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(54) **AUTOINJECTOR WITH EXTENDABLE NEEDLE PROTECTOR SHROUD**

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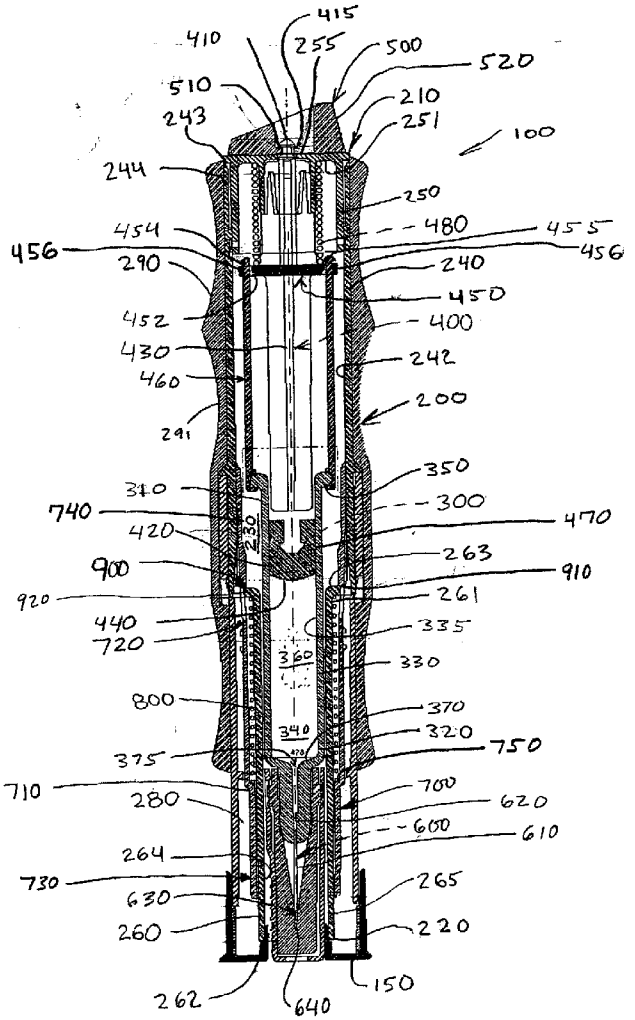
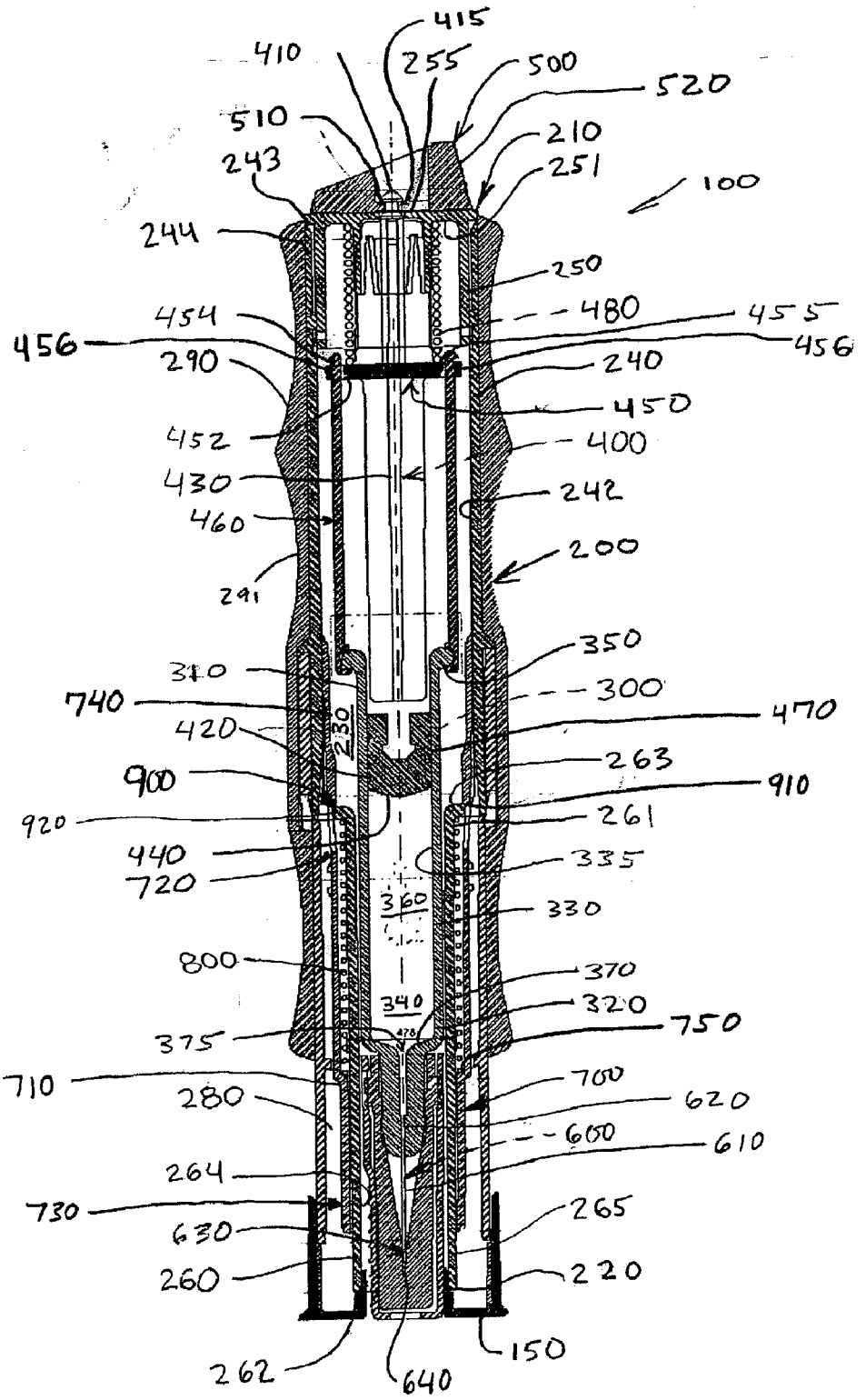
(57) **ABSTRACT**

The invention provides a syringe and a method for using the same. The syringe includes a housing having a reservoir disposed therein and a plunger to be received by the reservoir, the plunger being moveable between a first plunger position and a second plunger position. The syringe also includes a plunger spring to urge the plunger toward the second plunger position and an actuator to deploy the plunger spring. The syringe also includes a needle proximate the distal end of the housing displaceable from a first needle position to a second needle position, and a shroud coupled with the housing. The shroud is moveable between a retracted position and an extended position, the shroud surrounding at least a portion of the needle when in the extended position. The syringe also includes an interlocking assembly, a shroud spring, and a locking assembly configured to inhibit movement of the shroud.




415
410
255
500
520
510
210
243
251
100
244
250
454
480
455
456
456
290
240
450
452
400
430
242
460
200
291
350
310
300
740
470
420
230
263
900
910
920
261
440
335
720
360
330
800
370
340
320
375
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700
280
620
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610
264
730
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630
260
220
262
640
150

FIG. 1

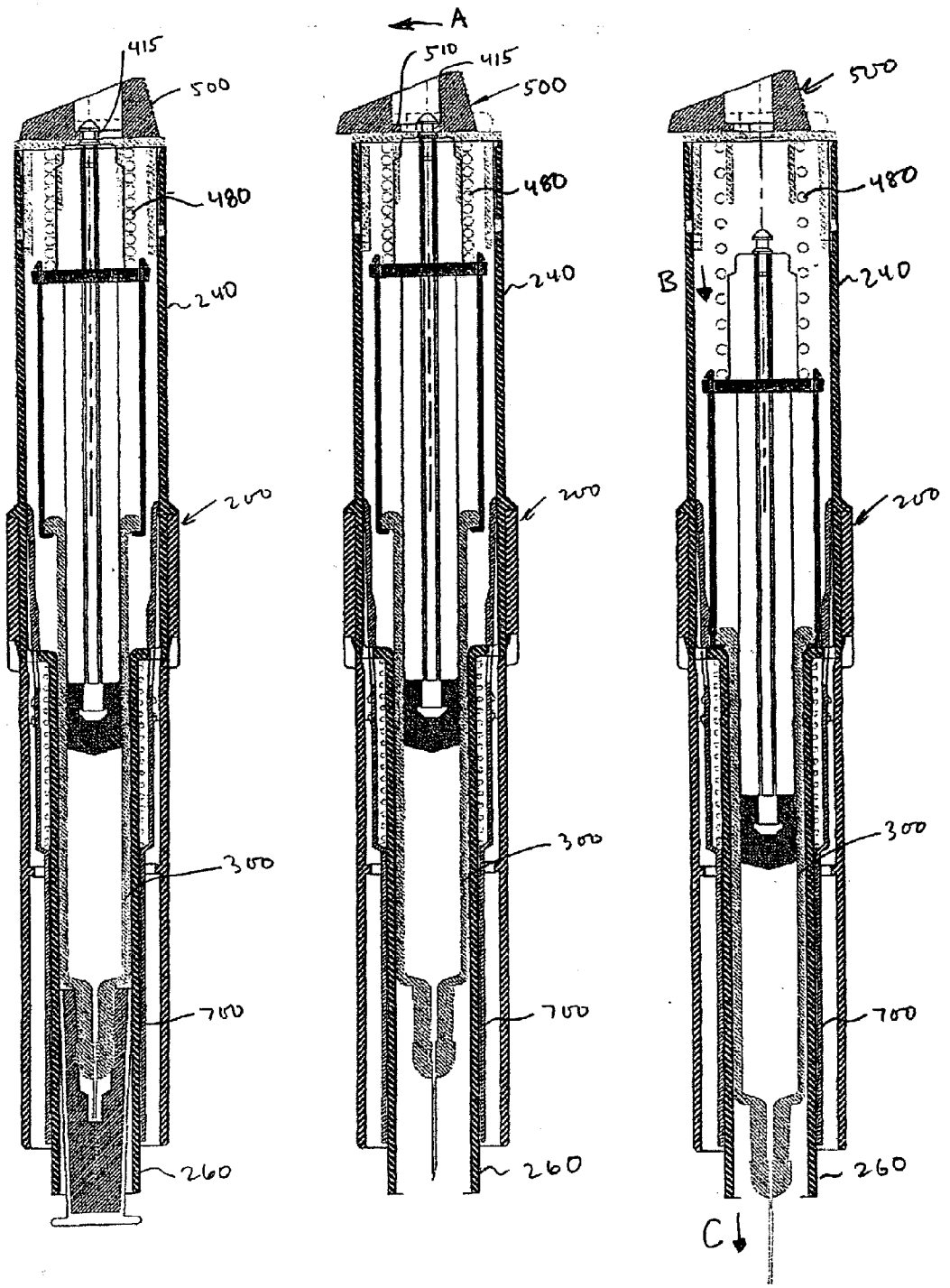

FIG. 2(a) FIG. 2(b) FIG. 2(c)

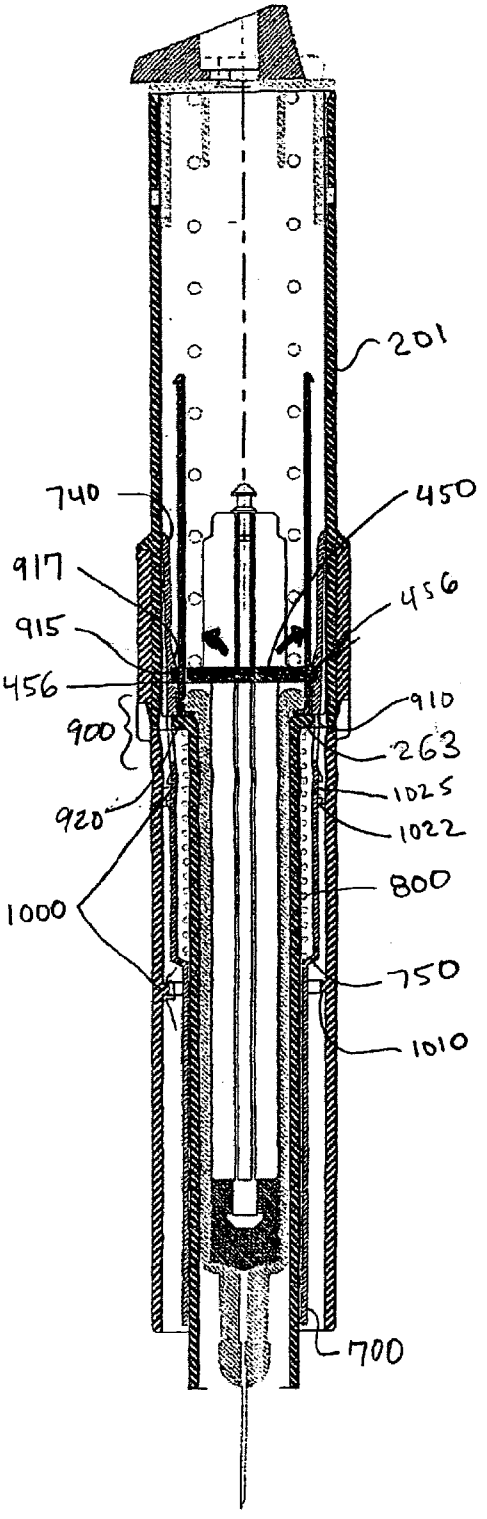
201
740
450
917
456
915
456
900
910
263
1025
920
1022
1000
800
750
1010
700

FIG. 2(d)

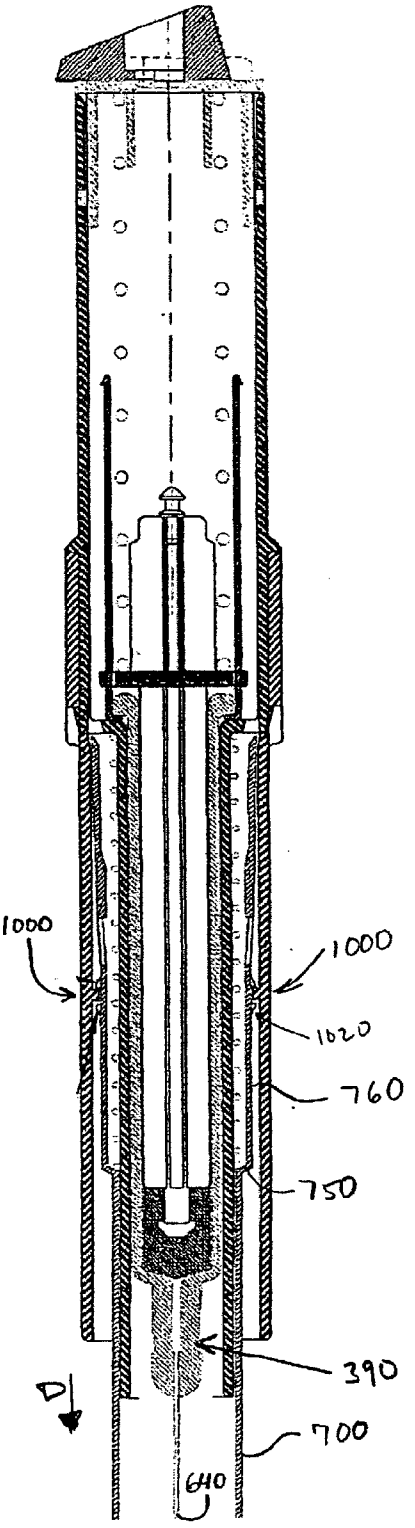
1000
1000
1020
760
750
390
D
700
640

FIG 2(e)

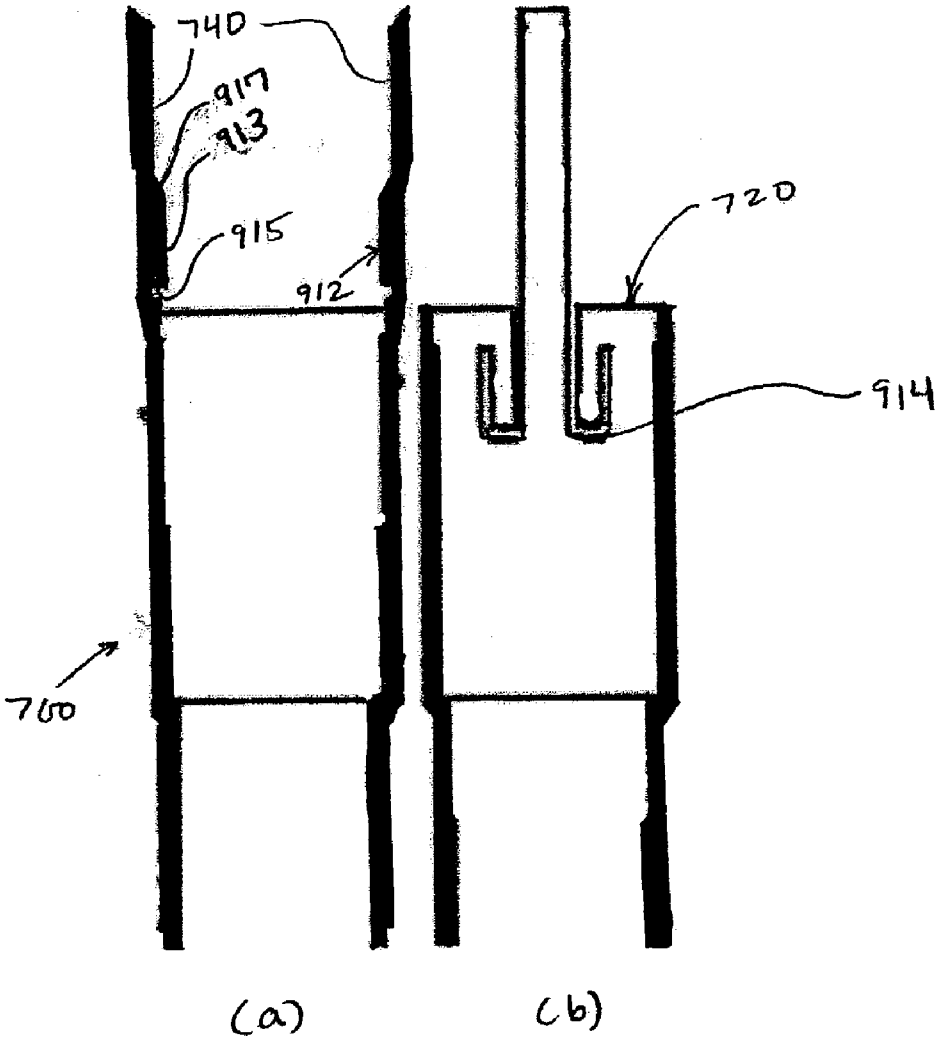

FIG. 3

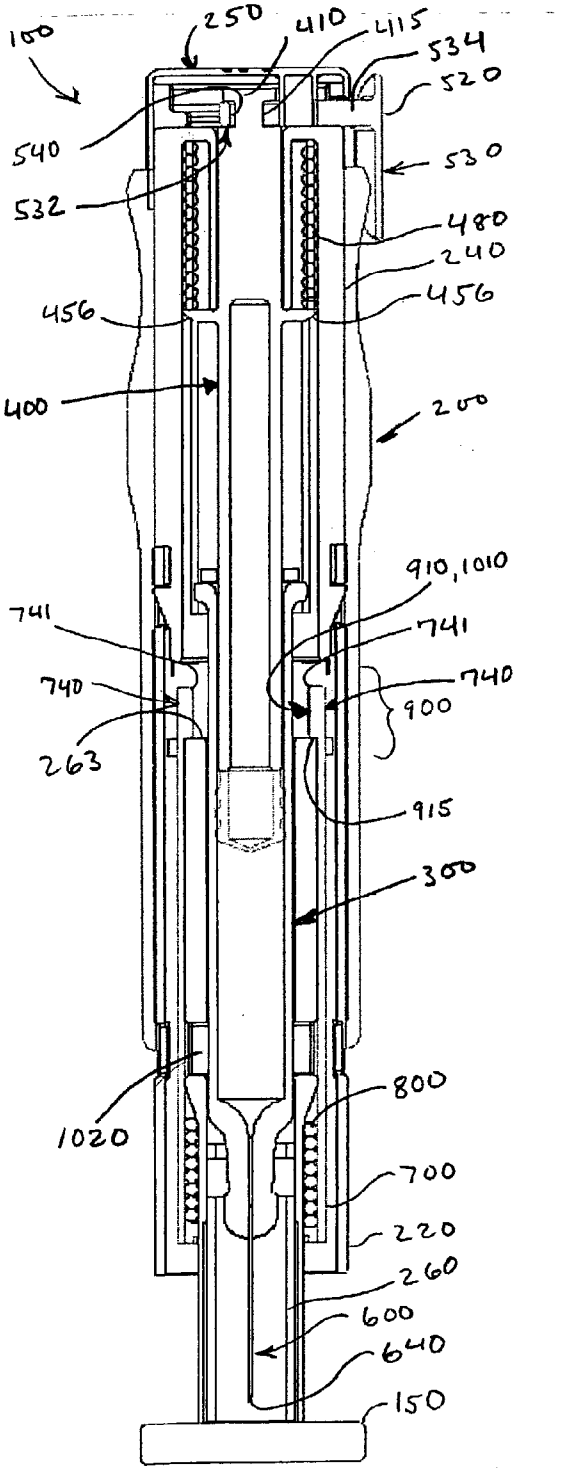
100
250
410
415
534
520
540
530
532
480
240
456
456
400
200
910,1010
741
741
740
740
900
263
915
300
800
1020
700
220
260
600
640
150

FIG. 4(a)

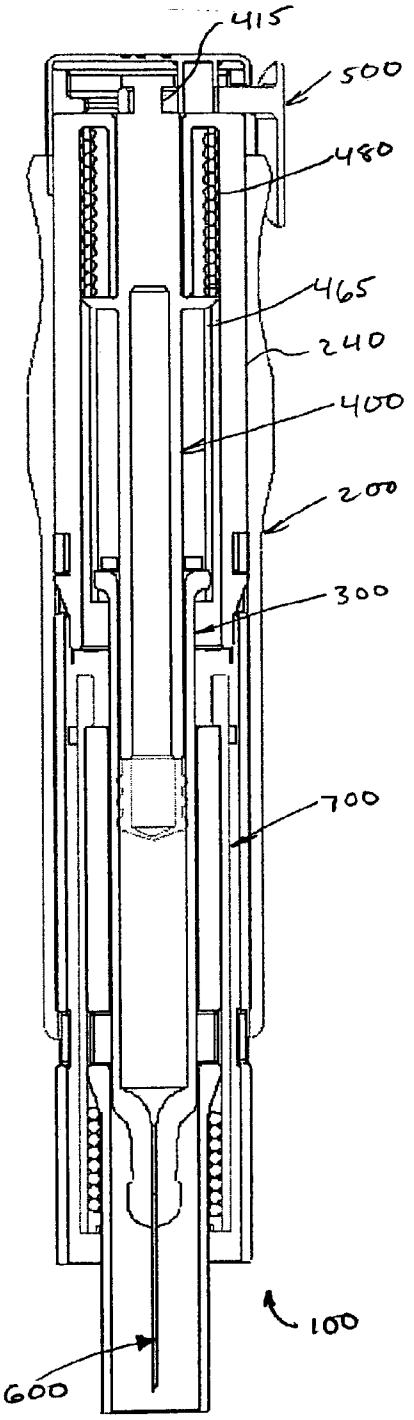
415
500
480
465
240
400
200
300
700
100
600

FIG. 4(b)

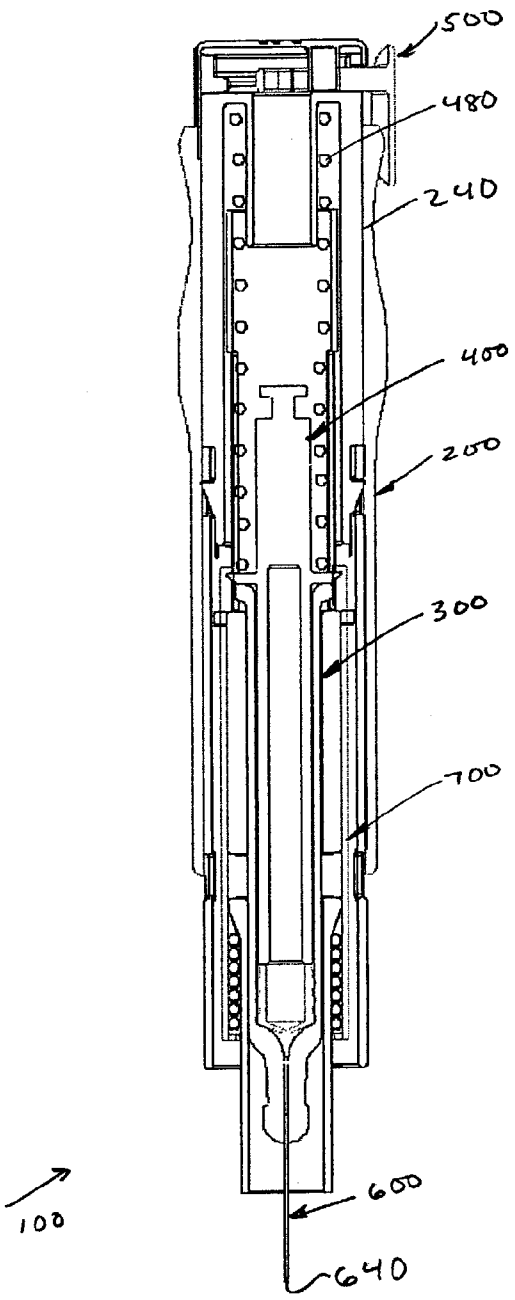
500
480
240
400
200
300
700
600
640
100

FIG. 4(c)

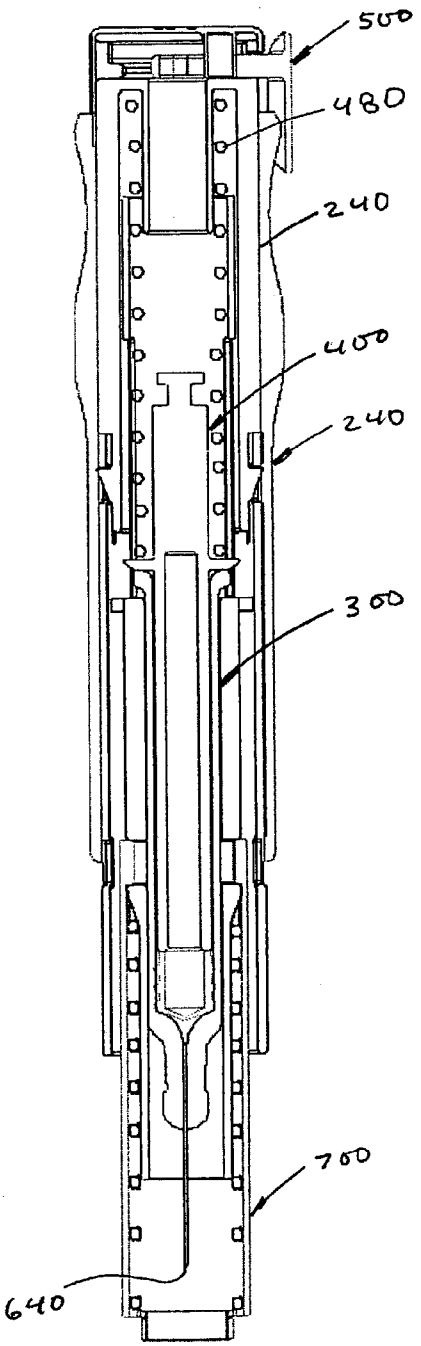
500
480
240
400
240
300
700
640

FIG. 4(d)

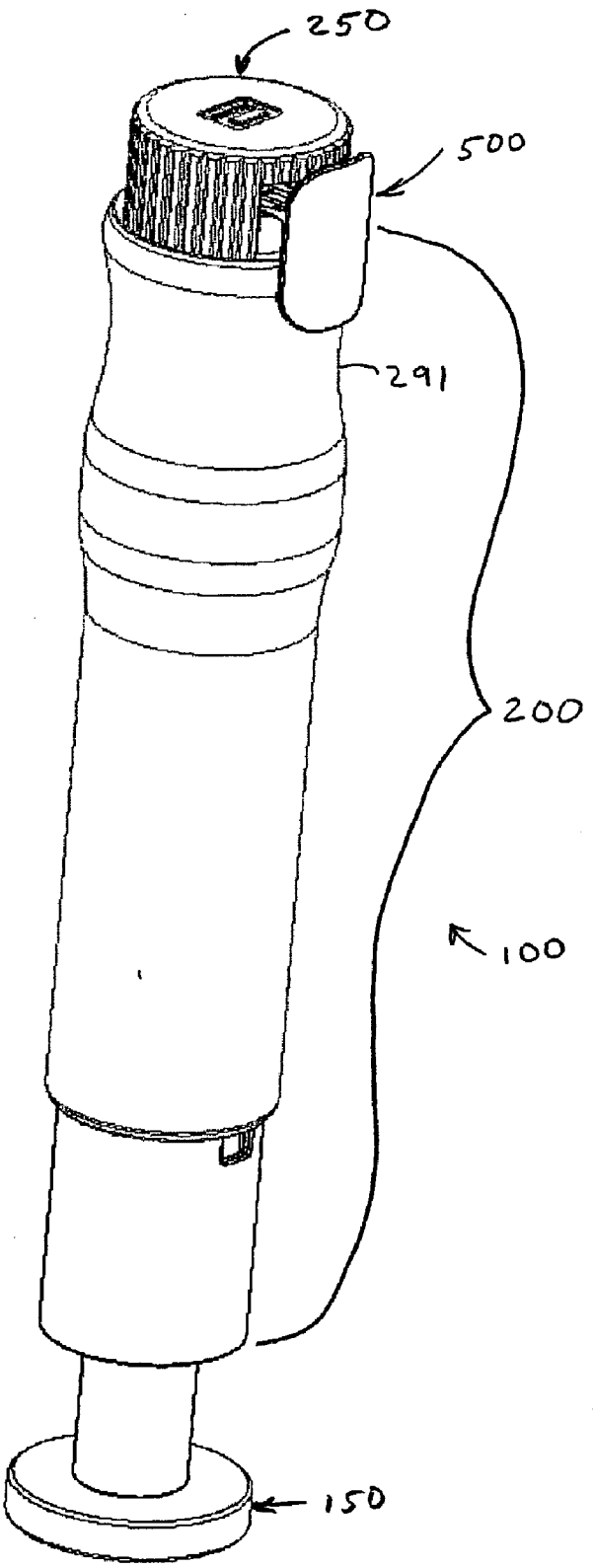

FIG. 5

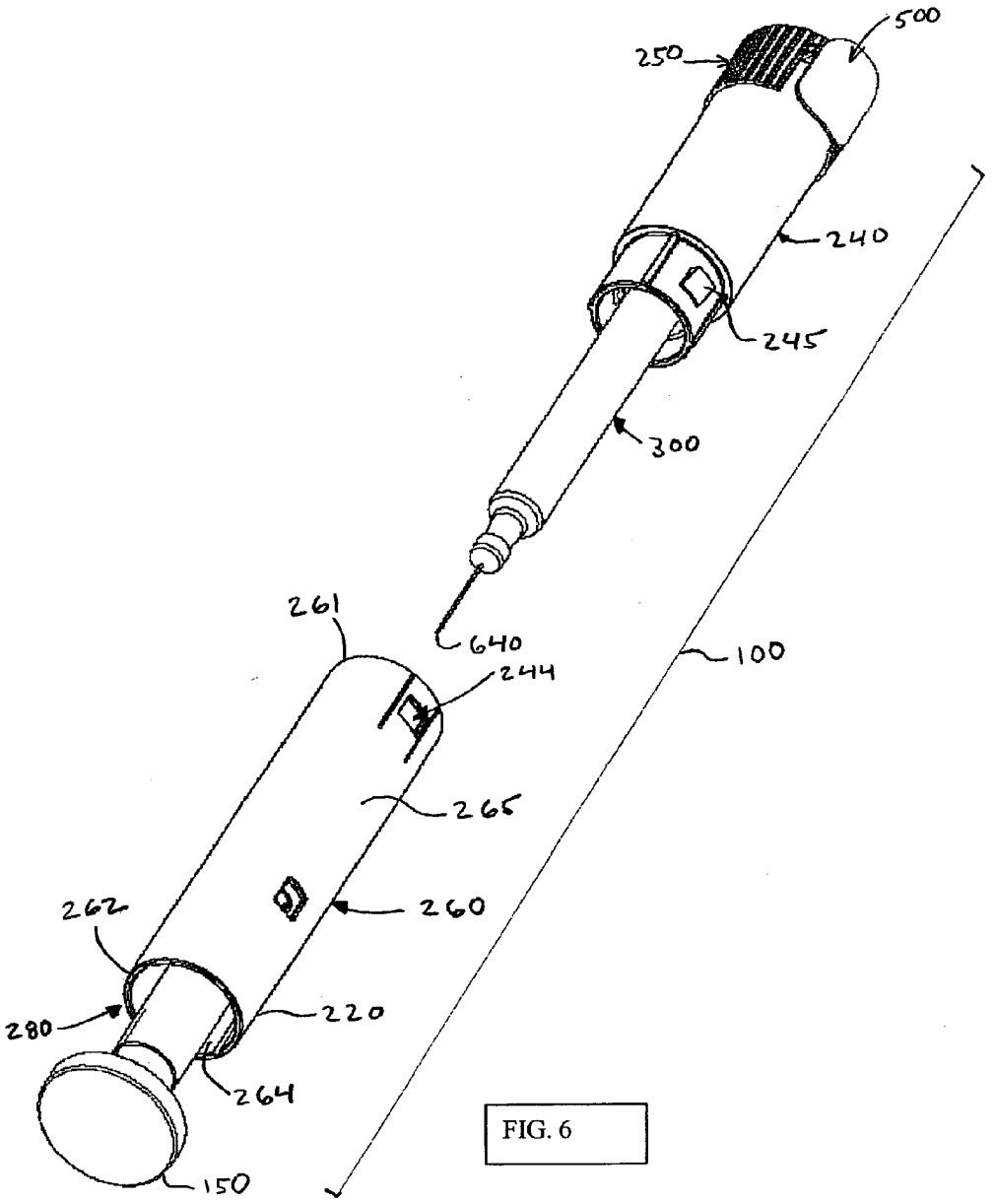

FIG. 6

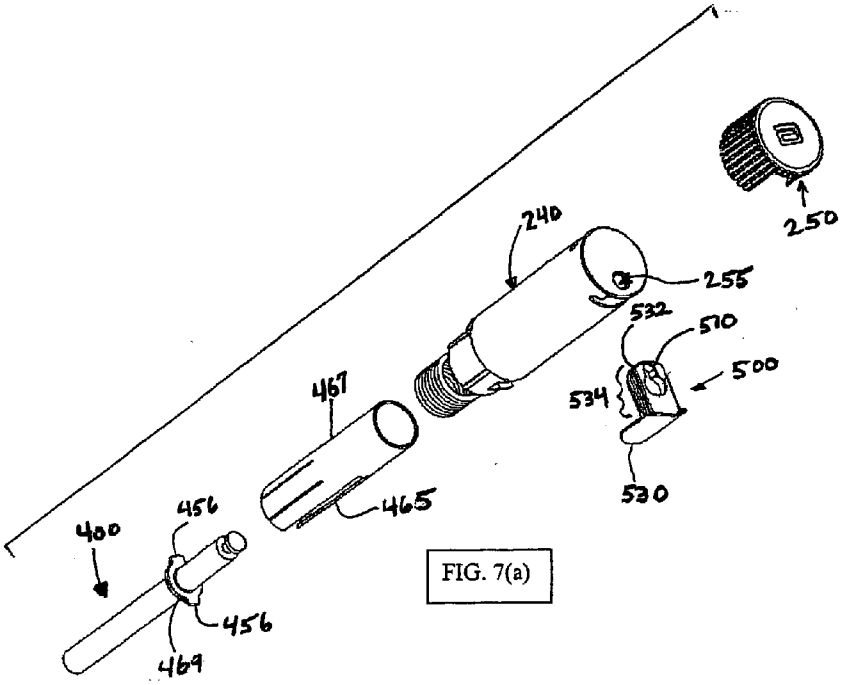
240
250
255
532
510
500
534
467
530
465
456
400
456
469

FIG. 7(a)

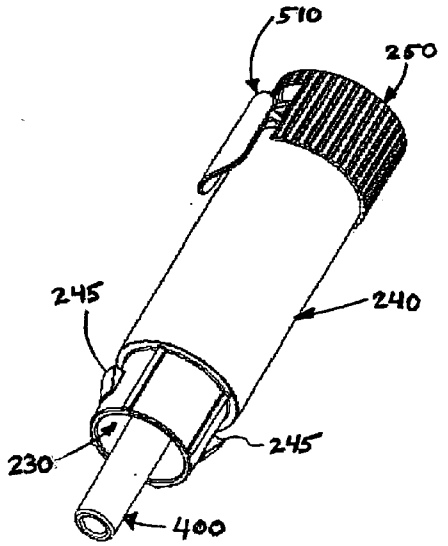
510
250
245
240
230
245
400

FIG. 7(b)

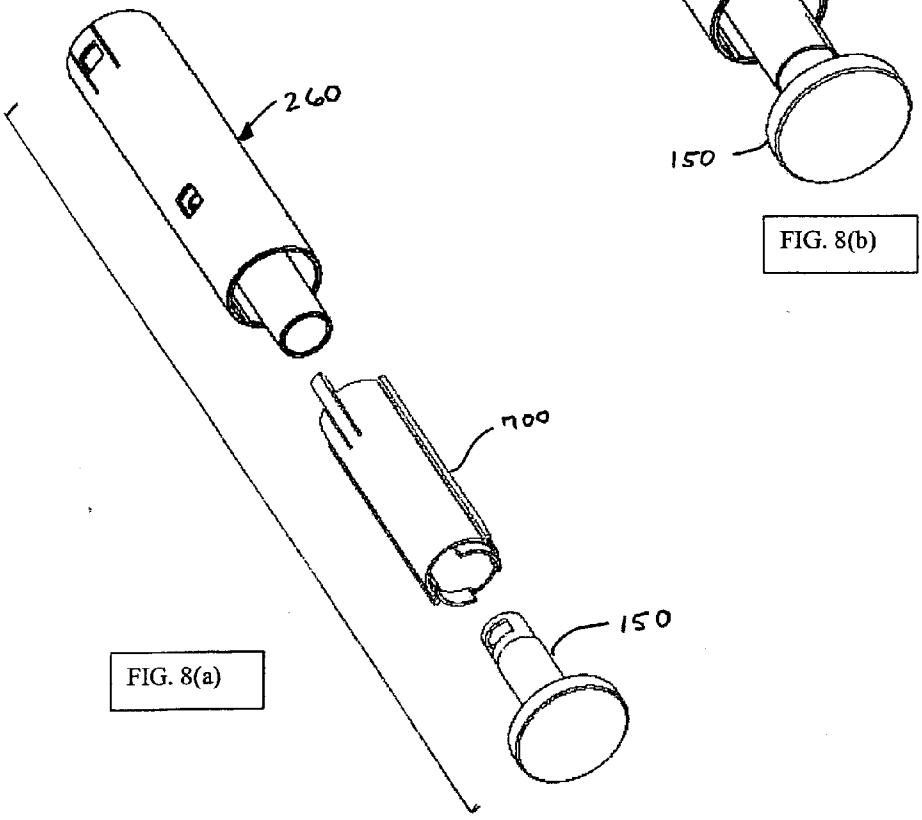

FIG. 8(a)

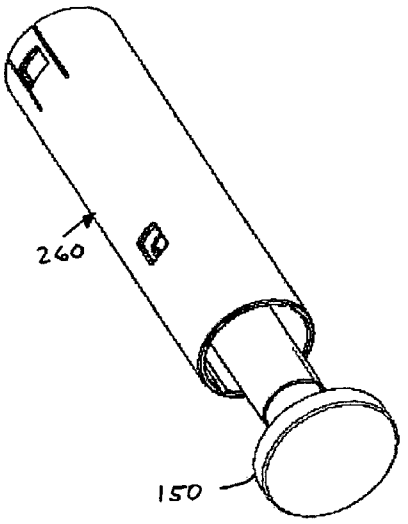

FIG. 8(b)

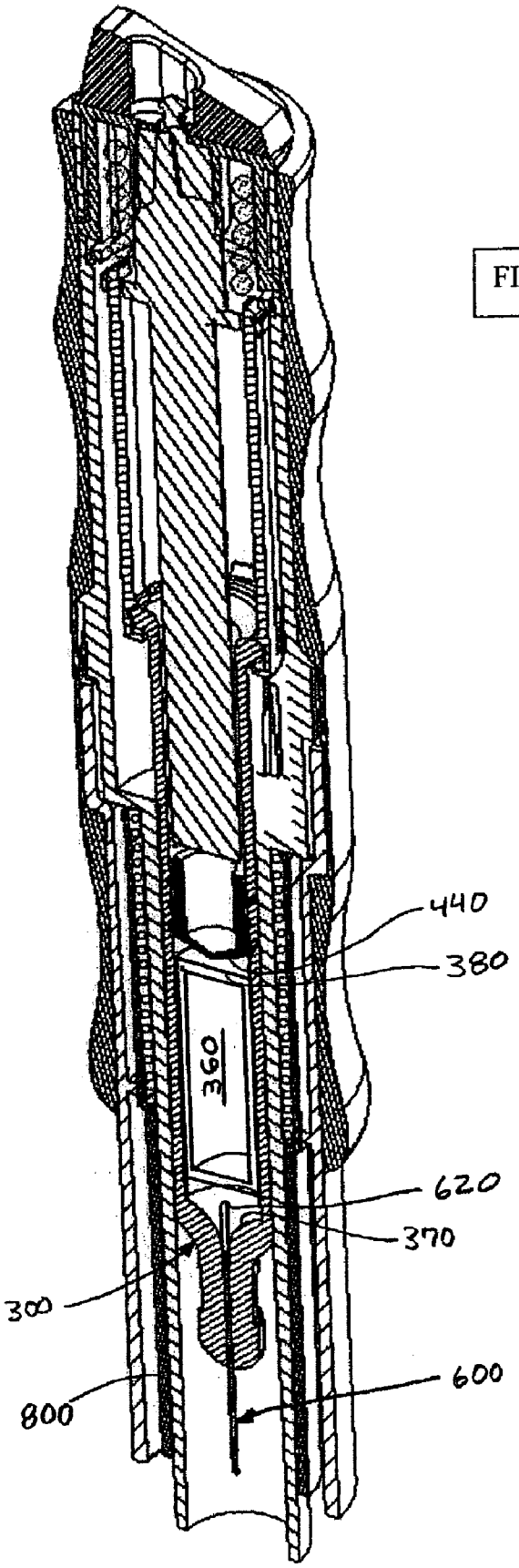

FIG. 9

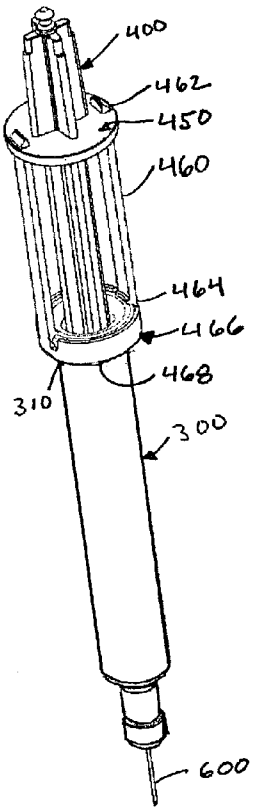

FIG. 10

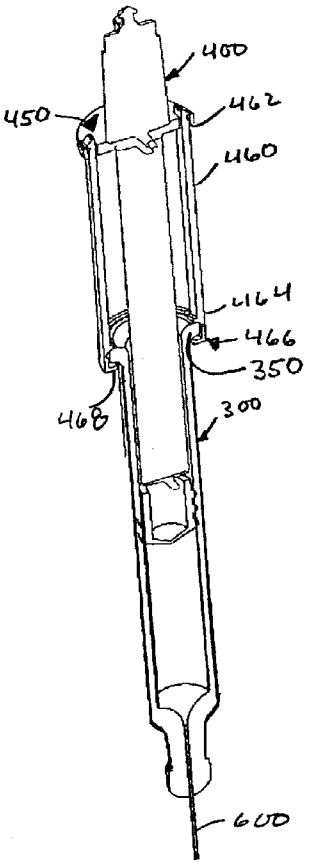

FIG. 11

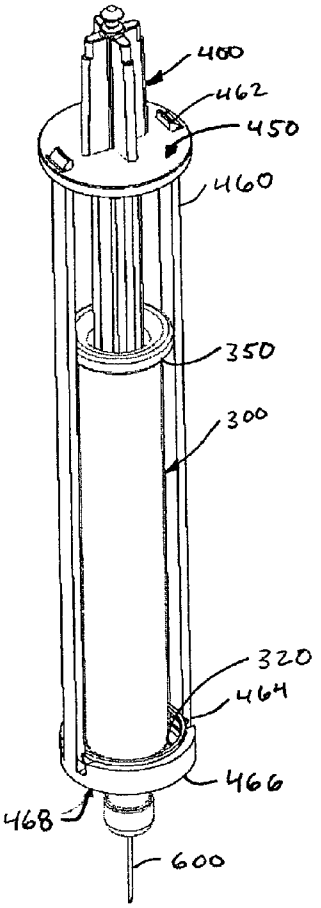

FIG. 12

AUTOINJECTOR WITH EXTENDABLE NEEDLE PROTECTOR SHROUD

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention

[0002] The present invention relates to an autoinjector syringe for administering a beneficial agent to a patient. Particularly, the present invention is directed to a syringe including a spring-activated plunger and a spring deployed extendable shroud in combination with a needle or similar penetrator.

[0003] 2. Description of Related Art

[0004] The use of a sharp-pointed piercing element, such as a syringe needle or the like, entails the risk of accidental needle sticks. To avoid such accidents, a variety of safety systems are known and available to protect the user of a syringe.

[0005] A first type of safety system includes a rigid cylindrical safety shield arranged to telescope over the syringe barrel. Such a shield can be moved between a retracted position to expose the syringe needle for use, and an extended position to surround the needle with the shield. For example, U.S. Pat. No. 6,419,658, U.S. Pat. No. 6,322,540, U.S. Pat. No. 6,319,234, U.S. Pat. No. 6,319,233, U.S. Pat. No. 4,425,120, U.S. Pat. No. 4,573,976, U.S. Pat. No. 4,850,994 and U.S. Pat. No. 4,923,447 disclose various extendable shield systems for a hypodermic syringe. It is ordinarily desirable to lock the needle shields in the protected position, and a number of prior art designs provide for such locked conditions. Furthermore, some systems, such as those disclosed in U.S. Pat. No. 5,201,708, U.S. Pat. No. 5,242,240 and U.S. Pat. No. 5,318,538 are also designed to allow the shields to be retracted from their locked, extended positions.

[0006] The above-described device using a spring loaded sheath can be disadvantageous because the spring and shroud are generally mounted on the outside of the syringe barrel and are thereby vulnerable to mechanical interference with foreign objects. Moreover, such devices are manually deployed, which is not particularly conducive for self-administering medication by those who suffer from arthritis or similar ailments that limit digital dexterity.

[0007] Another type of safety system has been developed for use with a device commonly referred to as an autoinjector. An autoinjector is generally a syringe configured to automatically extend a needle and inject a beneficial agent into a patient when a button or similar actuator is deployed. Hence, it is known for some autoinjectors to be configured to retract the needle into the housing of the device when the injection is complete. Devices of this type are described, for example, in U.S. Pat. No. 6,099,503, U.S. Pat. No. **5,779,677**, and U.S. Pat. No. 5,300,030. These types of devices are advantageous because only a single hand is needed to complete an injection. Furthermore, the needle can be configured to be extendable such that the syringe needle is not normally visible to the user before or after the injection. This is advantageous for self-administered drug therapy.

[0008] Such conventional methods and systems generally have been considered satisfactory for their intended purpose. However, the autoinjector described above can not be used for its intended purpose if the mechanism that returns the needle into the housing should fail for some reason. Stated another way, if the needle does not retract automatically, the user has no safe means of covering the needle point.

[0009] There thus remains a continued need for an efficient and economic method and system for automatically injecting a beneficial agent that is easy to use and helps prevent against accidental needle sticks after use.

SUMMARY OF THE INVENTION

[0010] The purpose and advantages of the present invention will be set forth in and apparent from the description that follows, as well as will be learned by practice of the invention. Additional advantages of the invention will be realized and attained by the methods and systems particularly pointed out in the written description and claims hereof, as well as from the appended drawings.

[0011] To achieve these and other advantages and in accordance with the purpose of the invention, as embodied and broadly described, the invention is directed to a syringe including a housing having a proximal end and a distal end. The housing has a reservoir disposed therein. The syringe also includes a plunger to be received by the reservoir. The plunger is moveable between a first plunger position and a second plunger position. A plunger spring is also provided to urge the plunger toward the second plunger position when the plunger spring is deployed. The plunger spring can be deployed by an actuator. The syringe also includes a needle or similar penetrator proximate the distal end of the housing. Also provided is a shroud coupled with the housing. The shroud is moveable between a retracted position and an extended position. The shroud surrounds at least a portion of the needle when in the extended position. A shroud spring is biased to urge the shroud toward the extended position when the shroud spring is deployed. Further, an interlocking assembly in communication with the shroud is provided. The interlocking assembly has a first condition to maintain the shroud in the retracted position and a second condition to deploy the shroud spring and allow movement of the shroud toward the extended position.

[0012] Preferably, the interlocking assembly can be coupled with the plunger so as to be switched from the first condition to the second condition when the plunger is moved to the second plunger position. For example, the interlocking assembly can include at least one flexible tab provided on the shroud and an engagement surface provided on the plunger, whereby the engagement surface flexes the tab when the plunger is moved to the second plunger position. Alternatively, the interlocking assembly can include a switch operable from outside the housing to manually switch the interlocking assembly from the first condition to the second condition.

[0013] In accordance with a further aspect of the invention, the actuator can include an engagement element to retain the plunger in the first position. The engagement element acts to release the plunger and thus deploy the plunger spring when the actuator is actuated. In a preferred embodiment, the plunger spring can be a mechanical spring element although known springs, such as hydraulic or pneumatic, can be used. The syringe can further comprise a removable cover positioned on the distal end of the housing before the syringe is used

[0014] Optionally, the needle is caused to be in fluid communication with the reservoir when the plunger is moved toward the second plunger position.

[0015] Additionally, the needle can be displaceable from a first needle position to a second needle position, such that the point of the needle extends from the housing when in the second needle position. The needle thus can be moved to the second needle position when the plunger is moved from the first plunger position toward the second plunger position.

[0016] Alternatively, and in accordance with a further aspect of the invention, the needle can be secured to the reservoir and the reservoir can be displaced with the needle.

[0017] In accordance with a further aspect of the invention, the syringe is provided with at least one guide element to provide registration between the reservoir and the plunger. The at least one guide element has a proximal end and a distal end. In one embodiment of the invention, the distal end of the guide element is fixedly attached to a mounting element that surrounds the reservoir. The mounting element is attached at a desired location along the reservoir, such as the proximal end of the reservoir. The mounting element may also be attached at the distal end of the reservoir.

[0018] Additionally, a locking assembly configured to inhibit movement of the shroud when moved to the extended position can also be provided. The locking assembly can include a protuberance to be received by a corresponding recess.

[0019] The invention also includes a method that includes providing a syringe as described above; loading a beneficial agent in the reservoir of the syringe; positioning the needle of the syringe at an injection site of a patient; moving the plunger toward the second plunger position to dispense the beneficial agent from the reservoir through the needle; and switching the interlocking assembly to the second condition to deploy the shroud spring and allow movement of the shroud toward the extended position. Optionally, the movement of the shroud toward the extended position provides an indication to a patient that beneficial agent has been injected.

[0020] It is to be understood that both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the invention claimed.

[0021] The accompanying drawings, which are incorporated in and constitute part of this specification, are included to illustrate and provide a further understanding of the syringe and method of the invention. Together with the description, the drawings serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] **FIG. 1** is a cross-sectional side view of a first representative embodiment of the syringe in accordance with the present invention.

[0023] FIGS. **2**(*a*)-**2**(*e*) are schematic views depicting steps of one method of using the syringe of **FIG. 1** in accordance with the present invention.

[0024] FIGS. **3**(*a*)-**3**(*b*) are cross-sectional side views of the shroud of the syringe of **FIG. 1**.

[0025] **FIG. 4**(*a*)-**4**(*d*) are a cross-sectional side views depicting steps of a method of using a second representative embodiment of the syringe in accordance with the invention.

[0026] **FIG. 5** is a perspective side view of the exterior of the second representative embodiment of the syringe of **FIG. 4**.

[0027] **FIG. 6** is an exploded perspective view of the second representative embodiment of the syringe of **FIG. 5**.

[0028] **FIG. 7**(*a*) is an exploded perspective view of a distal portion of the second representative embodiment of the syringe of **FIG. 4** in an unassembled state.

[0029] **FIG. 7**(*b*) is an exploded perspective view of a distal portion of the second representative embodiment of the syringe of **FIG. 4** in an assembled state.

[0030] FIGS. **8**(*a*) is an exploded perspective view of a proximal portion of the second representative embodiment of the syringe of **FIG. 4** in an unassembled state.

[0031] FIGS. **8**(*b*) is an exploded perspective view of a proximal portion of the second representative embodiment of the syringe of **FIG. 4** in an assembled state.

[0032] **FIG. 9** is a perspective cross-sectional view of a third representative embodiment of the syringe in accordance with the invention.

[0033] **FIG. 10** is a perspective view of the selected components of **FIG. 1**.

[0034] **FIG. 11** is a perspective cross-sectional view of selected components of the embodiment of **FIG. 1**.

[0035] **FIG. 12** is a perspective view of selected components depicting another embodiment of the syringe in accordance with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0036] Reference will now be made in detail to the present preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. The method and corresponding steps of the invention will be described in conjunction with the detailed description of the apparatus. The methods and apparatus presented herein can be used for injecting beneficial agents into a patient. The present invention is particularly suited for the self-administration of beneficial agents, particularly in the case of those who suffer from debilitating diseases, such as arthritis or the like. In accordance with the invention, it is possible and desired to provide an autoinjector mechanism that simplifies the complete injection cycle involving a sharp needle tip, and concludes with a shroud positioned about the needle tip to protect the user and others from the needle tip. This is of particular advantage where a user suffers from arthritis, and has limited digital dexterity.

[0037] For purpose of explanation and illustration, and not limitation, an exemplary embodiment of the syringe in accordance with the invention is shown in **FIG. 1** and is designated generally by reference character **100**. This exemplary embodiment is also depicted in FIGS. **2**(*a*)-**2**(*e*). Additional embodiments are shown in **FIGS. 4-9** for purpose of illustration and not limitation.

[0038] Generally, a syringe includes a tubular body and a needle having a needle point. For example, and for purpose of illustration only, **FIG. 1** shows a syringe **100** in accordance with the invention having a housing **200**, a reservoir **300**, a plunger **400**, a plunger spring **480**, an actuator **500**, a needle **600** and an interlocking assembly **900**. Alternative embodiments or variations of a syringe also are suitable for the present invention as will be recognized from the description below. Additionally, although not necessary, a removable cover **150**, can be provided for the syringe **100**, as shown in **FIG. 1**.

[0039] The syringe **100** of the present invention can be provided with a beneficial agent contained in the reservoir prior to syringe distribution. The syringe is preferably provided in a "loaded" condition ready for use. Preferably, the syringe also has a guard when distributed. The guard protects the actuator from accidental deployment of the syringe. The syringe **100** can therefore be distributed with the needle disposed in a first needle position inside the housing with the removable cover covering the needle. In preparation for injection, the removable cover is removed and the syringe is positioned at an injection site of a patient. The actuator is then actuated, thereby deploying the plunger spring. The plunger spring causes the plunger, reservoir and needle to advance distally from the actuator, and the needle pierces the skin of the patient. The plunger spring continues to push on the plunger, causing the contents of the reservoir to be dispensed into the patient. After the reservoir has been evacuated, the shroud is deployed. The deployment of the shroud is an indication to the user that the injection cycle has completed. The user then removes the syringe needle from the skin by pulling the syringe **100** away from the injection site. Once pulled away from the patient's skin, the shroud fully extends to a fully extended position and snaps into place, covering the needle point. Advantageously, the user is inhibited from seeing the needle point throughout the procedure.

[0040] In accordance with the present invention, the syringe device includes a housing to contain a reservoir, and if desired, a needle before the syringe is used.

[0041] For example and not for purposes of limitation, **FIG. 1** depicts a housing **200** as embodied herein; the housing having a proximal end **210** and a distal end **220**. As embodied herein, the housing **200** has a generally tubular exterior wall portion **240** and a generally tubular interior wall portion **260**. An optional outer grip layer **290** can be formed around exterior wall portion **240**. Grip layer **290** preferably has recessed portions **291** that enable secure gripping by a user. Interior wall portion **260** is preferably, but not necessarily, disposed concentrically inside exterior wall portion **240**. Interior wall portion **260** has a proximal end **261** and a distal end **262**. As embodied herein, the proximal end **261** of interior wall portion **260** has an outwardly projecting portion **263** integrally formed therewith.

[0042] The interior surface **264** of interior wall portion **260** and the interior surface **242** of exterior wall portion **240** collectively define a hollow, cylindrically shaped cavity **230**. An additional, annularly shaped cavity **280** is defined by the interior surface **242** of exterior wall portion **240** and the exterior surface **265** of interior wall portion **260**.

[0043] A variety of alternative configurations and structures can be used for housing **200**. Interior wall portion **260** and exterior wall portion **240** can be separate pieces as described above or can be integrally formed as a single unit. If formed as separate pieces, interior wall portion **260** and exterior wall portion **240** can be attached to one another by way of machine threads, adhesive bonding, solvent welding, or any other way as known to those skilled in the art. For example, and with reference to **FIG. 6**, exterior wall portion **240** can be secured to interior wall portion **260** together by way of interlocking tabs **245** and openings **244**. Interior and external wall portions **260**, **240** are preferably formed of a plastic material, but can also be formed from any other suitable material, such as metal and/or composite materials. Additionally, in some applications housing **200** can alternatively be configured such that shroud **700** moves around the outside thereof instead of inside the housing **200**. This is advantageous when sheath **700** is to be actuated manually with or without the presence of shroud spring **800**. The housing **200** as embodied herein is provided with a cylindrical shape, having a generally circular cross-section. If desired, however, the housing can be provided with an elliptical or generally rectangular cross section, or any other cross section that permits operation of the syringe.

[0044] The exterior wall portion **240** has a proximal end opening **243** at its proximal end **244**, to which an end cap **250** can be attached. The cavity **230** is thus configured to house a reservoir **300**, a plunger **400**, a plunger spring **480**, and if desired, a needle **600**, to be described in detail below.

[0045] In accordance with the present invention and as noted above, the syringe includes a reservoir disposed inside the housing to contain a beneficial agent.

[0046] For example and not for purposes of limitation, **FIG. 1** depicts a reservoir **300** as embodied herein, having an open proximal end **310** and a distal end **320**. The reservoir **300** includes a generally tubular wall **330**, preferably made of plastic, glass, or similar material so as to define a chamber **340** therein. The wall **330** preferably terminates at the proximal end **310** of the reservoir **300** with an outward projection **350**, such as an annular lip or a plurality of tabs, to prevent the proximal end **310** of the reservoir **300** from advancing distally beyond the outwardly projecting portion **263** of the proximal end **261** of interior wall portion **260**. The distal end of the reservoir **300** is configured for fluid communication with a needle. For example, and as depicted in **FIG. 1**, the distal end **320** includes a wall defining a needle mounting hub **390** with an orifice **375** defined therethrough.

[0047] A variety of alternative configurations and structures can be used for reservoir **300**. For example, and with particular reference to **FIG. 9**, the reservoir **300** can be configured substantially as described above, except that a frangible membrane can be provided at the distal end of the reservoir so as to burst upon the application of sufficient pressure with the chamber. Alternatively, the beneficial agent **360** can be contained within a frangible cylindrical cartridge **380** housed inside the chamber. In this embodiment of the invention, a proximal end **620** of the needle **600** extends past the distal end wall **370** located at the distal end **320** of the reservoir **300** and into the chamber **340**. The proximal end **620** of the needle **600** is sufficiently sharp to pierce the frangible cartridge **380** when the cartridge **380** is pressed against the proximal end **620** of the needle **600**, for example, by the face **440** of the plunger **400**. This establishes

fluid communication between the beneficial agent **360** contained in the cartridge **380** and the needle **600**. Alternate embodiments of frangible membranes are disclosed in U.S. Pat. No. 4,983,164, the disclosure of which is expressly incorporated by reference herein.

[**0048**] The beneficial agent **360** is provided in a form that is conducive to being delivered through a needle, such as liquid form. Any beneficial agent can be used that is appropriate for use with a syringe.

[**0049**] In accordance with the present invention, the syringe also includes a plunger disposed inside the housing.

[**0050**] As seen in the exemplary embodiment in **FIG. 1**, the plunger **400** extends through an opening **255** in the end cap **250** of the housing **200**. The plunger has a distal end **420** having a face **440**, a shaft **430** and a proximal end **410**. As embodied herein, a platform **450** is formed around on shaft **430** of the plunger. The platform **450** optionally defines openings **452** on opposite sides **454**, **455** thereof, each to receive a guide element in the form of, for example, a rail **460**. The rails **460** act to guide the platform **450** as the plunger **400** travels in a distal direction to dispense beneficial agent **360** from the reservoir. The plunger face **440** is configured to form at least a liquid-tight seal between the outer surface **470** of the plunger **400** and the inner surface **335** of tubular wall **330** of the reservoir **300**. The plunger **400** can be further configured to include a mating surface **415** at its proximal end **410**. The mating surface **415** is configured to mate with an engagement element **510** on actuator **500**, as described in detail below.

[**0051**] A variety of alternative configurations and structures can be used for plunger **400**. For example, the plunger can be made from more than one piece, such as a rigid shaft **430** and a more flexible end **420**, or can be integrally formed as a single part. Plunger **400** can be made from any suitable materials such as metal or fiber reinforced composites, although plastic is preferred. Plunger **400** can also constitute a hollow, tubular member to permit filling of the reservoir **300** with a beneficial agent **360**. In accordance with this alternative embodiment, a passage (not shown) defined through plunger **400** can have a one-way valve (not shown) disposed therein to permit flow into the reservoir **300** through the passage, but not in the opposite direction. A separate bleed line (not shown) can be provided or desired if necessary.

[**0052**] In further accordance with the present invention, the syringe also includes a plunger spring preferably disposed inside the housing.

[**0053**] As seen in the exemplary embodiment in **FIG. 1**, the plunger spring **480** is disposed around the shaft **430** of the plunger **400**, and is biased to urge the plunger **400** in a distal direction with respect to the housing **200**. The plunger spring **480** is maintained in a compressed condition before use of the syringe between the platform **450** and interior surface **251** of end cap **250**, as a result of the mating surface **415** of the plunger being in engagement with the engagement element **510** on the actuator **500**. When the mating surface **415** is not engaged with the engagement element **510**, the plunger spring **480** acts to move the distal end **420** of the plunger **400** distally within the reservoir **300**.

[**0054**] In a preferred embodiment of the present invention, the reservoir **300** is configured to move distally inside the housing **200**. In this manner, and with the needle **600** mounted at the distal end **320** of the reservoir **300**, the needle **600** is extended from the housing **200** by moving the reservoir **300** in a distal direction. If the proximal end **620** of the needle **600** is attached to the distal end **320** of the reservoir **300**, the plunger spring **480** acts to move plunger **400**, reservoir **300** and needle **600** distally until the limit tab(s) **350** of reservoir **300** come into physical contact with the outwardly projecting portion **263** of the proximal end **261** of interior wall portion **260**. After this occurs, the plunger spring **480** continues to press against the plunger **400**, causing the plunger **400** to move distally along one or more guide elements, or as embodied herein, rails **460** and, in the process, evacuate beneficial agent **360** from the reservoir **300** through the needle.

[**0055**] A variety of alternative configurations and structures can be used for plunger spring **480**. While a compressive spring has been illustrated, any mechanical or electro-mechanical means of selectively urging the plunger in a distal direction are within the spirit and scope of the invention. For example, a tensile spring can be used that is biased to pull the plunger **400** in a distal direction instead of pushing it. Likewise, a pneumatic device including a cartridge containing a compressed gas could be used to cause the plunger to move and evacuate beneficial agent **360** from reservoir **300**. In selected applications, an electromagnetic solenoid could also potentially be used to exert such a force.

[**0056**] Further in accordance with the invention, the syringe is provided with at least one guide element for registration between the reservoir **300** and the plunger **400**. For example, and as shown in the embodiment of **FIGS. 1 and 10-11**, the guide member can include one or more rails **460**. The rails **460** each have a proximal end **462** and a distal end **464**. The proximal end **462** of each rail is engaged with platform **450**. The distal end **464** of each rail is attached to a mounting element **466** or similar mounting structure (such as clips) that surrounds the reservoir **300**.

[**0057**] Alternatively, and as shown in the embodiment of **FIG. 7**(*a*), guide elements can be supplied in the form of recesses, or tracks **465** formed into guide structure **467** instead of rails **460** tracks **465** provide registration between protrusions **469** on which engagement surfaces **456** are formed and the guide structure **467**. This provides alignment between plunger **400** and reservoir **300** (See also **FIG. 4**(*b*)).

[**0058**] As embodied herein, the mounting element **466** can be configured to surround the proximal end **310** of the reservoir **300**. In this manner, mounting element **466** engages outward projection **350** when the plunger spring **480** is deployed to advance the reservoir **300**, needle **600**, mounting element **466** and rails **460** in a distal direction until the distal face **468** of mounting element **466** contacts outwardly projecting portion **263** of housing **200** as depicted, for example, in **FIG. 2**(*c*).

[**0059**] Alternatively, the mounting element **466** can be configured to engage any location along the length of the reservoir **300**. For example, as shown in **FIG. 12**, mounting element **466** can engage the distal end **320** of the reservoir **300**. The rails **460** of this embodiment would be increased in length accordingly. In this manner, mounting element **466** engages reservoir **300** when the plunger spring **480** is deployed to advance the reservoir **300**, needle **600**, mounting element **466** and rails **460** in a distal direction until the

distal face **468** of mounting element **466** contacts a projection (not shown) at the distal end **220** of housing **200**.

[**0060**] In further accordance with the present invention, the syringe also includes an actuator disposed at the proximal end of the housing for actuating the syringe to inject a beneficial agent.

[**0061**] As embodied in **FIG. 1**, the actuator **500** is provided with engagement element **510** that mates with mating surface **415** on the proximal end **410** of plunger **400**. The actuator **500** is in direct physical contact with the end cap **250** of housing **200**, and is configured to slide along a direction generally transverse to a longitudinal direction of the housing. The actuator **500** further can be provided with a digit interface surface **520** for a user to press so as to move the engagement element **510** out of engagement with the mating surface **415**. In this manner, the plunger spring **480** is released and deployed to actuate the syringe **100**. The actuator **500** can optionally ride in a track (not shown) in the end cap **250** to facilitate sliding movement, and a guard or lock (not shown) can be provided to prevent sliding movement of the actuator.

[**0062**] Alternatively, and as shown in the second embodiment of **FIGS. 4 and 7**(*a*), the end cap **250** can at least partially cover the actuator **500** engagement element **510**. In this second embodiment of the invention, the actuator **500** includes digit interface surface **520** formed on the surface of an enlarged member **530**. The engagement element **510** is mounted on the terminal end **532** of an arm **534** fixably attached to the enlarged member **530**. In this embodiment of the invention, the engagement element **510** defines a keyhole shaped slot having an arcuately shaped edge **540** that partially circumscribes the mating surface **415** on the proximal end **410** of the plunger **400**. A guard or lock (not shown) can also be provided to prevent the actuator **500** from accidentally being moved resulting in deploying the syringe **100**.

[**0063**] A variety of alternative configurations and structures can be used for actuator **500**. While a mechanical switch has been shown in the drawings, it would also be possible for the actuator to be a frangible member, such that the frangible member can be ruptured by exerting digital pressure on the digit interface surface **520** of the actuator **500**, thereby releasing the plunger **400**. Such an embodiment would be advantageous where the device is intended for a single use.

[**0064**] In further accordance with the present invention, the syringe also includes a needle proximate the distal end of the housing. The needle is configured to be in fluid communication with the reservoir during deployment of the syringe. In a preferred embodiment, as shown in FIGS. **2**(*b*)-**2**(*c*), the needle can be displaceable from a first needle position to a second needle position. The needle has a needle point that extends from the housing when the needle is in the second needle position.

[**0065**] As embodied in **FIG. 1**, the needle **600** has a proximal end **620**, an elongate tubular shaft **610** and a needle point **640** at a distal end **630** thereof. The needle **600** can be sized and constructed according to conventional techniques. The needle **600** can be a separate assembly from the reservoir **300** or can be fitted into the distal end **320** of the reservoir **300**. The proximal end **620** of the needle **600** is preferably in constant fluid communication with the distal end **320** of the reservoir **300**. As embodied in **FIGS. 1 and 2**(*b*), the needle has a first needle position inside the housing **200**. When the plunger spring **480** is deployed, needle **600** is moved to a second needle position, as shown in **FIG. 2**(*c*).

[**0066**] Optionally, the needle **600** can be configured to be in fluid communication with the reservoir **300** when the plunger **400** is moved toward the second plunger position.

[**0067**] For example, as shown in **FIG. 9**, the needle **600** can be configured for fluid communication with a beneficial agent **360** only upon deployment of the plunger **400**. As embodied in **FIG. 9**, the needle **600** of **FIG. 9** includes a sharpened proximal end **620** that pierces a frangible membrane of cartridge **380** containing a beneficial agent **360** when the syringe **100** is actuated by a user and the plunger spring **480** moves the face **440** of the plunger **400** in a distal direction, as previously described above.

[**0068**] Similarly, by way of further example, instead of using a cartridge **380** to isolate the beneficial agent from needle **600**, it is also within the scope of the invention to provide reservoir **300** with a frangible membrane (not shown) near the proximal end **620** of the needle. In accordance with this aspect of the invention, when the plunger spring **480** deploys, the face **440** of the plunger increases the fluid pressure in the reservoir **300** by a predetermined amount sufficient to cause the membrane to rupture, thereby establishing fluid communication between the beneficial agent **360** and the needle **600**.

[**0069**] In further accordance with the present invention, the syringe also includes a shroud coupled with the housing. The shroud is moveable between a retracted position and an extended position; the shroud surrounding at least a portion of the needle when in the extended position.

[**0070**] As embodied in **FIG. 1**, the shroud **700** includes a tubular wall portion **710** having a proximal end **720** and a distal end **730**. Preferably, the shroud **700** also has a spring engagement element, such as spring engagement surface **750** depicted in **FIG. 1** to engage with a shroud spring **800**, as discussed in detail below. The cross-section of the shroud **700** preferably, although not necessarily, will be similar to that of housing **200**, but will be sized to fit freely inside the inner surface of the housing **200**.

[**0071**] The shroud **700** as embodied herein is moveable between a retracted position and an extended position such that the shroud **700** surrounds the needle point **640** when shroud **700** is in the extended position. **FIG. 2**(*d*) shows shroud **700** in a retracted position. In its retracted position, shroud **700** preferably is wholly contained in annularly shaped cavity **280** of housing **200**. Interlocking assembly **900**, as discussed in detail below, maintains shroud in its retracted position. In its retracted position, shroud **700** is protected from interference with foreign objects that would impede its function. **FIG. 2**(*e*) shows shroud **700** in an extended position. In its extended position, shroud **700** is preferably locked in place by locking assembly, as discussed in detail below. As seen in **FIG. 2**(*e*) in its extended position, shroud **700** surrounds the needle **600**, thus protecting the user from accidental needle sticks after syringe **100** has been used. In use, it is preferable that the shroud **700** be deployed before the syringe is taken away from the skin. The shroud **700** of the present invention is therefore configured to act as

an indication to the user that the injection has completed. When the user pulls the syringe away from the skin of the patient, the shroud **700** will fully extend.

[**0072**] In further accordance with the present invention, the syringe also includes a shroud spring biased to urge the shroud from a retracted position toward an extended position when the shroud spring is deployed.

[**0073**] As embodied in **FIG. 1**, shroud spring **800** is a compressed mechanical spring, although any suitable spring can be used in a manner similar to plunger spring **480**. The shroud spring **800** is biased to urge the shroud **700** toward the extended position when the shroud spring **800** is deployed. The shroud spring **800** is disposed within the shroud **700** and around the exterior surface **265** of interior wall portion **260** of the housing **200**. In this manner, both the shroud **700** and the shroud spring **800** are protected from damage or interference with foreign objects. Preferably, the shroud spring **800** as embodied herein is a mechanical spring made of metal or plastic. Before the syringe **100** is used, the shroud **700** is initially in a retracted position, as shown in **FIG. 2**(*d*). In this position, shroud spring **800** is in a compressed state, held in place between spring engagement surface **750** and outwardly projecting portion **263** of interior wall portion **260**.

[**0074**] A variety of alternative configurations and structures can be used for shroud **700** and shroud spring **800**. For example, if desired, the shroud **700** can be configured to slide along the exterior of housing **200** (not shown). In accordance with this aspect of the invention, the shroud spring **800** preferably would be housed between the interior surface **770** of shroud **700** and the exterior surface **201** of housing **200**. In this manner, shroud spring **800** is still protected from interference with foreign objects.

[**0075**] In further accordance with the present invention, the syringe also includes an interlocking assembly in communication with the shroud. The interlocking assembly has a first condition to maintain the shroud in the retracted position and a second condition to deploy the shroud spring and allow movement of the shroud toward the extended position.

[**0076**] As embodied herein and with reference to FIGS. **2**(*d*)-**2**(*e*) and **FIG. 3**, interlocking assembly **900** includes at least one interlocking element **910** configured for engagement with a corresponding first receiving portion **920**. For example, and as embodied in FIGS. **2**(*d*)-**2**(*e*) and **FIG. 3**, interlocking element **910** includes at least one flexible tab **740** extending proximately from the proximal end **720** of the shroud **700**. The flexible tab **740** has an extension **912** with a seating surface **915** configured to engage with outwardly projecting portion **263** of interior wall portion **260**. When shroud **700** is in a retracted condition as shown in **FIG. 2**(*d*), surface **915** seats on outwardly projecting portion **263** of housing **200**, thus preventing shroud **700** from moving toward its extended position.

[**0077**] In accordance with a further aspect of the invention, the interlocking assembly is coupled with the plunger so as to be switched from the first condition wherein the shroud is maintained in the retracted position, to the second condition, wherein the shroud spring is deployed to allow movement of the shroud toward the extended position.

[**0078**] For purpose of illustration, and not limitation; the interlocking assembly embodied in **FIGS. 1-3** is provided with cam surface **917**. The cam surface is configured to be engaged by a corresponding engagement surface **456** provided on the plunger **480**. After syringe **100** is actuated and the face **440** of the plunger **400** approaches a predetermined location proximate the distal end **320** of the reservoir **300**, one or more engagement surfaces **456** on the periphery of platform **450** contact and bias tabs **740** outwardly. In this manner, the flexible tabs **740** will be flexed outwardly to disengage seating surface **915** from portion **263**.

[**0079**] With reference to **FIG. 3**, distal tab **740** preferably is attached to shroud **700** at hinge point **914**. Locating the hinge point **914** at a location distal to the proximal end **720** of shroud **700** permits a sufficient bending moment to be created by engagement surfaces **456** urging against receiving surfaces **913** so as to permit seating surfaces **915** to disengage with outwardly projecting portion **263**. As a consequence, seating surface **915** is forced out of engagement with outwardly projecting portion **263** of interior wall portion **260** of housing **200**. This release deploys shroud spring **800** against spring engagement surface **750**, thereby pushing shroud **700** in a distal direction. If the movement of shroud **700** is unimpeded by the skin of the user, shroud **700** will fully extend to its extended position covering the needle point **640**, as seen in **FIG. 2**(*e*). Preferably, however, the shroud **700** is extended against the skin of the patient so as to provide a tactile indication that the injection cycle is completed. As the needle is withdrawn from the injection site, it is automatically surrounded by the shroud **700**. Interlocking elements **910** are preferably formed of an injection-molded plastic material that is sufficiently flexible to enable the interlocking elements **910** to flex for purposes of disengagement from outwardly projecting portion **263** of interior wall portion **260** of housing **200**.

[**0080**] A variety of alternative configurations and structures can be used for interlocking assembly **900**. For example, interlocking elements **915** can instead be frangible members configured to hold the shroud in its retracted position. These frangible members can be ruptured when the distal tabs **740** are splayed outwardly by engagement surfaces **456** on platform **450**. In accordance with a different embodiment of the invention, and with reference to **FIGS. 4 and 6**, an alternative interlocking assembly **900** is shown. This interlocking assembly **900** works in a manner similar to the embodiment of **FIG. 1**. However, instead of having a cammed surface attached to the shroud that facilitates outward movement of flexible tabs **740**, a cammed surface is provided on engagement surfaces **456**. Distal movement of plunger thereby moves engagement surfaces **456** against the corner portions **741** of flexible tabs **740** to urge them outward, disengaging seating portions **915** from outwardly projecting member **263**, thereby disengaging interlocking element **900**. Shroud **700** is now free to move distally as described above with regard to the embodiment of **FIGS. 1-3**.

[**0081**] In accordance with another aspect of the invention, a locking assembly is also provided. The locking assembly is configured to inhibit movement of the shroud when the shroud is moved to an extended position.

[**0082**] As embodied herein and with reference to FIGS. **2**(*d*) and **2**(*e*), for purpose of illustration and not limitation, locking assembly **1000** includes locking element **1010**, such as a ridge or annular bead, formed on the interior surface **242**

of exterior wall portion **240** of housing **200**. The locking element **1010** is configured to mate with a lock receiving portion **1020** that, as depicted in the first exemplary embodiment of the invention, is formed on the exterior surface **760** of shroud **700**. As seen in **FIG. 2**(*d*), lock receiving portion **1020** has an inclined surface **1022**, which acts as a ramp, to permit locking element **1010** to slide into an adjacent recess **1025** when the shroud **700** extends in a distal direction with respect to housing **200**. After locking element **1010** has slid along the inclined surface **1022** of lock receiving portion **1020**, it snaps into recess **1025**. Shroud **700** is thus locked into place, and inhibited from further movement.

[**0083**] A variety of alternative configurations and structures can be used for locking assembly **1000**. With reference to **FIG. 4**, in an alternative embodiment of the syringe in accordance with the invention, lock receiving portion **1020** defined as a recess in interior wall portion **260** of housing **200** and locking element **1010** is defined by interlocking element **910** as shown in **FIG. 4** above. Alternatively, an adhesive or bonding surface (not shown) can be used in lieu of a snap-fit arrangement as described above. According to this alternative embodiment, a surface on the shroud is provided with a thin layer of adhesive or bonding material not in engagement with any other surface before the shroud **700** is deployed, but configured to contact and securely attach such of syringe **100** together when the shroud **700** is extended. By way of further example, lock receiving portions **1020** can have a small quantity of gel-type adhesive disposed in recess **1025** to form a strong mechanical bond with locking element **1010** after shroud **700** is deployed. As another example, the action of deploying the shroud can rupture a membrane between two small reservoirs built into the shroud (not shown) having contents that, when mixed, quickly expand and cure to form a voluminous foam that fills the interior space of the shroud **700**, or otherwise form a secure bond to lock the shroud in place.

[**0084**] In accordance with another aspect of the invention, a syringe is provided wherein the interlocking assembly includes a switch operable from outside the housing to manually switch the interlocking assembly from the first condition to the second condition.

[**0085**] For purposes of illustration and not limitation, a syringe similar to that in **FIG. 1** or **FIG. 4**(*a*) can be provided, but modified to be actuated manually if desired. A shroud spring can still be employed. However, rather than having interlocking assembly **900** be disengaged solely by movement of the plunger **400**, syringe **100** can be configured to disengage interlocking assembly manually. For this purpose, a shroud actuator (not shown), similar to actuator **500**, can be provided having an exterior portion with a digit interface surface and an arm or similar structure that can protrude through an opening (not shown) in the housing **200** and contact cam surface **917**. When actuated by a user, the arm of shroud actuator disengages seating surface **915** from outwardly projecting portion **263** and allows shroud **700** to deploy under the force of shroud spring **800** as described above.

[**0086**] Reference will now be made to describe a representative method of using the present invention. The method of the present invention includes providing a syringe as described in detail above; loading beneficial agent into the reservoir of the syringe; positioning the needle of the syringe at an injection site of a patient; moving the plunger toward the second plunger position to dispense the beneficial agent from the reservoir through the needle; and switching the interlocking assembly to the second condition to deploy the shroud spring and allow movement of the shroud toward the extended position.

[**0087**] As embodied herein, and with specific reference to FIGS. **2**(*a*)-**2**(*e*), the method of the present invention includes providing a device **100** as described in detail above. Although the embodiment of **FIG. 1** is shown in FIGS. **2**(*a*)-**2**(*e*), any of the disclosed embodiments of the device are suitable for the method of the present invention. For example, a second representative embodiment of the invention is shown in FIGS. **4**(*a*)-**4**(*d*).

[**0088**] In accordance with the method of the invention, beneficial agent is loaded into the reservoir of the syringe. The beneficial agent loading step can occur at any of a number of different times during the method. For example, in the case of a preloaded, disposable syringe, the beneficial agent loading step can occur during manufacture. The reservoir **300** can be directly injected with a beneficial agent **360** or loaded with a cartridge **380** containing beneficial agent **360** prior to assembly of syringe **100**.

[**0089**] Alternatively, such as when a cartridge **380** is used, syringe **100** could be configured to be loaded by a pharmacist or other medical personnel. This is particularly attractive, because the inert syringe can be kept in storage virtually indefinitely and loaded with a cartridge **380** containing fresh beneficial agent **360** when needed. To facilitate this embodiment, syringe **100** is configured such that it can be easily disassembled or sold in a disassembled condition to permit beneficial agent **360** to be introduced. For example, the syringe can be provided in two sections as shown in **FIG. 6**, which is easily loaded with a cartridge of beneficial agent and then snap fit together. As another option (not shown), syringe **100** can be configured with an opening through housing **200** to accept a cartridge **380** into reservoir **300**. Syringe **100** also can be filled by configuring plunger **400** to include a hollow member that provides a hollow passage (not shown) spanning between the face **440** of plunger **400** and the proximal end **410** of plunger **400**. As mentioned above, such a passage could be provided with a one-way valve (not shown) and accompanying bleed line to permit introduction of liquid beneficial agent **360** through the proximal end **410** plunger **400** into chamber **340** of reservoir **300** but prevent flow in the opposite direction. When a syringe **100** according to this embodiment of the invention is actuated, beneficial agent **360** will flow through the needle point **640** into the patient as described above instead of flowing backward through the passage due to the one way valve preventing any such flow.

[**0090**] In accordance with the method of the invention, the needle of the syringe is positioned at an injection site of a patient. The distal end of syringe **100** should be pressed firmly against the user's skin to ensure that the needle point **640** penetrates the skin of the patient without unnecessarily damaging the skin.

[**0091**] If provided, an actuator lock (not shown) covering the actuator **500** is preferably removed before the syringe positioning step. Once the actuator lock is removed, syringe **100** can be deployed to administer a beneficial agent.

[**0092**] In accordance with the method of the invention, the plunger is then moved toward the second plunger position to

dispense the beneficial agent from the reservoir through the needle. As embodied herein and for purpose of illustration as depicted in FIGS. **2**(*a*)-**2**(*b*) with respect to the embodiment of **FIG. 1** (and as depicted in FIGS. **4**(*a*)-**4**(*b*) with respect to the second representative embodiment), actuator **500** is moved as shown by arrow A to disengage engagement element **510** from mating surface **415** on the proximal end **410** of the plunger **400**. The plunger spring **480** then causes the beneficial agent **360** to be injected as described above, and as shown in FIGS. **2**(*c*)-**2**(*d*) with respect to the embodiment of **FIG. 1** (see also **FIG. 4**(*c*) with respect to the second representative embodiment).

[**0093**] As further depicted in **FIG. 2**(*c*), and in accordance with another aspect of the invention, the needle is moved (as shown by arrow C) from a first needle position to a second needle position when the plunger is moved from the first plunger position toward the second plunger position. In accordance with this aspect of the invention, the needle has a needle point extending from the housing when in the second needle position. In further accordance with this aspect of the invention, the positioning step includes placing the distal end of the housing against the injection site.

[**0094**] In accordance with this aspect of the invention and as shown in **FIG. 2**(*c*), when the plunger spring **480** is released, it moves the reservoir **300** and the needle **600** in a distal direction, such that the point **640** of the needle **600** protrudes from the housing. Preferably, the positioning step will have occurred before the needle has moved to a point protruding from the housing for purposes of facilitating the injection. Using syringe **100** in this manner helps prevent unnecessary damage to the patient's skin.

[**0095**] In further accordance with the method of the invention, after the beneficial agent is introduced, the interlocking assembly is then switched from the first condition to the second condition to deploy the shroud spring and allow movement of the shroud toward the extended position. Preferably, the shroud **700** is deployed automatically, as described above and as shown by arrow D in FIGS. **2**(*d*)-**2**(*e*). **FIG. 4**(*d*) shows the shroud **700** in a deployed position with regard to the second representative embodiment. Particularly, and with reference to the embodiment of **FIG. 2**(*d*), the interlocking assembly of the syringe provided by the providing step is coupled with the plunger so as to be switched from the first condition to the second condition when the plunger is moved to the second plunger position; and further wherein the switching step is performed by moving the plunger to the second plunger position. Alternatively, shroud **700** can be deployed manually. This would be particularly practical in an embodiment of the invention where the shroud **700** is configured to slide about the exterior of the housing **200**. In accordance with such an alternative embodiment, the shroud **700** could be held in place by tabs engaged with receiving surfaces whereby the act of squeezing the shroud would act to release the shroud **700**. After releasing the shroud, the user would advance the shroud until it snaps into place in an extended position covering the needle point **640**, at which point it could optionally be locked using an interlocking assembly **900** as described above.

[**0096**] The syringe and method of using a syringe of the present invention, as described above and shown in the drawings, provide for a convenient way for a patient to self medicate, particularly, for example, where the patient has arthritis. Using any suitable material of construction, any of a number of known and conventional manufacturing techniques, such as injection or vacuum molding, can be employed to manufacture the syringe of the present invention. It will be apparent to those skilled in the art that various modifications and variations can be made in the method and system of the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention include modifications and variations that are within the scope of the appended claims and their equivalents.

What is claimed is:

1. A syringe comprising:

a housing having a proximal end and a distal end, the housing having a reservoir disposed therein;

a plunger to be received by the reservoir, the plunger being moveable between a first plunger position and a second plunger position;

a plunger spring configured to urge the plunger toward the second plunger position when the plunger spring is deployed;

an actuator to deploy the plunger spring;

a needle proximate the distal end of the housing, the needle in fluid communication with the reservoir;

a shroud coupled with the housing, the shroud being moveable between a retracted position and an extended position, the shroud surrounding at least a portion of the needle when in the extended position;

a shroud spring biased to urge the shroud toward the extended position when the shroud spring is deployed; and

an interlocking assembly in communication with the shroud, the interlocking assembly having a first condition to maintain the shroud in the retracted position and a second condition to deploy the shroud spring and allow movement of the shroud toward the extended position.

2. The syringe of claim 1, wherein the actuator includes an engagement element to retain the plunger in the first position, the engagement element releasing the plunger to deploy the plunger spring when the actuator is actuated.

3. The syringe of claim 1, wherein the plunger spring is a mechanical spring element.

4. The syringe of claim 1, further comprising a cover to cover the distal end of the housing before the syringe is used.

5. The syringe of claim 1, wherein the needle is displaceable from a first needle position to a second needle position, the needle having a needle point extending from the housing when in the second needle position.

6. The syringe of claim 5, wherein the needle is configured to be moved from the first needle position to the second needle position when the plunger is moved from the first plunger position toward the second plunger position.

7. The syringe of claim 5, wherein the needle is secured to the reservoir, the reservoir being displaceable so as to displace the needle from the first needle position to the second needle position.

8. The syringe of claim 1, wherein the interlocking assembly is coupled with the plunger so as to be switched from the first condition to the second condition when the plunger is moved to the second plunger position.

9. The syringe of claim 8, wherein the interlocking assembly includes at least one flexible tab provided on the shroud and an engagement surface provided on the plunger, the engagement surface flexing the tab when the plunger is moved to the second plunger position.

10. The syringe of claim 1, wherein the interlocking assembly includes a switch operable from outside the housing to manually switch the interlocking assembly from the first condition to the second condition.

11. The syringe of claim 1, further comprising a locking assembly, the locking assembly configured to inhibit movement of the shroud when moved to the extended position.

12. The syringe of claim 11, wherein the locking assembly includes a protuberance to be received by a corresponding recess.

13. A syringe comprising:

a housing having a proximal end and a distal end, the housing having a reservoir disposed therein;

a plunger to be received by the reservoir, the plunger being moveable between a first plunger position and a second plunger position;

at least one guide element to provide registration between the reservoir and the plunger;

a plunger spring configured to urge the plunger toward the second plunger position when the plunger spring is deployed;

an actuator to deploy the plunger spring;

a needle proximate the distal end of the housing, the needle in fluid communication with the reservoir;

a shroud coupled with the housing, the shroud being moveable between a retracted position and an extended position, the shroud surrounding at least a portion of the needle when in the extended position;

a shroud spring biased to urge the shroud toward the extended position when the shroud spring is deployed; and

an interlocking assembly in communication with the shroud, the interlocking assembly having a first condition to maintain the shroud in the retracted position and a second condition to deploy the shroud spring and allow movement of the shroud toward the extended position.

14. The syringe of claim 13, wherein the at least one guide element is a rail having a proximal end and a distal end, the distal end of the rail attached to a mounting element, the mounting element engaging the reservoir.

15. The syringe of claim 14, wherein the mounting element is a retaining ring.

16. The syringe of claim 14, wherein the mounting element surrounds a proximal end of the reservoir.

17. The syringe of claim 14, wherein the mounting element surrounds a distal end of the reservoir.

18. The syringe of claim 13, wherein the guiding element is a recess defined in a guide structure, and the recess is configured to receive a protrusion extending from the plunger.

19. A method of delivering a beneficial agent to a patient, the method comprising the steps of:

providing a syringe including

a housing having a proximal end and a distal end, the housing having a reservoir disposed therein,

a plunger to be received by the reservoir, the plunger being moveable between a first plunger position and a second plunger position,

a plunger spring configured to urge the plunger toward the second plunger position when the plunger spring is deployed,

an actuator to deploy the plunger spring,

a needle proximate the distal end of the housing for delivering beneficial agent from the reservoir to a patient,

a shroud coupled with the housing, the shroud being moveable between a retracted position and an extended position, the shroud surrounding at least a portion of the needle when in the extended position,

a shroud spring biased to urge the shroud toward the extended position when the shroud spring is deployed, and

an interlocking assembly in communication with the shroud, the interlocking assembly having a first condition to maintain the shroud in the retracted position and a second condition to deploy the shroud spring and allow movement of the shroud toward the extended position;

loading beneficial agent in the reservoir of the syringe;

positioning the syringe at an injection site of a patient;

moving the plunger toward the second plunger position to dispense the beneficial agent from the reservoir through the needle; and

switching the interlocking assembly to the second condition to deploy the shroud spring and allow movement of the shroud toward the extended position.

20. The method of claim 19, wherein the needle is in fluid communication with the reservoir when the plunger is moved toward the second plunger position.

21. The method of claim 19, wherein the moving step includes actuating the actuator to deploy the plunger spring.

22. The method of claim 19, wherein the needle of the syringe provided by the providing step is displaceable from a first needle position to a second needle position when the plunger is moved from the first plunger position toward the second plunger position, the needle having a needle point extending from the housing when in the second needle position; and further wherein the positioning step includes placing the distal end of the housing against the injection site.

23. The method of claim 19, wherein the interlocking assembly of the syringe provided by the providing step is coupled with the plunger so as to be switched from the first condition to the second condition when the plunger is moved to the second plunger position; and further wherein the switching step is performed by moving the plunger to the second plunger position.

24. The method of claim 19, wherein movement of the shroud toward the extended position provides an indication to a patient that beneficial agent has been injected.

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