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(54) Title: VACUUM-OPERATED RETRACTABLE SAFETY SYRINGES

(57) Abstract: The present disclosure relates generally to vacuum-operated safety syringes designed to prevent an accidental needle prick, wherein the needle of the syringe is retracted after use into a vacuum created within the hollow plunger and/or the syringe barrel of the syringe. Retraction of the needle assembly is accomplished from minimal moving parts according to an exceedingly simple design. In one aspect, negative pressure (i.e., vacuum) is created within a hollow plunger (e.g., of cylindrical shape) and/or the interior of the syringe barrel during the act of injection as the plunger is depressed through the syringe barrel towards the retractable needle assembly. Upon complete depression of the plunger through the syringe barrel, the retractable needle assembly is drawn into the syringe barrel by the vacuum created in the interior of the syringe barrel. In some embodiments, one or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection. In some embodiments, the plunger of the inventive safety syringe is manufactured to be pre-conditioned at negative pressure.

VACUUM-OPERATED RETRACTABLE SAFETY SYRINGES

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Patent Application Ser. No. 61/481,610 filed May 2, 2011, the entire contents of which are incorporated by reference in their entirety.

FIELD

[0002] The present disclosure relates generally to hypodermic syringes wherein the hypodermic needle is retracted after use into a vacuum created within the interior of the hypodermic syringe. Retraction of the needle is designed to prevent an accidental needle prick.

BACKGROUND

[0003] Hypodermic syringes are commonly used in the healthcare industry to inject therapeutics below the skin of patients. Despite their utility, hypodermic syringes present significant safety risks to healthcare practitioners, patients, and anyone who could accidentally be pricked by the exposed needle of a hypodermic syringe. The resulting injury could be as simple as a minor skin laceration, or as deadly as an infection from a virus in the patient's blood.

[0004] Numerous individuals are at risk of injury from injuries resulting from the exposed needle of a hypodermic syringe. Healthcare practitioners are exposed to this danger in routine medical practice. Diabetics and others who self-administer daily injections are at risk, as are members of their household. After disposal, conventional syringes may continue to pose a risk to sanitation workers and anyone else who comes in contact with landfills and waste management processes. Some syringes will undoubtedly be disposed of or handled improperly

prior to disposal, increasing the chance of injury. Thus, conventional syringes clearly pose a danger to healthcare practitioners.

[0005] Several hypodermic syringes with retractable are available. The retraction of the needle into the barrel of the syringe after use reduces the risk of "needle prick", or the accidental pricking of the person giving the injection after the syringe has been used.

[0006] Some of the recently patented retractable needle syringes include U.S. Pat. No. 4,692,156 (Haller); U.S. Pat. No. 4,675,005 (DeLuccia); U.S. Pat. No. 4,747,830 (Gloyer, *et al.*); U.S. Pat. No. 4,790,822 (Haining); and U.S. Pat. No. 4,950,251 (Haining). All of the syringes disclosed include a hypodermic needle mounted on a carrier which slides in the barrel. The plunger is locked to this carrier after the injection has been given and is withdrawn up into the barrel by withdrawal of the plunger. One disadvantage of the above syringes is that the intricate locking mechanism is relatively complex and takes up some space in the barrel of the syringe and may prevent all of the measured liquid from being ejected by the plunger. This problem is exacerbated in the very small syringes such as the 1 cc tuberculin type. The liquid left in the barrel may be a substantial portion of the measured dose. In addition, the narrowness of the barrel of the 1 cc syringe makes it difficult to design a needle carrier and locking mechanism that will fit in the barrel without enlarging the diameter so much as to make the calibration useless.

[0007] Automatic retractable needle syringes have become more popular with the first syringes having springs which, when released, retract the needle into the barrel. One example of this type is U.S. Pat. No. 5,885,257 (Badger). Vacuum powered retraction mechanisms are disclosed in U.S. Pat. No. 5,000,736 (Kaufhold *et al.*) and U.S. Pat. No. 6,846,301 (Smith *et al.*). Importantly, each of the vacuum powered retraction mechanisms in the patents of Kaufhold *et al.* and Smith *et al.* is relatively complex. In the syringes described by Kaufhold *et al.*, the vacuum is provided in the syringe as shipped and breaking a seal activates the mechanism. In syringes described by Smith *et al.*, the vacuum is created by movement of the plunger within the barrel. One drawback to the device by Smith *et al.* is that the entire volume of the barrel has to be evacuated and the resulting force that can be applied over the entire cross sectional area is

relatively small. Further, the retraction mechanism of Smith *et al.* requires numerous moving parts that are prone to failure and contribute to increased manufacturing costs. For example, the vacuum created by the syringes of Smith *et al.* is prone to failure. This is so because the vacuum is maintained by a stopper that primarily serves as a seal located between the exterior of the plunger and the interior of barrel. Apart from being a seal, this stopper of Smith *et al.* is further intended to function as a one-way valve to minimize the loss of vacuum created within the interior of barrel. However, leakage of vacuum can occur through the stopper-based one-way valves of Smith *et al.* Consequently, a vacuum-operated safety syringe is needed that benefits from a simpler and more cost-effective design. In particular, a vacuum-operated safety syringe is needed that utilizes superior one-way valves to more effectively maintain a vacuum within the syringe and thereby improve the ability of the syringe to safely and effectively retract the needle assembly.

SUMMARY

[0008] Applicants have developed a safety syringe with a vacuum-operated retractable needle that benefits from an exceedingly simple design that requires minimal moving parts. Applicants have also developed superior one-way valves relative to such valves currently used in existing syringes. The one-way valves that are incorporated into the present safety syringes more effectively maintain a vacuum within the syringe and thereby improve the ability of the syringe to safely and effectively retract the needle assembly. Further, the dislcosed safety syringe may be produced at low cost relative to existing syringes. Another significant advantage of the present safety syringe is that it may be safely and reliably operated relative to existing syringes by a healthcare practitioner. In some embodiments, the disclosed safety syringe can also be used in non-medical applications, such as chemical handling processes and or in analytical applications.

[0009] The vacuum operated safety syringe of the present disclosure retracts its needle into the interior of a hollow plunger or syringe barrel to prevent the healthcare practitioner from accidentally getting stuck by the exposed needle. The retractable needle protects various people,

including healthcare practitioners, their patients, and sanitation workers involved with disposal of medical waste. The safety syringe may prevent or reduce injuries ranging from minor skin lacerations to serious contamination by medications, germs, or viruses. In some embodiments, the syringe is a disposable, single-use device, and may be available in various sizes and shapes. It is an object of the present disclosure to provide an improved vacuum operated safety syringe with a retractable-needle.

[0010] In one aspect, the safety syringe includes a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and plunger handle posts (e.g., of non-hollow shape) that fit into the syringe barrel. In some embodiments, negative pressure (i.e., vacuum) is created within the interior of the syringe barrel during the act of injection as the plunger handle posts are depressed through the syringe barrel towards the retractable needle assembly. In some embodiments, one or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection, while no positive pressure is built up during loading of the syringe. Upon complete depression of the plunger handle posts through the syringe barrel, the retractable needle assembly is drawn into the syringe barrel by the vacuum created in the interior of the syringe barrel.

[0011] In one aspect, the safety syringe includes a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a hollow plunger (e.g., of cylindrical shape) that fits into the syringe barrel. In some embodiments, negative pressure is created within the interior of the syringe barrel during the act of injection as the hollow plunger is depressed through the syringe barrel towards the retractable needle assembly. One or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection (while avoiding positive pressure build up during loading of the syringe). Upon substantial or complete depression of the hollow plunger through the syringe barrel, one or more orifice(s) in the wall of the hollow plunger enter the interior of the syringe barrel. Thus, the negative pressure of the interior of the syringe barrel evacuates air from the interior of the cylindrical plunger and distributes negative pressure throughout both the syringe barrel and the cylindrical plunger. Upon engagement of the hollow syringe barrel with the

retractable needle assembly, the retractable needle assembly is drawn into the interior of the hollow plunger by the vacuum created in the hollow plunger or syringe barrel by the act of injection.

[0012] In one aspect, the safety syringe includes a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a plunger that fits into the syringe barrel, where the interior of the plunger is manufactured to be at negative pressure. Thus, in some embodiments, negative pressure (i.e., vacuum) is incorporated within the interior of the plunger at the time of manufacture rather than being created during the act of injection. Upon complete depression of the plunger through the syringe barrel, and engagement of the syringe barrel with the retractable needle assembly, the retractable needle assembly is drawn into the interior of the plunger by the pre-existing negative pressure that was incorporated within the interior of the plunger at the time of manufacture.

[0013] In one aspect, a syringe is disclosed including: a retractable needle assembly; a syringe barrel for the withdrawal or injection of fluids; and a plunger including one or more plunger handle posts that fit into the syringe barrel. In some embodiments, the syringe barrel and plunder handle posts are configured and arranged such that negative pressure is created within the interior of the syringe barrel during an act of injection as the plunger handle posts are depressed through the syringe barrel towards the retractable needle assembly.

[0014] Some embodiments include a one-way valve which prevents airflow into an interior volume of the syringe barrel and thereby maintain the negative pressure that is created during an act of injection, while no positive pressure is built up during loading of the syringe.

[0015] In some embodiments, the syringe barrel includes an end cap including at least one one-way valve.

[0016] In some embodiments, upon complete depression of the plunger handle posts through the syringe barrel, the retractable needle assembly is drawn into the syringe barrel by the negative pressure created in the interior of the syringe barrel.

[0017] In another aspect, a syringe is disclosed including: a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a hollow plunger that fits into the syringe barrel. In some embodiments, the syringe barrel is configured and arranged such that negative pressure is created within the interior of the syringe barrel during an act of injection as the hollow plunger is depressed through the syringe barrel towards the retractable needle assembly.

[0018] Some embodiments include one or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the negative pressure that is created during the act of injection.

[0019] In some embodiments, upon substantial or complete depression of the hollow plunger through the syringe barrel, an orifice in the wall of the hollow plunger enters the interior of the syringe barrel such that the syringe barrel in placed in pneumatic communication with an internal volume of the hollow plunger to facilitate retraction of the needle assembly.

[0020] In some embodiments, where the one way valve includes: a seal member configured such that the plunger passes through the seal ember into the syringe barrel. In some embodiments, the seal member is retained in a groove in the syringe barrel and is configured to provide an air tight seal when negative pressure is created in the internal volume of syringe barrel by movement of the plunger in a distal direction toward the needle assembly. In some embodiments, the groove and the shaft are configured and arranged such that: an increase of negative pressure created when the plunger is moved in the distal direction causing the airtight seal to become more robust, and the airtight seal is broken such that pressure in the syringe barrel is released when the plunger is actuated in a proximal direction away from the needle assemble.

[0021] In some embodiments, the one way valve includes a purge valve affixed to the syringe barrel covering an orifice in the syringe barrel, the purge valve configured to: provide an airtight seal when negative pressure is created in the internal volume of the syringe barrel, and release the airtight seal when positive pressure is created in the internal volume.

[0022] In some embodiments, the purge valve includes an elastomeric band disposed about the syringe barrel and covering the orifice in the syringe barrel.

[0023] In some embodiments, the purge valve includes: a valve member that extends through an orifice in the syringe barrel, seals against the syringe barrel in response to negative pressure in the syringe barrel, and unseals in response to positive pressure in the syringe barrel; and a valve retaining member that retains the valve member in position when the valve member is unsealed.

[0024] In another aspect, a syringe is disclosed including: a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a plunger that fits into the syringe barrel, where the interior of the plunger is manufactured to be at negative pressure. In some embodiments, upon on complete depression of the plunger through the syringe barrel, and engagement of the syringe barrel with the retractable needle assembly, the retractable needle assembly is drawn into the interior of the plunger by the preexisting negative pressure that was incorporated within the interior of the plunger at the time of manufacture.

[0025] In some embodiments, the syringe is pre-filled.

[0026] In some embodiments, the retractable needle assemble is pre-retracted.

[0027] In some embodiments, the plunger includes a needle catch configured to attach to the needle assembly when the plunder is depressed.

[0028] In some embodiments, the needle catch includes a bung member that is configured to be pierced by a portion of the needle assembly extending into the syringe barrel when the plunder is depressed.

[0029] In some embodiments, the needle catch includes a bung member that is configured to attach to a portion of the needle assembly extending into the syringe barrel when the plunder is depressed.

[0030] In some embodiments, a method is disclosed including, using the syringe of any of any of the types described herein: dispensing a fluid from the syringe; upon dispensing the fluid, causing at least a portion of the needle assemble to retract into the syringe barrel. Some embodiments include, prior to dispensing the fluid from the syringe, loading the syringe with the fluid.

[0031] Healthcare practitioners can operate the presently disclosed safety syringes in the conventional manner that syringes are used to inject a patient. A plunger is used to draw fluid into the syringe and inject fluid from the syringe into the patient. During injection of the patient, the plunger and a one-way valve gradually generate a vacuum within the plunger or syringe barrel. Following injection, the vacuum within the plunger automatically pulls the piston toward the rear end of the plunger, retracting the needle safely into the interior of the plunger or syringe barrel.

[0032] These and further objects, features, and advantages of the present disclosure will become apparent from the following detailed description, wherein reference is made to the figures in the accompanying drawings. Each reference, U.S. patent, and U.S. patent application that is disclosed herein is incorporated by reference in its entirety.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Various embodiments of safety syringes are shown in FIGS. 1-7. The drawings in FIGS. 1-7 are not necessarily to scale, emphasis instead is generally being placed upon illustrating the principles of this aspect of the disclosure.

[0034] FIG. 1 depicts a safety syringe, comprising plunger handle posts 11, that retracts cannula assembly 1 and 2 into the interior of syringe barrel 4 upon complete depression of plunger handle posts 11 by the user. The top panel shows the plunger handle prior to depression. The middle panel shows the plunger partially depressed. The bottom panel shows the plunger fully depressed, and the needle retracted.

[0035] FIG. 2 depicts a safety syringe, comprising a hollow plunger 27, that retracts cannula assembly 1 and 2 into the hollow plunger 27, upon complete depression of the hollow plunger 27 by the user. The top panel shows the plunger handle prior to depression. The middle panel shows the plunger partially depressed, with an inset showing a detail of the valve. The bottom panel shows the plunger fully depressed, and the needle retracted.

[0036] FIG. 3 depicts a safety syringe, comprising a hollow plunger 37 and one-way purge valve 310, that retracts cannula assembly 31 and 32 into the hollow plunger 37, upon complete depression of the hollow plunger 37 by the user The top panel shows the plunger handle prior to depression. The middle panel shows the plunger partially depressed, with an inset showing a detail of the valve. The bottom panel shows the plunger fully depressed, and the needle retracted.

[0037] FIG. 4 depicts a safety syringe, comprising a hollow plunger 47, one-way valve including the purge valve 410, valve retainer 45, and orifice(s) 411, that retracts cannula assembly 41 and 42 into the hollow plunger 47, upon complete depression of the hollow plunger 47 by the user. The top panel shows the plunger handle prior to depression. The middle panel shows the plunger partially depressed, with an inset showing a detail of the valve. The bottom panel shows the plunger fully depressed, and the needle retracted.

[0038] FIG. 5 depicts a safety syringe, comprising a hollow plunger 57, that retracts cannula assembly 51 and 52 into the hollow plunger 57, upon complete depression of the hollow plunger 57 by the user. The top panel shows the plunger handle prior to depression. The middle panel shows the plunger partially depressed. The bottom panel shows the plunger fully depressed, and the needle retracted.

[0039] FIG. 6 depicts a safety syringe, comprising a hollow plunger 67 that is pre-conditioned at negative pressure, and that retracts cannula assembly 61 and 62 into the inner diameter of plunger 67, upon complete depression of plunger 67 by the user. The top panel shows the plunger handle prior to depression. The middle panel shows the plunger partially depressed. The bottom panel shows the plunger fully depressed, and the needle retracted.

[0040] FIG. 7 depicts a safety syringe that is pre-filled with liquid, and features an initially retracted, deployable needle. The top panel shows the plunger handle prior to depression with the needle retracted. The middle panel shows the plunger partially depressed. The bottom panel shows the plunger fully depressed.

DETAILED DESCRIPTION

[0041] The present disclosure relates generally to vacuum-operated safety syringes designed to prevent an accidental needle prick, where the needle of the syringe is retracted after use into a vacuum created within the hollow plunger or the syringe barrel of the syringe. Applicants have developed syringes in which the retraction of the needle assembly is achieved using minimal moving parts according to an elegant design. In various embodiments, negative pressure (i.e., vacuum) is created within a hollow plunger (e.g., of cylindrical shape) or the interior of the syringe barrel during the act of injection as the plunger is depressed through the syringe barrel towards the retractable needle assembly. Upon complete depression of the plunger through the syringe barrel, the retractable needle assembly is drawn into the syringe barrel by the vacuum created in the interior of the syringe barrel. In some embodiments, one or more one way valves are utilized to prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection. These one way valves may also operate to allow air to escape from the syringe during loading, thereby reducing or elimination unwanted build up of positive pressure. In some embodiments, the plunger of the safety syringe is manufactured to be pre-conditioned at negative pressure.

[0042] For the purposes of the present disclosure, the term "plastic" refers to a class of materials including injection molded polypropylene plastic, synthetic resins, polyolefin resins such as polyethylene and polypropylene, polyvinyl chloride, PET (polyethylene terephthalate), EVA (ethylene-vinyl acetate copolymer), EVOH (ethylene-vinyl alcohol copolymer), polyamide, polyvinylidene chloride, polyvinyl fluoride, polytrifluorochloroethylene, polyester, nylon, mixtures thereof and laminated bodies thereof, the material is not limited especially if it is known

for use as a medical equipment material and does not interact with the medicine or liquid accommodated in the barrel of the syringe.

[0043] The term "elastomer" refers to elastic materials having sealing property (in other words, gas-tight property) can be used. Thus the following elastomers can be used: injection molded thermoplastic elastomer, natural rubber, isoprene rubber, butyl rubber, butadiene rubber, styrene-butadiene rubber, silicone rubber, styrene-butadiene-styrene block copolymer, hydrogenated styrene-butadiene copolymer, hydrogenated styrene-ethylene-butylene-styrene block copolymer, ethylene-α-olefin copolymer rubber, thermoplastic elastomer, elastomers of polyurethane family, elastomers of polyamide family, elastomers of polyester family, vulcanized isoprene rubber, vulcanized butyl rubber, vulcanized styrene-butadiene-styrene block copolymer, and mixtures of these substances.

[0044] Referring to FIG. 1, a safety syringe includes a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and plunger handle posts (e.g., of nonhollow shape) that fit into the syringe barrel. In some embodiments, the plunger handle posts are cylindrical. In some embodiments, negative pressure (i.e., vacuum) is created within the interior of the syringe barrel during the act of injection as the plunger handle posts are depressed through the syringe barrel towards the retractable needle assembly. In some embodiments, one or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection. Upon complete depression of the plunger handle posts through the syringe barrel, the retractable needle assembly is drawn into the syringe barrel by the vacuum created in the interior of the syringe barrel by the act of injection.

[0045] The safety syringe as depicted in FIG. 1, includes a cannula assembly 1 and 2 made up of a cannula 1 (e.g., a needle) held by a hub 2 that are located at the distal end of the syringe barrel 4. The cannula 1 can be of various sizes. In some embodiments, cannula 1 is permanently attached to the hub 2. In some embodiments, the proximal end of the cannula assembly 1 and 2 are positioned in the center of a washer 3. The washer 3 creates a water tight seal at the hub 2 and syringe barrel 4. In some embodiments, a needle catch 5 can be permanently attached to a

piston bung 6. In some embodiments, a barrel seal 8 is affixed to a needle catch adapter 7. The needle catch assembly 5 and 6 is held in the inner diameter of the needle catch adapter 7. The bung 6 creates an air tight seal with the inner diameter of the needle catch adapter 7. The size of features on needle catch 5 is such that there is some amount of interference with the inner diameter of the needle catch adapter 7. In some embodiments, syringe barrel end cap 9 is affixed to proximal end of syringe barrel 4 to provide an airtight seal between the two. In some embodiments, the plunger handle posts 11 can be affixed to needle catch adapter 7. In some embodiments, the plunger handle posts 11 can be supplied loose. Plunger handle posts 11 are affixed to needle catch adapter 7 by inserting it through end cap seals 10. End cap seals 10 create air tight seals with plunger handle posts 11.

[0046] As illustrated, the safety syringe of FIG. 1 is designed to retract the cannula 1 into the interior of the syringe barrel 4 upon complete depression of plunger handle posts 11 by the user. The retraction of cannula 1 is accomplished by the creation of a vacuum in the interior of the syringe barrel 4 upon depression of plunger handle posts 11 by the user. In some embodiments, one or more one-way valving is used to create a vacuum in the interior of the syringe barrel 4 during depression of the plunger handle while allowing air to escape during retraction of the handle (e.g., during loading of the syringe from a liquid reservoir, not shown). For example, the end cap 9 may have one-way valving to allow for purging of trapped air in the interior of the syringe barrel 4. The one way valving enables air to exit the syringe barrel 4 upon retraction of the plunger handle posts 11 away from the cannula 1, but air cannot enter the syringe barrel 4 upon depression of the plunger handle posts 11 toward the cannula 1. Thus, depression of the plunger handle posts 11 creates a vacuum in the interior of the syringe barrel 4 upon complete depression of plunger handle posts 11 by the user, which thereby draws the cannula 1 into the interior of syringe barrel 4. In some embodiments, the airtight seals 10 may be one way valve type seals (e.g., of the type illustrated in Fig. 2), to provide the one way valving. [0001] For example, upon filling the syringe barrel 4 with the liquid to be injected, the plunger handle posts 11 are retracted away from the cannula 1. Upon subsequent injection of liquid, plunger handle posts 11 are then depressed toward from cannula 1, where the needle catch 5 engages the hub 2

and becomes affixed. As the plunger 7 is depressed negative pressure is created on the proximal side of the barrel seal 8. While depressing the plunger the shoulder feature on the needle catch adapter 7 will displace the washer 3 so that the cannula assembly 1, 2 is free to move. Immediately after release of the cannula assembly 1,2 from the washer 3, further depression of the plunger handle posts in the distal direction will push the needle catch 5 through the inner diameter of needle catch adapter 7 thus releasing the needle catch assembly 5 and 6 along with the affixed cannula assembly 1 and 2. At this time the needle catch assembly 5 and 6 and cannula assembly 1 and 2 will be aspirated into the syringe barrel 4 portion which is proximal to the barrel seal 8 by the negative pressure previously created. Note that, aside from a small volume occupied by the plunger handle posts, nearly the entire interior volume of the syringe barrel 4 is available for retention of the cannula assembly 1 and 2.

[0047] In some embodiments, the syringe as shown in FIG. 1 can incorporate any permutation of the features described in FIGS. 1-7. In some embodiments, the plunger handle posts 11, needle catch adapter 7, barrel seal 8, and syringe barrel end cap 9 as shown in FIG. 1 can be replaced with the hollow plunger as shown in FIGS. 2-5. In some embodiments, the plunger handle posts 11, needle catch adapter 7, barrel seal 8, and syringe barrel end cap 9 as shown in FIG. 1 can be replaced with a plunder, which is pre-conditioned at negative pressure, as shown in FIG. 6. In some embodiments, the syringe as shown in FIG. 1 can include the cannula assembly and the needle catch bungas illustrated in FIGS. 4 and 5. Syringe barrel 4 may incorporate any valve described in FIGS. 3 and 4, to allow air to escape from the proximal side of the barrel seal 8 when the plunger 7 is withdrawn, but which seals airtight when the plunger 7 is depressed. In some embodiments, the syringe barrel 4 as shown in FIG. 1 can include a one-way valve as described in FIG. 3, such as the purge valve 310. In some embodiments, the syringe barrel 4 as shown in FIG. 1 can include a one-way valve as described in FIG. 4, including the purge valve 410, valve retainer 45, and orifice(s) 411. In some embodiments, the interior of the syringe barrel as shown in FIG. 1 is pre-filled with fluid and/or features a pre-retracted and deployable cannula assembly, e.g., as illustrated in Fig. 7.

[0048] The safety syringe of FIG. 1 can be assembled from components made from a variety of materials. In some embodiments, cannula 1 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing). In some embodiments, the cannula 1 is of various sizes (e.g., in the range of fractions of a centimeter or less to tens of centimeters or more). In some embodiments, the hub 2 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 1 may be assembled to the hub 2 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, washer 3 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the syringe barrel 4 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the needle catch 5 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the bung 6 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the bung 6 can be molded separately. In some embodiments, the bung 6 can be overmolded onto needle catch 5. In some embodiments, the needle catch adapter 7 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the barrel seal 8 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the barrel seal 8 can be molded separately. In some embodiments, the barrel seal 8 can be overmolded onto needle catch adapter 7. In some embodiments, syringe barrel end cap 9 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, end cap seal 10 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, end cap seal 10 is made of rubber. In some embodiments, plunger handle 11 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic).

[0049] Referring to FIGS. 2-5, various embodiments of safety syringes include a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a hollow plunger (e.g., of cylindrical shape) that fits into the syringe barrel. In some embodiments, negative pressure is created within the interior of the syringe barrel during the act of injection as the hollow plunger is depressed through the syringe barrel towards the retractable needle assembly.

One or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection, while allowing air to escape during the loading of the syringe. Upon substantial or complete depression of the hollow plunger through the syringe barrel, one or more orifice(s) in the wall of the hollow plunger enter the interior of the syringe barrel. Thus, the negative pressure of the interior of the syringe barrel evacuates air from the interior of the cylindrical plunger and distributes negative pressure throughout both the syringe barrel and the cylindrical plunger. Upon engagement of the hollow syringe barrel with the retractable needle assembly, the retractable needle assembly is drawn into the interior of the hollow plunger by the vacuum created in the hollow plunger or syringe barrel by the act of injection.

[0050] Referring to FIG. 2, a safety syringe includes a cannula 21. The cannula 21 may be permanently attached to a hub 22 to form a cannula assembly 21 and 22. The cannula assembly 21 and 22 are located at the distal end of the syringe barrel 24. The proximal end of the cannula assembly 21 and 22 are positioned in the center of a washer 23. The washer 23 creates a water tight seal at the hub 22 and syringe barrel 24. The needle catch 25 is permanently attached to piston bung 26. The barrel seal 28 is affixed to plunger 27. The needle catch assembly 25 and 26 is held in the inner diameter of plunger 27. The bung 26 creates an air tight seal with he inner diameter of the plunger 27. The size of features on the needle catch 25 is such that there is some amount of interference with the distal orifice diameter of the plunger 27. The proximal end of the syringe barrel 4 which the plunger 27 passes through can be a separate piece assembled to the majority of the syringe barrel 24 providing an airtight seal between the two pieces. The plunger shaft passes through one, two, or more shaft seals 29 to provide an air tight seal between the syringe barrel 4 and the plunger 27. The shaft seal 29 is retained in the groove 210 to provide an air tight seal when negative pressure is created in the internal volume of syringe barrel 24 by the plunger 7 moving in the distal direction. The geometry of the groove 210 and the shaft seal 29 is such that the increase of negative pressure created when the plunger 27 is moved in the distal direction causes airtight seal to become more robust. The geometry of the groove 210 and the

shaft seal 29 is such that trapped air may be released when the plunger is actuated in a proximal direction.

[0051] In some embodiments, the safety syringe of FIG. 2 is designed to retract cannula assembly 21 and 22 into the internal volume of the plunger 27 upon complete depression of the plunger 7 by the user. After filling of the device with liquid, the plunger 27 is depressed where the needle catch 25 engages the hub 22 and becomes affixed. As the plunger 27 is depressed negative pressure is created on the proximal side of the barrel seal 28. Prior to release of the cannula assembly 21 and 22 an orifice 211 enters the negative pressure volume of the syringe barrel 24 joining the negative pressure volume of the syringe barrel 4 and the internal volume of plunger 27. While depressing the plunger 27 the shoulder feature on plunger 27 will displace the washer 23 so that the cannula assembly 21 and 22 is free to move. Immediately after release of the cannula assembly 21 and 22 from the washer 23, further travel of the plunger handle in the distal direction will push the needle catch 25 through the distal orifice diameter of plunger 7 thus releasing the needle catch assembly 25 and 26 along with the affixed cannula assembly 21 and 22. At this time the needle catch assembly 25 and 26 and cannula assembly 21 and 22 will be aspirated into the plunger 27 portion which is proximal to the distal orifice in plunger 27 by the negative pressure previously created. Note that nearly the entire interior volume of the plunger 27 is available for retaining the cannula assembly 21 and 22, allowing for the use of large cannula sizes.

[0052] In some embodiments, the syringe as shown in FIG. 2 can incorporate any permutation of the features described in FIG. 1 and FIGS. 3-7. In some embodiments, the hollow plunger 27 as shown in FIG. 2 can be replaced with the plunger handle posts, needle catch adapter, barrel seal 8, and syringe barrel end cap as shown in FIG.1. In some embodiments, the hollow plunger 27 as shown in FIG. 2 can be replaced with the plunger as shown in FIG. 6, which is pre-conditioned at negative pressure. In some embodiments, the syringe as shown in FIG. 2 can include the cannula assembly and the needle catch bung as described in FIGS. 4 and 5. In some embodiments, the syringe barrel 24 as shown in FIG. 2 can include a one-way valve as described in FIG. 3, including the purge valve 310. In some embodiments, the syringe barrel

24 as shown in FIG. 2 can include a one-way valve as described in FIG. 4, including the purge valve 410, valve retainer 45, and orifice(s) 411. In some embodiments, the interior of the syringe barrel as shown in FIG. 2 is pre-filled with fluid. In some embodiments, the syringe barrel as shown in FIG. 2 is pre-filled with fluid and/or features a pre-retracted and deployable cannula assembly, e.g., as illustrated in Fig. 7.

[0053] The safety syringe of FIG. 2 can be assembled from components made from a variety of materials. In some embodiments, cannula 1 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing). In some embodiments, cannula 21 is of any suitable size as described above. In some embodiments, the hub 22 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 21 may be assembled to hub 22 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, washer 23 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the syringe barrel 24 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the needle catch 25 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the bung 26 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the bung 26 can be molded separately. In some embodiments, the bung 26 can be overmolded onto needle catch 25. In some embodiments, the plunger 27 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the plunger 27 has one or more orifice(s) 211. In some embodiments, the barrel seal 28 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the barrel seal 28 can be molded separately. In some embodiments, the barrel seal 28 can be overmolded onto the plunger 27. In some embodiments, the shaft seal 29 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the shaft seal 29 is made of rubber.

[0054] Referring to FIG. 3, the safety syringe, in one embodiment, includes cannula 31. The cannula 31 is permanently attached to the hub 32 to form a cannula assembly 31 and 32. The cannula assembly 31 and 32 are located at the distal end of the syringe barrel 34. The proximal

end of the cannula assembly 31 and 32 are positioned in the center of washer 33. A washer 33 creates a water tight seal at the hub 32 and the syringe barrel 34. The needle catch 35 is permanently attached to the piston bung 36. The barrel seal 38 is affixed to plunger 37. The needle catch assembly 35 and 36 is held in the some size inner diameter of plunger 37. The bung 36 creates an air tight seal with an inner diameter of plunger 37. The size of features on the needle catch 35 is such that there is some amount of interference with the distal orifice diameter of the plunger 37. The proximal end of the syringe barrel 34 which the plunger 37 passes through can be a separate piece assembled to the majority of the syringe barrel 34 providing an airtight seal between the two pieces. The plunger shaft passes through one, two or more shaft seals 39 to provide an air tight seal between the syringe barrel 34 and the plunger 37. A purge valve 310 is affixed to the syringe barrel 34 covering an orifice 312 in the syringe barrel 34. This provides an airtight seal when negative pressure is created in the internal volume of the syringe barrel 34 that is proximal to the barrel seal 8, but the seal is released when positive pressure is created in said volume.

[0055] In some embodiments, the safety syringe of FIG. 3 is designed to retract the cannula assembly 31 and 32 into the internal volume of plunger 37 upon complete depression of plunger 37 by the user. After filling of the device, the plunger 37 is depressed where the needle catch 35 engages the hub 32 and becomes affixed. As the plunger 37 is depressed negative pressure is created on the proximal side of the barrel seal 38. Prior to release of the cannula assembly 31 and 32, an orifice 311 enters the negative pressure volume of the syringe barrel 34 joining the negative pressure volume of the syringe barrel 34 and the internal volume of the plunger 37. While depressing the plunger 37 the shoulder feature on plunger 37 will displace the washer 33 so that the cannula assembly 31 and 32 is free to move. Immediately after release of the cannula assembly 31 and 32 from the washer 33, further travel of the plunger handle in the distal direction will push the needle catch 35 through the distal orifice diameter of plunger 37 thus releasing the needle catch assembly 35 and 36 along with the affixed cannula assembly 31 and 32. At this time the needle catch assembly 35 and 36 and cannula assembly 31 and 32 will be aspirated in to the plunger 37 portion which is proximal to the distal orifice in plunger 37 by the

negative pressure previously created. Again, nearly the entire interior volume of the plunder 37 is available for retention of the cannula assembly 31 and 32.

[0056] In some embodiments, the syringe as shown in FIG. 3 can incorporate any permutation of the features described in FIGS. 1-2 and FIGS. 4-7. In some embodiments, the hollow plunger 37 as shown in FIG. 3 can be replaced with the plunger handle posts, needle. catch adapter, barrel seal, and syringe barrel end cap as shown in FIG. 1. In some embodiments, the hollow plunger 37 as shown in FIG. 3 can be replaced with the plunger 67 as shown in FIG. 6, which is pre-conditioned at negative pressure. In some embodiments, the syringe as shown in FIG. 3 can include the cannula assembly and the needle catch bung as described in FIGS. 4 and 5. In some embodiments, the syringe barrel 34 as shown in FIG. 3 can include a one-way valve as described in FIG. 4, including the purge valve 410, valve retainer 45, and orifice(s) 411. In some embodiments, the interior of the syringe barrel as shown in FIG. 3 is pre-filled with fluid. In some embodiments, the syringe barrel as shown in FIG. 3 is pre-filled with fluid and/or features a pre-retracted and deployable cannula assembly, e.g., as illustrated in FIG. 7.

[0057] The safety syringe of FIG. 3 can be assembled from components made from a variety of materials. In some embodiments, cannula 31 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing). In various embodiments, the cannula 1 is of any suitable size, as described above. In some embodiments, the hub 32 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 31 may be assembled to hub 32 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, the washer 33 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the syringe barrel 34 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the needle catch 35 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the bung 36 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the bung 36 can be molded separately. In some embodiments, the bung 36 can be overmolded onto needle catch 35. In some embodiments, the plunger 37 is made of plastic (e.g., polypropylene plastic or injection molded

polypropylene plastic). In some embodiments, the plunger 37 has one or more orifice(s) 11. In some embodiments, the barrel seal 38 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the barrel seal 38 can be molded separately. In some embodiments, the barrel seal 8 can be overmolded onto plunger 37. In some embodiments, the shaft seal 39 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the shaft seal 39 is made of rubber. In some embodiments, the purge valve 310 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the purge valve 310 is made of plastic (e.g., injection molded plastic, polypropylene plastic, or injection molded polypropylene plastic). In some embodiments, the purge valve 310 is made of metal (e.g., steel or spring type steel) with an elastomeric material laminated to the inside. In some embodiments, the purge valve 310 is made of metal (e.g., steel or spring type steel) and overmolded with an elastomer (e.g., injection molded thermoplastic elastomer).

[0058] Referring to FIG. 4, in one embodiment, the safety syringe includes cannula 41. The cannula 41 is permanently attached to the hub 42 to form a cannula assembly 41 and 42. The cannula assembly 41 and 42 is located at the distal end of the syringe barrel 44. The proximal end of the cannula assembly 41 and 42 are positioned in the center of washer 43. A washer 43 creates a water tight seal at the hub 42 and syringe barrel 44. A barrel seal 48 is affixed to plunger 47. A needle catch bung 46 is held at an inner diameter of the plunger 47. The needle catch bung 46 creates an air tight seal with a some size inner diameter of plunger 47. The proximal end of syringe barrel 4 which the plunger 47 passes through can be a separate piece assembled to the majority of the syringe barrel 44 providing an airtight seal between the two pieces. The plunger shaft passes through one, two or more shaft seals 49 to provide an air tight seal between the syringe barrel 4 and the plunger 47. A purge valve 410 is affixed to the proximal end of syringe barrel 44. The purge valve 410 can be attached to the syringe barrel 44 with the valve retainer 45 or directly to syringe barrel 44. The purge valve 410 covers an orifice 411 in syringe barrel 44 providing an airtight seal when negative pressure is created in the

internal volume of the syringe barrel 44 that is proximal to the barrel seal 48, but the seal is released when positive pressure is created in said volume.

[0059] In some embodiments, the safety syringe of FIG. 44 is designed to retract the cannula assembly 41 and 42 into the internal volume of plunger 47 upon complete depression of the plunger 47 by the user. After filling of the device, the plunger 47 is depressed and the needle catch bung 46 engages the cannula 41 and becomes affixed. The needle catch bung 46 and cannula 41 can become affixed via piecing or other interlocking geometry. As shown, the cannula 41 includes a sharp proximal end that pierces into (but not through) the bung 46.

[0060] As the plunger 47 is depressed negative pressure is created on the proximal side of the barrel seal 448. Prior to release of the cannula assembly 41 and 42, orifice 412 enters the negative pressure volume of the syringe barrel 44 joining the negative pressure volume of the syringe barrel 44 and the internal volume of plunger 47. While depressing the plunger 47 the shoulder feature on plunger 47 will displace the washer 43 so that the cannula assembly 41 and 42 is free to move. Immediately after release of the cannula assembly 41 and 42 from the washer 43, further travel of the plunger 47 handle in the distal direction will push the needle catch bung 46 through the distal orifice diameter of plunger 47 thus releasing the needle catch bung 46 along with the affixed cannula assembly 41 and 42. At this time the needle catch bung 46 and cannula assembly 41 and 42 will be aspirated in to the plunger 47 portions which is proximal to the distal orifice in plunger 47 by the negative pressure previously created. In some embodiments, the bung 46 may frictionally (or otherwise) engage the inner surface of the plunger 47 to mechanically secure and retain the cannula assembly within the plunger.

[0061] In some embodiments, the syringe as shown in FIG. 4 can incorporate any permutation of the features described in FIGS. 1-3 and FIGS. 5-7. In some embodiments, the hollow plunger 47 as shown in FIG. 4 can be replaced with the plunger handle posts, needle catch adapter, barrel seal, and syringe barrel end cap as shown in FIG. 1. In some embodiments, the hollow plunger 47 as shown in FIG. 4 can be replaced with the plunger 67 as shown in FIG. 6, which is pre-conditioned at negative pressure. In some embodiments, the syringe as shown in

FIG. 4 may include the cannula assembly and the needle catch assembly as described in FIGS. 1-2. In some embodiments, the syringe barrel 44 as shown in FIG. 4 may include a one-way valve as described in FIG. 3. In some embodiments, the syringe barrel 44 as shown in FIG. 4 can omit a one-way valve as described in FIG. 4. In some embodiments, the interior of the syringe barrel as shown in FIG. 4 is pre-filled with fluid. In some embodiments, the interior of the syringe barrel as shown in FIG. 4 is pre-filled with fluid. In some embodiments, the syringe barrel as shown in FIG. 4 is pre-filled with fluid and/or features a pre-retracted and deployable cannula assembly, e.g., as illustrated in FIG. 7.

[0062] The safety syringe of FIG. 4 can be assembled from components made from a variety of materials. In some embodiments, the cannula 41 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing). In various embodiments, the cannula 41 is of any suitable size, as described above. In some embodiments, the hub 42 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 41 may be assembled to the hub 42 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, the washer 43 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the syringe barrel 44 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the valve retainer 45 is made of plastic (e.g., polypropylene plastic, injection molded plastic, or injection molded polypropylene plastic). In some embodiments, the valve retainer 45 is made of metal (e.g., steel, stainless steel, or spring steel). In some embodiments, the needle catch bung 46 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the plunger 47 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the plunger 47 has one or more orifice(s) 412. In some embodiments, the barrel seal 48 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the barrel seal 48 can be molded separately. In some embodiments, the barrel seal 48 can be overmolded onto plunger 47. In some embodiments, one or more shaft seals may be included, e.g., made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, one or more

shaft seals are made of rubber. In some embodiments, the purge valve 410 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the purge valve 410 is made of plastic (e.g., injection molded plastic, polypropylene plastic, or injection molded polypropylene plastic). In some embodiments, the purge valve 410 is made of metal (e.g., steel or spring type steel) with an elastomeric material laminated to the inside. In some embodiments, the purge valve 410 is made of metal (e.g., steel or spring type steel) and overmolded with an elastomer (e.g., injection molded thermoplastic elastomer).

[0063] Referring to FIG. 5, the safety syringe, in one aspect, includes a cannula 51. The cannula 51 is permanently attached to a hub 52. The cannula assembly 51 and 52 are located at the distal end of the syringe barrel 54. The proximal end of the cannula assembly 51 and 52 are positioned in the center of a washer 53. The washer 53 creates a water tight seal at the hub 52 and the syringe barrel 54. The barrel seal 58 is affixed to plunger 57. A needle catch bung 56 is held a some size inner diameter of plunger 57. Needle catch bung 56 creates an air tight seal with an inner diameter of plunger 57. The proximal end of the syringe barrel 54 which the plunger 57 passes through can be a separate piece assembled to the majority of the syringe barrel 54 providing an airtight seal between the two pieces. The plunger shaft passes through one, two or more shaft seals 55 to provide an air tight seal between the syringe barrel 54 and the plunger 57. A in the embodiment shown in FIG. 2 (inset), the shaft seal 55 is retained in groove 510 to provide an air tight seal when negative pressure is created in the internal volume of syringe barrel 54 by the plunger 57 moving in the distal direction. The geometry of groove 510 and shaft seal 59 is such that the increase of negative pressure created when the plunger 57 is moved in the distal direction causes the airtight seal to become more robust. The geometry of groove 510 and shaft seal 59 is such that trapped air may be released when the plunger is actuated in a proximal direction.

[0064] In some embodiments, the safety syringe of FIG. 5 is designed to retract the cannula assembly 51 and 52 into the internal volume of plunger 57 upon complete depression of the plunger 57 by the user. After filling of the device, the plunger 57 is depressed where the needle catch bung 56 engages the cannula 51 and becomes affixed. The needle catch bung 56 and the

cannula 51 can become affixed via piecing or other interlocking geometry. The needle catch bung 56 and cannula 1 can become affixed via piecing or other interlocking geometry. As shown, the cannula 51 includes a sharp proximal end that pierces into (but not through) the bung 56.

[0065] As the plunger 57 is depressed negative pressure is created on the proximal side of the barrel seal 58. Prior to release of the cannula assembly 51 and 52, orifice 59 enters the negative pressure volume of the syringe barrel 54 joining the negative pressure volume of the syringe barrel 54 and the internal volume of plunger 57. While depressing the plunger 57 the shoulder feature on plunger 57 will displace the washer 53 so that the cannula assembly 51 and 52 is free to move. Immediately after release of the cannula assembly 51 and 52 from the washer 53, further travel of the plunger 57 handle in the distal direction will push the needle catch bung 56 through the distal orifice diameter of plunger 57 thus releasing the needle catch bung 56 along with the affixed cannula assembly 51 and 52. At this time the needle catch bung 6 and the cannula assembly 51 and 52 will be aspirated in to the plunger 57 portion which is proximal to the distal orifice in the plunger 57 by the negative pressure previously created. In some embodiments, the bung 56 may frictionally (or otherwise) engage the inner surface of the plunger 57 to mechanically secure and retain the cannula assembly within the plunger.

[0066] In some embodiments, the syringe as shown in FIG. 5 can incorporate any permutation of the features described in FIGS. 1-4 and FIGS. 6-7. In some embodiments, the hollow plunger 57 as shown in FIG. 5 can be replaced with the plunger handle posts, needle catch adapter, barrel seal, and syringe barrel end cap as shown in FIG. 1. In some embodiments, the hollow plunger 57 as shown in FIG. 5 can be replaced with the plunger 67 as shown in FIG. 6, which is pre-conditioned at negative pressure. In some embodiments, the syringe as shown in FIG. 5 may include the cannula assembly and the needle catch assembly as described in FIGS. 1-2. In some embodiments, the syringe barrel 54 as shown in FIG. 5 may include a one-way valve as described in FIG. 3, including purge valve 310. In some embodiments, the syringe barrel 54 as shown in FIG. 5 may include a one-way valve as described in FIG. 4, including the purge valve 410, the valve retainer 45, and the orifice(s) 411. In some embodiments, the interior of the

syringe barrel 54 as shown in FIG. 5 is pre-filled with fluid. In some embodiments, the syringe barrel as shown in FIG. 5 is pre-filled with fluid and/or features a pre-retracted and deployable cannula assembly, e.g., as illustrated in FIG. 7.

[0067] The safety syringe of FIG. 5 can be assembled from components made from a variety of materials. In some embodiments, the cannula 51 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing. In various embodiments, the cannula 51 is of any suitable size, as described above. In some embodiments, the hub 52 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 51 may be assembled to the hub 52 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, the washer 53 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the syringe barrel 54 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the one or more shaft seals 5 are made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the one or more shaft seals 55 are made of rubber. In some embodiments, the needle catch bung 6 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the plunger 57 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the plunger 57 has one or more orifice(s) 59. In some embodiments, the barrel seal 58 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the barrel seal 58 can be molded separately. In some embodiments, the barrel seal 58 can be overmolded onto plunger 57.

[0068] Referring to FIG. 6, in one embodiment, a safety syringe, includes a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a plunger that fits into the syringe barrel, where the interior of the plunger is manufactured at negative pressure. Thus, vacuum is preconditioned in the interior of the plunger prior to use. Thus, in some embodiments, negative pressure (i.e., vacuum) is incorporated within the interior of the plunger at the time of manufacture rather than being created during the act of injection. Upon complete depression of the plunger through the syringe barrel, and engagement of the syringe barrel with

the retractable needle assembly, the retractable needle assembly is drawn into the interior of the plunger by the negative pressure that was incorporated within the interior of the plunger at the time of manufacture.

[0069] In some embodiments, the safety syringe as depicted in FIG. 6, includes a cannula 61. The cannula 61 is permanently attached to the hub 62 to form a cannula assembly 61 and 62. The cannula assembly 61 and 62 are located at the distal end of the syringe barrel 64. The proximal end of cannula assembly 61 and 62 is positioned in the center of a washer 63. The washer 3 creates a water tight seal at the hub 62 and the syringe barrel 64. A needle catch 65 is permanently attached to a piston bung 66. The barrel seal 68 is affixed to plunger 67. The needle catch assembly 65 and 66 is held in an inner diameter of the plunger 67. The bung 66 creates an air tight seal an inner diameter of plunger 67. The size of features on the needle catch 5 is such that there is some amount of interference with the distal orifice diameter of the plunger 67. The internal volume of plunger 67 sealed with the piston bung 67 is at negative pressure.

[0070] In some embodiments, the safety syringe of FIG. 6 is designed to retract cannula assembly 61 and 62 into the internal volume of the plunger 67 upon complete depression of the plunger 67 by the user. After filling of the device, the plunger 67 is depressed so that the needle catch 65 engages the hub 62 and becomes affixed. While depressing the plunger 67 the shoulder feature on plunger 67 will displace the washer 63 so that cannula assembly 61 and 62 is free to move. Immediately after release of the cannula assembly 61 and 62 from the washer 63, further travel of the plunger handle in the distal direction will push the needle catch 65 through the distal orifice diameter of plunger 67 thus releasing the needle catch assembly 5 and 6 along with the affixed cannula assembly 61 and 62. At this time the needle catch assembly 65 and 66 and cannula assembly 61 and 62 will be aspirated in to the plunger 67 portion which is proximal to the distal orifice in plunger 67 by the supplied negative pressure.

[0071] In some embodiments, the syringe as shown in FIG. 6 can incorporate any permutation of the features described in FIGS. 1-5 and FIG. 7. In some embodiments, the syringe as shown in FIG. 6 can include the cannula assembly and the needle catch bung as described in

FIGS. 4 and 5. In some embodiments, the syringe barrel 64 as shown in FIG. 6 can include a one-way valve as described in FIG. 3, such as the purge valve 310. In some embodiments, the syringe barrel 64 as shown in FIG. 6 can include a one-way valve as described in FIG. 4, including the purge valve 410, valve retainer 45, and orifice(s) 411. In some embodiments, the interior of the syringe barrel as shown in FIG. 6 is not pre-filled with fluid. In some embodiments, the interior of the syringe barrel as shown in FIG. 6 is pre-filled with fluid. In some embodiments, the syringe barrel as shown in FIG. 6 is pre-filled with fluid and/or features a pre-retracted and deployable cannula assembly, e.g., as illustrated in FIG. 7.

[0072] The safety syringe of FIG. 6 can be assembled from components made from a variety of materials. In some embodiments, the cannula 61 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing). In various embodiments, the cannula 61 is of any suitable size, as described above. In some embodiments, the hub 62 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 61 may be assembled to hub 62 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, the washer 63 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the syringe barrel 64 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the needle catch 65 is made of plastic (e.g., polypropylene plastic, injection molded plastic, or injection molded polypropylene plastic). In some embodiments, the bung 66 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the bung 66 can be molded separately. In some embodiments, the bung 66 can be overmolded onto needle catch 65. In some embodiments, the plunger 67 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the barrel seal 68 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the barrel seal 68 can be molded separately. In some embodiments, the barrel seal 8 can be overmolded onto plunger 67. The plunger assembly 65, 66, and 67 may be assembled in a negative pressure atmosphere to precondition the internal volume of the plunger, and/or evacuated and sealed.

[0073] Referring to FIG. 7, in one embodiment a pre-filled safety syringes includes a retractable needle assembly, a syringe barrel for the withdrawal or injection of fluids, and a hollow plunger (e.g., of cylindrical shape) that fits into the syringe barrel. The retractable needle assembly may be pre-retraced, such that the device ships with the needle safely housed within the syringe body. The retractable needle assembly is initially deployed by depressing the plunger.

[0074] In some embodiments, negative pressure is created within the interior of the syringe barrel during the act of injection as the hollow plunger is depressed through the syringe barrel towards the retractable needle assembly. One or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the vacuum that is created during the act of injection. Upon substantial and/or complete depression of the hollow plunger through the syringe barrel, one or more orifice(s) in the wall of the hollow plunger enter the interior of the syringe barrel. Thus, the negative pressure of the interior of the syringe barrel evacuates air from the interior of the cylindrical plunger and distributes negative pressure throughout both the syringe barrel and the cylindrical plunger. Upon engagement of the hollow syringe barrel with the retractable needle assembly, the retractable needle assembly is drawn into the interior of the hollow plunger by the vacuum created in the hollow plunger and/or syringe barrel by the act of injection.

[0075] For example, in one embodiment, a safety syringe includes a cannula 71. The cannula 71 is permanently attached to a hub 72 to form a cannula assembly 71 and 72. The cannula assembly 71 and 72 are initially located internal to the syringe barrel 74 at the distal end of the syringe barrel 74. The proximal end of the cannula 71 is held in the center of a needle shuttle bung 711. A syringe barrel feature locates needle assembly 71, 72 centrally to the syringe barrel 74. Needle shuttle seal 79 is permanently attached to a needle shuttle 710 to form a needle shuttle assembly 79 and 710. The needle shuttle bung 711 is held by the needle shuttle assembly 79 and 710 creating a seal between the needle shuttle bung 711 and the syringe barrel 74. Barrel seal 78 is affixed to plunger 77. Needle catch bung 6 is held in a certain size inner diameter of plunger 77. Needle catch bung 76 creates an air tight seal with a certain size inner diameter of plunger

77. The prefilled fluid exists in the space between the needle shuttle assembly 79, 710 and 711 and the plunger assembly 76, 77 and 78. The proximal end of the syringe barrel 74 which the plunger 77 passes through can be a separate piece assembled to the majority of the syringe barrel 74 providing an airtight seal between the two pieces. The plunger 77 shaft passes through one, two or more shaft seals 75 to provide an air tight seal between the syringe barrel 74 and plunger 77. Purge valve 710 is affixed to the proximal end of syringe barrel 74.

[0076] Depressing plunger 77 in a distal direction causes the fluid, shuttle assembly 79, 710, 711 and cannula assembly 71, 72 to move in a distal direction until the hub 72 becomes engaged with the distal end of syringe barrel feature 73. Further depressing the plunger 77 causes the proximal end of the cannula 71 to pass through the needle shuttle bung 711. This allows the pre-filed fluid to pass through the internal diameter of the cannula 71. The needle shuttle bung 711 will come to rest after the cannula 71 has passed through it and mayor may not be in contact with the hub72 at this time. The plunger 77 is depressed where the needle catch bung 76 engages the cannula 71 and becomes affixed. The needle catch bung 76 and the cannula 71 can become affixed via piecing or other interlocking geometry. At this time fluid flow through the inner diameter of cannula 71 will stop. As the plunger 77 is depressed negative pressure is created on the proximal side of the barrel seal 8. Prior to release of the cannula assembly 71 and 72, the orifice 711 on the plunger 77 enters the negative pressure volume of the syringe barrel 74 joining the negative pressure volume of the syringe barrel 4 and the internal volume of the plunger 77. While depressing the plunger 77 further, features on plunger 77 or needle catch bung 76 will displace the shuttle assembly 79,710 causing needle shuttle bung 711 to be released from shuttle 10 so that the cannula assembly 71, 72 and attached needle shuttle bung 711 are free to move. After release of the cannula assembly 71, 72 and the needle shuttle bung 711 further travel of the plunger 77 handle in the distal direction will push the needle catch bung 76 through the distal orifice diameter of plunger 77 thus releasing the needle catch bung 6 along with the affixed cannula assembly 71, 72 and needle shuttle bung 711. At this time the needle catch bung 76, cannula assembly 71, 72 and needle shuttle bung 711 will be aspirated in to the plunger 77

portion which is proximal to the distal orifice in plunger 77 by the negative pressure previously created.

[0077] In some embodiments, the syringe as shown in FIG. 7 can incorporate any permutation of the features described in FIGS. 1-6. In some embodiments, the hollow plunger 77 as shown in FIG. 7 can be replaced with the plunger handle posts, needle catch adapter, barrel seal, and syringe barrel end cap as shown in FIG. 1. In some embodiments, the hollow plunger 77 as shown in FIG. 7 can be replaced with the plunger 67 as shown in FIG. 6, which is pre-conditioned at negative pressure. In some embodiments, the syringe as shown in FIG. 7 may include the cannula assembly and the needle catch assembly as described in FIGS. 1-2. In some embodiments, the syringe as shown in FIG. 7 can include the cannula assembly and the needle catch bung as described in FIGS. 4-5. Syringe barrel 74 may incorporate any valve described in FIGS. 3 and 4, as described herein, to allow air to escape from the proximal side of the barrel seal when the plunger is withdrawn, but which seals airtight when the plunger is depressed. In some embodiments, the syringe barrel 74 as shown in FIG. 7 can include a one-way valve as described in FIG. 3, including purge valve 310. In some embodiments, the syringe barrel 74 as shown in FIG. 7 can include a one-way valve as described in FIG. 4, including the purge valve 410, valve retainer 45, and orifice(s) 411. In some embodiments, the interior of the syringe barrel 74 as shown in FIG. 7 is shown in FIG. 7 is not pre-filled with fluid, allowing the syringe to operate in the conventional fashion.

[0078] The safety syringe of FIG. 7 can be assembled from components made from a variety of materials. In some embodiments, cannula 71 is made of stainless steel tubing (e.g., medical hypodermic stainless steel tubing). In various embodiments, cannula 1 is of any suitable size, as described above. In some embodiments, hub 72 is made of plastic (e.g., injection molded polypropylene plastic). In some embodiments, the cannula 1 may be assembled to hub 72 by any method known to one of ordinary skill (e.g., over molding, UV glue bonding, or other any other bonding method). In some embodiments, the syringe barrel 4 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the shaft seals 75 are made of an elastomer (e.g., injection molded thermoplastic elastomer). In some

embodiments, the bung 76 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, needle plunger 77 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic). In some embodiments, the barrel seal 8 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, barrel seal 78 can be molded separately. In some embodiments, barrel seal 78 can be overmolded onto needle catch adapter 77. In some embodiments, the needle shutter seal 79 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, the needle shuttle 710 is made of an elastomer (e.g., injection molded thermoplastic elastomer). In some embodiments, end cap seals 10 is made of plastic (e.g., polypropylene plastic or injection molded polypropylene plastic).. In some embodiments, the needle shuttle bung 711 plunger handle 711 is made of an elastomer (e.g., injection molded thermoplastic elastomer).

[0079] Devices of the types described herein may be used for any suitable purpose including, but not limited to, injections and or phlebotomy.

[0080] The present disclosure is not to be limited in terms of the particular embodiments described in this application, which are intended as illustrations of various aspects. Many modifications and variations can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. Functionally equivalent methods and apparatuses within the scope of the disclosure, in addition to those enumerated herein, will be apparent to those skilled in the art from the foregoing descriptions. Such modifications and variations are intended to fall within the scope of the appended claims. The present disclosure is to be limited only by the terms of the appended claims, along with the full scope of equivalents to which such claims are entitled. It is to be understood that this disclosure is not limited to particular methods, reagents, compounds compositions or biological systems, which can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

[0081] With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the

plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

[0082] It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims (e.g., bodies of the appended claims) are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to embodiments containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an" (e.g., "a" and/or "an" should be interpreted to mean "at least one" or "one or more"); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should be interpreted to mean at least the recited number (e.g., the bare recitation of "two recitations," without other modifiers, means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to "at least one of A, B, and C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., " a system having at least one of A, B, and C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). In those instances where a convention analogous to "at least one of A, B, or C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., " a system having at least one of A, B, or

C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

[0083] In addition, where features or aspects of the disclosure are described in terms of Markush groups, those skilled in the art will recognize that the disclosure is also thereby described in terms of any individual member or subgroup of members of the Markush group.

[0084] As will be understood by one skilled in the art, for any and all purposes, such as in terms of providing a written description, all ranges disclosed herein also encompass any and all possible subranges and combinations of subranges thereof. Any listed range can be easily recognized as sufficiently describing and enabling the same range being broken down into at least equal halves, thirds, quarters, fifths, tenths, etc. As a non-limiting example, each range discussed herein can be readily broken down into a lower third, middle third and upper third, etc. As will also be understood by one skilled in the art all language such as "up to," "at least," "greater than," "less than," and the like include the number recited and refer to ranges which can be subsequently broken down into subranges as discussed above. Finally, as will be understood by one skilled in the art, a range includes each individual member. Thus, for example, a group having 1-3 cells refers to groups having 1, 2, or 3 cells. Similarly, a group having 1-5 cells refers to groups having 1, 2, 3, 4, or 5 cells, and so forth.

[0085] All definitions, as defined and used herein, should be understood to control over dictionary definitions, definitions in documents incorporated by reference, or ordinary meanings of the defined terms.

[0086] While the present invention has been described in connection with the preferred embodiments of the various figures, it is to be understood that other similar embodiments may be

used or modifications or additions may be made to the described embodiment for performing the same function of the present invention without deviating therefrom. Therefore, the present invention should not be limited to any single embodiment, but rather construed in breadth and scope in accordance with the recitation of the appended claims.

WHAT IS CLAIMED IS:

1. A syringe comprising:

a retractable needle assembly;

a syringe barrel for the withdrawal or injection of fluids; and

a plunger comprising one or more plunger handle posts that fit into the syringe barrel;

wherein the syringe barrel and plunder handle posts are configured and arranged such that negative pressure is created within the interior of the syringe barrel during an act of injection as the plunger handle posts are depressed through the syringe barrel towards the retractable needle assembly.

2. The syringe of claim 1, further comprising:

a one-way valve which prevents airflow into an interior volume of the syringe barrel and thereby maintain the negative pressure that is created during an act of injection, while no positive pressure is built up during loading of the syringe.

3. The syringe of claim 2, wherein the syringe barrel comprises an end cap comprising at least one one-way valve.

4. The syringe of claim 3, wherein, upon complete depression of the plunger handle posts through the syringe barrel, the retractable needle assembly is drawn into the syringe barrel by the negative pressure created in the interior of the syringe barrel.

5. A syringe comprising:

a retractable needle assembly,

a syringe barrel for the withdrawal or injection of fluids, and

a hollow plunger that fits into the syringe barrel;

wherein the syringe barrel is configured and arranged such that negative pressure is created within the interior of the syringe barrel during an act of injection as the hollow plunger is depressed through the syringe barrel towards the retractable needle assembly.

6. The syringe of claim 5, further comprising one or more one-way valves prevent airflow into the interior of the syringe barrel and thereby maintain the negative pressure that is created during the act of injection.

7. The syringe of claim 6, wherein upon substantial or complete depression of the hollow plunger through the syringe barrel, an orifice in the wall of the hollow plunger enters the interior of the syringe barrel such that the syringe barrel in placed in pneumatic communication with an internal volume of the hollow plunger to facilitate retraction of the needle assembly.

8. The syringe of claim 7, wherein the one way valve comprises:

a seal member configured such that the plunger passes through the seal ember into the syringe barrel; and

wherein the seal member is retained in a groove in the syringe barrel and is configured to provide an air tight seal when negative pressure is created in the internal volume of syringe barrel by movement of the plunger in a distal direction toward the needle assembly.

9. The syringe of claim 8, wherein the groove and the shaft are configured and arranged such that:

an increase of negative pressure created when the plunger is moved in the distal direction causing the airtight seal to become more robust, and

the airtight seal is broken such that pressure in the syringe barrel is released when the plunger is actuated in a proximal direction away from the needle assemble.

10. The syringe of claim 7, wherein the one way valve comprises a purge valve affixed to the syringe barrel covering an orifice in the syringe barrel, the purge valve configured to:

provide an airtight seal when negative pressure is created in the internal volume of the syringe barrel, and

release the airtight seal when positive pressure is created in the internal volume.

11. The syringe of claim 10, wherein the purge valve comprises an elastomeric band disposed about the syringe barrel and covering the orifice in the syringe barrel.

12. The syringe of claim 10, wherein the purge valve comprises:

a valve member that extends through an orifice in the syringe barrel, seals against the syringe barrel in response to negative pressure in the syringe barrel, and unseals in response to positive pressure in the syringe barrel; and

a valve retaining member that retains the valve member in position when the valve member is unsealed.

13. A syringe comprising:

a retractable needle assembly,

a syringe barrel for the withdrawal or injection of fluids, and

a plunger that fits into the syringe barrel, where the interior of the plunger is manufactured to be at negative pressure.

14. The syringe of claim 13, wherein:

upon on complete depression of the plunger through the syringe barrel, and engagement of the syringe barrel with the retractable needle assembly, the retractable needle assembly is drawn into the interior of the plunger by the preexisting negative pressure that was incorporated within the interior of the plunger at the time of manufacture.

15. The syringe of any preceding claim wherein the syringe is pre-filled.

16. The syringe of any preceding claim, wherein the retractable needle assemble is pre-retracted.

17. The syringe of an preceding claim, wherein the plunger comprises a needle catch configured to attach to the needle assembly when the plunder is depressed.

18. The syringe of claim 17, wherein the needle catch assembly comprises a bung member that is configured to be pierced by a portion of the needle assembly extending into the syringe barrel when the plunder is depressed.

19. The syringe of claim 17, wherein the needle catch assembly comprises a bung member that is configured to attach to a portion of the needle assembly extending into the syringe barrel when the plunder is depressed.

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20. A method comprising, using the syringe of any preceding claim:

dispensing a fluid from the syringe;

upon dispensing the fluid, causing at least a portion of the needle assemble to retract into the syringe barrel.

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21. The method of claim 20, further comprising, prior to dispensing the fluid from the syringe, loading the syringe with the fluid.

:

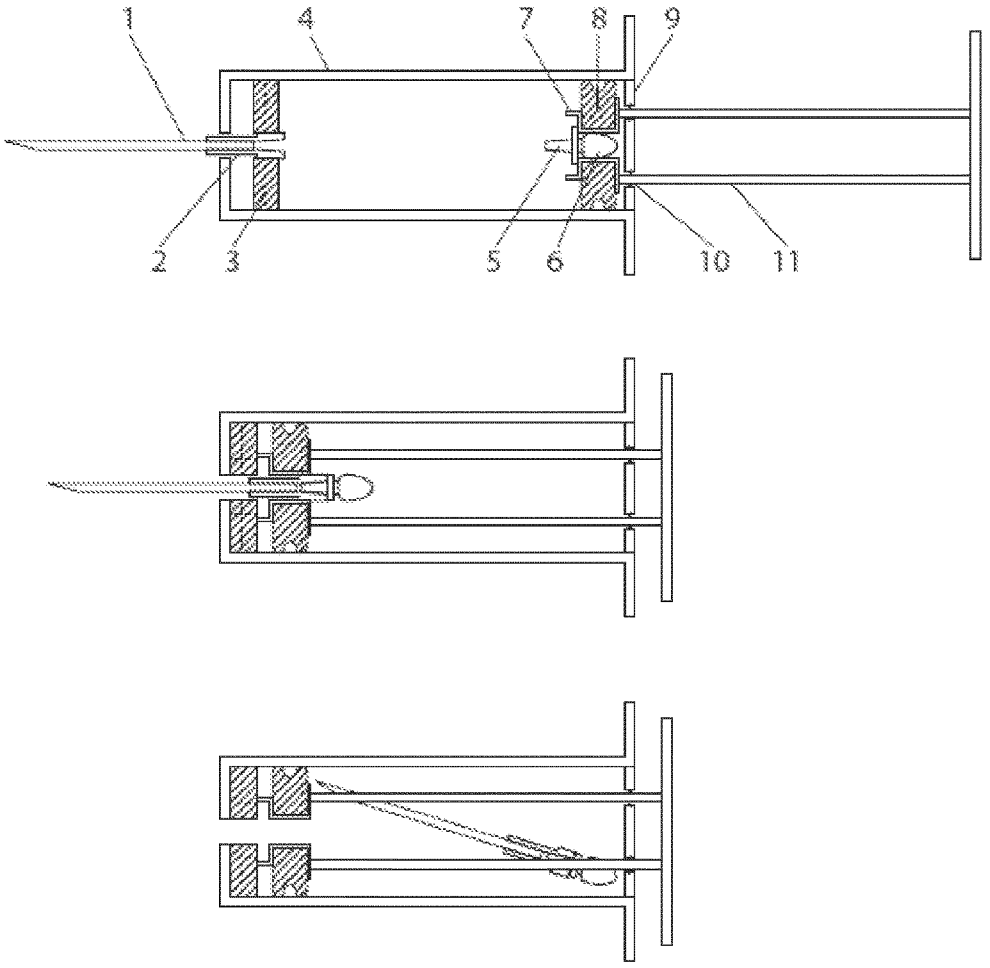

FIG. 1

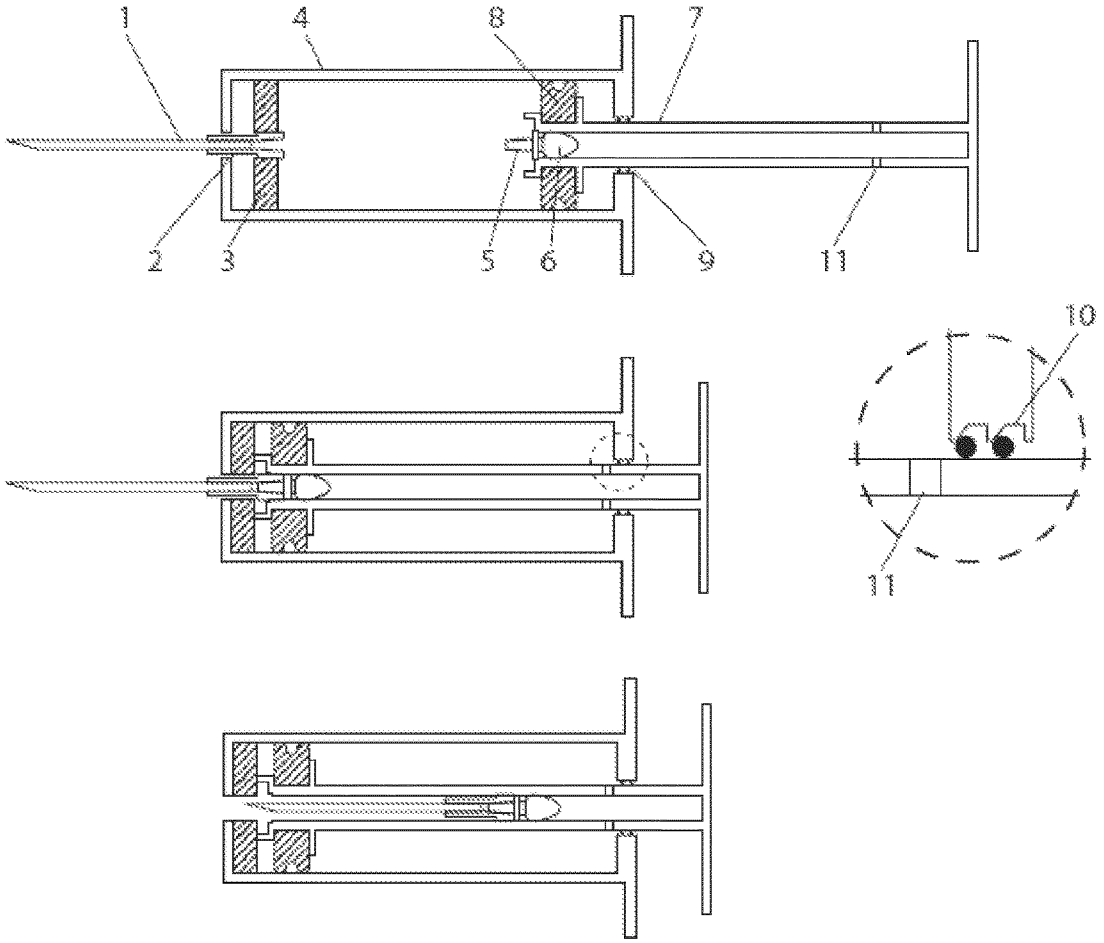

FIG. 2

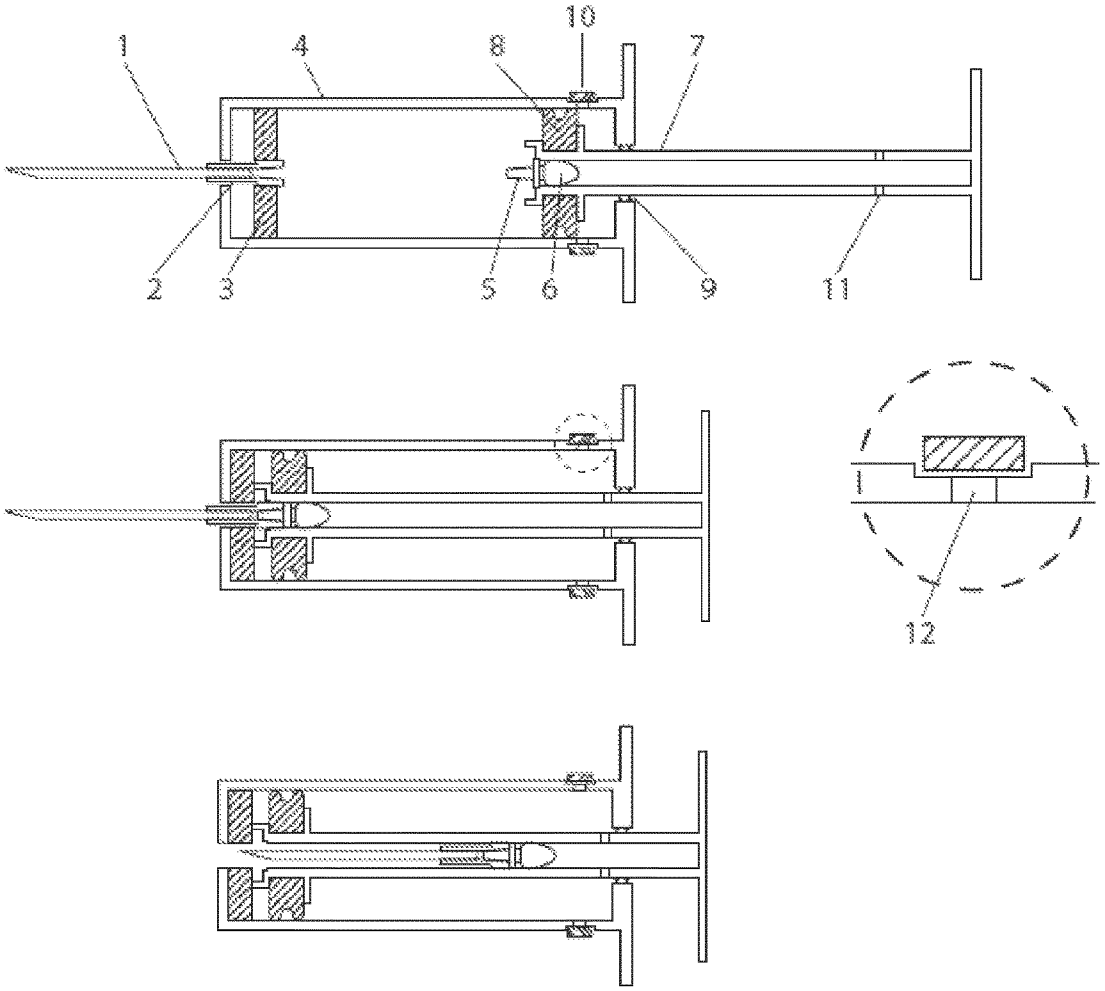

FIG. 3

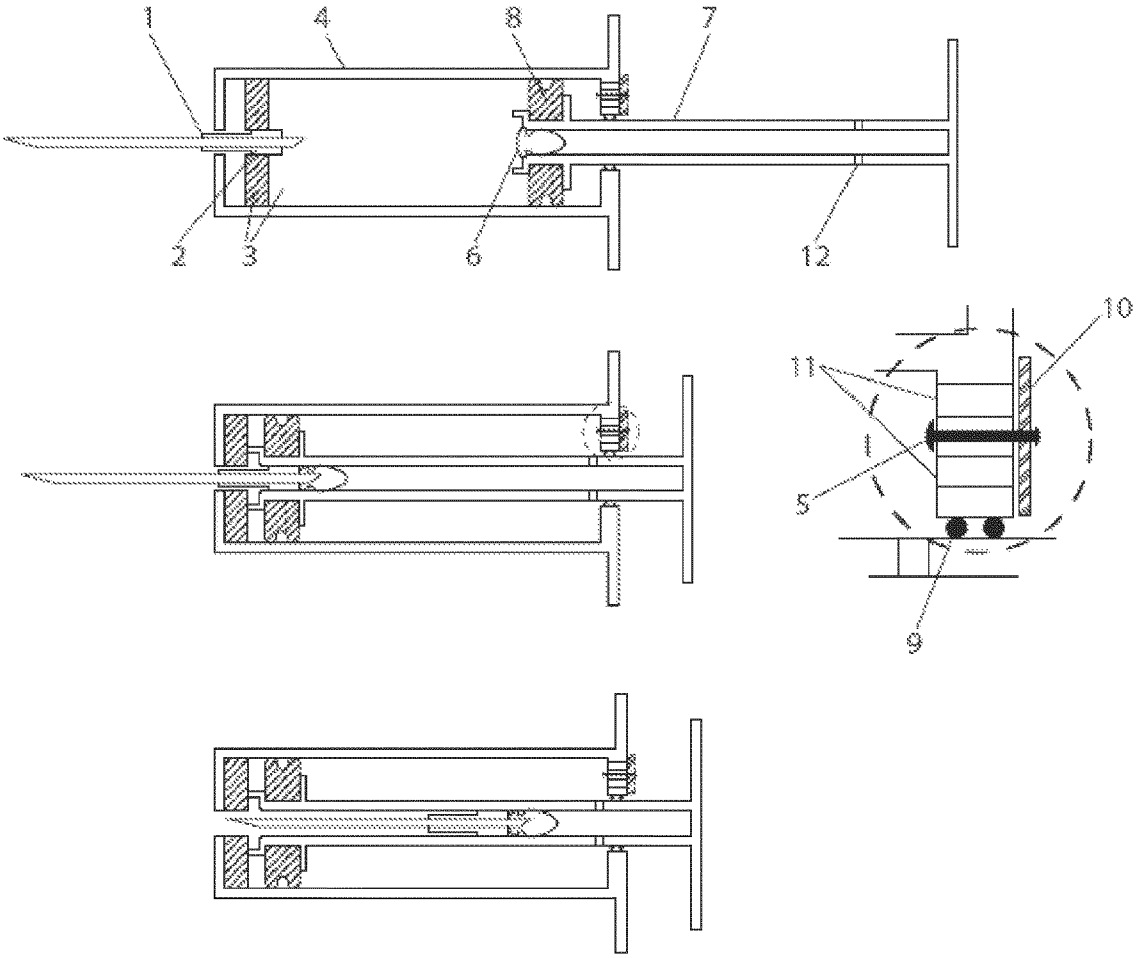

FIG. 4

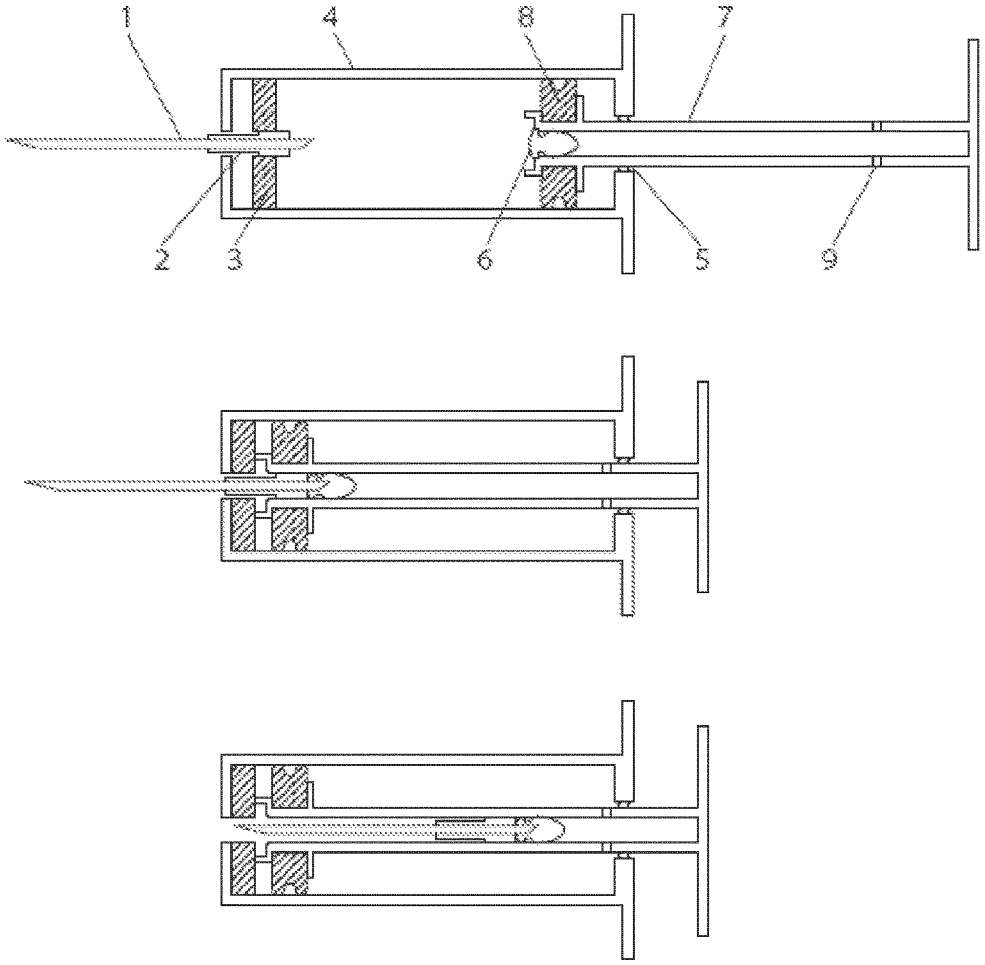

FIG. 5

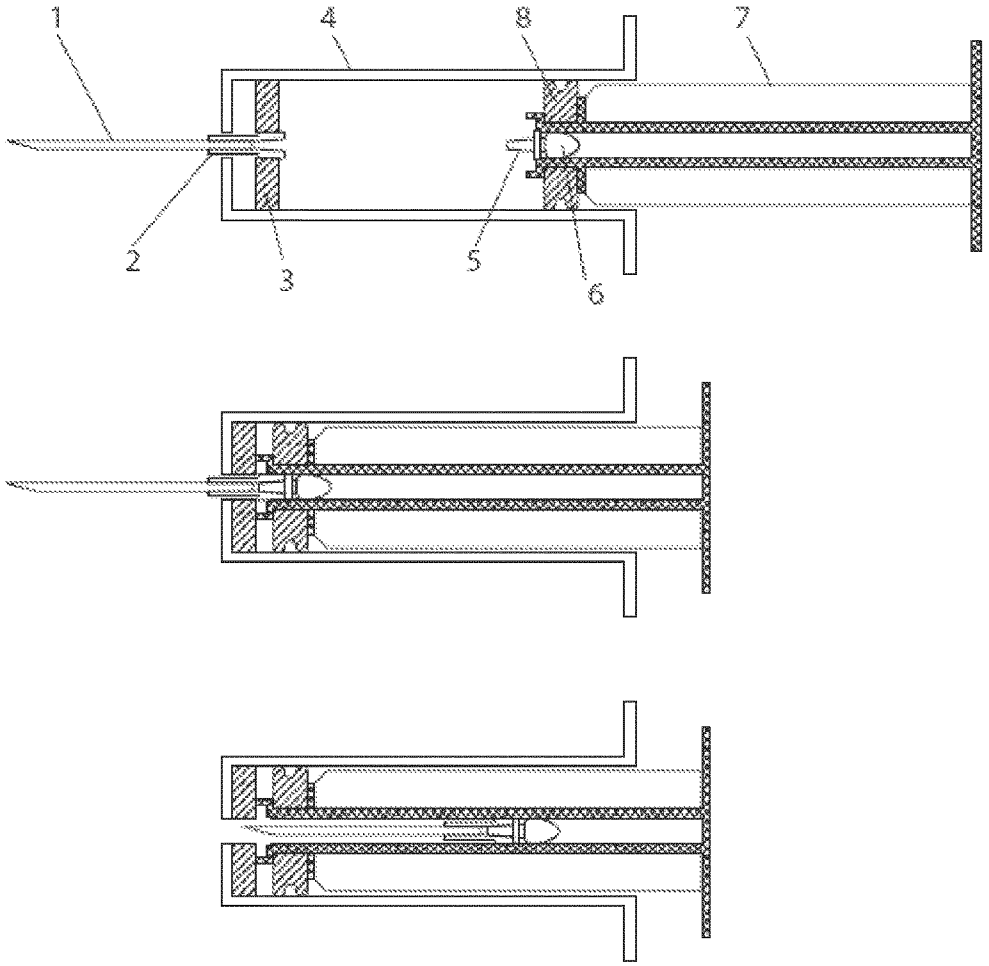

FIG. 6

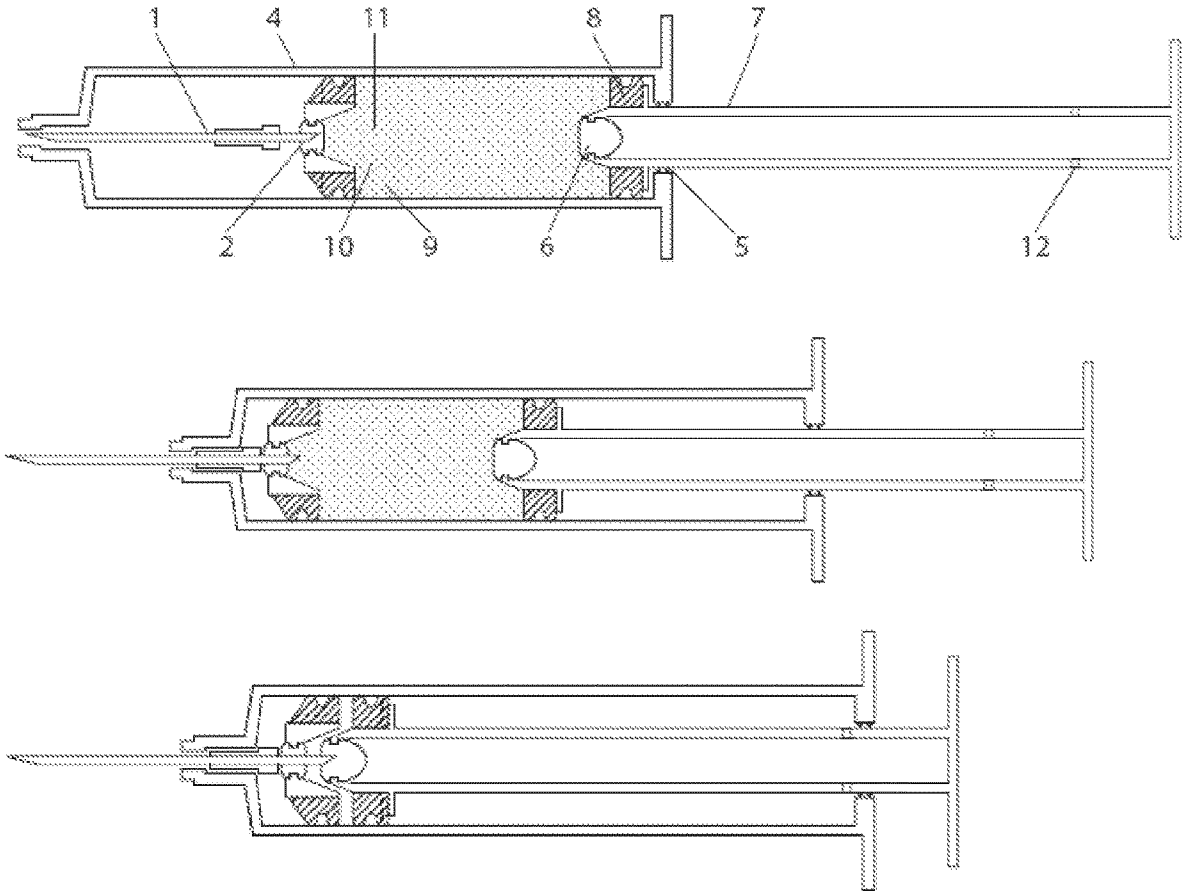

FIG. 7