(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 September 2002 (19.09.2002)

PCT

(10) International Publication Number
WO 02/072171 A2

(51) International Patent Classification[7]: A61M

(21) International Application Number: PCT/US02/07712

(22) International Filing Date: 13 March 2002 (13.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/275,568 13 March 2001 (13.03.2001) US

(71) Applicant *(for all designated States except US)*: **MDC INVESTMENT HOLDINGS INC.** [US/US]; Suite 200, 900 Market Street, Wilmington, DE 19801 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BARKER, John** [US/US]; 155 Sunset View Court, Ventura, CA 93003 (US). **HALSETH, Thor** [US/US]; 159 Stonebrook Street, Simi Valley, CA 93065 (US). **CHALLIOL, Bernardo** [US/US]; 3031 Luna Drive, Ventura, CA 93003 (US). **MCWETHY, Robert** [US/US]; 1543 Daffodil Avenue, Ventura, CA 93004 (US). **KOVALSKI, Joseph** [US/US]; 1296 Martha's Vineyard Court, Ventura, CA 93001 (US).

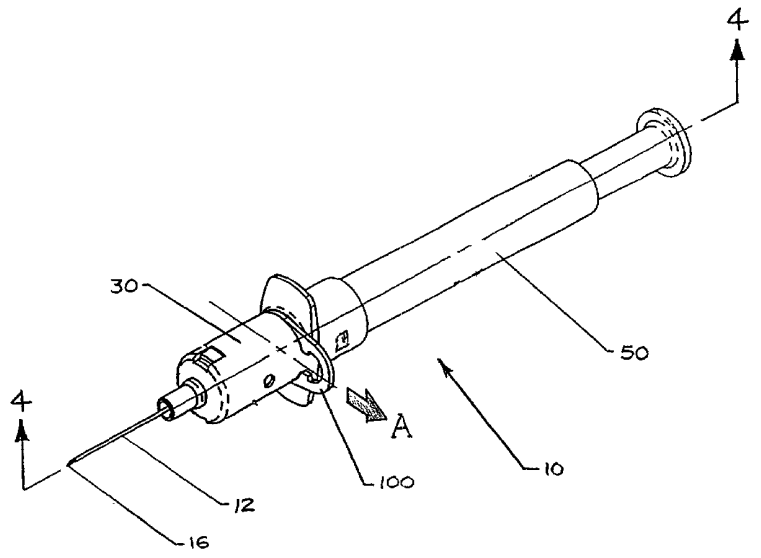
(74) Agent: **ELAND, Stephen**; Dann, Dorfman, Herrell & Skillman, Suite 720, 1601 Market Street, Philadelphia, PA 19103 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: PRE-FILLED SAFETY DILUENT INJECTOR



(57) Abstract: A safety needle-bearing device (10, 110, 210, 310) for mixing and injecting medication from a two-chambered cartridge (50, 150, 250, 350) is provided. The device includes a needle (12, 112, 212, 312) that extends through the forward end of a barrel (30, 130, 230, 330). The two-chambered cartridge (50, 150, 250, 350) is attached to the barrel (30, 130, 230, 330) and contains components of a medication stored separately in the chambers. A plunger (40, 140, 240) in the rearward end of the cartridge can be advanced into the cartridge to combine the separate components and prepare the medication. As the cartridge (50, 150, 250, 350) is advanced forwardly into the barrel (30, 130, 230, 330), the medication is injected through the needle (12, 112, 212, 312) and into a patient. At the completion of the injection stroke, the cartridge (50, 150, 250, 350) engages a needle retainer to actuate needle retraction. The needle is subsequently retracted to shield the contaminated needle.

WO 02/072171 A2

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PRE-FILLED SAFETY DILUENT INJECTOR

PRIORITY CLAIM

This application claims priority to U.S. Provisional Application No. 60/275,568, filed March 13, 2001, which is hereby incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to medical devices and more particularly to medical devices having a cartridge with two chambers that store separate components of a medication and allow the components to be mixed and subsequently injected into a patient.

BACKGROUND

Pre-filled syringes store and allow for mixing of separate medicinal components. Many of these syringes, sometimes called "mixing syringes," store a first component in one compartment and a diluent or a second component in a second compartment. These syringes allow the two components to be stored separately until just before the syringe is used, at which time the components can be mixed within the syringe and immediately injected into a patient.

Pre-filled mixing syringes are advantageous for many types of pharmaceuticals. Some medications, like antibiotics, vitamins and hormones, must be packaged and stored in component parts to enhance shelf life. These medications may need to be stored as a powdered component and a diluent, or as a separate pair of solutions. Pre-filled mixing syringes allow medications to be stored in component parts right up until the medication is

injected. In addition, pre-filled mixing syringes eliminate the burden of measuring medicinal components and mixing diluents from separate containers.

Despite these advantages, prior mixing syringes have not offered reliable safety features to protect the syringe user from accidental needle sticks following injection. In particular, prior syringe assemblies have not provided a mixing syringe that operates integrally with an injection needle that can be automatically shielded upon completion of the injection.

SUMMARY OF THE INVENTION

With the foregoing in mind, the present invention provides a pre-filled medical device for mixing separate components of a medication and injecting the medication into a patient. The device includes a two-chambered container, such as a cartridge, connected to a needle that retracts automatically after use. After retraction, the contaminated needle tip is enclosed within the device to prevent inadvertent needle sticks.

The device includes a hollow barrel surrounding the needle and having a generally open rearward end that forms a socket. A two-chambered cartridge containing component parts of a medication is adapted to engage the socket. Prior to use, the components are stored separately in the two cartridge chambers. During use, a plunger disposed in the rearward end of the cartridge is advanced into the cartridge to combine the two components in one chamber for mixing. Subsequent pressure on the plunger advances the medicinal mixture through the needle into a patient.

The injection needle is operable between an extended position and a retracted position. In the extended position, the forward tip of the needle projects forwardly from the barrel. In the retracted position, the forward tip is enclosed within the barrel. When the needle is in the extended

position, a biasing element biases the needle toward the retracted position. A needle retainer releasably retains the needle in the extended position against the force of the biasing element. During the injection stroke, the cartridge disengages the needle retainer to allow the biasing element to propel the needle rearwardly into the barrel.

DESCRIPTION OF THE DRAWINGS

The foregoing summary as well as the following detailed description of the preferred embodiments will be best understood when read in conjunction with the following drawings, in which:

Fig. 1 is perspective view of a pre-filled cartridge injector having a two-chambered container that stores component parts of a medication;

Fig. 2 is an exploded perspective view of the cartridge injector shown in Fig. 1;

Fig. 3 is an enlarged view of a locking clip of the cartridge injector shown in Fig. 2;

Fig. 4 is a sectional view of the cartridge injector shown in Fig. 1 taken along the line 4-4;

Fig. 5 is a sectional view of the cartridge injector shown in Fig. 4 taken along the line 5-5;

Fig. 6 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device prior to mixing the component parts of the medication;

Fig. 7 is a sectional view of the cartridge injector shown in Fig. 1, illustrating

the device after mixing with the cartridge locked to impede injection;

Fig. 8 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after mixing the cartridge unlocked to allow injection;

Fig. 9 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device, after injection, just prior to needle retraction;

Fig. 10 is a sectional view of the cartridge injector shown in Fig. 1, illustrating the device after needle retraction.

Fig. 11 is an enlarged fragmentary sectional view of the cartridge injector shown in Fig. 1, illustrating the tamper resistant connection between the cartridge and barrel after the needle is retracted.

Fig. 12 is a sectional view of a second embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 13 is a sectional view of the device shown in Fig. 12 taken along the line 13-13.

Fig. 14 is a sectional view of the device shown in Fig. 12 illustrating the device during mixture of the medicinal components in the cartridge transfer of one component of medicine between chambers.

Fig. 15 is a sectional view of the device shown in Fig. 12 illustrating the device after mixture of the medicinal components.

Fig. 16 is a sectional view of the device shown in Fig. 12 illustrating the device after needle retraction.

Fig. 17 is a sectional view of a third embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 18 is a sectional view of the cartridge portion of the device illustrated in Fig. 17.

Fig. 19 is a sectional view of the device shown in Fig. 17 illustrated without the cartridge, illustrated prior to use.

Fig. 20 is a sectional view of the cartridge in Fig. 18 illustrating the device during mixture of the medical components.

Fig. 21 is a sectional view of the device shown in Fig. 18 illustrating the device after mixture of the medical components.

Fig. 22 is a sectional view of the device shown in Fig. 17 illustrating the device at the completion of an injection.

Fig. 23 is a sectional view of the device shown in Fig. 17 illustrating the device after needle retraction.

Fig. 24 is an exploded perspective view of a fourth embodiment of a two-chambered pre-filled cartridge injector having a retractable needle.

Fig. 25 is a sectional view of the device illustrated in Fig. 24.

Fig. 26 is a sectional view of the device in Fig. 24 illustrating the device after mixture of the medical components.

Fig. 27 is a sectional view of the device shown in Fig. 24 illustrating the device at the completion of an injection.

Fig. 28 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

Fig. 29 is a sectional view of the device shown in Fig. 24 illustrating the device after needle retraction.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures in general, and to Figs. 1-11 specifically, an injector device **10** is shown with a needle **12** having a sharpened distal tip **16** for insertion into a patient. As shown in Fig. 4, the injector device **10** has an attached cartridge **50** having a first chamber **52** and a second chamber **56**. The two chambers **52, 56** are pre-filled with component parts of a medication that are to be mixed prior to injection. The cartridge **50** also includes a plunger **40** that is slidable within the cartridge. Initially, advancing the plunger 40 in the cartridge 50 expels the medicinal component from the first chamber 52 into the second chamber 56 to mix the two medicinal components. After mixing the components, advancing the plunger drives the cartridge forwardly to inject the medicine into a patient. Upon completion of the injection stroke, the medical professional releases pressure from the plunger to allow automatic retraction of the needle **12** into the device **10** to protect the contaminated needle 12 from inadvertent contact.

The injector device **10** includes a double-ended needle **12**, a generally cylindrical barrel **30**, a compression spring **26** and a needle retainer **20** releasably retaining the needle against the bias of the spring. As shown in Figs. 4 and 5, the needle **12** has a sharpened proximal tip **14** and a sharpened distal tip **16.** The spring **26** circumscribes the needle **12** and is compressed against the interior of the barrel **30** at the barrel's distal end. The rearward end of the spring **26** bears against the interior of the needle retainer **20** to bias the needle **12** and needle retainer in the rearward direction.

The needle **12** is operable between two positions, an extended position and a retracted position. In the extended position, the needle **12** projects forwardly from the forward end of the barrel **30**. In the retracted position, the needle **12** is retracted into the barrel **30** so that the sharpened tip **16** of needle **12** is enclosed within the barrel to prevent inadvertent contact with the sharpened tip. When the needle is in the extended position, the spring **26** biases the needle **12** rearwardly toward the retracted position. The needle retainer **20** releasably retains the needle **12** in the extended position, against the bias of the spring **26**. During the injection stroke, the cartridge **50** cooperates with the needle retainer **20** to allow the needle to retract into the barrel **30**, as shown in Fig. 10.

Referring now to Figs. 5-7, the cartridge **50** includes a first chamber **52** containing a first medicinal component **54** and a second chamber **56** containing a second medicinal component **58**. The chambers **52, 56** are separated by a mid wall **60** containing an orifice **62.** A rear seal 70 seals the first chamber 52 to prevent the components from being mixed prior to use. When the rear seal 70 is pierced and the plunger **40** is advanced into the cartridge **50**, the first component **54** flows into the second chamber **56** through the orifice 62, where it combines with the second component **58** to form the medication **59**, as shown in Figs. 6-7. Subsequent pressure on the plunger **40** and cartridge **50** forces the medication **59** through the needle **12** and into the patient.

Referring now to Figs. 4-6, the elements of the injector device **10** will be described in greater detail. The barrel **30** is generally cylindrical and the distal end of the barrel has a tapered nose **32**. The nose **32** has an opening through which the needle **12** extends so that the sharpened tip **16** of the needle can be inserted into a patient. The rearward end of the barrel **30** is open, forming a cylindrical socket **34** adapted to receive the cartridge **50**. Two laterally extending flanges **36** project outwardly from the barrel **30**,

transverse the longitudinal axis of the barrel, forming a pair of finger grips for operating the device **10**. The barrel **30** further includes a pair of retaining apertures **38** and a pair of lockout windows **39** that cooperate with the needle retainer **20** as described further below.

As shown in Fig. 5, a hub **21** projects from the rearward end of the needle retainer **20**. The hub **21** is a generally cylindrical element having a central bore **23**. The needle **12** is disposed within the central bore **23** of the hub **21** so that the rearward end **14** of the needle **12** projects rearwardly from the hub and the forward end **16** of the needle projects forwardly from the hub. The needle **12** can be attached to the hub **21** in one of several ways. For example, the needle **12** can be attached to the hub **21** by an adhesive such as a UV curable adhesive. Alternatively, the needle **12** can be molded into the hub **21**, which is formed of plastic. The rearward end of the hub **21** includes a circumferentially barbed connector **25** configured to cooperate with the cartridge **50** to connect the cartridge to the needle hub 21 as discussed further below.

The needle retainer **20** is axially displaceable within barrel **30** to facilitate needle retraction. The needle retainer **20** can be molded out of a rigid, high strength resin, such as polycarbonate. Prior to retraction, the needle retainer **20** is maintained in a fixed axial position while the medication **59** is expelled from the cartridge **50**. After the injection, the needle retainer **20** and the attached needle **12** are displaced rearwardly by the compression spring **26**.

The spring **26** is a compression spring and may be formed of stainless steel, treated carbon steel wire or other suitable non-corrosive spring metal. The residual compression of the spring prior to disengagement of the needle retainer is of sufficient magnitude to facilitate complete needle retraction and overcome the frictional resistance between sliding components within the device **10**.

Referring now to Fig. 6, the needle retainer **20** includes a pair of retaining arms **22** that extend radially outwardly and forwardly from the distal end of the needle retainer **20**. During operation, the needle retainer **20** is operable between a locked position and an unlocked position. In the locked position, the retaining arms **22** engage the retaining apertures **38** in the barrel wall to maintain the needle in a fixed axial position with the forward tip **16** of needle **12** projecting forwardly from the barrel **30**. More specifically, in the locked position, the retaining arms **22** engage the barrel **30** to hold the needle hub **21** and needle **12** against the rearward bias of the spring **26**. In the unlocked position, the retaining arms **22** are positioned so as to allow the needle hub 21 and needle **12** to be retracted rearwardly. More specifically, in the unlocked position, the retaining arms **22** are disengaged from the retaining apertures **38**, allowing the spring 26 to propel the needle hub **21** and needle **12** rearwardly.

As discussed above, the retaining arms **22** on the needle retainer **20** project forwardly and outwardly into engagement with the retaining apertures **38** in the wall of the barrel **30**. The terminal end of each arm forms a retaining tab **24** that is configured to project into a retaining aperture **38**. More specifically, the retaining tabs **24** engage the lip formed by each retaining aperture **38** in the wall of the barrel **30**. In this way, the retaining tabs **24** operate as a pair of latches to retain the needle hub 21 and needle **12** against the rearward bias of the spring.

Referring again to Figs. 4 and 5, the cartridge **50** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate, or a rigid inert plastic such as polyolefin or polyester. The midwall **60** that separates the first and second chambers may be formed of a rigid inert plastic such as polyolefin or polyester. The barrier or midwall **60** can be molded as part of the cartridge **50** or bonded to the inside wall of the cartridge. Each chamber is filled with a predetermined amount of a

medication during manufacturing of the device **10**.

The front end of the forward chamber **56** is sealed by an elastomeric front seal **80**, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The front seal **80** is generally cylindrical, having a plurality of axially-spaced circumferential ribs **81**. The ribs **81**, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the container to provide a fluid tight seal, thereby preventing fluid from leaking from the cartridge **50**. The front seal **80** also has a front end that is pierceable by the rearward sharpened tip **14** of needle **12**. After being pierced, the front end of the front seal **80** reseals around the needle **12** to prevent fluid from leaking from the cartridge **50**.

Referring now to Figs. 5 and 6, the front seal **80** has a socket 82 configured to cooperate with the barbed connector 25 on the needle hub 21. The socket **82** includes two radially relieved recesses, **82a** and **82b**, that mate with the barbed connector **25**. Specifically, the barbed connector **25** matingly engages the front seal **80** in a first position and a second position.

In the first position, the barbed connector **25** engages the first recess **82a**, as shown in Fig. 5. In this position, the cartridge is attached to the hub, but the rearward end of the needle does not pierce the front seal 80. Applying pressure to the plunger **40** displaces the cartridge forwardly relative to the hub, thereby displacing the barb into to the second position. In the second position, the barbed connector **25** engages the second recess **82b**, as shown in Fig. 6. In this position, the rearward end of the needle **12** pierces the front seal 80.

The front seal **80** includes a hollowed cavity **84** at its rearward end. In this way, a pierceable wall **86** is formed in the front seal **80** between the cavity **84** and the second recess **82b**. As shown in Fig. 5 prior to use, the

cartridge 50 is mounted in the first position so that the barbed connector **25** engages the first recess **82a**. In this position, the needle **12** does not penetrate the pierceable wall **86**. As the **hub 21** is displaced from the first position to the second position, the rearward end **14** of the needle**12** pierces the wall **86** and extends into the cavity **84** as shown in Fig. 6. The cavity **84** opens into the interior of the second chamber **56** of cartridge **50** so that when the needle **12** projects into the hollowed section **84**, the needle is in fluid communication with the interior of the cartridge. After the needle **12** penetrates the pierceable wall **86**, the wall reseals around the needle to form a fluid-tight seal and prevent medication in the cartridge **50** from leaking around the needle.

To prepare the injection device **10** for use, the medical professional displaces the cartridge **50** forwardly relative to the needle retainer **20**, so that the forward seal **80** is driven over the barbed connector **25**, such that the barbed connector engages the second recess **82b.** At the same time, the proximal tip **14** of needle **12** pierces the pierceable wall **86**, so that the needle is in fluid communication with the second chamber, as shown in Fig. 6.

The connection between the front seal **80** and the needle hub **21** is preferably a one-way engagement. In other words, when the front seal **80** is mounted on the barbed connector **25**, the cartridge **50** can be displaced forwardly relative to the barbed connector, but the cartridge cannot be displaced rearwardly relative to the barbed connector. In this way, the cartridge **50** cannot be readily removed from the needle hub 21 in barrel **30**, such that the cartridge is substantially permanently attached to the needle hub and barrel.

The one-way connection is facilitated by the rearward-facing tapered shoulder of the barbed connector **25** and the square shaped forward-

facing shoulder of the barbed connector. In particular, the rearward-facing shoulder of the barbed connector **25** cooperates with tapered sides in the first and second radial recesses **82a** and **82b** to permit relative displacement of the plug from the first recess to the second recess. Reverse displacement from the second recess **82b** back to the first recess **82a** is resisted by the square shaped forward-facing shoulders on barbed connector **25**, which act to impede reverse displacement.

Referring now to Fig. 4, the front seal **80** is configured to prevent ejection of fluid when the barbed connector **25** is displaced from the first position, in which the barbed connector **25** engages the first radial recess **82a**, to the second position, in which the barbed connector engages the second radial recess **82b**. Specifically, the front seal **80** includes a flared head **88** or circumferential flange at the forward end of the front seal. The open distal end of the cartridge **50** terminates with a beaded rim **51** that seats against the rearward edge of the flared head **88**. The outside diameter of the flared head **88** is greater than the inside diameter of the open distal end of the cartridge **50**, thereby impeding rearward displacement of the front seal **80** into the cartridge when force is initially applied to the plunger **40**. In addition, the force required to overcome the frictional engagement between the outer circumference of the front seal **80** and the inner wall of the cartridge **50** is greater than the force required to displace the plug **25** from the first recess **82a** to the second recess **82b**. Accordingly, when force is initially applied to the plunger **40**, the front seal **80** remains in a fixed position relative to the cartridge **50**, while the barbed connector **25** is displaced into the second position. This restriction on the front seal **80** limits the release of fluid from the cartridge **50** when the needle **12** pierces the wall **86**.

During storage of the injection device **10**, the medication is divided into two separate components stored in the cartridge **50**, as shown in Fig. 5. Specifically, a first component **54** of the medicine is stored in the rear

chamber **52** and a second component **58** of the medicine is stored in the forward chamber **56**. The two chambers are separated by the mid-wall **60** containing an orifice **62** and a hollow piercing member **64** mounted in the orifice. The orifice **62** is located axially at the center of the midwall **60**. In addition, a small vent hole **63** is located just off center in the midwall **60** to vent the air from the dead space area between the mid wall and the mid seal 70. Preferably, the piercing member **64** is fabricated out of suitable non-corrosive material such as stainless steel or treated carbon steel wire. When the plunger **40** is axially advanced in the cartridge **50**, the first component **54** in the rear chamber **52** advances through the piercing member **64** and into the forward chamber **56** to combine with the second component **58**.

Prior to use of the injection device **10**, fluid communication between the first and second chambers is prevented by an elastomeric mid seal **70**, which may be molded in a self-sealing biocompatible elastomer such as polyisoprene. The mid seal **70** is initially slidably disposed in the first chamber **52** between the piercing member **64** and the first component **54**, as shown in Figs. 4-5. The mid seal **70** is generally cylindrical, having a plurality of axially-spaced circumferential ribs **71**, as shown more clearly in Fig. 2. The ribs **71** frictionally and sealingly engage the inner wall of the cartridge **50** to provide a fluid-tight seal. This fluid-tight seal prevents fluid in the first chamber from entering the piercing member **64**. The mid seal **70** also includes a hollowed section **72** formed in the forward end of the mid seal that opens to the first chamber **52** at the rearward end of the mid seal. The forward end of the mid seal **70** is closed by a membrane **78** that is pierceable by the piercing member **64**. Upon piercing the membrane **78**, fluid communication is established between the first and second chambers to allow the first and second components of the medication to be mixed.

Like the front seal **80** and mid seal **70**, the plunger **40** is generally cylindrical, preferably having a plurality of axially-spaced

circumferential ribs **41**. The plunger **40** may be molded in a self-sealing biocompatible elastomer such as polyisoprene. Alternatively, the plunger **40** could be a two-part assembly in which a cylindrical elastomeric seal is mounted to a rigid plastic plunger rod. The ribs **41**, which are more clearly shown in Fig. 2, frictionally and sealingly engage the interior of the cartridge **50** to provide a fluid tight seal, thereby preventing fluid from leaking from the proximal end of the cartridge.

The plunger **40** is slidable within the first chamber **52** in response to pressure applied to the thumb pad **42**. When the plunger **40** is axially advanced into the cartridge **50**, the first component **54** is compressed against the rearward end of the mid seal **70** in the first chamber **52**. As back pressure on the mid seal **70** overcomes the frictional resistance between the mid seal and the cartridge **50**, the mid seal is displaced into the piercing member **64** until the membrane **78** is pierced, as shown in Fig. 6. As the mid seal advances, air from the space between the mid seal and mid wall vents through the vent hole **63** in the mid wall. At such time, the piercing member **64** penetrates through the hollowed section **72** to connect the first chamber **52** and second chamber **56** in fluid communication.

After the mid seal **70** is pierced, pressure applied to the plunger **40** advances the first component **54** through the piercing member **64** and into the second chamber **56** where the first and second components are subsequently mixed to form the medication **59**. The plunger **40** is displaced forwardly relative to the first chamber **52** until the flanged portion of the thumb pad **42** contacts the proximal end of the cartridge **50**, as shown in Fig. 7. The outside diameter of the thumb pad **42** is larger than the inside diameter of the cartridge **50**, thereby preventing further displacement of the plunger **40** once the thumb pad contacts the proximal end of the cartridge **50**. Preferably, the distance between the forward end of the plunger **40** and the rearward end of the mid seal **70** is equal to the distance between the flanged portion of the

thumb pad **42** and the proximal end of the cartridge **50**. Once the thumb pad **42** contacts the proximal end of the cartridge **50**, the plunger is fixed relative to the cartridge **50**. At this point, axial advancement of the cartridge **50** relative to the barrel **30** is restricted, as described in more detail below.

Preferably, the injection device **10** includes a locking mechanism for preventing accidental release of the contents in the second chamber prior to mixing the two components. In the present embodiment shown in Fig. 7, the barrel **30** includes a locking clip **100** in the barrel wall to prevent accidental discharge of the medicinal components. The wall of the barrel **30** includes a pair of radial slots **104** formed in a plane that is transverse the longitudinal axis of the barrel. When the locking clip **100** is inserted through the slots **104**, the clip prevents inadvertent forward displacement of the cartridge **50** relative to the front seal **80**, thereby preventing accidental advancement of the medicinal components through the needle **12**. The locking clip **100** is preferably formed of a resilient high strength and high modulus resin, such as acetyl or polycarbonate, and is configured to releasably engage the slots **104** in the barrel **30**.

Referring to Figs. 1-3, the locking clip **100** is preferably a flat member having a pair of resiliently deflectable legs **101** that join to form a U-shape. The open end of the locking clip **100** has tapered edges **102** that allow the legs **101** to deflect outwardly as the locking clip **100** is inserted into the sidewall of the barrel **30**. In addition, the locking clip **100** has a plurality of teeth **103** on the inside edge of the legs **101** that are adapted to engage the edges of radial slots **104**.

As the locking clip is inserted into the sidewall of the barrel **30**, the legs **101** deflect outwardly to allow the teeth **103** to clear the edges of radial slots **104**. Upon being deflected outwardly, the resilience of legs **101** bias the legs radially inwardly toward their original position. Once the teeth

103 are disposed within the slots **104**, the legs **101** deflect radially inwardly toward their original position and releasably engage the outer edges of the needle retainer **20** in barrel **30**. In the inserted position, the closed end of the locking clip **100** remains outside the barrel **30**, as shown in Figs. 1 and 4.

After the medicinal components are mixed within the cartridge, the locking clip **100** is removed to permit injection of the medicine **59**, as shown in Fig. 8. The locking clip **100** is removed from the barrel **30** by pulling the closed end of the clip in a direction transverse to the longitudinal axis of the barrel. This direction is marked "A" in Fig. 1. By pulling the clip in this manner, the legs **101** are deflected outwardly from the slots **104** to allow the teeth **103** to clear the edges of slots **104**.

After the locking clip **100** is removed from the barrel **30**, the medication **59** is injected into the patient by advancing the cartridge forwardly into the barrel. Pressure applied to the thumb pad **42** causes the plunger **40** and cartridge **50** to move forwardly relative to the barrel **30**. With the barbed connector **25** mounted in the second recess **82b** in the front seal **80**, the front seal remains stationary while the cartridge **50** is advanced forwardly, as shown in Fig. 9. The front seal **80** and flared head **88** are configured to form a sliding fit with the interior of the cartridge **50** so that the cartridge can slide over the front seal. As the cartridge **50** is advanced, the mid seal **70** and the mid wall 60 are displaced toward the front seal **80**. This causes a reduction of volume in the second chamber **56**, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid wall **60** bears against the rearward end of the front seal **80**, as shown in Fig. 9.

Referring now to Figs. 9-10, the automatic retraction of the needle **12** shall be described. The cartridge **50** is axially advanced to the

proximal end of the barrel **30** until the medication **59** is completely expelled from the second chamber **56**. As the cartridge **50** is advanced, the beaded circumferential rim **51** of the cartridge is displaced into engagement with the retaining arms **22** of needle retainer **20**. Preferably, the cartridge **50** is configured so that the longitudinal distance between the rearward end of the front seal **80** and the mid wall **60** corresponds to the longitudinal distance between the circumferential rim **51** of the cartridge and the retaining arms **22** when the cartridge is mounted on the barbed connector **25** in the second position. In this way, the rim **51** of the cartridge **50** engages the retaining arms **22** when substantially all of the medication **59** is expelled from the device **10**.

After the rim **51** of cartridge **50** engages the retaining arms **22**, continued axial advancement of the cartridge deflects the retaining arms radially inwardly so that the retaining tabs **24** are displaced inwardly, as shown in Fig. 9. In the inward position, the retaining tabs **24** are disengaged from the retaining apertures **38** of the barrel **30**. In this way, the cartridge **50** operates as an actuator, such that axial advancement of the cartridge displaces the needle retainer **20** into an unlocked position. In the unlocked position, the needle retainer **20** is no longer locked in place against the force of the spring **26**. After the needle retainer **20** is in the unlocked position and the user releases pressure on the plunger **40**, the spring **26** propels the needle **12** rearwardly until the sharpened distal tip **16** of the needle is enclosed within the barrel **30**.

As shown in Fig. 10, when the needle **12** is retracted, the needle, needle retainer **20** and cartridge **50** are displaced rearwardly together. During retraction, the retaining arms **22** are biased radially outwardly so that the retaining tabs **24** ride along the inside wall of the barrel. The force of the spring **26** is sufficiently strong to overcome the frictional resistance generated between the guide arms 28 and the barrel **30**.

Preferably, the injection device **10** includes a mechanism for limiting rearward displacement of the retracted elements. Referring now to Figs. 2, 4 and 10, the needle retainer **20** includes a pair of guide arms **28** that cooperate with a pair of alignment channels or grooves **31** formed in the interior wall of the barrel **30**. The guide arms **28** may be molded out of a rigid, resilient high strength resin, such as polycarbonate. The guide arms **28** extend forwardly from the needle retainer **20** and project radially outwardly into engagement with the alignment grooves **31**.

Each guide arm **28** includes a linear elongated rear portion which preferably is generally parallel to the longitudinal axis of barrel **30**. The forward portion of each guide arm **28** bends outwardly transverse to the longitudinal axis of the barrel **30** and extends into one of the alignment grooves **31**. When the needle retainer **20** is disposed within the barrel, the guide arms **28** are deflected radially inwardly from their natural state. In this position, the guide arms **28** are biased radially outwardly against the inner wall of the barrel **30** due to the resilient properties of the guide arms.

The forward ends of guide arms **28** are preferably contained within the alignment grooves **31** to substantially limit rotation of the needle and needle retainer **20** during needle retraction. This engagement ensures that the guide arms are aligned with the lockout windows 39 so that the guide arms snap into the lockout windows at the end of retraction. In this way, the needle retainer **20** is limited to axial displacement during needle retraction. During retraction, the frictional resistance between the forward ends of the guide arms **28** and the inside wall of the barrel **30** is overcome by the expansion force of the spring **26**.

As shown in Fig. 4, the linear elongated rear portion of each guide arm **28** is spaced radially inwardly from the inner wall of the barrel **30** to create a clearance space between the linear portion of the guide arms and

the barrel. Preferably, the minimum radial thickness of the clearance space is greater than the thickness of the wall of the cartridge **50** or the cartridge rim **51**. In this way, when the cartridge **50** is advanced forwardly to disengage the retaining arms **22**, advancement of the cartridge will not be impeded by the guide arms **28**.

Each alignment groove **31** is substantially parallel to the longitudinal axis of the barrel **30.** In Fig. 4, the groove 31 is shown extending to rearward end of the barrel. However, it may be desirable to terminate the groove forward of the rearward end of the barrel. The rearward portion of each alignment groove **31** intersects a lockout window **39** formed in the wall of the barrel **30**. The lockout windows **39** are adapted to receive the forward ends of the guide arms **28**, as shown in Fig. 10. In particular, as the front end of each guide arm **28** aligns with the corresponding lockout window **39** during needle retraction, the radially outward bias of the guide arm displaces the arm outwardly so that the forward end projects into the lockout window. The engagement between the guide arms **28** and lockout windows **39** prevent further axial movement of the retainer **22**. As a result, the retracted elements are limited from further displacement in the forward or rearward direction.

Preferably, the injection device **10** includes a mechanism to limit tampering or removal of the cartridge **50** from the barrel socket **34**. Referring now to Fig. 11, the present embodiment includes an annular lip **35** that projects radially inwardly from the inside wall of the socket **34** in barrel **30**. The lip **35** is adapted to seat against the beaded rim **51** on the cartridge **50** so that the cartridge can not be easily pulled out of the rear of the barrel **30**. As a result, access to the retracted elements, and the contaminated needle in particular, is limited.

Referring now to Figs. 4-10, the operation of the injection device

10 will be described. Prior to use, the needle **12** is disposed in an extended position so that the distal end **16** of the needle projects forwardly from the barrel **30**, as shown in Fig. 4. Preferably, the device **10** is shipped with the cartridge **50** already mounted in barrel **30** so that the barbed connector **25** is engaged in the first recess **82a**. Alternatively, the cartridge **50** may be shipped separately from the barrel **30**, so that the cartridge must be attached to the barrel prior to use.

With the cartridge **50** and barrel **30** assembled, the device **10** is held vertically so that the distal end **16** of needle **12** points upwardwardly. The user holds the device **10** by placing the user's thumb in a supporting position beneath the thumb pad **42** of plunger **40**. In addition, the user places a finger over each finger grip **36** to control the operation of the device **10**. With the user's fingers anchored over the finger grips **36**, the user applies a slight squeezing pressure on the thumb pad **42**, much like a conventional syringe. The squeezing pressure displaces the cartridge **50** forwardly relative to the barrel so that the barbed connector **25** on the needle retainer **20** engages the second recess **82b** in front seal **80** and the needle **12** pierces the wall **86**. As the front seal **80** is pierced, entrapped air in the forward chamber **56** is vented through needle **12**.

Continued advancement of the plunger 40 drives the seal 70 toward the piercing element 64 until the piercing element pieces the mid seal, thereby providing fluid communication between the forward and rearward chambers 52, 56. At this point, the first component **54** may be advanced into the forward chamber **56**. Pressure is applied on the thumb pad **42** until the first component **54** is completely expelled from the rearward chamber 52 into the forward chamber **56** and the forward end of the plunger meets the rearward end of the mid seal **70**. The user then shakes the injector device **10** to mix the first and second components **54**, **58** inside the forward chamber **56**.

During mixing, the locking clip **100** prevents the cartridge **50** from being advanced forwardly into the needle retainer **20**. This constraint on the cartridge **50** limits the potential for inadvertent discharge of the medication **59** from the needle **12** and premature needle retraction. Once the medication **59** is adequately mixed, the user removes the locking clip **100** from the barrel **30** so that the cartridge **50** can be advanced forwardly within the barrel. At this point, initial pressure applied to the thumb pad **42** advances the cartridge and vents excess air out of the second chamber **56**.

The needle is then inserted into a patient and the plunger **40** is depressed to axially advance the cartridge **50** relative to the barrel **30**, thereby injecting the medication **59** from the cartridge into the patient. At the end of the injection stroke, the beaded rim **51** on the cartridge **50** engages the retaining arms **22**, thereby displacing the retaining tabs **24** radially inwardly to disengage the needle retainer **20** into the unlocked position. Although the needle retainer **22** is in the unlocked position, the needle **12** does not retract until the user releases pressure from the thumb pad **42**. In this way, the user can retain pressure on the thumb pad **42** until after the needle is withdrawn from the patient. The user can then release pressure from the thumb pad **42** so that the needle is propelled rearwardly by the spring **26**. Alternatively, the user can release pressure from the thumb pad **42** while the needle **12** is still inserted in the patient. Once the thumb pad **42** is released, the spring **26** propels the needle **12** rearwardly so that the contaminated distal tip **16** of the needle is enclosed within the barrel **30**.

Referring now to Figs. 12-16 in general, and to Figs. 12-13 specifically, a second embodiment of a pre-filled safety diluent injector is shown. The injector device **110** includes elements that are substantially similar to the elements described above in connection with the first embodiment 10, illustrated in Figs. 1-11. These elements include: a double-ended needle **112**, a generally cylindrical barrel **130**, a compression spring

126, a needle retainer **120** releasably retaining the needle against the bias of the spring, a locking clip **200**. The needle **112** has a sharpened proximal tip **114** and a sharpened distal tip **116**. The spring **126** circumscribes the needle **112** and is compressed against the interior of the barrel **130** at the barrel's forward end. The rearward end of the spring **126** bears against the interior of the needle retainer **120** to bias the needle **112** and needle retainer in the rearward direction.

In contrast to the previous embodiment, the second embodiment utilizes a cartridge 150 having a selectively sealable by-pass fluid passage **160** to separate the two medicinal components, rather than a mid wall and a pierceable seal as described above with the first embodiment. Prior to use, a mid seal **170** within the cartridge **150** separates the two medicinal components 154, 158. Prior to use, the mid seal **170** is displaced forwardly adjacent the by-pass passage **160**, which provides a fluid passage, allowing the two medicinal components **154, 158** to be mixed. The mixed components can then be injected into the patient.

Referring to Figs. 12, 13, the detail of the Cartridge 150 will be described in greater detail. The cartridge is a generally cylindrical container. The forward end of the cartridge is sealed by the pierceable forward seal **180**. The rearward end of the cartridge is sealed by a piston **143** that forms a fluid-tight seal with the interior wall of the cartridge. Intermediate the forward seal **180** and the piston **143**, a mid seal **170** forms a fluid-tight seal with the interior wall of the cartridge, separating the cartridge into two chambers, a forward chamber **156** for receiving a first component **158**, and a rearward chamber **152** for receiving a second component **154**.

The cartridge **150** includes a bubble-like fluid passage **160** that protrudes outwardly from the side of the cartridge. The fluid passage **160** forms an area in which the diameter of the cartridge is greater than the

diameter of the mid seal. The fluid passage **160** is an axially elongated channel having a length that is greater than the axial length of the mid seal **170**, and preferably, is shorter than the combined length of the mid seal and the piston **143**.

Although the fluid passage 160 is illustrated as a bubble-like protrusion, the fluid passage may be formed in other configurations. For instance, the fluid passage may be a recess or axial groove formed in the interior wall of the cartridge 150, so that the fluid passage does not protrude from the exterior surface of the cartridge. Similarly, the fluid passage may be an annular recess formed in the interior wall of the cartridge.

Referring to Fig. 12, the device **110** is illustrated in a "storage" position. In this position, the mid seal **170** prevents the two medicinal components from mixing. Therefore, the sealed cartridge **150** can be stored for an extended period, if desired, without compromising the efficacy of the medicinal components. In the stored position, the mid seal **170** is disposed rearwardly of the fluid passage **160** so a fluid-tight seal is formed between the mid seal and the interior wall of the cartridge, around the entire circumference of the mid seal.

During storage of the injection device **110**, the medication is divided into two separate components stored in the cartridge **150**, as shown in Figs. 12-13. Specifically, the first component **154** of the medicine is stored in the first chamber **152** and the second component **158** of the medicine is stored in the second chamber **156**. As discussed further below, preferably, when the cartridge is being filled during manufacture, a quantity of air remains within the second chamber **156**.

A plunger **140** is slidably disposed in the rearward end of the cartridge **150**. The plunger **140** is comprised of a plastic molded plunger rod

141 and an elastomeric piston **143**. The piston **143** forms a fluid-tight seal with the inner wall of the cartridge, and is slidably displaceable within the cartridge. The plunger rod **141** can be connected to the plunger seal **143** in a number of ways. In the present embodiment, the plunger rod **141** includes external screw threads that are configured to engage internal threads inside the plunger seal **143**, whereby the plunger rod and seal can be screwed together.

Referring now to Fig. 14, the transfer of the first medicine component **154** into the second chamber **156** shall be described. The mid seal **170** is advanced axially until it registers with the fluid passage **160**. The fluid passage **160** then provides a by-pass passage so that the component in the rearward chamber can be injected into the forward chamber. Since the forward chamber preferably includes a quantity of air (or other compressible fluid), the material in the forward chamber can be compressed to allow the mid seal to be advanced into registry with the fluid passage **160**. Alternatively, the forward chamber may include a vent for venting the air from the forward chamber when the fluid is transferred from the rearward chamber into the forward chamber. If a vent is included, preferably the vent is sealable to prevent leakage of the mixed components during injection.

Specifically, to mix the two components in the cartridge, the plunger **140** is axially advanced into the cartridge **150**, to compress the first component **154** against the rearward end of the mid seal **170** in the first chamber **152**. As back pressure on the mid seal **170** overcomes the frictional resistance between the mid seal and the cartridge **150**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **170** is displaced into alignment with the fluid passage **160**, a passage is created between the mid seal and the inside wall of the fluid passage, as shown in Fig. 14.

The fluid passage **160** is sufficiently large to allow the first

substance **154** to flow around the mid seal and into the second chamber **156** where it is mixed with the second substance **158**. Once the first component is completely transferred to the second chamber **156**, the plunger seal **143** is advanced until it abuts the mid seal **170**, as shown in Fig. 15. The combined axial length of the mid seal **170** and piston **143** is slightly longer than the length of the fluid passage **160**. Therefore, the mid seal and piston seal off the entire length of the fluid passage. This prevents the contents of the second chamber **156** from backflowing during mixing of the components.

After mixing of the components is completed, the locking clip **200** is removed to allow injection of the medication into the patient. Pressure is applied to the cartridge **150** to discharge the medication from the second chamber **156**. At the completion of the injection stroke, the cartridge **150** actuates the needle retainer **120**. Pressure on the cartridge **150** is then released so that the needle can be retracted, as shown in Fig. 16.

Referring now to Figs. 17-23 in general, and to Fig. 17 specifically, another embodiment of a pre-filled safety diluent injector is designated generally 210. The injector device **210** includes a double-ended needle **212**, a generally cylindrical barrel **230** that houses the needle and a generally cylindrical cartridge **250**. The barrel **230** further includes a compression spring **226** and a needle retainer **220** releasably retaining the needle **212** against the bias of the spring. The needle **212** has a sharpened rearward tip **214** and a sharpened forward tip **216**. The spring **226** circumscribes the needle **212** and is compressed against the interior of the barrel **230** at the barrel's forward end. The rearward end of the spring **226** bears against the interior of the needle retainer **220** to bias the needle **212** and needle retainer in the rearward direction.

In this embodiment, the transferring and mixing of the medication components is done in the cartridge **250** prior to attaching the

cartridge to the needle hub 221. Since the cartridge **250** is not connected to the needle assembly during mixing, there is no risk of inadvertently retracting the needle during the mixture of the components. As a result, the barrel does not include a locking clip, as in the other embodiments.

Referring now to Figs. 18-19, the cartridge **250** and barrel **230** are packaged and distributed so that the two are disassembled. The cartridge **250** is a generally cylindrical vessel that may be molded out of pharmaceutical quality glass such as borosilicate or a rigid inert plastic such as polyolefin or polyester. A cartridge cap **253** is disposed over the distal end of the cartridge **250**. The cartridge **250** is configured similar to the cartridge 150 illustrated in Figs. 12 - 16, and includes a bubble-like fluid passage **260** that protrudes outwardly from the side of the cartridge. A mid seal **270** is slidably disposed in the cartridge **250** and divides the cartridge into a first chamber **252** and a second chamber **256**. Each chamber of cartridge **250** is filled with a predetermined amount of a component of medication during manufacturing of the device **210**. In particular, the first chamber **252** is prefilled with a first component **254** of the medication and the second chamber **256** is prefilled with a second component **258**.

Referring now to Fig. 20, a plunger **240** is slidably disposed in the proximal end of the cartridge **250**. The plunger **240** is comprised of a plastic molded plunger rod **241** and an elastomeric plunger seal **243**. When the plunger **240** is axially advanced into the cartridge **250**, the first component **254** is compressed against the rearward end of the mid seal **270** in the first chamber **252**. As back pressure on the mid seal **270** overcomes the frictional resistance between the mid seal and the cartridge **250**, the mid seal is displaced forwardly in the cartridge. Once the mid seal **270** is displaced into alignment with the fluid passage **260**, a passage is created between the mid seal and the inside wall of the fluid passage to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed

with the second substance **258**.

The fluid passage **260** is sufficiently long to allow the first substance **254** to flow around the mid seal and into the second chamber **256** where it is mixed with the second substance **258**. Once the first component is completely transferred to the second chamber **256**, the plunger seal **243** is advanced until it abuts the mid seal **270**, as shown in Fig. 21. The combined axial length of the mid seal **270** and plunger seal **243** is slightly longer than the maximum length of the fluid passage **260** so that the mid seal and plunger seal close off the entire length of the fluid passage. This prevents the contents of the second chamber **256** from backflowing during mixing of the components.

Referring again to Fig. 18, the cartridge **250** includes an elastomeric front seal **280** in the distal end of the cartridge. The front seal **280** may be molded of a self-sealing biocompatible elastomer such as polyisoprene. The front seal **280** is generally cylindrical with a wide cylindrical rearward end **282** disposed within the cartridge and a reduced diameter forward end **284** projecting forwardly from the forward end of the cartridge. The rearward end **282** has an outside diameter that is similar to the inside diameter of the cartridge **250**. In addition, the rearward end **282** has a plurality of axially-spaced circumferential ribs **286** that frictionally and sealingly engage the interior of the cartridge to provide a fluid tight seal and prevent fluid from leaking from the cartridge.

The forward end **284** of front seal **280** includes an external thread **288** about its circumference. The distal end **284** also contains a shallow frontal cavity **290**. A narrow bore **292** in fluid connection with the second chamber **256** extends from the proximal end of the front seal **280** and terminates within the reduced diameter distal end **284**. Fluid communication between the frontal cavity **290** and the bore **292** is obstructed by a pierceable

membrane **294**.

Referring now to Fig. 19, the barrel **230** is generally cylindrical and has a tapered nose **232** at its distal end. The nose **232** has an opening through which the needle **212** extends. In addition, the nose **232** is configured to receive a needle cover 211 that fits over the nose to prevent accidental needle sticks when the needle **212** is in an extended position. The proximal end of the barrel **230** is open, forming a cylindrical socket **234** adapted to receive the cartridge **250**. Prior to attachment with the cartridge **250**, the rearward open end of the barrel **230** is closed by a cylindrical barrel cap **233**. The barrel further includes a pair of retaining apertures **238** that cooperate with the needle retainer **220** to releasably retain the needle, and a pair of lockout windows that cooperate with locking tabs to lock the needle in the retracted position.

The needle retainer **220** includes a generally cylindrical body **221** and a pair of retaining arms **222** that extend radially forwardly from the body **221**. A generally cylindrical aperture **296** is disposed within the proximal end of the needle retainer body **221**. The inner wall of the aperture **296** includes internal screw threads **298** that are adapted to receive the external screw thread **288** of the front seal **280** in the cartridge **250**.

The cartridge cap **253** and barrel cap **233** are removed from the cartridge **250** and barrel **230**, respectively, to prepare the cartridge and barrel for assembly. The cartridge **250** is connected to the barrel **230** by inserting the forward end of the front seal through the open end of the barrel **230** and screwing the cartridge clockwise into the aperture **296**. The frontal cavity **290** in the front seal **280** is preferably coaxial with the needle **212**, such that attachment of the cartridge **250** to the barrel **230** causes the proximal needle tip **214** to enter the cavity **290** and pierce the membrane **294**, thereby connecting the second chamber of the cartridge in fluid communication with

the needle **212**, as shown in Fig. 17.

Referring to Fig. 17, the cartridge **250** is connected to the barrel **230**, the medication can be injected into the patient by advancing the cartridge forwardly into the barrel. The proximal end of the front seal **280** is configured to form a sliding fit with the interior of the cartridge **250** so that the cartridge slides over the front seal during advancement of the cartridge. As the cartridge **250** is advanced, the rearward end of the front seal **280** bears against the needle retainer **220**, thereby keeping the front seal stationary during advancement of the cartridge. At the same time, the mid seal **270** at the rear of the second chamber **256** is displaced toward the front seal **280**. This causes a reduction of volume in the second chamber **256**, whereby the medication is displaced into the needle to facilitate the injection. At the completion of the injection, the mid seal **270** bears against the rearward end of the front seal **280**, as shown in Fig. 22.

As in the previous embodiments, the needle **212** is retracted by actuating the needle retainer **220**. In particular, the needle **212** is retracted by disengaging the retaining arms **222** from the retaining apertures **238** in the barrel wall to allow the spring **226** to propel the needle **212** rearwardly. To actuate the needle retainer **220**, pressure is applied to the cartridge **250** to advance the cartridge over the needle retainer body **221**, as shown in Fig. 22. During advancement, the distal end of the cartridge **250** engages a cylindrical sleeve **300** that is disposed around the distal end of the needle retainer body **221**. The inside and outside diameters of the release sleeve **300** are preferably equal to the inside and outside diameters of the cartridge **250** so that the distal end of the cartridge mates with the proximal end of the sleeve. Prior to engagement with the cartridge **250**, axial movement of the release sleeve **300** along the needle retainer is limited by an internal flange **302** that slides within an annular fluid passage **223** on the needle retainer body **221**. After the cartridge **250** engages the sleeve **300** continued advancement of

the cartridge drives the sleeve axially forwardly into engagement with the retaining arms **222**. The release sleeve **300** deflects the retaining arms radially inwardly and out of engagement with the retaining apertures **238**, allowing the spring **226** to propel the needle **212** rearwardly, as shown in Fig. 23.

As described above, the third embodiment includes a threaded engagement between the front seal **280** and the needle retainer **220** rather than a barbed connection as described in the first two embodiments. Using a threaded connection can increase the overall length of the needle retainer **220**, which in turn increases the distance between the distal end of the cartridge **250** and the retaining arms **222**. One manner for accommodating this increased length is to increase the length of the barrel **230**. However, by incorporating the release sleeve **300**, the length of the barrel **230** need not be substantially increased. The release sleeve **300** compensates for the increased distance by acting as an extension of the cartridge **250**. This eliminates the need to increase the overall length of the device **210**. Preferably, the length of the release sleeve **300** is slightly longer than the length of the threaded engagement between the front seal **280** and the needle retainer **220**.

Referring now to Figs. 24-29 in general, and to Figs. 24-25 specifically, a fourth embodiment of a pre-filled safety diluent injector is shown. The injector device **310** includes a double-ended needle **312**, a generally cylindrical barrel **330** that houses the needle and a generally cylindrical cartridge assembly **350** mounted within the proximal end of the barrel. Like the previous embodiments, the barrel further includes a compression spring **326** and a needle retainer **320** releasably retaining the needle **312** against the bias of the spring. The device **310** also includes a U-shaped locking clip **400** in the barrel wall to prevent accidental discharge of medication from the device **310**.

The cartridge assembly **350** has a two-part design that offers the advantage of using cost-efficient plastic in the assembly. The cartridge assembly **350** includes a front cylinder **351** having an open proximal end and a rear cylinder **353** having an open distal end telescopically mounted to the proximal end of the front cylinder. The front cylinder **351** contains an internal wall **360** that divides the cartridge assembly **350** into a first chamber **352** and a second chamber **356**. The first chamber **352** contains a predetermined amount of a first component **354** of medication, and the second chamber **356** contains a predetermined amount of a second component **358** of medication. The proximal end of the front cylinder **351** is closed by a pierceable elastomeric front seal **380**.

In many applications, the second component **358** will be a dry powdered component. Dry components do not require a glass container and can be stored in plastic containers without jeopardizing long term stability of the component. Since it is more cost-efficient to mold complex parts out of plastic than glass, it is preferable to minimize the complexity of the glass portion of the cartridge assembly **350**. To this end, the front and rear cylinders **351**, **353** are configured so that the first component **354** is stored entirely within the rear cylinder and the second component **356** is stored entirely within the front cylinder. In this arrangement, the front cylinder **351** comprises a more complicated structure to allow the rear cylinder to be a simple cup-shaped container. Therefore, the more complex forward cylinder can be molded out of cost-efficient plastic for those devices that store a dry second component **358** in the second chamber **356**. Preferably, glass is only used, if at all, to mold the rear cylinder **353**.

As stated earlier, the rear cylinder **353** is telescopically mounted on the proximal end of the front cylinder **351**. The outside diameter of the rear portion of the rear seal is generally equal to the inside diameter of the rear cylinder **353** so as to frictionally engage the interior of the rear cylinder

and provide a fluid tight seal. The rear cylinder **353** is adapted to slide axially over the rear seal 340 in response to pressure applied to the proximal end of the rear cylinder.

The barrel **330** has an inside diameter large enough to accommodate the outside diameter of the rear cylinder **353**. As a result, the outside wall of the front cylinder **351** is separated from the interior wall of barrel **330** by a clearance space, as shown in Fig. 25. The front cylinder **351** is maintained in a concentric relationship with the much larger barrel **330** by a pair of opposing longitudinal ribs **355** on the outside wall of the front cylinder. The longitudinal ribs are illustrated in Fig. 24.

An elastomeric rear seal **340** is disposed between the front cylinder **351** and rear cylinder **353**. The rear seal **340** includes a reduced diameter end **342** partially disposed in the open proximal end of the front cylinder **351**. The rear seal **340** also includes a flanged end **344** disposed within the rear cylinder **353**. The reduced diameter end **342** and flanged end **344** frictionally and sealingly engage the interior of the front cylinder **352** and rear cylinder **354**, respectively. This engagement provides a fluid tight seal with the interior of both cylinders, while allowing the rear seal **340** to be displaced relative to either cylinder. Forward advancement of the rear seal **340** relative to the front cylinder **351** is limited by the proximal end of the front cylinder, which is configured to matingly engage the flanged portion of the rear seal.

As stated earlier, the front cylinder **351** contains an internal wall **360**. The internal wall **360** is adjacent the rearward open end of the cartridge, forming a socket for receiving the rear seal **340**. The internal wall **360** contains an orifice **362** mounted in the center of the wall **360**. A hollow piercing member **364** is mounted in the orifice and extends rearwardly toward the rear seal **340**. In addition, it may be desirable to provide a vent opening in

the internal wall **360** to vent the air between the rear seal **340** and the internal wall when the rear cylinder is advanced to pierce the rear seal.

The distal end of the rear seal **340** is closed by a membrane **348** that is configured to be pierced by piercing member **364**. The rear seal **340** includes a hollowed mid section **346** that is connected in fluid communication with the first chamber **352** through the proximal end of the rear seal. Once the membrane **348** is pierced, a fluid passage is created through the piercing member **364** and rear seal **340**, such that the first and second chambers, **352**, **356** are connected in fluid communication. The rear seal **340** may be molded in a high elongation self-sealing biocompatible elastomer, such as polyisoprene.

The operation of the device **310** will now be described. A slight squeezing pressure is applied to the proximal end of the rear cylinder **353** to axially advance the rear cylinder over the front cylinder **351**. This causes the first component **354** to become compressed between the rear seal **340** and the closed proximal end of the rear cylinder **353**. Continued pressure on the rear cylinder **353** creates back pressure on the rear seal **340** which axially displaces the rear seal forwardly into the piercing member **364**. At this time, the membrane **348** is pierced to create a fluid passage between the first and second chambers **352**, **356**.

The rear cylinder **353** is advanced forwardly relative to the front cylinder **351** to expel the first component **354** from the first chamber **352** into the second chamber **356**. Once the first component **354** is completely expelled from the first chamber **352**, additional pressure on the rear cylinder **353** advances the rear cylinder forwardly relative to the front cylinder **351** until the closed proximal end of the rear cylinder abuts the proximal end of the rear seal **340**, as shown in Fig. 26. At this point, the device **310** is shaken to mix the components within the second chamber **356**. During the mixing process,

displacement of the cartridge assembly **350** is prevented by the locking clip **400**, thereby minimizing the potential for accidental discharge of the medication.

After the components are mixed, the locking clip 400 is removed. The cartridge assembly is then displaced forwardly so that the rearward end of the needle 312 pierces the forward seal 380. The air is then vented from the forward chamber. Further pressure is applied to the cartridge assembly **350** to discharge the medication from the second chamber **356** and through the needle **312**. At the completion of the injection stroke, the proximal end of the cartridge assembly **350** actuates the needle retainer **320**, as shown in Fig. 27. Pressure on the cartridge assembly **350** is then released so that the needle **312** can be retracted, as shown in Figs. 28 and 29.

In some instances, it may be desirable to store the cartridge in its component parts. In other words, the rear cylinder 353 may be detached from the forward cylinder **351**. Prior to use, the rear cylinder **353** would be attached to the forward cylinder 351 and the combined assembly would be utilized as described above. In such instances, the separate rear container **353** may include a separate cap to cover its forward end. Similarly, the forward cylinder **351** may include a cap to cover its rearward end. The detachable rearward cylinder **353** may permit a variety of pre-measured medicinal components to be stored and readily combined in various combinations prior to use.

The terms and expressions which have been employed are used as terms of description and not of limitation. There is no intention in use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It is recognized, however, that various modifications of the embodiments described herein are possible within the scope and spirit of the invention. For instance, the embodiments

described above include a needle retainer having a pair of radially displaceable arms to automatically release the needle for retraction after use. However, the devices may be modified by utilizing different needle retainers that may or may not automatically retract the needle after use. Accordingly, the invention incorporates variations that fall within the scope of the following claims.

CLAIMS

1. A medical device, comprising:
a barrel having an open proximal end and a distal end;
a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;
a cartridge in fluid communication with the needle, comprising:
a first chamber containing a first substance;
a second chamber containing a second substance;
a fluid flow controller between the first chamber and the second chamber; and
a plunger slidably disposed within the cartridge;
a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and
a needle retainer releasably retaining the needle in the extended position;
wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and continued advancement of the plunger and cartridge relative to the barrel after the mixture is expelled from the cartridge actuates the needle retainer to release the needle, whereupon the biasing element displaces the needle relative to the barrel to shield the first sharpened tip.

2. The medical device in claim 1 wherein the medical device further comprises a needle carrier fixed to the needle.

3. The medical device in claim 1 wherein the needle has a second sharpened tip at its rearward end.

4. The medical device in claim **1** wherein the needle is retracted upon release of pressure on the plunger.

5. The medical device in claim **1** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened needle tip beyond the proximal end of the barrel as the needle is moved to the shielded position.

6. The medical device in claim **1** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

7. The medical device in claim **1** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

8. The medical device in claim **1** wherein the second substance is a powdered material.

9. The medical device in claim **1** wherein the second substance is a liquid material.

10. The medical device in claim **1** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

11. The medical device in claim **1** wherein the fluid flow controller comprises:
a wall between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber; and
a fluid flow pathway through the piercing element;
wherein axially displacing the cartridge toward the barrel displaces the plunger until the plunger is ruptured by the piercing element,

creating a passage through the plunger which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the plunger into the second chamber.

12. The medical device in claim 1 wherein the fluid flow controller comprises:

a barrier between the first and second chambers having an opening;

a hollow piercing element disposed through the opening having a sharpened end extending into the first chamber;

a fluid flow pathway through the piercing element; and

a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;

wherein axially displacing the plunger toward the barrel displaces the pierceable mid seal until the mid seal is ruptured by the piercing element, creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

13. The medical device in claim 1 wherein the fluid flow controller comprises:

a mid seal between the first and second chambers that is axially displaceable within the cartridge; and

an elongated fluid passage in the side wall of the cartridge;

wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

14. The medical device in claim 1 wherein the cartridge is substantially permanently attached to the barrel.

15. The medical device in claim **1** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

16. The medical device in claim **2** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

17. The medical device in claim **2** wherein the needle retainer comprises a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage a pair of windows in the barrel wall.

18. The medical device in claim **2** wherein a cylindrical sleeve having generally the same outside diameter as the cartridge is disposed around the circumference of the needle carrier in general axial alignment with the cartridge, such that axial advancement of the cartridge at the end of the injection stroke displaces the sleeve toward the distal end of the barrel to actuate the needle retainer.

19. The medical device in claim **3** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

20. The medical device in claim **19** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

21. The medical device in claim **19** wherein the distal end of the front seal

includes an external thread and the proximal end of the needle carrier includes a cavity adapted to receive the threaded end of the front seal.

22. A medical device, comprising:

a barrel having an open proximal end, a distal end and an opening through the barrel wall oriented perpendicularly to the longitudinal axis of the barrel;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;

a second chamber containing a second substance;

a fluid flow controller connecting the first chamber and the second chamber; and

a plunger slidably disposed within the cartridge;

a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip;

a needle retainer releasably retaining the needle in the extended position; and

a locking clip detachably connected to the barrel;

wherein axially advancing the plunger within the first chamber advances the first substance through the fluid flow controller and into the second chamber where said first substance combines with the second substance to form a medicinal mixture, and removal of the locking clip from the barrel permits further advancement of the plunger and cartridge relative to the barrel to expel the mixture from the second chamber, whereafter axially advancing the cartridge disengages the needle retainer to allow the biasing element to displace the needle relative to the barrel to shield the first sharpened tip.

23. The medical device in claim **22** wherein the medical device further comprises a needle carrier fixed to the needle.

24. The medical device in claim **22** wherein the needle has a second sharpened tip at its rearward end.

25. The medical device in claim **22** wherein the needle is retracted upon release of pressure on the plunger.

26. The medical device in claim **22** wherein the cartridge comprises a beaded circumferential rim on the distal end of the cartridge, and the barrel contains a lip projecting radially inwardly from the inner bore of the barrel at the barrel's proximal end, said lip adapted to engage the beaded rim of the cartridge to impede removal of the cartridge from the rear of the barrel after needle retraction.

27. The medical device in claim **22** wherein the medical device further comprises one or more stops that impede continued rearward displacement of the first sharpened tip beyond the open proximal end of the barrel as the needle is moved to the shielded position.

28. The medical device in claim **22** wherein the plunger is comprised of a plastic molded plunger rod connected to an elastomeric seal.

29. The medical device in claim **22** wherein the plunger is displaceable relative to the cartridge while the first substance is expelled from the first chamber, and the plunger is stationary relative to the cartridge when the mixture is expelled from the second chamber.

30. The medical device in claim **22** wherein the locking clip comprises a flat U- shaped disk having a plurality of teeth along the inner edge, said clip being configured to slide through the slits in the barrel in a direction perpendicular to the longitudinal axis of the barrel and at a location between the cartridge and the needle retainer, thereby impeding

contact between the cartridge and the needle retainer.

31. The medical device in claim **22** wherein the second substance is a powdered material.

32. The medical device in claim **22** wherein the second substance is a liquid material.

33. The medical device in claim **22** wherein the volume of the second chamber is greater than the combined volume of the first substance and the second substance.

34. The medical device in claim **22** wherein the fluid flow controller comprises:
a barrier between the first and second chambers having an opening;
a hollow piercing element disposed through the opening having a sharpened end extending within the first chamber;
a fluid flow pathway through the piercing element; and
a pierceable mid seal axially displaceable within the first chamber that provides fluid communication between the first and second chambers upon being pierced by the piercing element;
wherein initial axial displacement of the plunger toward the barrel displaces the pierceable mid seal into contact with the piercing element, piercing the mid seal and creating a passage through the mid seal which aligns with the fluid flow pathway in the piercing element to allow the first substance to pass through the mid seal into the second chamber.

35. The medical device in claim **22** wherein the fluid flow controller comprises:
a mid seal between the first and second chambers that is axially displaceable within the cartridge; and
an elongated fluid passage in the side wall of the cartridge between the

mid seal and the distal end of the cartridge;

wherein axially displacing the plunger toward the barrel displaces the mid seal into alignment with the fluid passage, creating a passage between said mid seal and the inside wall of the fluid passage that allows the first substance to flow around the mid seal into the second chamber.

36. The medical device in claim **23** wherein the biasing element comprises a compression spring disposed between the distal end of the barrel and the needle carrier.

37. The medical device in claim **23** wherein the needle retainer comprises a pair of forward windows in the barrel wall and a pair of forward tines extending radially outwardly from the needle carrier and configured to releasably engage the forward windows.

38. The medical device in claim **24** wherein the cartridge further comprises a front seal at the distal end of the cartridge that is configured to be pierced by the second sharpened tip to connect the needle and second chamber in fluid communication.

39. The medical device in claim **38** wherein the minimum axial force on the plunger that is required to pierce the front seal is less than or equal to the minimum axial force required to axially displace the plunger in the rear chamber.

40. A medical device, comprising:

a barrel having an open proximal end and a distal end;

a needle having a first sharpened tip and being operable between an extended position in which the first sharpened tip projects forwardly from the barrel and a shielded position in which the first sharpened tip is shielded to prevent inadvertent contact with the first sharpened tip;

a cartridge in fluid communication with the needle, comprising:

a first chamber containing a first substance;

a second chamber containing a second substance;

a fluid flow controller between the first chamber and the second chamber; and

a biasing element imparting a force capable of displacing the needle relative to the barrel to shield the first sharpened tip; and

a needle retainer releasably retaining the needle in the extended position;

wherein the fluid flow controller is adapted to keep the first and second substances separate prior to use, and also adapted to allow mixing of the first and second substances prior to an injection, wherein after use the needle is disposed in the shielded position.

41. A method for injecting medicine, comprising the steps of:

providing an injection device having a first chamber containing a first medicinal component, a second chamber containing a second medicinal component, and a needle;

transferring the first medicinal component from the first chamber to the second chamber;

mixing the first and second components to form a medicinal mixture;

expelling the medicinal mixture from the chamber; and

retracting the needle after expelling the medicinal fluid to shield the needle against contact.

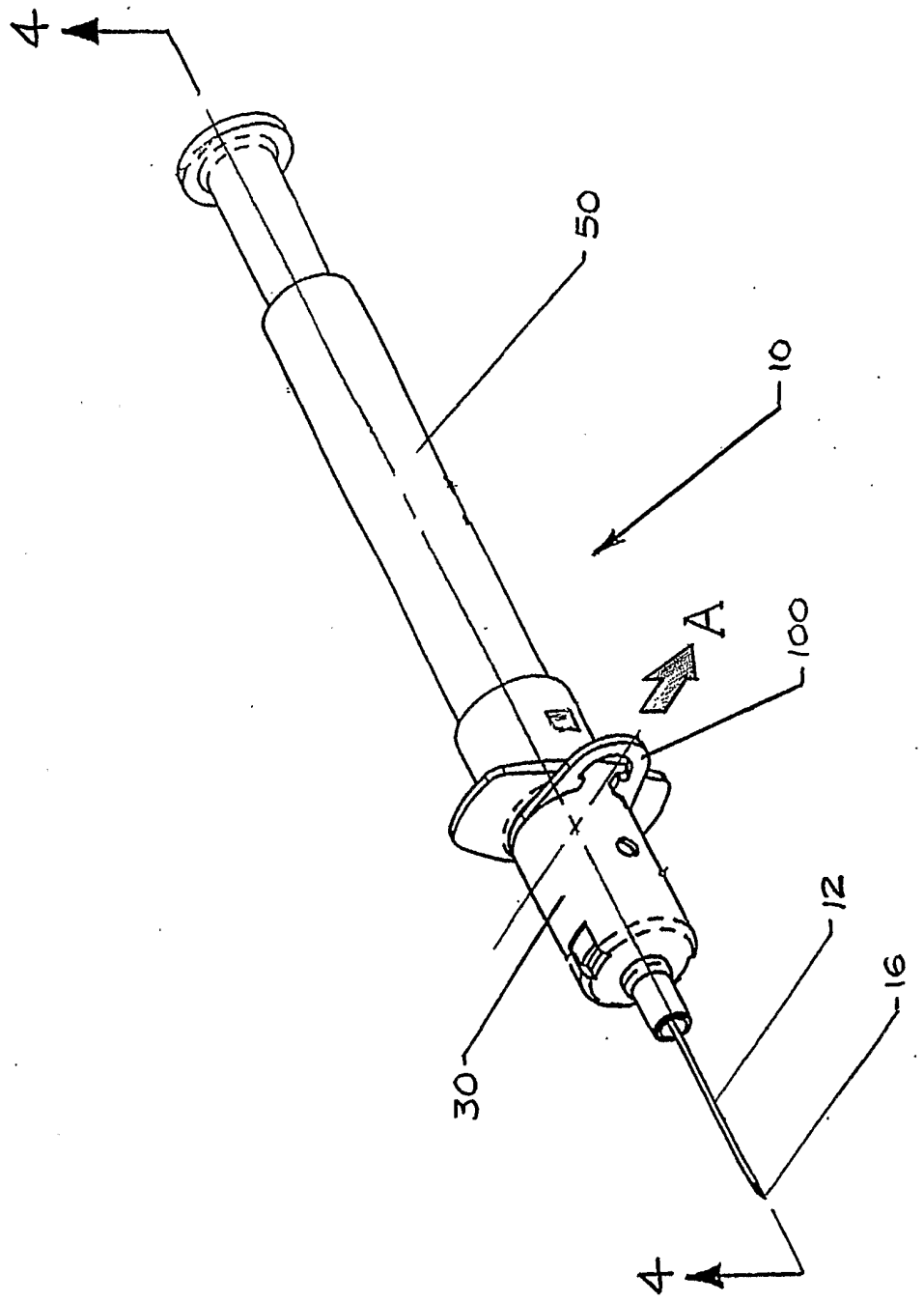


Figure 1

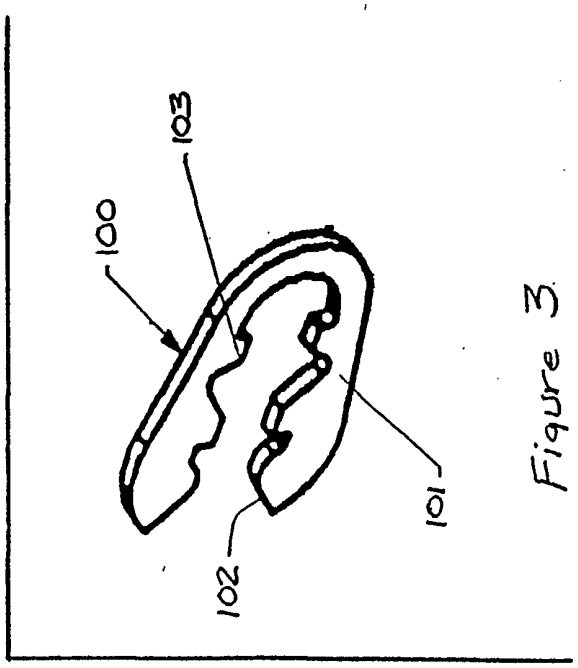


Figure 3

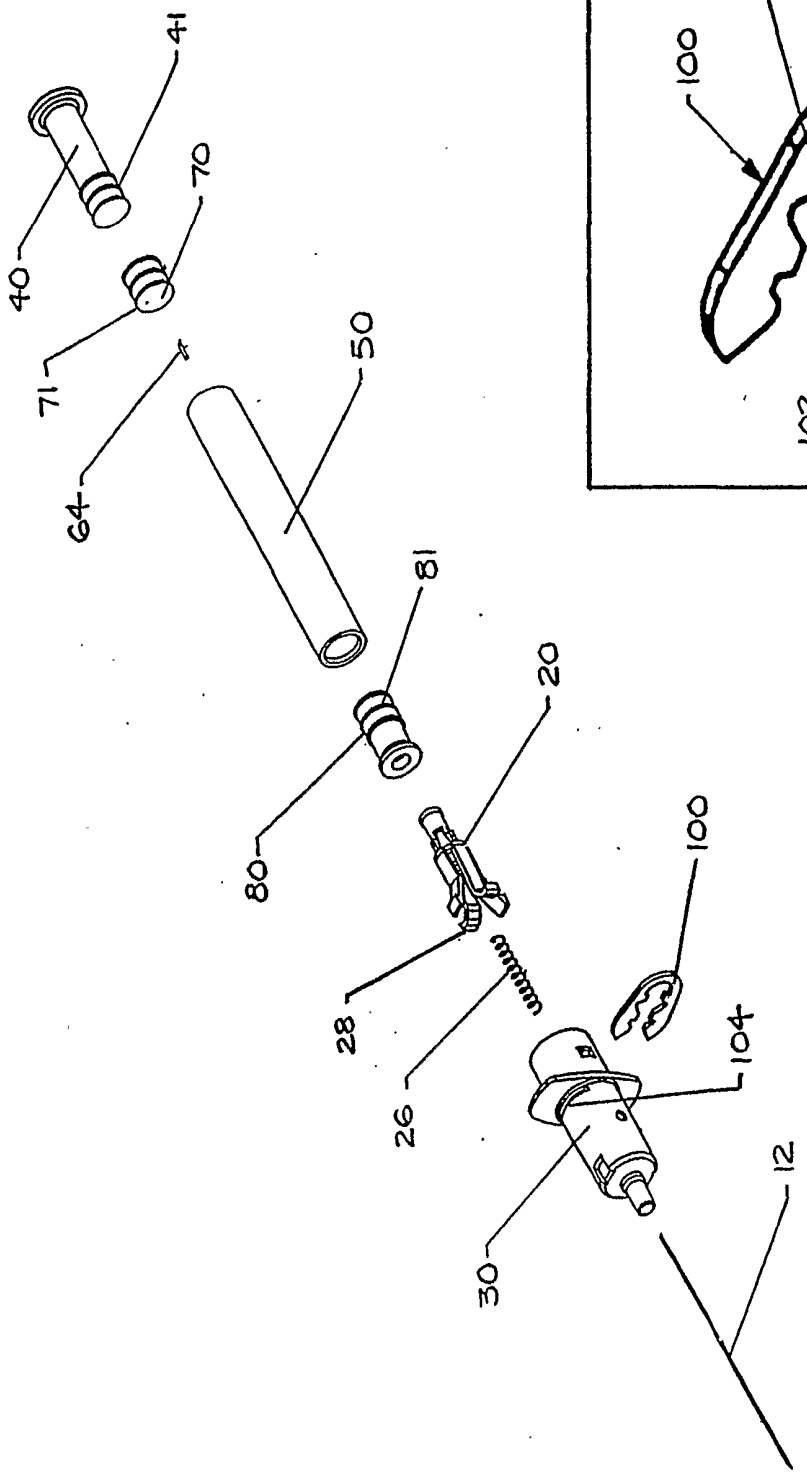


Figure 2

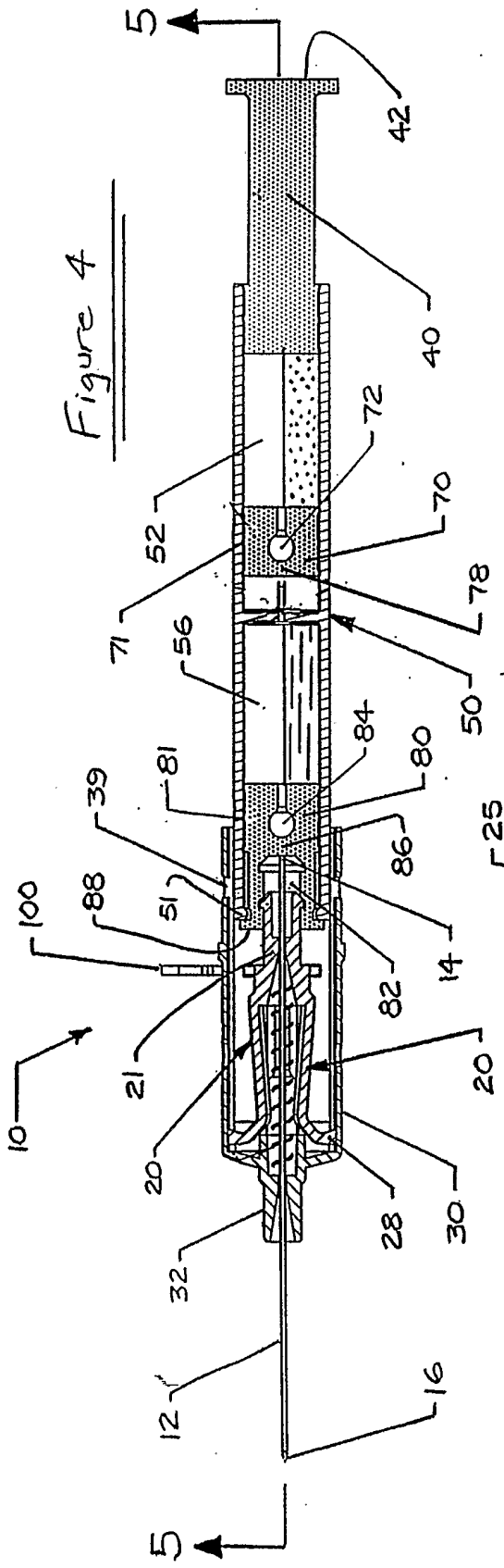


Figure 4

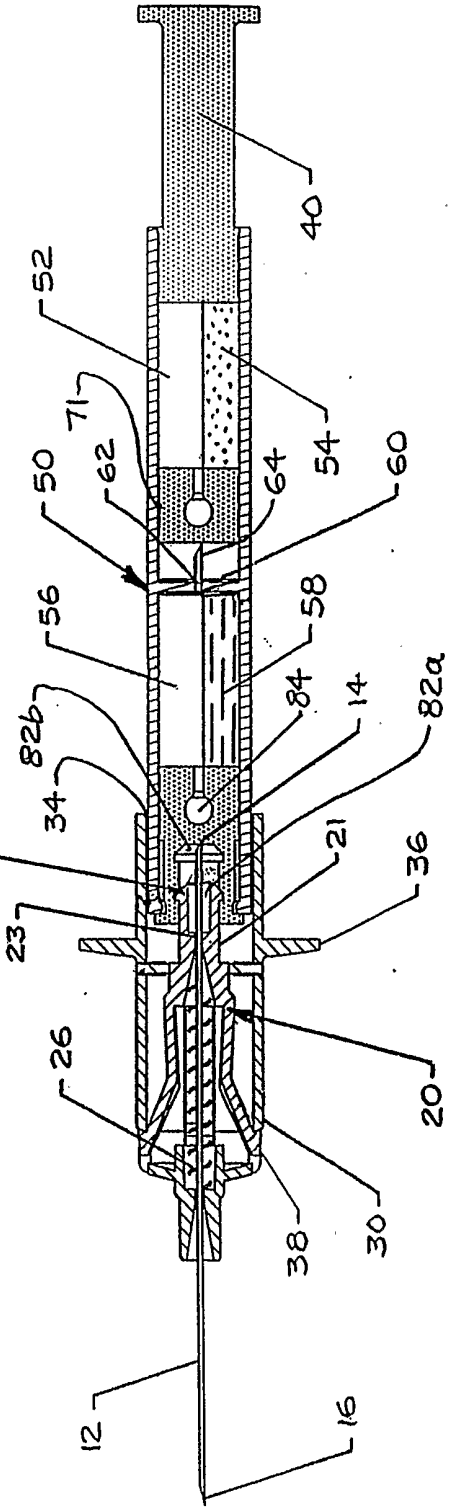
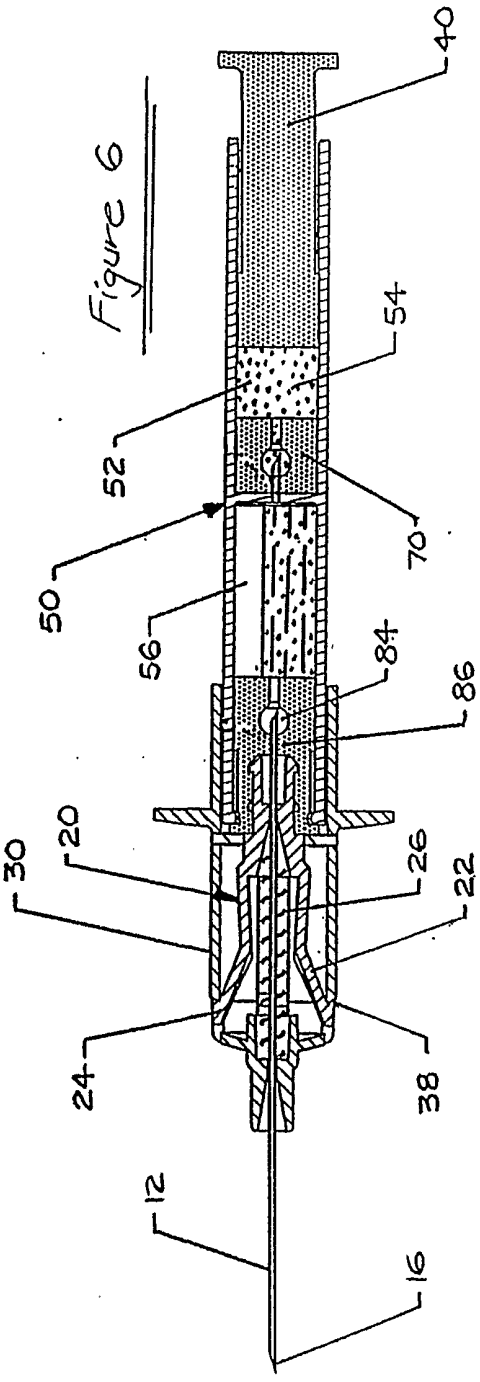


Figure 5

Figure 6



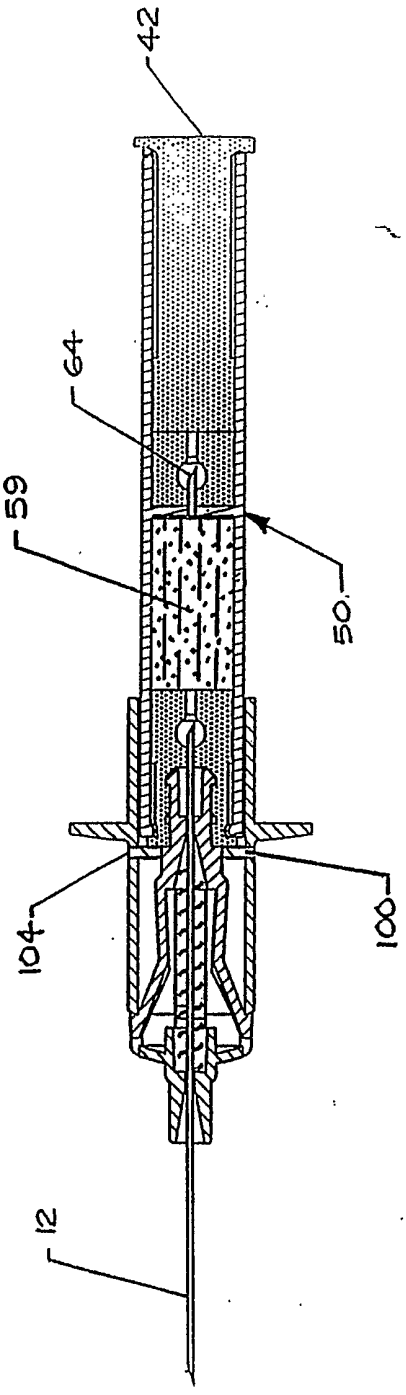


Figure 7

Figure 8

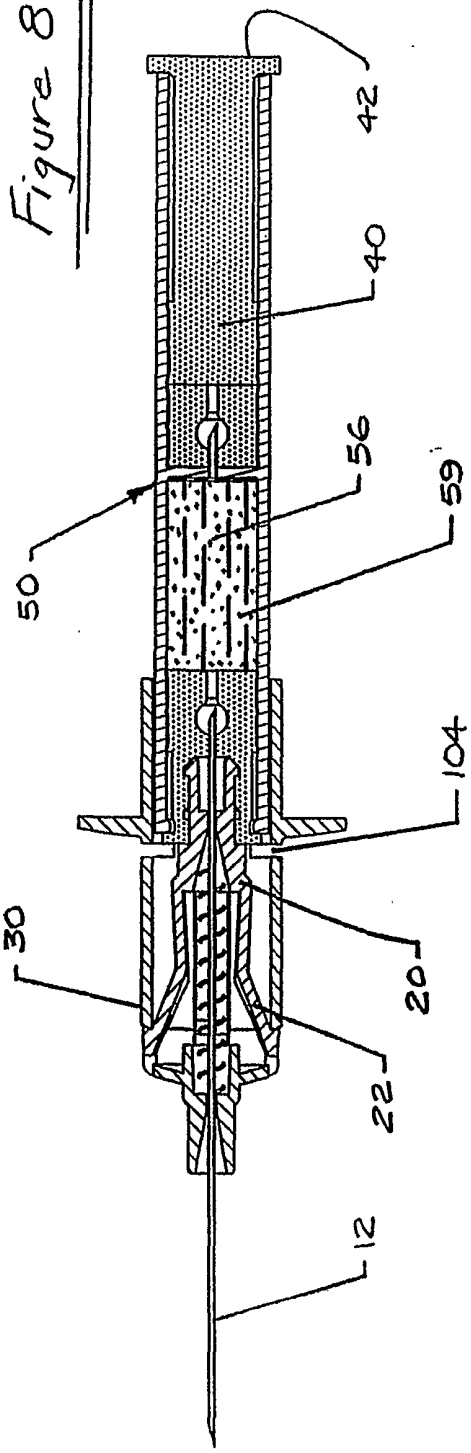
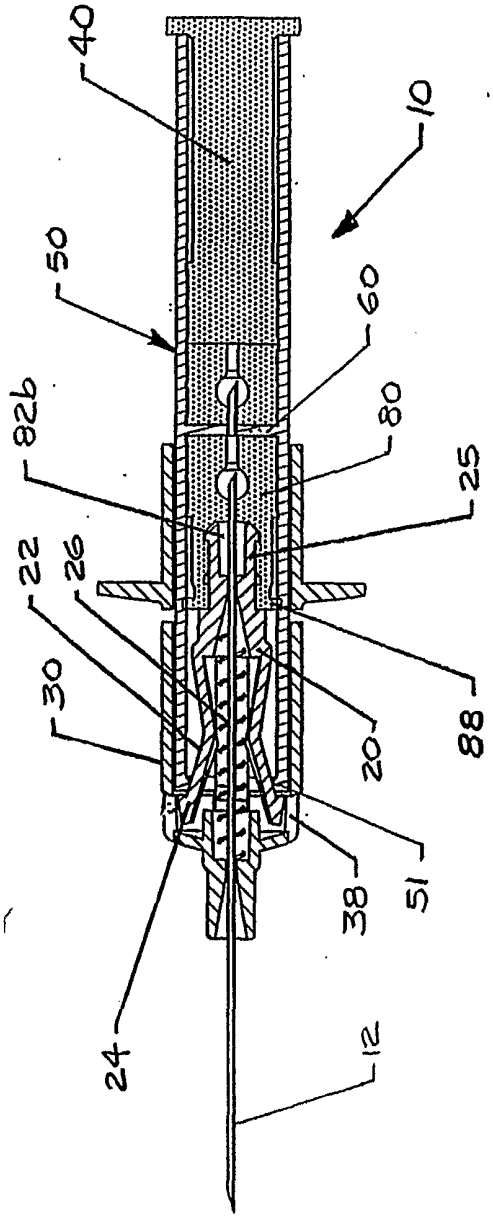


Figure 9



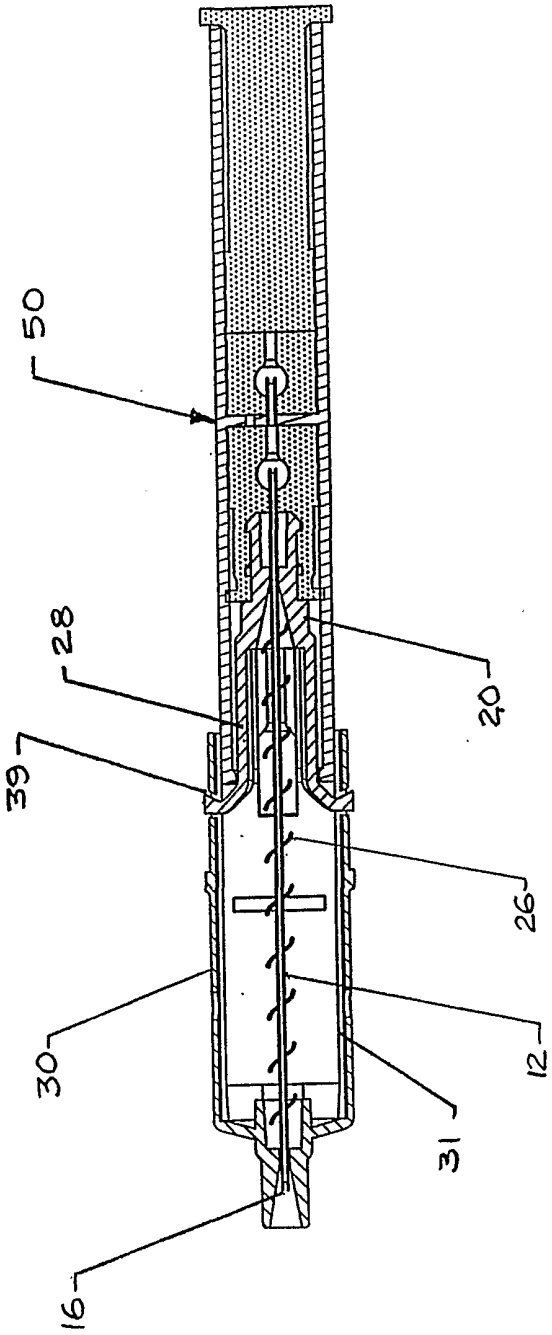


Figure 10

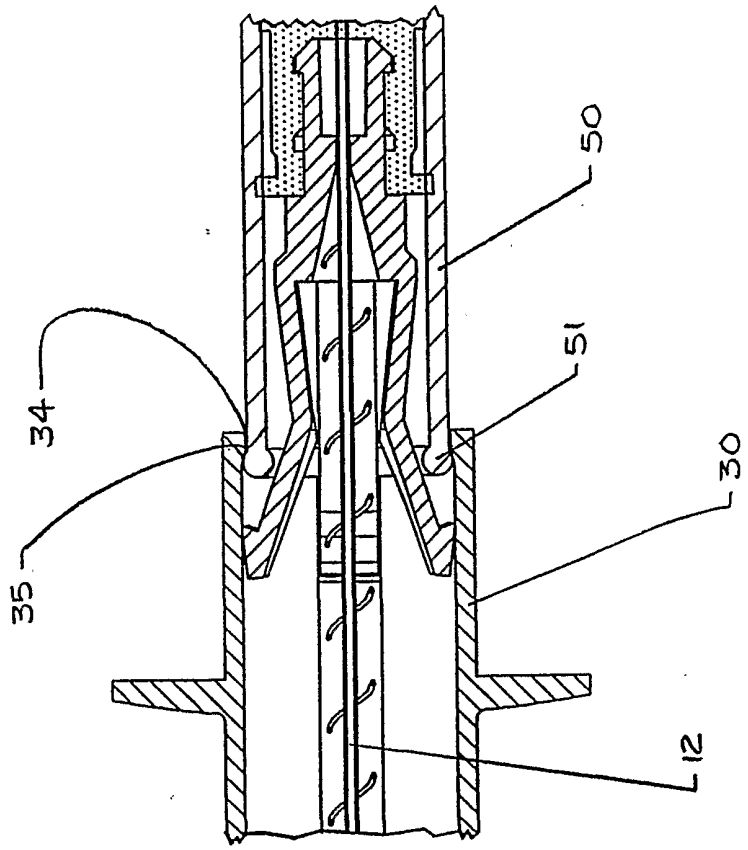


Figure 11

Figure 12

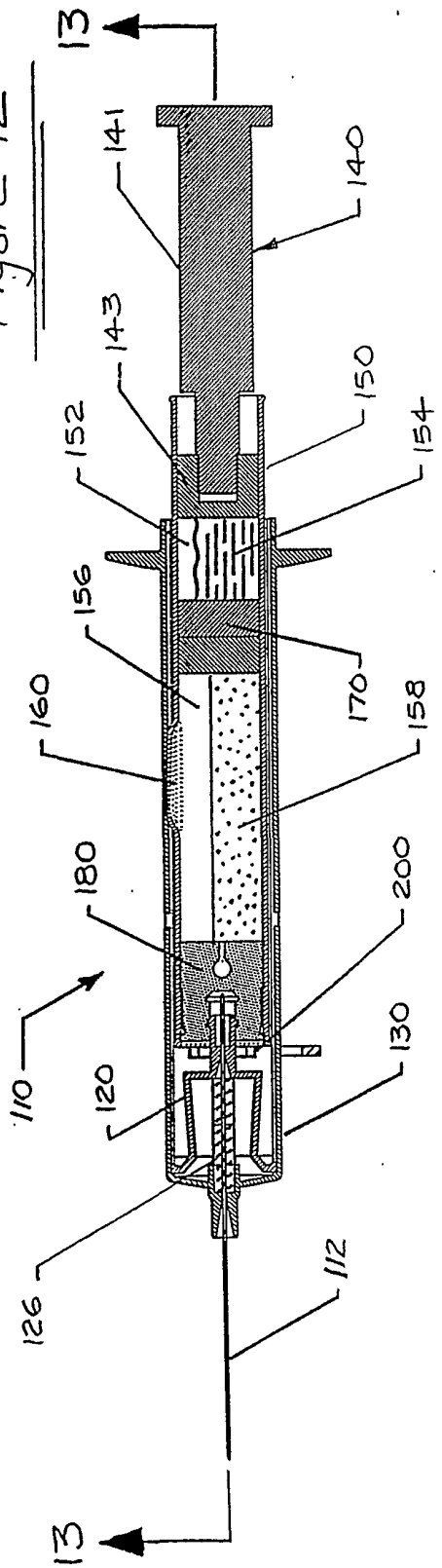


Figure 13

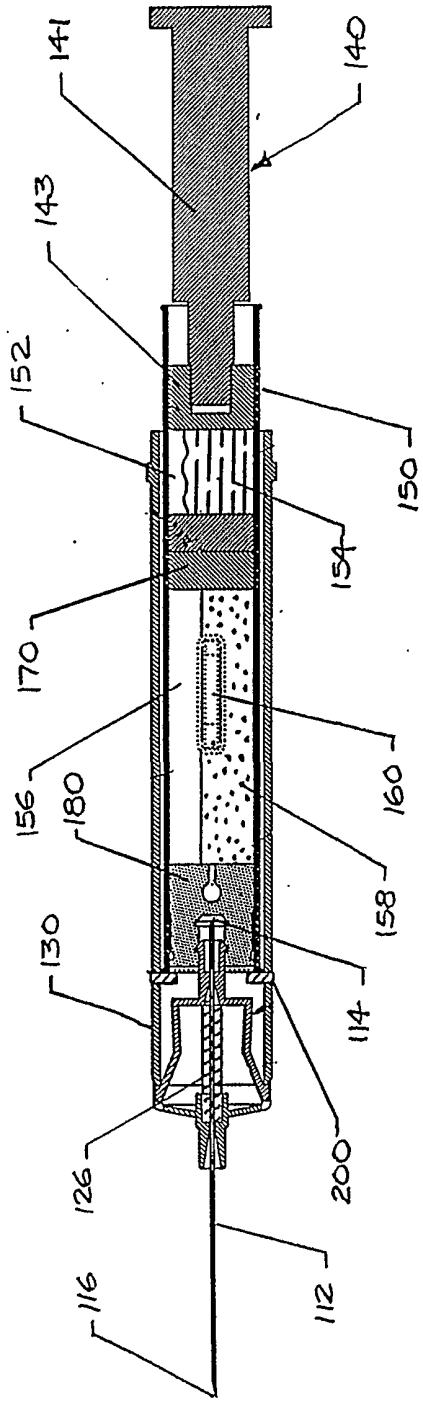


Figure 14

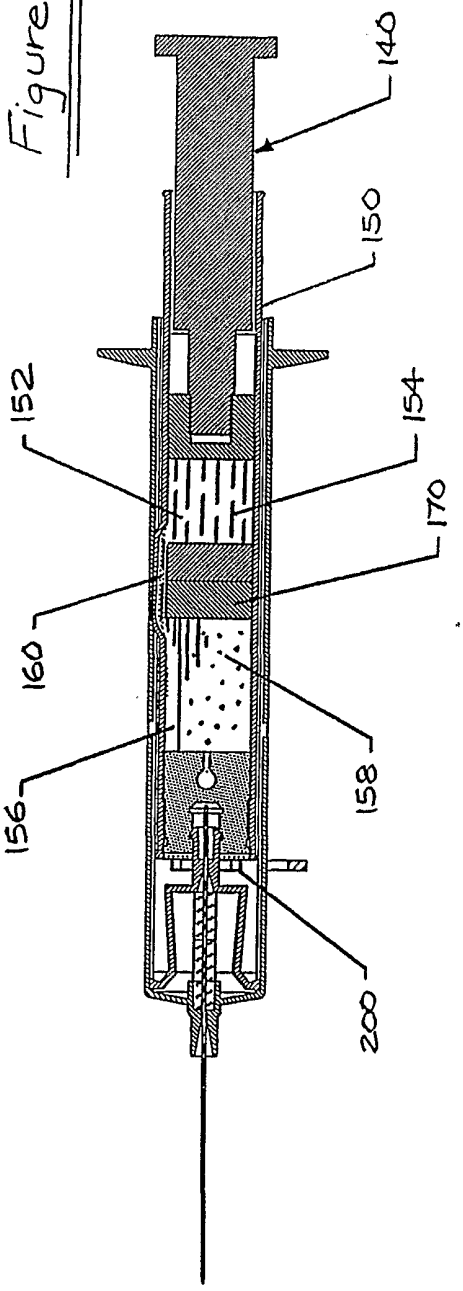
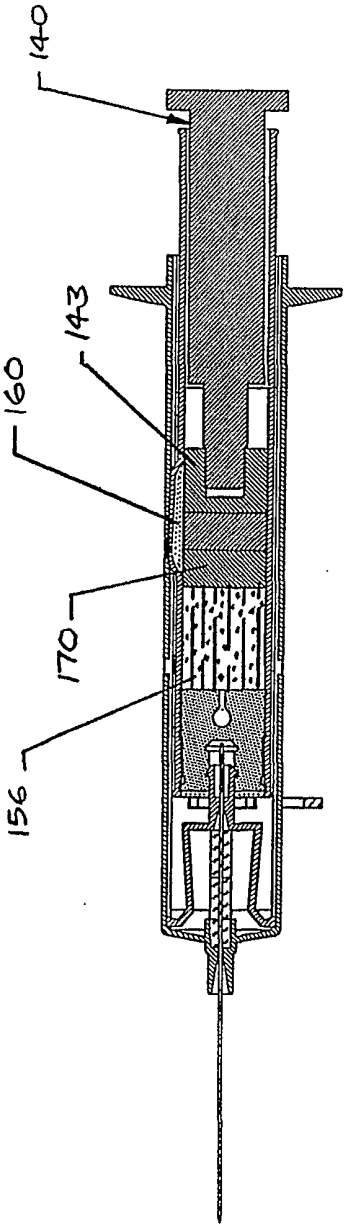


Figure 15



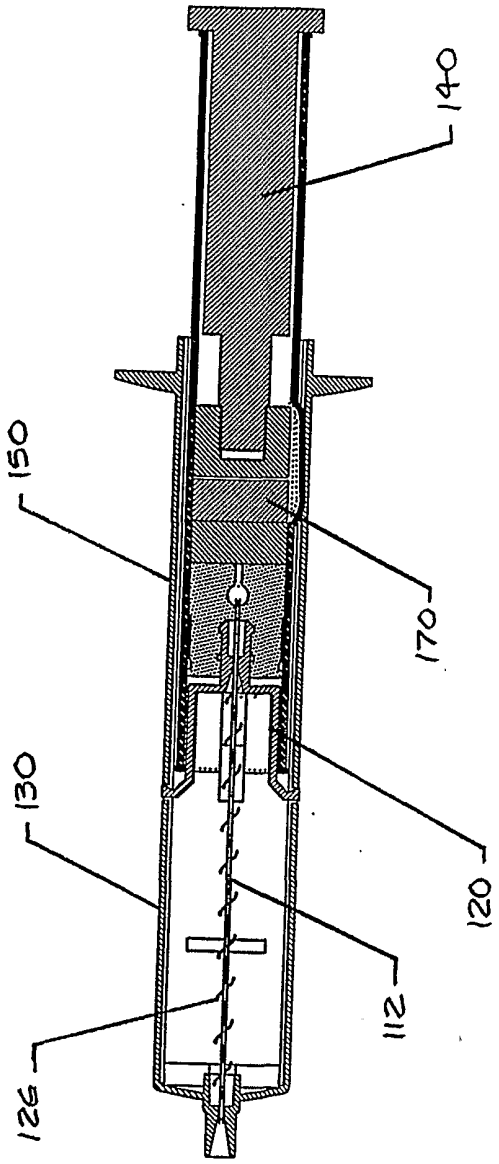


Figure 16

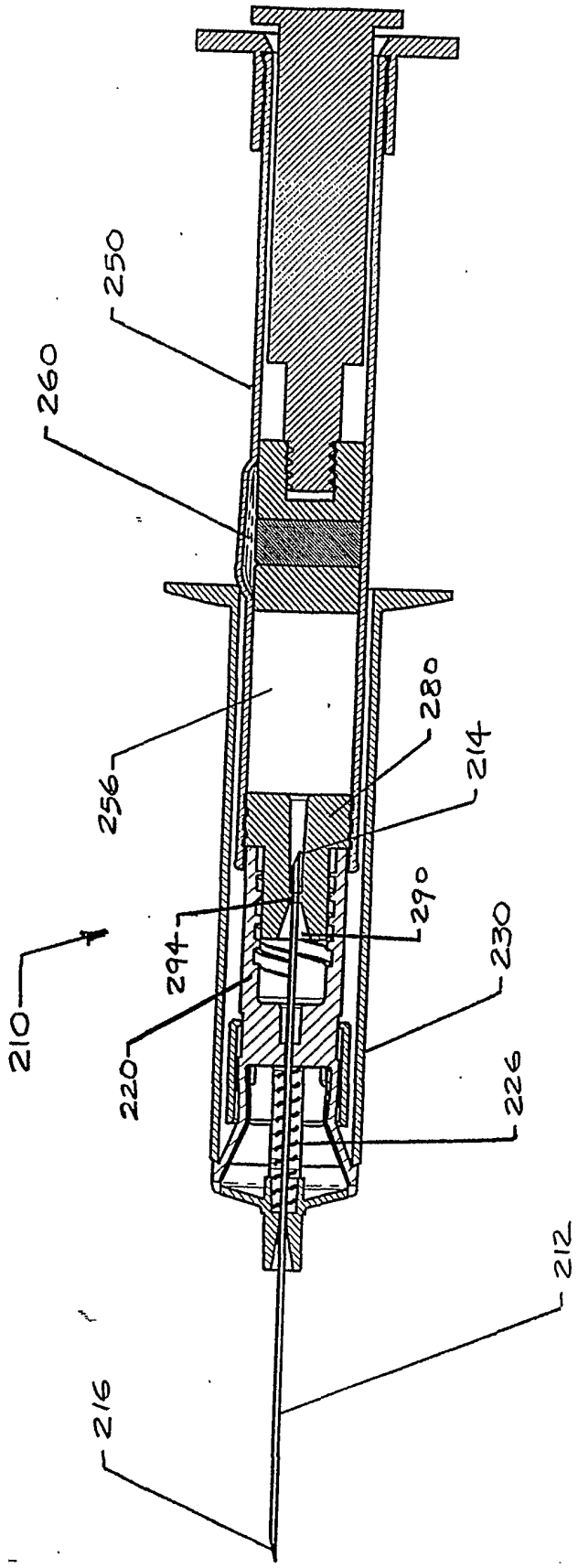


Figure 17

Figure 18

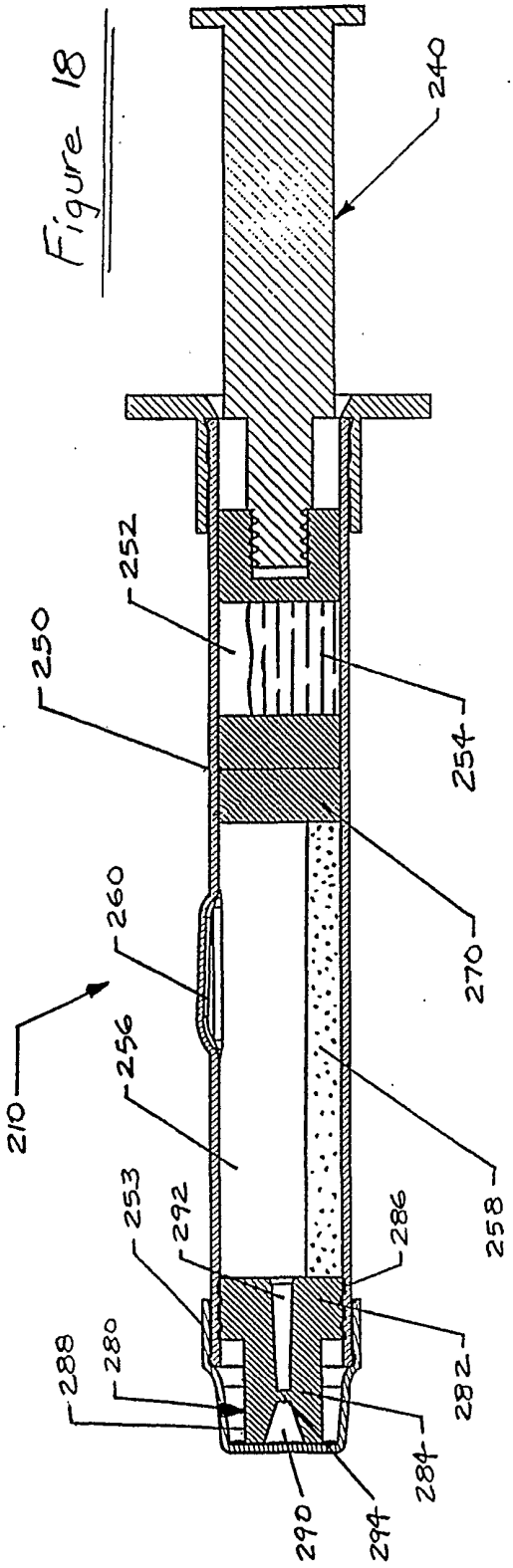


Figure 19

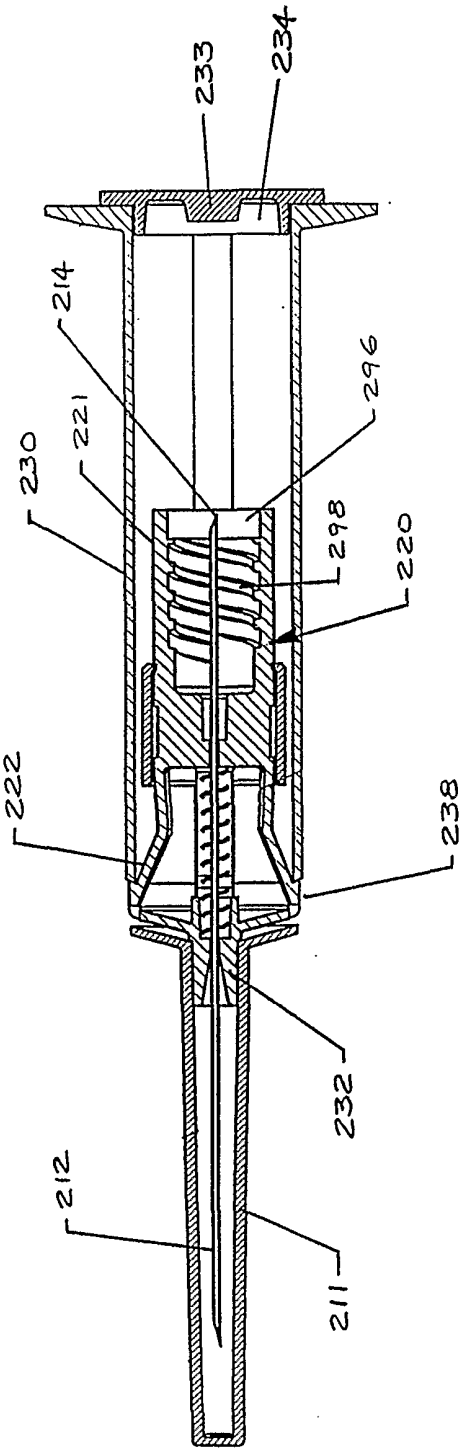
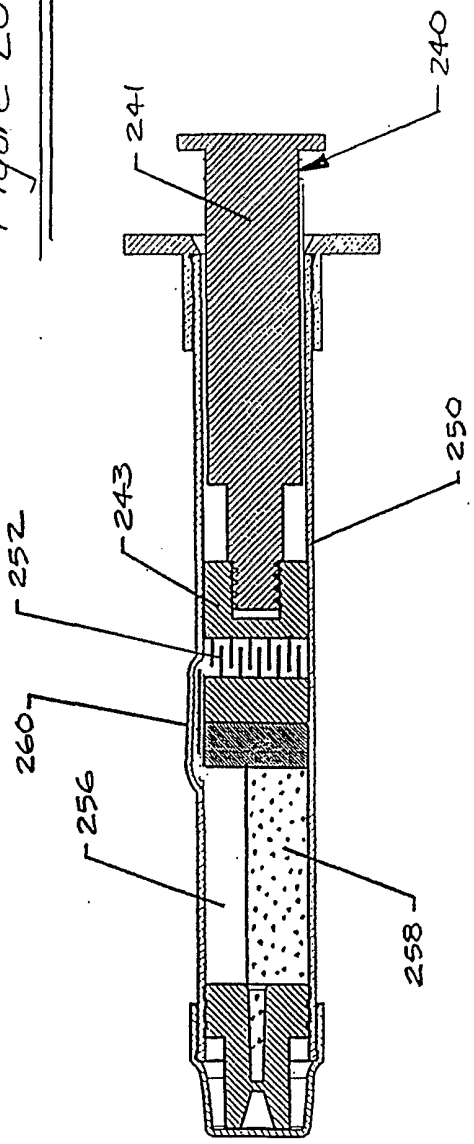


Figure 20



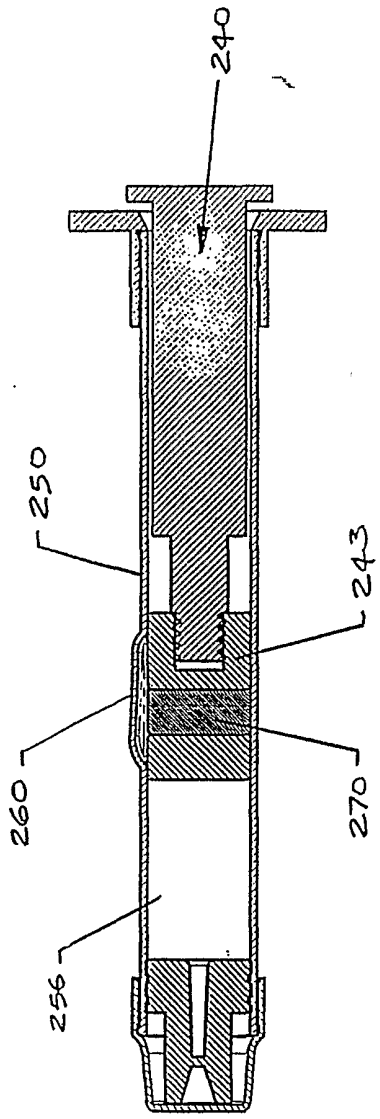


Figure 21

Figure 22

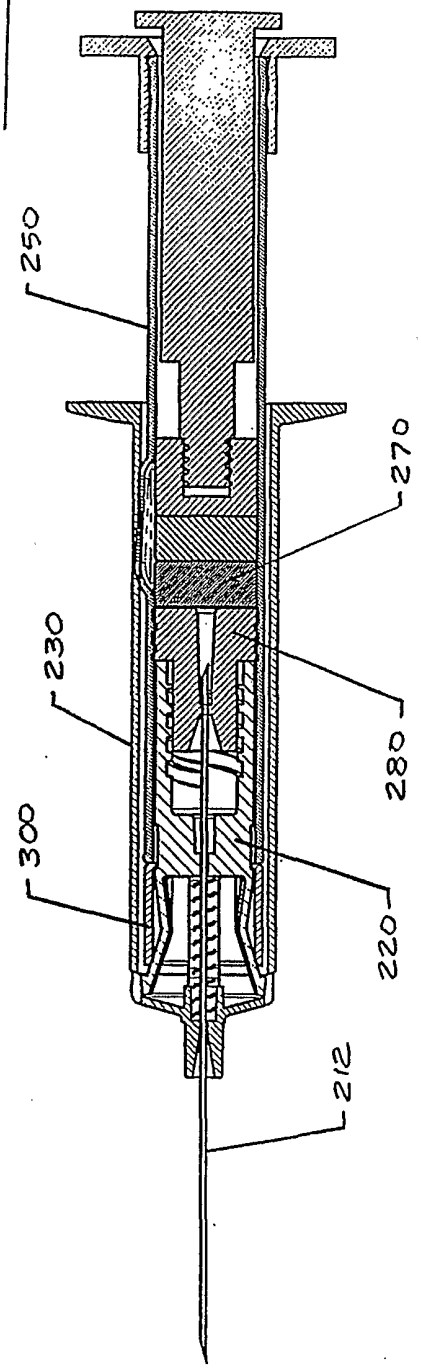
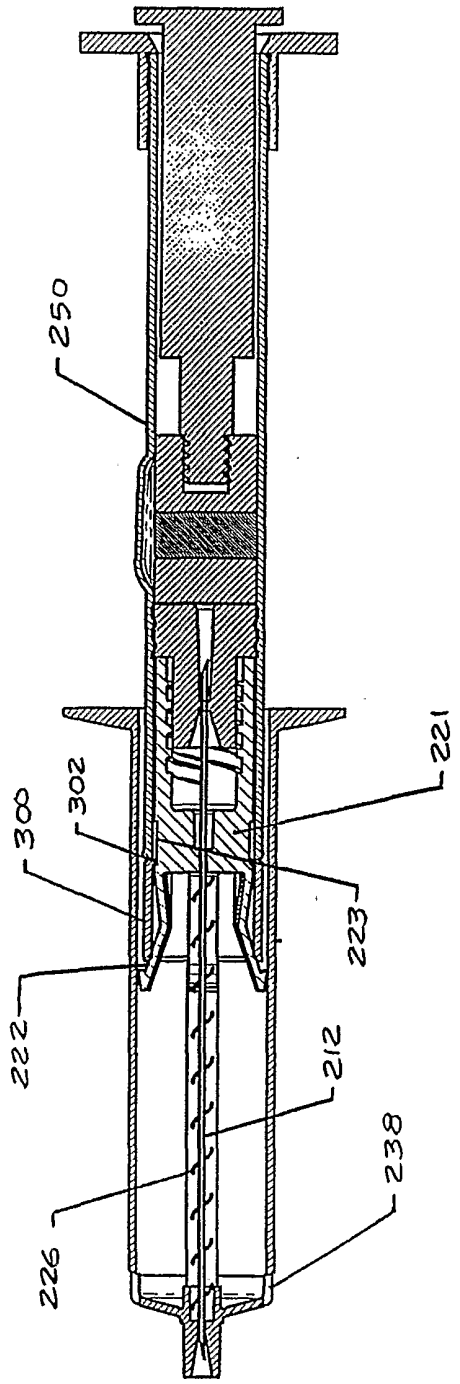


Figure 23



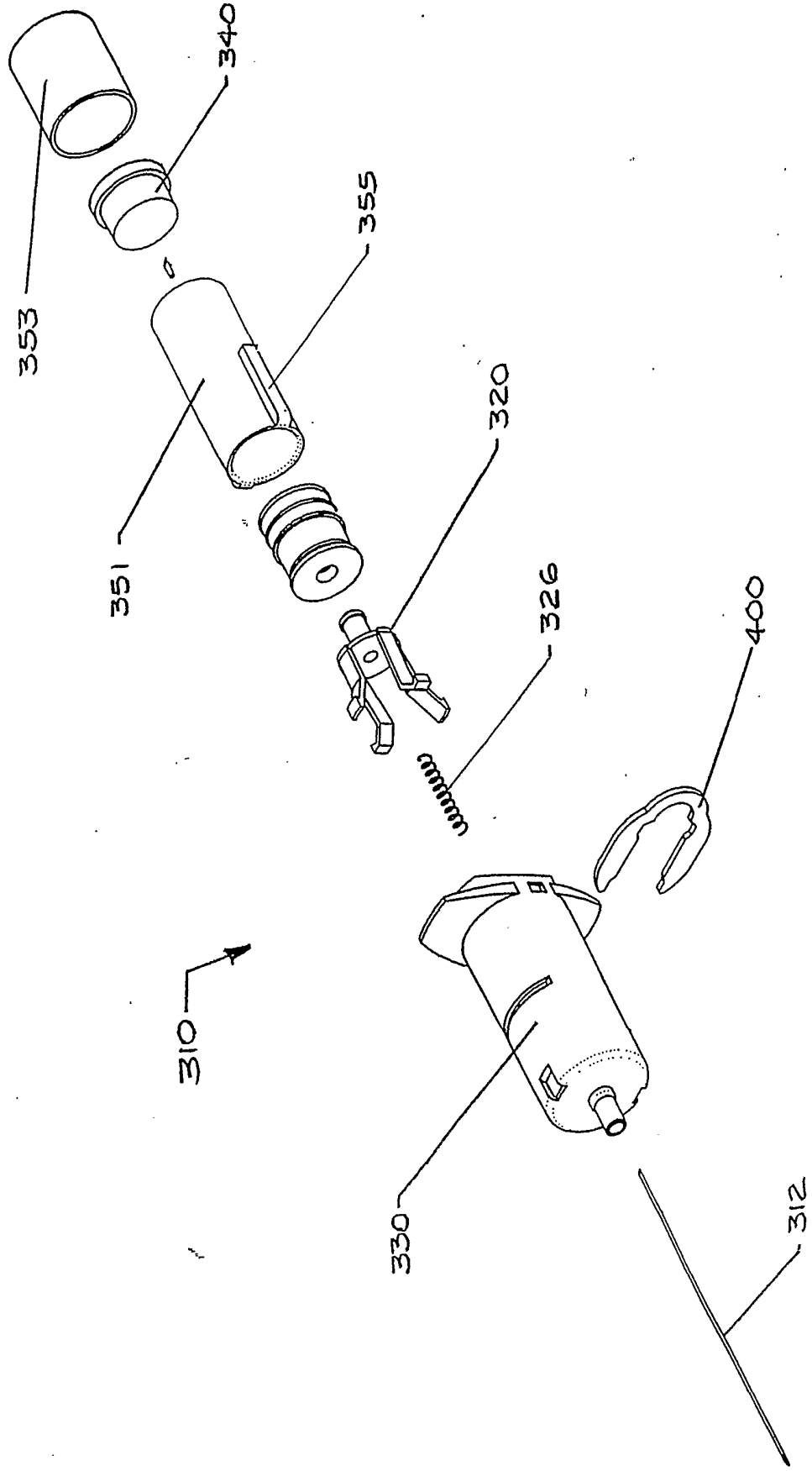


Figure 24

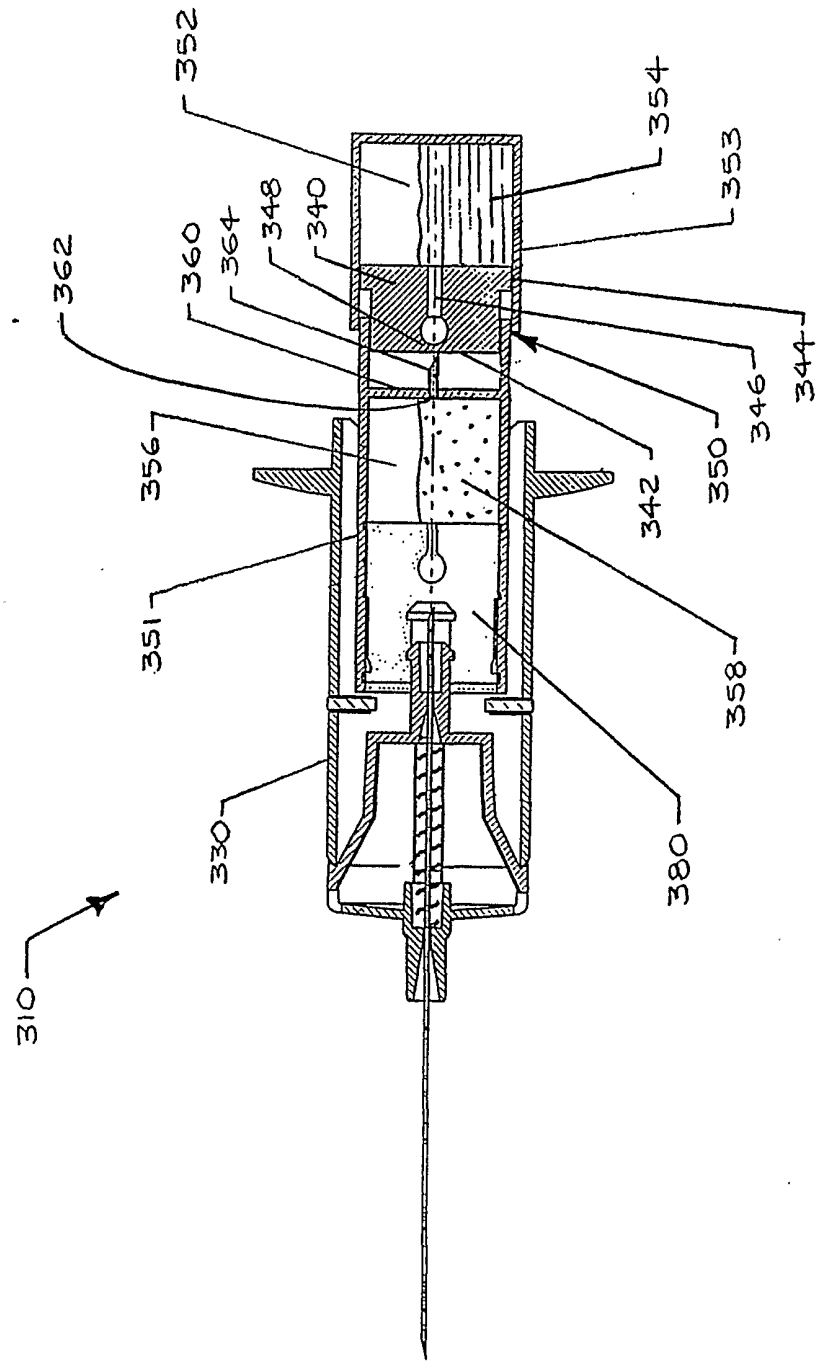

352
354
353
348
340
360
364
362
344
346
350
342
356
358
351
330
380
310

Figure 25

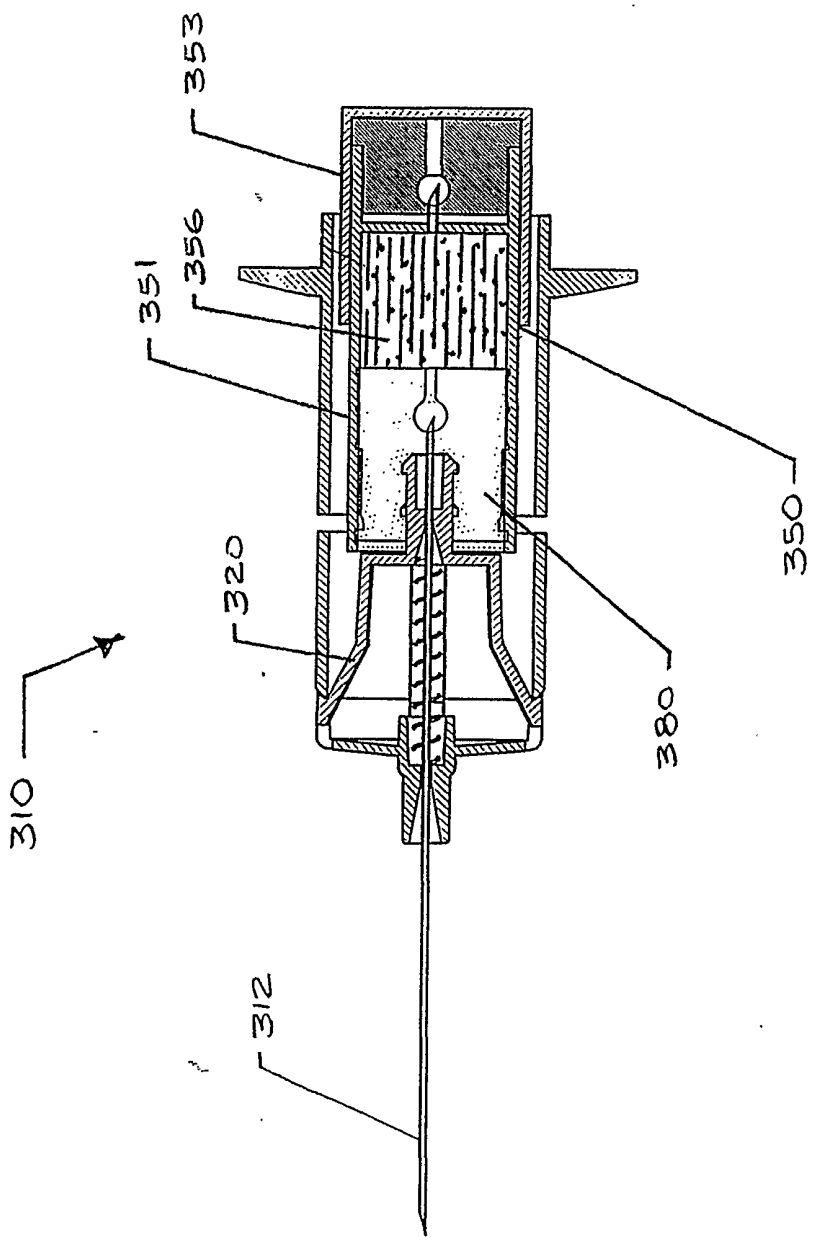


Figure 26

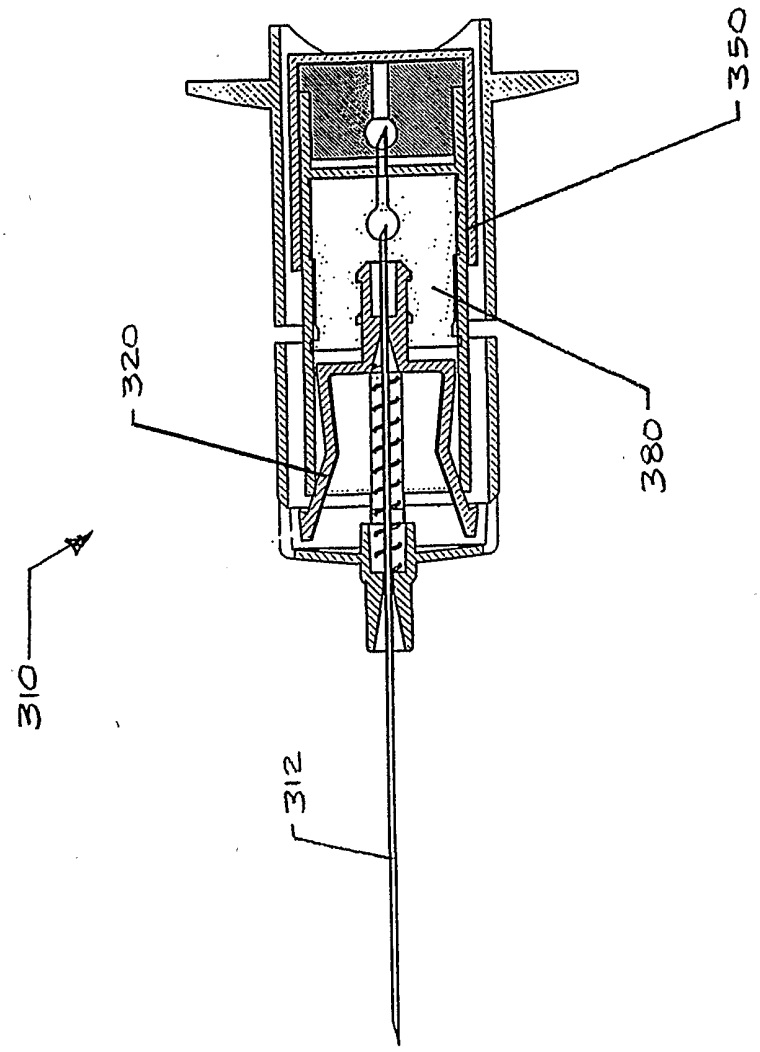


Figure 27

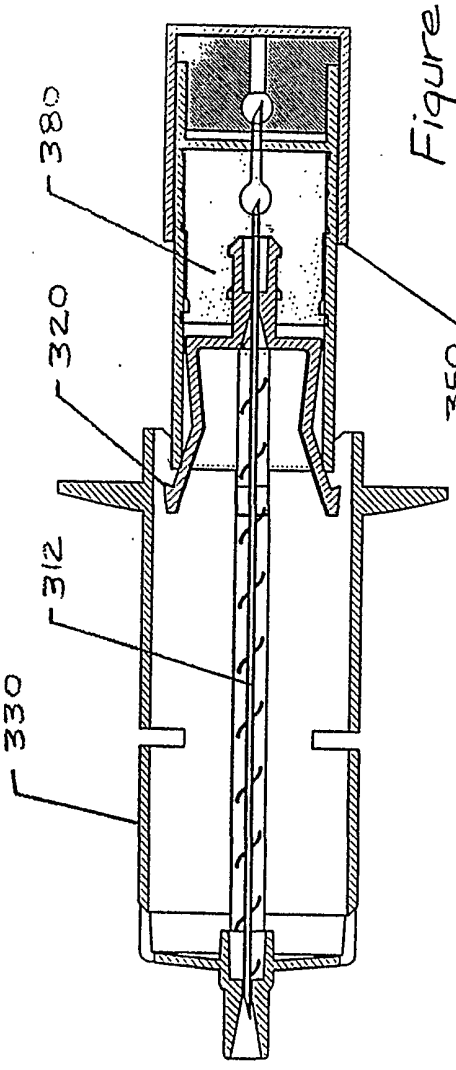


Figure 29

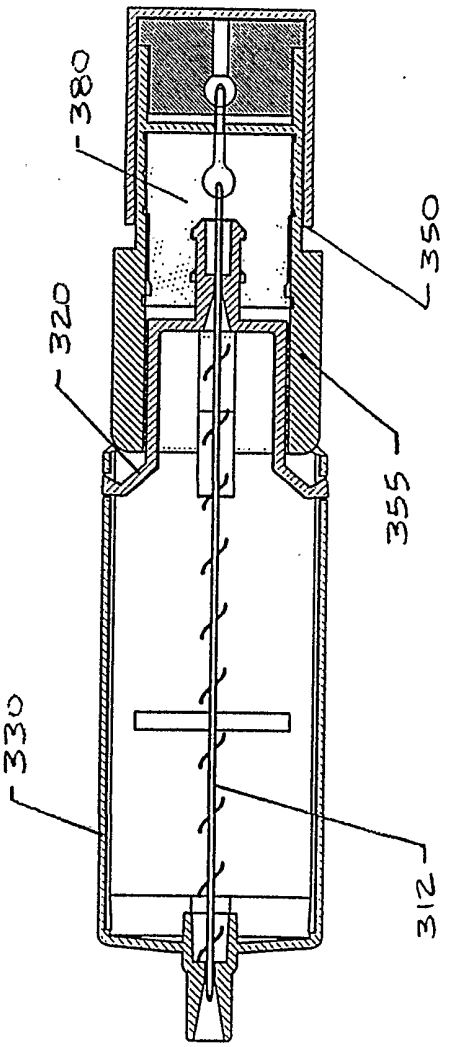


Figure 28