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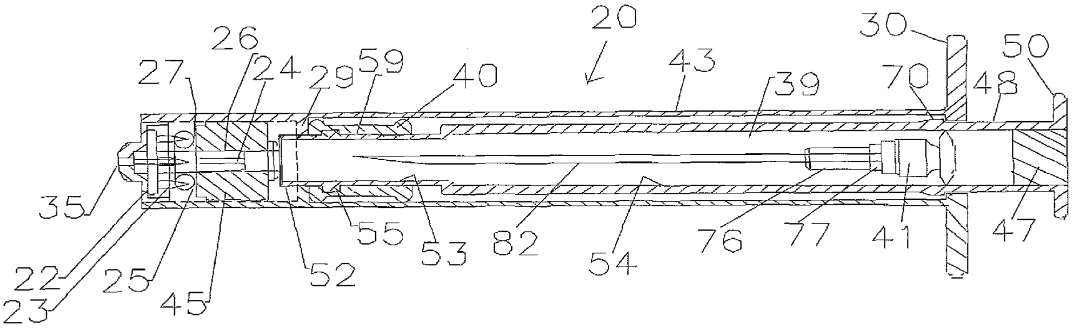
(54) Title: GAS-ACTUATED RETRACTABLE SYRINGE



(57) Abstract: A pneumatic retractable syringe has a plunger having an interior retraction lumen. The plunger and syringe barrel have cooperating locking elements so that the plunger is locked after use within the syringe barrel. After injection of medicament is completed, the needle is retracted into the lumen by compressed gas that is released from a gas cell within the syringe when the gas cell is ruptured just before the plunger reaches the end of its downstream path of travel.

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SINGLE-USE PNEUMATIC SAFETY SYRINGE WITH RETRACTABLE NEEDLE

FIELD OF THE INVENTION

[0001] The invention relates generally to a pneumatic safety syringe of the type for use with a hypodermic needle. In a syringe according to the present invention, following use of the syringe, the plunger is locked into the syringe body (barrel) and the needle is retracted into the retraction lumen of the plunger, thereby preventing accidental stabbing after use and unwanted re-extension of the plunger out of the barrel. The retraction of the needle is effected by the release of gas under pressure or other suitable pneumatic means; *e.g.* obtained by puncturing a gas cell or by causing a chemical reaction that will release gas. A syringe of this general type is sometimes referred to as a "retractable syringe"; what is meant by this term is that the needle retracts within the body of the syringe.

BACKGROUND OF THE INVENTION

[0002] It is well known that many dangerous communicable diseases are spread through contacting the body fluids of an infected person. After use of a syringe, residual body fluids are likely to remain on or within the syringe needle. For this reason, syringes are typically intended for a single use only. In order to be handled safely after use, the needle of a syringe must be covered to prevent it from accidentally stabbing a person who is, for example, collecting the syringe for disposal, thereby releasing residual body fluids into such person. Typically, a protective cap is provided with the syringe, which after use of the syringe, can be used to cover the tip of the needle. However, it sometimes happens that persons attempting to cap a used needle miss the cap and accidentally stab themselves, resulting in potential exposure to communicable diseases. Further, spread of communicable and dangerous diseases is effected by drug-addicted individuals sharing and re-using needles and syringes intended for single use.

[0003] There have been several attempts to address this problem by incorporating into syringes, mechanisms for retracting the needle into the syringe following use. U.S. Patent No. 5,334,155 (Sobel, 2 August 1994) discloses a needle guard comprising an evacuated double walled protective sheath. Before use, the partial vacuum within the protective sheath causes the sheath to fold inwardly upon itself so that the needle extends beyond the protective sheath and may be used for injections. Subsequent to injection, the double wall of the protective sheath can be breached in one place so that the inside of the protective sheath reaches atmospheric pressure. The protective sheath then extends to cover the projecting needle. However, the protective sheath may interfere with use of the syringe as it may obstruct the view of the point the needle is to be inserted into the patient. In addition, it is inconvenient to use; after injection, the user must change the user's hand position on the syringe in order to breach the double wall and activate the sheath. In this manner activation of the safety mechanism is not automatic following injection of the medicament.

[0004] The protective safety device shown in U.S. Patent No. 5,188,614 (Hart, 23 February 1993) is a hollow cylindrical casing that encompasses the syringe. A dual component foaming agent is disposed at the downstream end of the casing. Following injection, the two components of the dual component foaming agent are mixed, creating an expanding foam mixture that forces the syringe back within the casing and encompasses the needle. However, this device suffers from the disadvantages that the casing may interfere with the use of the syringe in making injections as it is designed to fit over a conventional syringe thereby changing the size and feel of the device as compared to a conventional syringe. In addition, a considerable amount of material is necessary in order to make the protective sheath, increasing the expense of both making and disposing of the device.

[0005] U.S. Patent No. 6,193,695 (Rippstein, 27 February 2001) discloses a safety syringe comprising a vacuum chamber on the upstream side of the plunger head. Following injection of medicament, the plunger head engages the needle head, the ambient atmospheric pressure external to the needle head acts on the needle head, forcing the needle and plunger back against the vacuum into the syringe body. The plunger arm may then be snapped off by the user to prohibit further use of the needle. This device suffers from the disadvantage that accidental re-extension of the needle is possible if the plunger arm is not snapped off by the user. A further disadvantage of this device is that if the user does not apply a constant injection force, there is the possibility that the plunger will retract under the vacuum before the medicament is completely injected, thereby causing the syringe to work in reverse.

[0006] U.S. Patent No. 6,413,236 (Van Dyke, 2 July 2002) discloses a safety syringe comprising a vacuum chamber on the upstream side of the plunger head. Following injection of medicament, the plunger head engages the needle head, and the ambient atmospheric pressure external to the needle head acts on the needle head, forcing the needle and plunger back against the vacuum into the syringe body. In this patent, in contrast to U.S. Patent No. 6,193,695, the needle is lodged in the syringe body at an angle so that the piercing tip end of the needle is pressed against the inner surface of the syringe prohibiting re-extension of the needle even though the plunger arm is fully extended outside the syringe body. However, this device still has the disadvantage that if the user does not apply a constant injection force, there is the possibility that the plunger will retract under the vacuum before the medicament is completely injected, thereby causing the syringe to work in reverse.

[0007] The device disclosed in U.S. Patent No. 5,868,713 (Klippenstein, 9 February 1999) embodies a significant improvement over the previous syringe technology. This earlier Klippenstein syringe includes a gas reservoir that contains a non-toxic compressed gas. Once the gas reservoir is ruptured by the needle header when the needle header is forced in a downstream direction, the released non-toxic compressed gas provides an upstream biasing pressure that biases the needle header and plunger to slide upstream, retracting the needle into the syringe body. A locking mechanism prevents downstream motion of the plunger after retraction of the needle. However, at the end of the retraction phase, the plunger continues to extend outside the barrel of the syringe, thus requiring the user to have changed his hand position by moving his thumb away from the thumb button at the end of the plunger. Further, due to the retention of the plunger in the locked extended position after retraction, the extended syringe takes more space in disposal containers than do conventional syringes. It is an objective of the present invention to overcome these and other disadvantages associated with this prior Klippenstein design.

[0008] A syringe designed to provide an optimal solution to the problem of prevention of accidental needle stabbing after the use of the syringe for injection would include the following characteristics:

1. The syringe mechanism should be relatively simple, in that it should be made from as few moving parts as possible consistent with its design objectives, and should be simple to operate, preferably with the look and feel of a conventional syringe..
2. The syringe mechanism should reliably retract the needle or otherwise reliably shield the needle after use, so that accidental stabbing is prevented.
3. The syringe should be relatively inexpensive to manufacture.
4. There should be a minimum of waste plastics and other materials to be disposed of after use of the syringe.
5. Safety-related means should not appreciably interfere with the feel of the syringe in the user's hand.
6. Once the needle has been retracted or shielded, a reliable safety device should prevent the needle from becoming once again exposed.

Note that simplicity of structure and operation, objective 1 above, may contribute to the achievement of the other five objectives listed above.

SUMMARY OF THE INVENTION

[0009] A principal objective of the present invention is to provide a syringe of the type for use with a hypodermic needle in which, after injection of medicament is complete, the needle is automatically retracted into the retraction lumen of the plunger and the plunger is locked within the syringe body (barrel). Further objectives include the elimination or reduction of disadvantages associated with prior syringe designs, including the prior Klippenstein syringe disclosed in U.S. Patent No. 5,868,713.

[0010] A safety syringe according to the invention comprises a syringe barrel, plunger, and means for assembling a needle in the syringe. (The needle may be part of the complete assembly or may be installed later, depending upon the design selected.) The gross structural characteristics and operating characteristics of syringes according to the invention may be generally similar to those of prior designs, except as herein described. Among the principal characteristics of syringes of the present invention that differentiate them from prior syringes are the following:

a. The plunger, axially movable within the barrel, has therewithin an axially extending retraction lumen open at its distal end to receive the needle after use of the syringe. The lumen is dimensioned to receive sufficient of the combined length of the needle and the needle carrier to be mentioned below that, after retraction, the needle point remains within the plunger lumen.

b. A gas release cell is located within the assembled syringe distally of the plunger. The gas release cell, which in relation to the preferred embodiments illustrated contains gas under pressure and is sometimes referred to herein as a gas cell, is intact and inoperative prior to substantial completion of injection of medicament by downstream motion of the plunger. For use in the preferred embodiments described in detail below, the gas cell is preferably a discrete self-contained component separately assembled into the syringe and containing suitably selected non-toxic non-corrosive gas under pressure. The gas cell is preferably rupturable to release the gas, but instead may comprise initially separated chemical constituents which may be controllably mingled after substantial completion of injection thereby to cause a chemical reaction that releases gas under pressure.

c. A gas release trigger means located within the assembled syringe between the distal end of the plunger and the gas release cell is operable, in response to downstream motion of the plunger as it approaches its downstream limit of travel, to cause the gas release cell to release gas into the interior of the syringe. In the preferred embodiments described herein for use with a discrete rupturable gas cell, the gas release trigger means preferably comprises a perforator having puncture lances, but instead could comprise tearing or crushing means for breaching the wall of the gas cell. If an alternative gas release cell is employed, such as a two-compartment cell, each compartment containing a separate chemical constituent, the constituents when mingled causing a chemical reaction that releases gas under pressure, then the gas release trigger could comprise, for example, means for rupturing a dividing wall between the two compartments after substantial completion of injection, and then concurrently or preferably shortly thereafter rupturing the outer wall of the gas release cell.

d. A needle carrier is coupled to the needle in the vicinity of the proximal end of the needle. The needle carrier is movable axially within the plunger lumen and has a distal bearing surface against which gas under pressure may bear. The needle carrier moves into the plunger lumen under gas pressure, carrying the needle with it, so as to retract the needle into the lumen. (Of course, there must be a suitable flowpath available for the gas to reach the needle carrier. In some cases, it may be desirable to constrict the flowpath to avoid a sudden surge of pressurized gas against the bearing surface of the needle carrier.) The needle may be formed so as to have a needle header at its proximal end or may be otherwise fixed to a needle header located at or near the proximal end of the needle. The needle carrier in such latter instances may be fixed or coupled to the needle header. The needle carrier preferably includes a sealing element slidingly engaging the walls of the lumen. Because in one preferred embodiment the lumen is constricted at its distal end, the sealing element in such embodiment should be resiliently expandable in diameter to provide a sealing contact with the walls of the large-diameter portion of the lumen once it moves upstream from the constricted distal portion of the lumen.

e. In addition to the needle carrier, whose design enables it to provide an acceptable level of gas sealing upstream of the gas under pressure, one or more further gas barriers are provided for preventing or impeding unwanted escape of gas from the syringe prior to full needle retraction. At least some of the gas barriers may be provided by suitably snug or tight fits between mating components. In some cases, sliding engagement of parts is sufficiently close that serious loss of gas is prevented. Some of these barriers may also serve to block unwanted escape of medicament from the syringe. The objectives are, of course, (i) to have substantially all of the medicament in the syringe injected into the patient and not to leak out of the syringe, and (ii) to have gas pressure drive the needle carrier into the plunger lumen after injection so that the needle becomes fully retracted, and not to have the pressurized gas dissipate before the needle-retraction phase of syringe operation is complete.

f. A needle re-emergence barrier is preferably provided for preventing or impeding downstream movement of the needle following its retraction into the lumen.

[0011] Of course, the principal function of the syringe, *viz* to draw medicament into the barrel and then to inject the medicament into a patient, must not be significantly impeded by incorporation into the syringe of the inventive features of the present invention. To this end, for example, upstream motion of the needle and needle carrier into the lumen must be impeded during filling of the syringe barrel with medicament and injection of medicament into the patient. To a major and possibly a complete extent, depending upon the specific syringe design elected, friction and hand pressure on the plunger may serve to meet the foregoing objectives.

[0012] The design of the gas flow path, the components and surfaces responsive to gas pressure, and the gas and liquid blocking elements in any implementation of a syringe design according to the invention should be effective to enable normal medicament charging and normal medicament injection phases of operation without appreciable risk of loss or leakage of medicament and without appreciable interference with normal operational look and feel of the syringe. The foregoing objectives are common to syringe designs of many types and should be readily addressable by any competent syringe designer with the assistance of the present description. Note that the syringe according to the invention should be designed so that the gas pressure is effective during the needle-retraction phase of operation to drive the needle into the plunger lumen, but not to drive the plunger upstream out of the barrel. To this end, the needle must be attached or coupled to a movable element responsive to the gas pressure; both that element and the needle must under gas pressure freely enter and travel upstream into the plunger lumen. When the movable element is forced upstream, the needle perforce travels with it. Further, the syringe must be designed so that the gas released from the gas release cell can reach the movable element and be able to apply an effective upstream force to it. During the retraction of the needle, upstream motion of the plunger should be impeded by the interaction or engagement of the component parts of the syringe and not merely by hand pressure of the user. Escape of gas downstream through the needle aperture and out of the syringe would be wasteful and inefficient, and should be prevented or impeded while the needle is being retracted. Once the needle has been retracted, its re-emergence from the plunger lumen should be blocked.

[0013] For realization of some of the principal advantages of preferred embodiments of the invention, a syringe according to the invention also comprises a plunger lock for impeding or preventing unwanted re-extension of the plunger out of the barrel after use of the syringe. The plunger lock comprises a plunger engagement element fixed to the plunger and a cooperating engagement element fixed to the barrel. The engagement elements are located so as to make engaging contact with one another near the downstream limit of travel of the plunger. Further downstream motion of the plunger past the point of engaging contact causes the locking of the plunger within the syringe at or near the downstream limit of travel of the plunger. In order to prevent unwanted gas-driven upstream displacement of the plunger prior to its locking, the plunger lock may be structured to lock the plunger to the barrel at a point in the downstream path of travel of the plunger slightly upstream of the point at which the gas release trigger means operates to cause the gas release cell to release gas. However, because the depression of the plunger to its downstream limit is usually effected in a continuous hand-driven motion, the momentum of that motion is normally sufficient to lock the plunger to the barrel and to rupture the gas release cell, whether the plunger locking precedes the rupturing or is substantially coincident with rupturing or even if the rupturing slightly precedes the plunger locking.

[0014] A syringe according to the invention may additionally have a needle re-emergence barrier located downstream of the tip of the needle after the needle has been retracted into the plunger lumen, for preventing or impeding downstream movement of the needle following its retraction into the lumen. This barrier may preferably be a suitable needle port closure means.

[0015] In some preferred embodiments of the inventive syringe, the barrel is divided internally into a smaller downstream chamber for housing the gas release cell and gas release trigger means, and an upstream chamber for containing medicament to be injected, the said chambers being separated by a radial chamber separator wall having an axial opening therein for discharge of medicament from the upstream chamber into the needle and for receiving the needle into the plunger lumen after injection.

[0016] The inventive syringe in the foregoing embodiments may further comprise within the downstream chamber an engagement ring slidably but with friction engaging the interior circumferential wall of the downstream chamber and axially movable therein. The engagement ring should be relatively immobile within the downstream chamber unless subjected to deliberately applied force. The engagement ring is located between the gas release cell and the radial separator wall and has a central aperture through which medicament from the upstream chamber into the needle may flow and through which passage of the needle into the plunger lumen occurs after injection. The engagement ring provides a buffer against which the gas cell is constrained so as to facilitate rupture of the gas cell by the perforator. The engagement ring engages the needle header to provide support thereto and facilitates alignment of the needle and the needle header within the downstream chamber. Optimally, the distal end of the plunger engages the upstream end of the engagement ring near the downstream limit of travel of the plunger, forcing the gas release cell into rupturing contact with the perforator upon completion of downstream movement of the plunger.

First exemplary embodiment

[0017] In one embodiment of the present invention, a single-use needle-retracting pneumatic safety syringe, for reducing the risk of accidental needle stabbing after use, comprises a syringe barrel, and operatively located within or partially within the barrel, the following components: a hollow plunger whose hollow interior defines a retraction lumen, a needle port seal, a needle header for holding a needle, a slidable displaceable cylindrical object with a central axial opening (hereinafter frequently and whimsically referred to as an "engagement ring", for reasons to be described below), a gas cell, a perforator, and a plunger lock. The syringe barrel is hollow and has an upstream barrel opening and a downstream barrel opening axially opposed to the upstream barrel opening. The plunger is dimensioned and configured to mate with the interior of the syringe barrel and is mounted for axial movement within the syringe barrel. The plunger has an upstream plunger end having a plug opening to receive a plug, the upstream plunger end projecting from the upstream opening of the syringe barrel, and a downstream plunger end. The downstream plunger end is of a narrower diameter than most of the length of the plunger barrel. The inner diameter of the plunger end is selected so that the needle port seal fits snugly within the downstream plunger end during the injection phase.

[0018] During the retraction phase following injection, the needle port seal is forced upstream into the retraction lumen of the plunger by the release of gas under pressure from the gas cell at the end of the plunger downstroke, as will be further described. The needle port seal frictionally engages the inner surface of the downstream end of the plunger, thereby impeding leakage of medicament past the needle port seal into the retraction lumen during administration of the medicament. The retraction lumen within the plunger is bounded by the needle port seal, the upstream plunger end and the inner surface of the plunger. The plug opening provides an opening whereby tools can be inserted to access the internal parts of the syringe during assembly in order to facilitate assembly of the component parts of the syringe. After assembly of the syringe, a plunger plug is snapped into the plug opening, thus sealing the retraction lumen of the plunger. A slidable plunger seal surrounds and is affixed to the downstream plunger end. The dimensions and material of the plunger seal are selected so that the plunger seal slidingly contacts the inner surface of the syringe barrel, (i) impeding leakage of medicament past the plunger seal, while (ii) permitting longitudinal displacement of the plunger.

[0019] The displaceable engagement ring slidingly but frictionally engages the inner surface of the syringe barrel and is located downstream of the plunger seal. The engagement ring is dimensioned and configured to mate with the interior of the syringe barrel and is positioned for limited axial displacement within the syringe barrel. To this end, the interior of the syringe barrel is divided axially into a longer upstream chamber and a shorter downstream chamber separated by a chamber separator wall having a central opening large enough to permit the narrow downstream end of the plunger to pass therethrough. Progressing from upstream to downstream within the downstream chamber are located (i) the engagement ring, embracing within its central opening in mating engagement the perforator neck and the needle header body; (ii) the gas cell; and (iii) the perforator body and puncture lances with the points of the latter facing the gas cell.

[0020] The engagement ring is not displaced from its initial rest position against the chamber separator wall until the end of the injection phase, whereafter the user's hand pressure applied to the plunger causes the plunger to continue to move axially downstream, resulting in the downstream end of the plunger impinging on the engagement ring and forcing the engagement ring to move axially downstream. This post-injection displacement of the engagement ring forces downstream displacement of the gas cell, thereby forcing the adjacent perforator and gas cell into contact with one another, ultimately causing the rupture of the gas cell by the perforator, whereupon the compressed gas that had been stored in the gas cell is released, forcing retraction of the needle into the retraction lumen, as described in more detail elsewhere in this description.

[0021] The hollow needle header is mounted in the central opening of the engagement ring. The diameter of the needle header is chosen such that a compression seal between the needle header and the engagement ring is created by forcing the needle header into the inner opening of the engagement ring during assembly, thereby prohibiting leakage of medicament downstream of the engagement ring between the engagement ring and needle header. A hollow needle is cemented or otherwise affixed to the downstream end of the needle header. When the syringe is charged with medicament, the medicament is confinable within the syringe barrel downstream of the plunger seal and needle port seal and upstream of the engagement ring and needle header. In one embodiment of the invention, the needle header is situated within the engagement ring in such a manner that the upstream portion of the needle header projects upstream out of the central opening of the engagement ring.

[0022] The engagement ring serves several purposes, *viz*

(a) by means of its engagement with the surrounding cylindrical wall of the syringe barrel, it provides stability and provides a compression seal to impede unwanted spurious fluid flow; (b) by means of the engagement of its central axial opening with the needle header, it holds the needle header and needle in place during injection of medicament into the patient;

(c) by means of the engagement of its central axial opening with the perforator neck and the engagement of that neck with the needle header, it prevents premature puncture of the gas cell by the perforator;

(d) by means of the foregoing engagements, it facilitates radial alignment of the gas cell and the perforator, promoting even positioning of the gas cell relative to the puncture lances, which in turn facilitates optimal puncturing of the gas cell at the end of the plunger downstroke;
(e) it facilitates accurate alignment of the needle port seal with the needle header, in turn facilitating precise connection of the needle port seal to the needle header and thereby facilitating precise retraction of the needle; and
(f) by means of its engagement with and displacement of the gas cell at the end of the plunger downstroke, displacing the gas cell downstream into rupturing contact with the perforator, it effects the release of compressed gas, thereby in turn causing retraction of the needle assembly into the retraction lumen of the plunger.

[0023] In this embodiment, the annular gas cell containing compressed gas is mounted within the syringe barrel downstream of the engagement ring. The gas cell is dimensioned and configured to fit within the syringe barrel. A perforator is mounted downstream of the gas cell. The perforator may either be cemented or otherwise affixed to the inner surface of the syringe barrel downstream of the engagement ring or the perforator may be cemented or otherwise affixed to a needle aperture mount which is cemented or otherwise affixed to the downstream barrel opening of the syringe. The perforator comprises one or more puncture lances, a neck, and an inner opening. The puncture lance(s) is/are mounted on the perforator in such a manner that the puncture lances project upstream from the perforator towards the gas cell. The neck of the perforator is mounted in such a manner that the neck projects upstream from the perforator and through the annular opening of the gas cell and into the inner opening of the engagement ring thus making contact with the needle header. The neck of the perforator allows for precise alignment of the needle header, gas cell and puncture lances and prevents downstream motion of the needle header and needle. The orientation of the perforator could if desired be reversed so that the puncture lances project downstream toward a gas cell located downstream thereof.

[0024] The perforator mount is provided with a needle aperture and a needle membrane, the latter serving as a needle port closure. The needle is mounted such that it passes through the inner opening of the perforator, through the needle membrane and projects out of and downstream of the needle aperture. The needle membrane is fixed to the needle aperture mount at and around the needle aperture and preferably is tapered about 30° to the axial where the needle membrane contacts the needle. Once the needle has been retracted, the needle membrane covers the needle aperture so as to impede the re-extension of the needle through the needle aperture. The needle aperture mount is cemented or otherwise affixed to a needle cover which provides a protective sheath for the needle prior to use and which may be twisted off, snapped off or otherwise removed from the needle aperture mount prior to use of the syringe so that the needle is exposed for use. The needle cover, perforator mount and perforator may be manufactured as separate pieces or they may be manufactured as one piece; in the latter case, there should be a capability of the needle cover to be twisted or broken off from the perforator mount without causing damage to the perforator prior to use.

[0025] In operation, after the syringe is charged with medicament, when a user applies an injection force to the plunger, the plunger seal at the downstream end of the plunger imparts a downstream biasing pressure to the medicament contained in the syringe barrel between the plunger seal and the engagement ring. This downstream biasing pressure applied to the plunger by the user is sufficient to force the medicament through the upstream intake of the needle and into a patient via the downstream tip of the needle. The releasable frictional force securing the engagement ring to the inner surface of the syringe barrel resists the downstream biasing pressure exerted on the engagement ring by the medicament as the medicament is forced through the upstream intake of the needle.

[0026] When essentially all of the medicament has been delivered to the patient, further downstream motion of the plunger forces the needle port seal, located at the downstream plunger end, to seal the needle header such that no further medicament or other fluids may be forced through the upstream intake of the needle and delivered to the patient. Further downstream force applied by the user to the plunger (the post-injection force) overcomes the releasable frictional force securing the engagement ring to the inner surface of the syringe, thereby permitting the engagement ring to slide axially downstream within the syringe barrel under hand pressure. Downstream motion of the needle header, however, is constrained by the neck of the perforator contacting the needle header. When the needle header contacts the neck of the perforator projecting upstream of the perforator, further downstream motion of the needle header is prevented. Continued application of a post-injection force on the plunger causes the engagement ring to slide axially downstream and contact the gas cell, thereafter forcing the gas cell to move downstream, eventually resulting in the gas cell impinging on the puncture lance(s) of the perforator. The puncture lances rupture the gas cell, resulting in the release of the non-toxic compressed gas from the gas cell into the syringe barrel in the area confined by the perforator, the engagement ring and the needle port seal.

[0027] The released compressed gas is confined within the syringe barrel. Its purpose is to provide an upstream biasing pressure within the syringe barrel upstream of the gas cell with sufficient pressure to overcome the frictional force between the needle port seal and the downstream plunger end. The upstream biasing pressure biases the needle port seal to slide upstream into the retraction lumen of the plunger. During this upstream motion of the needle port seal, the needle port seal remains coupled to the needle header, which is cemented or otherwise fixed to the needle, thereby affecting retraction of the needle into the retraction lumen. The released gas remains under pressure and generates a corresponding upstream biasing pressure that acts on the needle port seal, biasing the needle port seal, needle header and needle to slide upstream within the retraction lumen of the plunger, thereby effecting retraction of the needle within the retraction lumen.

[0028] Corresponding upstream motion of the plunger is prevented or impeded by a plunger lock that engages when the plunger has reached its downstream limit, thereby locking the plunger within the syringe barrel. In a preferred embodiment, a circumferential plunger verge is located on the outer surface of the plunger and is configured to have a shallow downstream side and a steep upstream side such that when a downstream force is applied to the plunger, the shallow downstream side of the plunger lock slides downstream of the upstream barrel opening of the syringe barrel, which is of a slightly smaller diameter than the outer diameter of the plunger. When the gas cell is ruptured releasing the compressed gas, the upstream biasing pressure resulting from release of the compressed gas is insufficient to force the steep upstream side of the plunger verge to move upstream past the upstream barrel opening of the syringe barrel. The shallow downstream side of the verge permits the plunger to slip downstream relatively easily past the upstream barrel opening.

[0029] There has to be enough gas under pressure in the gas cell such that the upstream biasing pressure is sufficient to generate enough force to move the needle port seal to move upstream through the required distance. In syringes designed for evaluation as pre-manufacture prototypes, typical values for the gas pressure in the gas cell are expected to range from about 5 to about 20 p.s.i.g; the pressure preferably would not exceed about 9 p.s.i.g. Note that the speed and reliability of needle retraction are heavily dependent upon the gas pressure selected; an empirical approach should be taken. The gas pressure should be sufficient to retract the needle relatively quickly but should not be excessive to the point that the gas discharge upon puncture is unduly shocking to the user or to the component parts of the syringe, nor should the needle retraction cause splattering of bodily fluids. These objectives are readily achievable in syringes constructed in accordance with the present invention, particularly in contrast to previous designs in which the needle retraction was effected by spring action.

[0030] Preferably, most of the component parts of the syringe are fabricated from plastics materials. Preferably the needle port seal, engagement ring and the plunger seal are fabricated from rubber or the like as these components function better if made from a more flexible material than the syringe barrel. All rubber parts within the syringe are coated with a medical fluid lubricant as typically used in the industry. Typically, the needle will be made of stainless steel or a specialty hard, strong plastics material.

[0031] The foregoing syringe embodiment of the present invention can be adapted for multiple volume sizes of syringes including, but not limited to, 1, 1.5, 2, 3, 5, 10 and 20 mL syringes.

Second exemplary embodiment:

[0032] In a second embodiment of the present invention, the syringe manifests a few significant modifications relative to the first exemplary embodiment of the invention described above. In particular, the engagement ring is modified and elongated such that the needle header, including the upstream end of the needle header, may be positioned within the central cylindrical opening of the engagement ring in such a manner that the upstream end of the needle header is flush with the upstream end of the engagement ring. Further, the needle port seal is initially mounted in the downstream end of the plunger such that the downstream end of the needle port seal is flush with the downstream limit of the downstream end of the plunger. These modifications allow for better alignment of the needle port seal with the needle header during the post-injection phase of the operation of the syringe relative to the first embodiment, thus resulting in a more accurate coupling mechanism between the needle port seal and the needle header as compared with the first embodiment.

[0033] In this second embodiment, the plunger lock functions in a manner generally similar to the functioning of the plunger lock of the first embodiment, but instead of using the upstream barrel opening of the syringe barrel as an element of the lock, there is provided on the interior surface of the barrel a circumferential verge similar in design to the verge on the outer cylindrical surface of the plunger, but sloped in the opposite sense. The two verges are positioned to engage one another just before the plunger reaches its downstream limit of travel. The shoulder-to-shoulder engagement of the two verges in that locking position is secure against all but high disruptive forces applied to the syringe.

Third exemplary embodiment:

[0034] In a third syringe embodiment of the present invention, the perforator, rather than being located downstream of the gas cell and having puncture lances that project upstream from the perforator towards the gas cell, is mounted on the downstream plunger end and has puncture lances that project downstream from the downstream plunger end towards the gas cell.

[0035] An engagement disc is positioned within the downstream end of the plunger and prevents medicament from entering the retraction lumen of the plunger during injection of the medicament into a patient. A needle port seal is fixed to the downstream end of the engagement disc. Further, a header lock is fixed to the engagement disc and projects downstream from the engagement ring. In the embodiment illustrated, the header lock comprises projecting barbed lances whose barbs grip the needle header. When the engagement disc retracts into the plunger, it carries with it the disc-shaped needle header and consequently the needle.

[0036] A hollow needle end cap is dimensioned and configured to mate with the downstream end of the syringe barrel. The needle end cap has a needle aperture oriented to be axially aligned with and opposed to the upstream barrel opening of the syringe barrel.

[0037] An alignment disc is securely mounted in the needle end cap near the upstream end of the needle end cap such that a gas cell chamber for containing the gas cell is formed between the base of the needle end cap and the downstream end of the needle end cap. The alignment disc has a central needle aperture and a circular recessed groove concentric with the central aperture of the alignment disc. The recessed groove is dimensioned and configured to receive the header lock lances when they move downstream to grip the needle header. The needle end cap is provided with one or more through holes dimensioned and configured to allow the puncture lances affixed to the downstream plunger end to pass therethrough.

[0038] Preferably, a needle membrane is fixed to the needle end cap at and around the needle aperture. The needle membrane serves as a needle port closure.

Advantages of the invention

[0039] It is an advantage of this invention that, once the needle has been retracted into the plunger lumen, the needle and any parts attached to it are completely detached from the distal end of the syringe barrel and from the distal end of the syringe plunger, and are retained in place within the plunger lumen.

[0040] It is an advantage of this invention that the safety mechanism is relatively simple to operate in that drawing medicament into the syringe and injecting medicament into the patient are substantially conventional. To initiate the needle-retraction phase of syringe operation, the user need only continue to apply a downstream force to the plunger to move the plunger through a further short displacement after the medicament has been substantially discharged from the syringe. The gross structure of the syringe incorporating the needle- retraction elements need not appreciably change the look and feel of syringes according to the invention as compared to the look and feel of a conventional syringe; this feature is common to the earlier Klippenstein syringe discussed briefly above, and contrasts with the safety mechanisms incorporated into the designs disclosed in U.S. Patent Nos. 5,334,155 and 5,188,614. .

[0041] It is a further advantage of preferred embodiments of this invention that in the needle-retraction phase of syringe operation, the needle is reliably retracted into the syringe barrel, and the plunger is reliably prevented from re-extending out of the barrel. Severe force would be required to defeat or reverse these two results. The needle retraction time, that is, the time required to retract the needle into the syringe, may be reliably controlled by selecting the pressure of the gas loaded into the gas cell during manufacture of the gas cell.

[0042] It is a further advantage of preferred embodiments of this invention that the safety mechanism, *i.e.* the operative needle-retraction and plunger lock components, employs a small number of moving parts. The simplicity of the design and the small number of moving parts of preferred embodiments of the syringe of the invention allows the use of the syringe in a broad range of climatic and temperature conditions. Further, material costs are reduced in the design of preferred embodiments of the inventive syringe due to the simplicity of the design and further due to the absence of mechanical parts found in other safety syringes, such as springs and metal sheaths. The need for such components in other safety syringes often requires considerable play between the syringe plunger and the syringe barrel of such other syringes, interfering with optimum fit of plunger with barrel for injection purposes.

[0043] It is a further advantage of preferred embodiments of this invention that the safety syringe according to the invention may be mass-produced on an automated assembly line (not *per se* constituting an aspect of this invention), thereby minimizing some labor costs associated with other needle-retraction syringes at present available in the industry. In particular, it is a feature of this invention that the gas cell of the invention may be manufactured separately from other component parts of the safety syringe according to the invention, and can therefore be loaded into the syringe on an automated assembly line, thereby facilitating a reduction in the use of relatively costly manual labor. This means that the syringe is relatively inexpensive to manufacture.

[0044] After the needle- retraction phase is complete, the component parts of the syringe of the invention are situated in a relatively compact terminal formation as compared to the component parts of the syringes described in U.S. Patents Nos. 5,868,713 and 6,413,236, thus allowing for ease of disposal of syringes according to the invention. The compact assembly of the component parts of the syringe following the retraction phase is achieved automatically once the needle-retraction phase has commenced, and without the need for further intervention by the user as is required in the use of syringes described in U.S. Patent No. 6,193,695.

[0045] The syringe of the present invention is designed such that the needle-retraction phase cannot commence until the injection phase is substantially complete, in contrast to the designs of the syringes disclosed in U.S. Patents Nos. 6,193,695 and 6,413,236. In accordance with the present invention, the needle-retraction phase is initiated automatically upon completion of the injection phase and does not require the user to change his or her hand position, as is required to initiate the safety phase of syringe operation disclosed in U.S. Patent Nso. 5,334,155; 6,193,695; 6,413,236; and 5,868,713.

[0046] Other advantages of syringes according to the invention will be apparent from a reading of detailed descriptions of preferred embodiments, below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0047] The present invention may be further understood from the following detailed description with reference to the accompanying drawings in which all views are schematic.

[0048] Fig. 1, in exploded longitudinal section view, illustrates the barrel, gas cell, perforator therefor, needle cover, and engagement ring of a single-use pneumatic retractable syringe in accordance with a preferred embodiment of a syringe made In accordance with the invention.

[0049] Fig. 2, in exploded longitudinal section view, illustrates the plunger, plunger seal, needle and needle header for use with the syringe components illustrated in Fig. 1.

[0050] Fig. 3, in longitudinal section view, illustrates the syringe of Figs. 1 and 2 fully assembled, with the plunger extended upstream out of the syringe barrel so that medicament can be drawn into the syringe.

[0051] Fig. 4, in longitudinal section view, illustrates the syringe of Fig. 3 with the plunger having been depressed downstream to the position in which substantially all medicament drawn into the syringe barrel would have been expelled, the plunger has been locked within the barrel, and the needle port seal has engaged and sealed the needle aperture port in the needle header.

[0052] Fig. 5, in longitudinal section view, illustrates the syringe of Fig. 4 wherein the needle, needle header and needle port seal are shown as having been retracted within the retraction lumen of the plunger.

[0053] Fig. 6, in longitudinal section view, illustrates an alternative embodiment of a single-use pneumatic retractable syringe according to the invention wherein the engagement ring has been dimensioned and configured such that the needle header is positioned within a central cylindrical opening of the engagement ring, and showing the plunger as extending upstream partially out of the barrel.

[0054] Fig. 7, in exploded longitudinal section fragment view, illustrates the downstream portion of the barrel of the syringe of Fig. 6 and associated interior components.

[0055] Fig. 8, in partially exploded longitudinal section fragment view, illustrates the plunger and associated components of the syringe of Fig. 6.

[0056] Fig. 9, in partially exploded longitudinal section view, illustrates a single-use pneumatic retractable syringe according to a further embodiment of the invention and a needle for use therewith.

[0057] Fig. 10 is a longitudinal section detail fragment view of the downstream plunger end of the syringe of Fig. 9.

[0058] Fig. 11 is a longitudinal section detail fragment view of an alternative embodiment of the downstream plunger end of the syringe of Fig. 9.

[0059] Fig. 12, in end view in the radial plane, illustrates the alignment disc of the syringe illustrated in Fig. 9.

[0060] Fig. 13, in longitudinal section view, illustrates the alignment disc of Fig. 12.

[0061] Fig. 14, in longitudinal section view, illustrates the syringe of Fig. 9 with the plunger partially extended upstream out of the syringe barrel.

[0062] Fig. 15, in longitudinal section view, illustrates the syringe of Fig. 9 with the plunger fully depressed and locked within the barrel of the syringe.

[0063] Fig. 16, in longitudinal section view, illustrates the syringe of Fig. 15 wherein the needle, needle header and needle port seal are shown as having been retracted within the retraction lumen of the plunger, and the plunger is locked within the syringe barrel.

DETAILED DESCRIPTION OF THE INVENTION

[0064] In the drawings and in this description, exemplary embodiments of syringes and syringe components made in accordance with various facets of the invention are illustrated. It is to be understood in this description that "the invention" may include a number of different inventive concepts and implementations, and that the words "the invention" may refer to one or more of them, as the context may require. The description and drawings illustrate representative embodiments of the invention and act as an aid to comprehension, and are not intended as a definition of the limits of the invention. The limits of the invention are as defined by the claims.

[0065] While in this specification, information is stated about materials selections and other parameters applicable to syringe designs according to the invention (the syringes described herein had not gone into commercial production as of this writing), the reader should keep in mind that an empirical approach should be taken to the final design of any given syringe. Trade-offs always have to be made between design refinement and cost of manufacture. Tolerances can significantly affect the performance of a syringe made to certain specifications. Materials of a given specification will be not be identical to other materials meeting the same specification. Not all casting molds have identical surface smoothness. Et cetera. Testing and routine trial-and-error approaches should be expected to be a part of product development. Further, as all illustrations to which this description relates are schematic, the reader should not rely upon absolute nor relative dimensions that the eye may perceive in these illustrations.

[0066] In this specification, qualifying words should be taken in a relative sense, not an absolute sense. For example, if one element "seals" or "sealingly engages" another element, an absolute seal is not necessary; it suffices if enough sealing capability exists that the function for which the sealing is provided can be effectively performed by the syringe. As another example, locking the plunger "within the barrel of the syringe" should not be taken as implying that the full length of the plunger is within the barrel, but only that most of it is, so as to render the combined length of the external elements of the syringe reasonably compact. As yet another example, the fit of various components with one another is not intended to be precisely described; while to a careful engineer, there is a clear distinction between the concepts close fit, tight fit, and snug fit, nevertheless in this specification the fit of mating parts is described somewhat liberally, and "fit" should be considered relative to the purpose being served. The fit of a component with another for the purpose of a sealing engagement and no relative motion would be expected to be tighter than the fit of two components that must move with respect to one another. An empirical approach should be taken to syringe design based on guidelines in the description.

[0067] Further, while information is provided herein relative to the implementation of the inventions to which this specification is directed, no comprehensive nor consistent attempt is made in this specification to cover topics significant to syringe design generally but not specific to the present set of inventions. For example, the production molds for the syringe barrel have to be designed so that the syringe barrel can at all times maintain adequate sidewall pressure to allow the barrel to withstand full loading under expected peak injection force. Problems, solutions and design choices of the foregoing sort are well understood in syringe design. Suitable design choices would be empirically made by a competent syringe designer. However, please note, continuing the foregoing example, that the barrel design must be adequate to enable the barrel to maintain enough sidewall pressure for proper needle retraction - a point of information specific to the present set of syringe inventions. Representative gas cell pressures are set forth in this specification, so knowing these expected pressures, and providing a margin of tolerance, a competent syringe designer will be able to apply known strength-of-materials methodology to the materials selected for manufacture of the barrel, so as to enable the syringe to serve without expectation of failure.

[0068] In this description:

the concept "fixed" includes direct and indirect attachment and includes elements formed integrally with one another;

the concept "coupled" includes linking and cooperative association, but does not necessarily imply a fixed relationship;

"downstream" is the direction in which medicament flows during the injection phase of operation of the syringe, and may refer to a location that is nearer the tip of the needle than to the thumb and fingers of the user's hand;

"upstream" is the opposite of "downstream";

"axial" means along or in the direction of or parallel to the longitudinal axis of the syringe;

"radial" means perpendicular to axial, or in the direction of a radius of a circular or cylindrical element or configuration;

"distal" means at or toward the end of an element being described that is nearer the tip of the needle than to the thumb and fingers of the user's hand; and

"proximal" is the opposite of "distal" and means at or toward the end of an element being described that is nearer the thumb and fingers of the user's hand than to the tip of the needle.

[0069] Referring first to Figs. 1 and 2, there is illustrated in exploded longitudinal section view a retractable pneumatic safety syringe **20** in accordance with a first preferred embodiment of the invention. The syringe **20** has for the most part circular symmetry about its longitudinal axis. The principal gross elements of the syringe **20** are a syringe barrel or body **43**, a plunger **48**, and a needle assembly **82**.

[0070] The hollow cylindrical syringe barrel **43** has a downstream compartment or chamber **32** and an upstream compartment or chamber **31** separated from one another by an annular separator wall **29** lying in a radial plane. The separator wall **29** has a central aperture **16**. The upstream chamber **31** has an inner cylindrical wall surface **33** while the downstream chamber **32** has an inner cylindrical wall surface **28**. The upstream end of the syringe barrel **43** is formed as or attached to flange **30** that may be, for example, circular and annular in its radial shape or alternatively may comprise opposed projecting tabs serving as finger grips. The flange **30** has a central access port opening or aperture **34** of slightly smaller diameter than the interior diameter of syringe barrel **43**. Thus, the flange **30** extends radially inwardly from inner cylindrical surface **33** of the syringe barrel **43** to provide an interior bearing surface against which plunger lock verge **70** can bear, as discussed further below. The syringe barrel **43** also has a downstream barrel opening **38**. The openings **16**, **34** and **38** are axially aligned.

[0071] The hollow cylindrical plunger **48** has a hollow plunger body **72** configured and dimensioned to mate with and slide with limited axial movement within the upstream chamber **31** of the syringe barrel **43**. The needle assembly **82** terminates at its distal end in a needle **37** that retracts into a retraction lumen **39** within the body **72** of the plunger **48** after use, as will be described in further detail below. The plunger body **72** is bounded by an inner cylindrical surface **54** and an outer cylindrical surface **57**, a circumferential upstream plunger end flange **50** having a plug opening **51** for a plunger plug **47**, and a downstream hollow cylindrical plunger end **52** and adjacent integral hollow neck **59**. A circumferential collar **55** intervenes between the plunger end **52** and the adjacent neck **59**. Apart from the collar 55, he end **52** and neck **59** have the same inner and outer diameters. The end **52** and neck **59** have appreciably smaller inner and outer diameters than those of the body **72** of the plunger **48**; however, Fig. 2 exaggerates the expected difference in diameters. The diameter of the outer cylindrical surface **57** of the plunger body **72** is dimensioned so that the plunger body **72** fits slidably within the syringe barrel **43** with a tolerance selected to constrain the plunger **48** from rattling within the syringe barrel **43** and to constrain the plunger body **72** to slide within the syringe barrel **43** with a small frictional resistance to longitudinal displacement of the plunger body **72** within the syringe barrel **43**.

[0072] The upstream plunger end flange **50** provides a bearing surface for two fingers on the downstream side thereof, permitting the user to withdraw the plunger **48** from the syringe barrel **20** when drawing medicament into chamber **74**. Thumb pressure applied to the distal end surface of the plug **47** may be applied to move the plunger **48** downstream from an extended position. This configuration, combined with the flange **50** against which counterforce from two fingers may be applied, is sometimes referred to as a "thumb grip". The upstream outer end of the plug **47** may optionally be formed as a thumb cradle or concave thumb button; compare thumb cradle **651** of Fig. 9. The plug opening **51** is dimensioned and configured to permit the plunger plug **47** to penetrate part way into the plug opening **51** but to run into increasing interference as the plunger plug **47** is pushed into the plug opening **51**. The plug opening **51** permits tools (not shown) to be inserted to access the internal parts of the syringe **20** during assembly thereof in order to facilitate assembly of the component parts of the syringe **20**.

[0073] The downstream plunger neck **59** has a cylindrical inner surface **53**. The internal diameter of the downstream plunger neck **59** is chosen such that a needle port seal **41** frictionally engages the inner surface **53** of the downstream plunger neck **59** with a fit approaching snug fit but permitting the needle port seal **41** to be driven upward in to the lumen **39** under gas pressure. At least the outermost circumferential portion of the needle port seal **41** is made of resilient material so that the needle port seal **41** may expand in diameter to fill the full cross-section of the lumen **39** when the needle port seal **41** enters the lumen **39** during the needle retraction phase of syringe operation.

[0074] A hollow deformable plunger seal **40** surrounds the downstream plunger end **52** and plunger neck **59** (see Fig. 3) with a snug or tight fit and is retained in position by means of the collar **55** that engages a mating annular recess **58** within the plunger seal **40**. The dimensions and material of the plunger seal **40** are selected so that the plunger seal **40** slidably engages the inner cylindrical wall surface **33** of the upstream chamber **31** of the syringe barrel **43** with a fit approaching a snug fit permitting the plunger **48** to slide within the barrel **43** but with a modest frictional resistance. The relatively snug fit impedes leakage of fluid (such as medicament present in the available medicament cavity **74** within chamber **31** or air), past the plunger seal **40** of the plunger **48**, while permitting longitudinal (axial) displacement of the plunger body **72** within the chamber **31**.

[0075] The dimensions of the separator wall **29** and its aperture **16** are selected so that downstream motion of the plunger seal **40** is stopped when the seal **40** abuttingly engages the upstream side of the separator wall **29**, whereas the cylindrical plunger end **52** and neck **59** downstream of the seal **40** may pass through the central aperture **16** of the separator wall **29** thereby allowing the distal cylindrical plunger end **52** to penetrate into the downstream chamber **32** of the syringe barrel **43**. At the same time that the distal cylindrical plunger end **52** penetrates into the downstream chamber **32**, the plunger seal **40** is forced slidingly upstream on the plunger neck **59** until the upstream motion of the plunger seal **40** is stopped by the engagement of the plunger seal **40** against an annular shoulder **56** formed at the upstream end of the neck **59**.

[0076] Referring to Figs. 1 and 2 an engagement ring **45**, having a central cylindrical opening **49**, slidably but frictionally engages the inner cylindrical wall surface **28** of the downstream chamber **32** of the syringe barrel **43** with which surface **28** the engagement ring **45** is dimensioned and configured to mate. The engagement ring **45** may move axially within the downstream chamber **32**, and in rest position the upstream end of engagement ring **45** abuts against the separator wall **29**. When the plunger **48** is fully extended upstream out of the syringe barrel **43**, as seen in Figure 2, the engagement ring **45** is at rest in the chamber **32**, whereas the plunger seal **40** and needle port seal **41** are at the upstream end of the chamber **31**. The engagement ring **45** will not move from its rest position as seen in Figure 2 until the end of the injection phase when downstream pressure applied to the plunger **48** by the user causes the downstream plunger end **52** to pass downstream through the aperture **16** of the separator wall **29**, whereafter further downstream displacement of the plunger end **52** forces the engagement ring **45** to slide axially downstream.

[0077] Fully assembled, the needle assembly **82** comprises the needle port seal **41**, a hollow needle header **42**, and the hollow needle **37**. The needle port seal **41** by itself or in combination with the needle header 42 constitute the needle carrier that is propelled by compressed gas into the plunger lumen 39 after injection. The diameter of the inner cylindrical surface **53** is selected relative to the outer diameter of the needle assembly **82** so that the needle assembly **82** may pass through the neck **59** of the plunger **48** into the lumen **39** of the plunger **48**. Also, the length of the lumen **39** is selected relative to the length of the needle assembly **82** such that the needle assembly **82** can be housed completely within the lumen **39** after use.

[0078] The needle header **42** has a downstream hollow cylindrical body **76**, a collar **77** and an upstream hollow end knob **78**. The needle **37**, having a downstream tip **36** and an upstream intake opening **75**, is crimped in or cemented to or otherwise securely fixed within the body **76** of the needle header **42**. The needle header **42** is dimensioned and configured such that during assembly of the syringe **20**, the body **76** of the needle header **42** may be inserted into the central cylindrical opening **49** of the engagement ring **45**, on the upstream side thereof, with a fit approaching a snug fit, thereby in its rest position impeding leakage of medicament contained in cavity **74** or other fluids between the needle header **42** and the engagement ring **45**. In that rest position, the collar **77** abuts the upstream end of the engagement ring **45** to prevent the needle header **42** from passing downstream completely through the central cylindrical opening **49**. The engagement ring **45** provides lateral support to the needle header **42**, thereby stabilizing the needle **37** and its header **42** and enabling them to withstand the impact of pressure placed on the needle **37** during injection, especially if a muscle injection is made.

[0079] The dimensions and configuration of the knob **78** are such that the knob **78** engages in a snap fit a mating downstream socket **79** in the needle port seal **41** when, after injection of medicament from cavity **74** into a patient (say), the socket **79** of the needle port seal **41** is forced onto the knob **78** of the needle header **42** thereby securing the needle header **42** to the needle port seal **41**, and thus prohibiting further escape of fluids through the needle **37**.

[0080] When the syringe **20** is charged with medicament in cavity **74**, the medicament is confinable within the upstream chamber **31** of the syringe barrel **43** downstream of the plunger seal **40** and needle port seal **41** (see Fig. 3), and upstream of the engagement ring **45** and needle header **42**, also as shown in Fig. 3. The snug fit of the cylindrical surface of engagement ring **45** with the mating interior cylindrical surface **28** of the syringe barrel **43** acts as a barrier seal for medicament in cavity **74**. The central opening **49** in the engagement ring **45** enables the engagement ring **45** to hold the needle header **42** and needle **37** in place and in alignment during injection of medicament from cavity **74** into the patient. It is important that the structure facilitate the alignment of the needle header **42** with the needle port seal **41**. In one embodiment of the invention (as shown in Figs. 1 to 4), the needle header **42** is situated within the engagement ring **45** in such a manner that the hollow knob **78** of the needle header **42** projects upstream of and out of the engagement ring **45**, as illustrated in Fig. 3.

[0081] A hollow perforator **46** comprises a base **22**, spaced puncture lance elements **23** fixed to the base **22** and projecting upstream therefrom, and an elongate central neck **26** projecting upstream from the base **22**, the neck **26** having an inner cylindrical opening **24**. The perforator **46** is positioned downstream of the engagement ring **45**. The base **22**, puncture lances **23** and the neck **26** of the perforator **46** may be machined as a single piece. In the embodiment of the invention illustrated in Figs. 1, 2 and 3, the perforator **46** is secured in position by laminating, cementing or otherwise affixing the base **22** of the perforator **46** to a perforator mount **69**. In this embodiment of the invention, the dimensions and material of the base **22** of the perforator **46** are preferably selected so that the base **22** of the perforator **46** may mate with the upstream end of the perforator mount **69** in a tight fit, thereby impeding leakage of gases or other fluids downstream. The perforator mount **69** is laminated, cemented or otherwise affixed to the inner wall **28** of the chamber **32** in the vicinity of the downstream barrel opening **38** of the syringe barrel **43**. The perforator **46** and the engagement ring **45** are axially positioned, with respect to each other, within the downstream chamber **32** of the syringe barrel **43** in such a manner that the neck **26** of the perforator **46** is inserted into the central cylindrical opening **49** of the engagement ring **45**. The neck **26** of the perforator **46** extends upstream and into the central cylindrical opening **49** of the engagement ring **45** to such an extent that the neck **26** of the perforator **46** contacts the body **76** of the needle header **42**.

[0082] The needle **37** extends downstream from the needle header **42** and through the inner cylindrical opening **24** of the perforator **46** such that the downstream tip **36** of the needle **37** projects out of and downstream of the perforator **46**. The neck **26** of the perforator **46** inhibits downstream motion of the needle header **42** or needle **37**. The needle header **42** will not move until the plunger **48** has completed its downward motion, at the end point of which the socket **79** of the needle port seal **41**becomes attached to the needle header **42**.

[0083] An annular gas cell **25**, dimensioned and configured to fit within the downstream chamber **32** of the syringe barrel **43**, is positioned within the downstream chamber **32** between the perforator **46** and the engagement ring **45**. The gas cell **25** has a central inner opening **27** and contains a suitable non-toxic compressed gas in its interior gas chamber **80**. The gas cell **25** is positioned such that the neck **26** of the perforator **46** projects through the inner opening **27** of the gas cell **25** thus facilitating proper alignment of the gas cell **25** with respect to the puncture lances **23** of the perforator **46** and facilitating proper alignment of the gas cell **25** with respect to the engagement ring **45**. The material of the gas cell **25** is selected such that when the gas cell **25** is forced (with a typical hand pressure of approximately 6 p.s.i.g.) onto the puncture lances **23**, the gas cell **25** is ruptured by the puncture lances **23**.

[0084] The perforator mount **69** has a needle aperture **35** (Fig. 3) and is provided with a needle port closing membrane **68** fixed to the perforator mount **69** in the vicinity of the needle aperture **35** . The membrane **68** is preferably a self-sealing membrane of the sort described in the referenced Klippenstein US patent No. 5,868,713 at column 4, lines 27-37. The membrane **68** can be made of resilient material such as soft surgical-grade rubber of the type used in some medication bottles. When the membrane **68** is cast into shape, it is preferably formed with a small slightly coned hole that has about a 30° taper relative to the syringe's longitudinal axis to facilitate passage of the needle **37** through the membrane **68** during assembly and to facilitate needle retraction after syringe use. When the needle is retracted into the plunger, since the material is very soft, it tends to flow into itself and seal the hole. The needle **37** is mounted such that it passes through the inner cylindrical opening **24** of the perforator **46**, and projects out of and downstream of the needle aperture **35**. The needle aperture **35** is dimensioned to fit the needle **37** and help stabilize the needle **37** during injection of medicament. In order to impede leakage of compressed gas from the needle aperture **35**, the needle membrane **68** tightly embraces the needle **37** where the needle **37** passes through the needle aperture **35**. Once the needle **37** has been retracted into the lumen **39**, the opening in the membrane **68** closes at least partially so that the needle membrane **68** covers the needle aperture **35** at least partially so as to impede downstream re-emergence of the needle **37** through the needle aperture **35**.

[0085] During assembly of the components of the needle assembly **82**, the upstream end of the needle **37** (in the vicinity of the intake opening **75**) slides into and is secured in the body **76** of the needle header **42** by compression, cementing, or other suitable means. During injection, the fluid to be injected passes into the needle **37** through the hollow knob **78** of the needle header **42**. The knob **78** is in this phase out of contact with the mating socket **79** in the needle port seal **41**. It is not until after substantially all the medicament has been pushed out of the syringe **20** through the needle **37** that the knob **78** engages and is stopped by the socket **79**.

[0086] Referring to Fig. 3, the lumen **39** is bounded by the needle port seal **41**, the upstream plunger end **50** and the inner surface **54** of the body **72** of the plunger **48**. The lumen **39** is dimensioned and configured to house the needle assembly **82** after administration of the medicament from cavity **74** is complete and the needle assembly **82** has been retracted into the lumen **39**. After assembly of the syringe **20**, the plunger plug **47** is inserted into the plug opening **51**, thus sealing the proximal upstream end of the lumen **39** of the plunger **48**. Because the needle port seal **41** engages the inner surface **53** of the downstream plunger end **52** with a relatively snug fit, the needle port seal **41** prevents or inhibits leakage of medicament from cavity **74** past the needle port seal **41** into the lumen **39** during administration of medicament. In this embodiment of the invention, the needle port seal **41** is mounted such that in the fully extended position of the plunger **48**, the downstream end of the needle port seal **41** projects downstream and out of the downstream plunger end **52** of the plunger **48**. Referring to Fig. 5, during the needle retraction phase of operation of the syringe **20**, the needle port seal **41** is forced upstream into the lumen **39** of the plunger **48**. The diameter of the lumen **39** is chosen such that, under an upstream biasing pressure sufficient to overcome the frictional force between the needle port seal **41** and the inner surface **53** of the downstream plunger end **52**, the needle port seal **41** is forced axially within the lumen **39** until further upstream movement of the needle port seal **41** is impeded by the plunger plug **47**. The dimensions of the needle port seal **41** are selected so that the needle port seal **41** frictionally engages the inner surface **54** of the body **72** of the plunger **48**.

[0087] Referring to Figs. 2 to 5, in this preferred embodiment of the invention, the syringe **20** further includes a plunger lock comprising a plunger lock engagement element and a syringe barrel lock engagement element acting together that, after use of the syringe **20**, constrain the plunger **48** to remain at or close to its downstream limit of travel. In other words, the plunger lock for the syringe **20** comprises an engagement element on the plunger **48** and another cooperating engagement element on the syringe barrel **43** that, at the downstream limit of travel of the plunger **48**, lock the plunger **48** in place within the syringe barrel **43**. In the embodiment illustrated in these figures of the drawings, the lock element of the plunger **48** is a plunger verge **70** formed as a raised circumferential ridge on the outer peripheral surface **57** of the plunger body **72** in the vicinity of the upstream end thereof. The lock element of the syringe barrel **43** comprises the inwardly extending verge of the end flange **30**, whose interior diameter, *i.e.* the diameter of end flange port hole **34**, is less than the outer diameter of the plunger verge **70**. The plunger verge **70** has an inclined surface progressively increasing in diameter from its downstream limit to its upstream limit, and terminating in an upstream shoulder. In other words, the plunger verge **70** is configured to have a shallow downstream side and a steep upstream side (which latter can have a generally radial surface) such that when the plunger verge **70** is just upstream of the flange **30**, a downstream force applied to the plunger permits the shallow downstream side of the plunger **48** to move downstream through the opening **34**, but once the plunger verge **70** has been displaced downstream of the flange **30**, the user will find it difficult or impossible thereafter to force the plunger **48** upstream, as the shoulder of the plunger verge **70** will bear substantially immovably against the inner circumferential surface of the flange **30**, thereby locking the plunger **48** within the syringe barrel **43** after injection has been completed.

[0088] In a preferred embodiment of the invention, as shown in Fig. 1, a needle cover **44** is laminated, cemented or otherwise affixed to the downstream end of the perforator mount **69** in such a manner as to enclose the needle **37** thereby providing a protective sheath for the needle **37**. In such an embodiment, the needle cover **44**, prior to use, may be twisted off, snapped off, or otherwise removed from the perforator mount **69** without causing damage to the needle **37**, the needle aperture **35** or the perforator **46**, and thus exposing the needle **37** projecting through and downstream of the needle aperture **35**, as shown in Fig. 3.

[0089] In operation, the syringe **20** is charged with medicament into cavity **74** in the same manner as a conventional syringe is charged with medicament. Fig. 3 illustrates, in a sectional view, the syringe **20** of Figs. 1 and 2 wherein the needle cover **44** has been twisted off or otherwise removed from the perforator mount **69**, thus exposing the needle **37** projecting downstream and out of the needle aperture **35**. A user applies a downstream force to the upstream plunger end **50** thereby causing the plunger **48** and plunger seal **40** to move axially downstream within the upstream chamber **31** of the syringe barrel **43**. The downstream motion of the plunger seal **40** forces most of air that is contained in the syringe barrel **43** through the upstream intake **75** of the needle **37** and out of the downstream tip **36** of the needle **37**. When nearly all of the air is forced out of the syringe barrel **43**, but before the plunger verge **70** engages the flange **30**, the downstream tip **36** of the needle **37** is submerged into medicament contained in a supply vial (not shown). While maintaining submersion of the tip **36** of the needle **37** in the medicament an upstream force is applied to the plunger **48** thereby effectuating withdrawal of the medicament from the supply vial (not shown) and into the syringe barrel **43**. Once the medicament is within the cavity **74** of the syringe barrel **43**, the syringe **20** is held such that the downstream tip **36** of the needle **37** is pointed skyward such that any residual air floats above the medicament in the syringe barrel **43** whereafter a downstream force is applied to the plunger **48** such that the residual air is forced out of the syringe barrel **43**. Referring to Fig. 3, when the syringe **20** is charged with medicament, the medicament is contained in cavity **74** entirely within the upstream chamber **31** of the syringe barrel **43** and confined between the plunger seal **40** of the plunger **48** and the engagement ring **45**.

[0090] After the syringe **20** is charged with medicament, as shown in Fig. 3, a downstream injection force is applied to the plunger **48** to force the plunger **48** to slide axially downstream thereby forcing medicament from cavity **74** into the needle header **42** and discharging medicament through the needle **37**. When a user applies a downstream injection force to the plunger **48**, the plunger seal **40** at the downstream plunger end **52** imparts a downstream biasing pressure to the medicament in cavity **74** between the plunger seal **40** and the engagement ring **45**. This downstream biasing pressure applied to the plunger **48** by the user is sufficient to force medicament through the upstream intake **75** of the needle **37** and into a patient via the downstream tip **36** of the needle **37**. Although the medicament while being injected is placed under pressure by the plunger **48** and therefore exerts a downstream biasing pressure on the engagement ring **45**, the resulting force on the engagement ring **45** is not sufficient to overcome the frictional force securing the engagement ring **45** to the inner cylindrical wall surface **28** of the downstream chamber **32** of the syringe barrel **43**. Nor is the concurrent upstream biasing pressure on the needle port seal **41** sufficient to overcome the frictional force between the needle port seal **41** and the inner surface **53** of the downstream plunger neck **59**.

[0091] Fig. 4 illustrates in sectional view the single-use pneumatic retractable syringe **20** of Fig. 3 wherein substantially all the medicament has been injected into the patient from cavity **74**, and the needle port seal **41** has engaged and sealed the needle header **42**. After substantially all of the medicament has been thus discharged, continued application of the injection force causes the downstream socket **79** of the needle port seal **41** to be forced onto the upstream end knob **78** of the needle header **42** thereby sealing the needle header **42** such that no further medicament or other fluids may be forced through the upstream intake **75** of the needle **37** and delivered to the patient. When the needle port seal **41** engages and seals the needle header **42** the needle assembly **82** is formed comprising the needle port seal **41**, the needle header **42** and the needle **37**. Downstream motion of the needle assembly **82** is restricted once the body **76** of the needle header **42** contacts the neck **26** of the perforator **46**. When the body **76** of the needle header **42** contacts the neck **26** of the perforator **46** projecting upstream of the perforator **46**, downstream motion of the needle assembly **82** is prevented.

[0092] Referring to Fig. 5 illustrates, in a sectional view, the single-use pneumatic retractable syringe **20** of Figs. 1, 2, 3, and 4. In the view of the syringe in Fig. 5 , needle retraction is complete; the needle assembly **82** is retracted within the lumen **39** of the plunger **48** and the plunger **48** is locked within the syringe barrel **43**. After all the medicament has been thus discharged, further downstream movement of the plunger seal **41** is restricted by the separator wall **29** of the syringe barrel **43**. Continued application of the downstream injection force (now a post-injection force) applied by the user to the plunger **48** causes the downstream plunger end **52** to move axially downstream and through the central aperture **16** of the separator wall **29** and forces the downstream plunger end **52** to impinge on the engagement ring **45**. The post-injection force applied by the user to the plunger **48** overcomes the frictional force between the engagement ring **45** and the inner cylindrical wall surface **28** of the downstream chamber **32** of the syringe barrel **43**, thereby causing the engagement ring **45** to slide axially downstream within the downstream chamber **32** of the syringe barrel **43**.

[0093] The engagement ring **45** serves several purposes, *viz*

(a) by means of its engagement with the surrounding cylindrical wall surface 33 of the syringe barrel 43, it provides stability and provides a compression seal to impede unwanted spurious fluid flow;

(b) by means of the engagement of its central cylindrical opening 49 with the needle header 42, it holds the needle header 42 and needle 37 in place during injection of medicament into the patient;

(c) by means of the engagement of its central cylindrical opening 49 with the perforator neck 26 and the engagement of that neck 26 with the needle header 42, it prevents premature puncture of the gas cell 25 by the perforator 46;

(d) by means of the foregoing engagements, it facilitates radial alignment of the gas cell 25 and the perforator 46, promoting even positioning of the gas cell 26 relative to the puncture lances 23, which in turn facilitates optimal puncturing of the gas cell 25 at the end of the plunger 48 downstroke;

(e) it facilitates accurate alignment of the needle port seal 41 with the needle header 42, in turn facilitating precise connection of the needle port seal 41 to the needle header 42 and thereby facilitating precise retraction of the needle 37; and

(f) by means of its engagement with and displacement of the gas cell 25 at the end of the plunger 48 downstroke, displacing the gas cell 25 downstream into rupturing contact with the perforator 46, it plays a part in effecting the release of compressed gas, thereby in turn causing retraction of the needle assembly 82 into the retraction lumen 39 of the plunger 48.

[0094] Further downstream force (the post-injection force) applied to the plunger **48** causes the engagement ring **45** to be forced onto the gas cell **25** thereby causing the gas cell **25** to slide axially downstream eventually resulting in the gas cell **25** impinging on the puncture lances **23** projecting upstream from the perforator **46**. This impingement causes the puncture lances **23** to rupture the gas cell **25**, thereby releasing the compressed gas from the gas cell **25** into the syringe barrel **43**. The released gas remains under pressure and is confined within the syringe barrel **43** in the area confined by the base **22** of the perforator **46**, the plunger seal **40** and the needle port seal **41**. Its purpose is to provide an upstream biasing pressure within the syringe barrel **43** upstream of the base **22** of the perforator **46** with sufficient pressure to overcome the frictional force securing the body **76** of the needle header **42** within the central cylindrical opening **49** of the engagement ring **45**. Further, the upstream biasing pressure is sufficient to overcome the frictional force between the needle port seal **41** and the inner surface **53** of the downstream plunger neck **59** of the plunger **48**. The upstream biasing pressure acting on the needle port seal **41** biases the needle assembly **82** to slide upstream into the lumen **39** of the plunger **48**, thereby effecting withdrawal of the needle **37** into the lumen **39** of the plunger **48**.

[0095] During the needle retraction phase, the needle port seal **41** slideably engages the inner surface **54** of the body **72** of the plunger **48** coming to rest at the plunger plug **47**, thus retracting the needle assembly **82** into the lumen **39** of the plunger **48**. There has to be enough gas under pressure that the upstream biasing pressure is sufficient to generate enough force to cause the needle assembly **82** to move upstream through the required distance. A suitable pressure range for gas stored within the gas cell **25** is expected to be about 5 to about 20 p.s.i.g. and preferably would not exceed about 9 p.s.i.g.

[0096] As the downstream tip **36** of the needle **37** passes upstream and through the needle aperture **35**, the tapered portion of the needle membrane **68** flattens to cover the needle aperture **35** thereby impeding re-extension of the needle **37**.

[0097] When the gas cell **25** is ruptured releasing the compressed gas, the upstream biasing pressure resulting from release of the gas is insufficient to force the plunger verge **70** upstream of the upstream port **34** of the syringe barrel **43**. Upstream displacement of the plunger **48** after use is prevented or inhibited by the plunger verge **70** that engages the inner circular edge of end flange **30** when the plunger **48** has reached its downstream limit, thereby locking the plunger **48** within the syringe barrel **43**. Once the plunger **48** is so locked within the syringe barrel **43** and once the needle assembly **82** is retracted into the lumen **39** of the plunger **48**, the needle **37** cannot be reused or cause bodily harm, and can be disposed of in a suitable manner.

[0098] Fig. 6, in a sectional view, illustrates another embodiment of a single-use pneumatic retractable syringe wherein the engagement ring **445** has been dimensioned and configured such that a needle header, including the upstream end of the needle header, is positioned within the central cylindrical opening of the engagement ring **445**. This embodiment of the invention differs in two major respects from the embodiment of the invention depicted in Figs. 1 to 5, *viz* (i) the initial physical positioning of the needle header with respect to the modified engagement ring and (ii) the initial physical positioning of the needle port seal with respect to the plunger seal and the downstream end of the plunger. The modifications described below and depicted in Figs. 6, 7 and 8 allow for better alignment of the needle port seal with the needle header than may be readily achieved in the syringe of Figs. 1 to 5.

[0099] The syringe **420** of Figs. 6, 7 and 8 comprises a hollow cylindrical syringe barrel **443** having a downstream chamber **432** and an upstream chamber **431** separated by an annular wall **429** lying in a radial plane, a flange **430** at the upstream extremity of the syringe barrel **443**

having an upstream barrel opening **434** therein, and a downstream barrel opening **438** axially opposed to the upstream barrel opening **434**. The annular wall **429** has a central aperture **416**. The openings **416**, **434**, and **438** are axially aligned. The upstream chamber **431** has an inner cylindrical wall surface **433** while the downstream chamber **432** has an inner cylindrical wall surface **428**.

[0100] A hollow cylindrical plunger **448** has a hollow plunger body **472** configured and dimensioned to mate with and slide within the upstream chamber **431** of the syringe barrel **443**. A needle assembly (not shown) terminates at its distal end in a needle **437** that retracts into a lumen **439** within the body **472** of the plunger **448** after use, as will be described in further detail below. The body **472** of the plunger **448** is bounded by an inner cylindrical surface **454** and an outer cylindrical surface **457**, an upstream plunger end **450** having a plug opening **451** for a plunger plug **447** (shown in Fig. 8), and a downstream hollow cylindrical plunger end **452** and adjacent hollow neck **459** separated by external collar **455**, the end **452** and neck **459** having the same inner and outer diameters and an appreciably smaller outer diameter than that of the body **472** of the plunger **448**. The diameter of the outer cylindrical surface **457** of the body **472** is dimensioned so that the body **472** fits slidably within the syringe barrel **443** with a tolerance selected to constrain the plunger **448** from rattling within the syringe barrel **443** and to constrain the plunger body **472** to slide within the syringe barrel **443** with a small frictional resistance to longitudinal displacement of the body **472** within the syringe barrel **443**.

[0101] The upstream plunger end **450** is flanged to provide a bearing surface for two fingers so that finger pressure thereon in combination with thumb pressure applied to the distal end surface of the plug **447** (shown in Fig. 8) may be applied to grip the plunger **448**, permitting the hand to move the plunger **448**. The plug opening **451** is dimensioned and configured to permit the plunger plug **447** (shown in Fig. 8) to penetrate part way into the plug opening **451** but to run into increasing interference as the plunger plug **447** (shown in Fig. 8) is pushed into the plug opening **451**. The plug opening **451** provides an opening whereby tools (not shown) can be inserted to access the internal parts of the syringe **420** during assembly thereof in order to facilitate assembly of the component parts of the syringe **420**.

[0102] The downstream plunger neck **459** has a cylindrical inner surface **453**. The internal diameter of the downstream plunger neck **459** is chosen such that a needle port seal **441** frictionally engages the inner surface **453** of the downstream plunger neck **459** with a snug fit but a fit permitting movement of the needle port seal **441** under gas pressure. In this embodiment of the invention, the needle port seal **441** is mounted in the downstream plunger end **452** such that the downstream distal end of the needle port seal **441** is flush with the distal end of the downstream end **452** of the plunger **448** (see Fig. 6).

[0103] A hollow deformable plunger seal **440** surrounds the downstream plunger end **452** and the plunger neck **459** (see Fig. 6) with a tight fit and is retained in position by means of the collar **455** that engages a mating annular recess **458** within the plunger seal **440**. The fit, dimensions and material of the plunger seal **440** are selected so that the plunger seal **440** slidingly engages the inner cylindrical wall surface **433** of the upstream chamber **431** of the syringe barrel **443** with some resistance, thereby, (i) impeding leakage of fluid, such as medicament in cavity **474** or air, past the plunger seal **440** of the plunger **448**, while (ii) permitting longitudinal displacement of the body **472** within the chamber **431**. The dimensions of the annular wall **429** and its aperture **416** are selected so that downstream motion of the plunger seal **440** is stopped when the seal **440** abuttingly engages the annular wall **429**, whereas the cylindrical plunger end **452** and neck **459** downstream of the seal **440** may pass through the central aperture **416** of the annular wall **429** thereby allowing the distal cylindrical plunger end **452** to penetrate into the downstream chamber **432** of the syringe barrel **443**. At the same time that the distal cylindrical plunger end **452** penetrates into the downstream chamber **432** of the syringe barrel **443**, the plunger seal **440** is forced slidingly upstream on the plunger neck **459** until the upstream motion of the plunger seal **440** is stopped by the plunger seal **440** engaging an annular shoulder **456** formed where the body **472** of the plunger **448** meets the neck **459**.

[0104] Referring to Figs. 6, 7 and 8, an engagement ring **445**, having a central substantially cylindrical opening **449**, slidably but frictionally engages the inner cylindrical wall surface **428** of the downstream chamber **432** of the syringe barrel **443** with which surface **428** the seal **445** is dimensioned and configured to mate. The engagement ring **445** may move axially within the downstream chamber **432**, and in rest position the upstream end of seal **445** abuts against the annular wall **429**. When the plunger **448** is fully extended upstream out of the syringe barrel **443**, as seen in Fig. 6, the engagement ring **445** is at rest in the chamber **432**, whereas the plunger seal **440** and needle port seal **441** are at the upstream end of the chamber **431**. The engagement ring **445** will not move from its rest position as seen in Fig. 6 until the end of the injection phase when downstream pressure applied to the plunger **448** by the user causes the downstream plunger end **452** to pass downstream through the aperture **416** of the annular wall **429**, whereafter further downstream displacement of the plunger end **452** forces the engagement ring **445** to slide axially downstream

[0105] Fully assembled just prior to needle retraction, the needle assembly (not shown assembled) comprises the needle port seal **441**, a hollow needle header **442**, and the hollow needle **437**. The needle port seal **441** by itself or in combination with the needle header **442** constitute the needle carrier. The diameter of the inner cylindrical surface **453** is selected relative to the outer needle port seal **441** so that the needle assembly may pass through the neck **459** of the plunger **448** into the lumen **439** of the plunger **448**. Also, the length of the lumen **439** is selected relative to the length of the needle assembly such that the needle assembly can be housed completely within the lumen **439** after use. During the injection phase, the needle header **442** is positioned within the engagement ring **445** such that the knob **478** of the needle header **442** is flush with the upstream end of the engagement ring **445** (as seen in Fig. 6). The needle header **442** has a downstream hollow cylindrical body **476**, a collar **477** and an upstream hollow end knob **478**. The needle **437**, having a downstream tip **436** and an upstream intake opening **475**, is cemented to or otherwise affixed within the body **476** of the needle header **442**.

[0106] When the syringe **420** is charged with medicament, the medicament is confinable within the upstream chamber **431** of the syringe barrel **443** downstream of the plunger seal **440** and needle port seal **441** and upstream of the engagement ring **445** and needle header **442** as shown in Fig. 6. The engagement ring **445** provides a containment surface for the medicament within cavity **474** and maintains a compression seal to hold the needle header **442** and needle **437** in place during injection of medicament into the patient. In the embodiment of the invention shown in Figs. 6, 7 and 8, the dimensions of the engagement ring **445** are selected so that the needle header **442** is surrounded by the engagement ring **445** in such a manner that the hollow knob **478** of the needle header **442** is flush with the upstream end of the engagement ring **445**. In this embodiment, the needle port seal **441** is configured such that the distal end of the needle port seal **441** may be inserted into the central cylindrical opening **449** of the engagement ring **445** thus facilitating accurate alignment of the socket **479** of the needle port seal **441** to the knob **478** of the needle header **442**. The engagement ring **445** maintains accurate positioning of the needle header **442** within the syringe barrel **443** so as to align the needle header **442** with the needle port seal **441**.

[0107] A hollow perforator **446** comprising a base **422**, spaced puncture lances elements **423** fixed to the base **422** and projecting upstream therefrom, an elongate neck **426** projecting upstream from the base **422**, and having an inner cylindrical opening **424**, is positioned downstream of the engagement ring **445**. An annular gas cell **25** intervenes axially between the engagement ring **445** and the perforator **446**. The base **422**, puncture lances **423** and the neck **426** of the perforator **446** may be machined as one piece. In the embodiment of the invention shown in Fig. 6, the perforator **446** is secured in position by laminating, cementing or otherwise affixing the base **422** of the perforator **446** to a perforator mount **469**. In such an embodiment of the invention, the dimensions and material of the base **422** of the perforator **446** are preferably selected so that the base **422** of the perforator **446** may mate with the upstream end of the perforator mount **469** in a tight fit, thereby impeding leakage of gases or other fluids downstream thereof. The perforator mount **469** is laminated, cemented or otherwise affixed to the inner wall **428** of the chamber **432** in the vicinity of downstream barrel opening **438** of the syringe barrel **443**. The perforator **446** and the engagement ring **445** are axially positioned, with respect to each other, within the downstream chamber **432** of the syringe barrel **443** in such a manner that the neck **426** of the perforator **446** is inserted into the central cylindrical opening **449** of the engagement ring **445**. The neck **426** of the perforator **446** extends upstream and into the central cylindrical opening **449** of the engagement ring **445** to such an extent that the neck **426** of the perforator **446** touches the body **476** of the needle header **442**. The needle **437** extends downstream from the needle header **442** and through the inner cylindrical opening **424** of the perforator **446** such that the downstream neck **436** of the needle **437** projects out of and downstream of the perforator **446**. The neck **426** of the perforator **426** prevents downstream motion of the needle header **442** or needle **437**. The needle header **442** will not move until the plunger **448** has completed its downward motion, at the end point of which the needle port seal **441** is fixed to the needle header **442**.

[0108] An annular gas cell **425,** dimensioned and configured to fit within the downstream chamber **432** of the syringe barrel **443**, is positioned within the downstream chamber **432** between the perforator **446** and the engagement ring **445**. The gas cell **425** has an central inner opening **427** and contains a suitable non-toxic compressed gas in its gas storage chamber **480**. The gas cell **425** is positioned such that the neck **426** of the perforator **446** projects through the inner opening **427** of the gas cell **425** thus facilitating proper alignment of the gas cell **425** with respect to the puncture lances **423** of the perforator **446** and facilitating proper alignment of the gas cell **425** with respect to the engagement ring **445**. The material of the gas cell **425** is selected such that when the gas cell **425** is forced (with a pressure of approximately 6 p.s.i.g.) onto the puncture lances **423**, the gas cell **425** is ruptured by the puncture lances **423**. The gas in the gas cell **425** is expected to be at a pressure within the range previously specified for the gas cell 25.

[0109] The perforator mount **469** has a needle aperture **435** and is provided with a needle membrane **468 serving as a** needle port closure. The needle **437** is mounted such that it passes through the inner cylindrical opening **424** of the perforator **446**, and projects out of and downstream of the needle aperture **435**. The needle aperture **435** is dimensioned such that the needle **437** is held firmly during the injection phase. In order to impede leakage of compressed gas from the needle aperture **435**, the needle membrane **468** preferably surrounds the needle **437** where the needle **437** passes through the needle aperture **435**. The needle membrane **468** is essentially similar to the membrane **68** previously described. Once the needle **437** has been retracted, the needle membrane **468** covers the needle aperture **435** so as to impede downstream re-extension of the needle **437** through the needle aperture **435**.

[0110] Note that the upstream intake opening **475** of the needle **437** terminates in the hollow knob **478** of the needle header **442**. The needle **437** during assembly slides into and is secured in the body **476** of the needle header **442**. During injection, the fluid to be injected passes into the needle **437** through the knob **478**, which in this phase of syringe operation is out of contact with the mating socket **479** in the needle port seal **441**. It is not until after substantially all the fluid has been pushed out of the syringe **420** through the needle **437** that the knob **478** engages and is stopped by the socket **479**.

[0111] A lumen **439** within the body **472** of the plunger **448** is bounded by the needle port seal **441**, the upstream plunger end **450** and the inner surface **454** of the body **472** of the plunger **448**. After assembly of the syringe **420**, a plunger plug **447** is inserted into the plug opening **451**, thus sealing the lumen **439** of the plunger **448**. Because the needle port seal **441** engages the inner surface **453** of the downstream plunger end **452** with a snug fit, the needle port seal **441** prevents or inhibits leakage of medicament past the needle port seal **441** into the lumen **439** during administration of medicament. In this embodiment of the invention, the needle port seal **441** is mounted such that in the fully extended rest position of the plunger **448**, the downstream end of the needle port seal **441** is flush with the downstream distal end **452** of the plunger **448** (as shown in Fig. 6). During the needle retraction phase of operation of the syringe **420**, the needle port seal **441** is forced upstream into the lumen **439** of the plunger **448**. The diameter of the lumen **439** is chosen such that, under an upstream biasing pressure sufficient to overcome the frictional force between the needle port seal **441** and the inner surface **453** of the downstream plunger end **452**, the needle port seal **441** is forced axially within the lumen **439** until further upstream movement of the needle port seal **441** is impeded by the plunger plug **447**. The dimensions and materials of the needle port seal **441** are selected so that the needle port seal **441** frictionally but slidably engages the inner surface **454** of the body **472** of the plunger **448**.

[0112] The syringe **420** is provided with a plunger lock that generally resembles that described with reference to Fig. 1 ff, but differing in that a plunger verge **470**, generally resembling plunger verge **70** in previous figures of the drawings, engages not an end flange on the syringe barrel but instead an interior lock-mate circumferential ridge or verge **471** in the vicinity of the upstream end of the syringe barrel **443**. Referring to Figs. 6, 7 and 8, the plunger verge **470** is located on the outer surface **457** of the plunger **458** and is configured to have an inclined surface leading to an upstream shoulder. The lock-mate verge **471** is shaped similarly to plunger verge **470** but in the opposite sense so that shoulder-to-shoulder locking will occur upon downstream displacement of the plunger **448** sufficient to place plunger verge **470** downstream of the lock-mate verge **471**. Note that the gentle inclination of the two verges **470, 471** in opposite senses facilitates passage of the verges **470, 471** past one another as the plunger is moved downstream.

[0113] The operation of the embodiment of the invention depicted in Figs. 6, 7 and 8 is analogous to the operation of the embodiment of the invention depicted in Figs. 1 to 5.

[0114] Preferably, the syringe barrel **443** and plunger **448** are fabricated from ASTM D 788 acrylic. Other materials suitable for use in the syringe **420** include USP class V1, PP [polypropylene] and rubber (as suitably selected) for many of the parts (other than the needle, of course, which is not part of the syringe *per se*). The needle **437** is suitably made of needle tubing by Popper, selection types 304 Hypodermic tubing, from 6G through 32 G (with burr-free ECG grinding), or equivalent from other manufacturers. . The syringe barrel **443** is preferably treated with a medical grade lubricant such as Dow Corning™ 360 Medical Fluid. Suitably, the compressed gas used in the gas cell **425** is Suva 134a (DUPONT™) or medical-grade nitrogen. As standard in the industry, the syringe **420** and all the components of the syringe **420** are preferably sterilized before packaging by oxide (EtO) gas using a suitable four-phase process. The foregoing materials selections are also generally suitable for other embodiments of syringes made in accordance with the invention.

[0115] Dimensions of the component parts of the syringe **420** and of the other syringes described herein will vary depending upon the volume of the syringe required. As of the writing of this specification, no commercial syringe in accordance with the invention had been manufactured, so reliable dimension figures were not available. An empirical approach should be taken in developing a commercial model from the drawings and description herein provided.

[0116] Referring to Fig. 9 and following figures, there is illustrated in an exploded cross-sectional view, a single-use pneumatic retractable syringe according to another embodiment of some aspects of the invention. This syringe more closely resembles the Klippenstein syringe of US Patent No. 5,868,713 than does the embodiment of Figs 1-5, and the Fig. 6 ff syringe does not embody some of the inventive characteristics of the syringe of Figs 1-5. The syringe **620** of this embodiment comprises a hollow cylindrical syringe barrel **643** having an inner cylindrical wall surface **633**, an upstream barrel opening **634**, and a downstream end **632** with a downstream barrel opening **638** axially opposed to the upstream barrel opening **634**.

[0117] A plunger **648** is dimensioned, configured and positioned within the mating syringe barrel **643** for sliding axial movement within the syringe barrel **643**. The plunger **648** is accordingly dimensioned to fit within the syringe barrel **643** within a tolerance permitting the plunger **648** to slide within the syringe barrel **643** while constraining the plunger **648** against rattling within the syringe barrel **643** and providing some frictional resistance to longitudinal sliding of the plunger **648** within the syringe barrel **643**. The plunger **648** is hollow, having an inner surface **654** and an outer surface **657**, an upstream plunger end **650** and a downstream plunger end **652**. The upstream plunger end **650** is preferably capped with a thumb cradle or abutment **651**.

[0118] An engagement disc **645** slidingly but frictionally engages the inner surface **654** of the plunger **648** at the downstream plunger end **652**. The solid engagement disc **645** is dimensioned and configured to mate with the inner surface **654** of the plunger **648** at the downstream plunger end **652** and is positioned for axial movement within the plunger **648**.

[0119] A lumen **639** within the plunger **648** is bounded by the engagement disc **645**, the upstream plunger end **650** and the inner surface **654** of the plunger **648**. The engagement disc **645** frictionally engages the inner surface **654** of the plunger **648**, thereby impeding leakage of medicament from cavity **674** (shown in Fig. 14) past the engagement disc **645** into the lumen **639** during administration of medicament. During the needle retraction phase, the engagement disc **645** is forced upstream into the lumen **639** of the plunger **648**. The diameter of the lumen **639** is chosen such that, under an upstream biasing pressure sufficient to overcome the frictional force between the engagement disc **645** and the inner surface **654** of the plunger **648**, the needle port seal **641** can move axially within the lumen **639** until further upstream movement of the needle port seal **641** is impeded by the thumb cradle **651**. A slidable plunger seal **640** surrounds the downstream plunger end **652** and is affixed thereto. Optionally, the plunger seal **640** and the engagement disc **645** may be made as a unit with a scored or perforated edge between the engagement disc **645** and the plunger seal **640**. The dimensions and material of the plunger seal **640** are selected so that the plunger seal **640** slidingly engages the inner cylindrical wall surface **633** of the syringe barrel **643** with a snug fit, thereby (i) impeding leakage of fluid, such as medicament past the plunger seal **640** of the plunger **648**, while (ii) permitting longitudinal displacement of the plunger **648** within the syringe barrel **643** by means of normal hand pressure. During the needle retraction phase, the engagement disc **645** slidingly engages the inner surface **654** of the plunger **648**, the engagement disc **645** coming to rest and frictionally engaging the inner surface **654** of the plunger **648** near the upstream plunger end **650** of the plunger **648** at the completion of the needle retraction phase.

[0120] A needle **637** for use in the syringe **620** has a generally disc-shaped needle header **642** integral with the upstream end thereof. The needle **637** and its header **642** have a central conduit for passage of medicament therethrough. A disc-shaped needle port seal **641** is affixed to the downstream end of the engagement disc **645**. The needle port seal **641** may be constructed as a separate piece from the engagement disc **645**, or the needle port seal **641** and the engagement disc **645** may be constructed as one piece. The purpose of the needle port seal **641** is to seal the upstream port of the medicament conduit in the needle **637** following injection.

[0121] A needle end cap **690** having an upstream end **692**, a downstream end **694**, and having formed within it needle aperture **635**, is affixed to the downstream end **632** of the syringe barrel **643**. The inner wall of the upstream end rim **692** of the needle end cap **690** is dimensioned and configured to mate with the outer cylindrical surface of the downstream end **632** of the syringe barrel **643** with a tight fit. For user convenience, the needle end cap **690** may be colour-coded to indicate needle size.

[0122] An alignment disc **646** is securely mounted in the needle end cap **690** near the upstream end **692** of the needle end cap **690** in such a manner that a gas cell compartment **696** is formed between the base of the alignment disc **646** and a circular recess formed in the needle end cap **690**. The alignment disc **646** establishes an initial buffer between the gas cell **625** and the downstream end **652** of plunger 648. Optionally, an annular tension seal (not shown) may surround the alignment disc **646** to facilitate its secure mounting in the needle end cap **690**.

[0123] A pair of diametrically spaced puncture lances **623** are affixed to the downstream plunger end **652** in alignment with spaced through-holes **658** in alignment disc **646**, the through-holes **658** being dimensioned and affixed to the downstream plunger end **652** to pass therethrough. The number of through-holes **658** and corresponding puncture lances **623** is not limited to two, but preferably the through-holes **658** and corresponding puncture lances **623** should be arranged about the aperture **624** in a circular symmetrical manner. Note that it is essential to this embodiment that when the end cap **690** is assembled to the barrel **643**, the alignment disc is oriented so that the through-holes **658** are aligned with the puncture lances **623**.

[0124] As shown in Figs. 9 and 10, the puncture lances **623** may be completely surrounded by the plunger seal **640**. Alternatively, as shown in Fig. 11, a syringe may be constructed wherein a puncture lance **823** projects downstream and through a plunger seal **840**. Optionally, the gas cell compartment **696** may be separately made unit surrounding the gas cell **625** but designed to permit ready access of the puncture lances **623** to the gas cell **625**.

[0125] In the assembly of the syringe **620**, prior to affixing the end cap **690** onto the syringe barrel **643**, the needle **637** is mounted in the needle end cap **690** by passing the downstream end of the needle **637** through the central aperture **624** of the alignment disc **646**, through the inner opening **627** of the gas cell **625**, and through the needle aperture **635** in the needle end cap **690**. The central aperture **624** of the alignment disc **646** and the needle aperture **635** of the needle end cap **690** are dimensioned and configured to embrace and support the needle **637** with a snug fit.

[0126] A needle header lock **656** is provided to provide, just before the end of the downstroke of the plunger **648**, a locking engagement between downstream plunger end **652** and needle header **642**. As illustrated, the header lock **656** comprises a pair of diametrically spaced barbed lances **659** affixed to the engagement disc **645** and projecting downstream therefrom. The barbed lances **659** are configured and dimensioned for locking engagement with the peripheral edge of the needle header **642**; this is facilitated by a circular recess **655** in the alignment disc **646** permitting the lance points as they move downstream to bend outwardly and overshoot the peripheral edge of the needle header **642** and then to spring inwardly to grip the needle header **642** in a locking engagement. The diameter of the needle header **642** is selected such that the peripheral edge of the needle header **642** partially covers the circular recessed groove **655** in the alignment disc **646**, facilitating retention of the header lock lances **659** by the needle header **642**. Other suitable snap-fit or other locking engaging components could be substituted for those illustrated, but the illustrated arrangement is compact and effective. The dimensions of this embodiment of the syringe should be selected to prevent any substantial gap occurring between the needle port seal 641 and the needle header 642. It is disadvantageous to leave any gap available in which medicament can collect; it is an objective to inject substantially all of the charge of medicament drawn into the syringe.

[0127] Fig. 12 illustrates, in a plan view, and Fig. 13 illustrates, in a cross-sectional view, the alignment disc **646** according to the embodiment of the invention illustrated in Fig. 9. The alignment disc **646** is generally circular with a central aperture **624** dimensioned and configured to allow a hollow needle **637** to pass therethrough. A circular recessed groove **655** dimensioned and configured to receive the barbed lances **659** attached to the engagement disc **645** is concentric with the central aperture **624** of the alignment disc **646**.

[0128] Reverting to Fig. 9, an annular gas cell **625** with an inner "doughnut hole" opening **627** and containing a suitable non-toxic compressed gas in its gas storage chamber **680** is dimensioned and configured to fit within the gas cell compartment **696**. The material of the gas cell **625** is selected such that when the puncture lances **623** are forced (preferably with a pressure of approximately 6 p.s.i.g.) against the gas cell **625**, the gas cell **625** is ruptured by the puncture lances **623**.

[0129] In order to impede leakage of compressed gas from the needle aperture **635** of the needle end cap **690**, an annular needle membrane **668** fixed to the needle end cap **690** surrounds the needle **637** at the upstream limit of the needle aperture **635** of the needle end cap **690**. The membrane **668** is essentially similar to the membrane **68** previously described and serves as a needle port closure. Once the needle **637** has been retracted into the lumen **674** after use of the syringe, the needle membrane **668** covers the needle aperture **635** so as to impede downstream penetration of the needle **637** through the needle aperture **635**.

[0130] In this embodiment of the invention, the syringe **620** further comprises a plunger verge **670** and a cooperating lock-mate verge **671** whose structure, location, and locking operation generally resemble those previously described with reference to plunger verge **470** and lock-mate verge **471**.

[0131] Referring to Figs. 14, 15 and 16, in operation, the syringe **620** is charged with medicament in the same manner as a conventional syringe is charged with medicament. A user applies a downstream force to the upstream plunger end **650** thereby causing the plunger **648** and plunger seal **640** to move axially downstream within the syringe barrel **643**. The downstream motion of the plunger seal **640** forces most of air that is contained in the syringe barrel **643** through the upstream intake of the needle **637** and out of the downstream tip of the needle **637**. When nearly all of the air is forced out of the syringe barrel **643**, but before the plunger verge **670** engages the lock-mate verge **671**, the downstream tip of the needle **637** is submerged into medicament contained in a supply vial (not shown). While maintaining submersion of the tip of the needle **637** in the medicament, an upstream force is applied to the plunger **648** thereby effectuating withdrawal of the medicament from the supply vial and into the cavity **674** in the syringe barrel **643**. Once the medicament is within the cavity **674**, the syringe **620** is held such that the downstream tip of the needle **637** is pointed skyward such that any residual air floats above the medicament in the syringe barrel **643** whereafter a downstream force is applied to the plunger **648** such that the residual air is forced out of the syringe barrel **643**. Referring to Fig. 14, when the syringe **620** is charged with medicament, the medicament is contained within the syringe barrel **643** and confined between the plunger seal **640** of the plunger **648**, the engagement disc **645** and the alignment disc **646**.

[0132] After the syringe **620** is charged with medicament, as shown in Fig. 14, a downstream injection force is applied to the plunger **648** to force the plunger **648** to slide axially downstream thereby forcing medicament into the needle header **642** and discharging medicament through the needle **637**. When a user applies a downstream injection force to the plunger **648**, the plunger seal **640** at the downstream plunger end **652** imparts a downstream biasing pressure to the medicament contained in the syringe barrel **643**. This downstream biasing pressure applied to the plunger **648** by the user is sufficient to force medicament through the upstream intake of the needle **637** and into a patient via the downstream tip of the needle **637**. Although the medicament while being injected is placed under pressure by the plunger **648** and therefore exerts a corresponding upstream biasing pressure on the engagement disc **645**, the resulting force on the engagement disc **645** is not sufficient to overcome the frictional force securing the engagement disc **645** to the inner surface **654** of the plunger **648**.

[0133] Referring to Fig. 15, after substantially all of the medicament has been thus discharged from the cavity **674**, continued application of the injection force causes the downstream end of the needle port seal **641** to be forced onto the needle header **642** thereby sealing the needle header **642** such that no further medicament or other fluids may be forced through the upstream intake of the needle **637** and delivered to the patient. When the needle port seal **641** engages and seals the needle header **642** the barbed lances **659** project into the recessed groove **655** of the alignment disc **646**. When a downstream force is applied to the plunger **648** the shallow downstream side of the barbed lances **659** is forced downstream of the outer edge of the needle header **642** and into the recessed groove **655** of the alignment disc **646**. The barbs on the barbed lances **659** engage the needle header **642** and secure the needle header **642** thereto since the steep upstream side of the barbed lances cannot be forced upstream past the outer edge of the needle header **642**.

[0134] Referring to Fig. 16, after all the medicament has been thus discharged from the cavity

674, continued application of the downstream injection force (now a post-injection force) applied by the user to the plunger **648** causes the puncture lances **623** to pass through the through holes **658** of the alignment disc **646** and forces the puncture lances **623** to impinge the gas cell **625**. Forcing the puncture lances **623** onto the gas cell **625** causes the puncture lances **623** to rupture the gas cell **625**, thereby releasing the compressed gas from the gas cell **625**. The released gas escapes through holes **658** and biases the plunger **648** to move within the syringe barrel **633** in an upstream direction. Movement of the plunger **648** out of the syringe barrel **633** is, however, prevented or inhibited by the engagement of plunger verge **670** with the lock-mate verge **671**. The released gas exerts an upstream biasing pressure within the syringe barrel **643** with sufficient pressure to overcome the frictional force between the engagement disc **645** and the inner surface **654** of the plunger **648** thus forcing the engagement disc **645** to slide axially upstream within the lumen **639** of the plunger **648**. As the engagement disc **645** slides upstream in the lumen **639** it carries the needle **637** into the lumen **639** as the needle header **642** is secured to the engagement disc **645** by the barbed lances **659** thereby withdrawing the needle **637** into the lumen **639** of the plunger **648**. (I n this embodiment, the needle carrier comprises the combination of the engagement disc **645 with the** header lock **656**.) Of course, there has to be enough gas under pressure in storage chamber **680** that the upstream biasing pressure is sufficient to generate enough force to cause the needle **637** to move upstream through the required distance. The pressure of the compressed gas within the gas cell **625** is expected to be within the range previously specified for the gas cell 25.

[0135] At the end of the needle retraction phase, further upstream movement of the needle **637** is restricted by the thumb cradle **651**. The engagement disc **645** frictionally engages the inner surface **654** of the plunger **648** near the upstream plunger end **650** of the plunger **648**, thus retaining the needle header 642 and needle **637** within the lumen **639** of the plunger **648**.

[0136] As the downstream tip of the needle **637** passes through the needle aperture **635**, the tapered portion of the needle membrane **668** flattens to cover the needle aperture **635** thereby impeding re-extension of the needle **637**.

[0137] When the gas cell **625** is ruptured, releasing the compressed gas from the gas storage chamber **680**, the upstream biasing pressure resulting from release of the compressed gas is insufficient to force the plunger verge **670** upstream of the lock- mate verge **671** of the syringe barrel **643**. Once the plunger **648** is so locked within the syringe barrel **643** and once the needle **637** is retracted into the lumen **639** of the plunger **648**, the needle **637** cannot be reused or cause bodily harm, and can be disposed of in a suitable manner.

[0138] In all described embodiments of the inventive syringe, when gas forces the needle, needle header and other syringe components upstream into the plunger lumen, the air previously in the lumen will tend to become compressed. The compressed air may be released by providing a small vent hole (not illustrated) in the plunger wall, preferably located upstream of the plunger lock verge, thereby facilitating needle retraction.

[0139] Variations in what has been described and illustrated in this specification will readily occur to those skilled in the technology. A few examples of possible improvements, modifications and variants follow:

[0140] The volume of the lumen **39** bounded by the inner surface **54** of the plunger **48**, the needle port seal **41** and the plug plunger **47** could be partially evacuated thereby aiding in the rapid retraction of the needle assembly **82** and allowing for a reduction in the gas pressure contained in the gas cell **25**.

[0141] Instead of being penetrated by puncture lances **23**, the gas cell **25** could be broken by being crushed by the plunger seal **40** or being torn away from the inner cylindrical wall surface **33** of the syringe barrel **43**, thereby being torn open by the downstream movement of the plunger **48**.

[0142] The puncture lances **23**, instead of being mounted on the perforator **46** in such a manner that the puncture lances **23** project upstream from the perforator **46** towards the gas cell **25**, could alternatively be mounted on a perforator fixed to (or, less desirably, placed immediately downstream of) the downstream end of the engagement ring **45** in such a manner that the puncture lances **23** project downstream from the engagement ring **45** towards the gas cell **25**. In such alternative embodiment, the perforator **46** could be secured in position by laminating, cementing or otherwise affixing the base **22** of the perforator **46** to the inner cylindrical wall surface **28** of the syringe barrel **43**. The fit or bonding of the circumferential periphery of the perforator to the interior of the syringe barrel should be effective to prevent or substantially impede leakage of gases or other fluids downstream of the perforator **46** other than through the needle.

[0143] The gas release cell , instead of containing pre-injection compressed gas, could contain chemically reactive liquids or possibly solids instead of gases in each of two or more sub-compartments, each subcompartment containing a discrete reagent. The subcompartments could be separated from one another by one or more walls to be punctured. Upon puncturing the separating wall or walls, the reagents in the sub-compartments would mingle and react so as to generate a gas under pressure, released when the cell is punctured. This alternative would be of some advantage in that such modified cell **25** would not be under any pressure until the syringe **20** is used.

[0144] The needle cover **44** and the perforator mount **69** could be manufactured as two distinct pieces and coupled together with a releasable holding means.

[0145] While it is considered preferable to manufacture and sell the syringe as a completely assembled article of manufacture, it is possible to manufacture and sell the syringe as a set of subassemblies. For example, the needle and needle header could be separately provided. The perforator and perforator mount in some embodiments could be sold detached from the barrel, and the gas cell could also be kept separate and installed just before use of the syringe, whereafter completion of assembly of the syringe could take place. Disadvantages of manufacture and sale of the syringe as a set of subassemblies include risk of damage to sensitive components such as the needle, risk of accidental stabbing, risk of premature rupture of the gas cell, and risk of misalignment of components. Advantages include the possibility of more compact packaging of the syringe for sale, and the possibility of separate packing of the gas cell, which could be packed within an outer container that is itself pressurized so as to reduce the stress on the gas cell wall or "skin" prior to use of the syringe.

[0146] Many mechanical expedients are known for interlocking two meshing or mating elements. Various of them could be selected in substitution for the plunger verge/lock-mate verge examples described and illustrated herein.

[0147] Many mechanical expedients are known for effecting support and alignment of components requiring such. Where radial alignment is required, the radial cross-section of aligned components can be non-circular, *e.g.* with one flattened side. Or tongue-and-groove alignment may be provided. Various alignment techniques could be selected in substitution for the alignment arrangements described and illustrated herein by way of example, and the same applies to support.

[0148] Many mechanical expedients are known for disabling elements after some mechanical event occurs. In the present case, it is an objective to disable the needle after use of the syringe, and to provide some means to prevent or inhibit its re-extension after it has been retracted into the plunger lumen. One means herein described for inhibiting needle re-extension is a resilient membrane located downstream of the needle header and through which the slender portion of the needle passes. After needle retraction has been completed, the membrane at least partially closes upon the aperture through which the needle has passed. But other means can be readily conceived for blocking the exit of the needle from the lumen, once it has been retracted..

[0149] Where components are to be secured to one another, some discretion is permitted to the designer and manufacturer. In many cases, tight-fit, snap-fit, twist-off, or threaded connection suffices, and may be preferred to gluing, as one may wish to avoid contact between glue and the interior of the syringe and particularly to avoid contact between glue and medicament to be injected.

[0150] The foregoing are exemplary only; other possible equivalents and substitutions will readily occur to those skilled in the mechanical design of hypodermic-needle-type syringes.

[0151] Accordingly, the invention is not to be limited by the specific embodiments described above; the scope of the invention is as defined in the claims.

Claims:

1. A safety syringe of the type for use with a hypodermic needle in which, following use of the syringe to inject medicament from its barrel, the needle is detached from the distal end of the syringe and retracted within the barrel of the syringe, thereby preventing accidental stabbing after use, comprising
   a. a plunger axially movable within the barrel and having therewithin a retraction lumen open at its distal end to receive the needle after use of the syringe;
   b. a gas release cell located within the assembled syringe distally of the plunger, intact and inoperative prior to substantial completion of injection of medicament by downstream motion of the plunger;
   c. gas release trigger means located within the assembled syringe between the distal end of the plunger and the gas release cell, and operable in response to downstream motion of the plunger as it approaches its downstream limit of travel to cause the gas release cell to release gas into the interior of the syringe; and
   d. a needle carrier for engaging the needle in the vicinity of its proximal end and carrying the needle into the lumen during retraction of the needle, the needle carrier having a distal bearing surface against which gas under pressure may bear, and movable into the plunger lumen under gas pressure so as to retract the needle into the lumen;

      wherein
   e. the lumen is dimensioned to receive sufficient of the combined length of the needle and the needle carrier that, after retraction, the needle is entirely within the syringe, and the needle thereafter remains in retracted position.

2. A syringe as defined in Claim 1, additionally having a plunger lock for impeding or preventing unwanted re-extension of the plunger out of the barrel after use of the syringe, the plunger lock comprising
   a. a plunger lock engagement element fixed to the plunger; and
   b. a cooperating lock-mate engagement element fixed to the barrel;

      wherein
   c. the engagement elements are located so as to make engaging contact with one another near the downstream limit of travel of the plunger; and
   d. downstream motion of the plunger past the point of engaging contact causes the locking of the plunger within the barrel at or near the downstream limit of travel of the plunger.

3. A syringe as defined in Claim 2, wherein the plunger lock is structured to lock the plunger to the barrel at a point in the downstream path of travel of the plunger coincident or approximately coincident with the point at which the gas release trigger means operates to cause the gas release cell to release gas.

4. A syringe as defined in Claim 3, wherein the plunger lock is structured to lock the plunger to the barrel at a point in the downstream path of travel of the plunger slightly upstream of the point at which the gas release trigger means operates to cause the gas release cell to release gas.

5. A syringe as defined in any of Claims 1 to 4, additionally having a needle re-emergence barrier that after retraction of the needle into th lumen is located downstream of the tip of the needle and operable after the needle has been retracted into the plunger lumen to prevent or impede downstream movement of the needle out of the lumen.

6. A syringe as defined in Claim 5 , wherein the needle re-emergence barrier comprises needle port closure means located within the barrel between the distal end of the plunger and the proximal end of the needle aperture when the needle has been assembled into the syringe and the plunger extends proximally outward from the barrel, the needle port closure means being operable as the plunger approaches the downstream limit of its path of travel to block the proximal end of the needle aperture.

7. A syringe as defined in any of Claims 1 to 6, additionally having a gas barrier for preventing or impeding downstream escape of gas out of the syringe from the gas release cell.

8. A syringe as defined in any of Claims 1 to 7, wherein the gas release cell is a closed cell containing a suitable substantially non-toxic non-corrosive compressed gas.

9. A syringe as defined in Claim 8, wherein the gas release cell is of overall toroidal shape, so that the opening in the torus may accommodate passage therethrough of the needle.

10. A syringe as defined in Claim 8 or 9, wherein the gas release trigger means comprises a perforator for rupturing the gas release cell.

11. A syringe as defined in any of Claims 1 to 10, wherein the needle carrier is provided with a circumferentially disposed seal for providing a sealing contact between the needle

carrier and the interior surfaces of the syringe through which the needle carrier passes.

12. A syringe as defined in any of Claims 1 to 11, whose barrel is divided internally into a smaller downstream chamber for housing the gas release cell and gas release trigger means, and an upstream chamber for containing medicament to be injected, the said chambers being separated by a radial chamber separator wall having an axial opening therein for discharge of medicament from the upstream chamber into the needle and for receiving the needle into the plunger lumen after injection.

13. A syringe as defined in Claim 12, wherein the plunger has a body and a distal end of diameter smaller than that of the body.

14. A syringe as defined in Claim 13, wherein nearing the downstream limit of travel of the plunger, the distal end thereof penetrates the chamber separator wall through the axial opening therein, and downstream movement of the distal end of the plunger beyond the chamber separator wall causes the gas release trigger means to operate.

15. A syringe as defined in Claim 14, additionally comprising within the downstream chamber an engagement ring slidably but with friction engaging the interior circumferential wall of the downstream chamber and axially movable therein, the engagement ring being located between the gas release cell and the radial separator wall and having a central aperture through which medicament from the upstream chamber into the needle may flow and for passage of the needle into the plunger lumen after injection, the engagement ring providing a buffer against which the gas cell is constrained so as to facilitate rupture of the gas cell by the perforator.

16. A syringe as defined in Claim 15, wherein distal end of the plunger engages the upstream end of the engagement ring near the downstream limit of travel of the plunger, forcing the gas release cell into rupturing contact with the perforator upon completion of downstream movement of the plunger.

17. For use with a needle having a needle header, a syringe as defined in Claim 15 or 16, wherein the engagement ring engages the needle header to provide support thereto and facilitates alignment of the needle and the needle header within the downstream chamber.

18. A syringe as defined in any of Claims 1 to 17, wherein the needle carrier includes a

needle port seal for blocking escape of gas and medicament through the needle and that is mounted within the distal end of the plunger for frictional but sliding engagement with the inner surface of the plunger, and wherein at least the outermost circumferential portion of the needle port seal is made of resilient material so that the needle port seal may expand in diameter to fill the full cross-section of the plunger lumen within the plunger body during the needle-retraction phase of syringe operation.

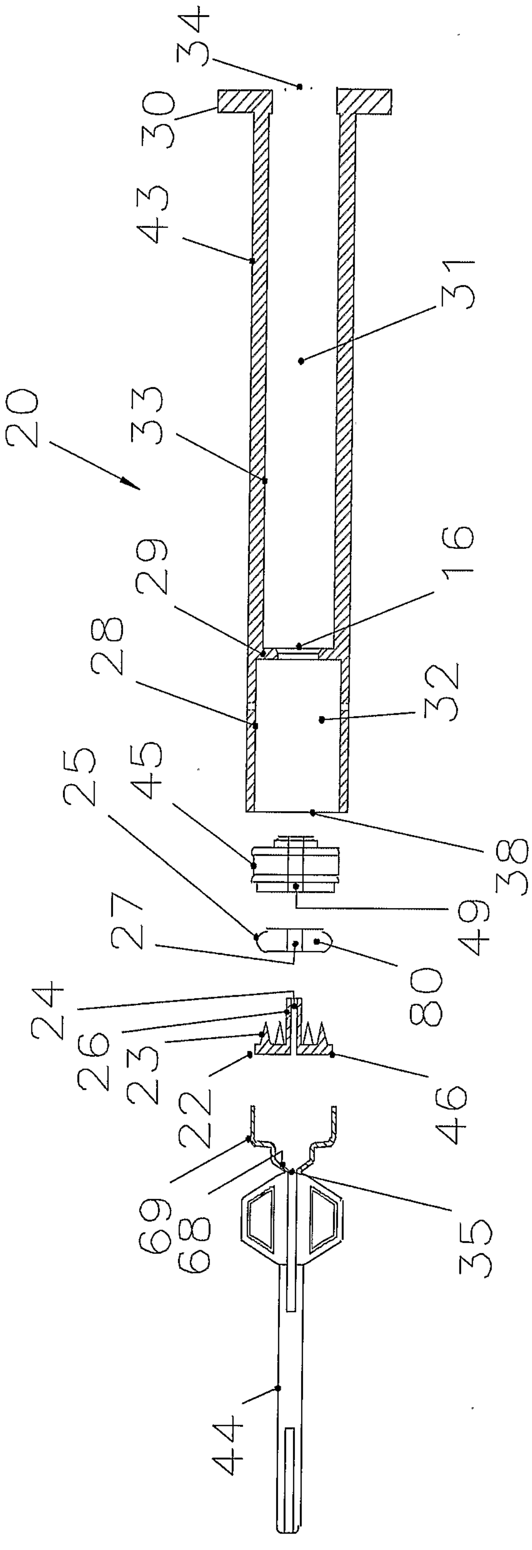
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FIG. 1

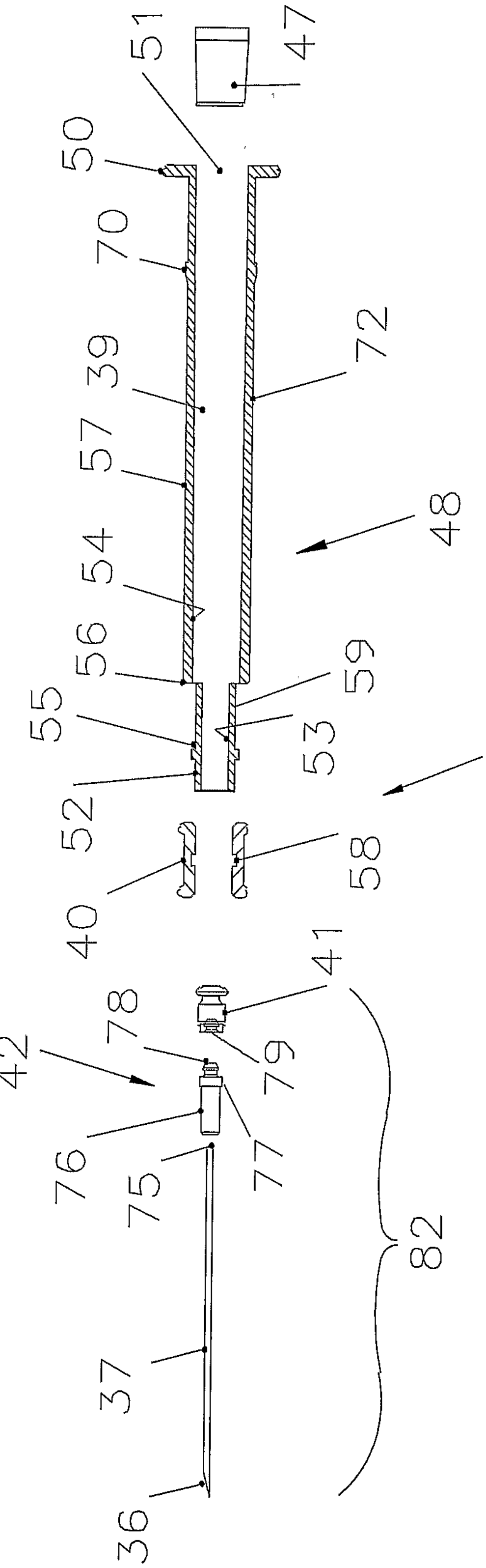
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FIG. 2

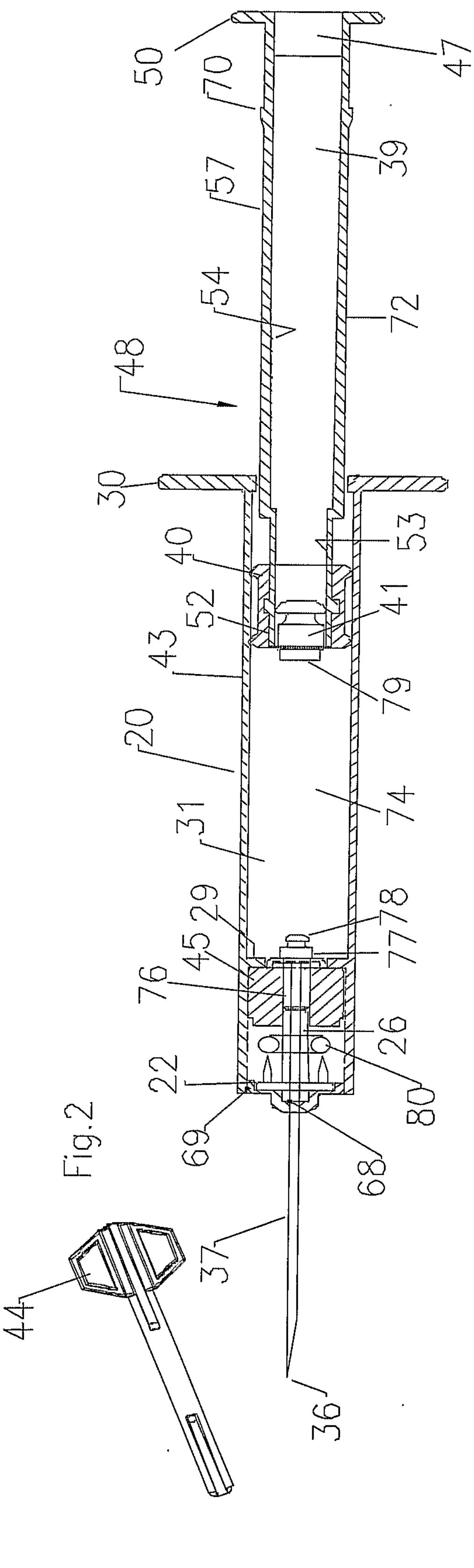
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Fig.2

FIG. 3

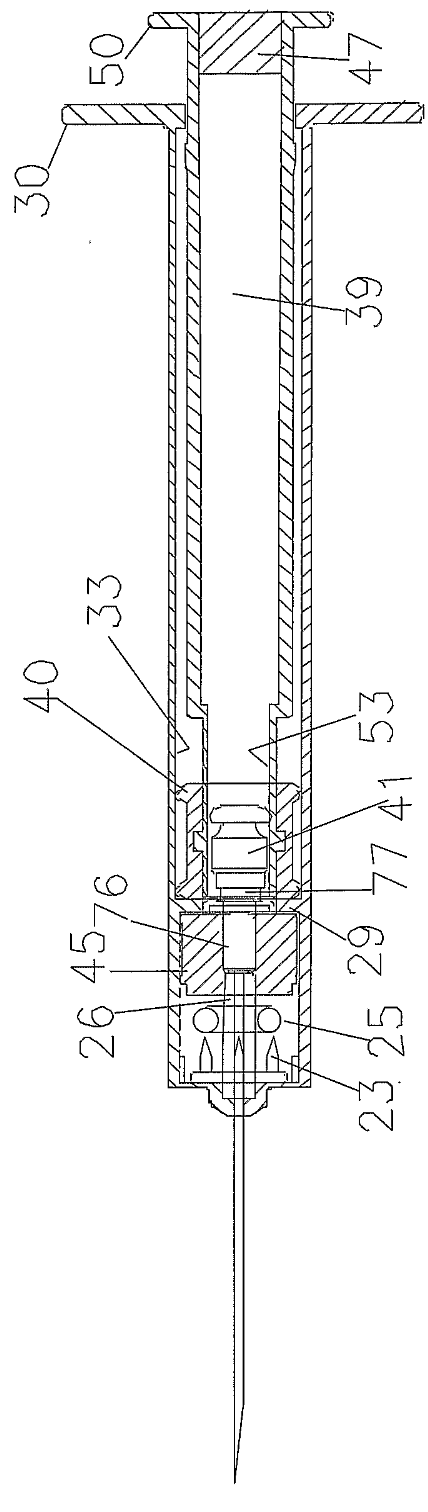

FIG. 4

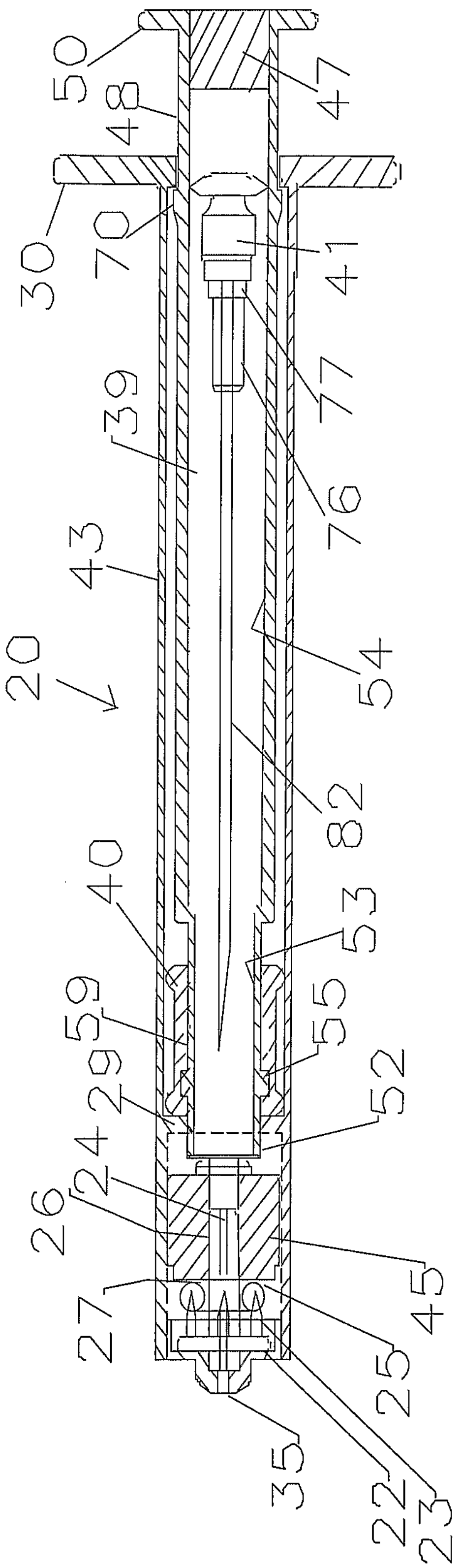
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FIG. 5

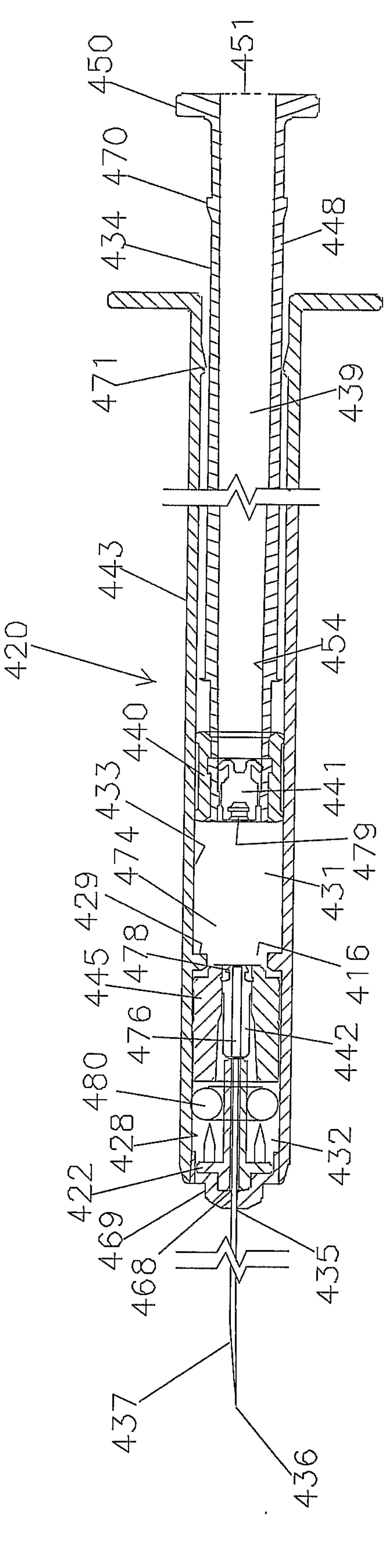
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FIG. 6

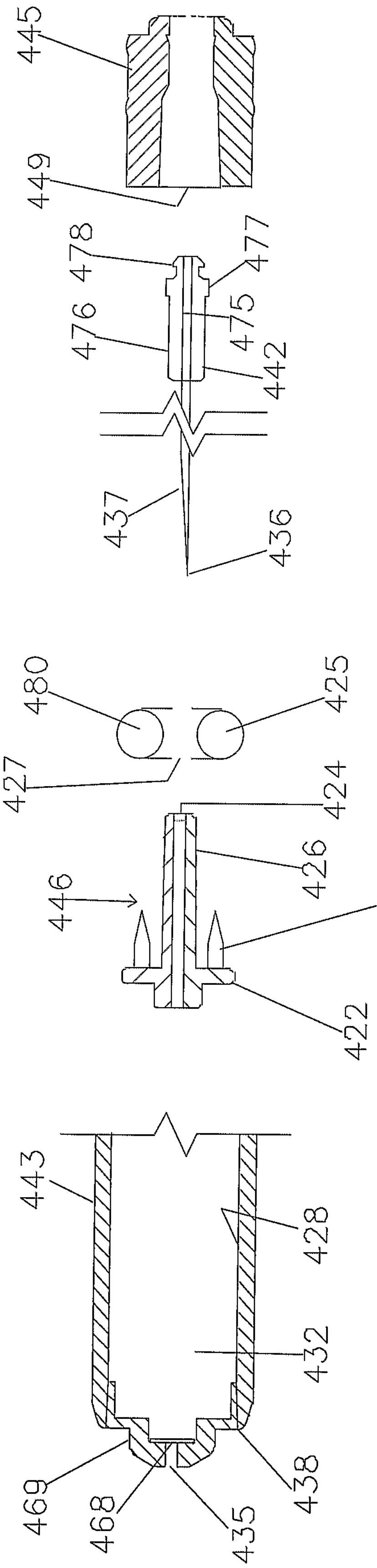
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FIG. 7

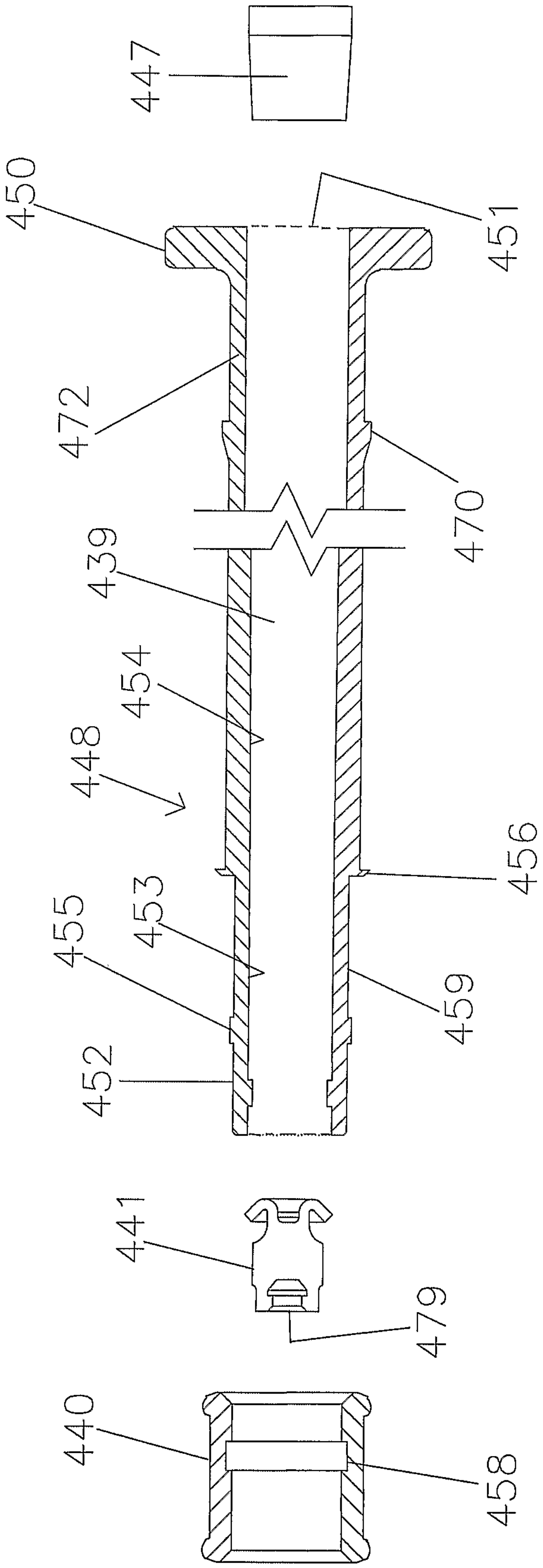
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FIG. 8

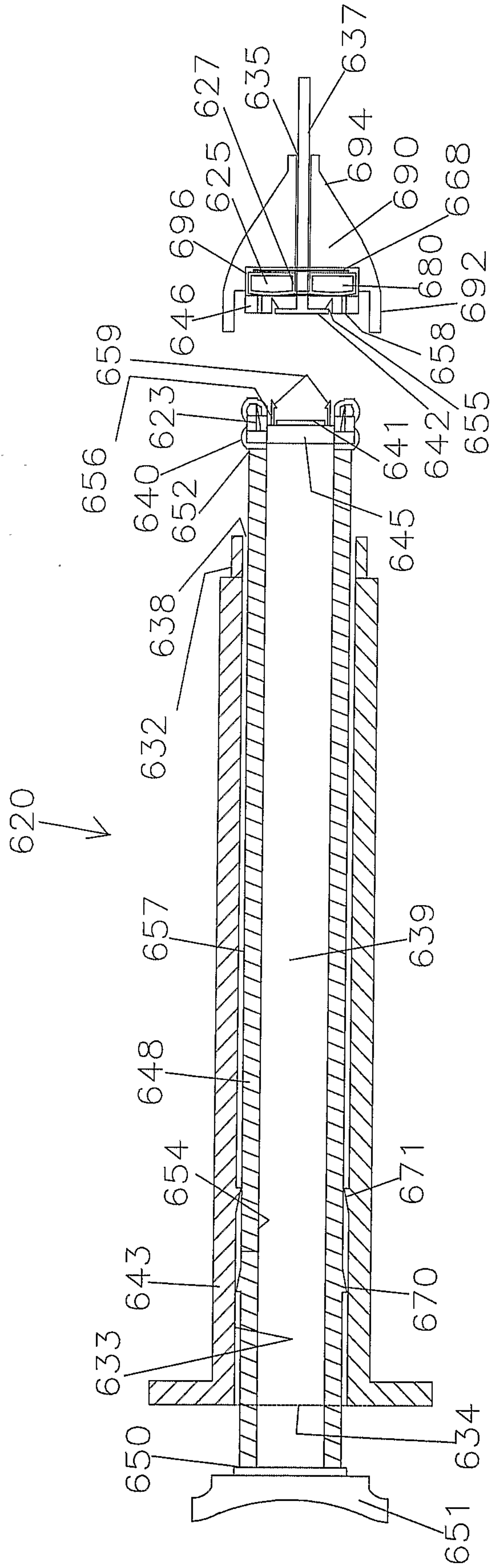

FIG. 9

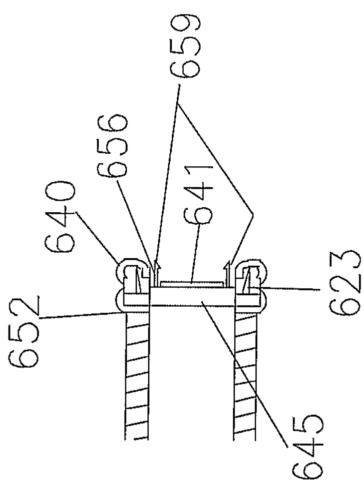

FIG.10

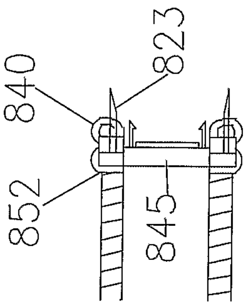

FIG.11

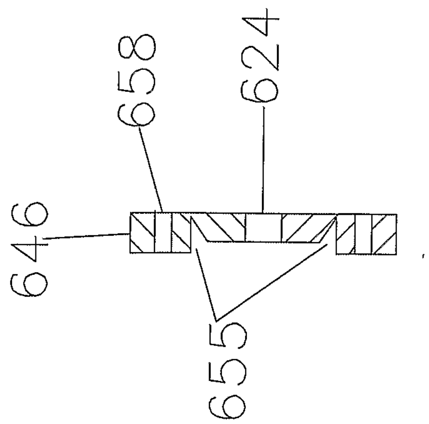

FIG. 13

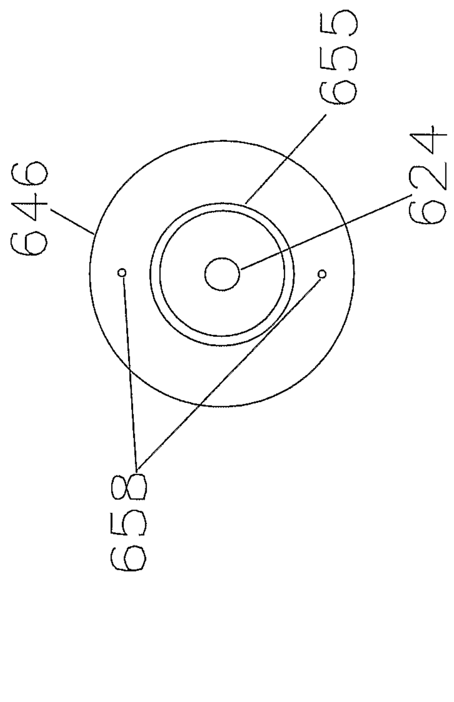

FIG. 12

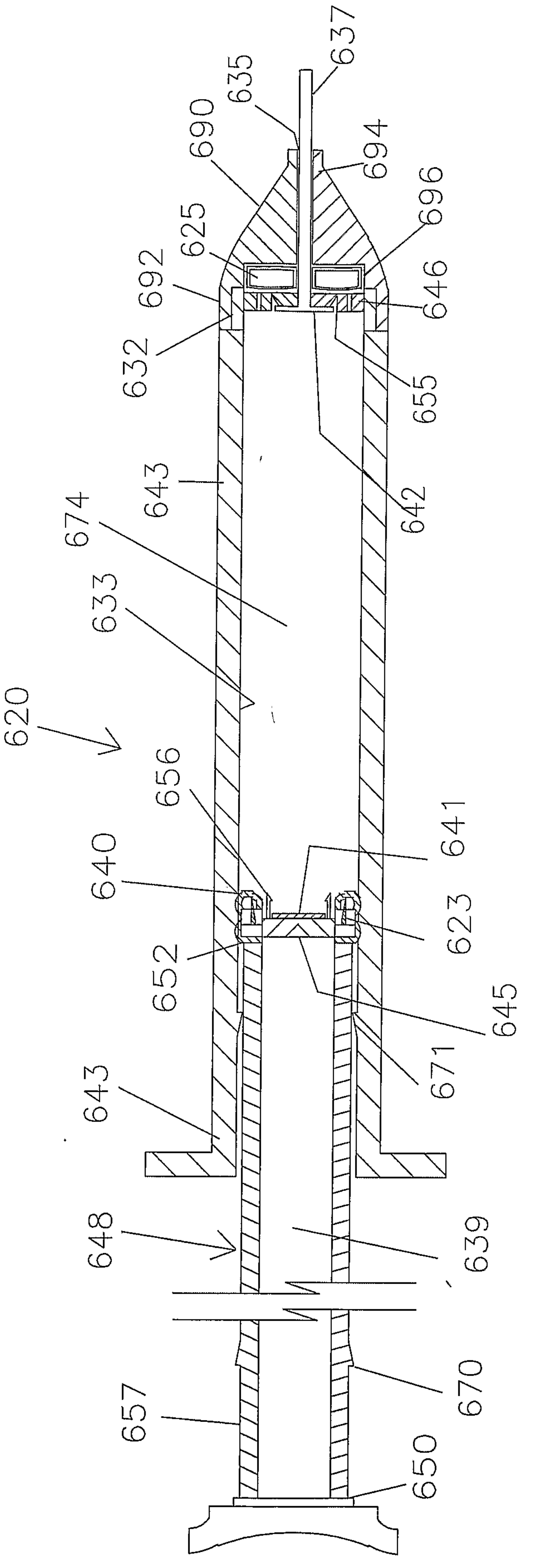
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FIG. 14

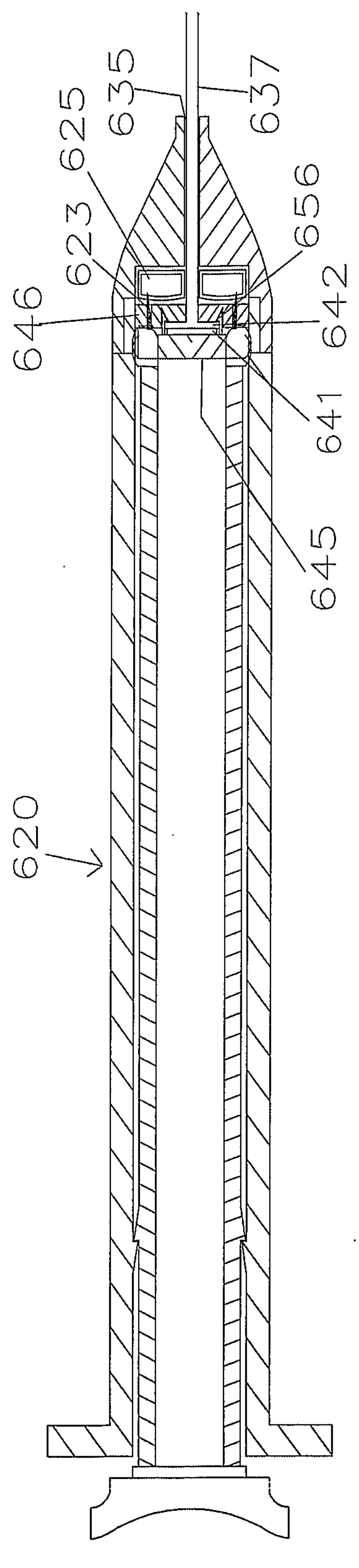
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FIG. 15

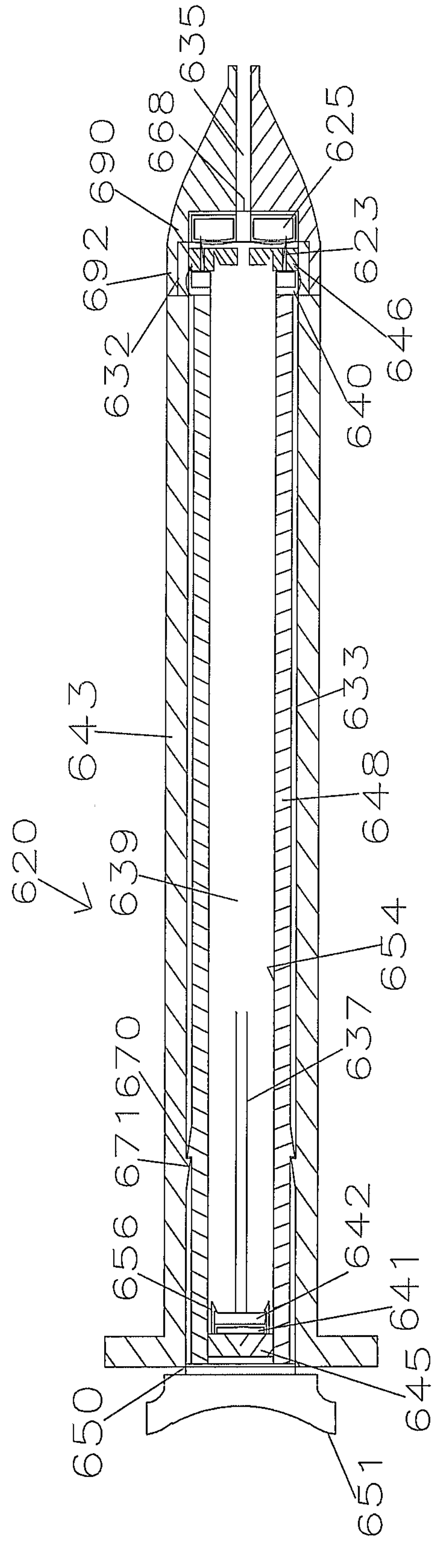
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FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2005/001341

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7): A61M 5/32, A61M 5/34, A61M 5/50

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)
IPC(7): A61M 5/32, A61M 5/34, A61M 5/50

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)
Delphion, Esp@cenet,
(keywords: hollow, gas, pneumatic)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5176640 A (NACCI, G. et al.) 5 January 1993 (05-01-1993) *whole document*	1-18
A	US 5868713 A (L.O.M. LABORATORIES) 9 February 1999 (09-02-1999) *whole document* (cited in the application)	1-18
A	US 5224936 A (GALLAGHER, B.) 6 July 1993 (06-07-1993) *whole document*	1-18

[ ] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :
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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 November 2005 (03-11-2005)	2 December 2005 (02-12-2005)

Name and mailing address of the ISA/CA
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Authorized officer
Heather Cardamore (819) 934-3470

INTERNATIONAL SEARCH REPORT

formation on patent family members

International application No.
PCT/CA2005/001341

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US5224936	06-07-1993	NONE	