** as modular needle assembly **22** is inserted onto syringe body **34**.

[0040] Modular needle assembly **22** includes a retaining member, which in the illustrated embodiment is a false wall **40**, for supporting needle **26** (via a needle hub as described below) and one or more distally projecting rupturing members **42** for rupturing a seal **44** containing a propellant within unitary propellant release structure **24** when needle **26** is to be retracted. In the

illustrated embodiment, distally projecting rupturing members **42** are formed integrally with a disc-like base **46** as a rigid substrate, and false wall **40** is formed as an elastomeric overmold of this rigid substrate. In alternative embodiments, any suitable method can be used to manufacture rupturing members **42** and false wall **40**, and these can be joined together in any suitable manner, for example using adhesives, suitable fasteners, or the like. In alternative embodiments, rupturing members **42** and false wall **40** are not joined together, for example false wall **40** and disc-like base **46** bearing rupturing members **42** are pressed inside the interior surface of the upper chamber **48** of modular needle assembly **22** with a friction fit to secure these elements in place.

[0041] In some embodiments, disc-like base **46** is not in contact with false wall **40** when modular needle assembly **22** is assembled, however, those skilled in the art will recognize that it will be easier to manufacture and provide greater consistency in embodiments in which rupturing members **42** and false wall **40** are not joined together to insert disc-like base **46** into modular needle assembly **22** so that it contacts false wall **40** and is securely retained in that position prior to the application of a post-injection force by a user.

[0042] Unitary propellant release structure **24** is provided within modular needle assembly **22**. In the illustrated embodiment, unitary propellant release structure **24** is formed as a generally cylindrical channel **50** defined within an interior portion of the body **52** of modular needle assembly **22**. In the illustrated embodiment, cylindrical channel **50** is positioned distally of upper chamber **48** of modular needle assembly **22**. Cylindrical channel **50** is defined by an inside cylindrical wall **54**, an outside cylindrical wall **56**, and a base **58** provided in body **52** of modular needle assembly **22**.

[0043] Propellant is sealed within unitary propellant release structure **24** by a seal **44**, which extends over cylindrical channel **50** at the proximal end thereof. In the illustrated embodiment, seal **44** is sealingly engaged with upper proximal edges **60**, **62** of inside wall **54** and outside wall **56**, respectively. Seal **44** can be secured to upper proximal edges **60**, **62** in any suitable manner, for example by heat sealing, ultrasonic welding, the use of suitable adhesives, or the like.

[0044] In use, the application of a post-injection force moves false wall **40** and rupturing members **42** in the distal direction, causing rupturing members **42** to rupture seal **44**, thereby releasing propellant into the upper chamber **48** of modular needle assembly **22**. The composition, pressure and volume of propellant contained within unitary propellant release

structure **24** by seal **44** should be sufficient to ensure that needle **26** is fully retracted when seal **44** is punctured, under a range of anticipated operating conditions.

[0045] In some embodiments, the use of a unitary propellant release structure **24** can facilitate the more efficient and/or less expensive manufacture and assembly of modular needle assembly **22** as compared with the use of a separate propellant release cell, for example as described in Patent Cooperation Treaty patent publication No. WO 2012/162821.

[0046] A perimeter wall **64** of modular needle assembly **22** extends proximally from channel **50**, to define the upper chamber **48** of modular needle assembly **22**. In the illustrated embodiment, perimeter wall **64** extends proximally from the outer circumference of upper proximal edge **62** of outside wall **56**, so that upper proximal edge **62** is inset or recessed within perimeter wall **64**. In the illustrated embodiment, upper proximal edges **60** and **62** are located at approximately the same distance in the distal direction from the body **52** of modular needle assembly **22**, which can facilitate sealing of seal **44** over channel **50**.

[0047] In the illustrated embodiment, the proximal portion of the outside surface of perimeter wall **64** is provided with an inwardly tapered portion **66**, which tapers inwardly in the proximal direction from the outside circumference of perimeter wall **64**. In use, inwardly tapered portion **66** engages with a correspondingly tapered surface **68** (Figure 3B) provided on syringe body **34**, to help sealingly engage modular needle assembly **22** with syringe body **34**. In alternative embodiments, other sealing structures could be used to sealingly engage modular needle assembly **22** within syringe barrel **30**. For example, an O-ring type seal or other compressible member could be compressed between the proximal portion of the outside surface of perimeter wall **64** and a lip formed on the inside surface of distal cavity **37** in place of correspondingly tapered surface **68**, or the force with which the two components are engaged could be sufficiently strong to provide a sealing engagement therebetween without using an O-ring seal or other compressible member therebetween.

[0048] Figures 3A and 3B show in more detail how modular needle assembly **22** is engageable with syringe body **34**. In the illustrated embodiment, threads **36** on needle assembly **22** are engageable with recessed grooves **38** that act as a correspondingly threaded surface on syringe body **34**. Any suitable means of engaging modular needle assembly **22** with syringe body **34** could be used, for example a sufficiently tight press or friction fit, snap-fit engagement members, or the like. In some embodiments, the engagement between modular needle assembly **22** and

syringe body **34** is reversible, i.e. after modular needle assembly **22** has been engaged with syringe body **34**, a user can uncouple modular needle assembly **22** from syringe body **34**. In some embodiments, the engagement between modular needle assembly **22** and syringe body **34** is irreversible, i.e. after modular needle assembly **22** has been coupled to syringe body **34**, modular needle assembly **22** cannot be removed.

[0049] With reference to Figure 4, the engagement of needle **26** within modular needle assembly **22** is shown in more detail. Needle **26** is releasably retained in its initial position via a needle hub **70**. Needle hub **70** is provided at or near the proximal end of needle **26**. In some embodiments, needle **26** is crimped in, cemented to, or otherwise securely fixed to needle hub **70**. In some embodiments, needle **22** is insert molded with needle hub **70** to create a single part. Needle hub **70** securely retains needle **26** in place against an injection force or a loading force, but is releasable in the proximal direction in response to the application of a post-injection force applied by a user to retract needle **26**.

[0050] Needle hub **70** is engageable with grasping features on plunger **28** to provide an assembly for retracting needle **26**. In the illustrated embodiment, a locking tip **72** of plunger **28** provides a grasping feature that can engage with needle hub **70** to form a retraction assembly (illustrated as **154** in Figure 9). Needle hub **70** is also sealingly engageable with false wall **40**, to initially secure needle hub **70** (and thus needle **26**) in place within modular needle assembly **22**.

[0051] While the needle hub and locking tip of the embodiment illustrated in Figure 4 is generally similar to that shown and described in Patent Cooperation Treaty patent application No. PCT/CA2015/051113, which is incorporated by reference herein, any suitable mechanism for engaging and retracting a pneumatically actuated retractable needle can be used, for example, that shown and described in Patent Cooperation Treaty patent application publication Nos. WO 2006/024172 and WO 2012/162821, each of which is incorporated by reference herein.

[0052] In the illustrated embodiment, needle hub **70** is initially secured in position by sealing features provided on the outside surface of needle hub **70** that engage with corresponding features provided on the inside surface of a central aperture **39** (Figure 2) that extends through false wall **40**. Needle hub **70** is also supported against movement in the distal direction by contact between a distal end **71** of needle hub **70** with upper proximal edge **60** of inside wall **54**, as best shown in Figure 4. Contact between distal end **71** of needle hub **70** with upper proximal

edge **60** as aforesaid prevents needle hub **70** from moving in the distal direction at all times, even upon the application of a post-injection force by a user.

[0053] Needle hub **70** has an O-ring seal **74** and two tapered seals **76**. O-ring seal **74** is provided as a sealing rib integrally formed with needle hub **70**, and sealingly engages with a recess **78** formed on the inside surface of false wall **40**.

[0054] The tapered seals **76** of needle hub **70** engage respectively with correspondingly shaped tapered regions **80** (Figure 2) of false wall **40** to provide an additional seal to help prevent medicament from flowing between needle hub **70** and false wall **40**. All of false wall **40**, O-ring seal **74** and tapered seals **76** are concentric, so that O-ring seal **74** and tapered seals **76** sealingly engage about their full circumferences with recess **78** of false wall **40**.

[0055] A pair of restraining projections **84** project radially inwardly from the inside surface of false wall **40** proximally and distally of tapered regions **80**. The engagement of O-ring seal **74** and tapered seals **76** of needle hub **70** with recess **78** and correspondingly tapered regions **80** of false wall **40** between restraining projections **84** restrains movement of needle hub **70** relative to false wall **40** in the axial direction during the application of a loading force or an injection force.

[0056] False wall **40** is frictionally but slidably engaged with the interior surface of perimeter wall **64** of modular needle assembly **22**. False wall **40** is axially slidable in response to the application of a post-injection force, but is retained in place by frictional force during the application of a loading or injection force. False wall **40** could be secured in place in any suitable manner that is sufficiently strong to retain false wall **40** in place during the application of a loading or injection force, but releasable in response to the application of a post-injection force. For example, false wall **40** can be initially held in place by frangible members, or weakly secured with adhesive.

[0057] In the illustrated embodiment, a plurality of false wall retention features **45** (Figure 3B) are provided on the interior surface of syringe barrel body **34**, to further prevent false wall **40** from being slid in the proximal direction inside syringe barrel body **34**, for example when needle **26** is inserted into a patient. In the illustrated embodiment, the false wall retention features comprise one or more radially inwardly extending projections **45** provided on the inside surface of syringe barrel body **34**. Radially inwardly extending projections **45** are provided within syringe barrel body **34** at an axial location just proximal of where the proximal portion of

perimeter wall **64** of modular needle assembly **22** contacts syringe barrel body **34** when modular needle assembly **22** is in the installed configuration.

[0058] In the illustrated embodiment, false wall **40** is provided with a pair of radially outwardly projecting O-ring features **82** (Figure 2) on its outer surface. O-ring features **82** provide the sealing frictional engagement between false wall **40** and perimeter wall **64**. In some embodiments, the use of two O-ring features **82** on false wall **40** assists in ensuring reproducible movement of false wall **40** in response to the application of a post-injection force, by maintaining an appropriate axial alignment of false wall **40** within modular needle assembly **22**.

[0059] When modular needle assembly **22** is not attached to syringe barrel **30**, the friction fit between O-ring features **82** and perimeter wall **64** holds false wall **40**, needle hub **70**, and needle **26** in position, so that these structures are not moved within body **52** of modular needle assembly **22**, for example by ordinary jostling or movement as might occur during the shipping and storage of modular needle assemblies **22**. In some embodiments, a friction fit between needle **26** and needle seal **118** (Figure 2) can also help to retain needle **26** in position in modular needle assembly **22**. When a cap **27** is affixed to needle **26** as described below, the cap **27** can assist in ensuring that false wall **40** does not move within the body **52** of modular needle assembly, by preventing forces from being applied against needle **26**. In alternative embodiments, O-ring features **82** are omitted, and the material and construction of false wall **40** are selected to provide an appropriate degree of frictional engagement with perimeter wall **64** to initially retain false wall **40**, needle hub **70** and needle **26** in position but still allow false wall **40** to be moved on the application of a post-injection force.

[0060] In the illustrated embodiment, false wall **40** is provided with a recessed central region **41** (Figure 2) at its proximal portion. Recessed central region **41** extends distally around central aperture **39** of false wall **40**, and receives the generally cylindrical locking element **86** of needle hub **70** described below. Recessed central region **41** allows locking tip **72** to move past and engage with the generally cylindrical locking element **86** (described below) to form a retraction assembly to retract needle **26**, without interference by false wall **40**.

[0061] In the illustrated embodiment, false wall **40** is symmetrical about a central radial axis. Thus, false wall **40** is provided with two recessed central portions **41**, one at its distal end and one at its proximal end, even though only one of these recesses receives the generally cylindrical locking element **86** of needle hub **70**. In some embodiments, providing a false wall **40** that is

symmetrical about a central radial axis avoids a need to ensure that false wall **40** is inserted with a particular orientation during manufacture of modular needle assembly **22**.

[0062] In the illustrated embodiment, the central aperture **39** of false wall **40** is provided with surface features to prevent the formation of an airtight seal between false wall **40** and needle hub **70** after needle hub **70** has been displaced from its initial position by the release of propellant from unitary propellant release structure **24**. This ensures that a passageway is available for the flow of propellant from unitary propellant release structure **24** after seal **44** has been ruptured to retract needle **26**. In the illustrated embodiment, the surface features that prevent formation of an airtight seal are channels **43** (Figure 2). Channels **43** extend axially along projections **84** of false wall **40** to provide a passageway for the flow of propellant between needle hub **70** and false wall **40** after needle hub **70** has been initially dislodged from false wall **40** (and the seals provided by O-ring seal **74** and tapered seals **76** have thereby been removed) by the application of a post-injection force by a user, to ensure propellant can flow and force the needle retraction assembly **154** in the proximal direction.

[0063] In the illustrated embodiment, the structure of false wall **40** also helps to ensure that no seal is formed between false wall **40** and inside wall **54**. For example, if false wall **40** had a recessed central portion **41** only at the proximal end thereof, there would be a risk that a seal could be formed between the distal edge of false wall **40** and upper proximal edge **60** of inside wall **54**. In such embodiments, alternative structures, such as appropriately located channels within false wall **40** or extensions of channels **43** could be provided to minimize the risk that a seal would be formed between false wall **40** and both upper proximal edges **60**, **62** of inside wall **54** and outside wall **56**, which could thereby contain propellant within channel **50** instead of allowing propellant to be released into upper chamber **48** of modular needle assembly **22** to retract needle retraction assembly **154**. In the illustrated embodiment, the tapered inside diameter provided at the distal portion of false wall **40** prevents a seal from being formed between false wall **40** and inside wall **54**. In some embodiments, the tapered inside diameter provided at the distal portion of false wall **40** could be different from the tapered inside diameter provided as recess **41** for receiving generally cylindrical locking element **86** of needle hub **70**, i.e. false wall **40** need not be symmetrical about a central radial axis.

[0064] In the illustrated embodiment, the proximal portion of needle hub **70** sits flush with the proximal portion of false wall **40**. In some embodiments, this configuration helps to minimize

the dead volume within retractable needle syringe **20**, and also minimizes the risk that needle hub **70** may be bumped or moved during shipping, storage, or assembly onto syringe body **34**. However, other configurations could be used, for example, the proximal end of needle hub **70** could project slightly in the proximal direction from false wall **40**, or could be slightly recessed within false wall **40**, as long as a corresponding recess is provided within false wall **40** to allow needle hub **70** to engage with locking tip **72**, as described below.

[0065] Locking tip **72** is positioned and configured to be engageable with needle hub **70** to form a retraction assembly for retracting needle **26**. In some embodiments, locking tip **72** is also positioned and configured to sealingly engage with needle hub **70**, to prevent any further flow of medicament and/or bodily fluids through needle **26**.

[0066] Needle hub **70** is provided with corresponding features for engaging with locking tip **72** to provide a retraction assembly for retracting needle **26**. In some embodiments, needle hub **70** is also provided with corresponding features to sealingly engage with locking tip **72**.

[0067] In the illustrated embodiment, needle hub **70** is provided with snap features to engage in a snap-fit engagement with locking tip **72**. In the illustrated embodiment, the snap features of needle hub **70** comprise a generally cylindrical locking element **86** at the proximal end of needle hub **70** that is positioned to engage with a locking channel **88** and locking edge **90** (Figure 4) provided on locking tip **72**. The generally cylindrical locking element **86** of needle hub **70** has an outer tapered portion **92** and a radially extending locking edge **94**. Outer tapered portion **92** flares radially outwardly in the distal direction from the proximal end of needle hub **70**, to provide locking edge **94** along the outside distal edge portion thereof. In use, outer tapered portion **92** can slide inside locking tip **72** of plunger **28**, to allow locking edge **94** to slide past and then engage in snap-fit engagement with locking channel **88**, as described below.

[0068] Although the outer tapered portion **92** and locking edge **94** of generally cylindrical locking element **86** of needle hub **70** have been described and illustrated as generally circular, it is alternatively possible for these elements to be provided as one or more discrete projections positioned to be engageable by locking channel **88** in use (i.e. generally cylindrical locking element **86** could be broken into one or more discontinuous pieces, rather than being one fully revolved element). In some embodiments, providing the locking element of needle hub **70** as a generally cylindrical locking element eliminates a need to ensure that needle hub **70** is placed in a specific orientation during the manufacture of modular needle assembly **22** (i.e. so that

locking element **86** will be available for engagement with locking channel **88** no matter what orientation it is inserted at within false wall **40**).

[0069] In some embodiments, including the illustrated embodiment, needle hub **70** also includes sealing features for sealingly engaging with locking tip **72**. In the illustrated embodiment, the sealing feature of needle hub **70** is provided by an inner tapered surface **96** that engages with a correspondingly tapered surface **98** provided on locking tip **72**. Inner tapered surface **96** is provided in the proximal portion of needle hub **70**, which is generally cylindrical with an axially extending opening **100** therethrough, so that fluid can flow through needle **26** into and out of medicament chamber **32**. Inner tapered surface **96** tapers inwardly in the distal direction, so that tapered surface **96** tapers inwardly towards the proximal portion of needle **28**. The proximal portion of opening **100** is thus wider than the distal portion of opening **100**, so that tapered surface **98** of locking tip **72** can be received therein in sealing engagement.

[0070] In the illustrated embodiment, locking tip **72** is made as a single part with two components as an overmold: a rigid component **102** and a more flexible overmolded component **104**, to enhance manufacturing convenience and provide a reduction in manufacturing cost. Rigid component **102** includes locking channel **88** for engaging with needle hub **70** in a snap-fit engagement. Rigid component **102** also engages locking tip **72** in place at the distal tip of plunger **28**. Overmolded component **104** sealingly engages with the interior surface of retraction lumen **29**, to prevent medicament from flowing past locking tip **72** and to ensure a good seal so that pressure can be applied by released propellant to move the needle retraction assembly in the proximal direction during needle retraction. Suitable examples of material for the manufacture of rigid component **102** include a rigid material such as rigid plastic like polycarbonate, Styrolux^{TM}, polypropylene, or the like. Suitable examples of material for the manufacture of overmolded component **104** include relatively more flexible materials such as silicone, thermoplastic elastomer or other similar polymer, or the like.

[0071] Rigid component **102** of locking tip **72** has a generally cylindrical shape so that it can fit within plunger lumen **29**, and includes at least one locking channel **88** formed on a distal edge thereof, for engaging in snap-fit engagement with locking edge **94** of needle hub **70** via locking edge **90**. While in the illustrated embodiment, locking channel **88** is shown as extending through a portion of rigid component **102**, any suitable configuration that allows for snap-fit engagement with locking edge **94** of needle hub **70** could be used. For example, two, three, or more locking

apertures could be provided for engagement with locking edge **94**. Additionally, while locking channel **88** has been shown as being formed as a slot or aperture through rigid component **102**, locking channel **88** could alternatively be formed as a channel on the inside surface of rigid component **102**, without extending fully therethrough.

[0072] Overmolded component **104** of locking tip **72** has a pair of sealing rings **106** that are provided by radially outwardly extending protrusions on the outside circumference of overmolded component **104**. Different numbers of sealing rings, or a continuous sealing surface, could be used. In some embodiments, the use of two sealing rings rather than just one sealing ring can help to ensure the linear travel of the needle retraction assembly during retraction. Sealing rings **106** are sealingly engaged with the inside surface of retraction lumen **29**.

[0073] Rigid component **102** of locking tip **72** also includes distal grooves **108** that engage with capture projections **110** on the inside surface of the distal end of plunger **28**, to secure locking tip **72** to plunger **28** prior to needle retraction. Distal groove **108** extends radially inwardly around a distal portion of the outside surface of locking tip **72**. Capture projections **110** extend radially inwardly from the inside surface of the distal end of plunger **28**.

[0074] In alternative embodiments, capture projections **110** and/or distal groove **108** could be omitted, and a different engagement between locking tip **72** and the distal end of plunger **28** could be used, for example, a sufficiently tight but releasable press or friction fit, connection by easily frangible connectors or a breakable piece of material that prevents locking tip **72** from releasing during the application of a loading or injection force but allows release of locking tip **72** in response to a post-injection force, or the like.

[0075] The engagement of distal grooves **108** and capture projections **110**, aided by the sealing engagement between sealing rings **106** and retraction lumen **29** is sufficiently strong that locking tip **72** does not move relative to plunger **28** in response to the application of a loading force or an injection force, but also such that the engagement between distal grooves **108** and capture projections **110** is broken by the application of a post-injection force, and sealing rings **106** permit locking tip **72** (and hence the needle retraction assembly) to slideably move within retraction lumen **29** in response to pressure applied by released propellant after the rupture of seal **44**.

[0076] Overmolded component **104** of locking tip **72** also includes a central cylindrical projection **112**, with a tapered surface **98** that is complementary to inner tapered surface **96** of

needle hub **70** (i.e. tapered surface **98** is tapered inwardly from its proximal end to its distal end), so that engagement of tapered surfaces **96**, **98** when a user applies a post-injection force provides a seal to prevent any further fluid flow through needle **26**. Central cylindrical projection **112** is positioned at the distal portion of overmolded component **104**, and sits within and is axially aligned with rigid component **102** so that it can engage with needle hub **70**.

[0077] To facilitate injection of medicament, the distal tip of plunger **28** is also provided with a plunger seal **114**. In the illustrated embodiment, plunger seal **114** is manufactured as an overmold to plunger **28**. In such embodiments, plunger seal **114** is an elastomeric overmold. In other embodiments, plunger seal **114** is manufactured as a separate part from plunger **28** and the two elements are joined together in any suitable manner, for example by a sufficiently tight friction fit, use of suitable adhesives, engagement of a projection on plunger seal **114** within a corresponding groove formed on the outer surface of the distal tip of plunger **28**, or the like. Plunger seal **114** surrounds the outside portion of the distal tip of plunger **28**, and sealingly but slidingly engages the interior surface of syringe body **34** to facilitate injection of medicament in a similar manner to conventional syringes.

[0078] Needle **26** is hollow and has a downstream tip **116** (Figure 1) for injection of medicament into a subject and an upstream intake opening for receiving medicament from medicament chamber **32**. In some embodiments, a needle seal **118** (Figure 2) is provided to seal the distal end of modular needle assembly **22**. In some embodiments, needle seal **118** is secured to modular needle assembly **22** in any suitable manner, for example by suitable adhesives, by compression fit between portions of modular needle assembly **22**, overmolding, or the like. Needle seal **118** is made from any suitable material, for example a soft, flexible material such as silicon or rubber, including polyisoprene. In the illustrated embodiment, needle seal **118** is held in place by a sealing projection **119**, provided on the portion of the body **52** of modular needle assembly **22** that contacts needle seal **118**. During assembly of modular needle assembly **22**, needle seal **118** can be swaged in place within body **52**, and is compressed against sealing projection **119** to prevent leakage of fluids or gases past the outer diameter of needle seal **118**.

[0079] In some embodiments, plunger **28** includes one or more passageways, such as vent holes **120**, formed therethrough. In some embodiments, vent holes **120** allow release of air from retraction lumen **29** upstream of the needle retraction assembly **154** when needle **26** is retracted. In some embodiments, vent holes **120** are positioned in a sidewall of plunger **28** proximally at or

close to the upstream limit of travel of the needle retraction assembly when fully retracted, to avoid a loss of propellant pressure (and resultant upstream biasing force) that could stop the upstream travel of needle **26** before it has been fully retracted as could occur if, for example, vent holes **120** are positioned too far distally of the upstream limit of travel of the needle retraction assembly. In some embodiments, vent holes **120** are positioned a sufficient distance proximally of locking tip **72** that the total combined length of the needle retraction assembly can be received within the syringe barrel distally of vent holes **120**, so that no part of needle **26** projects outside of modular needle assembly **22**. Once locking tip **72** moves proximally past the vent holes, a passageway is opened between upper chamber **48** and the external atmosphere via the gap between plunger **28** and syringe barrel **30**, so that any excess propellant is released to the atmosphere after needle **26** has been retracted. In some embodiments, as illustrated in Figure 7, vent holes **150** are provided through the proximal wall of plunger **28** in addition to and/or as an alternative to vent holes in a sidewall of plunger **28**, such as vent hole **120**.

[0080] As illustrated in Figure 5, in some embodiments, structural features are provided to assist a user in twisting modular needle assembly **22** to secure it to syringe body **34**. In the illustrated embodiment, engagement projections are provided on the outside surface of modular needle assembly **22**, which can be used to secure modular needle assembly **22** against rotational movement within cap **27**. Cap **27** is provided with corresponding recesses for receiving the engagement projections to provide this function.

[0081] In the illustrated embodiment, a plurality of radially outwardly projecting alignment tabs **122** are provided on the outside circumference of the body **52** of modular needle assembly **22**, and are positioned and configured to align with corresponding recessed channels **124** (Figure 6) formed at the proximal end of the inside surface of cap **27**. The sliding engagement of alignment tabs **122** and recessed channels **124** guides cap **27** to the secured position. To secure cap **27** in the secured position, the illustrated embodiment also includes a plurality of radially outwardly extending snap projections **126** (positioned one on each of the alignment tabs **122** in the illustrated embodiment), that are engageable with a plurality of corresponding snap depressions **128** formed on the inside of cap **27**. The described example embodiment is just one way that cap **27** can be secured to modular needle assembly **22** to cover needle **26**, and any suitable needle cover can be used for this purpose. For example, in some embodiments, cap **27** may be

laminated, cemented, snapped, press fit, or otherwise removably affixed in any other manner to modular needle assembly **22**.

[0082] In the illustrated embodiment, cap **27** further includes a plurality of radially outwardly extending ribs **130**, which can be grasped by a user to assist in applying rotational force to modular needle assembly **22** when securing modular needle assembly **22** on syringe body **34**. In use, cap **27** can be twisted or snapped off, or otherwise removed in any suitable manner, to expose needle **26** for use.

[0083] In some embodiments, structural features are provided to lock plunger **28** at or near its downstream limit of travel after syringe **20** has been used, for example to prevent re-use of needle **26** or to provide the used retractable needle syringe **20** with a more compact profile. Any suitable structural features can be used for this purpose, for example an inwardly extending flange projection from syringe barrel **30** that is engageable with an outwardly projecting plunger lock verge provided on the outer circumference of plunger **28** to permit only relative downstream movement of the plunger as described in U.S. Patent No. 7,811,259; or a snap-fit plunger locking mechanism as illustrated in Figure 7. In such an embodiment, a pair of snap-fit engagement members **132**, **134** are positioned at the proximal end of each of syringe barrel **30** and plunger **28**. In the illustrated embodiment, a syringe snap-fit engagement member **132** provided at the proximal end of syringe barrel **30** projects in the proximal direction from the proximal end of syringe barrel **30**, and has a radially inwardly extending locking projection **136** at its proximal end. Locking projection **136** has an inwardly angled sliding surface **138** past which a corresponding angled sliding surface **142** of plunger **28** can slide (inwardly angled sliding surface **138** is angled inwardly and distally relative to the outside edge of locking projection **136**), and a radially extending locking surface **140** located distally of sliding surface **138**. Locking surface **140** is configured to lock with corresponding locking surface **144** of plunger **28**. In the illustrated embodiment, locking surface **140** extends generally straight in the radial direction and locking surface **144** likewise extends generally straight in the radial direction, so that once locking surface **144** slides past angled sliding surface **138** and engages with locking surface **140**, plunger **28** cannot thereafter be withdrawn from syringe barrel **30**.

[0084] Plunger snap-fit engagement member **134** has an outwardly angled sliding surface **142** that can slide past inwardly angled sliding surface **138**, and a generally radially extending locking surface **144** that can slide past and engage with locking surface **140**. Angled sliding

surface **142** has a shape that is complementary to angled sliding surface **138** (angled outwardly and proximally relative to the proximal end of plunger **28** in the illustrated embodiment), and alternative complementary shapes that can slide past one another, e.g. slightly curved surfaces, could be used for surfaces **138**, **142** in alternative embodiments. In use, at or just before the end of the application of a post-injection force, a user will cause angled sliding surfaces **138**, **142** to move past one another, allowing locking surfaces **140**, **144** to come into contact in a snap-fit engagement, thereby locking plunger **28** within syringe barrel **30**.

[0085] In the illustrated embodiment, two pairs of snap-fit engagement members **132**, **134** are provided, one on each opposing side of syringe assembly **20**. Any desired number and location of snap-fit engagement members **132**, **134** could be used (e.g. three, four or more pairs of snap-fit engagement members **132**, **134**), so long as these can be used to lock plunger **28** within syringe barrel **30**.

[0086] In some embodiments, plunger **28** includes a plunger end flange **146** to provide a bearing surface for the fingers of a user to push and pull against to load and inject medicament into/out of medicament chamber **32** or apply a post-injection force. In some embodiments, plunger **28** includes a plurality of thumb ridges **148** on the distal portion of plunger **28** and/or on plunger end flange **146**. In some embodiments, thumb ridges **148** prevent a user's fingers from occluding vents **150** provided at the distal end of plunger **28** in some embodiments.

[0087] In some embodiments, including the embodiment illustrated in Figure 7, a generally circular anti-tamper ring **152** is provided that is shaped and positioned to receive therein the correspondingly shaped proximal end of plunger **28**. Anti-tamper ring **152** projects axially in the proximal direction from the proximal end of syringe body **34**, so that when snap-fit engagement members **132**, **134** are locked together, anti-tamper ring **152** encircles the proximal end of plunger **28**. While a generally circular shape is described and illustrated, other corresponding shapes could be used, so long as anti-tamper ring **152** generally surrounds the distal end of plunger **28** and prevents a user from inserting tools to pull plunger **28** out of syringe barrel body **34**.

[0088] In use, a user selects a modular needle assembly **22** and a syringe barrel **30** having a desired volume. The user couples modular needle assembly **22** to syringe barrel **30** by inserting perimeter wall **64** inside the distal cavity **37** of syringe barrel **30** and engaging threads **36** of needle assembly **22** with threaded grooves **38** of syringe body **34** by applying a relative twisting

motion. A user then removes cap **27** from needle **26** and draws medicament into medicament chamber **32** in the same manner as for an ordinary hypodermic needle syringe, applying a loading force to plunger **28** in the proximal direction. A user then expels undesired air from medicament chamber **32**, for example by inverting the syringe so that needle **26** extends generally vertically upwards, tapping the side of syringe body **34** to displace any air bubbles lodged within medicament chamber **32** vertically upwards, and depressing plunger **28** slightly to force air out of needle **26**. The medicament is thus ready for injection into a subject.

[0089] To administer the medicament, needle **26** is inserted through the skin of a subject, and plunger **28** is depressed in the conventional manner by the application of an injection force in the distal direction to force medicament out of needle **26** and into the subject. Needle **26** is then withdrawn from the subject, although needle **26** can be optionally left in the subject while the retraction process is carried out.

[0090] To retract needle **26**, a user continues to apply force against plunger **28** in the distal direction. This force is now a post-injection force. In some embodiments, the post-injection force required to retract needle **26** is greater than the injection force required to inject medicament into a patient. Continued application of the post-injection force moves the distal tip of plunger **28** and plunger seal **114** distally over false wall retention features **45**, causing the distal tip of plunger **28** to impinge on and apply a force in the distal direction on false wall **40**. The configuration of retractable needle syringe **20** after the application of a post-injection force by a user is shown in Figure 8.

[0091] The engagement of needle hub **70** in false wall **40** is sufficiently strong that needle hub **70** is prevented from relative movement with false wall **40** during the application of an injection force or a loading force by a user, but weak enough that movement of false wall **40** produced by the application of a post-injection force via plunger **20** forces false wall **40** to slide distally past needle hub **70** within upper chamber **48**. Needle hub **70** is itself restrained against distal movement via contact of its distal end **71** with the upper proximal edge **60** of inside wall **54**, which rigidly resists distal movement of needle hub **70**.

[0092] Similarly, the engagement of locking tip **72** within the distal tip of plunger **28** is sufficiently strong that locking tip **72** does not move within the distal tip of plunger **28** during the application of a loading force or an injection force. However, this engagement is broken by the application of a post-injection force by a user, so that locking tip **72**, needle hub **70**, and needle

26 can be retracted within retraction lumen **29** by propellant released from unitary propellant release structure **24**, as described below.

[0093] When a user applies a post-injection force, needle hub **70** is prevented from moving in the distal direction via the engagement of its distal tip **71** with the upper proximal edge **60** of inside wall **54** of unitary propellant release structure **24**. However, false wall **40** is slideable in the distal direction in response to the application of the post-injection force as transmitted through movement of the distal tip of plunger **28** pressing against false wall **40**, and upper restraining projection **84** of false wall **40** is forced to slide over tapered seals **76** and O-ring seal **74** of needle hub **70**, so that needle hub **70** is released from its engagement with false wall **40**.

[0094] As the distal tip of plunger **28** continues to move in the distal direction by reason of the application of the post-injection force, central cylindrical projection **112** of locking tip **72** slides into axially extending opening **100** of needle hub **70**. Tapered surface **98** of locking tip **72** is thus brought into engagement with inner tapered surface **96** of needle hub **70**, to provide a seal that prevents the further flow of medicament or bodily fluids through needle **26**. Movement of the distal tip of plunger **28** in the distal direction also causes locking channel **88** of locking tip **72** to slide past outer tapered portion **92** of needle hub **70**, so that locking edges **90**, **94** are brought into engagement to lock locking tip **72** and needle hub **70** together to provide (together with needle **26**) a needle retraction assembly (shown as **154** in Figure 9).

[0095] In the illustrated embodiment, the engagement of distal groove **108** of locking tip **72** and capture projections **110** of plunger **28** is broken by the application of a post-injection force by a user. The force required to disengage distal groove **108** from capture projections **110** should be greater than the force required to engage locking tip **72** with needle hub **70**. If the force required to disengage distal groove **108** from capture projections **110** is similar to or less than the force required to sealingly engage locking tip **72** with needle hub **70**, then there is a risk that locking tip **72** will disengage from distal groove **108** and be shifted proximally within retraction lumen **29** on the application of a post-injection force by a user, without engaging with needle hub **70**. This would result in no retraction of needle **26**.

[0096] Movement of false wall **40** in the distal direction also causes rupturing members **42** to move in the distal direction. Rupturing members **42** are oriented so that continued movement in the distal direction results in the rupture of seal **44**, thereby releasing propellant from unitary propellant release structure **24** into upper chamber **48** of modular needle assembly **22**. The

propellant is prevented from escaping past the needle retraction assembly **154** by the engagement of sealing rings **106** of locking tip **72** with the inside surface of plunger **28**. The propellant is prevented from flowing out through needle **26** by the sealing engagement of tapered surfaces **96**, **98** of needle hub **70** and locking tip **72**, respectively.

[0097] The released propellant applies a proximal force against the needle retraction assembly **154** (i.e. needle hub **70**, locking tip **72**, and needle **26**), so that needle **26** is retracted. The engagement of sealing rings **106** of locking tip **72** allows the needle retraction assembly **154** to slide within retraction lumen **29** under the influence of the released propellant. A sufficient amount of propellant is provided within unitary propellant release structure **24** so that needle **26** is retracted a distance sufficient that the tip **116** of needle **26** sits fully within syringe body **34** or the body **52** of modular needle assembly **22**, so that syringe **20** no longer presents a sharps hazard. Any excess propellant pressure is vented after locking tip **72** passes vent hole **120**, and the retraction assembly will come to a rest within retraction lumen **29**, as illustrated in Figure 9.

[0098] While unitary propellant release structure **24** has been described above with reference to a generally cylindrical channel **50** formed in modular needle assembly **22** and covered by a seal **44**, it will be apparent to those skilled in the art that other configurations could be used to achieve the same function. For example, with reference to Figures 10A and 10B, example embodiments in which channel **50** has been provided with irregular shapes are contemplated.

[0099] In the example embodiment of a modular needle assembly **22A** illustrated in Figure 10A, channel **50A** has been provided with a relatively wide lower portion and a narrower upper portion. Channel **50A** is provided with sufficient volume to hold a sufficient amount of propellant to be able to perform retraction of needle **26**, and channel **50A** is still positioned and configured to allow rupturing members **42** to rupture seal **44** and release propellant from unitary propellant release structure **24A**. Upper proximal edge **60A** of inside wall **54A** and upper proximal edge **62A** of outside wall **56A** are still provided, so that seal **44** can be sealingly secured in place over channel **50A** to contain propellant within unitary propellant release structure **24A**.

[0100] Similarly, in the example embodiment of a modular needle assembly **22B** illustrated in Figure 10B, channel **50B** has been provided with a different shape, having a generally triangular upper portion and a generally triangular lower portion connected by a connecting passageway. Again, channel **50B** is provided with sufficient volume to hold a sufficient amount of propellant

to be able to perform retraction of needle **26**, and channel **50B** is still positioned and configured to allow rupturing members **42** to rupture seal **44** and release propellant from unitary propellant release structure **24B**. Upper proximal edge **60B** of inside wall **54B** and upper proximal edge **62B** of outside wall **56B** are still provided, so that seal **44** can be sealingly secured in place over channel **50B** to contain propellant within unitary propellant release structure **24B**.

[0101] In some embodiments, as illustrated in Figures 11-13, a modular filler needle assembly **222** is provided that is engageable with syringe barrel **30**. Parts of modular filler needle assembly **222** that are similar to those of modular needle assembly **22** are referred to with reference numerals incremented by 200 in the description below. In some embodiments, modular filler needle assembly **222** is provided with a smaller gauge of needle (i.e. a needle having a larger diameter) than modular needle assembly **22**, to make it easier to load medicament into medicament chamber **32**. In some embodiments, the needle **226** of modular filler needle assembly **222** is an 18 to 21 gauge needle. Such embodiments may be particularly useful where the medicament to be injected into a patient is particularly thick and/or where a large volume of syringe is used, such that drawing such medicament into medicament chamber **32** using the same gauge of needle as would be used to inject the medicament into a patient would be time-consuming and/or labour intensive.

[0102] Because modular filler needle assembly **222** is used only for loading medicament into syringe barrel **30**, and not for injecting medicament into a patient, needle **226** will not become contaminated with bodily fluids in the ordinary course of use. Furthermore, in some embodiments, needle **226** is provided with a blunt end, as shown in the illustrated embodiment. Thus, needle **226** can relatively safely be disposed of by simply capping needle **226** and removing it from syringe barrel **30**, and needle **226** does not need to be retracted into the syringe. Modular filler needle assembly **222** is therefore not provided with a needle hub **70**, unitary propellant release structure **24**, or other components used for needle retraction. This simplifies and reduces the cost of manufacture of modular filler needle assembly **222**.

[0103] The base **382** of modular filler needle assembly **222** is provided with external threads **236**, which can engage with threads **38** of syringe body **34**. Modular filler needle assembly **222** is also provided with an inwardly tapered portion **266** at its proximal end, which tapers inwardly in the proximal direction from the outer circumference of a support disc **380** provided at the proximal end of modular filler needle assembly **222**. Support disc **380** is spaced in the proximal

direction away from the base portion **382** of modular filler needle assembly **222** by a projection **384** that is shaped and configured to space support disc **380** a sufficient distance from base portion **382** so that modular filler needle assembly **222** has the same overall dimensions as modular needle assembly **22**. This allows modular filler needle assembly **222** to be engaged with syringe body **34**. Inwardly tapered portion **266** is engageable with correspondingly tapered portion **68** of syringe body **34**, to sealingly engage therewith so that medicament can be drawn into medicament chamber **32**.

[0104] Needle **226** is supported by the other components of modular filler needle assembly **222** in any suitable manner. For example, in some embodiments, needle **226** is secured to support disc **380** by using suitable adhesives. In some embodiments, needle **226** is secured to support disc **380** by a press fit, or needle **226** may be crimped in, cemented to or otherwise securely fixed to support disc **380** or other components of modular filler needle assembly **222**. In some embodiments, needle **226** is insert molded with other components of modular filler needle assembly **222** to create a single component.

[0105] In some embodiments, modular filler needle assembly **222** includes features for engaging with a cap to cover needle **226**. In some embodiments, these features are the same as those present on modular needle assembly **22**. For example, in the illustrated embodiment, modular filler needle assembly **222** includes ribs **330** and snap projections **326** (Figure 12) for engaging with channels **124** and snap depressions **128** in a cap **27**, so that needle **226** can be covered using a cap **27** that is the same as that used to cover needle **26**.

[0106] In some embodiments, a kit for injecting medicament into a patient using a modular retractable needle assembly is provided. The kit has at least one syringe body **34** having any desired volume, a modular filler needle assembly **222**, and a modular needle assembly **22**. In some embodiments, the kit has a plurality of syringe bodies **34** having different volumes, a modular filler needle assembly **222**, and a modular needle assembly **22**. A user can select a syringe body **34** having a desired volume for a particular task, optionally use modular filler needle assembly **222** to fill that syringe body **34** with medicament for injection into a patient, remove and discard modular filler needle assembly (for example including a step of covering used needle **226** with a cap **27** before removing and discarding it, which in some embodiments provides additional grip to remove needle **226** by virtue of the engagement of ribs **330** and snap projections **326** with channels **124** and snap depressions **128** in a cap **27**), engage modular needle

assembly **22** with the filled syringe body **34** and inject medicament into a patient, and finally retract needle **26** of modular needle assembly **22** as described above. The needles used on modular filler needle assembly **222** and modular needle assembly **22** can have any selected diameter (i.e. be of any gauge) as suited to a given task to be performed.

[0107] In alternative embodiments, other structures can be used in place of needle hub **70** and locking tip **72** to form a needle retraction assembly to retract needle **26**. For example, as illustrated in Figure 14 in which reference numerals referring to elements that are the same as in retractable-needle syringe **20** have been incremented by 400, in modular needle assembly **422**, needle hub **470** is generally similar to needle hub **70**, except that the proximal portion thereof is modified as described below to engage with locking tip **472** in a manner different from the way that needle hub **70** and locking tip **72** engage. The function of locking tip **472** is somewhat similar to locking tip **72**, but the distal portion thereof is modified as described below.

[0108] The proximal end of needle hub **470** is provided with one or more barbs **469**. In the illustrated embodiment, barbs **469** project radially outwardly and in a distal direction from the central axis of needle hub **470**. Needle hub **470** does not have a generally cylindrical locking element with a locking edge like locking edge **94** of needle hub **70**. In some embodiments, barbs **469** are provided as a fully revolved feature extending fully around the outer perimeter of the proximal portion of needle hub **470**. In some embodiments, barbs **469** are provided as one or a plurality of discrete features around the outer perimeter of the proximal portion of needle hub **470**. It will be clear to those skilled in the art that the position of barbs **469** at the proximal end of needle hub **470** and the exact configuration of barbs **469** is not essential, as long as barbs **469** are positioned on needle hub **470** so that they can engage with locking tip **472** as described below.

[0109] Barbs **469** are positioned and configured so that when locking tip **472** is forced over the proximal portion of needle hub **470** by the application of a post-injection force, barbs **469** bite into the relatively softer material from which locking tip **472** is formed, thereby securing locking tip **472** and needle hub **470** to provide a needle retraction assembly. The engagement between the proximal portion of needle hub **470** and the relatively softer material of locking tip **472** provides a sufficient seal to allow for needle retraction and to prevent further flow of medicament through the needle.

[0110] Additionally, because barbs **469** are provided on needle hub **470**, locking tip **472** is formed as a single component made from a material into which barbs **469** can engage or bite (e.g. from silicone, an elastomer, or other suitable polymer), rather than being formed as two components, one relatively rigid and one more flexible, as is the case for locking tip **72**. The material from which needle hub **470** is made should be more rigid than the material from which locking tip **472** is made, to facilitate barbs **469** engaging with locking tip **472** as aforesaid.

[0111] Because needle hub **470** is provided with barbs **469**, the distal portion of locking tip **472** does not have special structural features on its inside surface (e.g. similar to locking channel **88** or central cylindrical projection **112**) for engagement with needle hub **470**. Locking tip **472** is formed so that barbs **469** can engage with the interior surface thereof. For example, in the illustrated embodiment, a central indentation **489** is provided at the distal end of locking tip **472**. Central indentation **489** is positioned and configured to receive the proximal end of needle hub **470**, so that barbs **469** can bite radially outwardly into the material of locking tip **472** within central indentation **489**. The features of the outer edges of locking tip **472** that sealingly engage with the interior of retraction lumen **429**, including sealing rings **506**, are the same as described for locking tip **472**.

[0112] To secure locking tip **472** within the distal tip of plunger **428**, in some embodiments, including the illustrated embodiment, one of the sealing rings **506** is initially positioned distally of capture projections **510**, to prevent movement of locking tip **472** during the application of a loading force or an injection force, but this engagement is broken by the application of a post-injection force (when locking tip **472** is ultimately restrained against further movement in the distal direction by needle hub **470**), so that locking tip **472** (and therefore the needle retraction assembly carrying needle **426**) can be retracted within retraction lumen **429**.

[0113] The force required to engage barbs **469** with locking tip **472** should be less than the force required to disengage the engagement of sealing rings **506** and capture projections **510** and displace the vacuum seal securing locking tip **472** in place, to facilitate reliable needle retraction.

[0114] The operation of retractable-needle syringe **420** is generally as described for retractable-needle syringe **20**, except that the sealing engagement between the locking tip **472** and needle hub **470** is provided by the engagement of barbs **469** with the relatively softer material of locking tip **472** upon the application of a post-injection force by a user.

[0115] Suitable materials for the manufacture of modular needle assemblies and retractable

needle syringes can be selected by those skilled in the art, and should be selected to be compatible with the medicament to be administered to the subject. For example, the syringe barrel and plunger may be made from any suitable plastic or thermoplastic, for example, polycarbonate, acrylic, copolyester, SBC (styrene-butadiene copolymer) (e.g. Styrolux^{TM}), or the like. Any suitable material can be used for the construction of the false wall that allows it to initially retain the needle hub and then release it on the application of a post-injection force. In some embodiments, the false wall is made from an elastomer having a suitable durometer to release the needle hub when a post-injection force is applied. The plunger seal may be made from any suitable material, for example silicone, thermoplastic elastomers, or the like. In some embodiments, the plunger seal is a self-lubricating seal. In some embodiments, the syringe barrel and/or plunger seal are treated with a medical grade lubricant. The needle may be made of medical grade needle tubing. The propellant used in the unitary propellant release structure may be any suitable propellant, for example a pharmaceutical-grade hydrofluorocarbon such as heptafluoropropane, 1,1,1,2-tetrafluoroethane or medical-grade nitrogen. In some embodiments, heptafluoropropane is the propellant, and is selected based on its expansion properties and lack of toxicity.

[0116] While a number of exemplary aspects and embodiments are discussed herein, those of skill in the art will recognize certain modifications, permutations, additions and sub-combinations thereof. It is therefore intended that the following appended claims and claims hereafter introduced are not to be limited to the preferred embodiments described herein, but are to be interpreted to include all such modifications, permutations, additions and sub-combinations as are consistent with the broadest interpretation of the specification as a whole.

WHAT IS CLAIMED IS:

1. A modular retractable needle assembly for engagement with a barrel of a retractable needle syringe having a plunger, the modular retractable needle assembly comprising:

a body having an upper chamber at a proximal end thereof;

a propellant chamber defined within the body;

a seal sealingly engaged over the propellant chamber to seal a propellant in the propellant chamber;

a retention member initially engaged within the upper chamber, the retention member being moveable in a distal direction in response to the application of a post-injection force to the plunger by a user;

a needle hub initially engaged within the retention member, the needle hub being engageable with a retractable locking tip of the plunger upon the application of the post-injection force to the plunger by the user;

a needle for injecting medicament into a patient engaged with the needle hub and projecting distally from the body; and

a rupturing member projecting in the distal direction, the rupturing member being moveable in the distal direction in response to the application of the post-injection force to the plunger by the user to rupture the seal and thereby release propellant into the upper chamber.

2. A modular retractable needle assembly as defined in claim 1, further comprising engagement members on an outer surface of the body for engaging the body with the barrel.

3. A modular retractable needle assembly as defined in claim 2, wherein the engagement members comprise threads.

4. A modular retractable needle assembly as defined in claim 2, wherein the engagement members comprise a Luer lock fitting.

5. A modular retractable needle assembly as defined in any one of claims 1 to 4, wherein the propellant chamber comprises a generally cylindrical channel formed in the body, wherein the seal is engaged with upper edges of inner and outer walls defining the channel.

6. A modular retractable needle assembly as defined in claim 5, wherein the upper edges of both the inner and outer walls are located at approximately the same distance in a distal direction from a proximal end of the modular retractable needle assembly.

7. A modular retractable needle assembly as defined in any one of claims 1 to 6, wherein the propellant chamber is positioned distally of the upper chamber, and wherein the upper chamber contains the retention member.

8. A modular retractable needle assembly as defined in any one of claims 1 to 7, wherein a proximal end of the upper chamber comprises a tapered sealing surface for sealingly engaging a correspondingly tapered surface provided proximate a distal end of the barrel.

9. A modular retractable needle assembly as defined in any one of claims 1 to 8, comprising a cap for covering the needle, an outer surface of the body comprising projections for engaging with corresponding recesses provided in the cap to secure the modular retractable needle assembly against rotational movement within the cap.

10. A modular filler needle assembly for engagement with a barrel of a syringe, the modular filler needle assembly comprising:

a base engageable with the barrel;

a support disc spaced apart from the base and positioned to provide a sealing engagement with the barrel; and

a needle supported on the support disc for loading medicament into the syringe, the needle projecting distally from the base.

11. A modular filler needle assembly as defined in claim 10, wherein the base comprises

engagement members on an outer surface of the base for engaging with the barrel.

12. A modular filler needle assembly as defined in claim 11, wherein the engagement members comprise threads.

13. A modular filler needle assembly as defined in claim 11, wherein the engagement members comprise a Luer lock fitting.

14. A modular filler needle assembly as defined in any one of claims 10 to 13, wherein the support disc comprises a proximal tapered sealing surface for sealingly engaging a correspondingly tapered surface provided proximate a distal end of the barrel.

15. A modular filler needle assembly as defined in any one of claims 10 to 14, wherein the needle comprises a blunt needle.

16. A modular filler needle assembly as defined in any one of claims 10 to 15, wherein the support disc is spaced apart from the base by a sufficient distance to allow the modular filler needle assembly to be secured on a syringe having a distal cavity for receiving a modular retractable needle assembly as defined in any one of claims 1 to 9.

17. A syringe for use with a modular retractable needle assembly as defined in any one of claims 1 to 9 or a modular filler needle assembly as defined in any one of claims 10 to 16, the syringe comprising:

a barrel;

a plunger slideable within the barrel for loading or injecting medicament from a medicament chamber of the barrel, the plunger having a retraction lumen therein for receiving a needle retracted from the modular retractable needle assembly;

a locking tip initially engaged within the retraction lumen, the locking tip being engageable with a needle hub of the modular retractable needle assembly upon application of a post-injection force by a user, the locking tip being retractable into the retraction lumen when a propellant chamber of the modular retractable needle assembly

is ruptured; and

a recess at a distal end of the barrel for receiving a modular needle assembly or a modular filler needle assembly as defined in any one of the preceding claims.

18. A syringe as defined in claim 17, comprising threaded grooves in the recess, the threaded grooves being engageable with a correspondingly threaded surface of the modular needle assembly or the modular filler needle assembly.

19. A syringe as defined in claim 18, wherein the threaded grooves comprise recessed threaded grooves.

20. A kit comprising:

a syringe as defined in any one of the claims 17 to 19; and

a modular retractable needle assembly as defined in any one of claims 1 to 9.

21. A kit as defined in claim 20, further comprising a modular filler needle assembly as defined in any one of claims 10 to 16.

22. A kit as defined in claim 21, wherein the modular filler needle assembly comprises a needle having a smaller gauge than the needle of the modular retractable needle assembly.

23. A kit as defined in claim 22, wherein the gauge of the needle of the modular filler needle assembly is between 19 and 21.

24. A kit as defined in any one of claims 20 to 23, comprising a plurality of syringes as defined in any one of claims 17 to 19, wherein at least some of the plurality of syringes have different volumes.

25. A method of using a modular retractable needle assembly comprising:

selecting a syringe as defined in any one of claims 17 to 19;

affixing a modular filler needle assembly as defined in any one of claims 10 to 16 to a distal end of the syringe;

loading the syringe with medicament;

removing the modular filler needle assembly from the syringe;

affixing a modular retractable needle assembly as defined in any one of claims 1 to 9 to the distal end of the syringe;

injecting the medicament into a subject; and

applying a post-injection force to retract the needle within the syringe.

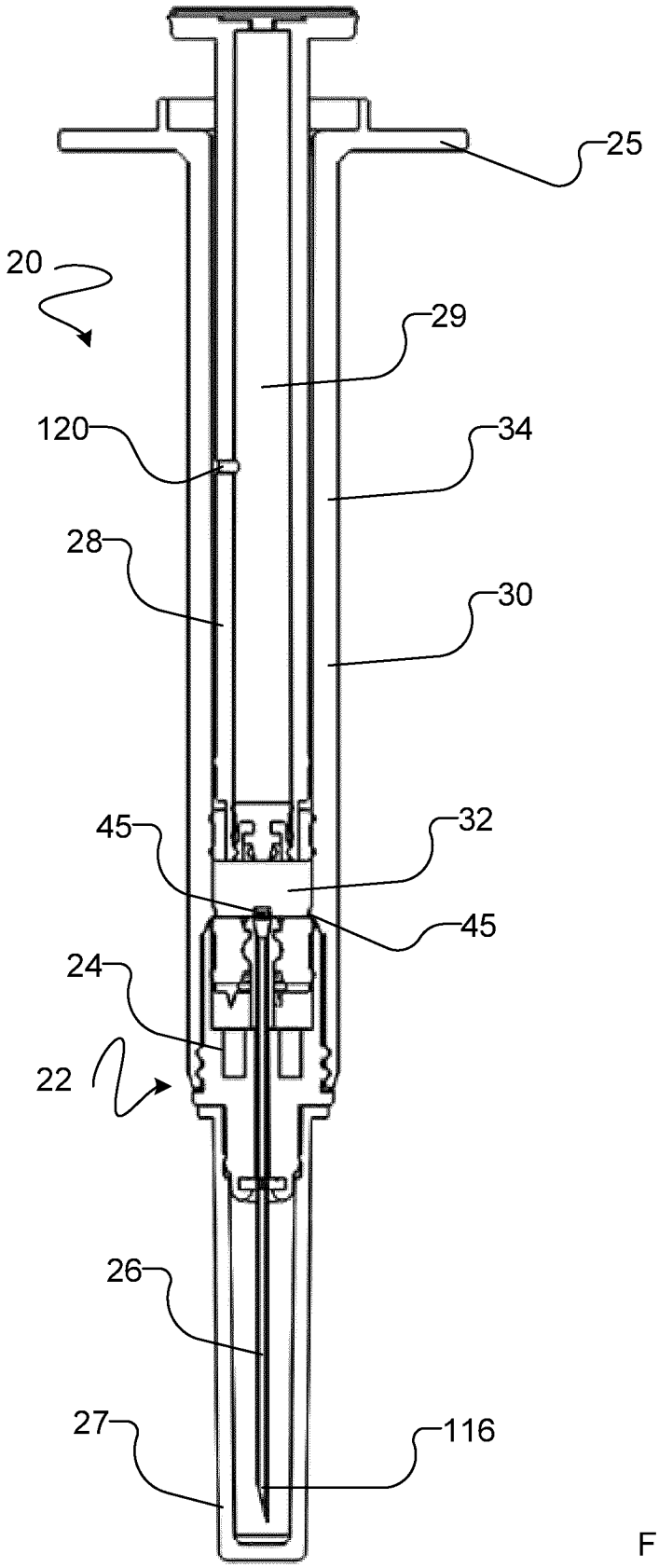

FIGURE 1

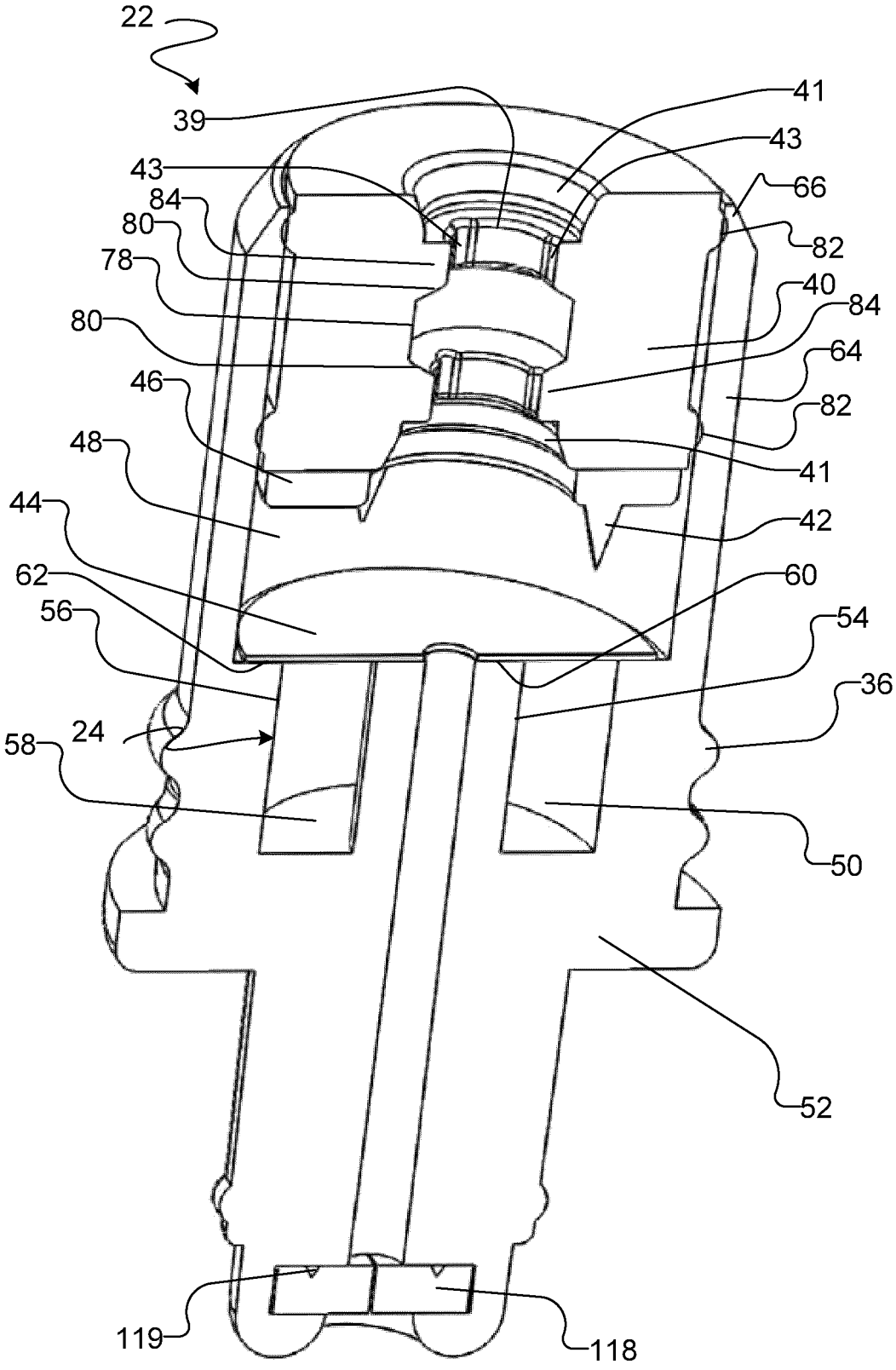
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FIGURE 2

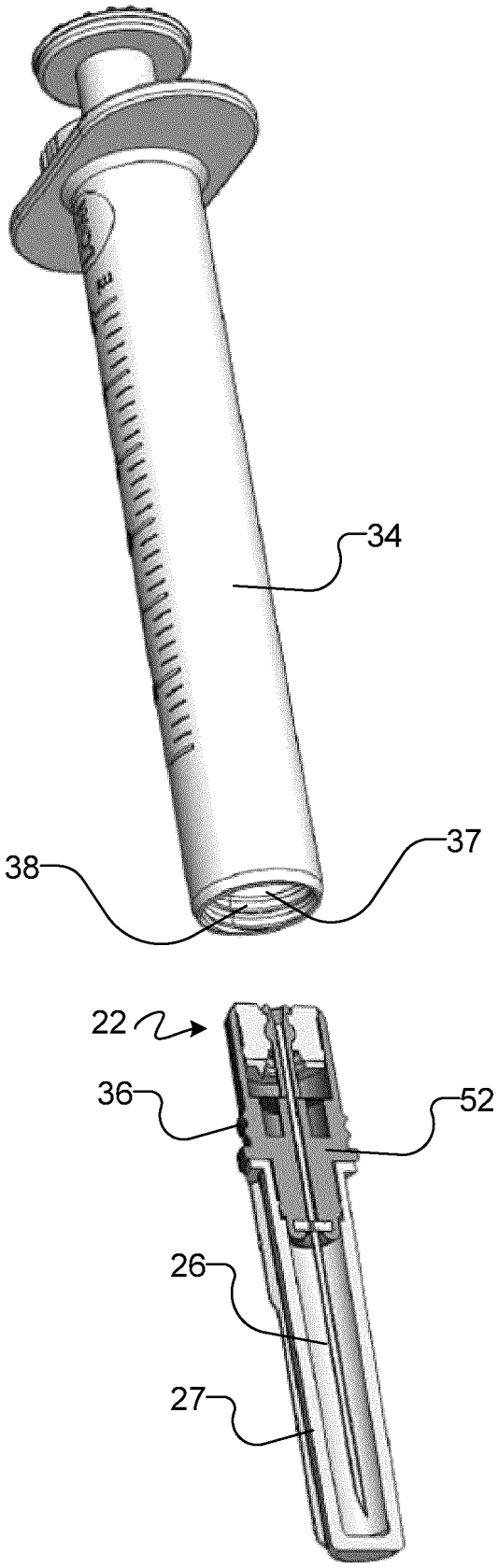

FIGURE 3A

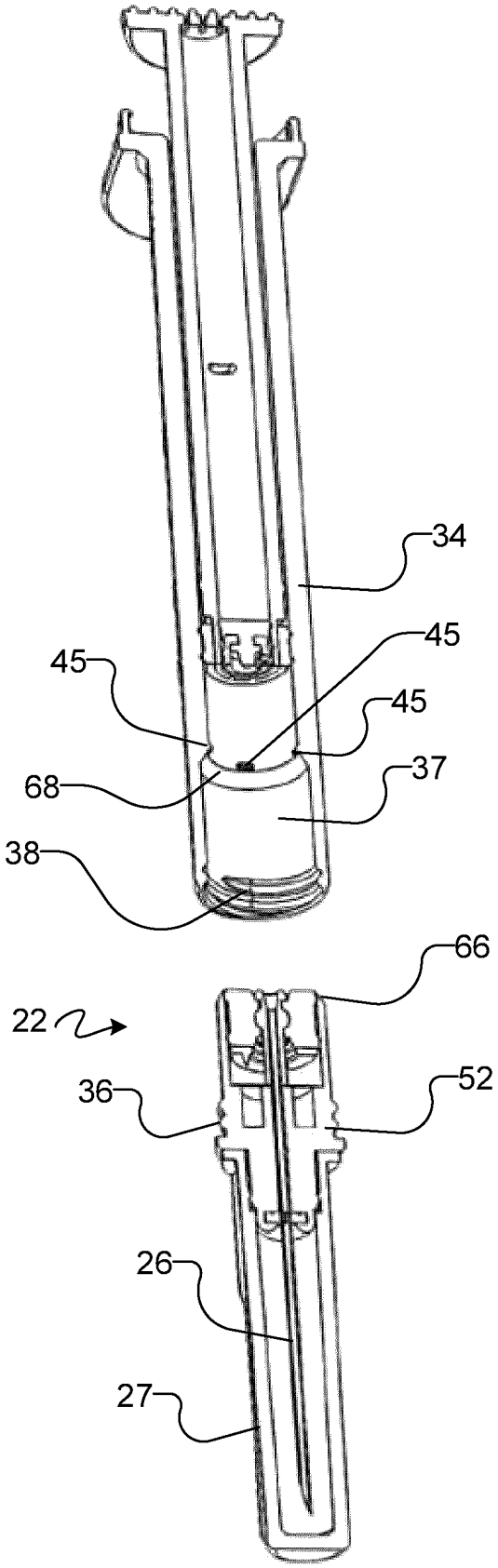

FIGURE 3B

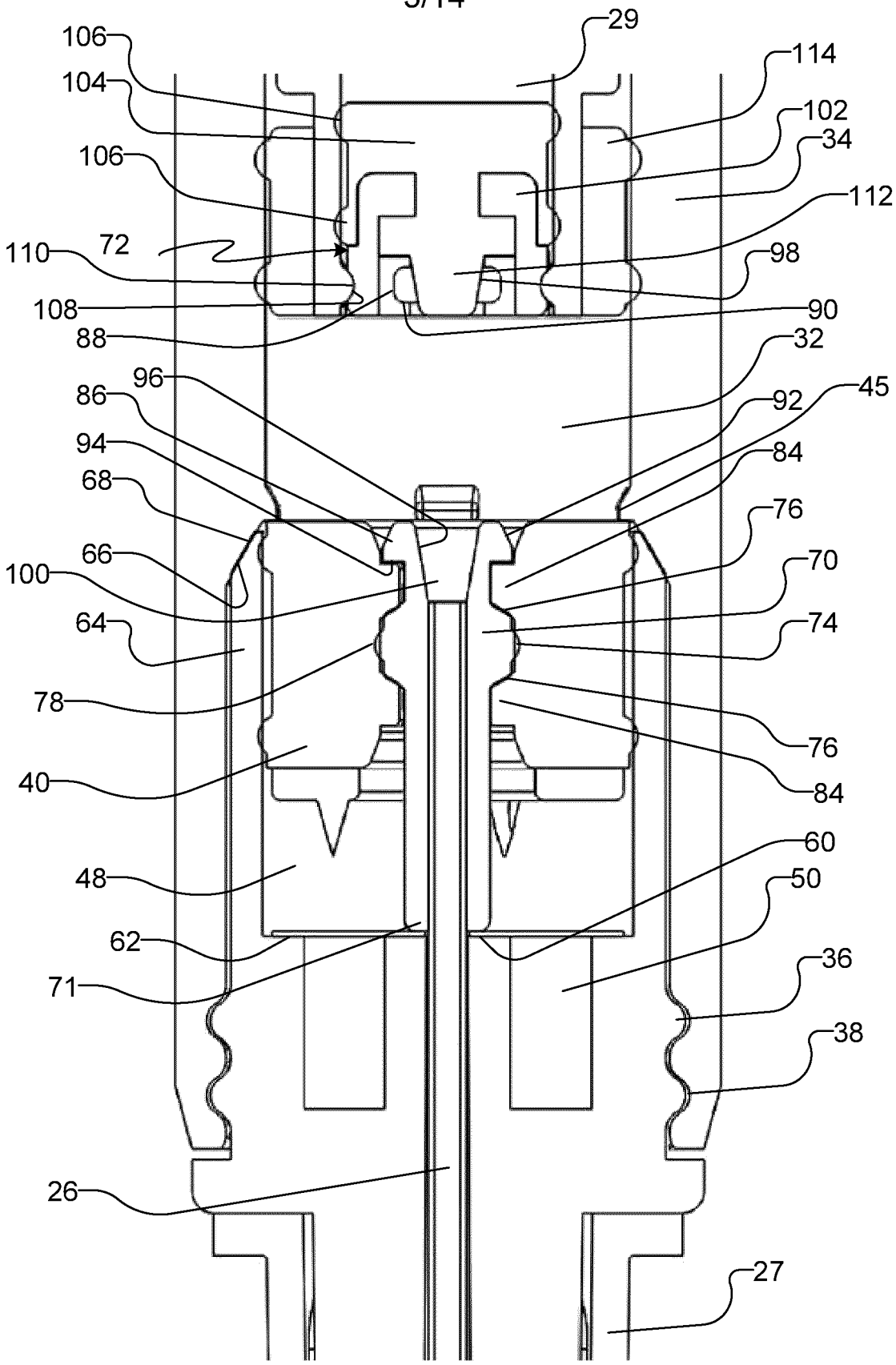
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FIGURE 4

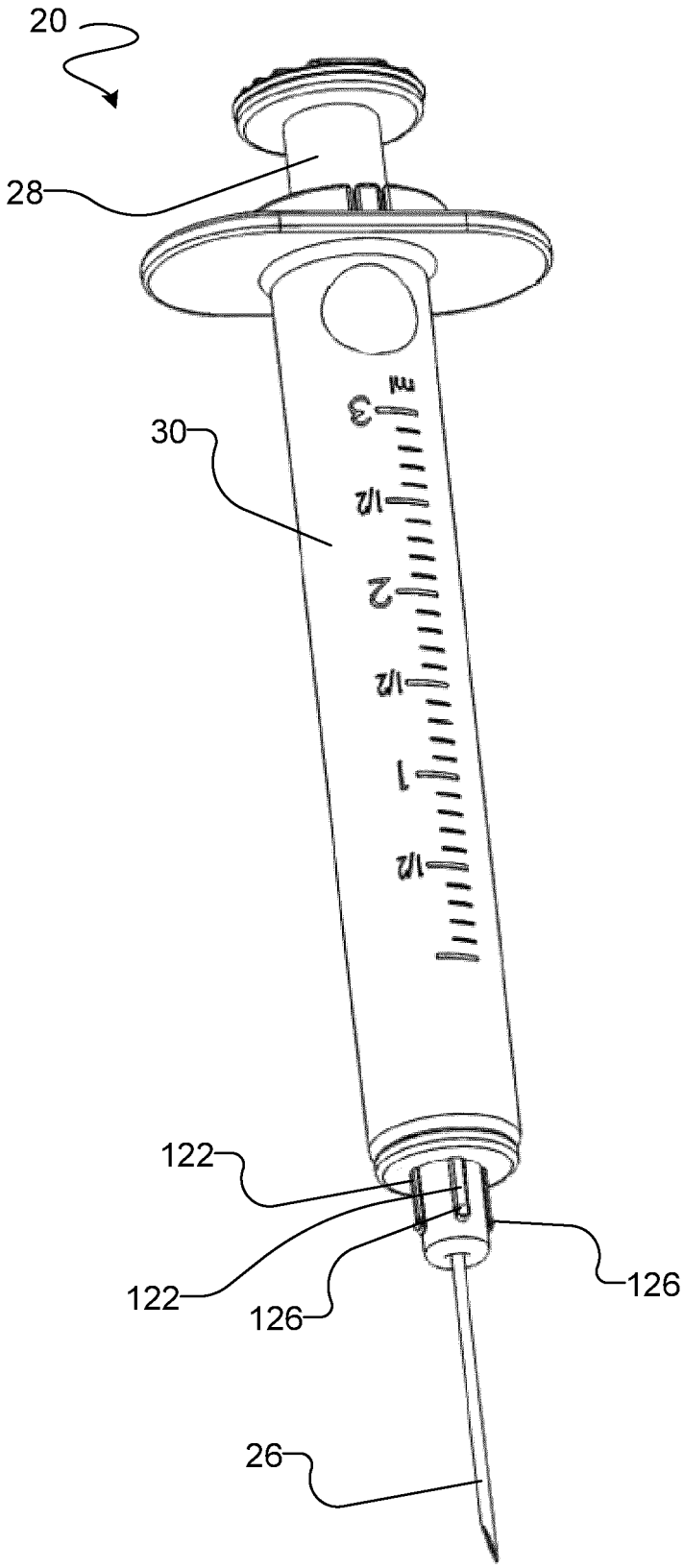

FIGURE 5

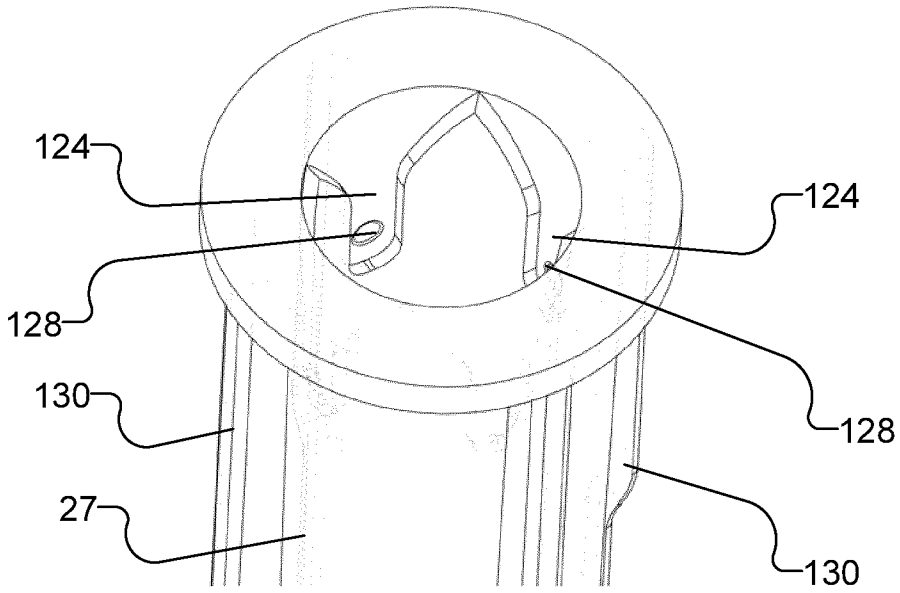

FIGURE 6

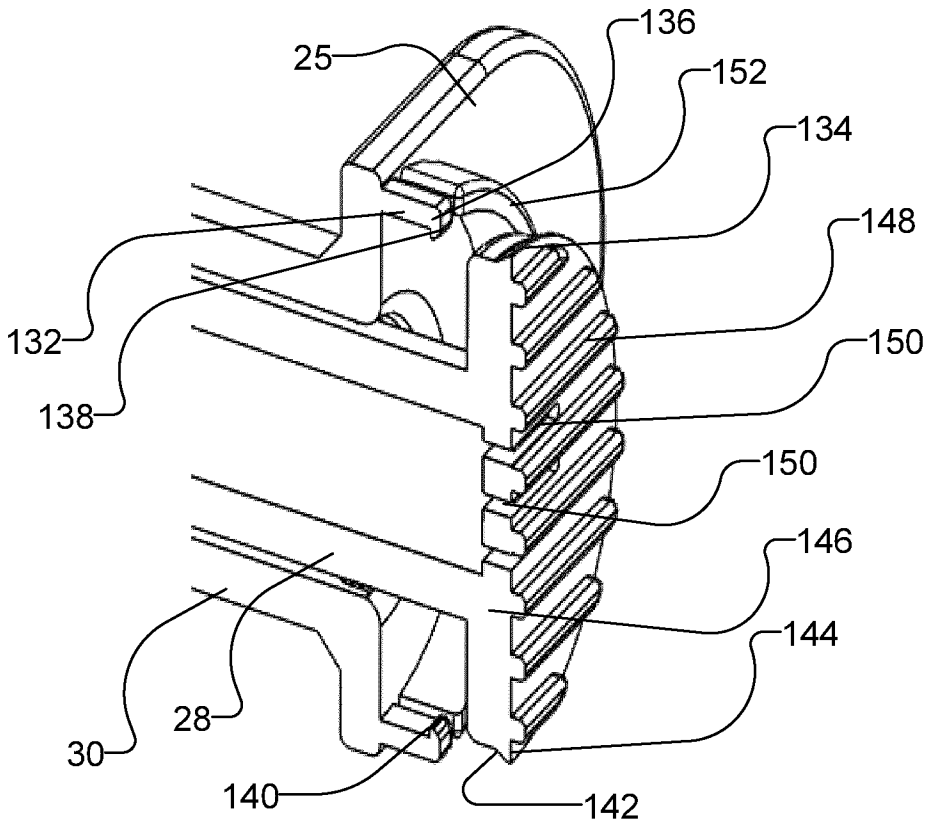

FIGURE 7

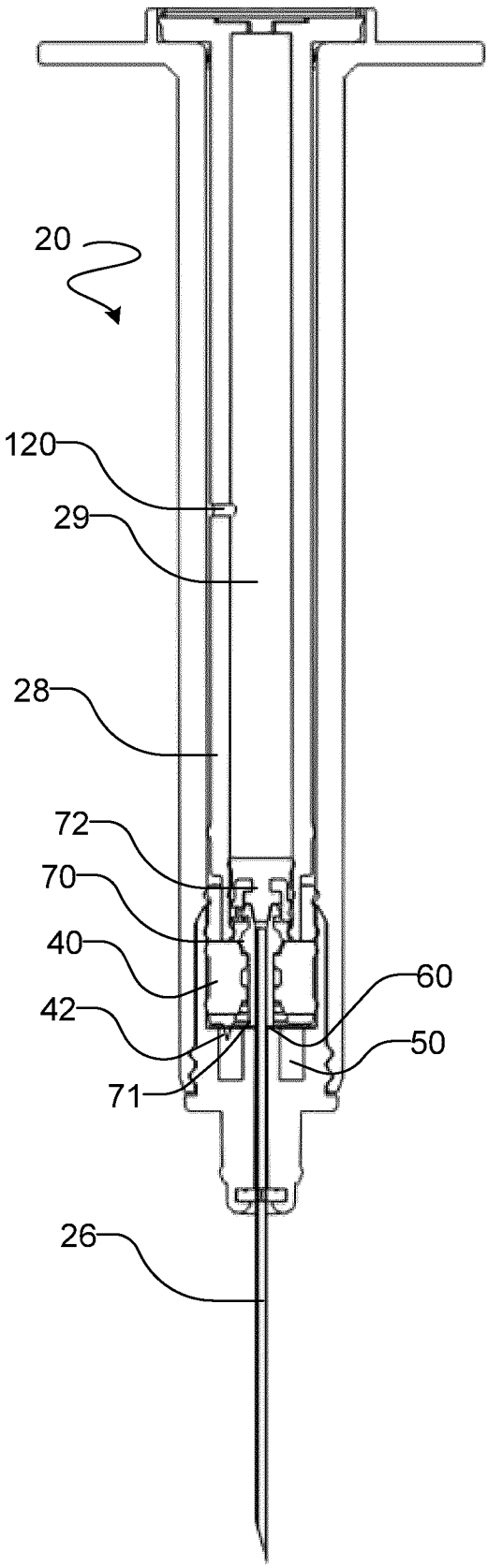

FIGURE 8

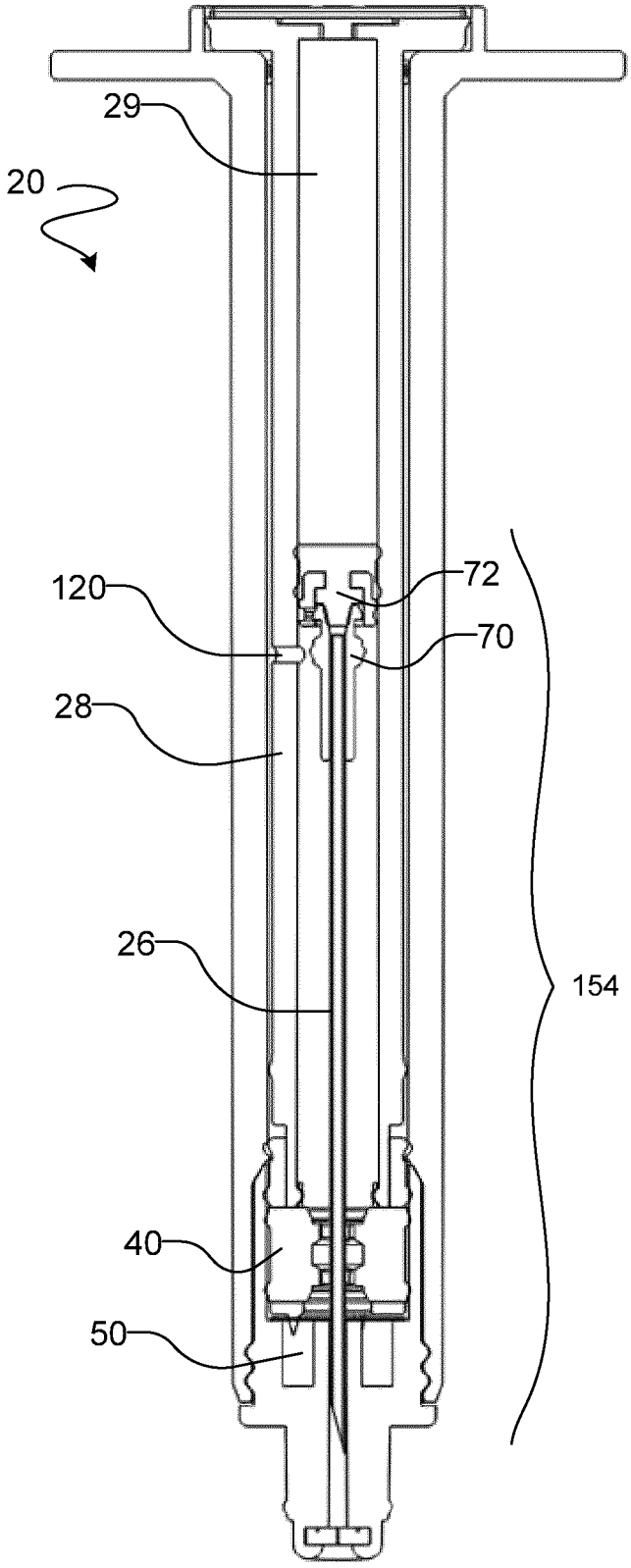

FIGURE 9

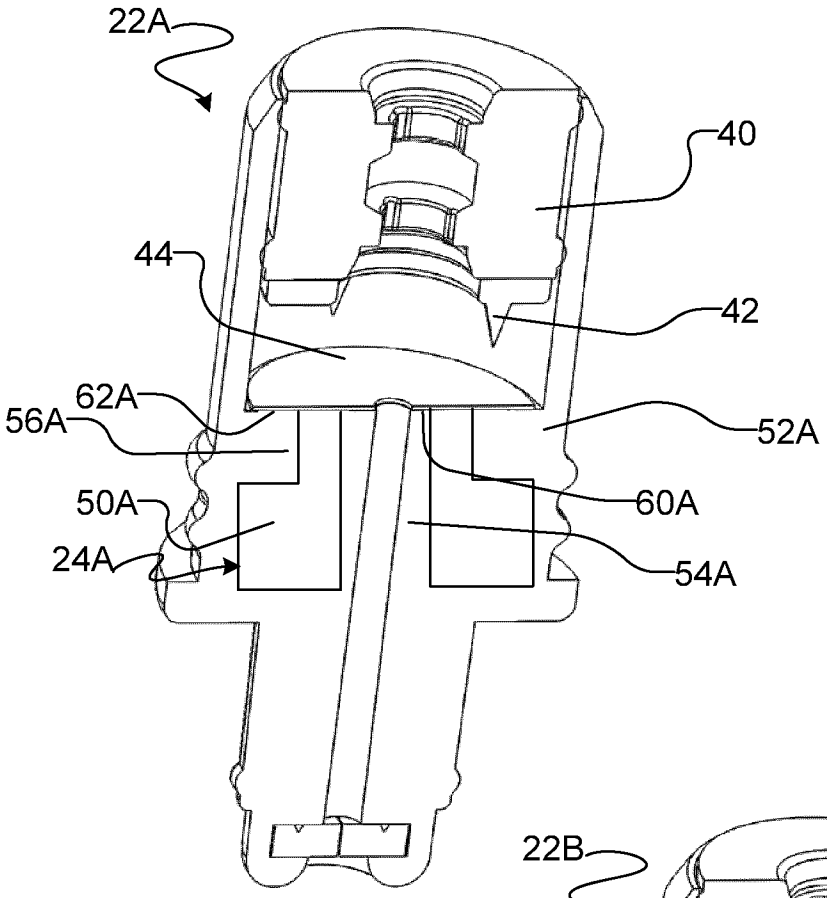

FIGURE 10A

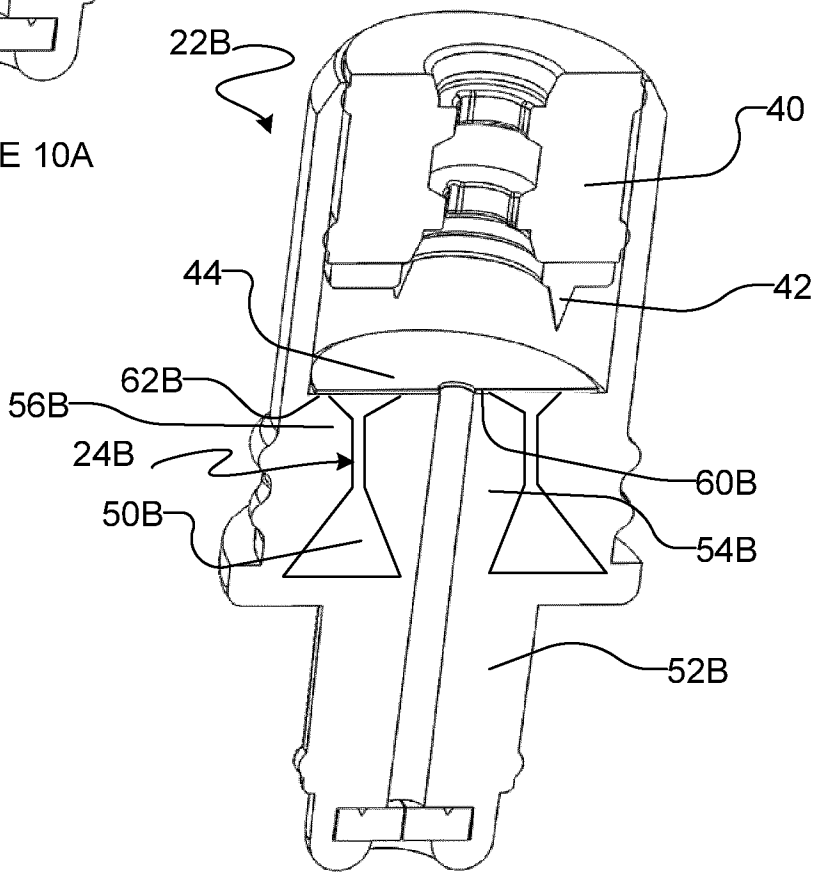

FIGURE 10B

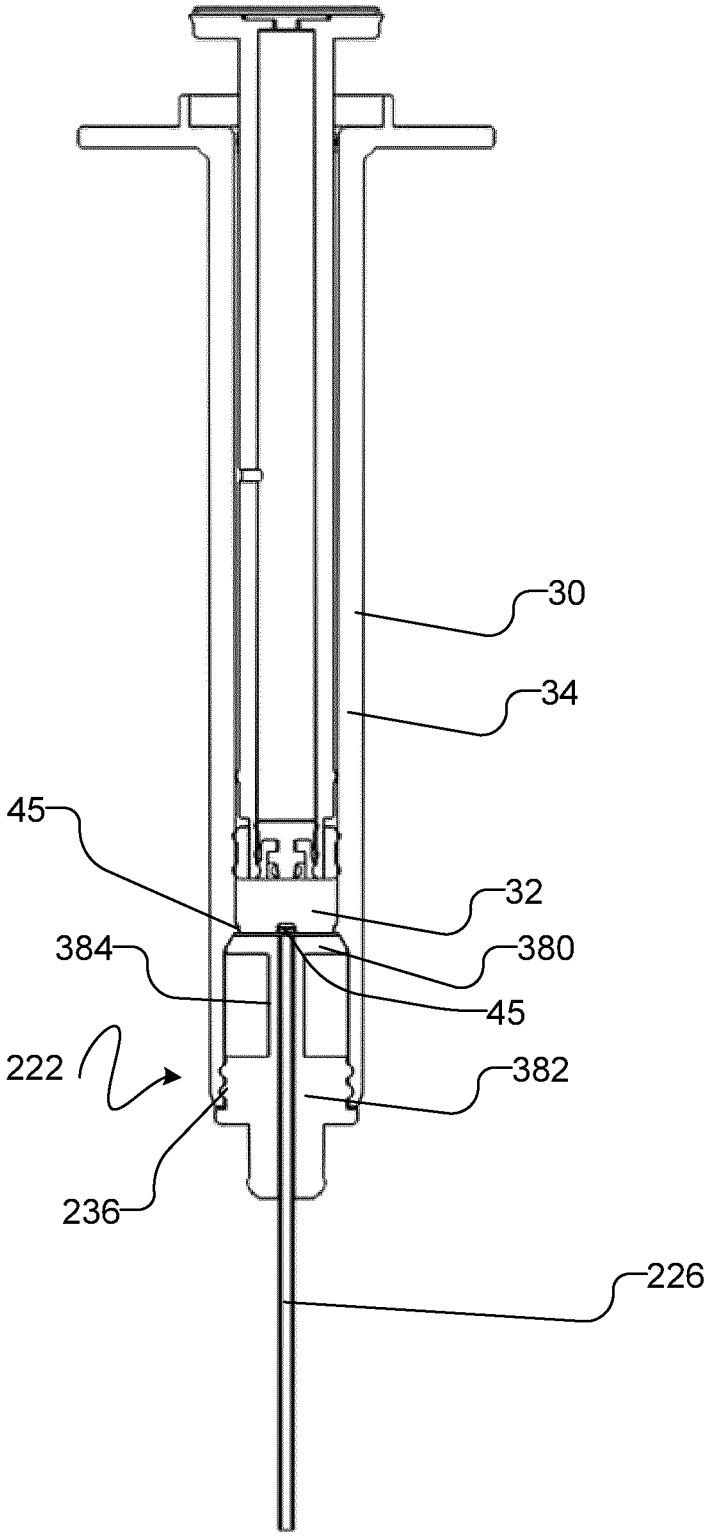

FIGURE 11

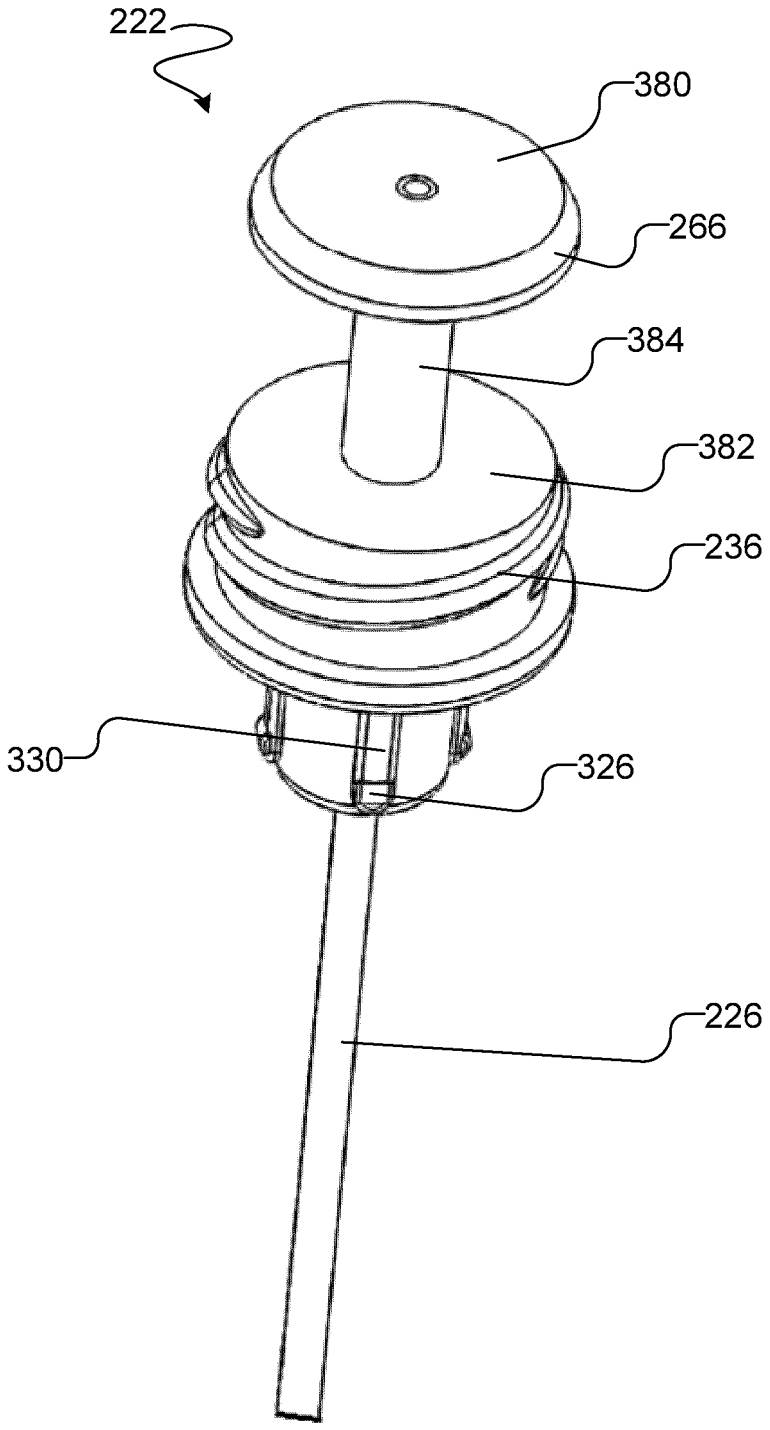

FIGURE 12

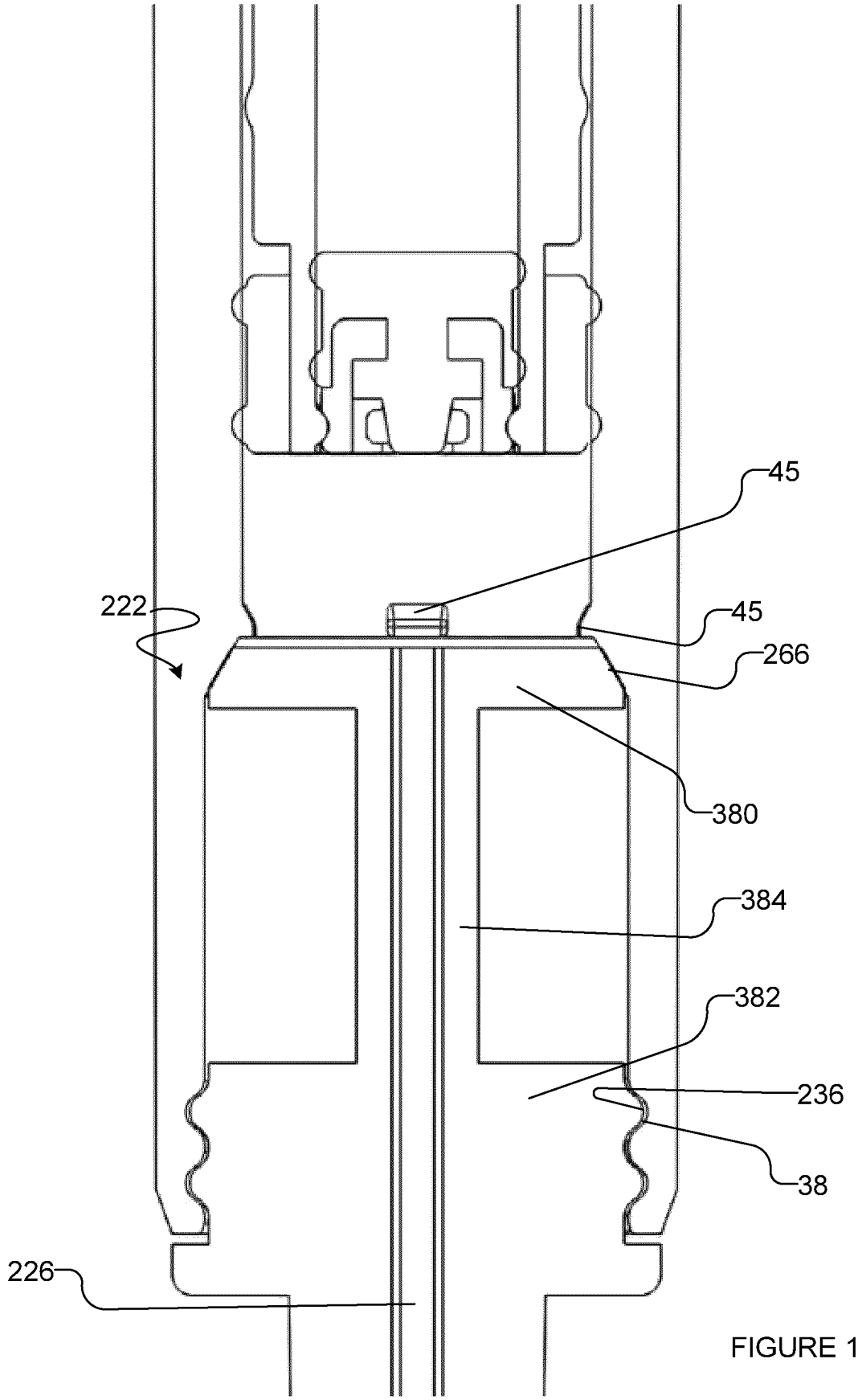

FIGURE 13

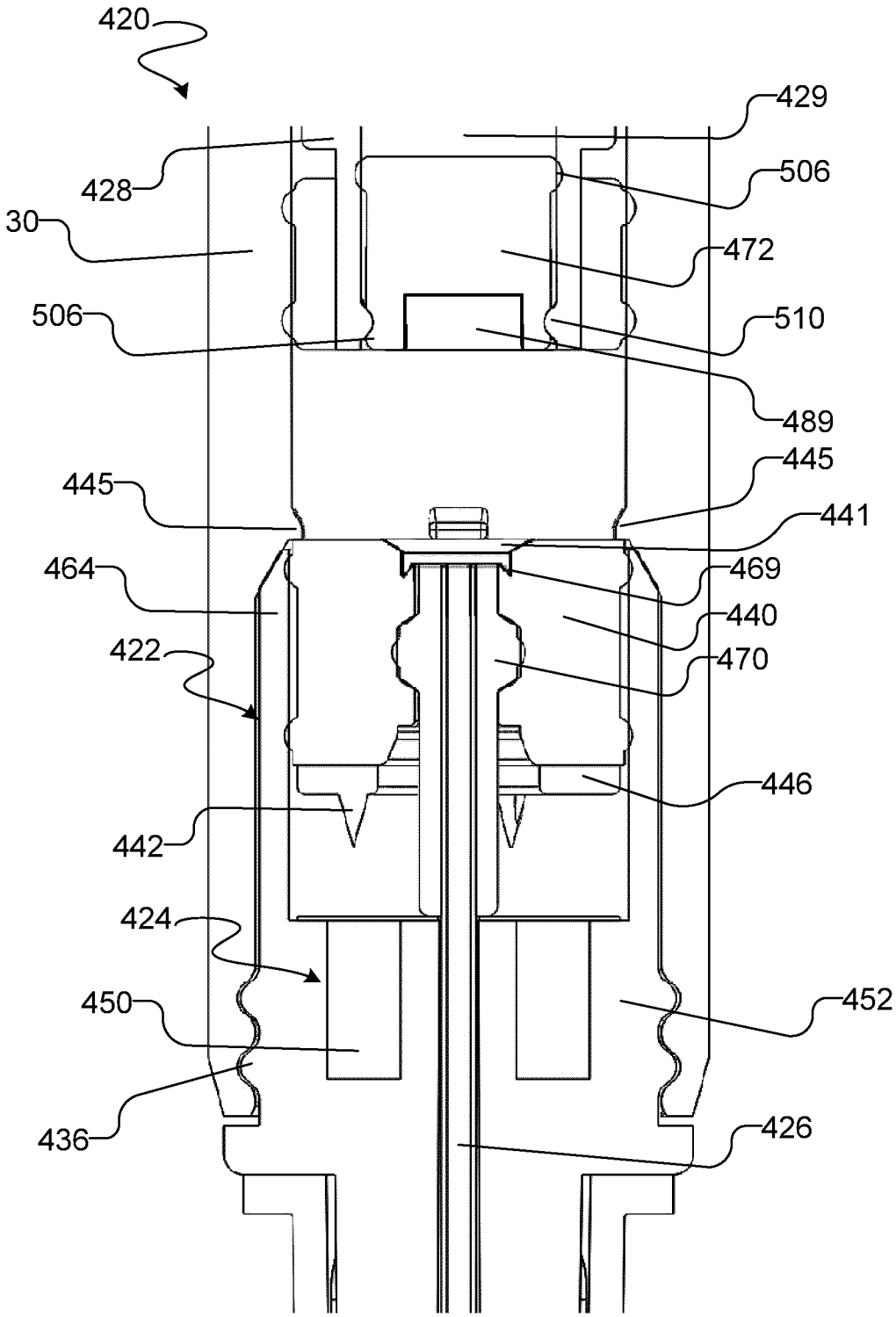
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FIGURE 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2016/050041

A. CLASSIFICATION OF SUBJECT MATTER
IPC: ***A61M 5/32*** (2006.01) , ***A61M 5/50*** (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M (2006.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)
QUESTEL ORBIT (FAMPAT)

Keywords: propellant, gas, needle, cannula

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO2012162821A1, (Darichuk et al.) 06 December 2012 (06-12-2012)	1-9
A	US7811259B2, (Klippenstein, J.) 12 October 2010 (12-10-2010)	1-9
A	US5868713A, (Klippenstein, J.) 09 February 1999 (09-02-1999)	1-9

☐ Further documents are listed in the continuation of Box C.

☑ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier application or patent but published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 29 April 2016 (29-04-2016)	Date of mailing of the international search report 29 April 2016 (29-04-2016)
Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 819-953-2476	Authorized officer Heather Scott (819) 639-7898

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2016/050041

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group A - claims 1-9 and claims depending therefrom: A modular retractable needle assembly for engagement with a barrel of a retractable needle syringe having a plunger, the modular retractable needle assembly comprising a body, a propellant chamber, a seal, a retention member, a needle hub, a needle and a rupturing member.

Group B - claims 10-16 and claims depending therefrom: A modular filler needle assembly for engagement with a barrel of a syringe, the modular filler needle assembly comprising a base, a support disc and a needle.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos.:

4. ☑ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos.: 1-9

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2016/050041

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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		EP1011765B1	03 December 2003 (03-12-2003)
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		PT1011765E	31 March 2004 (31-03-2004)
		WO9844971A1	15 October 1998 (15-10-1998)