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(54) **RETRACTABLE NEEDLE SINGLE USE SAFETY SYRINGE**

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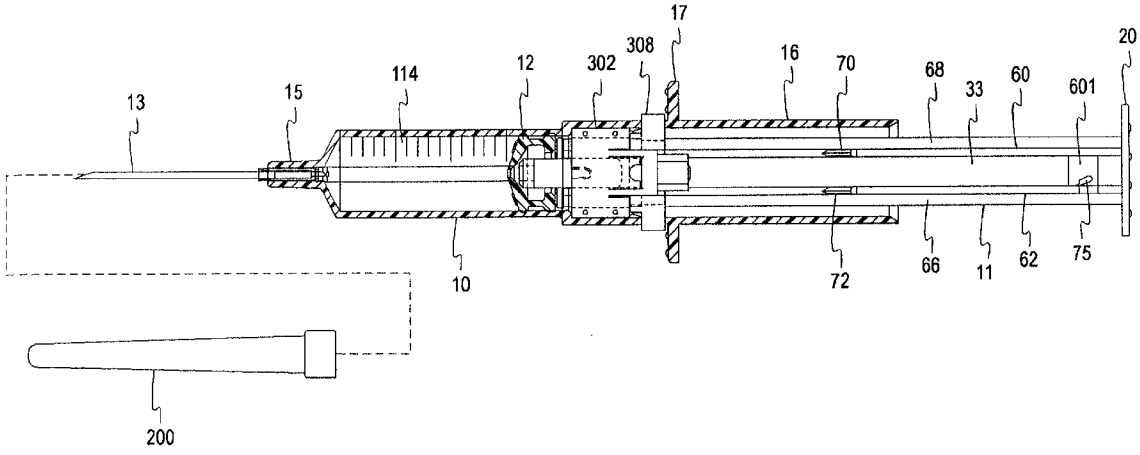
(51) **Int. Cl.**[7] **A61M 5/32**

(52) **U.S. Cl.** **604/192**; 128/919

(57) **ABSTRACT**

A safety syringe assembly includes an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of the barrel and opening into the interior of the barrel. A plunger is slidably mounted in the barrel and has a longitudinal open channel. A needle holder mounts a needle at a distal end thereof and is slidably mounted in the longitudinal open channel of the plunger for movement between an advanced position in which the needle on the distal end of the needle holder projects from a distal end of the nozzle, and a retracted position in which the needle is retracted within the barrel. A compression spring is mounted inside of the barrel, and a spring retainer element has a spring support portion extending from the interiorly of the barrel to a portion for mounted within the barrel and supporting a distal end portion of the spring against expansion. The spring urges the needle holder toward its retracted position. A latch has a closed position in which the needle holder is latched relative to the barrel to hold the needle holder in its advanced position against the urging of the spring, and an open position in which the needle holder is unlatched relative to the barrel to allow the spring to expand in a proximal direction to move the needle holder to its retracted position.



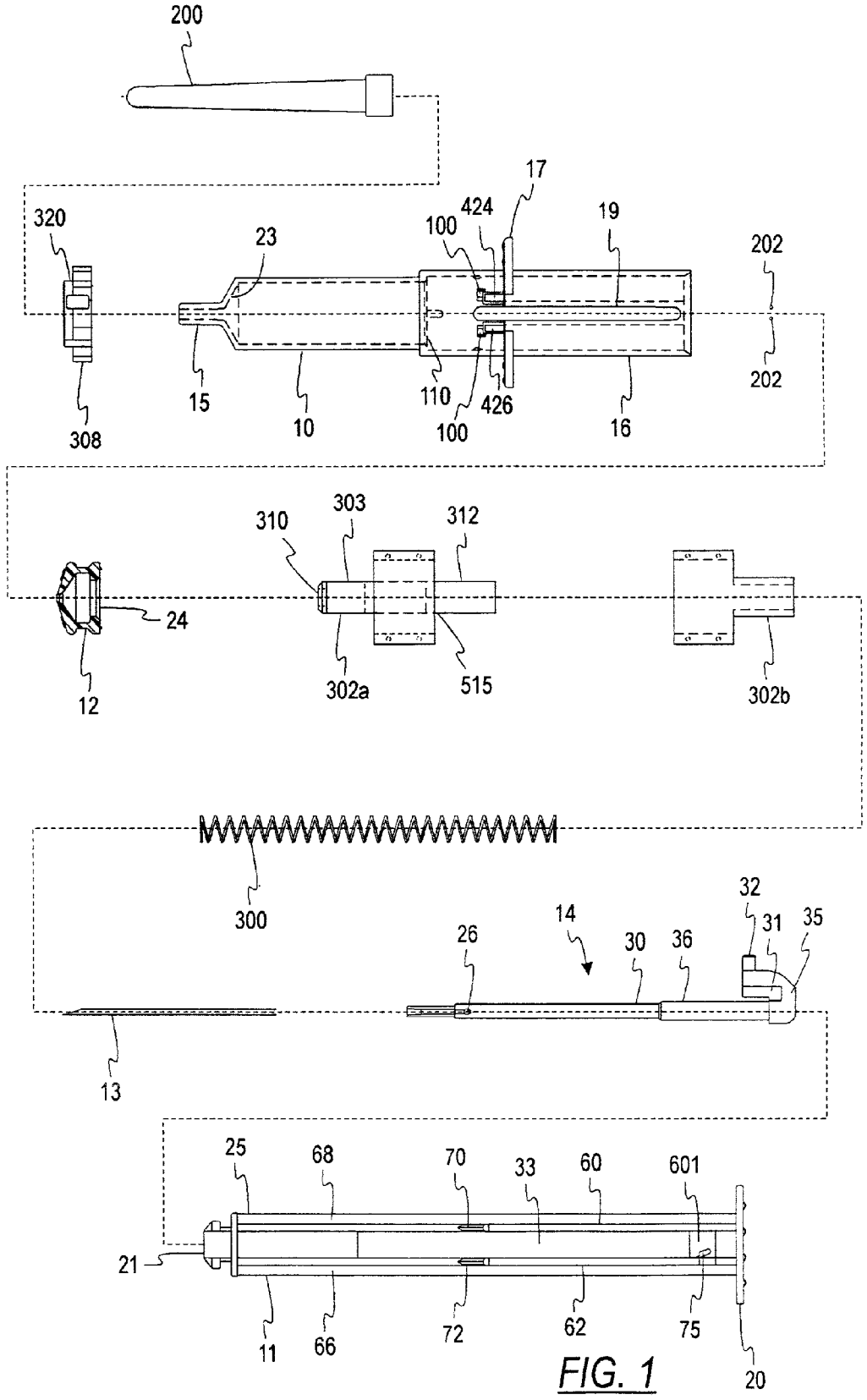

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FIG. 1

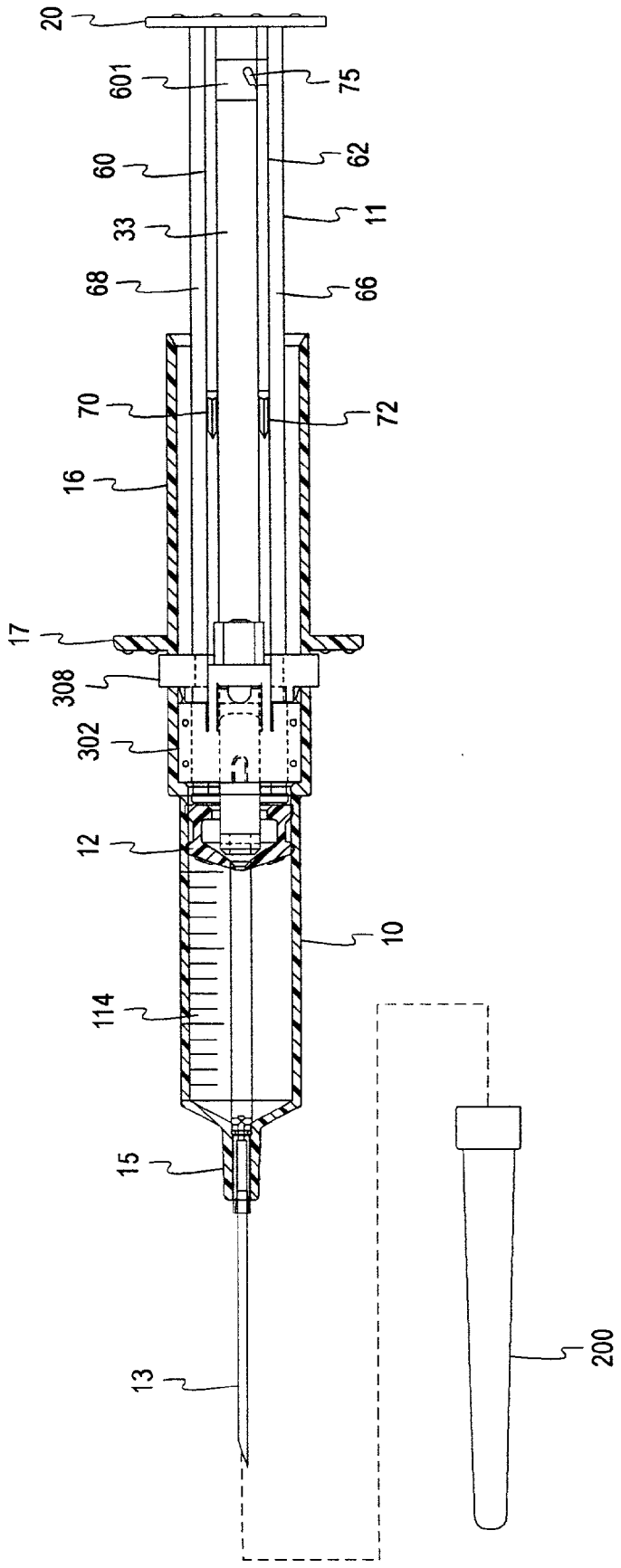
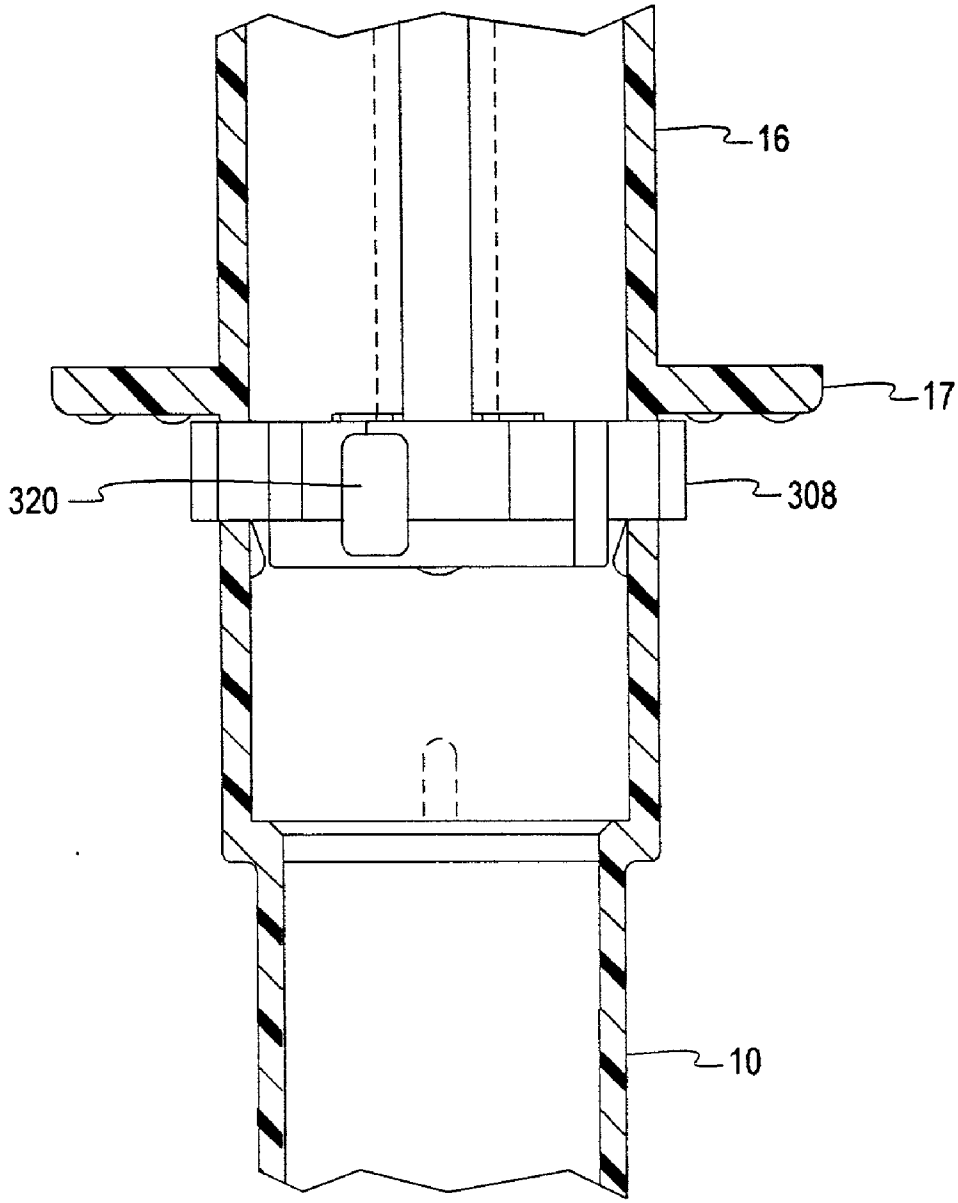


FIG. 2



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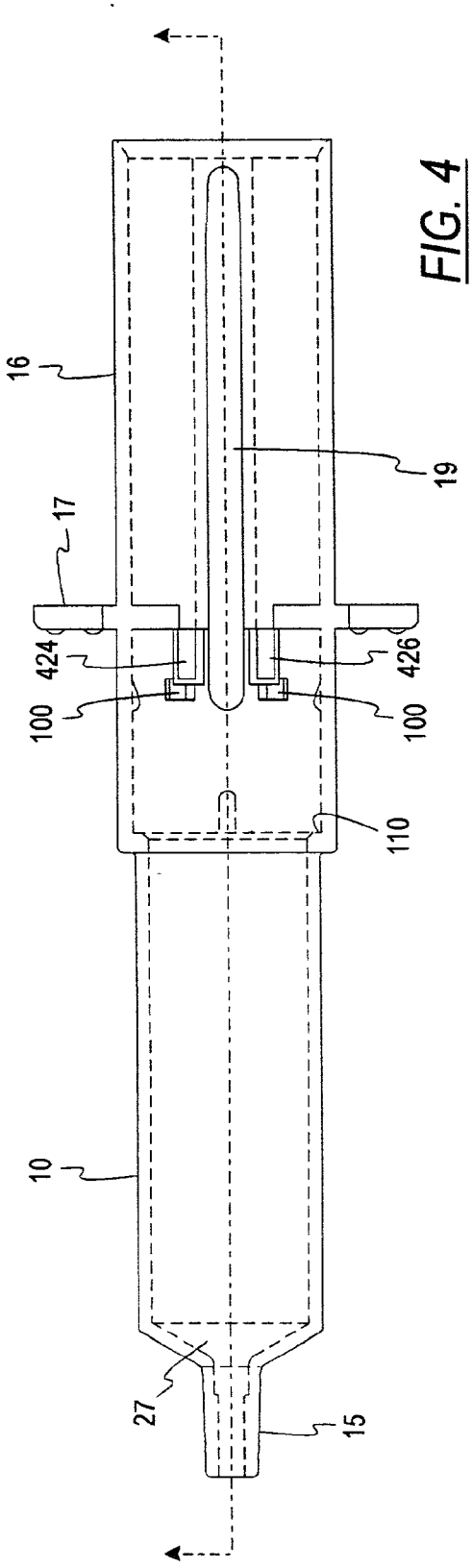

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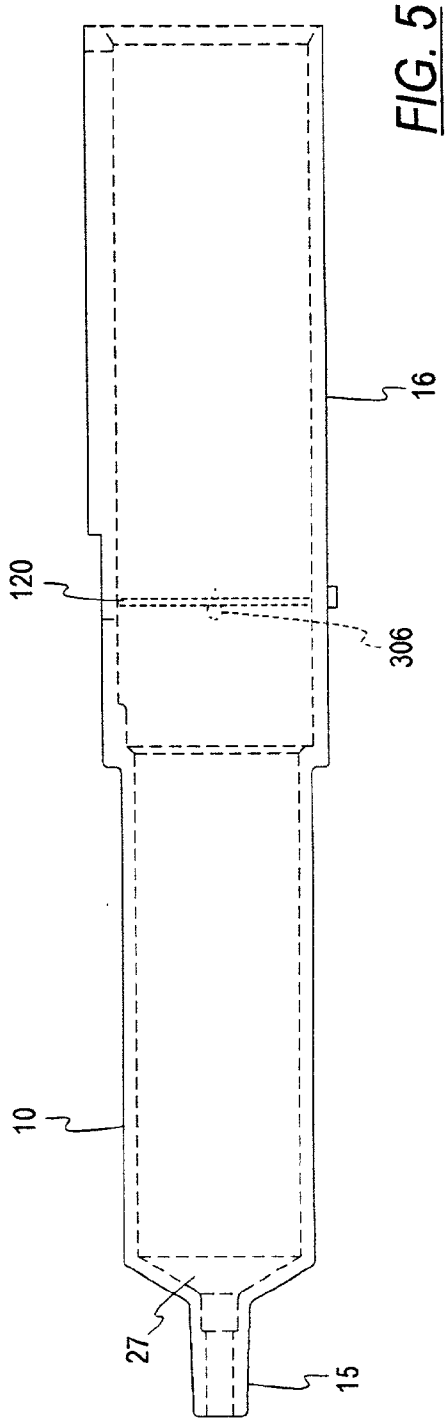

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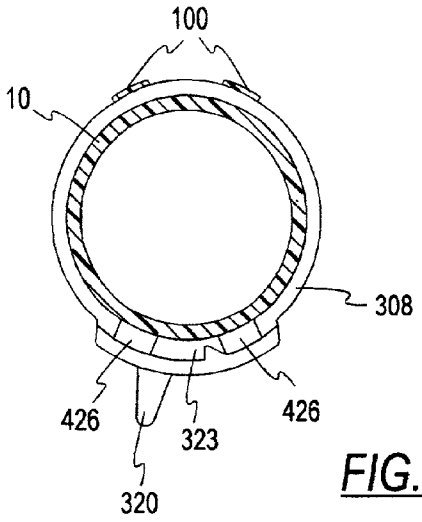

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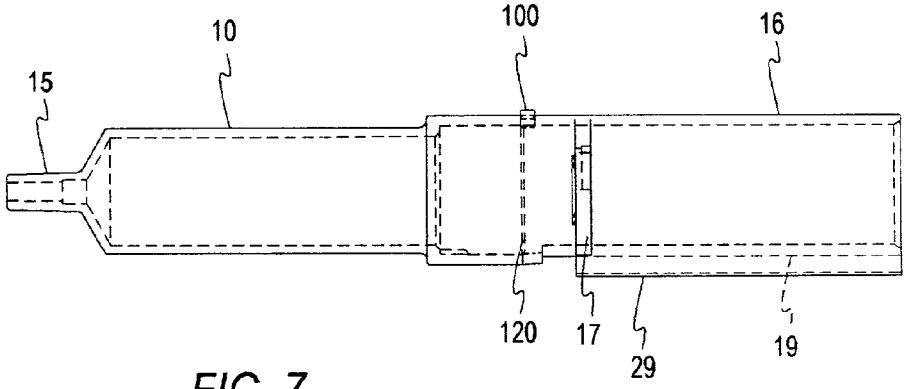

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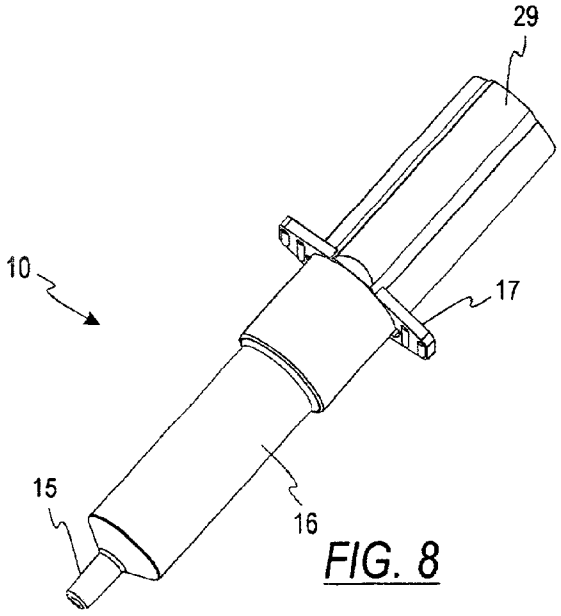

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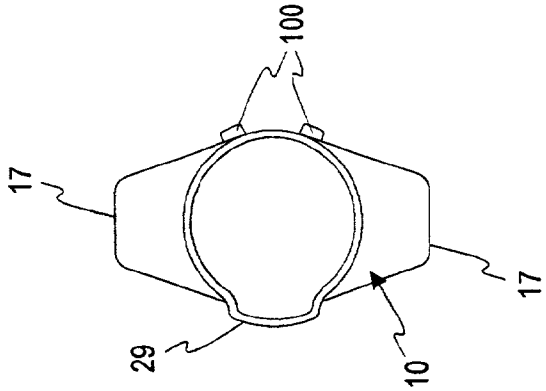

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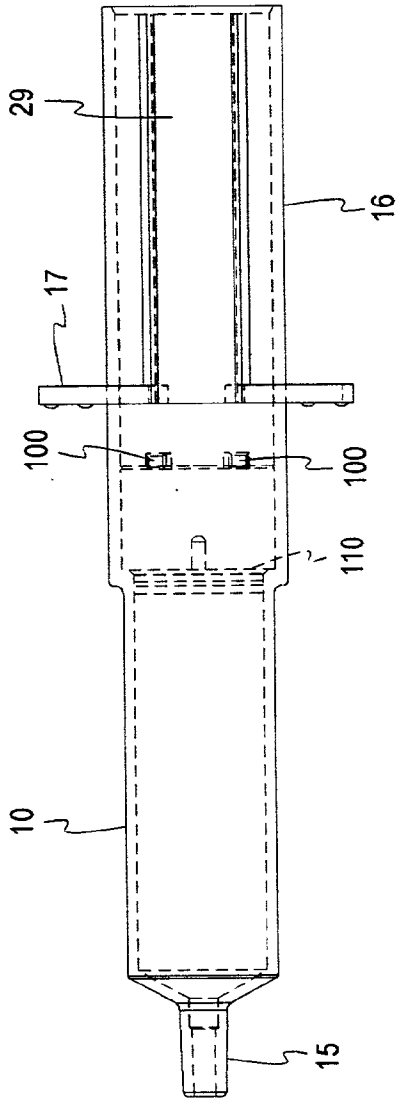

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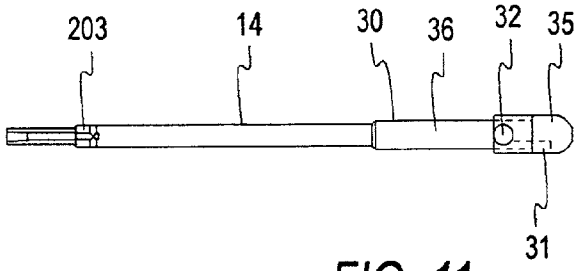

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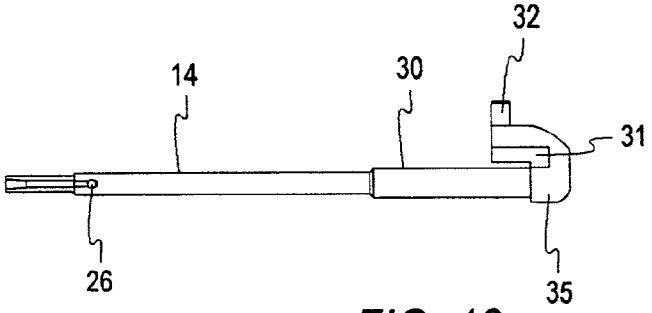
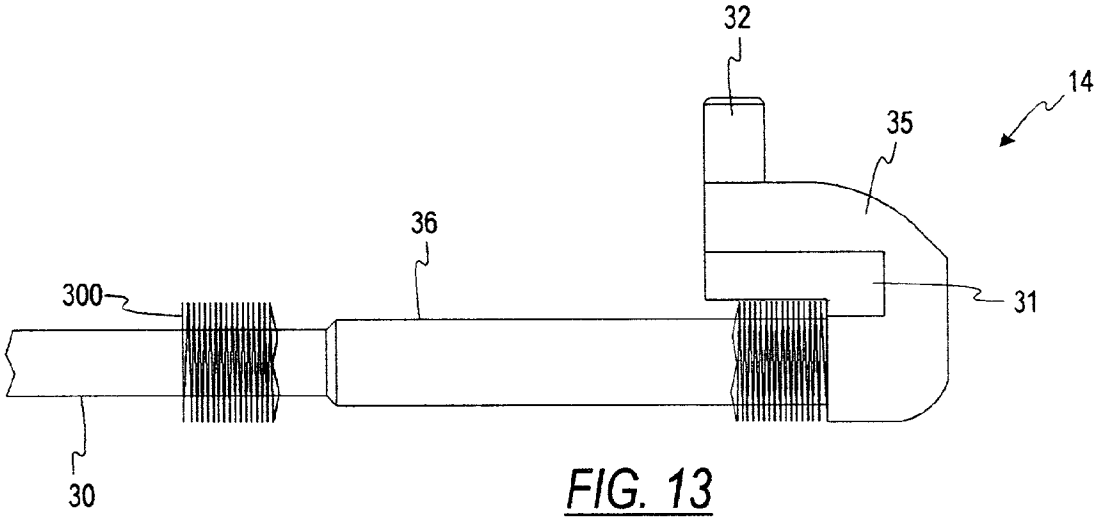


FIG. 12



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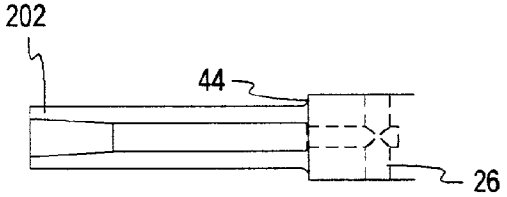

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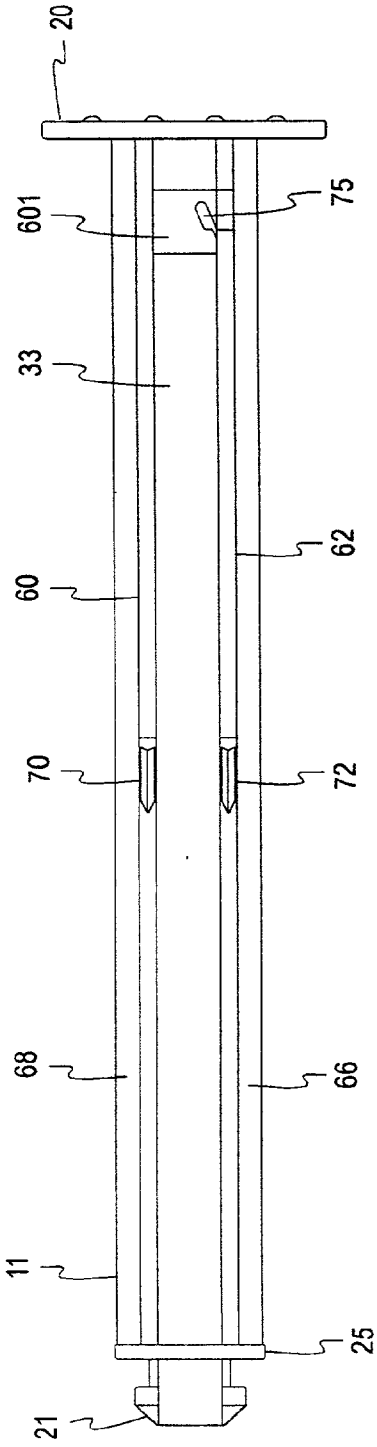

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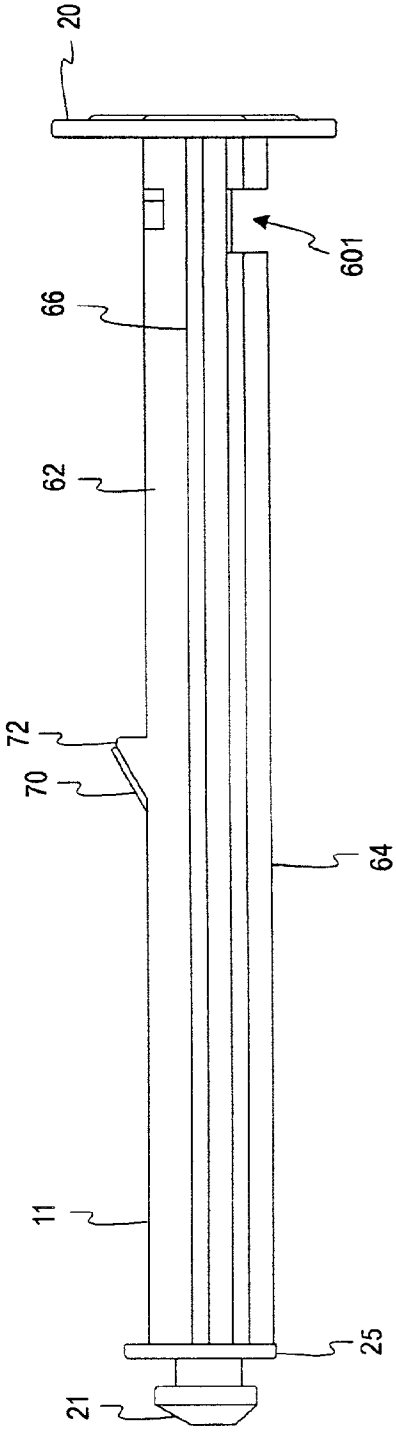

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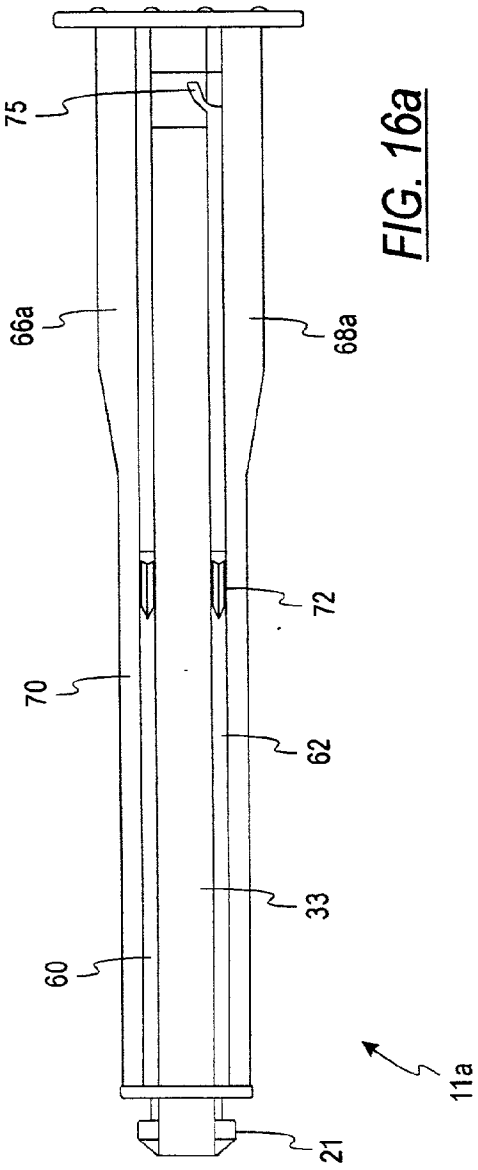

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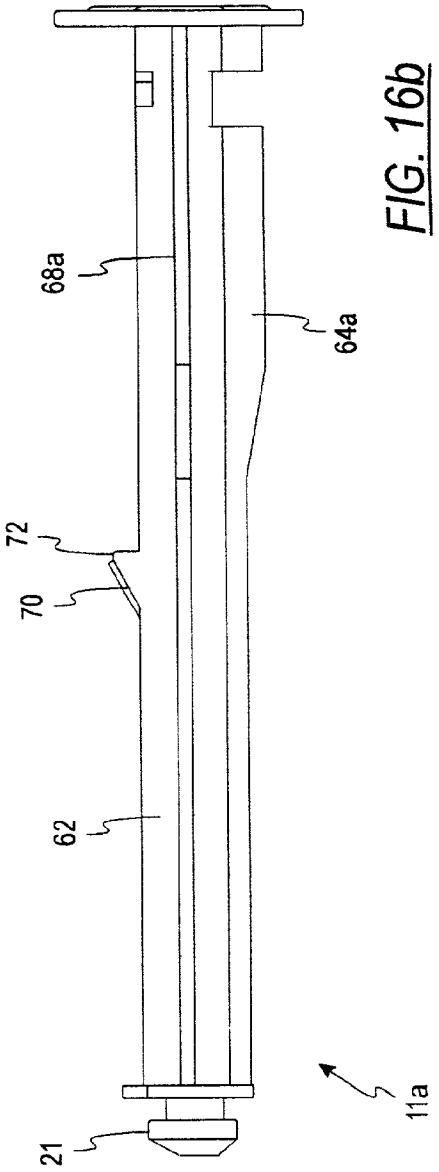
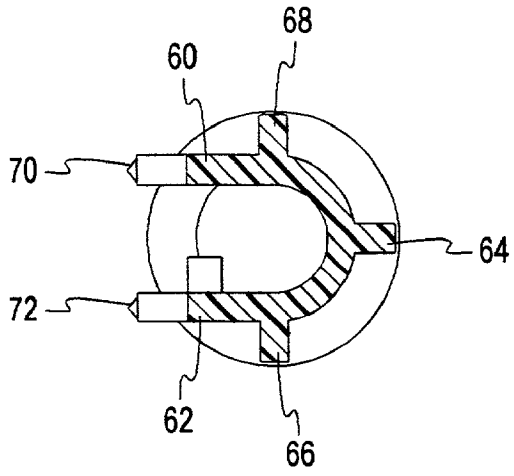


FIG. 16b



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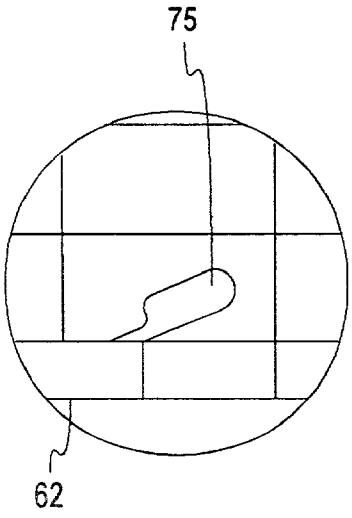

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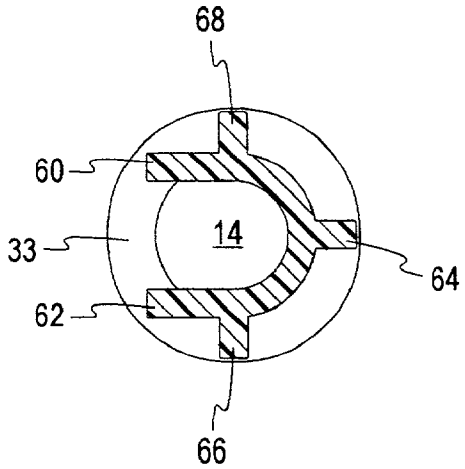

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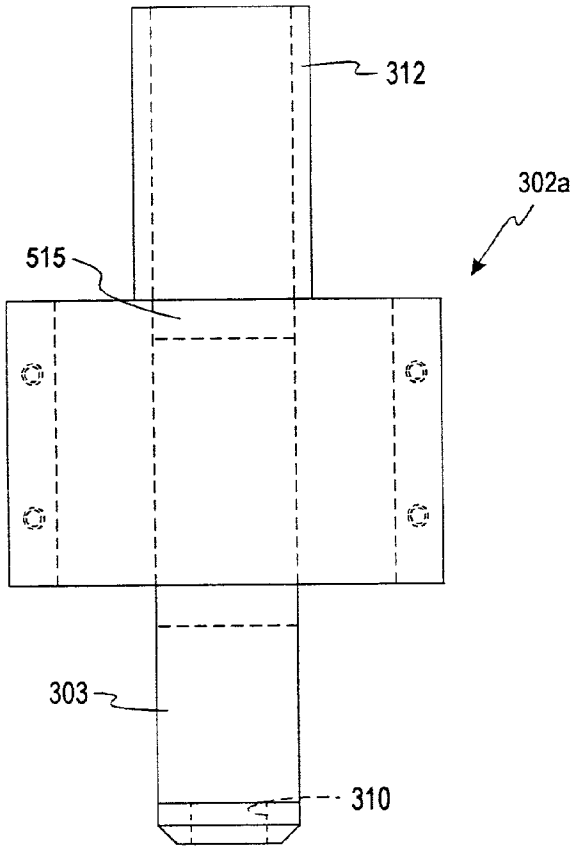

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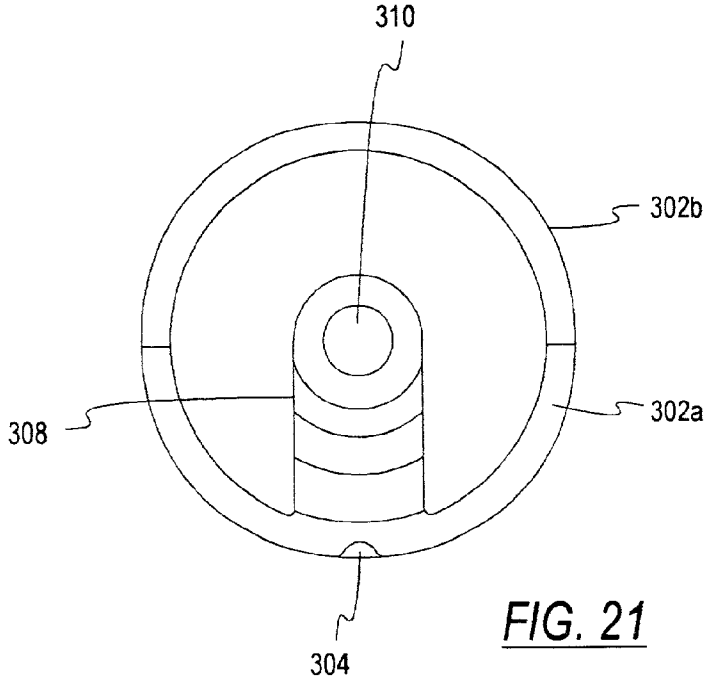

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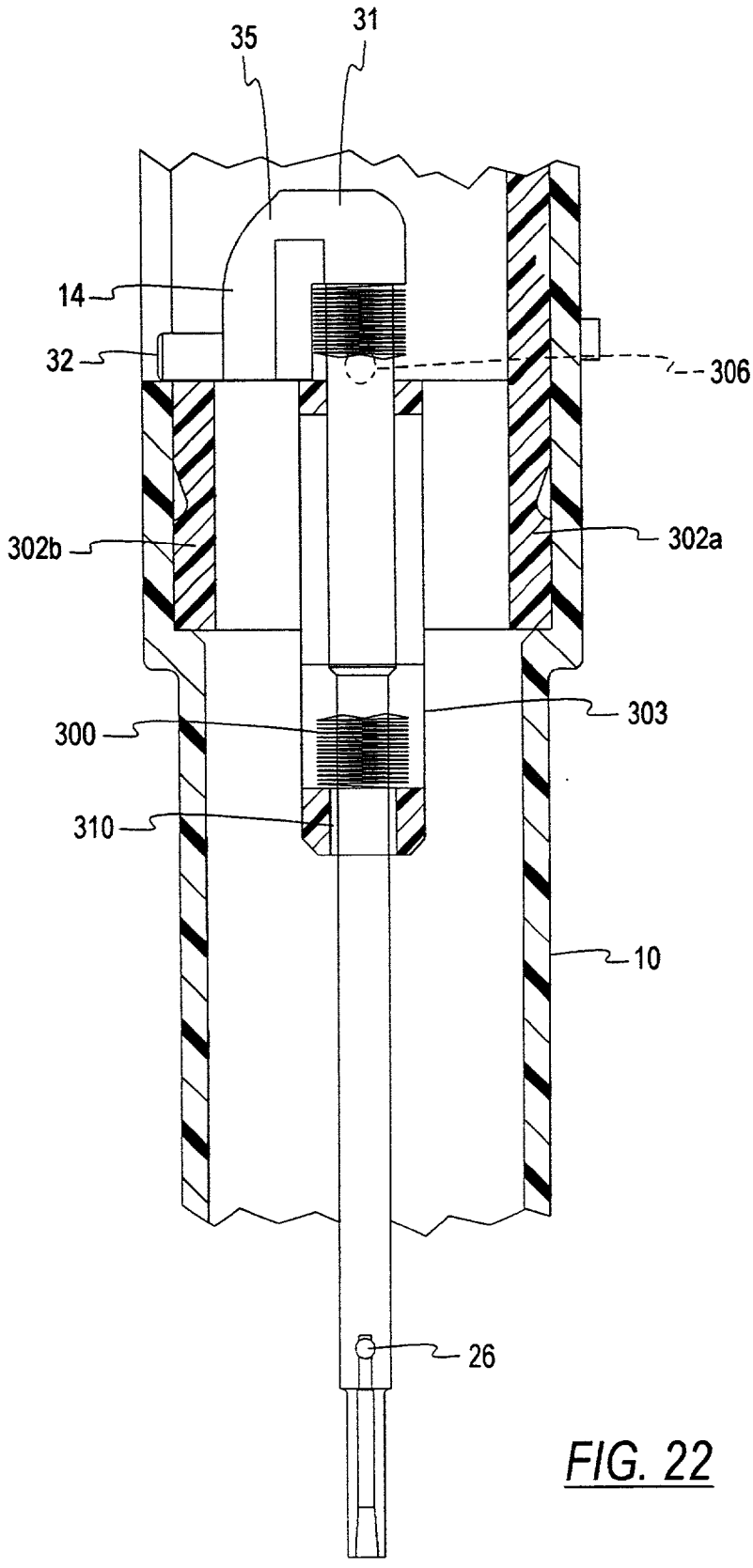

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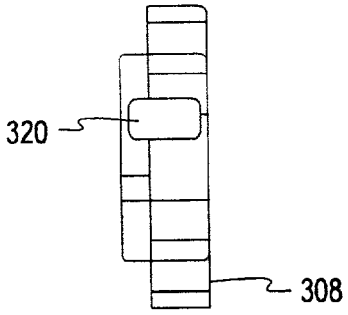

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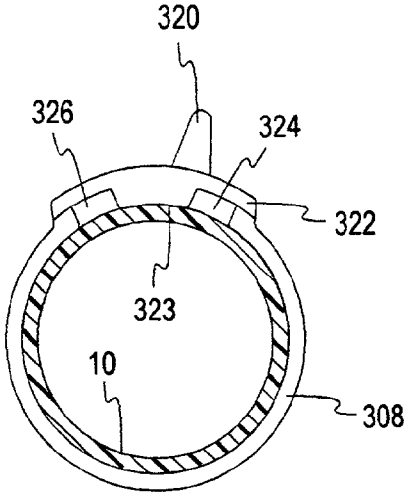

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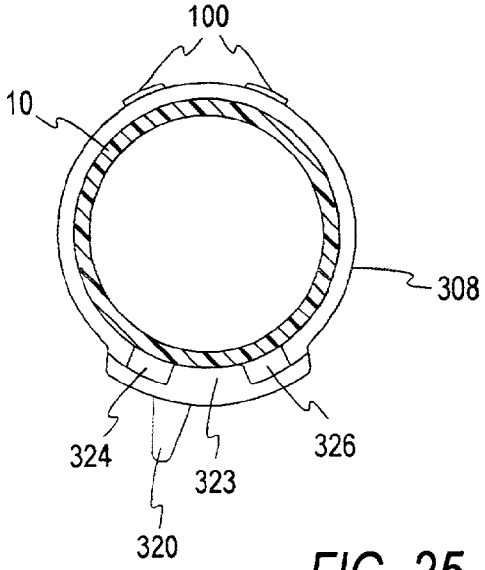

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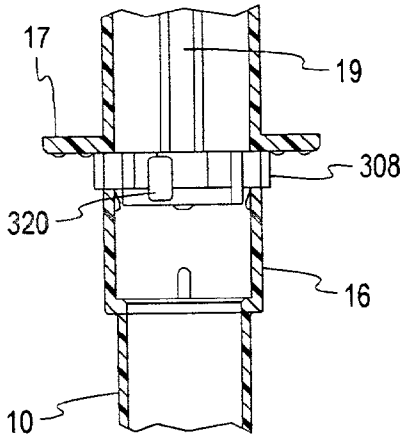

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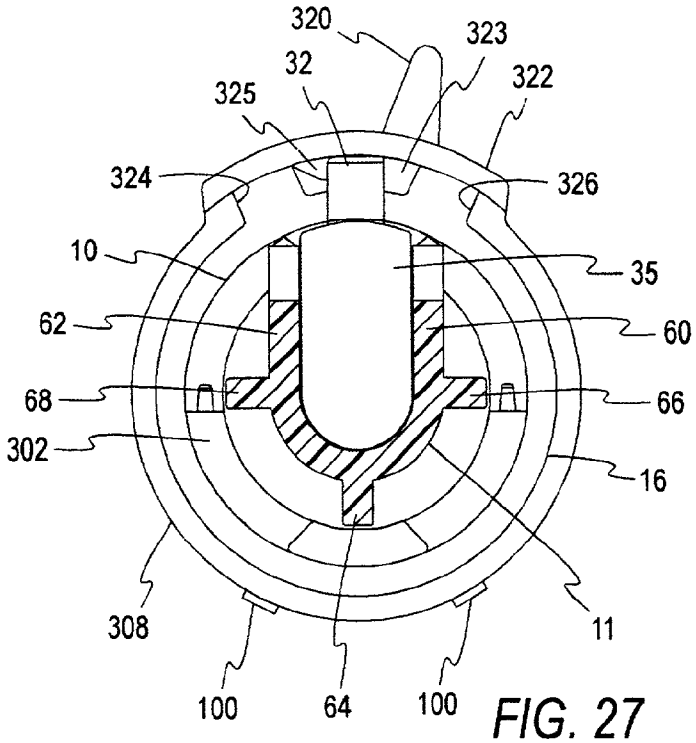
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FIG. 27

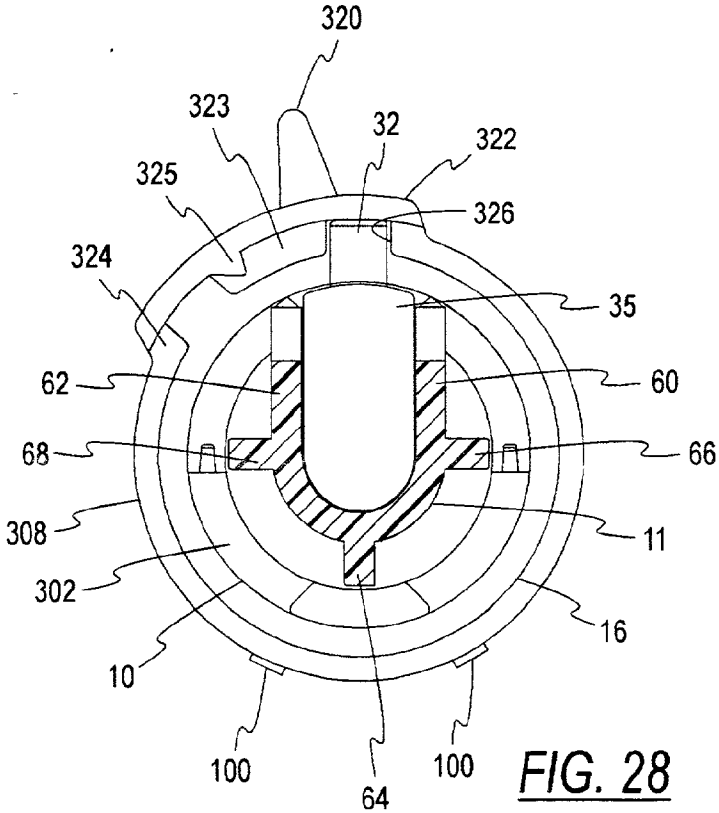
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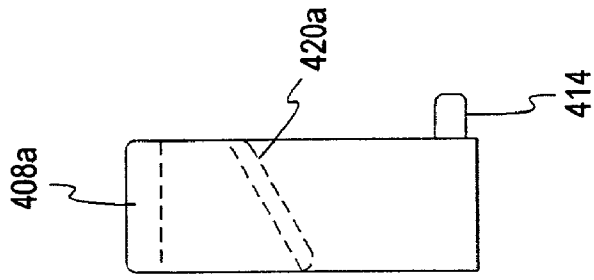
FIG. 28



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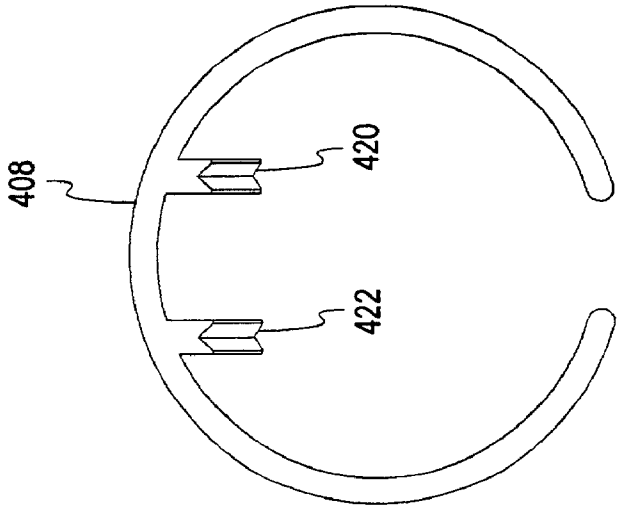

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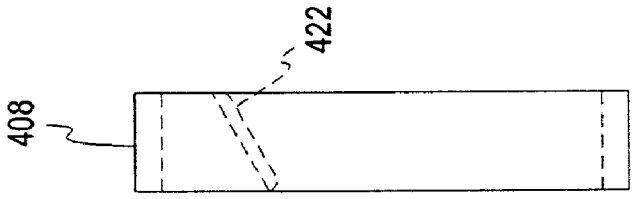

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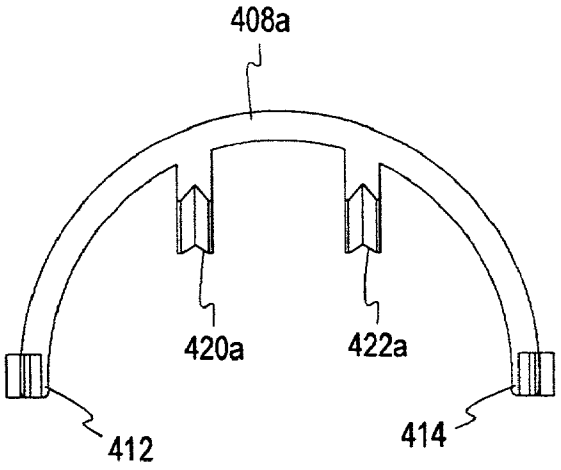

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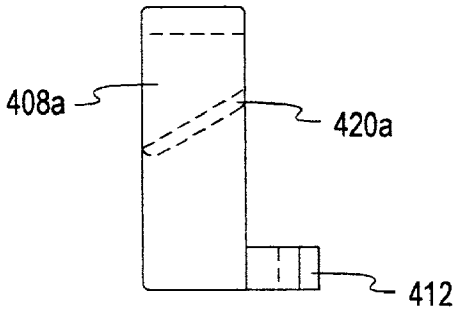

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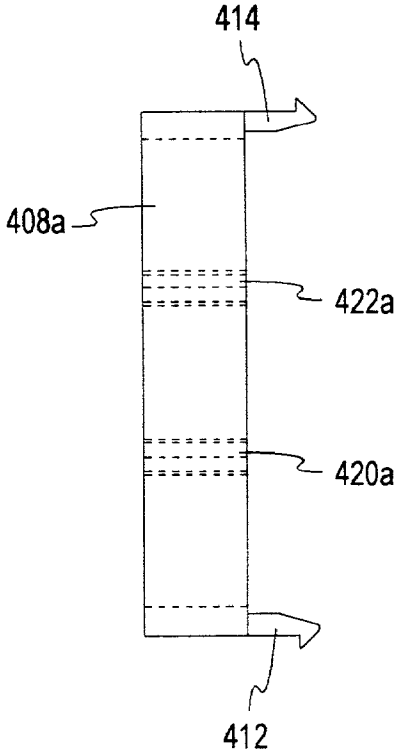

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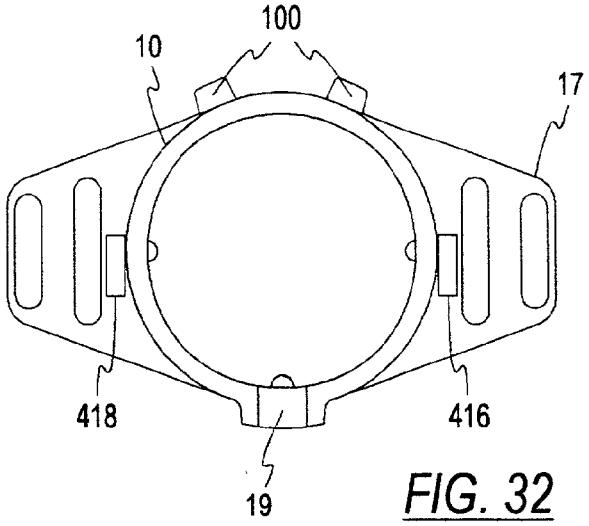

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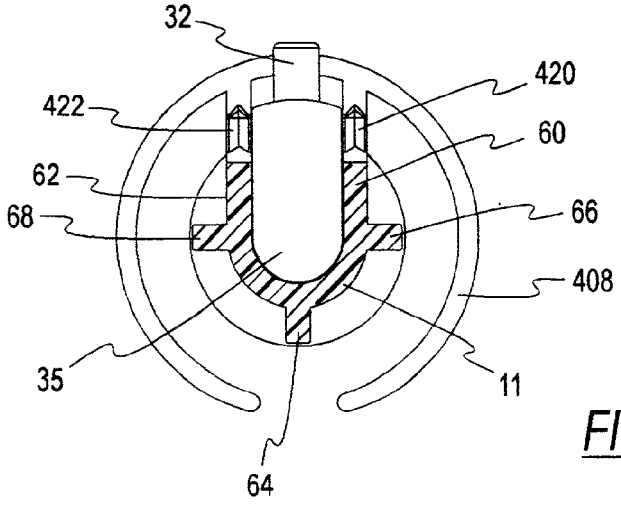

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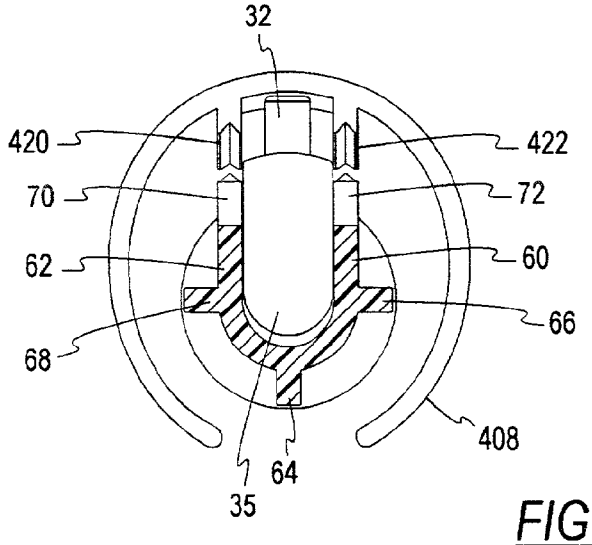

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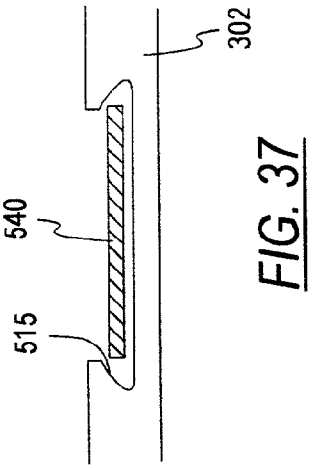

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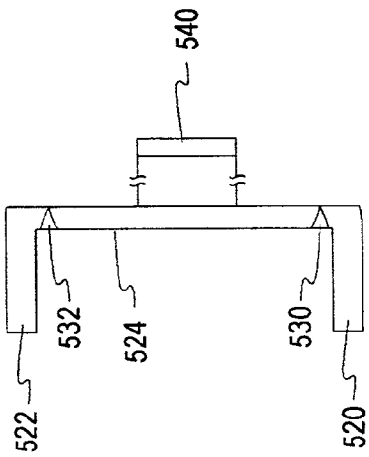

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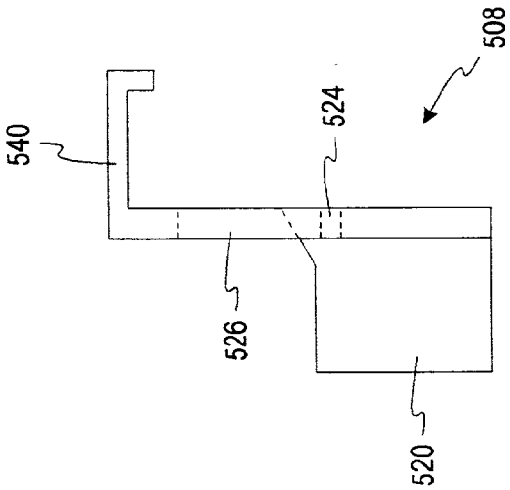

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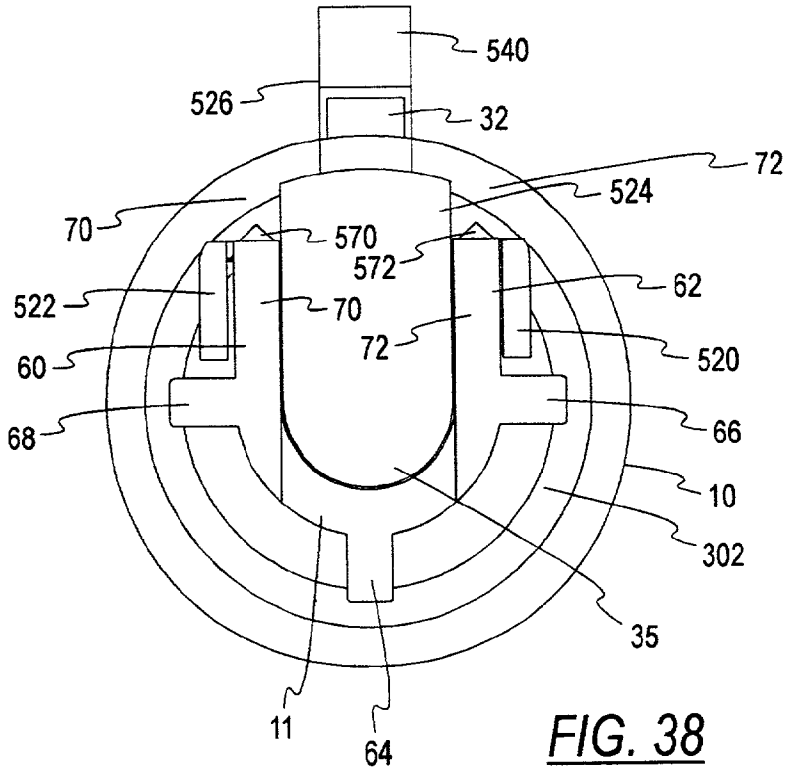
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FIG. 38

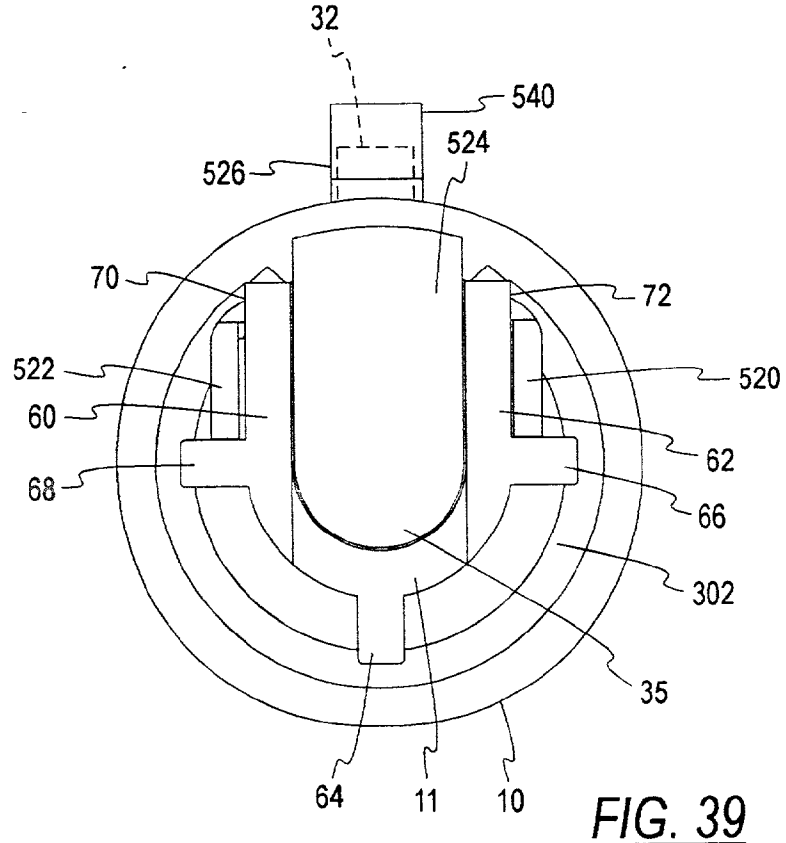
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FIG. 39

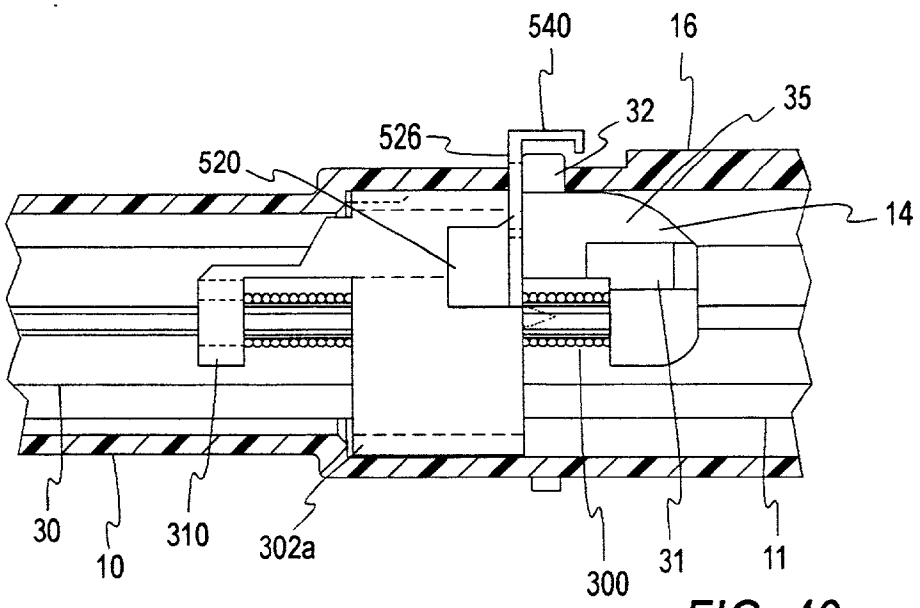
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FIG. 40

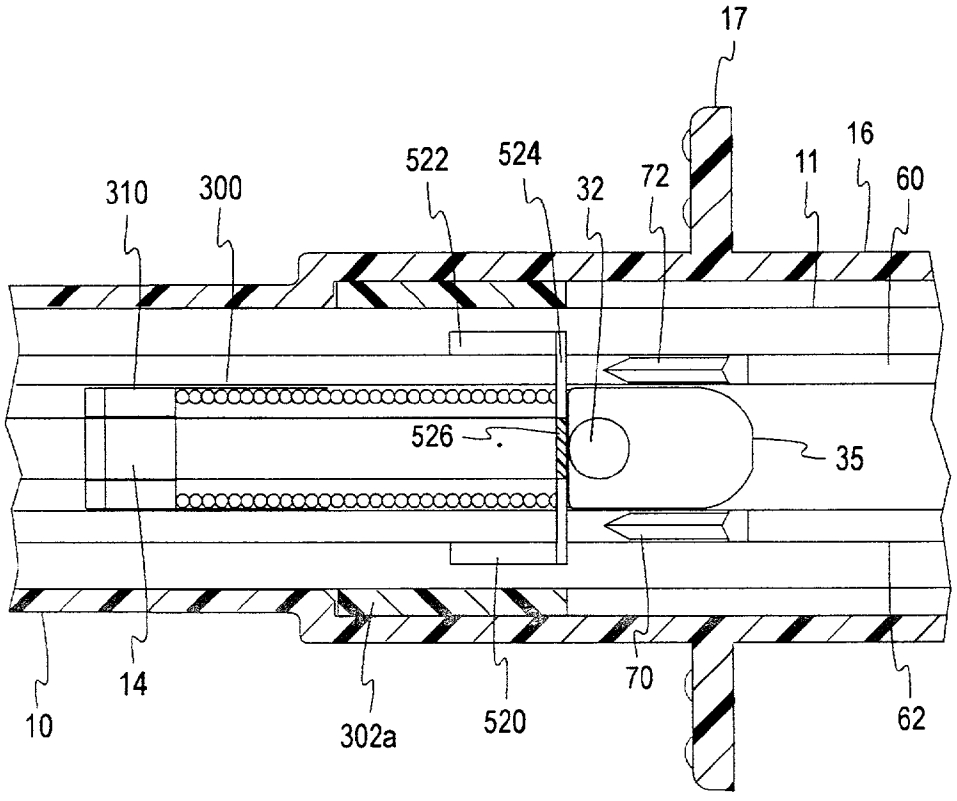
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FIG. 41

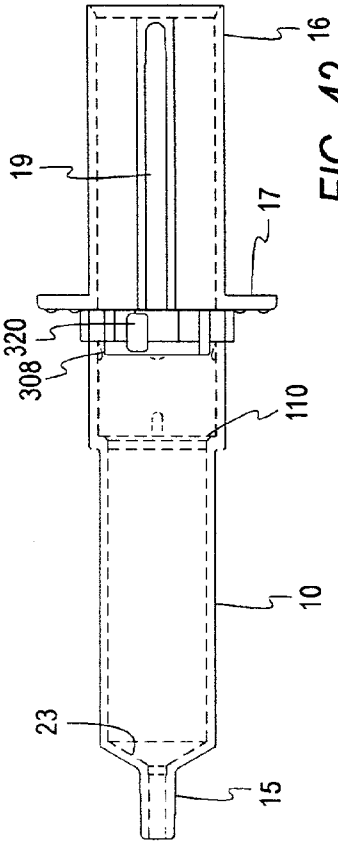

FIG. 42

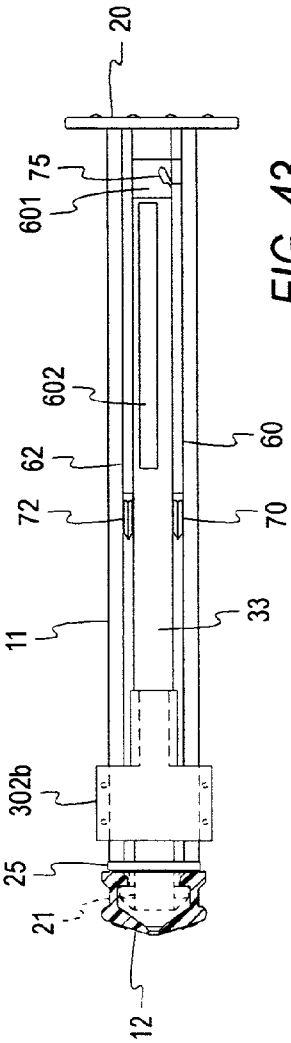

FIG. 43

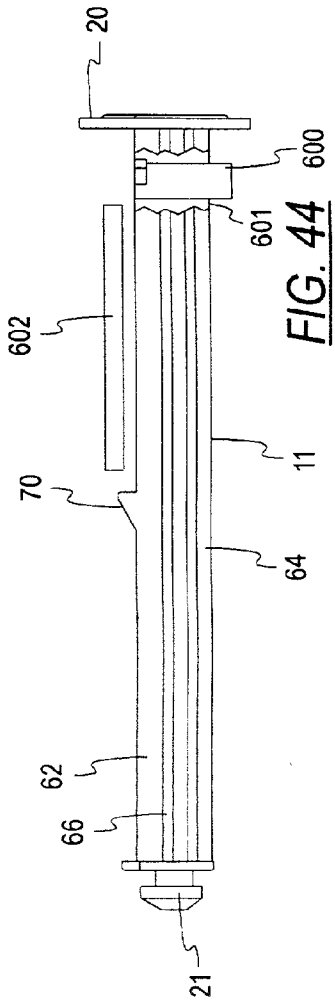

FIG. 44

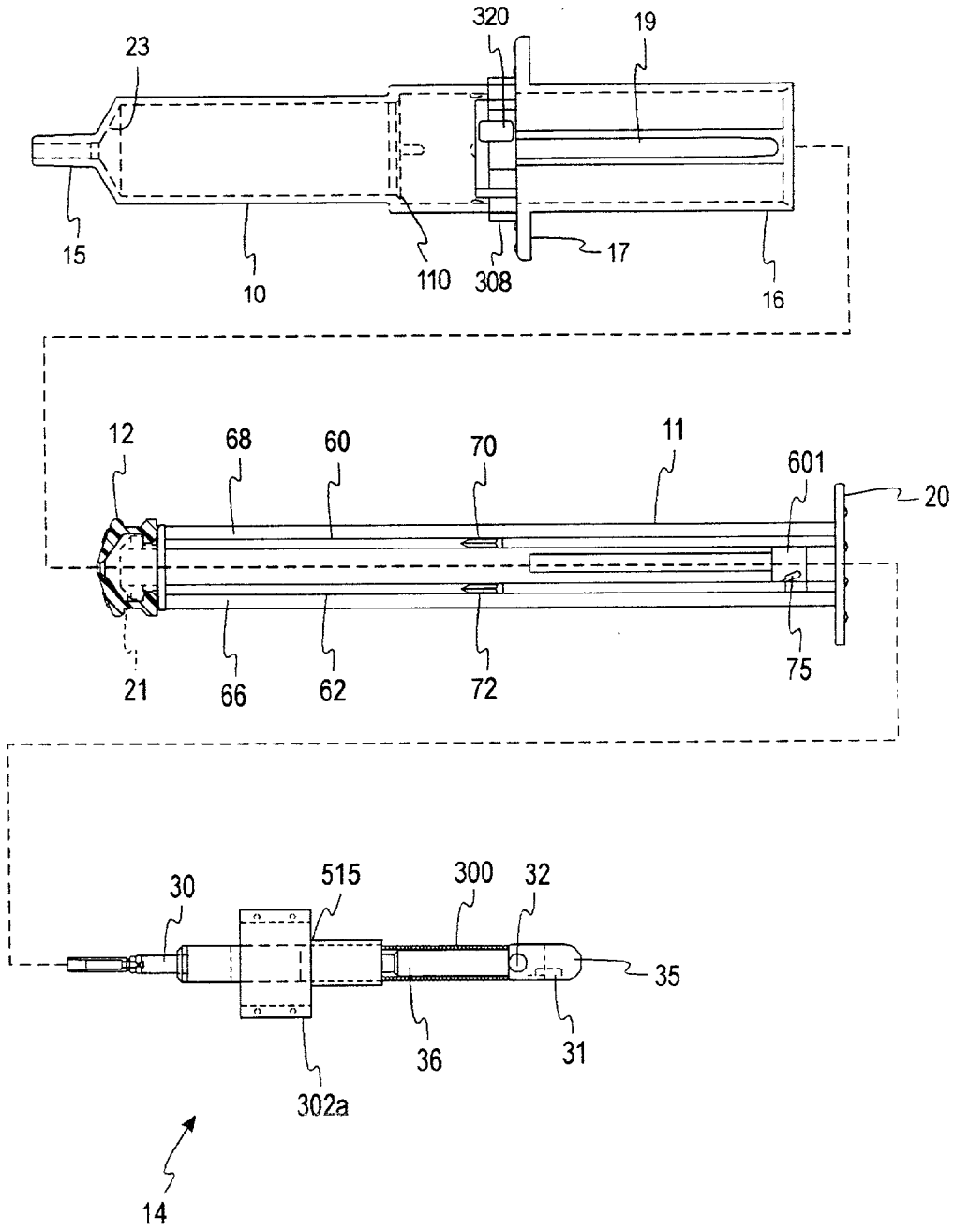
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FIG. 45

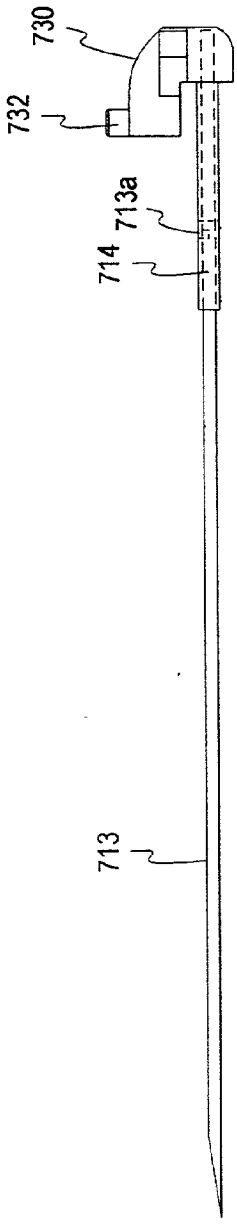

FIG. 48

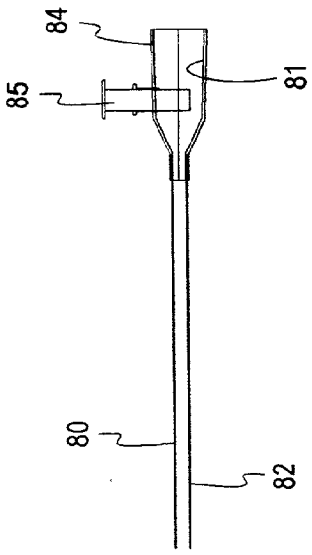

FIG. 49

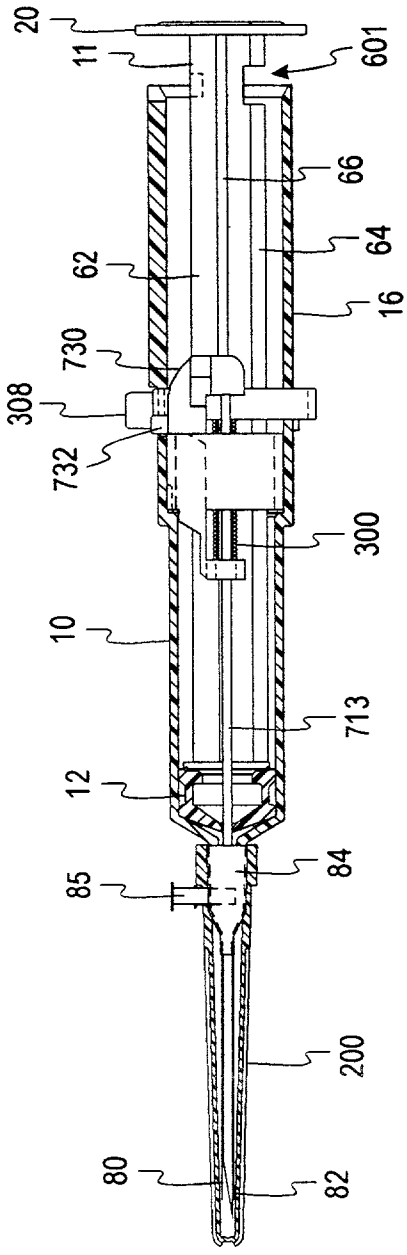
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FIG. 50

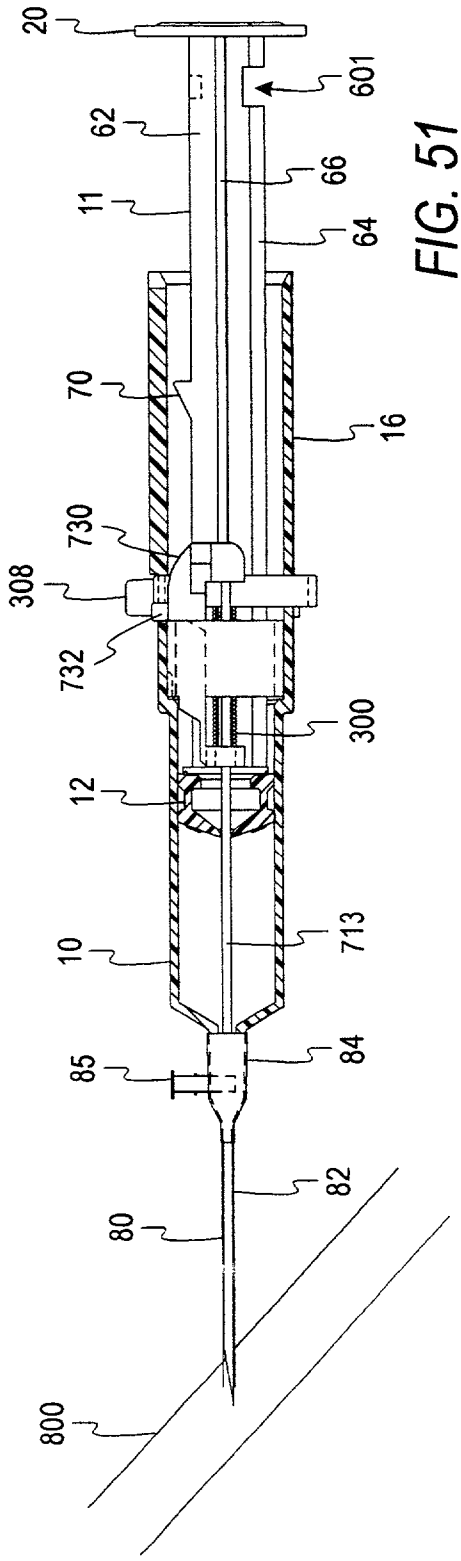
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FIG. 51

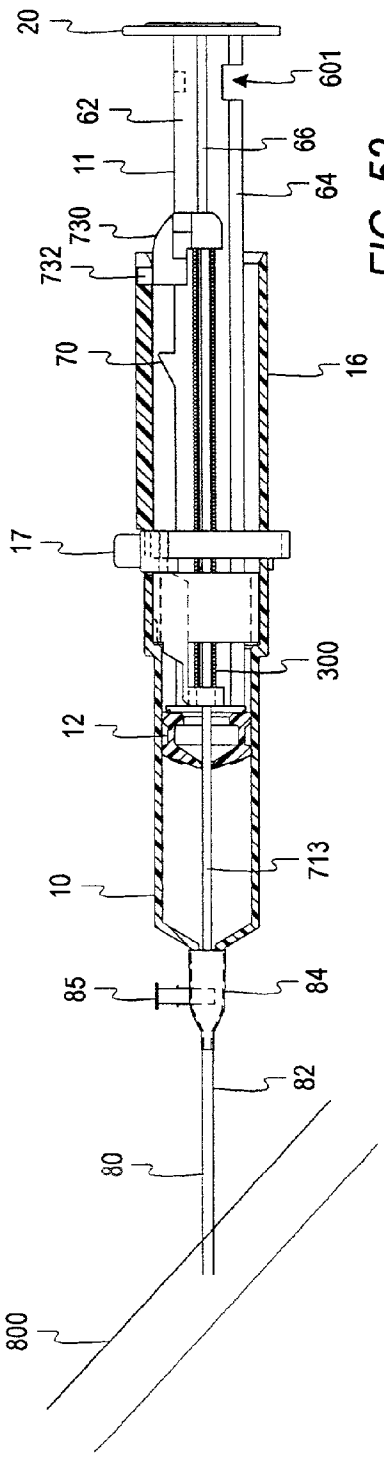
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FIG. 52

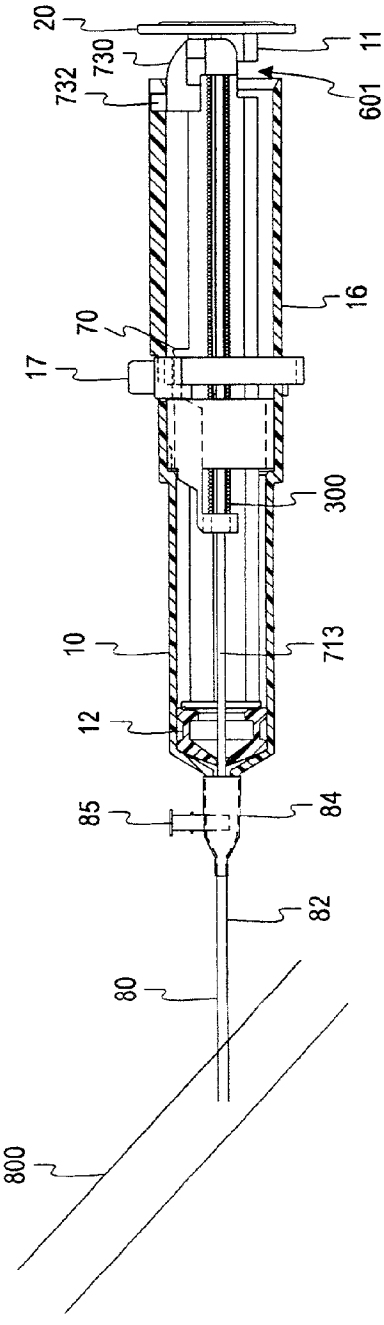
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FIG. 53

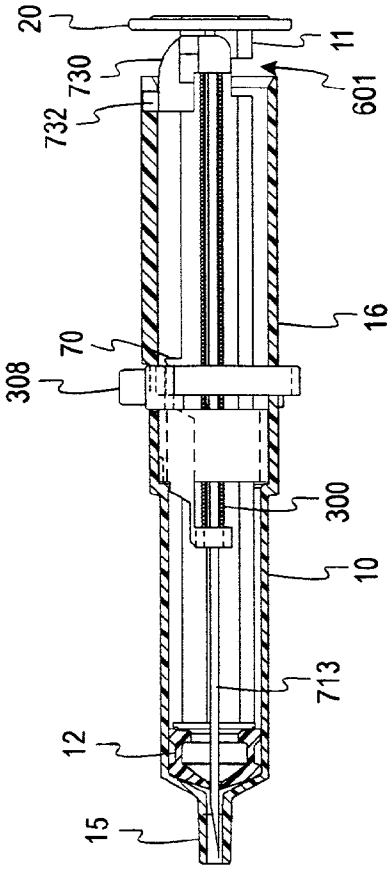
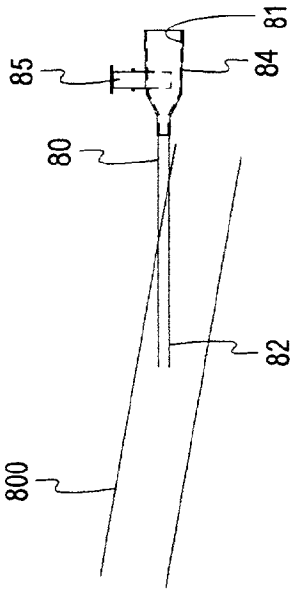


FIG. 54



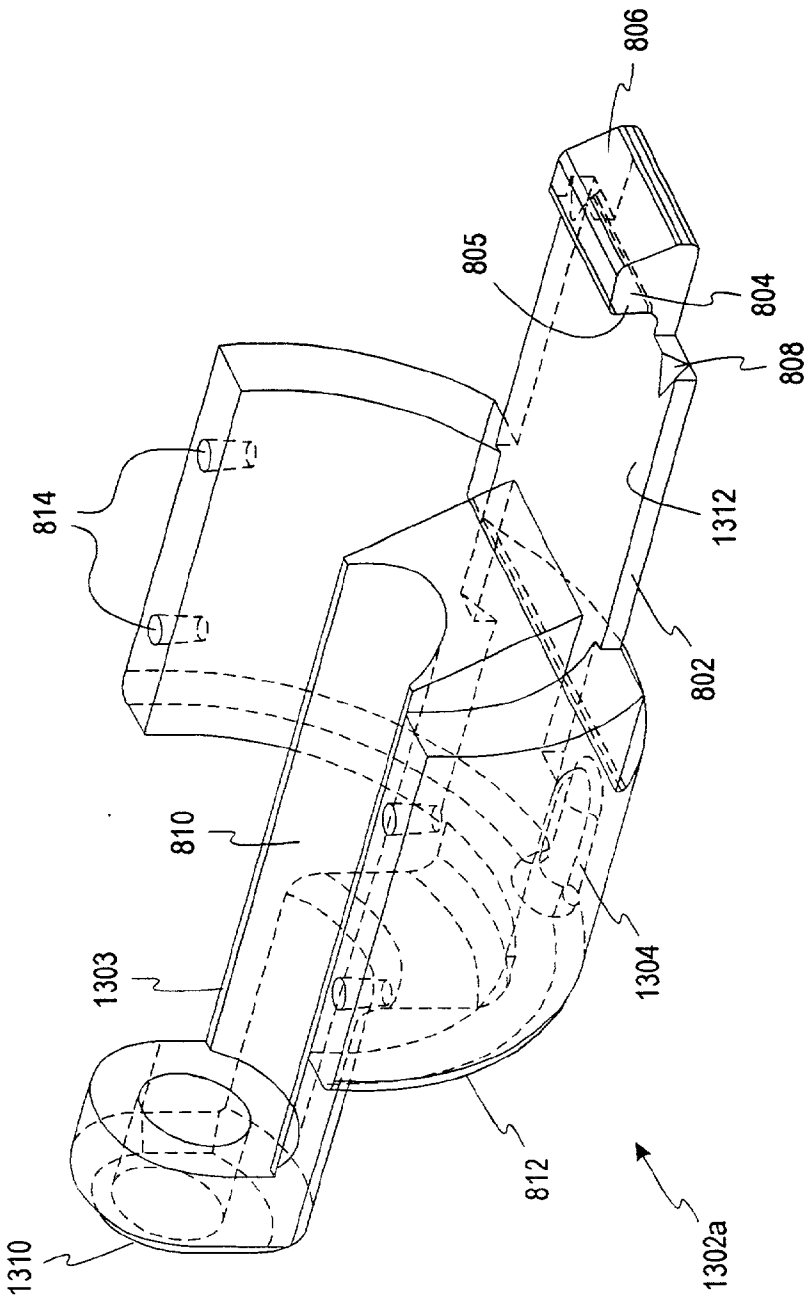


FIG. 55

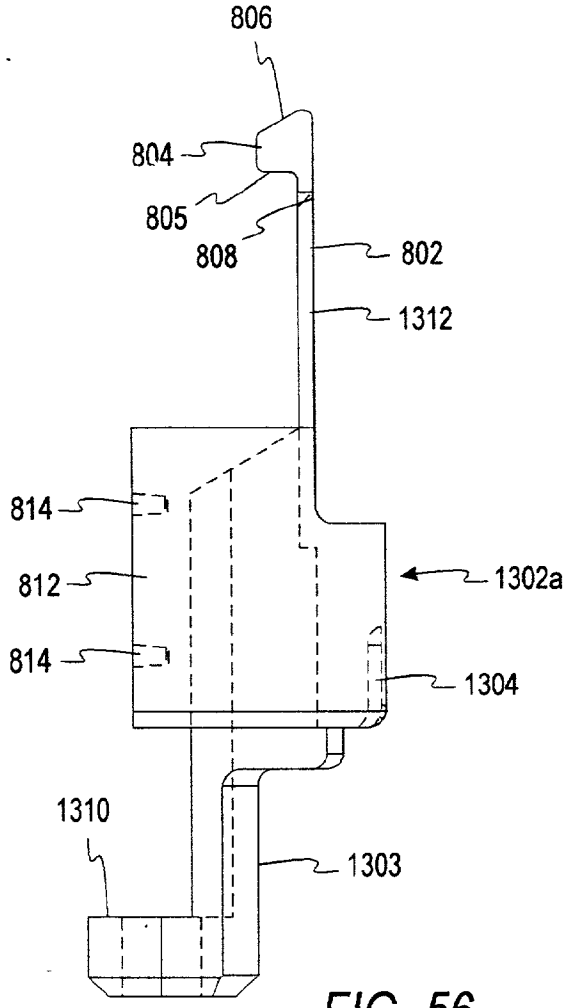

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FIG. 56

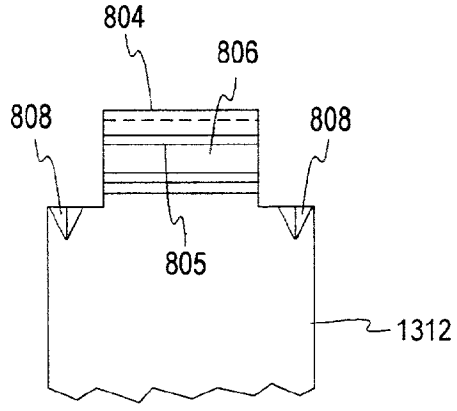
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FIG. 57

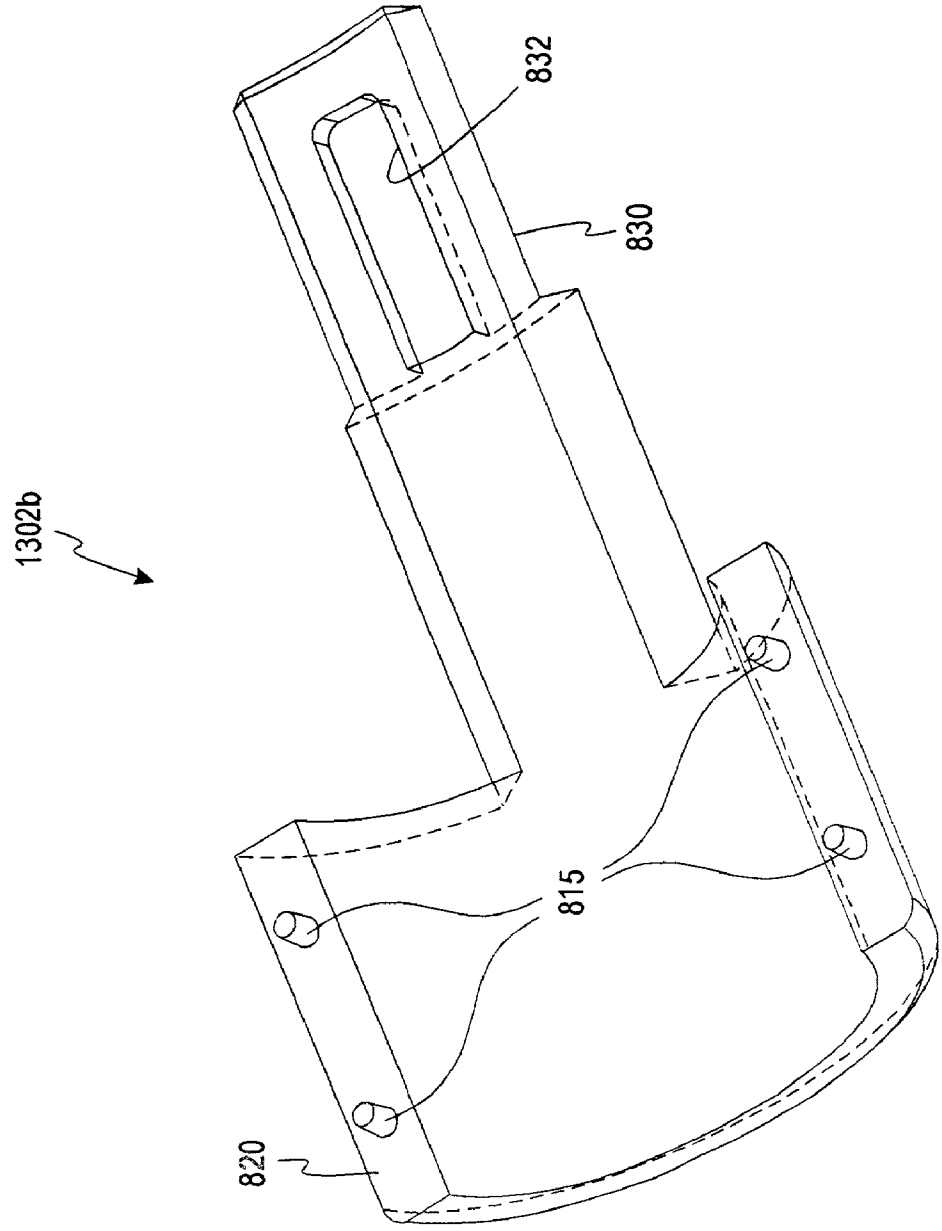

FIG. 58

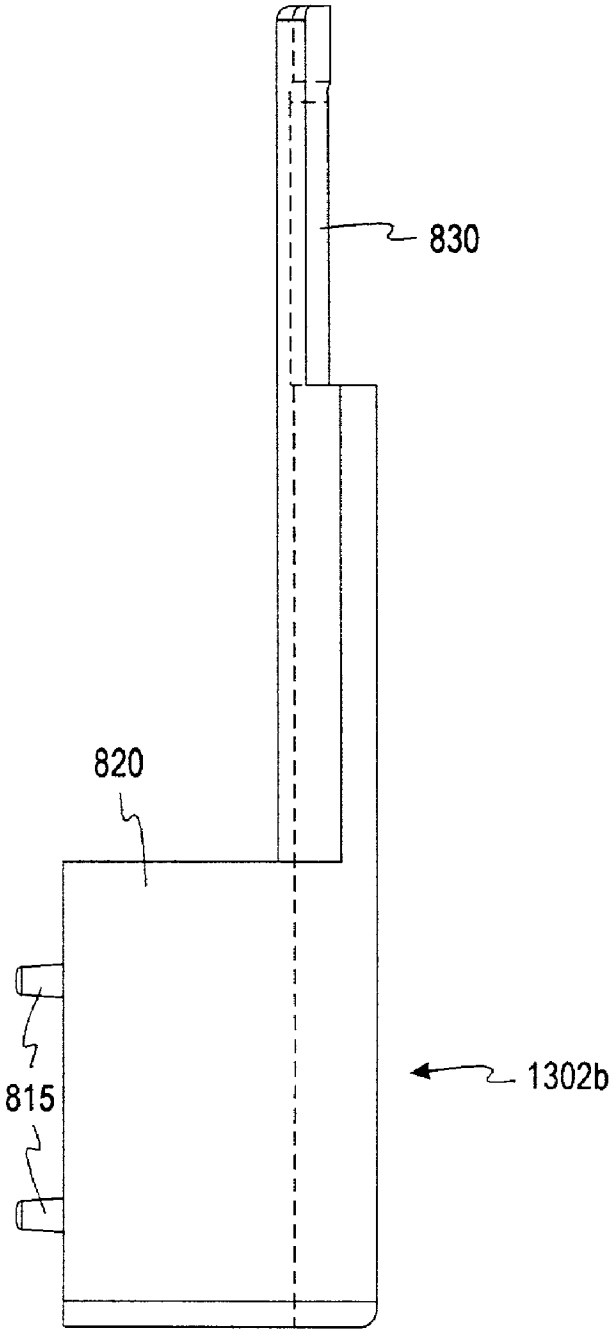

FIG. 59

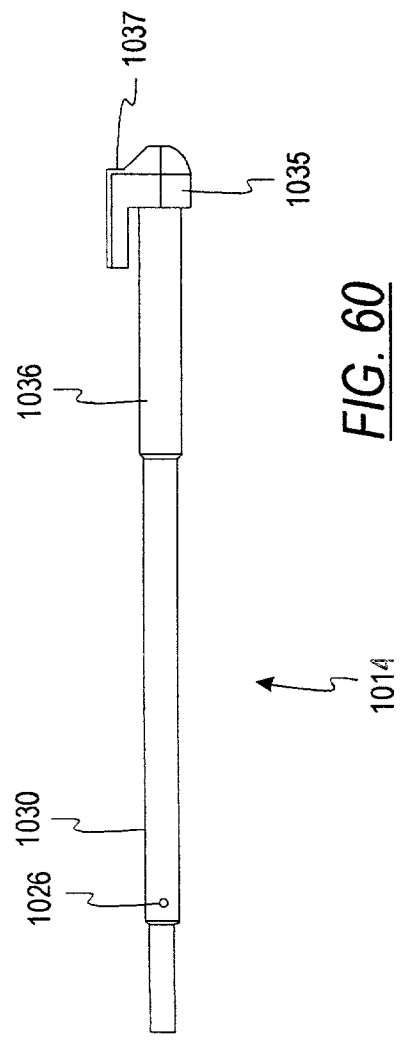
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FIG. 60

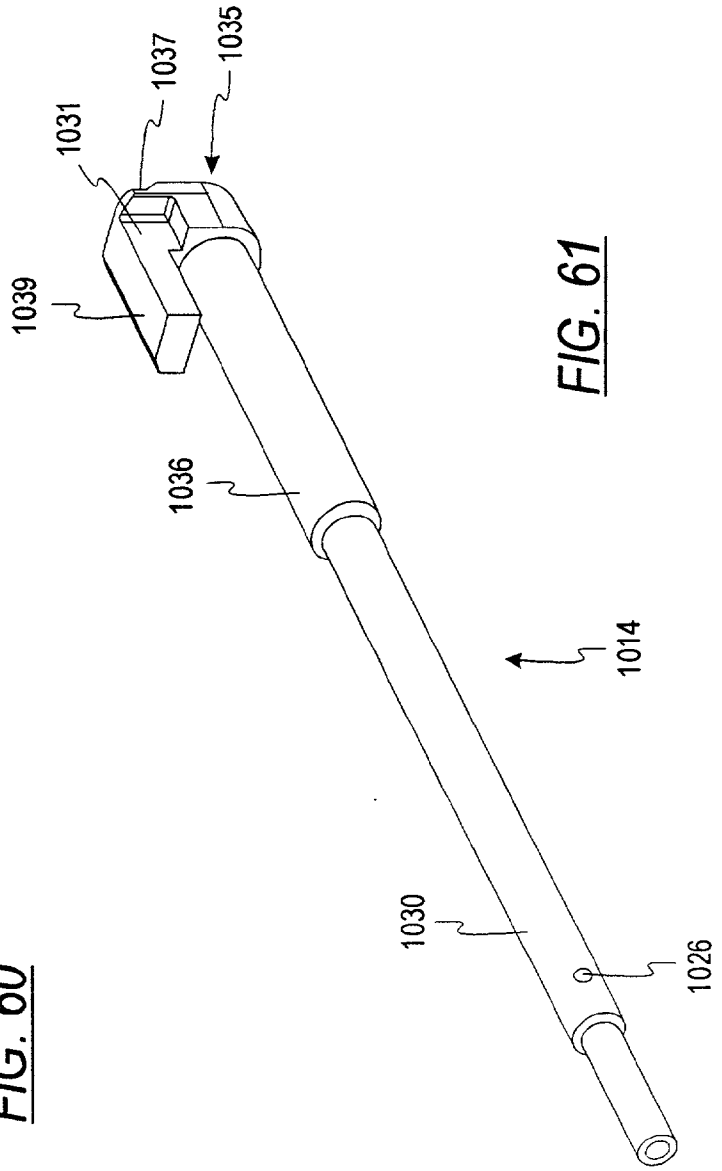
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FIG. 61

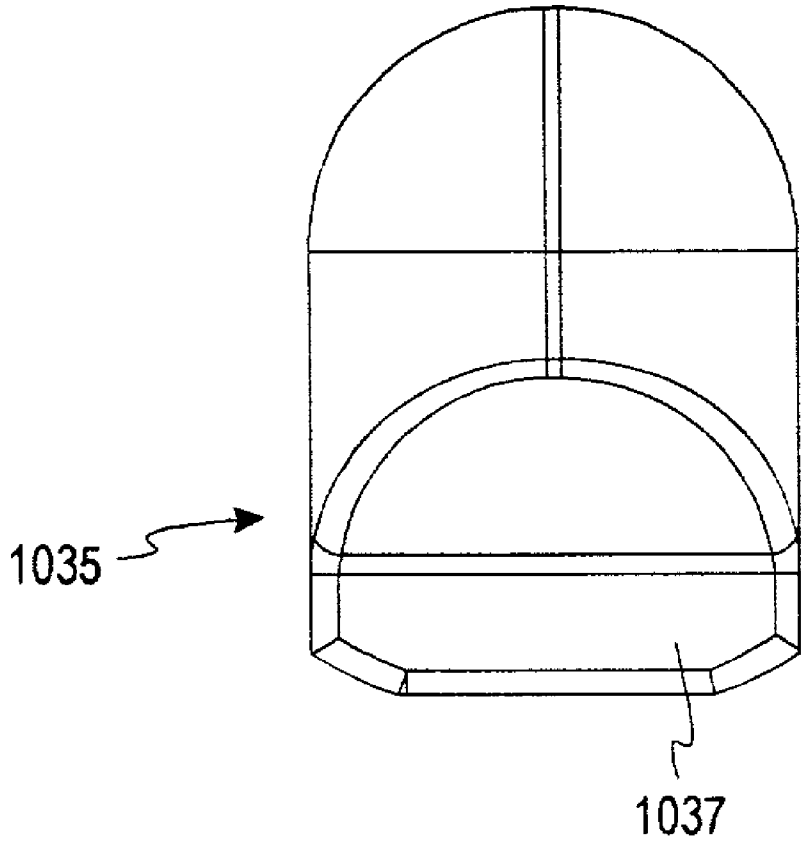

FIG. 62

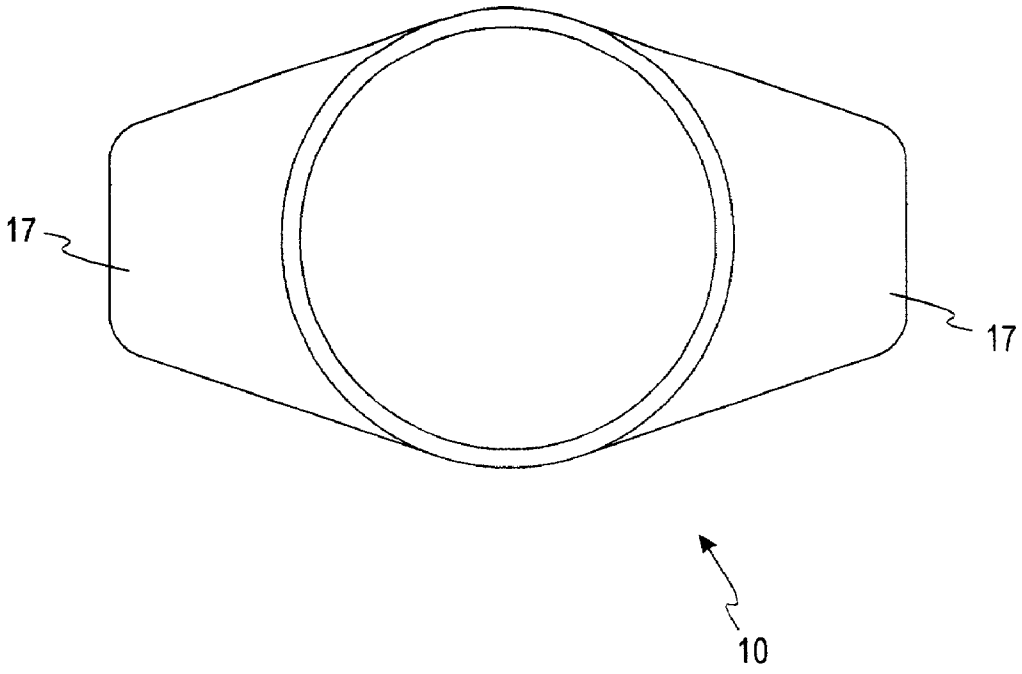

FIG. 63

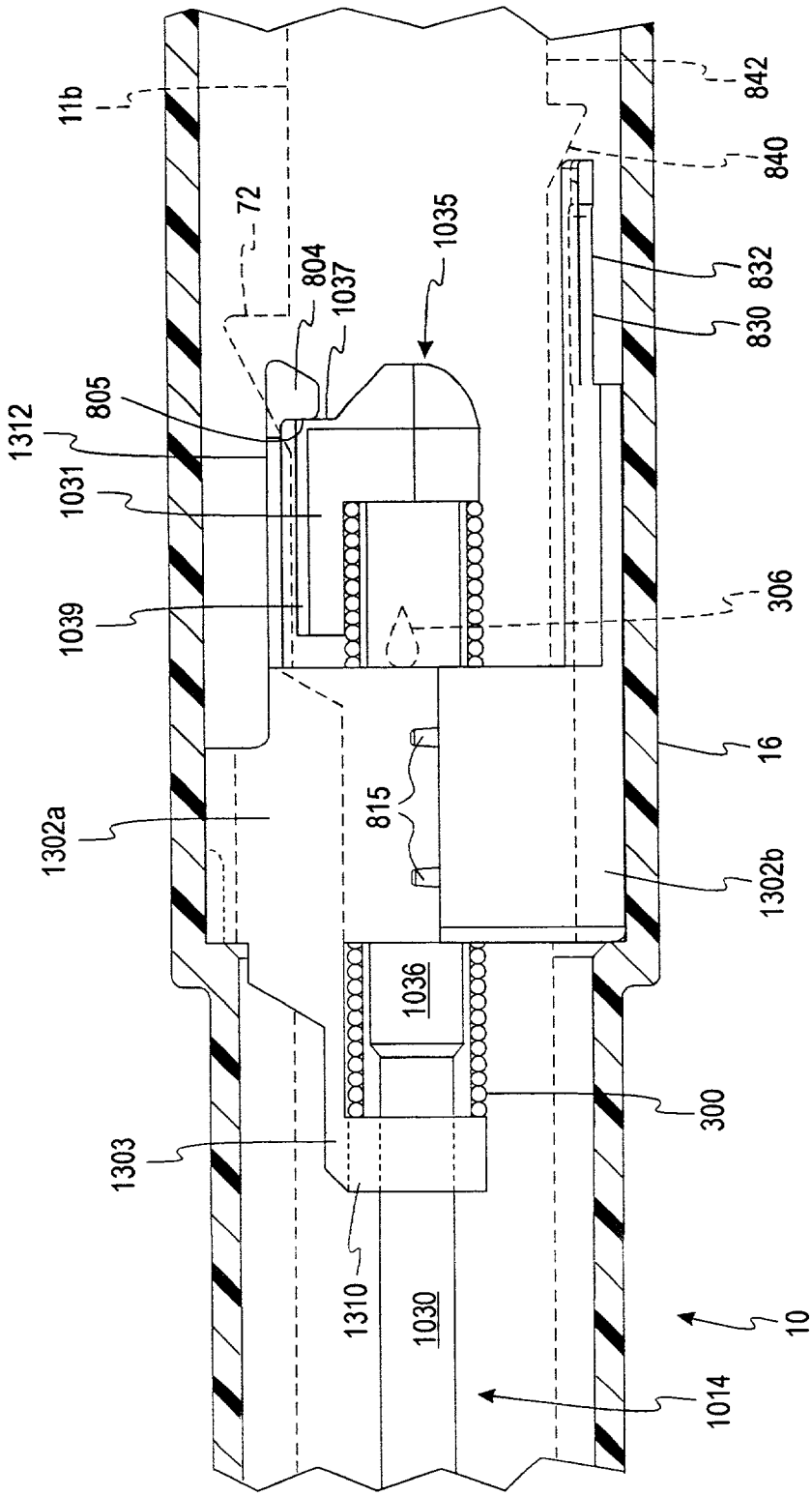
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FIG. 64

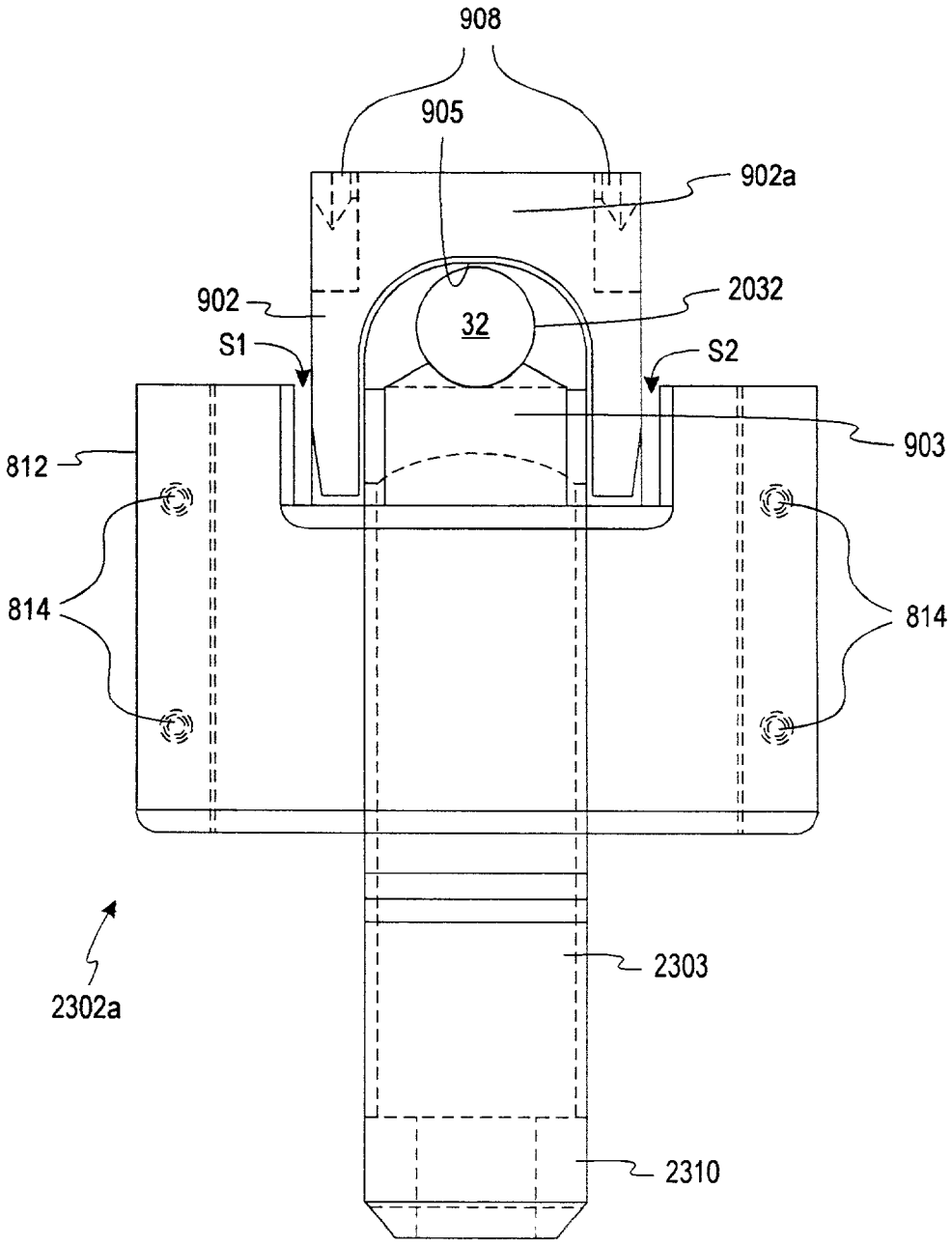

FIG. 65

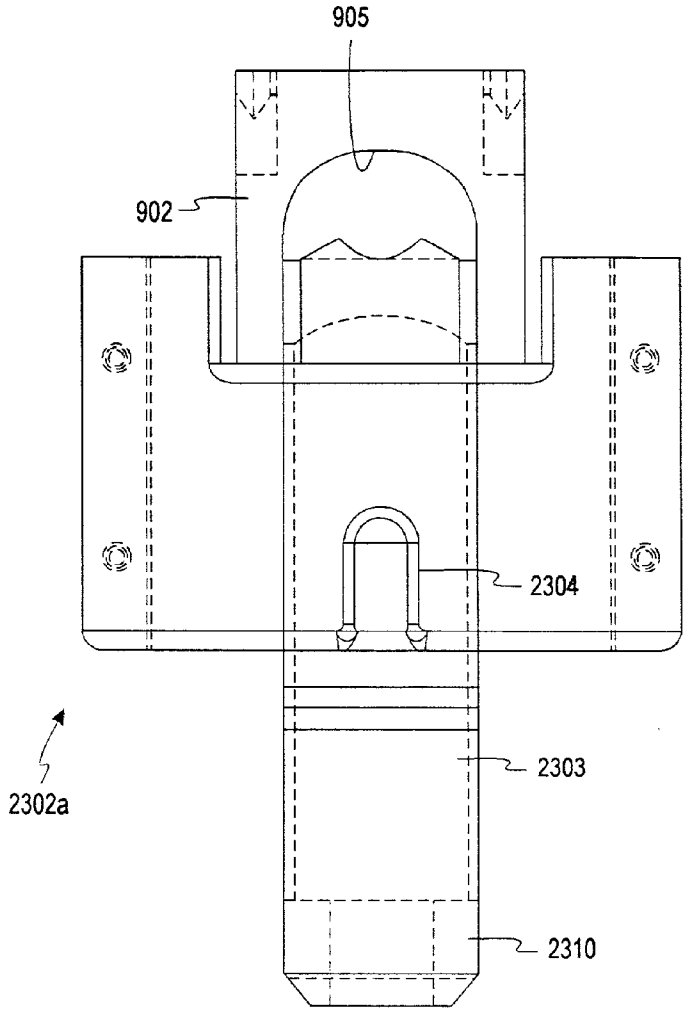

FIG. 66

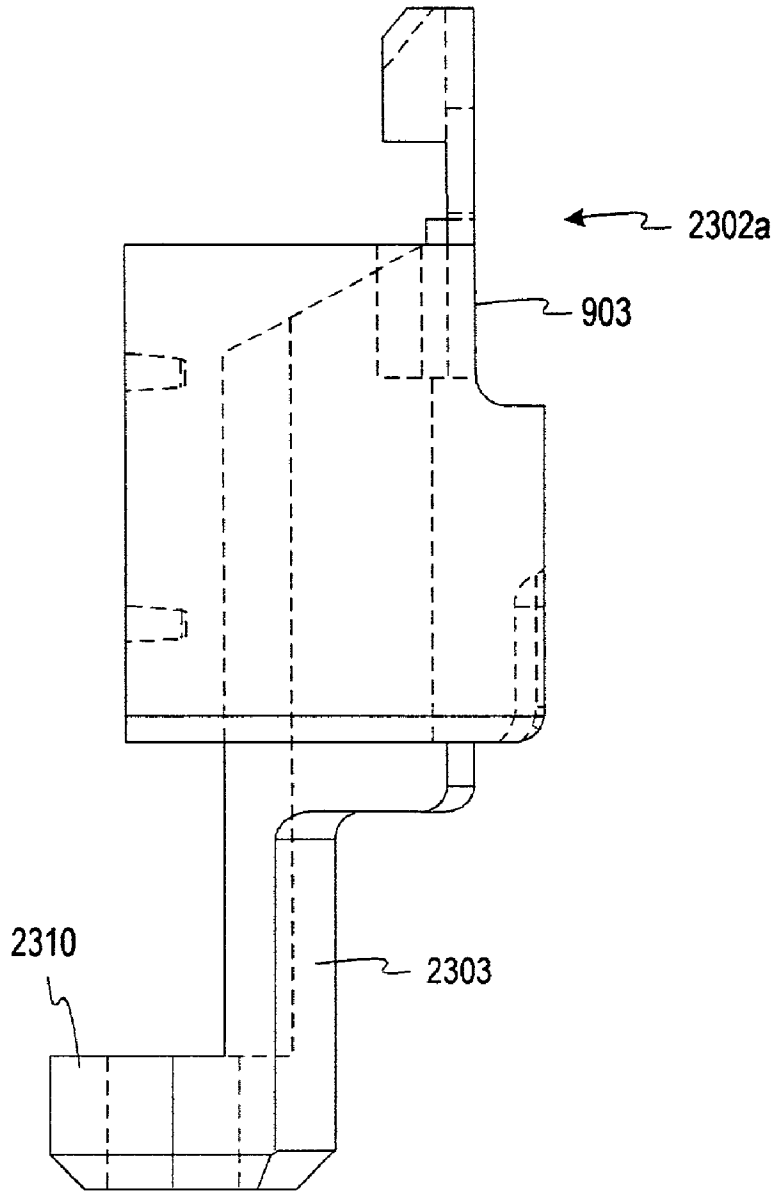

FIG. 67

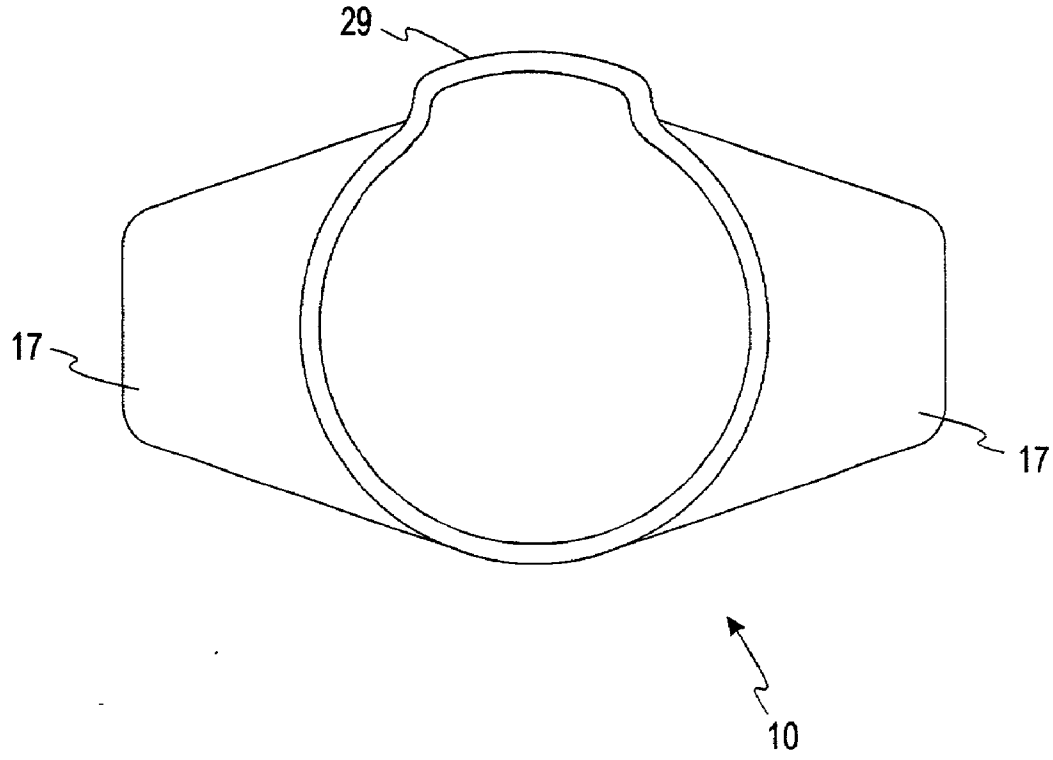

FIG. 68

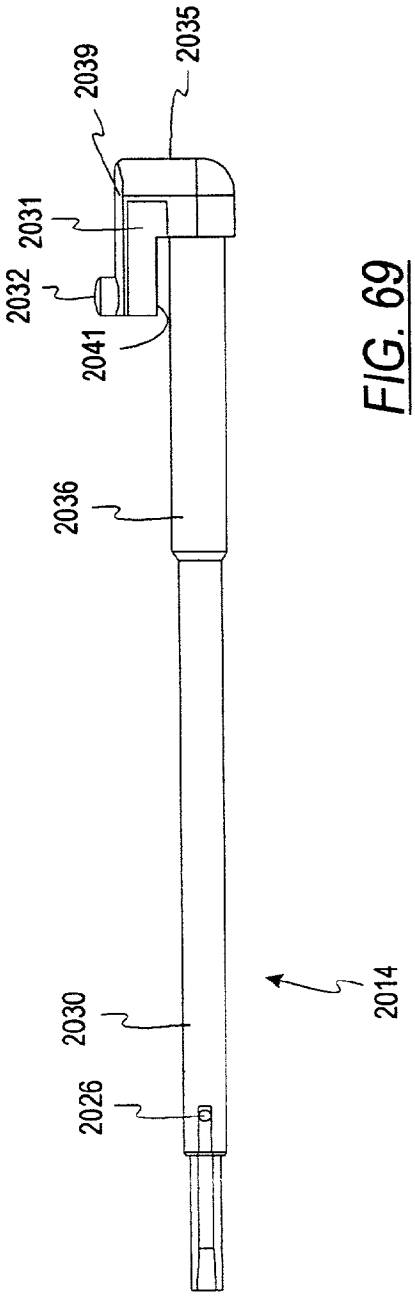

FIG. 69

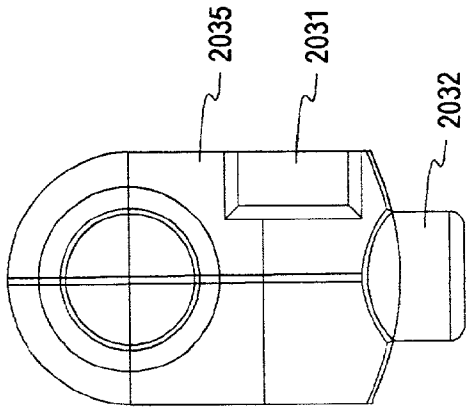

FIG. 70

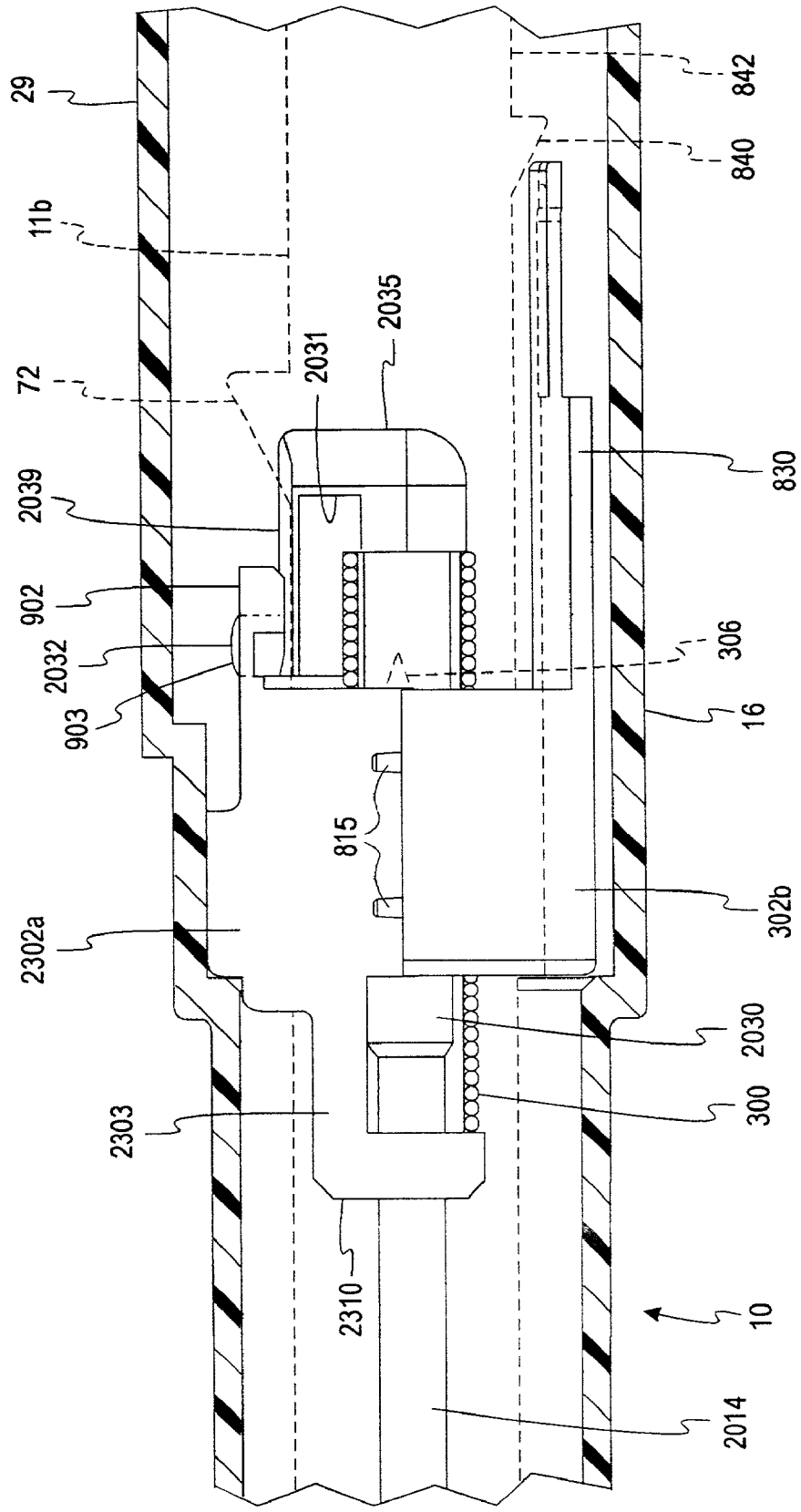
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FIG. 71

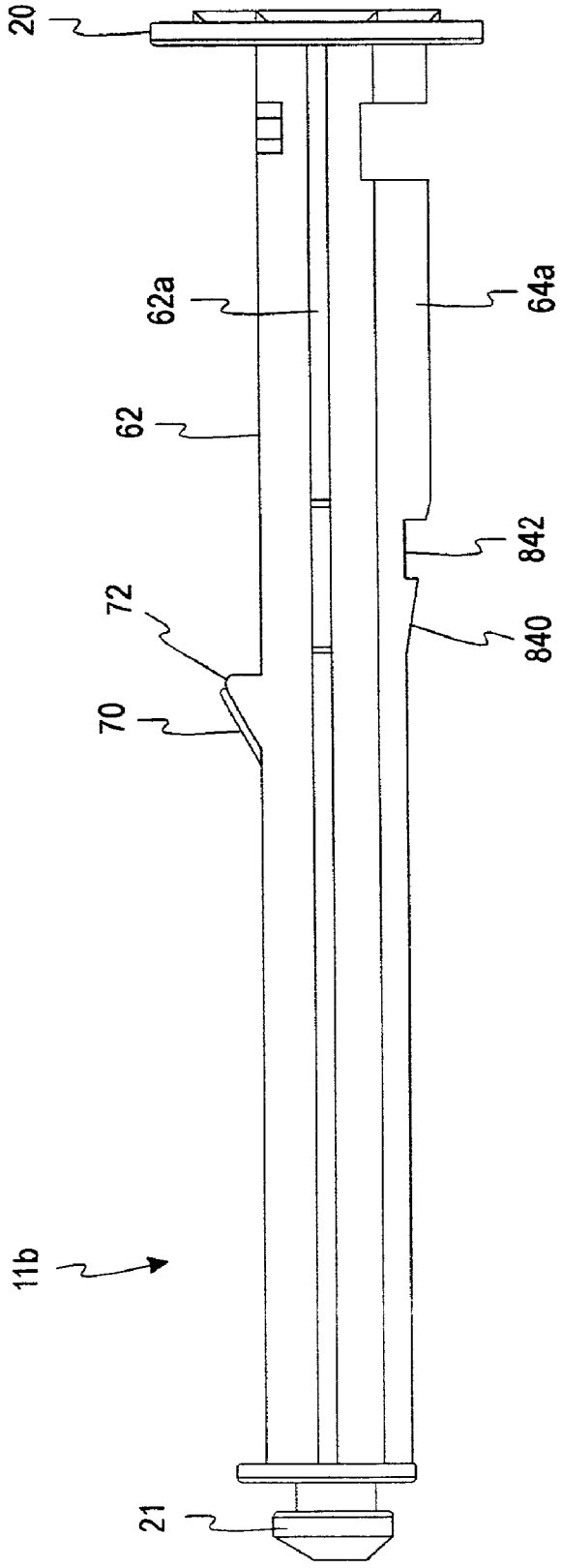

FIG. 72

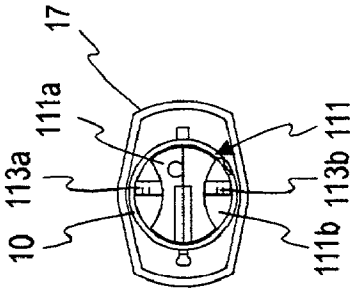
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FIG. 74

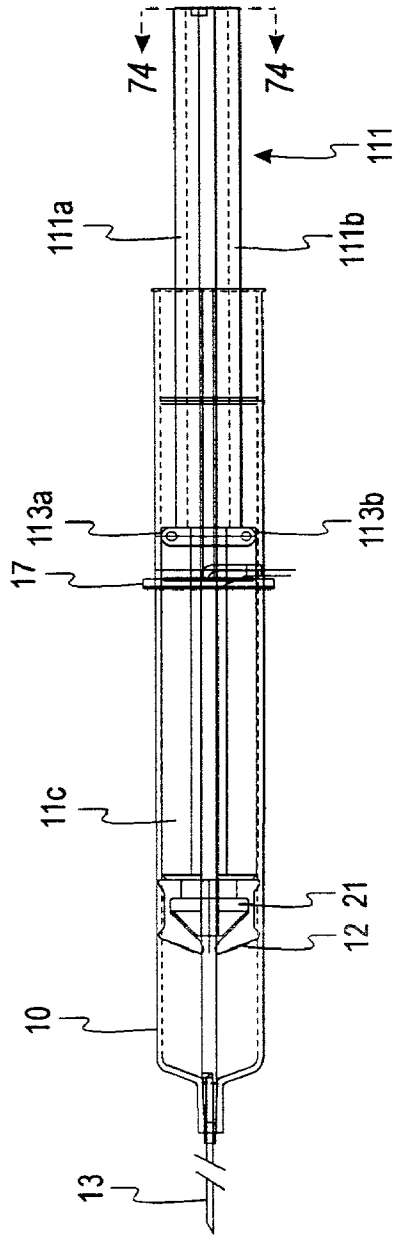
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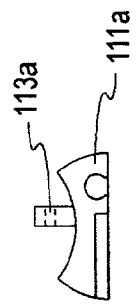
FIG. 73



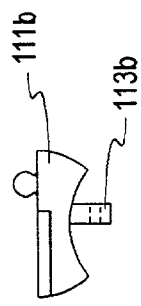
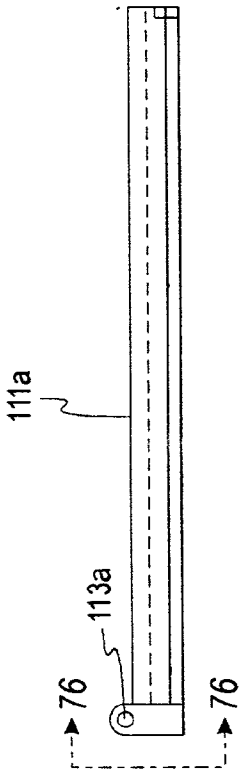


FIG. 76



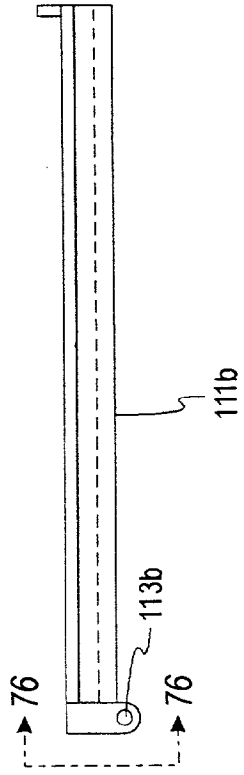


FIG. 75

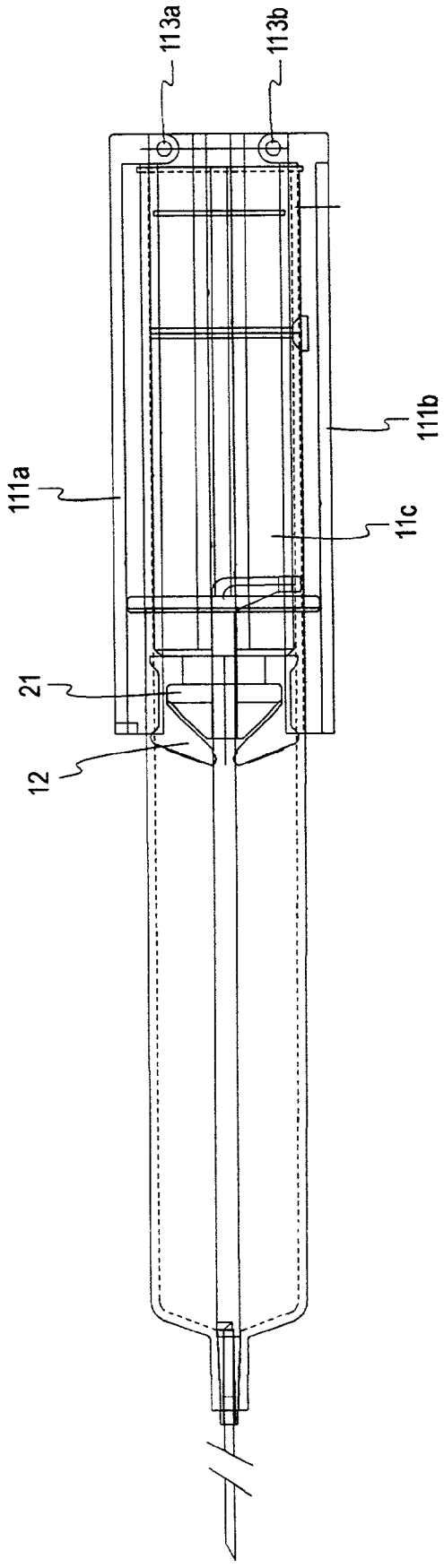


FIG. 77

RETRACTABLE NEEDLE SINGLE USE SAFETY SYRINGE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of priority of U.S. Provisional Patent Application Ser. No. 60/333,721, filed Nov. 28, 2001.

FIELD OF THE INVENTION

[0002] The present invention generally relates to syringes for use with hypodermic needles. In particular, the present invention relates to a needle-syringe assembly which withdraws the sharp point of the hypodermic needle following, use so as to render it non-reusable. An over-the-needle (OTN) catheter may also be used with the syringe assembly of the invention.

BACKGROUND OF THE INVENTION

[0003] A hypodermic needle has many applications in modern medicine. One application is to fit the hypodermic needle onto a syringe and to then insert the needle into a person's body for intra-muscular, subcutaneous, or intravenous injection of medications. Another application of the hypodermic needle is to coaxially mount a catheter over a hypodermic needle and to puncture a vein of a person's body with the needle. Following needle puncture, the over-the-needle (OTN) catheter is advanced into and retained in the vein, the needle is removed, and the catheter is connected to an intravenous line for fluid infusions into the vein.

[0004] A hypodermic needle entering into a patient's body is invariably contaminated by the patient's blood and body fluids. Following use of the needle, the needle presents a risk to physicians, nurses, and other health care personnel because the needle might transmit an infection or disease to such personnel if it were to accidentally puncture them. Thus, health care personnel are in constant danger of contracting infections and diseases, some of which may be deadly. Other potential victims of accidental needle punctures include sanitation workers who later dispose of garbage containing the hypodermic needle. The diseases which may be transmitted by a contaminated hypodermic needle include Immune Deficiency Virus, Hepatitis, Rabies, Kure, Encephalitis, and Arbor viruses. The outcome of contracting one of these diseases is often fatal because there are no known cures for any of these diseases. Often a needle puncture in a person's skin is so trivial that it remains unrecognized until the person becomes seriously ill.

[0005] Many existing OTN catheters suffer from penetration problems because of long length needles and unsecured needle supports. In addition, many existing OTN catheters still present the danger of causing needle pricks due to ineffective encasement of the puncturing needles following use.

[0006] The impact of needle stick injuries has shaken the healthcare industry. Several new products have been introduced and their disadvantages are now becoming apparent. An inventive improvement is required to remove these disadvantages.

[0007] The United States Congress has passed "Needle Stick Safety and Prevention Act (H.R.5178.ENR)". The President has signed the bill into law that Is effective Apr. 18, 2002. The law, FDA, OSHA, Center For Disease Control, National Institute for Occupational Safety and Health and other regulatory bodies have also mandated and/or recommend several improvements in syringes.

[0008] It will be clear from the reading of the disclosure that the present invention does possess all the improvements deemed mandatory and/or recommended by regulatory agencies.

[0009] A number of improvements required and/or recommended by health care regulatory bodies contained in the present invention are listed below.

[0010] 1. The syringe as well as retraction mechanism should be single hand operable, sparing another hand of physician for additional tasks. [Improved Industry Standard]

[0011] 2. The switches and functional components are inseparable from the syringe and available in any emergencies. [Improved Industry Standard]

[0012] 3. Activation of the retraction mechanism must occur from proximal plunger end. [Improved Industry Standard]

[0013] 4. The worker's hand must remain behind the needle as it is covered. (FDA guidance on 510(k) Submission March 1995)

[0014] 5. The safety feature must be an integral part of the device. (FDA guidance on 510(k) Submission March 1995)

[0015] 6. The safety feature remains activated before disassembly and disposal. (FDA guidance on 510(k) Submission March 1995)

[0016] 7. The safety feature should be simple and should require as little or no user action or training to use it safely and effectively. (FDA guidance on 510(k) Submission March 1995)

[0017] 8. The safety feature is an integral part of the device. National Institute of Occupational Safety and health (NIOSH) desirable characteristics DHHS (NIOSH) alert. Publication No. 2000-108, November 99

[0018] 9. The device preferably works passively. DHHS (NIOSH) alert. Publication No. 2000-108, November 99

[0019] 10. The user can easily tell whether the safety feature is activated. DHHS (NIOSH) alert. Publication No. 2000-108, November 99

[0020] 11. The safety feature cannot be deactivated and remains protective through disposal DHHS (NIOSH) alert. Publication No. 2000-108, November 99

[0021] 12. The device performs reliably. DHHS (NIOSH) alert. Publication No. 2000-108, November 99

[0022] 13. The device is easy to use and practical. DHHS (NIOSH) alert. Publication No. 2000-108, November 99

[0023] 14. The device is safe and effective for patient care. DHHS (NIOSH) alert. Publication No. 2000-108, November 99.

[0024] 15. Cost reduction by avoiding sharp container requirement for non-safe syringes Government Regulatory Agencies mandate use of the "sharp containers" at hospitals, physician offices and clinics as well as emergency rooms.

These containers are strong steel boxes with a one way window through which used non-safety syringe and needles are dropped. The sharp protection service is operated by licensed companies that pick up the contents of the "Sharp containers" and dispose them at specially run facilities. This service is expensive and impacts on the cost of health care. Two safety syringes currently on the market do retract the needles after use, however the retracted needle and spring freely floats within the plunger cavity. If by chance the plunger is pulled off by minimum efforts the potential of needle stick injury does exist. FDA requires sharp containers for these because there is a chance of the needle stick injury. It adds to the expense.

[0025] One purpose of inventing the present safety syringe is to lock the retracted needle securely within the interlocked syringe itself rather than sharp container and save the expense. It is essential that the entire syringe must be interlocked and disposed off in biological recyclable waste to avoid the expense of sharp container fees. This objective is incorporated in the present invention

[0026] 16. Premature disablement of devices. Advance of plunger in the barrel is a normal function of the syringe to inject the medicine. However in two devices on market retraction of the needle and disablement of syringe results from advance of the plunger within the barrel cavity, even before physician has a chance to use the syringe for patient. The syringe is wasted. The safety mechanism incorporated in the present invention and procedure of use avoids this accidental retraction and disablement.

[0027] 17. Low dead space. At the end of the injection, medicine still remains within the nozzle and the female luer end. The cost of biotechnology medicines such as Epo, and newer insulins are very high and wastage is unacceptable. The present invention avoids the female luer connector that connects hypodermic needle with the nozzle—the cause of dead space.

[0028] 18. Aerosolization. In certain devices on the market, after the injection of the medicine and advance of the plunger, a spring is released and the needle and spring flies back within the air-filled plunger. When the needle shoots back the air escapes out through the open needle due to the backward momentum and causes the fluid/medicine to escape from the needle. The escaping fluid may be contaminated.

[0029] The FDA has allowed the use of such syringes only for intra-muscular and subcutaneous application. Further it requires on use of such syringes that the retraction must be initiated and completed when the needle of the syringe is still within the body of the patient.

[0030] In the present invention the proximal end of the needle is closed and glued to the needle holder. Further the exit and entry of the fluid occurs at the peripheral wall of the needle, which is a zero velocity zone during needle retraction, and heavy construction. Also, the weight of the needle holder arm dampens the retroactive velocity of the needle. A reactive aerosolization is therefore not likely to occur, i.e., the present invention avoids aerosol problems.

[0031] 19. Hydraulic disablement. Robust design of the present invention prevents disablement of retractable needle syringe that could result from increased hydraulic pressure inside the barrel.

[0032] Accordingly, there exists a need for a hypodermic needle assembly which overcomes the above-noted drawbacks associated with many existing assemblies.

[0033] The problem of suffering accidental needle punctures is well recognized. As a result, enormous inventive effort has been devoted to concealing the sharp needle point of hypodermic needles. Such efforts are described in the present applicant's U.S. Pat. No. 5,338,311, issued Aug. 16, 1994 and U.S. Pat. No. 6,156,013, issued Dec. 5, 2000.

[0034] Apart from the above patents, in certain of the syringes that are in the market, the hypodermic needle is assembled within the compression spring and installed in the nozzle of the syringe by a bushing or "O" ring. After injection of the medicine the bushing is displaced forward by plunger end. The displacement of the bushing releases the spring and the needle as well as the plug in the plunger cavity. The retracted spring, hypodermic needle and plug freely float in the plunger.

[0035] In situations (1) when the plunger is pushed fast before medicine could escape, (2) When the medicine is viscous and needs higher gradient to escape through the needle, (3) when the needle is thin and offers resistance, (4) when there is partial block in needle or has been inserted in thick tissue, hydraulic force generated in barrel displaces the bushing causes retraction. This happens even though plunger is not advanced and medicine is still in the syringe. The present invention prevents this mishap because of mechanical continuity and robust design.

SUMMARY OF THE INVENTION

[0036] One aspect of this invention comprises an improved needle-syringe assembly which provides a simple and reliable mechanism to retract the needle after it has been used.

[0037] One aspect of the present invention was to identify the retraction control mechanism from the conventional hypodermic injection syringe, minimally supplement it with needed components, and systematically modify existing components of the syringe while preserving their normal function yet recruiting them to transform into a precision needle retraction syringe machine. Functional elements assembled with a spring retainer and plunger become a retraction control module to be installed in a conventional barrel. Indirect coupling of a needle holder to the barrel via a "switch" forms a retraction control system.

[0038] Another aspect of the present invention comprises an improved needle-syringe assembly which facilitates fabrication, and reduces the cost, of the assembly.

[0039] Still another aspect of the present invention comprises an improved needle-syringe assembly which facilitates the operation of the assembly, particularly when it is desired to retract the needle prior to disposing of the needle-syringe assembly.

[0040] Another aspect of the present invention comprises an improved needle-syringe assembly which improves the acceptability of the assembly by providing an external appearance which is virtually the same as that of conventional hypodermic needle assemblies which do not provide for needle retraction.

[0041] Yet another aspect of the invention comprises a needle-syringe assembly which provides for conventional operation for normal use, while needle retraction, once voluntarily activated, is automatic and complete.

[0042] Still another aspect of the invention comprises a needle-syringe assembly wherein the retracted position of the needle avoids puncture of the barrel and accidental sticking of medical staff.

[0043] Other aspects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the accompanying drawings.

[0044] In accordance with one aspect of the present invention, a syringe assembly, operable in a normal mode and convertible to a retraction mode, comprises a safety syringe assembly which includes an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel, a plunger slidably mounted in said barrel and having a longitudinal cavity, a needle holder slidably mounted in said longitudinal cavity of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle and a retracted position in which said needle is retracted within said barrel, elastic biasing means mounted inside said barrel and coupled to said needle holder for urging said needle holder toward its retracted position, and a latch releasably engageable with said needle holder and movable between a closed position in which said needle holder is latched to hold said needle holder in its advanced position against the urging of said biasing means, and an open position in which said needle holder is unlatched to allow said biasing means to move said needle holder to its retracted position.

[0045] In accordance with another aspect of the invention there is further provided an retractable needle, over-the-needle catheter and means for releasably securing the catheter to the above-mentioned safety syringe assembly, as well as modification of the present invention for a prefilled syringe.

[0046] Other improvements will be apparent after reading the appended description and claims which constitute their self supporting disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0047] In the drawings:

[0048] **FIG. 1** is an exploded view of a safety syringe in accordance with the invention;

[0049] **FIG. 2** is an assembled view of the syringe of **FIG. 1**, partially in section;

[0050] **FIG. 3** is a partial elevation of the syringe of **FIGS. 1 and 2**;

[0051] **FIG. 4** is an elevation, partially in section, of a barrel portion of the syringe of **FIGS. 1 and 2**;

[0052] **FIG. 5** is a sectional view rotated 90° from the view of **FIG. 4**;

[0053] **FIG. 6** is a sectional view illustrating assembly of a switch or latch element with the barrel of **FIGS. 4 and 5**;

[0054] **FIGS. 7 and 8** are an elevation similar to **FIG. 5** and an isometric view showing an alternate embodiment of a barrel;

[0055] **FIG. 9** is an elevation similar to **FIG. 4** showing an alternate embodiment of a barrel;

[0056] **FIG. 10** is a section through the view of **FIG. 9**, similar to the section shown in **FIG. 7**;

[0057] **FIGS. 11 and 12** are respective elevations of a needle holder rotated respectively 90° from each other;

[0058] **FIGS. 13 and 14** are enlarged views of portions of the needle holder of **FIGS. 11 and 12**;

[0059] **FIGS. 15 and 16** are elevations rotated respectively by 90° from each other, of a plunger element of the syringe of the invention;

[0060] **FIGS. 16*a*** and **16*b*** show an alternate embodiment of the plunger;

[0061] **FIGS. 17 and 19** are two sections through the plunger of **FIGS. 15 and 16**;

[0062] **FIG. 18** is an enlarged view of a portion of the plunger shown in **FIG. 15**;

[0063] **FIGS. 20, 21** and **22** are respectively a front elevation, an end or top view and a side elevation of a spring retainer element of the syringe assembly of the invention;

[0064] **FIGS. 23 and 24** are a side elevation and plan view respectively of a latch or switch element in accordance with one embodiment of the invention;

[0065] **FIG. 25** is a sectional view of the latch or switch element of **FIGS. 23 and 24** assembled with a barrel;

[0066] **FIG. 26** is a partial side elevation of a barrel showing the latch or switch element of **FIGS. 23 and 24** assembled therewith;

[0067] **FIGS. 27 and 28** are respective sectional views, similar to **FIG. 25** showing the assembled syringe assembly with the latch or switch element respectively in a locked and unlocked positions;

[0068] **FIGS. 29 and 30** are respective elevation and plan views of a latch or switch element in accordance with another embodiment of the invention;

[0069] **FIGS. 31, 31*a*, 31*b*** and **31*c*** are elevation side and top views of an embodiment of a latch or switch similar to the embodiment of **FIGS. 29 and 30**;

[0070] **FIG. 32** is a partial sectional view showing assembly of the switch element of FIGS. **29-31** with a barrel;

[0071] **FIGS. 33 and 34** are partial sectional views illustrating locking and unlocking positions of the switch or latch of FIGS. **29-31** with respect to activating or unlocking elements on a plunger of the type shown in **FIGS. 15 and 16**;

[0072] **FIGS. 35 and 36** are respective side and top views showing a switch or latch element in accordance with yet another embodiment;

[0073] **FIG. 37** is a partial sectional view showing a portion of the latch element of **FIGS. 35 and 36** assembled with a spring retainer element of the type shown in **FIG. 20**;

[0074] **FIGS. 38 and 39** are respective sectional views showing the latch or switch element of **FIGS. 35 and 36** assembled with a syringe assembly and respectively in latched and unlatched positions;

[0075] **FIGS. 40 and 41** are partial side views, partially in section, illustrating further the operation of the latch element of **FIGS. 35 and 36**;

[0076] FIGS. **42-47** illustrate a sequence of assembly of the syringe assembly of the invention;

[0077] **FIGS. 48 and 49** illustrate a needle and over-the-needle catheter for use in an alternate embodiment of the syringe of the invention for placement of an over-the-needle (OTN) catheter;

[0078] FIGS. **50-54** illustrate a sequence of operation utilizing the syringe of the invention to place an over-the-needle catheter with respect to a vein of a patient;

[0079] **FIG. 55** is an isometric view of another embodiment of a spring retainer;

[0080] **FIG. 56** is a side elevation of the spring retainer of **FIG. 55**;

[0081] **FIG. 57** is a partial front elevation of the spring retainer of **FIG. 55**;

[0082] **FIG. 58** is an isometric view of a second piece of the spring retainer of FIGS. **55-57**;

[0083] **FIG. 59** is a side elevation of the spring retainer portion of **FIG. 58**;

[0084] **FIG. 60** is a side elevation of another embodiment of a needle holder used in connection with the spring retainer of FIGS. **55-59**;

[0085] **FIG. 61** is an isometric view of the needle holder of **FIG. 60**;

[0086] **FIG. 62** is an enlarged top view of the spring retainer of **FIGS. 60 and 61**;

[0087] **FIG. 63** is a top view of another embodiment of a barrel;

[0088] **FIG. 64** is a partial view of an assembled syringe, partially broken away, illustrating assembly of the components of FIGS. **55-63** therewith;

[0089] **FIG. 65** is a front elevation of another embodiment of a spring retainer element portion which may be coupled with the second retainer portion shown in **FIGS. 58 and 59** to form a spring retainer element in accordance with another embodiment of the invention;

[0090] **FIG. 66** is a rear elevation of the spring retainer element of **FIG. 65**;

[0091] **FIG. 67** is a side elevation of the spring retainer element of **FIGS. 65 and 66**;

[0092] **FIG. 68** is a top view of another embodiment of a barrel;

[0093] **FIG. 69** is a side elevation of another embodiment of a needle holder used in connection with the spring retainer element of FIGS. **65-67**;

[0094] **FIG. 70** is an enlarged top view of the needle holder of **FIG. 68**;

[0095] **FIG. 71** is a partial view of an assembled syringe, similar to **FIG. 64** showing the spring retainer and needle holder components illustrated in FIGS. **65-70**;

[0096] **FIG. 72** shows another embodiment of a plunger; and

[0097] FIGS. **73-77** show another embodiment of a plunger for a pre-filled syringe.

DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENT

[0098] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

[0099] Several different embodiments of the invention, each with its own unique features and alternate embodiments, are described. Permutations and combinations of these features will, however, lead to further embodiments.

[0100] Turning now to the drawings, **FIGS. 1 and 2** illustrate a needle-syringe assembly, including a barrel **10**, a plunger **11**, a hollow resilient (rubber) plunger cap **12**, a hypodermic needle **13**, and a needle holder **14**. The barrel **10** is a hollow cylinder which terminates in a hollow tapered nozzle **15** at the distal end thereof, and has a slightly enlarged outer diameter portion **16** extending from about midway along its axial length to its proximal end. The interior of the nozzle **15** communicates with the hollow interior of the tubular body portion of the barrel **10**. The barrel has outwardly extending flanges **17** on the proximal segment **16** of the barrel **10** which facilitate gripping of the barrel with the user's fingers when it is desired to move the plunger **11** relative to the barrel **10** linearly for normal use. The flange may be annular or oblong. A retracting means, such as an elastic or resilient biasing means, here illustrated as a compression spring **300** is mounted inside the barrel **10** and operatively contacts the needle holder **14** for urging the needle holder toward its retracted position, that is a position in which the needle **13** is retracted completely within the barrel **10** (see e.g., FIGS. **46-47**).

[0101] In the embodiment illustrated in **FIGS. 1 and 2**, the elastic biasing means takes the form of an elongate compression spring **300** of relatively small diameter which fits about the outer circumference of the needle holder **14**. This spring **300** is of such a diameter that it also inter-fits within an elongated channel or cavity **33** of the plunger **11**. However, the elastic biasing means or spring may take a number of other forms without departing from the invention.

[0102] On one side of the barrel **10** and distal to the flanges **17**, there are two square molded raised detents **100** intended to lock a cylindrical switch **308** (described later) between these detents and the flanges. During installation, recesses **426** on the switch **308** (see **FIG. 6**) clear the detents and the switch abuts the flange **17**. A 180-degree rotation of the switch causes it to lock against the square detents. However, engagement of the needle holder arm **32** with the switch **308** prevents its rotation beyond 12-15 degrees. Once assembled,

the switch is inseparable from the syringe, a safety requirement for all medical devices. As mentioned above, the proximal segment **16** of the barrel **10** beyond the flanges **17** has a somewhat larger diameter. The differential of internal diameters creates a structural shelf **110** that supports a cylindrical spring retainer **302** which can be a single piece or in two parts **302***a*, **302***b*. An elevated ring is molded within the barrel cavity to prevent proximal axial displacement of the spring retainer.

[**0103**] On the surface of the proximal segment **16** of barrel (see also FIGS. **4-8**), opposite to the square detents **100** there is an open or closed channel or track **19** for locking the needle holder arm **32** (e.g., by switch **308**) at its distal end and a serving as retracting track or guide once the needle holder **14** is released. The proximal segment **16** of the barrel **10** may be about one and one half inch in length for storing the needle holder with attached hypodermic needle in fully retracted, locked and secured in straight position within the plunger channel, in the center of the syringe. The distal part of the proximal chamber **16** also contains the spring retainer and spring. The needle holder, in turn is releasably locked to the barrel via the switch **308**. The needle protector cap **200** provides an air and water tight seal at the nozzle before use, while after use it will prevent leakage of any contaminant, and the entire syringe can be disposed of in biological waste. The cap **200** and nozzle may have interlocking luer tapers or, even threads to secure the caps, for example, for a pre-filled syringe.

[**0104**] In an alternate barrel embodiment (see FIGS. **7-10**), the slot that permits the retraction of the needle holder arm proximally is covered by an increased diameter wall segment **29**, which merges with the barrel circumference at its margins. The distal end of the wall segment **29** may be open to permit engagement of the needle holder arm **32** by the latch/switch **308**, or closed, for use with an internal latch/switch described later. Such a "covered" design may be advantageous because it can be molded by straight pull tooling. This reduces the cost of tool by avoiding complex side action slides (i.e., to mold the track **19**), and increasing the density of the parts in the mold. The barrel without the exposed track **19** has a more esthetic appearance and is also more hygienic. Further, the distal end of the wall **29** if open, is covered by the switch **308** or **408**, which provides a uniform surface to the syringe.

[**0105**] This alternate design (FIGS. **7-10**) is otherwise similar to the above-described embodiment (FIGS. **4-8**) of the barrel.

[**0106**] The outer surface of the barrel **10** may contain graduations **114** (**FIG. 2**) indicating the volume level of fluid in the barrel. These graduations take into account the volume of the internal components such as the needle holder **14**.

[**0107**] The proximal end of the plunger **11** forms a knob **20** that can be grasped by a user to effect linear movement of the plunger **11** relative to the barrel **10**. The periphery of the knob **20** can be serrated or engraved to prevent slipping of the knob during the use of the plunger. The distal end of the plunger **11** forms a head **21** to mount the hollow rubber plunger cap **12** thereto. The outside diameter of the resilient cap **12** is reduced in the central portion so that the cap engages the inside wall of the barrel **10** only at the pliable margins of the ends of the cap. The diameter of the engaging end portions of the cap **12** is slightly larger than the inside diameter of the barrel **10** so that the cap presses firmly against the inside wall of the barrel to form an air-tight and liquid-tight seal at the cap/barrel interface. The inner margins of the cap **12** make a similar tight contact with the outer surface of the needle holder **14**. The distal end **22** of the cap **12** is conical to conform to the conical distal end **23** of the inside surface of the barrel **10** when the plunger **11** is fully advanced within the barrel. This reduces the dead space and assures complete emptying of medicine into the patient. The outer wall of the cap **12** may be thickened somewhat to prevent its collapse during the in barrel assembly process (described later).

[**0108**] The head **21** of the plunger **11** is configured to fit within the hollow plunger cap **12**. With the cap **12** locked onto the head **21** of the plunger, the flat proximal end **24** of the cap abuts the flat surface of a circular disc **25** at the base of the plunger head **21**. The disc **25** transmits advancing force to the rubber cap **12**. Due to the air-tight and liquid-tight seal between the plunger cap **12** and the barrel **10**, as well as the needle holder **14**, advancing movement of the plunger **11** inside the barrel **10** creates pressure in the interior of the barrel between the plunger cap and the distal end of the barrel. Similarly, retracting movement of the plunger **11** creates a vacuum in that portion of the barrel interior.

[**0109**] The distal end of the plunger head **21** is flat or frustoconical while the mating inner surface of the cap **12** is conical with space for a lose fit. This mismatch is intentional and functional. The significance is described later in disclosure.

[**0110**] Referring to FIGS. **11-14**, the hypodermic needle **13** is mounted on the distal end of the elongated needle holder **14**, which is detachably interlocked to the barrel **10** (in channel or track **19**). Prior to use of the needle-syringe assembly, the needle **13** is covered by a protective cap **200** mounted on the nozzle **15** which prevents needle pricks, preserves sterility prior to use, and preserves the barrel pneumatic volume. In addition, the nozzle may have an external or male luer taper that mates with an internal or female luer taper of the protective cap. When engaged they form strong locking contact to prevent accidental separation of parts during transport or handling. The luer lock also creates an air and water tight seal that prevents air from the barrel from escaping and maintaining a positive air pressure within the syringe barrel. Positive air pressure in the syringe barrel prevents intentional as well as accidental advance of the plunger in barrel. This assures that the retraction mechanism will not be activated until the user removes the protective cap from nozzle. The medicine aspirated in the syringe before expelling the air also assures that the plunger does not advance to the point of causing retraction. If these instructions are followed there is no chance of premature/accidental retraction of the hypodermic needle and disablement of the syringe.

[**0111**] Both the needle **13** and the distal portion of the needle holder **14** are hollow, and the interior of the hollow needle **13** communicates with the interior of the hollow distal portion of the needle holder **14**. The needle holder **14** further communicates with the interior of the barrel **10** through an aperture **26** which extends through the side wall of a hollow portion of the needle holder **14** at a distal end thereof (**FIG. 14**). Prior to and during use of the needle-syringe assembly for injection of medicine (hereafter

referred to as "normal use"), the aperture **26** is positioned at the base of the barrel nozzle **15**, sometimes within a small cylindrical cavity (not shown). The side aperture **26** permits medicine to enter or exit from the barrel **10** via the needle holder **14** and the needle **13**. The proximal end of needle **13** is not directly open to air and therefore the needle does not have an "open" end on retraction, as in some prior art arrangements. Instead it is glued within the cavity of the needle holder, and fluid transport occurs through the side hole **26** at a boundary zone A small rubber O-ring **202** is located against a distal shoulder **27** of the barrel interior (see FIGS. **3-4**) to promote sealing engagement with a distal end **41** of the needle holder **14** when the distal end **41** is stepped down as shown in **FIG. 14** to provide a shoulder. A set of luer tapers may be used as an alternate form of sealing.

[**0112**] During normal use of the needle-syringe assembly, the needle holder **14** is directly or indirectly locked to the barrel **10** (in track **19**), and the plunger **11** with its cap **12** is free to slide longitudinally back and forth along the needle holder within the barrel. In one embodiment, (see FIGS. **11-13**) the needle holder **14** includes a generally L-shaped rod having a longitudinal body portion **30** extending to the aperture **26** and hollow from the aperture **26** to its distal end, and a lateral arm **32**, supported on an enlarged, shaped end part **35** of the needle holder **14**, for extending radially across the barrel **10** and through the track **19**, at a proximal end of the body **30**.

[**0113**] The lateral arm **32** of the needle holder **14** may also include an enlarged diameter circumferential shoulder surface **35** for engagement with outermost surfaces of plunger ribs **60**, **62** (described below) which form the channel **33**, so as to position the needle holder **14** at the proper depth with respect to the channel **33**.

[**0114**] A proximal part **36** of the straight portion **30** of the needle holder has a larger diameter for supporting the compressed length of the spring **300** within a spring retainer **302** (described below). The lateral arm **32** is also heavier to resist the vertical force of the spring **300** as well as to dampen the peak velocity of the retraction when released.

[**0115**] The end portion **35** of the needle holder **14** has a rectangular recess **31** on the side as shown in **FIGS. 12 and 13**. This recess **31** locks with a detent **75** within the plunger channel **33** (see **FIGS. 14 and 17**) when the needle holder is retracted. This interlocks the syringe assembly in a safe position. In addition, the expansion of the spring also maintains the needle holder at this location.

[**0116**] Referring also to FIGS. **15-19**, to permit relative sliding movement between the plunger **11** and the needle holder **14** in the longitudinal direction, the needle holder is mounted in a longitudinal cavity or channel **33** formed as an integral part of the plunger **11**. Multiple pairs of resilient retaining elements or detents (not shown) project toward each other from the opposed walls of the channel **33** to retain the needle holder **14** within the channel.

[**0117**] Referring also to **FIG. 19**, the plunger **11** will be seen to have a plurality of ribs. A first pair of these ribs **60**, **62** define the longitudinal channel **33** for receiving the needle holder **14** as described above. A single rib **64** projects diametrically oppositely of these ribs **60** and **62**, it forces the needle holder arm **32** through the track **19** and assures stable engagement and retraction. A further pair of diametrically oppositely extending ribs **66** and **68** are formed in a plane at right angles to the ribs **60**, **62** and **64**. In the embodiment of **FIGS. 16*a*-16*b***, in the proximal one and one half portion of the plunger, the three ribs **64*a***, **66*a***, **68*a***, collectively extend transversely across the interior of the barrel **10** so as to help maintain the circular configuration of the barrel, for example, to counteract any weakness caused by the track **19**. This also helps to ensure the locking engagement of the lateral arm **32** with the track **19**.

[**0118**] The plunger **11** is the sole moving part of the syringe in normal operation, and makes contact with the fluid chamber defined in the barrel via the rubber stopper **12**. The linear movements of the plunger within the barrel determine the amount of the fluid taken in and injected into the patient. These movements and location of the plunger can therefore be mechanically indexed to the functional outcome of the syringe, retraction of the needle holder as well as disablement of the syringe. Two triangular projections **70** and **72** on the margins of flanges **60** and **62** are designed and located to interact with a switching mechanism or "instant switch" as explained later.

[**0119**] In the illustrated embodiment, the opposed walls or ribs **60**, **62** of the channel **33** extend toward the inside wall of the barrel **10** (see **FIG. 19**), thereby constraining the lateral arm **32** of the needle holder against any angular or rotational displacement relative to the plunger **11**. That is, the plunger **11** and the needle holder **14** can rotate if ever only in unison with each other, although they may move freely independently of each other in the longitudinal direction to permit needle restriction after normal use. At the proximal end of the channel **33**, a locking detent **75** locks the end portion **35** of the needle holder and plunger together to prevent relative longitudinal movement after retraction of the needle holder **14** is complete.

[**0120**] In the illustrated embodiment, the proximal end of the needle holder **14** is directly or indirectly, locked to the barrel **10**, via the lateral arm **32**. This arm **32** extends radially beyond the plunger channel **33** and fits into the track **19** in the barrel **10**. The arm **32** can be locked to the barrel **10** at the distal end of the track **19** and, when so locked, permits only reciprocal linear movement of the plunger **11**, to create vacuum to withdraw medication and pressure to deliver medication to the patient via the hypodermic needle **13**. When the needle holder recess **31** is locked in the plunger detent **75**, following use, the entire assembly is interlocked and inoperative. During normal use, the needle holder holds the needle completely advanced or projecting from the nozzle **15** of the barrel **10**.

[**0121**] When fully expanded, the compression spring **300** guarantees full retraction of the hypodermic needle **13** and needle holder **14** as well as subsequent maintenance of the needle holder **14** in the retracted state. The retraction force interlocks the needle holder detent **31** with the plunger detent **75** (**FIG. 7**) as well as plunger arm **32** with the barrel track **19**. This renders the syringe components totally interlocked and inoperative.

[**0122**] The spring **300** is supported on a robust foundation provided by a spring retainer **302** shown in **FIGS. 1 and 20-22**. The spring retainer, which may be either unitary **302** or two parts (**302*a*** and **302*b***), is installed in the barrel at the shelf like projection **110** defined by the proximal segment **16** of the barrel **10**. Mating detents **304**, **306** provided on the

contacting surfaces of barrel **10** and spring retainer **302** restricts rotary movements of spring retainer **302** inside the barrel **10**. Proximally, an elevated ring **120** (see **FIG. 5**) molded within the barrel just above the margins of the spring retainer **302** securely locks it in place, once the spring retainer **302** has been axially advanced past the ring **120** during assembly. A distal axial extension **303** of the spring retainer **302** holds the spring **300** at the margins at one end thereof while permitting the needle holder **14** to pass through a central hole **310**. The spring **300** is retained in compressed state by releasably locking the needle holder arm **32**, via the switch (e.g., **308**) to the barrel **10**. The opening **310** of the spring retainer **302**, the spring **300** and the needle holder **14** are concentric with the plunger channel **33** and with the axis of the barrel cavity.

[**0123**] Additional features of spring retainer **302** include a proximal projection **312** which extends along the inner surface of the barrel **10** and provides mechanical support. This minimizes the play with the barrel and holds the needle holder tightly locked within the barrel.

[**0124**] As mentioned above, a switch or latching means or mechanism **308** controls the position of the needle holder **14** relative to the barrel **10** for presenting the needle either fully advanced or fully retracted with respect to the barrel. In the embodiment shown in **FIGS. 1, 2** and **6**, the latching mechanism **308** takes one form. However, other equivalent forms may be used without departing from the invention, some of which are further described hereinbelow. In the embodiment shown in **FIGS. 1 and 2**, the latching means or switch comprises a needle holder locking element **308**, having an aperture **310** which inter-fits about a free end portion of the radially projecting arm **32** of the needle holder **14** which projects outwardly of the track **19** in the barrel **10**, as described above.

[**0125**] A number of regulatory bodies require or recommend that in the safety syringe devices, the switch is inseparable from the syringe. In general, these requirements or recommendations state that the functional attachments of a medical device which alters the functions of the device such as clamps, switches etc. should be inseparable from the device. These switches or other attachments must move and work, but they should not be removable. In the present invention, the ring switch as well as the barrel where the switch is installed were designed to comply with these medical device standards and regulations.

[**0126**] Referring also to FIGS. **23-28**, the switch **308** comprises a closed cylindrical ring with an internal diameter which interfits about the outer diameter of the proximal portion **16** of the barrel. A small lock-release lever **320** is molded on the outer surface of an outwardly projecting portion **322** which has an inward projection **323** to engage and lock the needle holder arm **32** that projects out from the track **19**. Needle holder arm **32** has only linear mobility in the track **19** along the axis of the syringe. The switch holds the needle holder arm **32** in position with the spring in a compressed state. Further, the switch **308** can not be displaced or rotated because it is engaged with needle holder arm **32** exiting from the slot on the barrel. The switch lever **320** can rotate to disengage the needle holder by the flip of the thumb of the same hand that is also holding the syringe. The switch completely encircles the barrel between the flanges **17** and the switch retainers-square detents **100** so as to lock the linear movement of the switch on barrel When engaged It can only rotate one way 15-20 degrees to release the needle holder. It has no other mobility and can't go anywhere. The switch **308** is inseparable from the syringe until the syringe itself is disabled.

[**0127**] The installation of the switch is as follows. Two slots or recesses **324** and **326** axially slide over the square detents **100** molded on barrel wall for assembly. The switch is inserted on the barrel from the nozzle side (distal end) so that the square switch detents **100** on the barrel are negotiated through the recesses **324** and **326** of the ring switch. Once the recesses are negotiated, the switch makes a contact with the flange **17**. At this time the switch **308** is rotated **180** degrees to engage and lock with the arm **32** of the needle holder and therefore with the barrel (**FIG. 24**). A small detent **325** of the switch **308** engages the lateral arm **32** and limits switch rotation to one direction. The square detents **100** are now locked against switch **308**, locking the switch **308** in place between these detents **100** and flange **17**, since the recesses **324, 326** are now moved to a diametrically opposite location (see **FIG. 25**). Now, only the user can voluntarily rotate the switch lever **320**, 15-20 degrees of rotation one way to retract and disable the syringe by just a flip of thumb of the same hand that is also holding the syringe. This causes retraction of needle holder, by aligning one of the slots **324, 326** (**326** in the illustrated embodiments in **FIG. 28**) with the lateral arm **32** and disables the syringe.

[**0128**] The ring switch **308** is, therefore, actuated only upon a conscious decision and voluntary effort on the part of the user to engage and rotate lever **320**. This avoids accidents, and reduces chance factors in retraction and disablement of the syringe.

[**0129**] Two other embodiments (FIGS. **29-34** and **35-38**) of the invention are provided with an improved "instant" switch. Operation of this switch requires that contents of barrel are completely injected and that a slight additional push is given on the plunger to release needle holder and initiate retraction, and thereupon to interlock and disable the syringe. This requires some action of operator, but can be called "involuntary," in that it does not require the operator to engage or manipulate any additional elements but only to press the plunger a bit further after completing the injection and withdrawing the needle from the patient.

[**0130**] During injection, the plunger **11** is the sole moving part of the syringe and makes contact with the fluid chamber **27** via the rubber stopper **12**. The linear movements of the plunger within the barrel determine the amount of the fluid taken in and injected into the patient. These movements and location of the plunger can therefore be mechanically indexed to the retraction of the needle holder as well as disablement of the syringe. The two projections **70** and **72** on the margins of flanges **60** and **62** as shown in FIGS. **15-17** are precisely designed and located. They interact with the switching mechanism of the "instant" switch as explained below.

[**0131**] The principle of the instant switch is based on the linear indexing of the plunger advance within the barrel that is proportioned with the force applied to the plunger head by the operator's thumb. At a normal fluid injection force of a fraction of PSI the distal circular plate **25** pushes the rubber piston to the end of the barrel and injects the contained medicine via needle and one limit of the plunger advance is

reached at this force. The barrel is completely emptied but it does nothing to the switching mechanism. The design of the present invention includes a flat surface **21** of the plunger end that is placed within the conical cavity **24** of the rubber piston **12** creating an empty or mismatched space. It also selects a situation specific compressible resilient rubber piston. These elements together provide an additional range for the plunger to advance within the barrel at a higher compression force-PSI. This additional travel of the plunger within the barrel creates a contact between the plunger ramps **70, 72** with corresponding parts of the switch resulting in the release of the instant switch and release of the needle holder and retraction of the hypodermic needle inside the barrel. This mechanism can be further fine tuned by adjusting the internal diameter of the distal end of the barrel, which will increase the force required to advance the plunger, or incorporating an internal ring or another stop or detent surface (not shown) in the barrel that will alert the operator of the peak force and imminent retraction moment. In addition placing a spring between the plunger plate and the cavity of the resilient cap will also predictably alter the linear length of plunger advance and improve the efficacy of the switch.

[**0132**] Referring to FIGS. **29-34**, the "instant" switch **408** comprises a cylindrical ring, having an open circumferential portion, that partially encircles the barrel **10** just distal to the flanges **17** and proximal to the square detents **100** and holds the arm **32** of the needle holder in place in the distal end of the track **19**, anchored to the barrel **10** under its distal margin. This location axially locks the switch to the barrel **10** and prevents its linear movement along the axis of the barrel **10**. The only movement that is possible is the radial displacement of the switch away from the barrel **10**, solely because the switch has an opening **410** in its circumference. However the resilient material or memory of the switch **408** normally keeps it in contact with the barrel. In a modified form (**FIGS. 31***a-c*), the switch **408***a* may be semi-cylindrical and have inwardly projecting detents **412** and **414** that engage slots **416, 418** on the flanges **17** of the barrel **10**. This prevents rotation and helps to retain the switch on the barrel.

[**0133**] The switch **408** (**408***a*) has two ramp-like projections **420** (**420***a*) and **422** (**422***a*) which extend from its inner surface and enter the barrel **10** through two windows **424** and **426** in barrel outer wall. The windows also permits projections **420, 422** (**420***a*, **422***a*) of the instant switch **408** (**408***a*) to make a contact with the ramps **70-72**, located on the plunger flanges **6062**. The windows are ultimately and totally covered by the switches installed on the barrel at this location as is the open channel underneath. The projections **420, 422** (**420***a*, **422***a*) have angled edges and juxtapose against the identical angular ramps **70** and **72** projecting from the plunger plates **60-62** when the plunger is fully advanced. The angles on the two sets of projections/ramps are identical but face in opposite in direction. During normal operation, these parts **420, 422** (**420***a*, **422***a*) and **70,72** have no contact with each other. It is only when the medicine is fully injected in the patient and the plunger is further advanced, that the parts **420, 422** and **70, 72** start making contact. Further distal linear movement of the plunger results in a radial outward movement of the switch **408** (**408***a*) that results in the release of the needle holder arm **32** that it was locking under its distal margin (see **FIGS. 33 and 34**).

[**0134**] Summarizing the above, movement of the switch **408** (**408***a*) away from barrel **10** releases the needle holder **32** instantly and effects the retraction of the needle. The linear advance of the plunger in the barrel causes the linear movement of the plunger to be transformed into the radial movement of the switch **408** (**408***a*) for releasing the needle holder (see **FIG. 34**). A normal advance of plunger **11** causes the plate **25** to push the rubber stopper **12** distally to make contact with the barrel cone **23** and the entire medicine is injected in the patient. An additional push on the plunger head **20** further advances the flat plunger end into the conical cavity of the rubber piston. The pressure squeezes the elastic rubber piston **12** and permits the further advance of plunger and consequently the ramps or plates **70, 72** contact the switch and actuate the "instant" switch **408** (**408***a*) for retraction and release of needle holder as well as disablement of the syringe as described above.

[**0135**] In one example, with a 3cc syringe constructed as described above and with an "instant" switch **408** a terminal 6.5 PSI force on the plunger head caused displacement of plunger head within the rubber stopper as well as some compression of rubber stopper to generate 0.040 inch distal displacement of the plunger ramps **70** and **72**. This displacement in turn radially displaces the "instant" switch by 0.040 inch and releases the needle holder arms to retract the needle holder as well as lock it to barrel and disable the syringe. These results depend on the size and length of the syringe, elasticity and durometer of the rubber piston, durometer of the plastic polymers and amount of the force exerted on the plunger knob as well as environmental/temperature variations which affect rigidity of polymers.

[**0136**] Referring to FIGS. **35-39**, another embodiment of an "instant switch"**508** comprises two thin flat plates **520, 522** which are connected by a bridge **524**. A flat projection **526** extends from the bridge in a direction opposite plates **520, 522** and terminates in a hook-like extension **540** which projects out through a slot **515** (see **FIG. 20**) molded in the margin of the spring retainer **302** (**FIG. 27**) inside the barrel **10**. The flat projection **56** can move only in the radial direction. The flat plates **520, 522** connected by the bridge **524** are assembled on the outside of the plunger plates **60-62**. The bridge **524** has triangular recesses **530, 532** that come in contact with the triangular projections **70** and **72** on the plunger flanges **60** and **62**. The plunger moves freely linearly between these flat plates. The flat projection **526** from the bridge passes under the needle holder arm **32**, exits out of the barrel **10** and the hook-like extension or L-shaped lip **540** extending from the projection **526** turns back to engage the needle holder arm **32** at the distal end of the track **19** (**FIG. 40**). An additional slot (not shown) in the barrel **10** is provided for this purpose. This essentially locks the needle holder arm to the barrel via the spring retainer.

[**0137**] A displacement of the flat plate **524** out of the barrel track **19** by linear movement of plunger distally, releases the needle holder arm **32** and retracts the hypodermic needle **13** (and needle holder **14**) in plunger channel **33**. In the normal operating position, the plunger moves within the switch. When the entire medicine is injected and a final push is given to the plunger which advances the resilient cap **12** as well as compresses it. Triangular projections **70** & **72** of the plunger engage the recesses **530, 532** and causes movement of the switch **508** so as to release the needle holder arm **32** and cause retraction of hypodermic needle by

the spring **300**. A formed wire can replace the projecting flat plate **526** and lip **540**. All that is required is a structure that can hold the needle holder against the spring force and anchor it to the barrel and be actuated by the plunger movement as described above.

[**0138**] Since the switch **508** is located inside the syringe there is no question of its separation from the device and therefore complies with regulatory requirements and/or recommendations. Those skilled in the art may device other specific switch constructions for accomplishing their goals without departing from the invention.

[**0139**] Each of the above-described switch arrangements accomplishes the above-stated objectives, as well as being non-removable. In this regard, when the latch or ring **308** is used to retract the needle holder, the plunger can be in any desired longitudinal position. For example, the plunger can be fully advanced, fully retracted, or at any intermediate position. This is advantageous because it might be desired to retract the needle after only a portion of a dose of medication has been injected into the patient, or it might be desired to retain all or a portion of a blood sample withdrawn from a patient within the syringe. With respect to the instant switches the plunger must be fully advanced to empty the syringe before the retraction mechanism is activated. To prevent the leakage of any fluid contained within the syringe at the time the needle is retracted, a latex seal (not shown) may be provided at the end of the nozzle **15**. Also, the plunger cap **12** may be provided with a slit valve that engages the needle and prevents leakage. The nozzle also can be capped because the hypodermic needle is locked within the syringe. This retractable needle safety syringe is supplied sterile and ready to use.

[**0140**] During normal use of the needle-syringe assembly, the barrel **10** and the needle holder **14** are held stationary, and the plunger **11** is free to move axially relative to both the barrel **10** and the needle holder **14**. Advancing movement of the plunger **11** is limited by contact of the plunger cap **12** with the end wall **23** of the barrel **10**. The needle holder **14** is releasably locked to the barrel **10** by the locking engagement of the lateral arm **32** to the wall of the barrel by a latch such as the latch **308**. Also, when used, the locking luer taper releasably locks the needle holder **14** to the barrel **10**. The plunger **11** is also free to move longitudinally relative to the needle holder **14**, because the needle holder is not locked to the plunger in that direction. However, the locking of the lateral arm **32** by the latch mechanism at the barrel wall, prevents rotation of the plunger. As long as the lateral arm **32** of the needle holder is locked to the barrel wall, the needle-syringe assembly is in its normal operating mode.

[**0141**] Following normal use of the needle-syringe assembly, the needle **13** can be retracted into the plunger **11** and the barrel **10**. This requires axial movement of the needle holder **14** within the barrel **10** toward the proximal end thereof, which in turn requires that the needle holder **14** be unlocked for movement, under the influence of the biasing or retracting means such as spring **300**, within the channel. Thus, to initiate retraction of the needle holder **14**, the arm **32** is unlocked by releasing the latching mechanism **308**, **408** or **508**.

[**0142**] The illustrative syringe need not be any longer than a conventional syringe because conventional syringes are made longer than required to provide more than the desired fluid volume, so as to avoid inadvertent withdrawal of the plunger and the resultant spillage of the syringe contents. The extra plunger barrel length to accommodate the user's fingers in the space between the plunger knob and the finger flanges contributes to excess length in conventional syringes. In the present invention, the extended barrel length is used to lock and store the retracted needle holder and the entire needle.

[**0143**] **FIG. 2** illustrates the assembled syringe and needle assembly with the cap **200** as it might be provided for use.

[**0144**] To operate the needle-syringe assembly, the protective cap **200** is removed from the needle **13**, and the required amount of medication is aspirated into the barrel **10** without advancing the plunger. Air bubbles if any are removed and quantity of medicine is adjusted. Next, the injection site on the body of a patient is determined and the skin is cleaned with an antiseptic solution. Following percutaneous entry of the needle into the patient, location of the needle tip in the vein is confirmed by aspirating a small amount of blood into the transparent barrel **10**. The plunger **11** is then advanced to inject the medication from the barrel **10** into the vein. After the medication is administered, the needle **13** is withdrawn from the patient, the latch mechanism **308** (**408**, **508**) is released and the spring **300** or other retracting means retracts the needle holder **14** and the needle **13** and locks the needle holder in the plunger detent **75**. With the needle **13** completely retracted inside the barrel **10**, all the components of the syringe are automatically interlocked and non-reusable, and the needle-syringe assembly can be safely discarded in its entirety. The cap **200** can be replaced to prevent leakage of any remaining fluid within the barrel **10**.

[**0145**] It can be seen from the foregoing description that the needle-syringe assembly performs all the conventional functions of injection syringes and yet, upon completion of injection, the hypodermic needle **13** is concealed within the barrel **10**. The needle-syringe assembly with switch **308** can receive and dispense medications any number of times for a given patient by reciprocal longitudinal movement of the plunger **11** within the barrel **10**. However, once the latch is released it cannot be reused.

[**0146**] The needle-syringe assembly of this invention is easy to manufacture, cost effective, and easy to use in the field. The parts can all be made by conventional plastic molding and using readily available medical grade stainless steel needles and compression springs. The plastic parts are made by injection molding of medical grade, gamma stable polymers such as polypropylene. The needle holder and spring retainer that require higher strength are molded from polycarbonate. The plunger seal or cap and "O" ring can be molded from non latex thermoplastics synthetic elastomers or silicones. The switches that require smooth friction free movements is made from HDPE. Of course the material selection is guided by the strength and functional requirement of components. The disclosed materials can be substituted by alternate or improved compounds that may or may not be presently available. The needle is glued by using ultraviolet cured adhesives. Syringes are assembled and packaged in a clean room and sterilized by gamma radiation.

[**0147**] While the drawings of components and description, for simplicity, show a syringe with central nozzle, the axis of all the components can be shifted to generate a syringe

with an eccentric nozzle without altering the concepts or components. Likewise, the cross-sectional shape of syringe components can also be modified without deviating from inventive description.

[0148] Because of the unique features of this invention the method of assembly is modified from the conventional syringe assembly. The method is illustrated in FIGS. **42-49**. The pre-capped plunger is oriented with open channel **33** facing up, is placed on a peg passing through the proximal window of the plunger while spring retainer half **302***a* is placed under the plunger. Since the proximal part of the plunger channel has a detent **75** that interlocks with the retracted needle holder, their contact is prevented by placing a spacer **602** between the components to prevent interlocking (FIGS. **43-44**). The spacer is placed in the plunger channel and is taken out only after the assembly, by pulling the plunger out of the barrel. A sub-assembly consisting of the needle holder surrounded by the compression spring and spring retainer is then placed in plunger channel **33**. Insertion of the plunger containing the foregoing assembled components in the barrel completes the assembly by rearranging each component because of the localized restrictions and structural geometry of the barrel.

[0149] In **FIG. 42**, the switch **308** is inserted on the barrel **10** from the nozzle **15** side past the detent **100**, and rotated 160 degrees, ready to receive and lock the Needle Holder Arm. In **FIG. 43**, the rubber cap **12** is aligned and pressed on the plunger **11**. Spring retainer **302** is aligned under the plunger **11** adjacent to the distal plunger plate. **25**. In **FIG. 44**, the plunger with open channel **33** is placed on a square indexing pin **600** passing through a detent window or opening **601** in the plunger provided for this purpose. It blocks the detent **75** and keeps plunger channel open for assembly of parts. Also, a spacer rod **602** is placed in plunger channel adjacent to the square indexing pin. In **FIG. 45, a** sub-assembly including the needle holder and spring **300** inserted into the spring retainer **302** is placed in the plunger channel next to the spacer rod **602**, and the spring retainer parts **302***a*, **302***b* are snapped together. In FIGS. **45-46**, the plunger assembly is inserted in the barrel **10** and switch **308** is rotated to lock the needle holder arm. All the components are now properly re-arranged, aligned and assembled automatically. In **FIG. 47**, the plunger **11** is pulled out to discard the spacer rod **602**.

[0150] Because the needle holder **14** is retracted directly into the plunger **11** itself, the rather than into the barrel cavity, the plunger **11** need not be fully extended out of the barrel for needle retraction to occur. Thus, when discarded following use, the needle-syringe assembly contributes minimally to the bulk of refuse. Since retraction of the needle **13** is effected by the spring or other elastic biasing means, upon releasing the latch, the hand of a user does not come into the vicinity of the needle point, thereby minimizing the possibility of a needle prick during retraction. Moreover, the assembly employs substantially the same number of components as conventional syringes, and does not require additional guards, sheaths, sleeves, etc. to conceal the needle following use.

Intravenous Catheter Insertion Syringe.

[0151] Intravenous access is a lifeline of critically ill patients as a primary avenue of administration of fluids and medicines, yet it can be a difficult procedure. There is therefore a need to place a catheter consisting of a non-traumatic flexible polymeric tube in a patient's vein. Since polymeric catheters, although non-traumatic to veins, can not penetrate the skin and vein, a hypodermic needle has to be used first to create an initial puncture and guide the catheter by sliding over it. This over-the-needle (OTN) catheter placement syringe is disclosed in **FIG. 48-54** and has essentially the same components of the retractable needle syringe as shown and described above. However, the needle holder **14** is replaced by an integral needle **713** which also functions as needle holder **714** and has all the functional features of the above-described needle holder **14** including a side hole **713***a* located in barrel cavity close to the nozzle. The remaining proximal part of the needle **714***a* is blocked beyond the side hole **713***a*. It has an insert-molded head **730** to support the spring **300** as well as side arm **732** to engage to the barrel via a switch. The "O" ring **202** is replaced by a synthetic elastomeric gasket **702** press fit in the nozzle **15** of the syringe. A step between the needle and needle holder is avoided to prevent back flow of the fluids when the plunger is advanced over the retracted needle that has a smaller diameter than the opening in the rubber stopper.

[0152] Veins are mobile and slippery structures. They are also tortuous. Hence a straight hypodermic needle cannot be pushed too far because of the danger of double puncture. A soft and non-traumatic catheter, once in vein can however be advanced for longer length. However, it is also essential to confirm that the fluid path is continuous, and that the catheter is in vein. A free flow of the heparinized saline indicates that the catheter is located in the vein and that it is open. Heparinized saline also prevents the clotting of blood in catheter as well as the vein. Infusion of heparinised saline as soon as venous access is obtained to prevent clotting of the vein by blood is a good strategy and is universally followed. Saline filled syringe to obtain venous access is good practice, and will be clear from the method of use depicted in FIGS. **50-54**.

[0153] In FIGS. **48-54**, over-the-needle ("OTN") catheter assembly includes an OTN catheter **80** and the above-described syringe assembly with a hypodermic needle **13** modified as noted above mounted therein. The catheter **80** is a polymeric catheter having an elongated tip **82**. Prior to use of the OTN catheter assembly, a proximal end female connector **84** of the OTN catheter **80** is coaxially mounted over the nozzle **15** and the hypodermic needle **713** protrudes through both the nozzle **15** and the OTN catheter **80**. Prior to and during normal use of the OTN catheter assembly, the OTN catheter **80** is held engaged over the nozzle **15** of the syringe assembly by suitable means, such as locking luer tapers on the outer surface of the nozzle **15** and the inner surface **81** of the end **84** of the catheter **80**. The elongated tip **82** of the catheter **80** follows the beveled tip of hypodermic needle **713**. Prior to use, i.e., prior to inserting the needle **713** and catheter tip **82** into a vein, the needle **713** and catheter tip **80** are enclosed by a removable cap similar to the cap **200**.

[0154] The illustrated embodiment of the catheter **80** includes an internal valve **85** that normally closes the cavity of the female luer end **84** of the catheter to prevent back flow of blood when disconnected from syringe or fluid line. The valve **85** opens to permit the entry of the nozzle end of the syringe and permits fluid communication. It again stops the

back flow of fluids when the syringe nozzle is withdrawn from the catheter. When another fluid line that also has a male luer end is subsequently connected to the luer end **84**, the valve **85** may be opened to permits fluid communication.

[**0155**] The purpose of the locking means, such as luer tapers, is to assure mechanical unity of the syringe with the OTN catheter so that insertion force applied to the syringe barrel is directly transmitted to the hypodermic needle **713** and catheter **80**. Release of the locking luer taper disassociates this mechanical unity, permitting the syringe (with the retracted needle **713**) to be removed from the catheter **80**.

[**0156**] To use the OTN catheter-syringe assembly, as shown in FIGS. **50-54**, the skin of a patient is first prepared and a peripheral vein **800** is made prominent and cleaned with antiseptics.

[**0157**] Under aseptic precautions, the OTN syringe cap **200** is removed and syringe is partially filled with heparinised saline. The vein is punctured with the needle **713** projecting at the catheter tip **82** (**FIG. 51**), and the location of the needle tip is judged by the change in color under the catheter or by the appearance of blood in the catheter and/or the flashback or aspiration of blood in the syringe.

[**0158**] Once the location of the needle tip in the vein is confirmed, by aspiration of blood and injection of saline in the vein, the needle holder is retracted by release of the switch as described above (**FIG. 52**). At this stage the plastic catheter can be advanced in the vein without fear of trauma since the sharp needle is already retracted, in the manner described above.

[**0159**] Continuity of catheter and its location and, confirmation that the needle **713** and catheter tip **82** are located in the vein can be made by viewing blood entering the catheter **80** by capillary action. It, however, is also possible to confirm a flashback within the syringe barrel by partially retracting the plunger **11** relative to the barrel **10** to assure that continuity between the barrel nozzle **15** and the vein is still established. In this regard, the side aperture of the needle holder **714** opens into the syringe. Confirmation of proper insertion in the vein therefore is indicated by blood entering the barrel chamber via the side aperture in the needle holder **714**.

[**0160**] When fluid path is continuous, the entire heparinised saline in the syringe is infused in the vein to fill the vein with anticoagulants to prevent clotting.

[**0161**] While securing and retaining the OTN catheter **82** in the vein, and blocking the female end of OTN by the valve **85** the syringe assembly is removed (**FIG. 54**) and an intravenous line is connected to the catheter **80**, as conventional. Finally, the catheter **80** is secured to the skin of the patient by adhesive tape. The syringe with the retracted and lo locked needle is then disposed of as biological waste. In order to prevent leakage of the fluid the syringe may be capped.

[**0162**] Without the improvements recited herein it was not possible to ascertain with certainty [1] the catheter is in fact in vein after the puncturing needle is withdrawn [2] that there is no false passage [3] that the vein is filled with anti-coagulant saline and that it is open—not clotted.

[**0163**] The various novel and improved syringe assemblies as described above offer a number of advantageous features, including but not limited to various combinations of the following:

[**0164**] The plunger channel **33** adds precision to the needle holder movement. For example, straight axial retraction of the needle in the plunger channel **33** avoids angulation of the needle and puncture of the barrel cavity. It does not require extending the overall length of the syringe as a result of the plunger being pulled out, and avoids the need for special measures such as breaking the plunger to prevent re-use. The linear movements of the plunger in the barrel are mechanically indexed to actuate retraction of the needle after the medicine is injected in the patient.

[**0165**] The number of the components in the present invention is not significantly different from a conventional syringe to keep it cost effective.

[**0166**] Use of the sliding needle holder eliminates the usual female needle holder on the barrel nozzle, which eliminates the associated dead-space and quantity of wasted medications left over in the syringe nozzle and the conventional needle holder.

[**0167**] The operation of the syringe is one-way so that accidental misuse is minimized, i.e, once retracted the needle holder is locked in place, so the needle cannot be re-extended.

[**0168**] Operation of the syringe is particularly safe because all the required manipulations of the various parts of the syringe are performed at or near the proximal end of the syringe, well away of the needle, during both the normal and retracting modes of operation.

[**0169**] In the rare event when only a partial dose of medicine is given to the patient, the syringe with leftover medicine can be rendered safe by retraction of the needle holder, while capping of the nozzle will prevent spillage.

[**0170**] It should be noted that the syringe assembly as described may be used to dispense medication or as a blood collection device. It may also be used to place an over-the-needle catheter, as described above.

[**0171**] With a few innovative modifications, present invention can be converted into a pre-filled retractable needle, single use safety syringe. These syringes are used in the pharmaceutical industry. Instead of packaging the injectable medications in vials or ampoules the sterile medications are filled in the syringe itself. It saves the entire packaging cost of ampoules and vials, as well as cost of professionals, who transfer the medication from the vials to the syringes in sterile atmosphere, before it is injected in the patients. With a pre-filled syringe, it is just inject the medicine and dispose of the syringe. One of the major problems involved in the pre-filled syringe technology is the compatibility of the syringe components with the medications stored in syringe for long shelf life. Newer plastics that can be used in this invention are sufficiently neutral, nonreactive and address that problem. A second consideration is that the medicine filled in a syringe should not leak, either from nozzle end or from rubber piston end. Further, the sterility of medicine must be preserved, and an accidental discharge of medicine must be avoided, until use. In addition, the syringe used to inject the medicine in patient must comply with the "needle stick" prevention regulations mentioned above.

[**0172**] Prevention of fluid leak is an important function of the syringe. The problem is that of maintaining a seal at either end over a long period of time. The nozzle of the

present syringe invention can be provided with male (external) luer taper to install a tight fitting cap **200** with female (internal) luer taper for protection of needle point, as well as preventing accidental needle stick, because the hypodermic needle emerges from within the nozzle. The luer taper lock requires an intentional compound roto-linear movement to disengage. It therefore resists vibratory as well as other forces ordinarily tending to separate the components.

[**0173**] A luer lock when re-enforced with a screw thread molded on contacting surfaces of the nozzle **15** as well as inside cap **200**, is further assurance that cap would not separate once installed to maintain the seal. The protective cap **200**, intended for the pre-filled syringe, is in addition partially filled with a nontoxic, tissue-compatible, inert, elastic non coring, material such as silicone to an appropriate length sufficient to enclose the tip portion part of the hypodermic needle of the retractable needle syringe. When such a needle protector is installed on the nozzle of the retractable needle syringe, it assures a perfect seal both to prevent the leak of air as well as any fluid contained within the prefilled barrel despite a modest in-advertent push on the plunger.

[**0174**] The rubber piston **12**, installed on the plunger head **21**, seals the needle holder in its center and seals with the barrel along its periphery. When the syringe is pre-filled with medicine, the rubber piston is supported by the spring retainer **302**. Further, the needle holder anchors it to the barrel of the syringe. Accordingly, the plunger and the rubber cap cannot be pulled out beyond this pre-filled location, unless this locking mechanism is intentionally and voluntarily disabled, so there is no chance of a leak from the proximal end.

[**0175**] The effective sealing at the nozzle as well as the above-mentioned mechanical anchoring of the rubber piston is not likely to permit movement of the plunger to effect a fluid leak. However, another barrel-plunger lock mechanism consisting of a clip that anchors to the barrel and a 90 degrees angled plate that engages with the linear slots on the proximal part of the plunger flange **64** immobilizes the plunger in relation to the barrel. This prevents any inadvertant pull or push to be transmitted to the medicine chamber and assures additional security against advancement of plunger within the barrel.

[**0176**] Since prefilled medicine obligates that the plunger be pulled out, and since the pulled out plunger is unprotected because it is out of the barrel, this assembly is further fortified. Referring to FIGS. **73-77**, the plunger portion **111** projecting out of barrel **10** is split in two halves **111***a*, **111***b*. Each half is provided with a hinge **113***a*, **113***b* that permits each half to be folded by the side of the barrel (see **FIG. 77**). The hinge mechanism is such that in normal use the hinge gets pushed within the barrel and can not come out nor can it be unfolded unless pulled out of the barrel. This mechanical arrangement offers ultimate security to the operation of the prefilled syringe.

[**0177**] The mechanical structures of the present invention described herein assure that the retraction mechanism cannot be disabled by the hydraulic pressure generated inside the barrel. Operation of a pre-filled syringe is simple in that everyone removes the protective cap before injection, and plunger lock invariably reminds one to rotate the locking ring to initiate the injection of medicine under aseptic precautions.

[**0178**] FIGS. **55-64** and FIGS. **65-71** illustrate two further embodiments of a retractable needle, single use safety syringe in accordance with the invention. These two additional embodiments differ from the embodiments heretofore described, in that the latch or switch arrangement is entirely internal to the barrel **10** of the syringe. The barrel therefore has no need for and therefore omits the slot or guide track **19** shown in the previous figures of drawing. In this regard, the barrel for use with the embodiment of FIGS. **55-64** is generally cylindrical and circular in cross-section without any breaks in the outer wall, as indicated generally by **FIG. 63**, while the barrel for use with the embodiment of FIGS. **65-70** is of the type shown in **FIG. 68**, with an enlarged wall portion **29** along one side thereof, similar to the barrel shown in **FIGS. 8 and 9** described above, however, without the detent elements **100**, such that the external surface is relatively smooth, having one enlarged diameter segment at the extended or radially outwardly extending wall portion **29**.

[**0179**] Referring initially to FIGS. **55-58**, an alternate embodiment of a two-piece spring retainer element **1302***a*, **1302***b* is illustrated. The elements **1302***a* and **1302***b* become one structure when snapped together. They can also be molded as a single piece with an identical function. The spring retainer element **1302***a* is similar to the spring retainer shown in **FIGS. 20 and 21**, in that it includes a generally semi-cylindrical body portion **812** having connector members **814** which mate with similar or complementary connectors on the second spring retainer element **1302***b*. The spring retainer element **1302***a* also includes an extension **1303** which terminates in a spring support or retaining element **1310** with a through opening for receiving the needle holder axially movable therethrough. An oppositely projecting extension **1312** functions to engage the needle holder within the plunger channel in fixed position in normal operative state. It retracts the needle holder at the point of plunger advance when the ramps deflect the plate radially. This structure eliminates the requirement of a switch for causing retraction and can be used with a conventional barrel.

[**0180**] In this regard, the extension **1312** terminates in a gripping lip or flange **804** which has a right angle **805** (that is, at right angles to the extension plate **1312**) for overlying a complementary flat surface portion **1037** at a top surface of a needle holder element **1014** shown in FIGS. **60-62**, and further described below. The retaining lip **804** also has a leading beveled surface **806** to facilitate initial passage of the enlarged head **1035** of the needle holder **1014** thereby for engagement with the flat top portion **1037** of the top surface of the enlarged head **1035** of the needle holder **1014** (see FIGS. **60-62**).

[**0181**] The extension **1303** has a semi-cylindrical channel **810** for receiving and holding in place the compression spring **300** described above.

[**0182**] The proximal extension plate or wall **1312** has opposing side surfaces **802** located and sized so as to span over the walls **60**, **62** of the channel **33** of the plunger **11**. An upper edge surface of the plate **1312** to either side of the retaining lip **806** has a generally V-shaped, ramped groove **808** which is of complementary form for gaging the upper ramped and V-shaped surfaces of the projections **70** and **72** of the plunger **11**.

[**0183**] Referring briefly to **FIGS. 58 and 59**, the second segment or portion of the spring retainers indicated by

reference numeral **1302***b* and has a semi-cylindrical portion **820** which has mating projections **815** for engaging with the apertures **814** in the portion **1302***a* shown in **FIG. 55** to assemble the two portions of the spring retainer together. In other respects, the spring retainer **1302***b* is substantially identical to the spring retainer element or portion **302***b*. However, the spring retainer portion **1302***b* has an additional axially extending reduced thickness portion **830** which has an elongated window **832** for interfitting with a detent **842** formed in a bottom rib **64***a* of a modified plunger **11***b* (see **FIG. 72**) which includes a ramp **840** which leads into a recess **842**, such that the ramp **840** will pass into and engage the window **832** upon the over-extension or over-advancement of the plunger for retraction of the needle as described above. The reduction in the thickness of extension plate **830** offers a spring-like action for positive engagement of the detent **842** on the rib **64** of the plunger.

[**0184**] Referring briefly to **FIG. 64**, the elements of FIGS. **55-63** are shown in assembled condition. Upon the above-described over-advancement of the plunger **11**, the projections **70** and **72** engage the grooved edges **808** of the extension **1312**, resiliently bending back the top portion of the plate so as to release engagement of the retaining lip **806** from the flat area **1037** on the top **1035** of the needle holder **1014**, thereby allowing the spring **300** to expand and retract the needle holder and needle. As also shown in **FIG. 64**, when this occurs, the detent comprising the ramp **840** and recess **842** engages the window **832** to hold the assembly in a locked condition so as to render it completely locked and nonreusable and prevent retraction of the plunger, as well.

[**0185**] Referring next to FIGS. **65-70**, another embodiment of a spring retainer **2302***a*, needle holder **2014** and barrel **10** for achieving for "instant" retraction entirely internally of the barrel, is shown. This embodiment, as also shown in the assembled view of **FIG. 71**, operates for releasing the needle holder to retract the needle and locking the components, including the plunger, in place in similar fashion to the embodiment of FIGS. **55-64** described above. That is, all of the mechanisms are carried internally of the barrel whereby no channel, slot, track or other opening in the barrel is needed or provided. In order to accommodate the mechanism of this embodiment, however, the barrel has a radially narrow increased diameter portion **29** as shown in **FIG. 68**, and mentioned above.

[**0186**] Referring initially to FIGS. **65-67**, the spring retainer portion **2302***a* interfits with the spring retainer portion **1302***b* as shown in **FIGS. 58 and 59**. In this regard, the window **832** in the spring retainer element **1302***b* interlocks in the same fashion as described above with respect to the detent portion **840**, **842** of the plunger **11***b* of **FIG. 72**, as also illustrated in **FIG. 71**. In this regard, the spring retainer portion **2302***a* includes a semi-cylindrical portion **812** which interfits snugly within the interior wall of the barrel **10** and is retained in place by a raised ring **120** as mentioned hereinabove. An extension **2303** and spring supporting portion **2310** with through aperture for receiving the needle holder are the same as in the above described embodiments. Also, as in the above described embodiments, a small slot or groove **2304** interfits with a mating projection within the barrel to properly index or position the spring holder and prevent rotation thereof with respect to the barrel **10**.

[**0187**] In the embodiment of **FIGS. 65 and 66**, a proximal flexible extension plate **902** similar to the plate **802** is provided and also is of a width to span and slidably engage the two walls or ribs **60**, **62** which form the channel **33** in the plunger **11**. In this regard, the plunger **11***b* of **FIG. 72** is utilized in connection with this spring retainer. In the same fashion as the embodiment of **FIG. 55**, the spring retainer **2302***a* has at an end of the plate or projection **902** a pair of shaped recesses or grooves **908** which are of complementary shape for engaging the upper edge portions of the spring release projections **70** and **72** of the plunger **11***b*.

[**0188**] Finally, in order to releasably retain the needle holder, a through opening or window **905** is defined between flexible plate **902** and a support plate **903**. The flexible plate **902** has an arch **902***a* and is rendered flexible by two slots **s1** and **s2**. The slots separate the plate **902** and offer flexibility so that it can flex radially outwardly in response to a mechanical push of the projections **70** and **72** located on the plunger. With the deflexion of the arch **902***a*, the needle holder locked underneath is released. The support plate **903** is fixed to the spring retainer **2302***a* and extends proximally to form a concave margin to accomodate the needle holder which is locked under the plate **902**.

[**0189**] As best viewed in **FIG. 71**, the opening **905** releasably engages a radially projecting, relatively short arm **2032** of the needle holder **2014** shown in **FIGS. 69 and 70**. This needle holder is substantially similar in all other respects to the needle holders **14** and **1014**, having a recess or slot **2041** formed by an elongate L-shaped extension **2039**. This extension **2039** mounts the lateral arm **2032** at its distal end. The slot or opening **2041** receives and guides one end of the compression spring **300**. The slot **2031** performs the same function as the slot **31** of the needle holder **11** described above, and the parts **2026**, **2030**, **2036** are also substantially the same as the parts **26**, **30** and **36** of the needle holder described hereinabove. The top surface of the enlarged head **2035** of the needle holder **2014** does not require, and is therefore shown without, the flat surface portion **1017** of the embodiment of FIGS. **50**, **60-62**. It will be noted that the enlarged portion **29** of the barrel is aligned, upon assembly and during operation, with the lateral arm **32** of the needle holder, and with the plate **902** of the spring retainer to provide a relief space for the plate to flex back sufficiently to release the radially extending arm **2032** upon overadvancement of the plunger in the manner described hereinabove for release of the needle holder assembly. This results in retraction of the needle and locking of the parts in a retracted and nonreusable condition, including locking the plunger in an advanced position, as described above.

[**0190**] While particular embodiments and applications of the present invention have been illustrated and described, it is to be understood that the invention is not limited to the precise construction and compositions disclosed herein and that various modifications, changes, and variations may be apparent from the foregoing descriptions without departing from the spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. A safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end

of said barrel and opening into the interior of said barrel and an expanded proximal segment;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle;

a needle holder mounting said needle at a distal end thereof and slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which said needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring mounted inside of said barrel, and a spring retainer element located in said expanded proximal segment of said barrel and having a stabilizing surface extending along and about a portion of the internal wall of said barrel, and a spring support portion extending from said stabilizing surface interiorly of said barrel and supporting a distal end portion of said spring against expansion, said spring retainer also having a through opening for freely receiving said needle holder therethrough; said spring urging said needle holder toward its retracted position; and

a latch having an engaged position in which said needle holder is latched relative to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched relative to said barrel to allow said spring to expand in a proximal direction to move said needle holder to its retracted position.

2. The syringe assembly of claim 1 wherein said latch is inseparably mounted to said barrel.

3. The syringe assembly of claim 1 wherein said spring is a helical spring disposed around said needle and said needle holder.

4. The syringe assembly of claim 1 wherein said latch is mounted so as to be activated by advance of said plunger.

5. The syringe assembly of claim 1 wherein said latch is mounted on an external surface of the barrel.

6. The syringe assembly of claim 1 wherein said barrel includes a track slot and wherein said needle holder includes a lateral arm extending laterally from said plunger open channel into said track slot, whereby said needle holder is guided by said track slot as it moves toward its retracted position.

7. The syringe assembly of claim 6 wherein said latch is mounted for movement into and out of registry with a distal end of said track slot for capturing and releasing said lateral arm at the distal end of said track slot.

8. A retractable needle safety syringe assembly, comprising:

a hollow generally cylindrical barrel, with a distal hollow nozzle communicating with the barrel;

a plunger slidably inserted in the barrel, having a polymeric piston at a distal end, and a longitudinal open channel;

a needle holder with a needle mounted at the distal end thereof and slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which said needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring wrapped around said needle holder;

said plunger having linear axial mobility independent of movements of the spring and needle holder;

a spring retainer located in said barrel supporting said compression spring;

a switch engaging the barrel and the needle holder and having two radial projections entering within the barrel cavity;

said plunger advancing the polymeric piston to make a surface contact of a distal conical end of the piston with a conical interior end of the barrel for injecting medicine through the needle by minimal force applied to said plunger;

said plunger being movable with an additional applied force to advance distally within a cavity formed in the piston as well as to compress the piston thereby additionally advancing distally within the barrel, a pair of plates projecting from the plunger engaging and radially displacing said projections of the switch upon said additional advance, so as to displace the switch radially outwardly causing the release and retraction of the needle holder.

9. The assembly of claim 8 having a barrel with proximal wider segment that accommodates a spring retainer.

10. The syringe assembly of claim 8 including a needle protector, and wherein said nozzle of said barrel has a male luer taper on its outer surface that mates with a female luer taper interior of the said needle protector creating a taper lock to form an air and water tight seal between the barrel nozzle and needle protector, whereby air or fluids residing in the sealed barrel prevent advance of the plunger to the distal end of the barrel, avoiding the retraction before the use of the syringe.

11. The syringe assembly of claim 9, wherein the switch mechanism is located outside a fluid chamber defined in said barrel, and advancement of the plunger in a fluid-filled barrel generates a hydraulic pressure gradient that is relieved by the exit of said fluid from the needle such that any increase in the hydraulic pressure in the barrel as a result of an imbalance of generation and relief of the pressures tends to prevent rather than encourage retraction of the needle.

12. The assembly of claim 11 wherein said hydraulic pressure gradient prevents accidental retraction by preventing the contact between the projecting parts on the plunger and on the latch.

13. The assembly of claim 8 wherein the spring and needle holder are located proximal to said polymeric piston mounted to a distal end of said plunger whose movements are responsible for generation of pressure and vacuum in the barrel and which is not affected by pressure gradients within the barrel.

14. The syringe assembly of claim 8 wherein said spring is a coil spring and is sized to fit in said open channel of said plunger.

15. A safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a spring mounted inside said barrel and urging said needle holder toward its retracted position; and

a latch having an engaged position in which said needle holder is latched to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched from said barrel to allow said spring to move said needle holder to its retracted position;

wherein said latch comprises a needle holder locking element non-removably, circumferentially mounted on said barrel for rotary movement between a locking position and non-locking position on the barrel relative to said needle holder.

16. The syringe assembly of claim 15 wherein said barrel has outwardly extending gripping flanges, and one or more detent elements parallel to and axially spaced from said outwardly extending gripping flanges and said needle holder locking element is mounted between said detent elements and said barrel flanges.

17. The syringe assembly of claim 16 wherein said needle holder includes a lateral arm which extends radially through an axial elongate slot through the barrel wall and distal to said flanges, and wherein said latch is located adjacent said flanges to engage a portion of said lateral arm.

18. The syringe assembly of claim 15 and further including a spring retaining member for supporting a distal end portion of the spring inside the barrel.

19. The syringe assembly of claim 17 and further including a retaining member for supporting a distal end portion of the spring inside the barrel, a proximal end of said spring abutting said lateral arm of said needle holder.

20. The syringe assembly of claim 15 wherein said latch has at least one inwardly projecting member extending through a wall of said barrel, and wherein said plunger includes at least one an outwardly projecting part for engaging said projecting member upon advancement of said plunger past a position for fully dispensing medication, for releasing said latch.

21. A retraction control unit for a retractable needle syringe comprising:

a cylindrical spring retainer with a distal axial cantilever extension, inserted coaxially and locked within a barrel of a syringe;

a plunger with a compressibly engaged resilient cap, one or more radial projections and a central channel, and capable of reciprocal linear movements, and inserted within said spring retainer clearing the cantilever;

a needle holder slidably mounted in said central open channel of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

the distal axial cantilever extension of the said spring retainer retaining a compression spring wrapped around said needle holder, such that said needle holder passes distally through an opening in the said axial extension;

a proximal surface of said spring retainer having a stabilizer plate to support the needle holder and a deflectable anchoring plate that releasably holds the needle holder against an expansion force of the spring until it is radially deflected by the projections of said plunger, in response to a force that exceeds a fluid injection force.

22. A needle retraction mechanism for a retractable safety syringe comprising:

support means in the form of a hollow cylindrical tubular segment engageable to the internal surface of a syringe barrel by mechanical or chemical means and having an axially extending cantilever means with an opening on its distal surface for supporting biasing means in the form of a compression spring engaged with a needle holder, and a needle holder anchoring plate having needle holder retaining geometry preventing needle holder means from retracting from the support means and located on a surface of support means opposite of the cantilever means;

needle holder means with a needle at its distal end slidably engaged in the opening of said cantilever means for linear movements between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of the syringe barrel, and a retracted position in which said needle is retracted within said syringe barrel;

plunger means with a compressably engaged elastic cap, and a central channel that clears the cantilever means and the needle holder means in the barrel for reciprocal linear movements to receive and inject medication from the syringe;

said plunger means having radially projecting ramps flanking said central channel and being advanceable to create a first pressure gradient to inject medicine through the needle and a second pressure gradient to compress a plunger-cap junction and the elastic cap so as to cause the plunger ramps to engage and displace the anchoring plate of the support means to disengage and retract the needle holder;

wherein said needle holder means is releasably engaged by said anchoring plate at a distal end of a retraction chamber of the barrel counteracting said compression spring and advancing the needle holder distally to define an operative mode of the syringe; and

wherein said support means are inseparable from the barrel in an operative mode but, when said anchoring plate is displaced, release the needle holder and needle within the barrel.

23. A syringe assembly, comprising:

an elongated, tubular barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger;

a latch for latching and unlatching said needle holder relative to said barrel; and

a spring for retracting said needle holder in response to unlatching of said needle holder by said latch;

wherein said needle holder has a lateral arm which extends radially, wherein said latch releasably engages the lateral arm of said needle holder; and wherein said latch inseparably engages said barrel.

24 The syringe assembly of claim 23 wherein said latch is rotatably mounted on said barrel for rotary movement between a locking position and non-locking position relative to said lateral arm.

25. The syringe assembly of claim 25 wherein said latch has an inwardly projecting member extending through a wall of said barrel, and wherein said plunger includes an outwardly projecting part for engaging said inwardly projecting member upon advancement of said plunger past a position for fully dispensing medication for releasing said latch.

26. The syringe assembly of claim 23 wherein said barrel has a cross section that is generally circular.

27. The syringe assembly of claim 23 wherein the barrel of the said syringe is cylindrical and circular in cross-section.

28. The syringe assembly of claim 25 wherein said plunger includes a portion for releasing engagement of said latch upon advancement of said plunger past a position for fully dispensing medication for releasing said latch.

29. The syringe assembly of claim 25 wherein a track slot is formed in a proximal wall portion of said barrel for receiving said lateral arm therethrough and guiding said lateral arm between a fully advanced position and a fully retracted portion, said latch being positioned for releasably engaging said lateral arm at a distal end of said track slot.

30. The syringe assembly of claim 25 wherein said longitudinal open channel of said plunger includes a detent for engaging and retaining said needle holder when in a fully retracted position.

31. The syringe assembly of claim 30 wherein said needle holder has a recess at a proximal end thereof for engaging said plunger detent.

32. A syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel,

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger;

a latch for latching and unlatching said needle holder relative to said barrel; and

a spring for retracting said needle holder in response to unlatching of said needle holder by said latch;

wherein said needle holder has a lateral arm which extends radially, and wherein said latch releasably engages the lateral arm of said needle holder; wherein said latch is located and configured so as to be activated by said plunger.

33. The syringe assembly of claim 32 wherein said latch has a lateral arm engaging portion for releasably engaging said needle holder lateral arm.

34. The syringe assembly of claim 32 wherein said plunger includes a portion for releasing engagement of said latch upon advancement of said plunger past a position for fully dispensing medication.

35. The syringe assembly of claim 34 wherein longitudinal walls of said plunger which define said longitudinal open channel include projecting release elements for engaging and radially displacing said latch so as to disengage said lateral arm engaging portion from said needle holder lateral arm upon advancement of said plunger past a position for fully dispensing medication.

36. A retractable needle pre-filled safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle at the distal end of said barrel and opening into the interior of said barrel;

an elastic O ring seated adjacent the nozzle;

a plunger with an elastic piston that seals around an interior of the barrel and is slidably mounted in said barrel, said plunger having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from said nozzle and seals against said O ring and a retracted position in which said needle is retracted within said barrel;

a compression spring mounted around said needle holder and retracting the needle holder proximally when expanded and the needle holder projecting distally when the spring is compressed;

wherein a medicine chamber defined in said barrel is proximally sealed with the rubber piston abutting against the needle holder while a needle lumen closed by mechanical means seals the chamber distally.

37. The assembly of claim 36 wherein said nozzle has a male taper on its outer surface; and further including a needle protector with a mating female taper on an interior surface to form an air and water tight seal between the barrel and needle protector.

38. The assembly of claim 36 wherein a medicine chamber defined within said barrel is totally sealed and isolated from a retraction mechanism comprising the needle holder and the compression spring.

39. The assembly of claim 36 wherein the needle protector is filled with a non-coring elastomer.

40. The assembly of claim 36 wherein the nozzle and needle protector are provided with mating luer tapers to securely lock the needle protector to the nozzle.

41. The assembly of claim 36 and further including a latch having an engaged position in which said needle holder is latched relative to said barrel to hold said needle holder in

its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched relative to said barrel to allow said spring to expand in a proximal direction to move said needle holder to its retracted position.

42. The assembly of claim 36 wherein said latch is inseparably mounted to said barrel.

43. The assembly of claim 36 wherein a portion of the plunger of the prefilled syringe that projects proximally from the barrel is split and folded along side of the barrel to reduce the volume of the prefilled syringe, and can be unfolded for injection of the medicine from the prefilled syringe.

44. The assembly of claim 43 wherein the split and folded plunger is incapable of spontaneous movements so as to preserve the integrity of the volume of medicine in the barrel.

45. A retractable needle safety syringe assembly, comprising:

a hollow generally cylindrical barrel, with a wider proximal segment and a distal hollow nozzle communicating with the barrel;

a needle holder holding a hollow hypodermic needle mounted at a distal end and a side aperture in said needle holder communicating with the needle;

a compression spring wrapped around the needle holder biasing said needle in a direction for retracting the needle;

a spring retainer located in the wider segment of the said barrel and supporting said compression spring;

a plunger slidably inserted in the barrel, and having an elastomeric piston at a distal end and a central cavity enclosing the needle holder and needle, the plunger having linear axial mobility in barrel independently of said spring and needle holder; and

a ring-like switch encircling the barrel and rotatably locked onto the barrel surface, and engaging with said needle holder to releasably compress the spring, said switch being inseparable from said syringe at least until release of said needle holder by said switch for retraction of the needle within the syringe assembly.

46. The assembly of claim 45 wherein the switch is coaxial with the barrel.

47. A retractable needle safety syringe assembly, comprising:

a hollow generally cylindrical barrel, with a wider proximal segment and a distal hollow nozzle communicating with said barrel;

a needle holder holding a hollow hypodermic needle mounted at a distal end of the needle holder and a side aperture in said needle holder communicating with the needle;

a compression spring wrapped around the needle holder for biasing said needle in a direction for retracting the needle;

a spring retainer located in the wider segment of said barrel and supporting said compression spring;

a plunger slidably inserted in the barrel, and having an elastomeric piston at a distal end and a central open channel enclosing the needle holder and needle, the plunger having linear axial mobility in barrel, that is independent of said spring and needle holder;

a latch having an engaged position in which said needle holder is latched relative to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched relative to said barrel to allow said spring to expand in a proximal direction to move said needle holder to its retracted position;

said latch comprising a semicircular element engaged on the barrel, and having two radial projections entering with the barrel cavity and engageable by said plunger for releasing said switch upon over-advancement of said plunger;

wherein said barrel includes a track slot and wherein said needle holder includes a lateral arm extending laterally from said plunger open channel into said track slot, whereby said needle holder is guided by said track slot as it moves toward its retracted position;

and wherein a distal margin of the switch engages the needle holder arm to compress the spring and thereby retain the needle extended out through the nozzle, and wherein the switch is inseparable from said syringe assembly until the switch is released to retract the needle within the syringe assembly.

48. The assembly of claim 47 wherein the switch is coaxial to the barrel.

49. The assembly of claim 47 wherein said track slot is located in a proximal part of barrel to engage the needle holder arm for proximal linear retraction.

50. The assembly of claim 47 wherein the track slot in the barrel wall is covered and closed.

51. The assembly of claim 47 wherein the barrel has outwardly extending gripping flanges, and the switch has two vertical diametric extensions that engage and project through respective slots on the flanges of the barrel and permit radial movement of the switch to release the needle holder arm.

52. The assembly of claim 47 wherein the needle holder arm is released by an outward radial displacement of the switch in response to linearly advancing the plunger within the barrel.

53. The assembly of claim 47 wherein said plunger has a pair of elongate, parallel radially extending walls which define said central open channel for receiving and positioning said needle holder and said compression spring, and wherein each of said walls includes a projection positioned for engagement with said switch projection upon over-advancement of said plunger.

54. A retractable needle safety syringe assembly, comprising:

a hollow generally cylindrical barrel having an increased diameter proximal segment and a distal hollow nozzle communicating with the said barrel;

a hollow needle;

a plunger slidably arrested in the barrel and having a longitudinal open channel;

a needle holder mounting said needle at a distal end thereof and slidably mounted in said longitudinal open

channel of said plunger for movement between an advanced position in which said needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring;

a spring retainer located in said increased diameter proximal segment of said barrel and supporting said compression spring around said needle holder, said needle holder having a lateral port communicating with the hollow needle;

wherein said barrel includes a track slot and wherein said needle holder includes a lateral arm extending laterally from said plunger open channel into said track slot, whereby said needle holder is guided by said track slot as it moves toward its retracted position;

an elastomeric piston at a distal end of the plunger;

a ring switch encircling the barrel and rotatably locked onto the barrel, distal to a pair of flanges and proximal to a pair of detents on the barrel surface, engaging with the arm of the said needle holder to compress the spring to bias the needle out through the nozzle, and inseparable from the syringe until the needle is retracted within the syringe assembly by release of the needle holder;

the nozzle of the syringe having a male taper on its outer surface; and

a needle protector with a complementary female taper on a mating surface to form an air and water tight seal between the barrel nozzle and needle protector, whereby pneumatic and hydraulic forces caused by sealed fluids in the barrel prevent advance of plunger and inadvertent retraction of the said needle.

55. The assembly of claim 54 wherein the barrel has a wider wall proximal segment defining said track slot.

56. The assembly of claim 54 wherein said slot is in a proximal part of barrel to engage the needle holder arm for proximal linear retraction.

57. The assembly of claim 54 wherein the slot in the barrel wall is covered and closed.

58. The assembly of claim 54 wherein the plunger has linear axial mobility independent of movements of the spring and needle holder.

59. A retractable needle safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle;

a needle holder mounting said needle at a distal end thereof, and releasably coupled to the said barrel for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted with said barrel;

a compression spring mounted around the needle holder biasing the needle holder in a direction for retracting the needle proximally when expanded;

said nozzle having a male taper on its outer surface with a needle protector with a mating female taper to form an air and water tight seal between the barrel and needle protector;

whereby fluids residing in the barrel preventing advance of the plunger to the distal end of the barrel and avoiding the retraction before the use of the syringe.

60. A retractable needle safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder receiving said needle at its distal end and slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which said needle projects form a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

wherein said barrel includes a track slot and wherein said needle holder includes a lateral arm extending laterally from said plunger open channel into said track slot, whereby said needle holder is guided by said track slot as it moves toward its retracted position;

a rotatable ring switch that encircles said barrel and engages with the needle holder arm projecting from the barrel wall;

a compression spring mounted around the needle holder and assembled to the barrel and biasing the needle holder for retracting the needle proximally when expanded;

the nozzle having a male taper on its outer surface, and a needle protector with a mating female taper to form an air and water tight seal between the barrel and needle protector;

whereby the retractable needle syringe assembly is sealed at the nozzle by the needle protector, such that in an operative state the syringe contains a quantum of air to prevent accidental advance of the plunger and to avoid premature retraction of the needle and disablement of the syringe.

61. A retractable needle safety syringe assembly, comprising:

a hollow generally cylindrical barrel, with a distal hollow nozzle communicating with the barrel;

a plunger slidably inserted in the barrel, having a polymeric piston at the distal end, and a longitudinal open channel;

a needle;

a needle holder mounting said needle at a distal end thereof and slidably mounted in said longitudinal open channel of said plunger for movement between an

advanced position in which said needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring wrapped around the said needle holder;

a spring retainer located in the said barrel supporting said compression spring;

said plunger having linear axial mobility independent of movements of the spring and needle holder.

a switch engaged on the barrel and having two radial projections entering within the barrel cavity;

said plunger advancing the polymeric piston to make a surface contact of a piston distal conical end with a conical interior end of barrel for injecting medicine through the needle by minimal force applied to said plunger;

said plunger being movable with an additional applied force to advance distally within a cavity formed in the rubber piston cavity and so as compress the elastic rubber piston thereby additionally advancing distally within the barrel; and

a pair of plates projecting from the plunger engaging and radially displacing said projections of the switch upon said additional advance, so as to displace the switch radially outwardly causing the release and retraction of the needle holder.

62. The assembly of claim 61 having a barrel with proximal wider segment that accommodates a spring retainer.

63. A retractable needle safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle;

a needle holder slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which said needle, held on the distal end of said needle holder, projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring mounted around the needle holder and assembled to the barrel, and biasing the needle holder in a direction for retracting the needle proximally when expanded;

said needle having an open proximal end mounted in and sealed by adhesives to a distal dead end of the needle holder such that the open proximal end of the needle is not exposed to air in the barrel;

an entry and exit hole for medication located in a lateral wall of the needle holder and in communication with said needle, that is a boundary zone of zero velocity and is only affected by a pressure gradient in the barrel and not by retraction of the needle;

said needle holder having a larger cross-section at its proximal portion which adds significant mass to dampen the retraction velocity of the needle holder, and wherein the expansion spring is always in contact with the needle holder to provide minimum recoil to needle and its contents.

64. A retractable needle safety syringe comprising:

an elongated, generally cylindrical body forming an aperture at the distal end of said cylindrical body and opening into the interior of said cylindrical body;

a needle holder carrying a hollow hypodermic needle projecting from said holder along the axis of said cylindrical body, said needle holder being mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body;

a releasable latch for releasably locking said cylindrical body and said needle holder to each other;

biasing means within said cylindrical body for biasing said needle holder toward said retracted position;

a plunger carrying said needle holder and mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body, said plunger being movable to a first advanced position in response to an applied manual force of a first magnitude, and to a second advanced position in response to an applied manual force of a second, greater magnitude; and

means for releasing said latch in response to movement of said plunger to said second advanced position, so that said needle holder is retracted by said biasing means upon movement of said plunger to said second advanced position.

65. The syringe of claim 64 which includes a resilient, compressible piston on the distal end portion of said plunger.

66. The syringe of claim 65 wherein an interface between said piston and said end portion of said plunger is formed to permit said plunger to advance further by compressing said piston after said piston has bottomed out on a distal end of the interior of said cylindrical body.

67. The syringe of claim 64 wherein said piston includes a substantially flat surface on a proximal end thereof, and said plunger includes a substantially flat annular flange engaging said substantially flat surface on said piston.

68. A retractable needle safety syringe comprising:

an elongated, generally cylindrical body forming an aperture at the distal end of said cylindrical body and opening into the interior of said cylindrical body;

a needle holder carrying a hollow hypodermic needle projecting from said holder along the axis of said cylindrical body, said needle holder being mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body;

a plunger carrying said needle holder and mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body;

biasing means within said cylindrical body for biasing said needle holder toward said retracted position; and

a releasable latch for releasably locking said cylindrical body and said needle holder to each other, said latch having a latch body that extends at least partially around the circumference of said cylindrical body and is attached to said cylindrical body, said latch being movable between an engaged position in which said needle holder is latched in its advanced position against he urging of said biasing means, and a disengaged position in which said needle holder is unlatched to allow said biasing means to move said needle holder to its retracted position.

69. A retractable needle safety syringe pre-filled with a liquid to be administered to a patient, said syringe comprising:

an elongated, generally cylindrical barrel of biocompatible thermoplastic forming a medicine chamber traversed by an axial biocompatible needle holder with a hypodermic needle attached to its distal end, and retained in the chamber by a reversible interlock of said barrel with said needle holder;

said needle holder being mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical barrel;

a releasable latch for releasably locking said cylindrical barrel and said needle holder to each other;

a compression spring within said cylindrical barrel for biasing said needle holder toward said retracted position;

a plunger carrying said needle holder and mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical barrel, the distal end of said plunger including a resilient piston which seals against an internal wall of the barrel;

wherein said needle holder is sealed by an "O" ring at a distal nozzle formed on said barrel, while the needle is also mechanically closed by a luer locked needle protector at the nozzle,

wherein proximally, the barrel including the needle holder is sealed by the resilient piston;

the plunger having a channel that permits an advance of the plunger for injection of medicine as well as retraction of the needle holder and the needle within the barrel when the medicine has been injected, and the latch has been released;

wherein the integrity of needle holder location and the retraction and locking of the needle holder in the barrel is achieved by the compression spring installed on a spring retainer and engaged with the needle holder; and

wherein sealing of the medicine chamber prior to injection of the medicine is additionally supported by the spring retainer.

70. A retractable needle safety saline filled syringe assembly for intravenous catheter placement, comprising:

an over-the-needle catheter comprising a flexible polymeric tubular catheter having a mounting connector with a female luer taper;

a hollow generally cylindrical barrel and a distal hollow nozzle communicating with said barrel, and having male luer taper on its outer surface that engages with said female luer taper of the over-the-needle catheter to thereby mount the catheter on the nozzle;

a hypodermic needle mounted to a needle holder;

said catheter being coaxially installable over the hypodermic needle emerging out through the nozzle and extending beyond the tip of said catheter;

a compression spring wrapped around the needle holder and urging said needle holder toward its retracted position;

a spring retainer element having a spring support portion extending interiorly in the center of the barrel and supporting a distal end portion of the compression spring encircling the hypodermic needle, while permitting the passage of the said hypodermic needle through the compressed spring and an opening in said support portion, through the nozzle and within said over-the-needle catheter;

a plunger slidably inserted in the barrel, having a resilient piston at its distal end, and a central cavity receiving said spring support, the spring and the needle holder;

said needle holder having a side arm at its proximal end which compresses the spring inside the spring retainer so as to cause said needle to project distally through the nozzle of the syringe and which is releasably attached to the barrel via a switch;

whereby in normal operative mode the saline filled syringe is used puncture the skin and a vein by the needle point to gain entry of the needle and the catheter into a vein, the hypodermic needle is retracted and the catheter remains on the nozzle for further advance and maintenance of fluid communication with said syringe for monitoring the location of the catheter and infusing fluids into the vein; and the hypodermic needle is retracted, while the flexible catheter is retained on the nozzle for non-traumatic manipulation and placement, and for monitoring the location of the catheter and fluid continuity through said catheter before connecting to intravenous fluid lines.

71. The assembly of claim 70 wherein the barrel has a wider proximal segment.

72. The assembly of claim 70 wherein a puncturing bevel point of said needle is exposed beyond the catheter while its female luer end is anchored onto the nozzle of the said barrel.

73. A retractable needle, single use syringe comprising:

a hollow generally cylindrical barrel, with a wider proximal segment and a distal hollow nozzle communicating with an interior of said barrel;

a needle;

a needle holder mounting said needle at a distal end thereof and slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which said needle projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring mounted inside said barrel and urging said needle holder toward its retracted position; and

a plunger slidably inserted in the barrel said plunger, having an elastomeric piston at a distal end, said plunger having linear axial mobility independent of movements of the needle holder and spring;

a switch mounted to said barrel and having an engaged position in which said needle holder is latched relative to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched relative to said barrel to allow said spring to expand in a proximal direction to move said needle holder to its retracted position to disable the syringe and prevent reuse of the syringe;

axially spaced flanges and detents on said barrel;

wherein the switch encircles the barrel and is locked onto the barrel, distal to the flanges and proximal to the detents on the barrel surface; said switch engaging with said needle holder to compress the spring and being inseparable from said barrel until the needle holder is released by the switch and the needle is retracted within the syringe.

74. The single use syringe of claim 73 wherein the expanded length of the spring exceeds the length of the needle, whereby the syringe is non-reusable once the needle holder is released and the needle is retracted within the syringe.

75. The single use syringe of claim 73 wherein the needle holder has a recess engageable with a detent located on a proximal portion of the plunger for locking the needle holder in its retracted position, whereby the syringe is non-reusable.

76. The single use syringe of claim 73 wherein the needle holder once retracted is non-removably locked with a margin of the proximal end of the barrel, whereby the syringe is non-reusable.

77. The single use syringe of claim 73 and further including a spring retainer for supporting a distal end portion of the spring inside the barrel wherein the spring retainer is locked within the wider proximal segment of the barrel between a shoulder formed thereby at a distal, narrower portion of the barrel and an internal elevated ring within the wider portion of the barrel, whereby the syringe is non reusable.

78. The single use syringe of claim 77 wherein the spring is locked between the spring retainer and the needle holder and cannot be taken out or recompressed, once expanded, whereby the syringe is non-reusable.

79. The single use syringe of claim 73 and further including a spring retainer element having a spring support portion extending interiorly of said barrel and supporting a distal end portion of said spring against expansion, said spring retainer also having a through opening for freely receiving said needle holder therethrough; and wherein upon retraction the spring retainer also engages a detent on the plunger and locks the plunger to the spring retainer, whereby the syringe is non reusable.

80. The single use syringe of claim 73 wherein the barrel circumference is rendered non deformable by projecting ribs on the plunger, whereby the needle holder cannot be removed and the syringe is non reusable.

81. The single use syringe of claim 73 wherein said barrel has outwardly extending gripping flanges, and one or more detent elements parallel to and axially spaced from said outwardly extending gripping flanges, and said switch is mounted between said detent elements and said barrel flanges.

82. The single use syringe of claim 73 wherein, upon retraction of the needle, every component of the syringe is directly or indirectly locked with every other component of the syringe, such that the entire assembly is interlocked whereby the syringe is non-reusable.

83. The single use syringe of claim 73 wherein said barrel has outwardly extending gripping flanges, and one or more detent elements parallel to and axially spaced from said outwardly extending gripping flanges, and said needle holder locking element is mounted between said detent elements and said barrel flanges; wherein said latch has an inwardly projecting member extending through a wall of said barrel, and wherein said plunger includes an outwardly projecting part for engaging said inwardly projecting member upon advancement of said plunger past a position for fully dispensing medication for releasing said latch.

84. A retractable needle safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle and is sealed with an "O" ring, and a retracted position in which said needle is retracted within said barrel;

a compression spring mounted around the needle holder and retracting needle proximally when expanded, and a latch which at least partly encircles the barrel and releasably engages with the needle holder to hold the spring in a compressed condition;

wherein said latch has an inwardly projecting member extending through a wall of said barrel, and wherein said plunger includes an outwardly projecting part for engaging said projecting member and disengaging said latch from said needle holder, upon advancement of said plunger past a position for fully dispensing medication for releasing said latch;

wherein advancement of the plunger in a fluid-filled barrel generates a hydraulic pressure gradient that is relieved by the exit of said fluid from the needle such that any increase in the hydraulic pressure in barrel as a result of an imbalance of generation and relief of the pressures tends to prevent rather than encourage retraction of the needle.

85. The assembly of claim 84 wherein said hydraulic pressure gradient prevents accidental retraction by preventing the contact between the projecting parts on the plunger and on the latch.

86. The assembly of claim 84 wherein the spring and needle holder are located proximal to a polymeric piston mounted to a distal end of said plunger whose movements are responsible for generation of pressure and vacuum in the barrel and which is not affected by pressure gradients within the barrel.

87. A syringe comprising:

an elongated, generally cylindrical body forming an aperture at the distal end of said cylindrical body and opening into the interior of said cylindrical body;

a needle holder carrying a hollow hypodermic needle projecting from said holder along the axis of said cylindrical body, said needle holder being mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body;

a releasable latch for releasably locking said cylindrical body and said needle holder to each other;

biasing means within said cylindrical body for biasing said needle holder toward said retracted position;

a plunger carrying said needle holder and mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body, said **30** plunger being movable to a first advanced position in response to an applied manual force of a first magnitude, and to a second advanced position in response to an applied manual force of a second, greater magnitude; and

means for releasing said latch in response to movement of said plunger to said second advanced position, so that said needle holder is retracted by said biasing means upon movement of said plunger to said second advanced position, wherein said latch is located inside of said barrel.

88. A safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel, said plunger being movable to a first advanced position in response to an applied manual force of a first magnitude, and to a second advanced position in response to an applied manual force of a second, greater magnitude;

a needle;

a needle holder mounting said needle at a distal end thereof and slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which said needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a compression spring mounted inside of said barrel, and a spring retainer having a spring support portion extending interiorly of said barrel and supporting a distal end portion of said spring against expansion, said spring retainer also having a through opening for freely receiving said needle holder therethrough; said spring urging said needle holder toward its retracted position; and

a latch having an engaged position in which said needle holder is latched relative to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched relative to said barrel to allow said spring to expand in a proximal direction to move said needle holder to its retracted position, wherein said latch is an integral part of said spring retainer.

89. The syringe assembly of claim 88 wherein said latch is located in said hollow interior of said barrel.

90. The syringe assembly of claim 88 wherein said latch is mounted so as to be activated by said plunger.

91. The syringe assembly of claim 88 wherein the plunger has a projection that irreversibly engages with the spring retainer when the plunger is in the second advanced position, whereby the syringe is non-reusable.

92. A safety syringe assembly comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a spring mounted inside and barrel and urging said needle holder toward its retracted position; and

a latch having an engaged position in which said needle holder is latched to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched from said barrel to allow said spring to move said needle holder to its retracted position; wherein said latch is inseparably mounted to said barrel, in said hollow interior of said barrel.

93. The syringe assembly of claim 91 wherein said latch is mounted so as to be activated by said plunger.

94. The syringe assembly of claim 88 including a spring retainer element mounted interiorly of said barrel and supporting a distal end portion of said spring against expansion, and wherein said latch is an integral part of said spring retainer.

95. The syringe assembly of claim 94 wherein the plunger has a projection that irreversibly engages with the spring retainer when the plunger is in the second advanced position, whereby the syringe is non-reusable.

96. A safety syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger for movement between an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle, and a retracted position in which said needle is retracted within said barrel;

a spring mounted inside said barrel and urging said needle holder toward its retracted position; and

a latch having an engaged position in which said needle holder is latched to said barrel to hold said needle holder in its advanced position against the urging of said spring, and a disengaged position in which said needle holder is unlatched from said barrel to allow said spring to move said needle holder to its retracted position;

wherein said latch comprises a needle holder locking element non-removably mounted to said barrel, in said hollow interior, and movable between a locking position and non-locking position relative to said needle holder.

97. The syringe assembly of claim 96 wherein said latch is mounted so as to be activated by said plunger.

98. The syringe assembly of claim 96 including a spring retainer element mounted interiorly of said barrel and supporting a distal end portion of said spring against expansion, and wherein said needle holder locking element is an integral part of said spring retainer.

99. A syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle slidably mounted in said longitudinal open channel of said plunger and having a radially projecting arm;

a latch for latching and unlatching said needle holder relative to said barrel; said latch engaging said radially projecting arm on said needle holder by which the needle holder engaged with the barrel, thereby releasably latching said needle holder relative to said barrel; and

a compression spring located in said barrel in surrounding relation to said needle holder and having a distal end held against expansion so as to expand in a proximal direction for retracting said needle holder in response to unlatching said needle holder by said latch; wherein said latch and said needle holder are at all times located in said hollow interior of said barrel.

100. The syringe assembly of claim 99 wherein said latch is mounted so as to be activated by said plunger.

101. The syringe assembly of claim 99 including a spring retainer element mounted interiorly of said barrel and supporting a distal end portion of said spring against expansion, and wherein said latch is an integral part of said spring retainer.

102. A syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger;

a latch for latching and unlatching said needle holder relative to said barrel; and

a spring for retracting said needle holder in response to unlatching said needle holder by said latch;

wherein said needle holder has a lateral arm which extends radially, and wherein said latch releasably engages the lateral arm of said needle holder; wherein said latch and said lateral arm of said needle holder are at all times located in said hollow interior of said barrel.

103. The syringe assembly of claim 102 including a spring retainer element mounted interiorly of said barrel and supporting a distal end portion of said spring against expansion, and wherein said needle holder locking element is an integral part of said spring retainer.

104. The syringe assembly of claim 102 wherein said latch is mounted so as to be activated by said plunger.

105. A syringe assembly, comprising:

an elongated, generally cylindrical barrel having a hollow interior forming a hollow nozzle located at a distal end of said barrel and opening into the interior of said barrel;

a plunger slidably mounted in said barrel and having a longitudinal open channel;

a needle holder slidably mounted in said longitudinal open channel of said plunger;

a latch for latching and unlatching said needle holder relative to said barrel; and

a spring for retracting said needle holder in response to unlatching said needle holder by said latch;

wherein said latch releasably engages said needle holder, wherein said latch is mounted so as to be activated by said plunger, and wherein said latch and said needle holder are at all times located in said hollow interior of said barrel.

106. The syringe assembly of claim 105 wherein said plunger being movable to a first advanced position in response to an applied manual force of a first magnitude, and to a second advanced position in response to an applied manual force of a second, greater magnitude, and means for releasing said latch in response to movement of said plunger to said second advanced position, so that said needle holder is retracted by said spring upon movement of said plunger to said second advanced position.

107. The syringe assembly of claim 105 including a spring retainer element mounted interiorly of said barrel and supporting a distal end portion of said spring against expansion, and wherein said latch is an integral part of said spring retainer element.

108. A syringe comprising:

an elongated, generally cylindrical body forming an aperture at the distal end of said cylindrical body and opening into the interior of said cylindrical body;

a needle holder carrying a hollow hypodermic needle projecting from said holder along the axis of said cylindrical body, said needle holder being mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body;

a releasable latch for releasably locking said cylindrical body and said needle holder to each other;

biasing means within said cylindrical body for biasing said needle holder toward said retracted position;

a plunger carrying said needle holder and mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body, said plunger being movable to a first advanced position in response to an applied manual force of a first magnitude, and to a second advanced position in response to an applied manual force of a second, greater magnitude; and

means for releasing said latch in response to movement of said plunger to said second advanced position, so that said needle holder is retracted by said biasing means upon movement of said plunger to said second advanced position, and means for locking said plunger in said second advanced position.

109. The syringe of claim 108 and further including a spring retainer element mounted interiorly of said barrel and supporting a distal end portion of said spring against expansion, and wherein said locking means includes cooperating elements located on said spring retainer element and on said plunger.

110. A syringe comprising:

an elongated, generally cylindrical body forming an aperture at the distal end of said cylindrical body and opening into the interior of said cylindrical body;

a needle holder carrying a hollow hypodermic needle projecting from said holder along the axis of said cylindrical body, said needle holder being mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body;

a releasable latch for releasably locking said cylindrical body and said needle holder to each other;

biasing means within said cylindrical body for biasing said needle holder toward said retracted position;

a plunger carrying said needle holder and mounted for longitudinal movement between retracted and advanced positions within said elongated cylindrical body, said plunger being movable to a first advanced position in response to an applied manual force of a first magnitude, and to a second advanced position in response to an applied manual force of a second, greater magnitude; and

means for releasing said latch in response to movement of said plunger to said second advanced position, so that said needle holder is released by said biasing means upon movement of said plunger to said second advanced position, the nozzle of the syringe having a male taper on its outer surface and a needle protector with a complementary female taper on a mating surface to form an air and water tight seal between the barrel nozzle and needle protector, whereby pneumatic and hydraulic forces caused by sealed fluids in the barrel prevent advance of plunger and inadvertent retraction of the said needle.

111. A method of administering a medication, using a retractable needle, single use syringe, said method comprising:

applying a manual force of a first magnitude in order to move a plunger of the syringe to a first advanced position for dispensing medication;

applying a manual force of a second greater magnitude in order to move said plunger to a second advanced position for releasing a latch, so that a needle holder is released and retracted thereby permanently retracting a needle within a body of the syringe.

112. A method of administering a medication using a retractable needle, single use syringe, said method comprising:

manually moving a plunger to a first advanced position in response to an applied manual force of a first magnitude for dispensing said medication; and

manually moving said plunger to a second advanced position in response to an applied manual force of a second greater magnitude for releasing a latch so that a needle holder is released and a needle is retracted within a body of said syringe.

113. A method of intravenous catheter placement using a retractable needle safety syringe assembly, said method comprising:

installing a flexible polymeric tubular catheter on a syringe coaxially with a nozzle of the syringe and with a hypodermic needle projecting out through the nozzle and catheter;

puncturing of the skin and vein by a needle point to gain entry of the needle and the catheter in a vein;

retracting said needle while said catheter remains on the nozzle for further advance; and

maintaining fluid communication through said catheter and said syringe for monitoring the location and infusing fluids in the vein; wherein said retracting includes manually moving said plunger to an over-advanced position in response to an applied manual force of a predetermined magnitude for releasing a latch so that a needle holder is released and the needle is retracted.

114. A method of dispensing a medication needle using a retractable single use syringe, said method comprising:

manually moving a plunger to an advanced position for dispensing said medication, and retracting a needle of said syringe;

said retracting including rotating a latch, that extends around at least a part of the circumference of a cylindrical syringe body, and is attached to said cylindrical body from an engaged position in which a needle

holder is latched in an advanced position with said needle extending from said syringe and a disengaged position in which said needle holder is unlatched to allow a biasing means to move said needle holder to a retracted position wherein said needle is retracted within a body of said syringe.

115. The method of claim 114 wherein manually moving the plunger comprises using a thumb for advancing the plunger to complete the injection of medicine and wherein said rotating comprises using said thumb to rotate said latch for retraction of the needle.

116. The method of claim 111 wherein the same hand achieves the injection of medicine and retraction of the needle.

117. The method of claim 112 wherein the same hand achieves the injection of medicine and retraction of the needle.

118. The method of claim 113 wherein the same hand achieves the placement of the catheter and retraction of the needle.

119. The method of claim 114 wherein the same hand achieves the placement of the catheter and retraction of the needle.

120. A method of intravenous catheter placement using a retractable needle safety syringe assembly, said method comprising:

installing a flexible polymeric tubular catheter on a syringe coaxially with a nozzle of the syringe and with a hypodermic needle projecting out through the nozzle and catheter;

puncturing of the skin and vein by a needle point to gain entry of the needle and the catheter in a vein;

retracting said needle while said catheter remains on the nozzle for further advance; and

maintaining fluid communication through said catheter and said syringe for monitoring the location and infusing fluids in the vein; wherein said retracting includes rotating a latch, that extends around at least a part of the circumference of a cylindrical syringe body and is attached to said cylindrical body, from an engaged position in which a needle holder is latched in an advanced position with said needle extending from said syringe and a disengaged position in which said needle holder is unlatched to allow a biasing means to move said needle holder to a retracted position wherein said needle is retracted within a body of said syringe.

121. The method of claim 120 wherein the same hand achieves the placement of the catheter and retraction of the needle.

122. A retractable needle safety syringe assembly, comprising:

a hollow generally cylindrical barrel, with a wider proximal segment and a distal hollow nozzle communicating with the barrel;

a needle holder having a hypodermic needle mounted at a distal end thereof;

a compression spring wrapped around the needle holder;

a plunger slidably inserted in the barrel, and having an elastomeric piston at a distal end and a central channel enclosing the spring wrapped needle holder and needle, and having linear axial mobility in barrel independently of said spring and said needle holder;

a tubular spring retainer having a distal extension for supporting said compression spring wrapped around the needle holder and biasing said needle in a direction for retracting the needle within the barrel, and a proximal extension plate having a projection that positively engages with the needle holder in the central channel of the plunger to maintain it in an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said nozzle;

the wider barrel segment forming a distal support shelf for supporting the spring retainer and an elevated internal ring within the proximal segment of said barrel for proximally stabilizing the spring retainer;

said plunger advancing the piston to make a surface contact of a piston distal conical end with a conical interior end of barrel for injecting medicine through the needle by minimal force applied to said plunger;

said plunger being movable with an additional applied force to advance distally within a cavity formed in the rubber piston cavity and so as compress the elastic rubber piston thereby additionally advancing distally within the barrel, whereby a pair of plates projecting from the plunger disengage the proximal plate projecting over the needle holder causing the release and retraction of the needle holder.

123. A retraction control module for retractable needle safety syringe, said module comprising:

a hollow cylindrical tube with a distal axial extension forming a central cantilever with a central through opening, and a proximal eccentric anchoring plate forming an engagement geometry to engage and anchor a needle holder to the module;

said needle holder having an advanced position in which a needle on the distal end of said needle holder projects from a distal end of said syringe, and a retracted position in which said needle is retracted within said syringe;

a helical compressed spring encircling the needle holder and supported by said axial extension and the central cantilever with the needle holder and an attached needle passing through the central through opening of said cantilever, and within the tube;

a plunger compressibly engaged with a resilient cap passing through said cylindrical tube and having two parallel walls defining a central open channel that contact with the eccentric anchoring plate without deflecting said anchoring plate;

said plunger having a distally advanced position and ramps on said parallel walls which deflect the anchoring plate radially to disengage the needle holder and cause retraction of the needle when the plunger is advanced to said distally advanced position;

said needle holder being slidably mounted in said central open channel of said plunger;

said anchoring plate with extension arising from the opposite surface of the hollow cylinder from said distal

axial estension and engaging with a proximal part of the needle holder preventing the expansion of said spring.

124. The retraction control module of claim 123 wherein two halves snap together to complete cylindrical tube.

125. The retraction control module of claim 123 which, when engaged to a syringe barrel, converts a conventional syringe into a retractable needle safety syringe.

126. The retraction control module of claim 123 wherein the cylindrical body is engaged to the barrel mechanically, chemically bonded or by physical means such as ultrasonic.

127. The retraction control module of claim 123 wheein when the anchoring plate is engaged with the needle holder, it urges the said needle holder distally exterior through the nozzle for normal use while when disengaged the expanded spring of the module urges the needle and the needle holder inside the barrel.

128. The retraction control module of claim 123 wherein said cylindrical tube has, on a proximal diameter opposite the anchoring plate, an extension plate that stabilizes the walls of the plunger inside the retraction control module.

129. The retraction control module of claim 128 wherein the extension plate has a detent that locks with a mating plunger detent on a posterior plunger flange, so as to engage and interlock the syringe.

130. The retraction control module of claim 123 wherein hydraulic forces in the syringe do not affect the retraction control module because it is outside a fluid chamber defined in the syringe.

131. The retraction control module of claim 123 where in the location of the retraction control module determines the volume of the medication taken in and injected and the length of the needle to be retracted.

132. A retraction control module for a retractable needle syringe, said module comprising:

a tubular module defining a cross-sectional geometry of a closed plane that fits within the barrel of a syringe by one of a mechanical fit, a chemical bond and an ultrasonic bond at a desired axial location;

said retraction control module having a central cantilever with a central opening arising from inside and at a distal surface thereof;

wherein said cantilever supports a compression spring wrapped around a part of a needle holder and locked between the cantilever and a proximal lateral part of the needle holder;

a plunger with a compressibly engaged elastic cap and a central channel;

a proximal surface of the tubular module having an anchoring plate juxtaposed to the plunger channel and having at one end a right angled bend towards the center to releasably engage a needle holder against the extensile force of a spring, so as to urge a needle out of the nozzle for a normal operative mode of the syringe;

said needle holder passing through the opening in the cantilever and having an axial linear mobility unless restricted by its engagement with the anchor plate of the said retraction control module or a detent in a proximal end of the plunger;

said plunger having linear axial movements within the retraction control module, **15** and having triangular projections on flanges which define the central channel which just contact the anchoring plate to inject the contents of the barrel, and wherein, in response to the plunger when forced further, said projections displace the anchoring plate so as to release the needle holder and needle.

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