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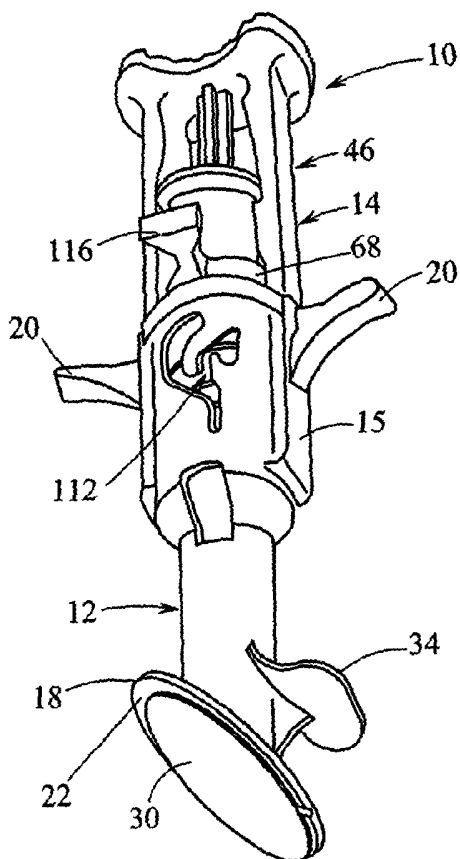
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(54) Title: INTRADERMAL DELIVERY DEVICE ADHESIVELY ATTACHABLE TO THE SKIN, AND METHOD OF INTRADERMAL DELIVERY



(57) Abstract: An intradermal delivery device for injecting a substance into the skin has a housing including a base defining a radially-extending mounting surface for releasably engaging the skin, and a needle aperture formed therethrough and defining a substantially planar needle penetration region on the skin. A pressure-sensitive adhesive is superimposed over the mounting surface for releasably securing the mounting surface to the skin and preventing relative movement of the needle penetration region of the skin and the mounting surface. A syringe body is reciprocally mounted within the housing and a plunger is reciprocally mounted within the syringe body. A needle is mounted to the syringe body and is movable through the needle aperture to penetrate the needle penetration region of the skin. A needle cap is mounted over the needle and forms an approximately airtight seal therebetween, and is penetrable by the needle upon passage through the needle aperture and into the skin.



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**INTRADERMAL DELIVERY DEVICE**  
**ADHESIVELY ATTACHABLE TO THE SKIN,**  
**AND METHOD OF INTRADERMAL DELIVERY**

**CROSS-REFERENCE TO RELATED APPLICATIONS**

This patent application claims priority on U.S. provisional patent application serial no. 60/396,514, filed July 16, 2002, and to the U.S. utility patent application filed on July 16, 2003, under Express Mail No. EV335596136US, both of which are entitled "Intradermal  
5 Delivery Device Adhesively Attachable To The Skin, And Method Of Intradermal Delivery", and is related to U.S. provisional patent application serial no. 60/394,618, filed July 8, 2002, entitled "Intradermal Delivery Device, And Method Of Intradermal Delivery", each of which is hereby expressly incorporated by reference as part of the present disclosure.

**BACKGROUND OF THE INVENTION**

**1. Field of the Invention**

The subject invention relates to instruments for injecting a substance into a person or animal, and more particularly, to an improved instrument for injecting the substance intradermally.

**2. Background of the Related Art**

15 Drug delivery into the soft tissue inside the dermis, i.e., intradermal delivery, with a very small needle has been shown to slow drug release time and reduce or eliminate nerve ending stimulation and hence patient reaction. The challenge to delivering drugs in this fashion include the need for precise control over needle penetration depth which can vary due  
20 to tissue compliance and penetration angle.

Techniques have been developed to improve the ability of individuals to administer injections. For example, U.S. Patent No 4, 393,870 to Wagner shows a suction injector for use by a patient. The suction injector of Wagner includes a medicine containing syringe slidably attached to an outer chamber. The outer chamber is a sealed vacuum chamber. An inner  
25 chamber is concentric and sealingly isolated with respect to the outer chamber. The inner chamber receives the syringe. A membrane maintains the sterility of the syringe and a bellows placed circumferentially about the outer chamber prevents the syringe from piercing the membrane. In use, as the syringe slides in the outer chamber, the bellows retract and the

vacuum seal between the inner chamber and outer chamber is broken. The skin is lifted under the resulting negative pressure and the medicine can be injected therein.

Some needle insertion devices, such as U.S. Patent No. 4,299,219 to Norris, Jr., have recognized that vacuum on the skin can increase the size of an underlying vein to facilitate locating the vein with the cannula. There are problems associated with the systems of Wagner and Norris, Jr., however. Both devices distort the surface of the skin in a calotte-shaped manner. The distortion creates a difficulty in controlling the insertion depth of the cannula. U.S. Patent No. 6,200,291 to Di Pietro shows a needle surrounded by a distal end of a skin contacting element. The distal end is conic shaped and deforms when pressed against the skin. When deformed, the needle extends beyond the skin contacting element into the patient's skin. The limited ability of the distal end to deform limits the insertion depth of the needle. Although limited, the device of Di Pietro requires deft control by the operator to provide consistent insertion depth. Microholes in the conic distal end prevent a vacuum effect so the device can be easily removed after injection.

There is a need, therefore, for an improved intradermal delivery device and method that repeatably provide a definite relative skin state for precise needle penetration and reduced negative patient reaction.

### **SUMMARY OF THE INVENTION**

The present invention is directed to an intradermal delivery device ("IDD") and method for injecting a substance into the skin. In accordance with one aspect of the present invention, the intradermal delivery device comprises an axially-elongated housing including a base defining a radially-extending mounting surface for releasably engaging the skin, and a needle aperture formed therethrough and defining a substantially planar needle penetration region on the skin located adjacent to the needle aperture. Preferably, the mounting surface is oriented at an acute angle relative to an axis of the device to facilitate penetrating the derma of the skin to a precise depth, and in turn facilitate efficient transfer of the substance from the syringe into the skin. In one embodiment of the invention, the base defines expansion slots which allow a portion of the mounting surface to actively tension the skin. An adhesive, such as a pressure-sensitive adhesive, is superimposed over the mounting surface for releasably securing the mounting surface to the skin and preventing relative movement of the needle penetration region of the skin and the mounting surface. Preferably, a releasable backing is superimposed over the adhesively-coated mounting surface prior to use.

The intradermal delivery device further comprises a syringe including a syringe body reciprocally mounted within the housing and a plunger reciprocally mounted within the syringe body. A needle extends axially from the syringe body and is movable through the needle aperture to penetrate the needle penetration region of the skin and inject a substance contained within the syringe body therein. Preferably, the needle is a non-coring needle defining an angled tip oriented at approximately the same angle relative to the axis of the device as is the mounting surface. The needle is movable through the needle aperture upon slidably moving the plunger through the syringe body to thereby penetrate with the needle the penetration region of the skin and inject the substance contained within the syringe body therein. In one embodiment of the present invention, the intradermal delivery device comprises a needle cap mounted over the needle forming an approximately airtight seal therebetween, and defining a penetrable surface formed adjacent to the needle tip for passage of the needle therethrough.

In accordance with another aspect, the present invention is directed to a method for intradermal delivery, comprising the following steps:

- (i) providing an intradermal delivery device including a housing having a mounting surface and a reciprocally mounted syringe therein;
- (ii) placing the mounting surface on the skin of a patient;
- (iii) adhesively attaching the mounting surface to the skin to thereby releasably secure the device to the skin;
- (iv) forming a substantially planar target penetration region on the skin;
- (v) introducing a needle of the syringe a predetermined depth into the substantially planar target penetration region of the skin; and
- (vi) injecting a substance from the syringe through the needle into the substantially planar target penetration region of the skin.

In one embodiment of the present invention, the method further comprises the step introducing the needle at a predetermined acute angle between the axis of the needle and the substantially planar target penetration region of the skin.

One advantage of the intradermal delivery device and method of the present invention is that the adhesively-coated mounting surface substantially prevents relative movement between the skin and mounting surface and thereby defines a substantially planar needle penetration region on the patient's skin facilitating insertion of the needle to a precise depth within the skin.

Other advantages of the intradermal delivery device and method of the present invention will become more readily apparent in view of the following detailed description of preferred embodiments and accompanying drawings.

5                                    **BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a perspective view of an IDD embodying the present invention.

FIG. 2 is another perspective view of the IDD of FIG. 1.

FIG. 3 is a cross-sectional view of the IDD of FIGS. 1 and 2.

10    FIG. 4 is an enlarged partial, cross-sectional view of the base of the IDD of FIG. 3 illustrating the releasable backing and pressure-sensitive adhesive layer on the base for adhesively attaching the IDD to a patient's skin.

FIG. 5 is a partial, perspective view of the housing of the IDD of FIGS. 1 and 2.

FIG. 6 is a top, perspective view of the housing of the IDD of FIGS. 1 and 2.

15    FIG. 7 is an enlarged, partial cross-sectional view of the adhesively-coated mounting surface, needle mount, and needle cap of the IDD of FIGS. 1 and 2.

FIG. 8 is an enlarged, partial side elevational view of the non-coring needle tip of the IDD of FIGS. 1 and 2.

FIG. 9 is an upper perspective view of the track follower of the IDD of FIGS. 1 and 2.

20    FIG. 10 is a partial, somewhat schematic, side elevational view of the housing of the IDD of FIGS. 1 and 2 illustrating the pin and slot arrangement for controlling actuation of the IDD.

FIG. 11 is a perspective view of the locking ring, spring, and plunger assembly of the IDD of FIGS. 1 and 2.

FIG. 12 is a perspective view of a sub-assembly of the IDD of FIGS. 1 and 2.

25    FIGS. 13-17 are sequential, perspective views illustrating operation of the IDD.

FIG. 18 is a perspective view of another IDD embodying the present invention.

FIG. 19 is a cross-sectional view of the IDD of FIG. 18 taken along line 19-19.

FIG. 20 is another cross-sectional view of the IDD of FIG. 18 taken along line 20-20.

30    FIG. 21 is an enlarged partial, cross-sectional view of the base of the IDD of FIG. 18 illustrating the tapered needle mount and adhesively-coated base for adhesively engaging and tensioning a patient's skin across the needle penetration region.

FIG. 22 is a perspective view of another housing for an IDD embodying the present invention.

FIG. 23 is a perspective view of another IDD embodying the present invention illustrating still another housing therefor.

### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

5       The present invention overcomes many of the prior art problems associated with devices for injecting substances, such as vaccines, pharmaceuticals, cosmetics, and other substances. The advantages, and other features of the device and method disclosed herein, will become more readily apparent to those having ordinary skill in the pertinent art from the following detailed description of the preferred embodiments taken in conjunction with the  
10       drawings which set forth representative embodiments of the present invention.

      In FIGS. 1-3, an intradermal delivery device ("IDD") embodying the present invention is indicated generally by the reference numeral 10. The IDD 10 comprises a housing 12 and a syringe 14 mounted within the housing 12. The housing 12 includes an axially-elongated housing body 15 defining a hollow interior 16, a base 18 formed at one end of the housing, and  
15       a pair of diametrically-opposed, first finger grips 20 formed at the other end of the housing. As shown best in FIGS. 2 and 3, the base 18 defines on its underside a radially-extending mounting surface 22 for releasably engaging the skin, and a needle aperture 24 formed through the approximate center of the base. As described in further detail below, and shown in FIG. 3, a substantially planar needle penetration region "X" is formed on the skin adjacent to the  
20       needle aperture 24 upon releasably attaching the base 18 of the IDD 10 to the skin. As shown best in FIG. 4, a layer of pressure sensitive adhesive 26 is superimposed over the mounting surface 22 for releasably attaching the mounting surface 22 to the skin and preventing relative movement of the needle penetration region X of the skin and mounting surface 22. As  
25       described further below, and as shown in FIG. 3, a needle 28 is fixedly secured to one end of the syringe 14 and is movable through the needle aperture 24 upon actuation of the syringe 14 to inject a substance contained within the syringe 14 into the substantially planar needle penetration region X of the skin.

      In a currently preferred embodiment of the present invention, the needle aperture 24 is sufficiently large to allow the needle 28 to pass therethrough. Otherwise, the diameter or width  
30       of the needle aperture 24 may be minimized in order to facilitate maintaining the needle penetration region X of the skin underlying the aperture 24 in a substantially planar condition during injection of the substance contained in the syringe 14 into the skin. In a currently preferred embodiment of the present invention, the gauge of the needle 28 is within the range

of about 27 gauge to about 30 gauge, and the needle aperture 24 defines a diameter or width within the range of about 1 to about 2 mm which, in turn, defines the diameter or width of the needle penetration region X of the skin. As may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, these dimensions are only exemplary, and may be  
5 changed as desired depending upon any of numerous different factors.

A releasable backing 30 defining a radially-extending peel tab 32 is superimposed over the pressure-sensitive adhesive layer 26. Immediately prior to use, a user pulls the peel tab 32 away from the base 18 to, in turn, remove the releasable backing 30 and expose the underlying adhesive layer 26. Then, as described further below, the user presses the adhesive layer 26  
10 onto the skin to releasably secure the mounting surface 22 to the skin. The housing 12 further defines a second finger grip 34 axially spaced adjacent to the base 18 to facilitate holding the mounting surface 22 against the skin. The adhesive layer 26 substantially prevents any relative movement between the skin and the mounting surface 22 to thereby define a fixed, substantially planar needle penetration region X on the skin. The ability to form a substantially  
15 planar needle penetration region X on the skin is a significant advantage of the IDD 10 of the present invention because the needle tip can be precisely located within the derma of the skin upon reaching the inward end of the plunger stroke. For example, the IDD 10 of the present invention may enable the needle tip to be precisely located within a penetration zone of less than about 5 mm in depth, and preferably within the range of about 1 mm to about 3 mm in  
20 depth. In addition, the IDD 10 of the present invention enables such precise locating of the needle tip from one IDD 10 to the next.

In the illustrated embodiment of the present invention, the mounting surface 22 defines a circular periphery and is tilted at an acute angle "A" relative to the axis of the IDD 10. Preferably, the angle A is within the range of about 30° to about 60°, and in the illustrated  
25 embodiment is about 45°. However, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the angle A may take different magnitudes to facilitate operation of the IDD 10. Similarly, the peripheral shape of the mounting surface 22 may take any of numerous different shapes, such as an oval shape, to facilitate releasably securing the skin or otherwise to facilitate the operation of the IDD 10. In addition, although  
30 the illustrated mounting surface 22 is smooth and planar, this surface may take any of numerous different shapes to facilitate engaging the skin or otherwise to facilitate operation of the IDD 10. The adhesive 26 and releasable backing 22 likewise may take the form of any of

numerous different types of adhesives and/or releasable backings that are currently or later become known for performing the functions of these components of the IDD 10.

As shown best in FIG. 3, the syringe 14 comprises a hollow syringe body 36 slidably received within the hollow interior 16 of the housing body 15. The syringe body 36 defines a  
5 hollow interior forming a chamber 38 therein for receiving the substance to be injected into the skin, a tip 40 formed at one end of the syringe body 36 and defining an aperture 42 therethrough in fluid communication with the substance chamber 38, and a peripheral flange 44 formed at the opposite end of the syringe body 36. In the currently preferred embodiment, the syringe body 36 is made of glass. However, as may be recognized by those of ordinary  
10 skill in the pertinent art based on the teachings herein, the syringe body 36 may be made of any of numerous different materials that are currently, or later become known for forming syringes and may take any of numerous different shapes or configurations.

A plunger assembly 46 of the syringe 14 includes a plunger shaft 47 slidably received within the chamber 38 of the syringe body 36, and a resilient tip 48 on the interior end of the  
15 plunger shaft 47 that sealingly engages about its periphery the interior wall of the syringe body 36. As shown in FIG. 3, the plunger tip 48 preferably defines a plurality of raised ribs 50 axially spaced relative to each other for forming a fluid-tight seal between the plunger assembly 46 and syringe body 36 while allowing slidable movement therebetween.

If desired, the plunger shaft 47 and plunger tip 48 may take the form of a resealable  
20 stopper as disclosed in co-pending U.S. patent application serial no. 09/781,846, filed February 12, 2001, entitled "Medicament Vial Having A Heat-Sealable Cap, And Apparatus And Method For Filling The Vial", and U.S. patent application serial no. 10/265,075, filed October 3, 2002, entitled "Syringe And Reconstitution Syringe", each of which is hereby expressly incorporated by reference as part of the present disclosure.

25 The plunger assembly 46 further includes a pair of diametrically-opposed actuation arms 52 radially spaced relative to the plunger shaft 47 and slidably received within the open end of the housing body 15. As shown best in FIGS. 3, 5 and 6, the housing defines a pair of diametrically-opposed actuation channels 58 for slidably receiving therein the actuation arms 52 of the plunger assembly 46. As shown best in FIG. 3, a shoulder 60 is formed at the base of  
30 each actuation channel 58 to stop further movement of the actuation arms and plunger assembly 46. The outer end of the plunger assembly 46 defines a ribbed surface 54 to facilitate gripping the IDD 10 by placing a thumb on the ribbed surface 54 and two fingers of the same hand (preferably the index and middle fingers) on each of the first finger grips 20. The user

may then place the thumb of the other hand on the second grip 34 to stabilize the IDD 10 against the skin while simultaneously depressing the plunger assembly 46 by pushing the thumb against the ribbed surface 54 to thereby actuate the IDD 10. The inward stroke of the plunger assembly 46 drives the syringe body 36 inwardly and, in turn, drives the needle 28  
5 through the needle aperture 24 and into the derma to thereby inject the substance contained in the chamber 38 therein, as described in further detail below.

Each actuation arm 52 of the plunger assembly 46 defines a cam surface 56 that tapers inwardly in the direction from the outer to the inner end of the plunger assembly. As can be seen, each cam surface 56 slidably engages the peripheral flange 44 of the syringe body 36  
10 upon pressing the plunger assembly 46 therein. As described further below, the taper of each cam surface 56 allows the plunger shaft 47 to slidably move relative to and within the syringe body 36, while simultaneously maintaining a downward pressure on the syringe body 36 to, in turn, drive the needle 28 through the needle aperture 28 and into the penetration region X of the skin.

Each actuation arm 52 defines a radially-expanded region 62 formed at the juncture of each arm 52 and the gripping portion 54 for capturing therein the peripheral flange 44 of the syringe body 36 upon reaching the end of the plunger stroke. Each actuation arm 52 also defines a first shoulder 64 formed at the inner end of each tapered cam surface 56 for engaging the underside of the peripheral flange 44 of the syringe body 36 and preventing further outward  
20 movement of the plunger assembly 46. Each actuation arm 52 further defines a first recess 66 axially spaced relative to the first shoulder 64 for receiving therein a locking ring 68 to prevent inadvertent or other unwanted actuation of the syringe 14. A second recess 70 and second shoulder 72 are formed at the inner end of each actuation arm 52 for capturing therein a rotatable track follower 74. A coil spring 76 is seated within the housing body 15 between a  
25 plurality of angularly spaced spring mounts 78 formed within the housing body 15 and the track follower 74, for biasing the plunger assembly 46 outwardly and, in turn, allowing for automatic withdrawal of the plunger assembly 46 and needle 28 from the skin upon injecting the substance therein.

As shown best in FIG. 3, a needle mount 80 is mounted over the inner end 40 of the syringe body 36 and defines on one end a peripheral flange 82 and an elongated aperture 84  
30 formed therethrough. The needle 28 is fixedly secured to the free end of the needle mount 80 and is coupled in fluid communication with the aperture 84 and syringe chamber 38. As also shown in FIG. 3, the peripheral flange 82 of the needle mount is slidably mounted within a

bore 86 of the housing body 15 to allow reciprocal movement of the syringe 14 and needle 28 within the housing body 15. A peripheral stop 88 is formed at the base of the bore 86 and is engageable with the flange 82 of the needle mount 80 to thereby define the inner end of the plunger/needle stroke. As can be seen, the axial distance between the peripheral stop 88 and base surface 22 may be precisely controlled to thereby precisely control the depth of needle penetration into the skin. This feature, in combination with the substantially planar needle penetration region X of the skin formed by the adhesive-coated base 18, enables reliable and precise penetration of the needle tip into the derma of the skin to thereby effectively inject the substance contained within the syringe 14 therein.

As shown in FIGS. 3 and 7, a needle cap 90 is mounted over the end of the needle mount 80 to seal the needle 28 and syringe 14 during filling and storage. As shown best in FIG. 7, the needle mount 80 defines an annular rib 92 and the needle cap 90 defines a corresponding annular recess 94 for receiving therein the rib 92 and fixedly securing the needle cap 90 to the needle mount 80. Preferably, the interface between the needle 28, cap 90 and needle mount 80 defines a fluid tight or hermetic seal to maintain the sterility of the needle and of the substance contained within the syringe 14.

As shown in FIGS. 7 and 8, the needle 28 is preferably a "non-coring" needle defining a closed end surface or tip 96 and at least one, and preferably two apertures 98 located adjacent to the closed tip 96. In the illustrated embodiment, the apertures 98 are located on diametrically opposite sides of the needle relative to each other. However, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, each needle aperture 98 may take any of numerous different shapes and/or configurations, and the needle 28 may include one or more of such apertures at different desired locations. Each needle aperture 98 is coupled in fluid communication with the syringe chamber 38 and, as indicated by the arrows "C" in FIG. 8, the fluid or other substance contained within the syringe chamber 38 flows laterally outwardly through the apertures 98 and into the derma upon penetration of the needle tip therein. As shown in FIG. 8, the closed end surface or tip 96 of the needle 28 is oriented at an acute angle "B" relative to the axis of the IDD 10. Preferably, the angle B is approximately equal to the angle A of the base surface 22 shown in FIG. 3 to facilitate penetration of the needle tip to a precise, predetermined depth into the skin and, in turn, facilitate efficient and effective injection of the substance of the syringe 14 into the derma of the skin. However, as may be recognized by those of ordinary skill in the pertinent art based

on the teachings herein, the angle "B" may be set as required to facilitate effective operation of the IDD 10.

A significant advantage of the non-coring needle 28 of the IDD 10 of the present invention is that the non-coring needle 28 facilitates in reducing the head loss that otherwise might be created by the occlusion of tissue cells that can occur in typical prior art needles. Such head loss undesirably increases the pressure required to depress the plunger assembly 46 which results in a correspondingly higher pressure of the substance released from the syringe 14. It is believed that in some cases the release pressure may be excessive to the point where the substance injected undesirably perforates the basal membrane of the derma. This problem is further alleviated by the inclusion of multiple release outlets in the non-coring needle which results in a correspondingly lower release pressure. Yet another advantage of the non-coring needle 28 of the IDD 10 is that the substance injected through the needle apertures 98 flows generally laterally through the derma, rather than inwardly and under the derma of the skin. Thus, the injected substance does not need to perforate the cells but just disconnect the adhesiveness of the cells and insinuate on the sides of the non-coring needle.

As shown in FIG. 7, the needle cap 90 includes a closed end 100 defining a normally-closed aperture 102 forming a needle guide for receiving therein the tip of the needle 28. The closed end 100 of the needle cap 90 defines a peripheral flange 104 having a diameter or width greater than the diameter or width of the needle aperture 24 formed through the base surface 22 of the housing 12. Accordingly, on the inward stroke of the plunger assembly 46 and needle 28, the peripheral flange 104 of the needle cap 90 engages the inner surface of the base 18 surrounding the needle aperture 24 to thereby prevent further inward movement of the needle cap 90. Then, the needle 28 continues to move inwardly through the needle guide 102 and pierces the end surface 100 of the needle cap 90 prior to passage through the needle aperture 24 and into the patient's skin. In the currently preferred embodiment, the needle cap 90 is made of an elastomeric material to facilitate forming a fluid-tight or hermetic seal between the needle cap and needle mount. In addition, as shown in FIG. 7, the tip of the needle cap 90 located within the injection path of the needle 28 is made relatively thin to facilitate ease of insertion of the needle tip therethrough. The needle cap 90 may be formed of rubber, Kraton™, PTFE, or any other suitable elastomeric or polymeric material. However, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the needle cap 90 may be made of any of numerous different materials that are currently or later become known for performing the function of the needle cap 90 disclosed herein.

As shown in FIG. 9, the track follower 70 is ring-shaped and defines a pair of diametrically-opposed followers or pins 106 projecting outwardly from the side wall thereof. As shown in FIGS. 3 and 9, the track follower 70 further defines a first raised annular bearing surface 108 formed on the outer end thereof for rotatably and slidably contacting the adjacent surface of the cam arms 52, and a second raised annular bearing surface 110 formed on the other end thereof (FIG. 3) for rotatably and slidably contacting the second shoulder 72 of each cam arm 52. As best seen from FIGS. 6, 9 and 10, each track pin 106 is received within a respective slot 112 formed on the side of the housing 12.

As shown in FIG. 6, the slots 112 are located on opposite sides of the housing 12 relative to each other, and each slot defines a plurality of track pin positions for controlling actuation of the IDD 10. As shown in FIG. 10, each slot 112 defines a first pin position 114 defining the entry point for the respective pin 106 into the slot, e.g., the storage position. When located in the first pin position 114, the locking ring 68 is releasably secured to the syringe body 36 and received within the recess 66 (FIGS. 1-3). As shown in FIGS. 1, 2 and 11, the locking ring 68 defines a radially-projecting tab 116 and an opening 118 extending through the locking ring 68. As can be seen, the locking ring 68 prevents inward movement of the plunger assembly 46 by means of the tab 116 abutting against the outer end of the housing 12. Prior to use, a user pulls the tab 116 radially outwardly to thereby release the locking ring 68 from the syringe body 18 and allow actuation of the syringe 14. As may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the locking ring 68 or like locking device may take any of numerous different shapes and/or configurations to prevent actuation of the IDD 10 prior to its intended use. For example, the locking ring 68 may be formed of a frangible member that must be broken to remove it from the IDD 10 and thereby further prevent reuse of the IDD 10 or components thereof.

Referring again to FIG. 10, each slot 112 defines a second pin position 120 spaced axially inwardly and to the side of the first pin position 114, e.g., the mounting position. As shown in FIG. 13, the locking ring 68 permits sufficient relative movement of the plunger assembly 46 and syringe body 36 to move the track follower 70 from the first pin position 114 into the second pin position 120. As can be seen in FIG. 10, the angled surfaces of the slots 112 cause the pins 106 to rotate with inward movement of the plunger assembly 46, and the outward pressure applied by the spring 76 (FIGS. 3 and 13) pushes the pins 106 into the second pin position 120 once located within the respective portion of the slot 112. When located in the second pin position 120, the IDD 10 is ready for use and cannot be disassembled. The third

pin position 122 of each slot 112 is spaced axially inwardly and angularly relative to the second pin position 120, and defines the point at which the plunger assembly 46 is fully depressed and the injection completed, e.g., the injecting position.

In order to actuate the IDD 10 and move the plunger assembly 46 from the second pin position 120 to the third pin position 22, the user must first remove the locking ring 68 by pulling outwardly on the tab 116. Upon completing the injection, the user releases the plunger assembly 46, and the spring 76 is allowed to drive the plunger assembly 46 outwardly until the track follower 70 and pins 106 are received within a fourth pin position 124, e.g., the retracted position. As shown in FIG. 10, each slot 112 defines a fifth pin position 126 axially spaced adjacent to the fourth pin position 124, e.g., the safety position. When located in the fourth pin position 124, any further attempts to actuate the IDD 10 will result in limited travel between the fourth and fifth pin positions, 124 and 126, respectively, and thus will prevent further actuation and/or use of the IDD 10. Accordingly, subsequently handling of the IDD 10 is safe in that the needle tip is not exposed as a potentially contaminated sharp hazard.

In order to assemble and fill the IDD 10, the empty syringe bodies 36 are assembled to the needle mounts 80 having the needles 28 fixedly mounted therein. Each needle mount 80 may be press fit onto the end of the respective syringe body 36, or if desired, an epoxy or other suitable bonding material may be applied to the interface to fixedly secure the needle mount 80 to the syringe body 36. As shown typically in FIG. 12, the needle caps 90 are fixed to the needle mounts 80 and the plunger assemblies 46 (including the track followers 70, but not the locking rings 68) are slidably mounted within the syringe bodies 36. Then, each subassembly including the syringe body 36, needle mount 80, needle cap 90 and plunger assembly 146 is sterilized, such as by the application of gamma radiation thereto. However, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, any of numerous different methods that are currently or may later become known may be employed to sterilize the components of the IDD 10 before and/or after filling with the substances to be contained therein. A significant advantage of the needle cap 90 of the IDD 10 disclosed herein is that it allows the syringes 14 to be sterilized and pre-filled prior to assembling the syringes 14 into the housings 12. Thus, the IDD 10 can be filled with the same type of equipment used to fill prior art syringes. Yet another advantage of the pierceable needle cap 90 of the IDD 10 is that it is contained within the housing 12, and therefore allows the needle aperture 98 in the housing 12 to be small enough to permit passage of the needle 28 only therethrough. The relatively small needle aperture 98 facilitates the formation of a substantially planar needle

penetration region X on the skin and, in turn, facilitates efficient and effective intradermal delivery.

The sterilized subassemblies are then seated within a filling fixture, such as a tray defining a plurality of recesses or other mounting surfaces for holding a plurality of such subassemblies and transporting them within any of numerous different types of sterile filling machines known to those of ordinary skill in the pertinent art. For example, such sterile filling machine may take the form of the filling machine disclosed in U.S. Patent No. 5,641,004 to Py, entitled "Process For Filling A Sealed Receptacle Under Aseptic Conditions", and which is hereby expressly incorporated by reference as part of the present disclosure. In addition, and particularly if the plunger shaft 47 and plunger tip 48 take the form of a resealable stopper as described above, the sterile filling machine may take the form of the filling machine disclosed in co-pending U.S. patent application serial no. 09/781,846, filed February 12, 2001, entitled "Medicament Vial Having A Heat-Sealable Cap, And Apparatus And Method For Filling The Vial", incorporated by reference above, or in the U.S. Patent Application entitled "Sterile Filling Machine Having Needle Filling Station Within E-Beam Chamber", filed June 19, 2003, under Attorney Docket No. 488180.0094, and which claims priority on U.S. Provisional Patent Application No. 60/390,212, entitled "Sterile Filling Machine Having Needle Filling Station Within E-Beam Chamber", filed June 19, 2002, each of which is hereby expressly incorporated by reference as part of the present disclosure.

Upon filling each syringe body 36 with the substance to be contained therein, the respective plunger assembly 14 is preferably vacuum capped to the syringe body 36 in a manner known to those of ordinary skill in the pertinent art to form a substantially airless interior within the syringe body 36. As described above, the interface between the plunger 48 and syringe body 36, and the interface between the needle cap 90 and needle mount 80 define substantially airtight or hermetic seals to maintain the airless condition of the substance within the syringe body 36 throughout its shelf life. The filled, airless syringe subassemblies 14 are then mounted within the housings 12 with the springs 76 mounted between the track followers 70 and the spring mounts 78, and the locking rings 68 secured to the syringe bodies 36.

In order to use the IDD 10 and as shown in FIG. 14, the user removes the locking ring 68 to allow the IDD 10 to be actuated, and removes the foil or like releasable backing 32 from the base 18 of the IDD 10 to expose the underlying adhesive layer 26 and needle aperture 24. Then, with reference to FIG. 15, the user places the adhesively-coated mounting surface 22 against the desired portion of the patient's skin and lightly presses the base 18 against the skin

by applying the thumb of the other hand to the finger grip 34. This, in turn, causes the mounting surface 22 to adhesively attach to the skin and thereby create the substantially planar needle penetration region X on the skin by preventing relative movement of the skin and mounting surface 22. The user then applies the index and middle fingers of the other hand to the finger grips 20, and applies the thumb of the same hand to the gripping portion 54 of the plunger assembly 46. Then, the user presses the plunger assembly 46 inwardly using the thumb, index and middle fingers in a "trigger-like" action to, in turn, cause the track follower 70 to compress the coil spring 76 and simultaneously cause the cam surfaces 56 of the actuation arms 52 to engage the peripheral flange 44 of the syringe body 36 and move the syringe body 36 inwardly. Prior to full compression of the spring 76, the plunger assembly 46 moves inwardly with the syringe body 36 and thus does not cause the plunger 48 to displace any substance from the syringe 14. At full compression of the spring 76, the track follower 70 and pins 106 are located in the third pin position 122 of FIG. 10. At this point, the needle tip 96 has pierced the end surface 100 of the needle cap 90 and is inserted at a predetermined depth into the needle penetration region X of the skin. Then, as the user continues to press inwardly on the gripping surface 54 of the plunger assembly 46, the plunger tip 48 moves through the syringe chamber 38 to dispense the substance contained therein through the needle holes 98 and into the skin. The actuation arms 52 of the plunger assembly 46 are sufficiently flexible to move over the flange 44 of the syringe body 36 to allow further actuation of the syringe 14. When the plunger tip 48 reaches the inner end or bottom of its stroke, the user releases the thumb from the gripping surface 54 of the plunger assembly 46. At this point, and as shown in FIG. 16, the flange 44 of the syringe body 36 is captured within the recessed portions 62 of the actuation arms 52, and the spring 76 is then allowed to drive the plunger assembly 46 and needle assembly 28 outwardly from the patient's skin. The user then detaches the adhesively-coated mounting surface 22 from the skin by pulling the mounting surface 22 away in, for example, a tilting action. As shown in FIG. 17, the spring 76 drives the track follower 70 and pins 106 into the fourth pin position 124 of FIG. 10 to thereby prevent further actuation of the IDD 10.

Referring now to Figures 18-21, another embodiment of an adhesively-attachable IDD of the present invention is indicated to generally by the reference numeral 210. As will be appreciated by those of ordinary skill in the pertinent art, the IDD 210 utilizes many of the same principles of the IDD 10 described above. Accordingly, like reference numerals preceded by the numeral "2", or the numeral "3" instead of the numeral "1", are used to

indicate like elements. In addition, the description herein is largely directed to the differences for simplicity. The IDD 210 comprises a housing 212 and a syringe 214 mounted within the housing 212. The housing 212 includes an axially-elongated housing body 215 with a base 218 formed at a lower end 219 of the housing 212. The base 218 includes on its underside an expandable mounting surface 222 defined by a plurality of discrete mounting surfaces 222a-c for tensioning the skin across the needle penetration region X. As indicated by dotted lines, a pressure-sensitive adhesive layer 226 is applied to the discrete mounting surfaces 222a-c for securing the IDD 210 in place. Expansion slots 223 formed in the lower end 219 of the housing allow mounting surfaces 222a, 222c to expand radially outward; however, mounting surface 222b remains fixed and stable to define the needle aperture 224 through which the needle tip extends. When the mounting surfaces 222a, 222c are placed against the patient's skin and the mounting surfaces 222a, 222c expand radially outward, the skin of the needle penetration region X is stretched across the needle aperture 224.

The ability to form a taut substantially planar needle penetration region X on the skin is a significant advantage of the IDD 210 of the present invention because the natural looseness of the skin has been decreased. As a result, when the needle tip penetrates the derma of the skin, the flatness of the needle penetration region X is substantially maintained to allow accurate prediction of the insertion depth of the needle tip.

As shown best in FIG. 21, a needle mount 280 is mounted over the inner end 240 of the syringe body 236 and defines on one end a peripheral flange 282 and an elongated aperture 284 formed therethrough. Outer walls 281 of the needle mount 280 are tapered for increasing interference with the housing 212 as the needle mount 280 travels toward the needle aperture 224. The resulting interference causes expansion of the lower end 219 of the housing 212 and, thereby, the mounting surfaces 222a, 222c expand radially outward as indicated by arrows "D". The needle 228 is fixedly secured to the free end of the needle mount 280 and is coupled in fluid communication with the syringe chamber 238. The needle mount 280 forms a peripheral flange 282 at an upper end and a peripheral shoulder 283 at a lower end. The needle mount 280 is slidably mounted within a bore 286 of the housing 212 to allow reciprocal movement of the syringe 214 and needle 228 within the housing 212. A peripheral stop 288 is formed at one end of the bore 286 and is engageable with the shoulder 283 of the needle mount 280 to thereby define the inner end of the plunger/needle stroke. As can be seen, the axial distance between the shoulder 283 of the needle mount 280 and the peripheral stop 288 of the

housing 212 may be precisely controlled to thereby precisely control the depth of penetration of the needle 228 into the skin without a practiced skill level on the part of the user.

It will be recognized by those of ordinary skill in the pertinent art based upon review of the subject disclosure that many variations are possible. For example, the principles and devices herein can be advantageously used to inject substances other than intradermally, such as sub-cutaneously. Similarly, the devices can be made of any of numerous different materials that are currently, or later become known for performing the functions of the various components of the devices described or otherwise disclosed herein. If desired, the devices may include more than one needle for simultaneously injecting the substance with a plurality of needles into the substantially planar or other target penetration region of the skin. Further, the stop surface or surfaces for controlling and/or setting the insertion depth of the needle can take any of numerous different shapes and/or configurations that are currently or later become known for performing this function. For another example, the number of discrete mounting surfaces may take a multitude of different configurations wherein a base 318 of a housing 312 may form five mounting surfaces 322a-e or seven mounting surfaces 322a-g (322g not shown), as illustrated in FIGS. 22 and 23, respectively.

Accordingly, while the invention has been described with respect to certain currently preferred embodiments, those skilled in the art will readily appreciate that various changes and/or modifications can be made to the invention without departing from the spirit or scope of the invention as defined by the appended claims. This detailed description of preferred embodiments, therefore, is to be taken in an illustrative as opposed to a limiting sense.

**WHAT IS CLAIMED IS:**

1. An intradermal delivery device, comprising:

a housing including a base defining a mounting surface and a needle aperture formed therethrough, and an adhesive located on the mounting surface for releasably securing the mounting surface to the skin and preventing relative movement of the skin and the mounting surface, and wherein the base forms a substantially planar needle penetration region on the skin located adjacent to the needle aperture;

a syringe including a syringe body coupled to the housing and a plunger slidably received within the syringe body;

a needle coupled in fluid communication with the syringe body and movable through the needle aperture to penetrate the needle penetration region of the skin and inject a substance contained within the syringe body therein; and

at least one stop surface fixed relative to at least a portion of the mounting surface to define a predetermined distance therebetween, and adapted to cooperate with the needle to limit a depth of insertion of the needle into the needle penetration region of the skin, wherein the needle is movable through the needle aperture upon slidably moving the plunger through the syringe body to thereby penetrate with the needle the penetration region of the skin and inject a substance contained within the syringe body therein.

2. An intradermal delivery device as defined in claim 1, further comprising a releasable backing superimposed over the adhesive.

3. An intradermal delivery device as defined in claim 1, wherein the mounting surface is approximately planar.

4. An intradermal delivery device as defined in claim 1, wherein the mounting surface is oriented at an acute angle relative to an axis of the intradermal delivery device.

5. An intradermal delivery device as defined in claim 4, wherein the acute angle is within the range of about 30° to about 60° relative to the axis of the intradermal delivery device.

6. An intradermal delivery device as defined in claim 4, wherein the acute angle is about 45° relative to the axis of the intradermal delivery device.

7. An intradermal delivery device as defined in claim 1, wherein a portion of the mounting surface is radially expandable in response to movement of the plunger through the syringe body to tension the substantially planar penetration region on the skin.

8. An intradermal delivery device as defined in claim 7, wherein the housing defines expansion slots for facilitating radial expansion of the mounting surface.

9. An intradermal delivery device as defined in claim 8, further comprising a needle mount for coupling the needle to the syringe body, the needle mount having a tapered wall for radially expanding the portion of the mounting surface.

10. An intradermal delivery device as defined in claim 1, wherein the needle is a non-coring needle defining a closed end surface and at least one aperture located in a side wall thereof in fluid communication with the syringe body.

11. An intradermal delivery device as defined in claim 1, further comprising a removable locking member attached to the syringe for preventing actuation of the intradermal delivery device prior to removal thereof.

12. An intradermal delivery device as defined in claim 1, wherein the syringe body includes a flange, and the plunger includes a plunger shaft slidably received within the syringe body and two actuation arms depending from an exterior end of the plunger shaft, each actuation arm defining a radially-expanded region formed at the juncture of each arm and the plunger shaft for capturing therein the flange of the syringe body upon reaching an end of a plunger stroke.

13. An intradermal delivery device as defined in claim 12, wherein each actuation arm includes a tapered inner surface for engaging the flange of the housing to facilitate inserting the needle prior to inserting the plunger assembly into the syringe body.

14. An intradermal delivery device as defined in claim 12, wherein each actuation arm further defines a first shoulder for engaging the housing and preventing outward movement of the plunger.

5 15. An intradermal delivery device as defined in claim 14, wherein each actuation arm further defines a first recess axially spaced relative to the first shoulder for receiving therein a locking ring to prevent undesirable actuation of the intradermal delivery device.

10 16. An intradermal delivery device as defined in claim 15, wherein each actuation arm further defines a second recess and second shoulder for capturing therein a rotatable track follower.

17. An intradermal delivery device, comprising:  
first means for defining a substantially planar target region on the skin;  
15 second means for adhesively attaching the first means to the skin and preventing relative movement of the target region of the skin and the first means;  
third means for storing a substance to be injected into the skin;  
fourth means for releasing the substance from the third means;  
fifth means in communication with the third means for penetrating the target region of  
20 the skin and injecting the substance contained within the third means therein; and  
sixth means for limiting the penetration depth of the fifth means.

18. An intradermal delivery device as defined in claim 17, further comprising a housing including a base defining a mounting surface and a needle aperture formed  
25 therethrough, wherein the first means is defined by the mounting surface.

19. An intradermal delivery device as defined in claim 17, wherein the second means is formed by an adhesive located on the first means.

30 20. An intradermal delivery device as defined in claim 17, further comprising a syringe including a syringe body defining a chamber, wherein the third means is defined by the chamber.

21. An intradermal delivery device as defined in claim 17, wherein the fourth means is a plunger slidably received within the third means.

22. An intradermal delivery device as defined in claim 17, wherein the fifth means  
5 is a needle.

23. An intradermal delivery device as defined in claim 17, further comprising a housing including a shoulder, wherein the sixth means is defined by the shoulder.

10 24. An intradermal delivery device as defined in claim 17, further comprising a window on the third means for inspecting the third means.

25. A method for intradermal delivery, comprising the following steps:  
providing an intradermal delivery device including a housing having a mounting  
15 surface and a reciprocally mounted syringe therein;  
placing the mounting surface on the skin of a patient;  
adhesively attaching the mounting surface to the skin to thereby releasably secure the device to the skin;  
forming a substantially planar target penetration region on the skin;  
20 introducing a needle of the syringe a predetermined depth into the substantially planar target penetration region of the skin; and  
injecting a substance from the syringe through the needle into the substantially planar target penetration region of the skin.

25 26. A method as defined in claim 25, further comprising the step introducing the needle at a predetermined acute angle between the axis of the needle and the substantially planar target penetration region of the skin.

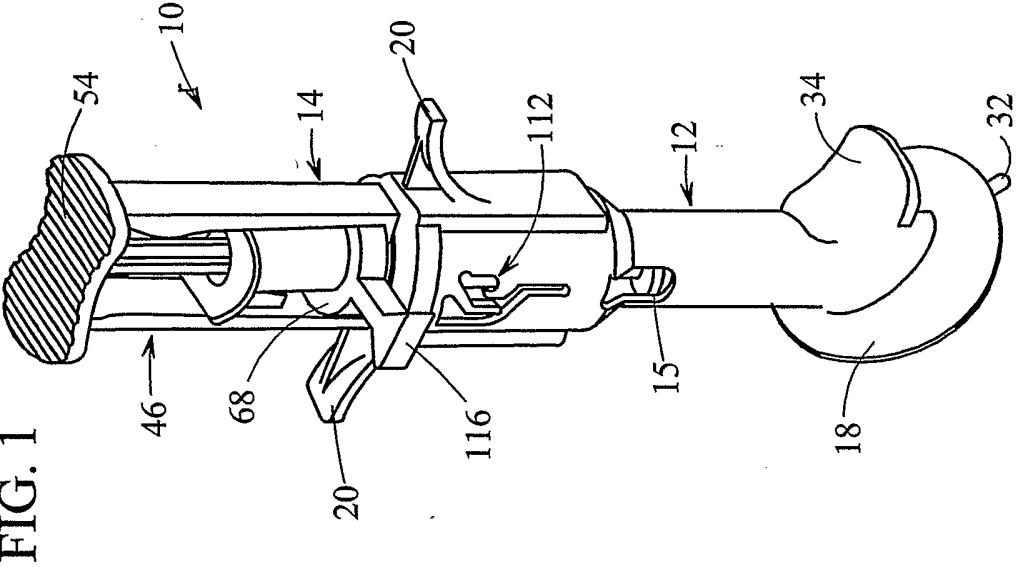
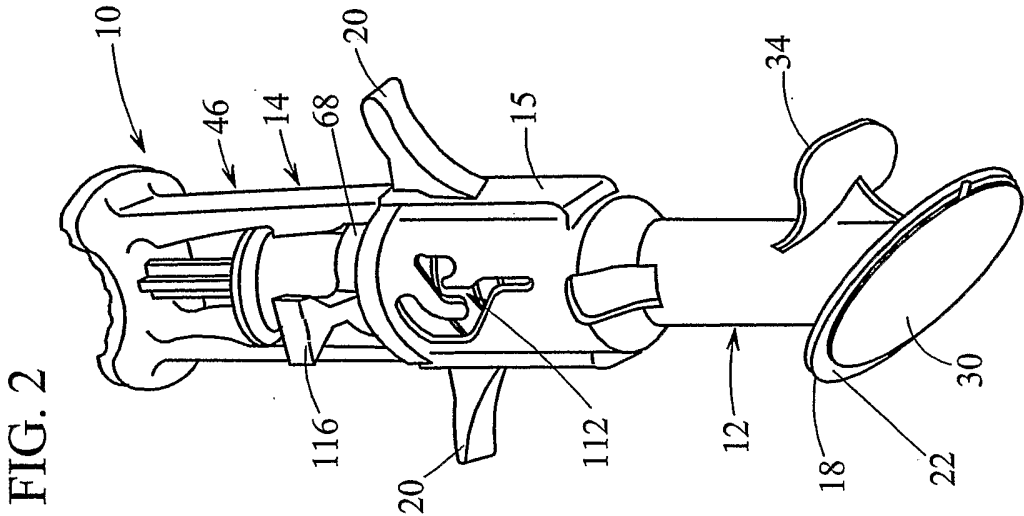


FIG. 3

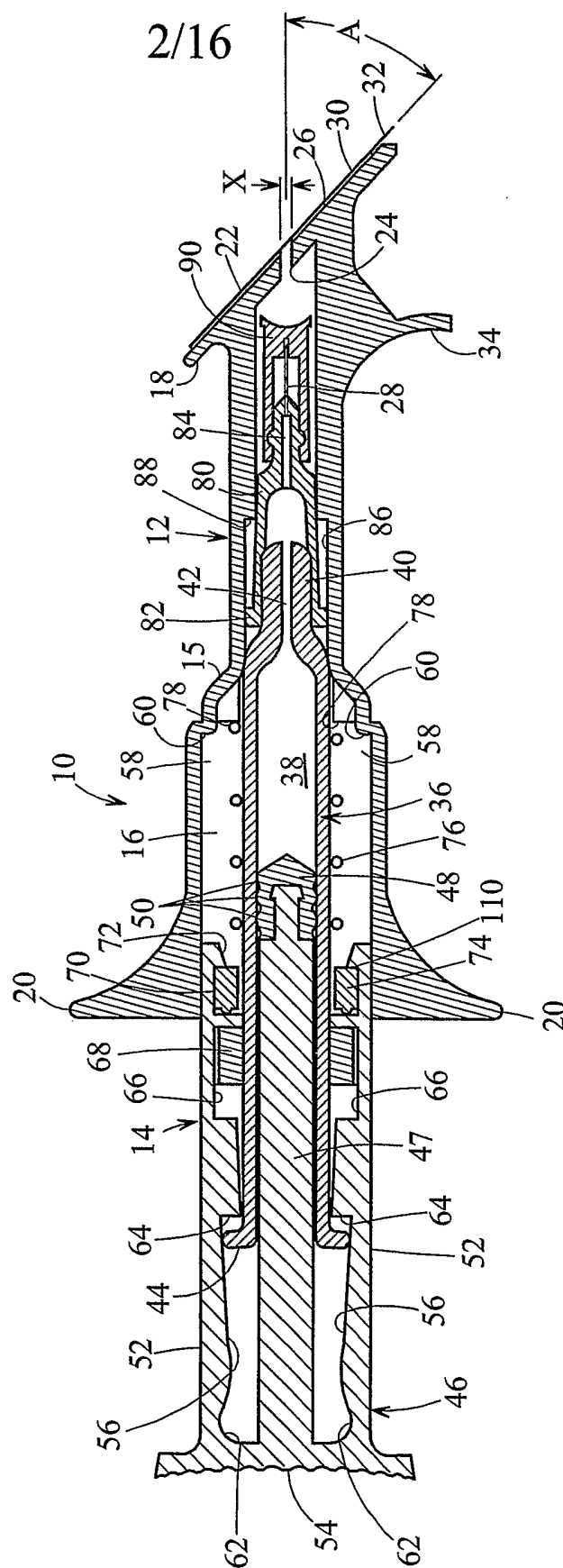


FIG. 4

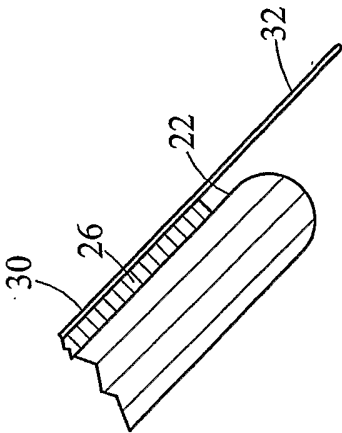
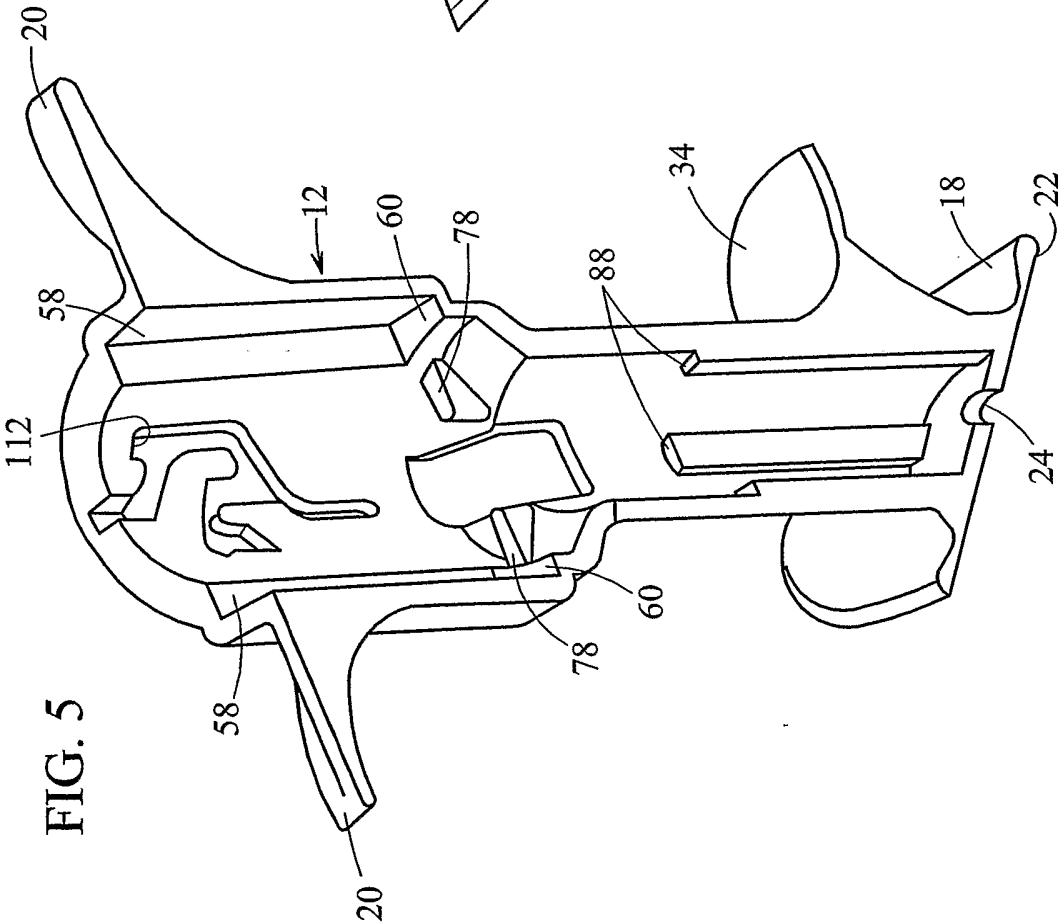
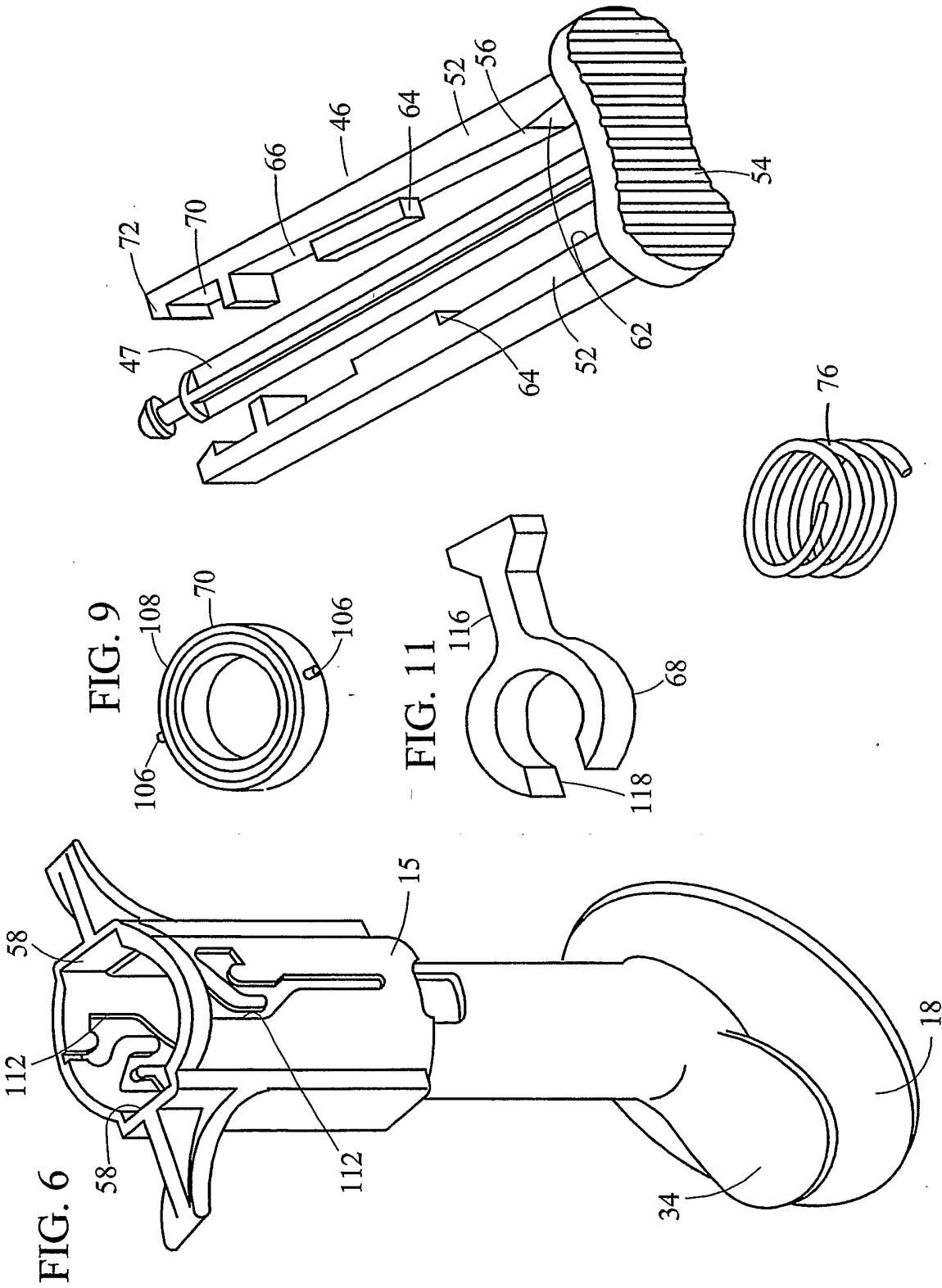


FIG. 5





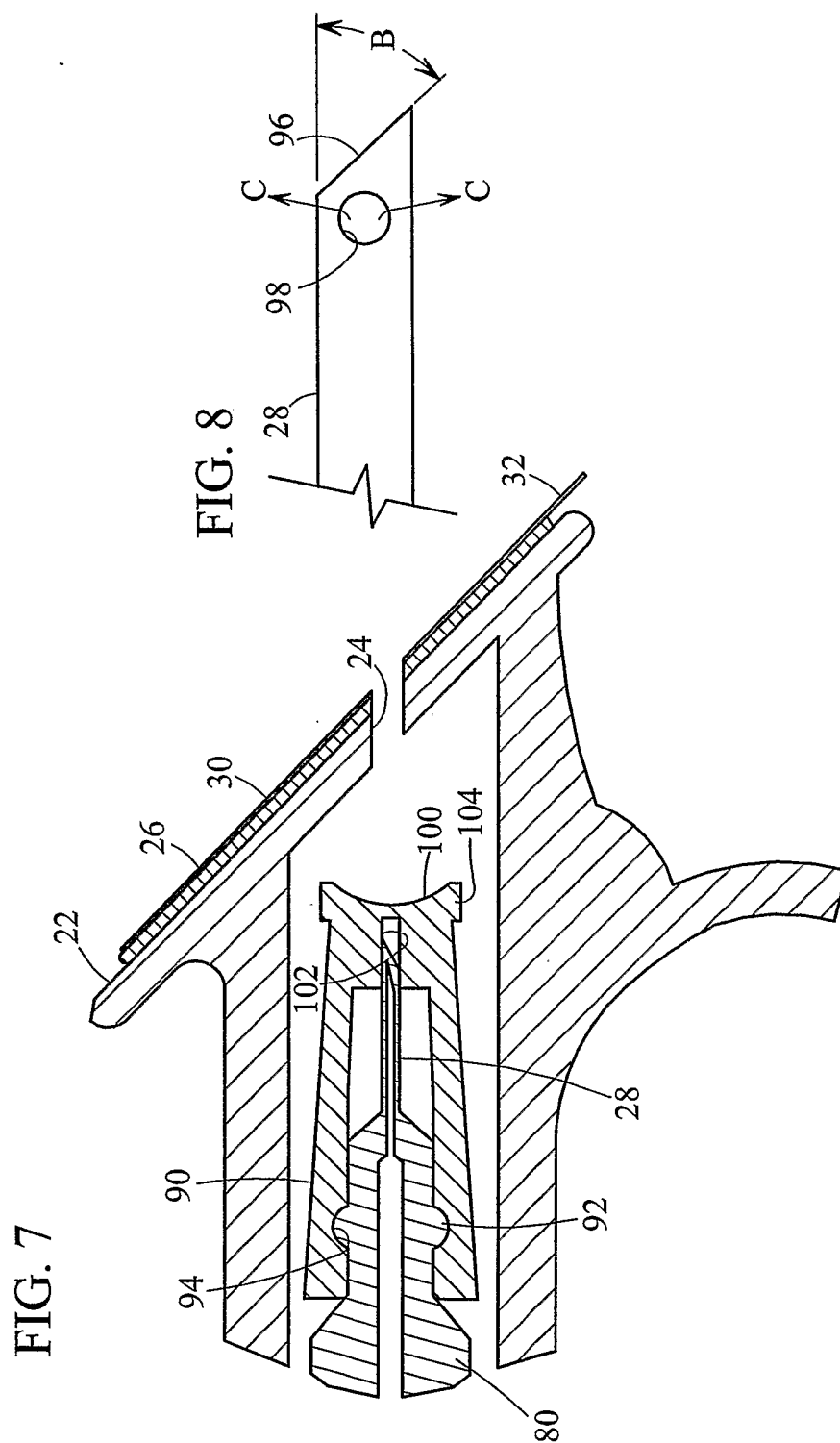
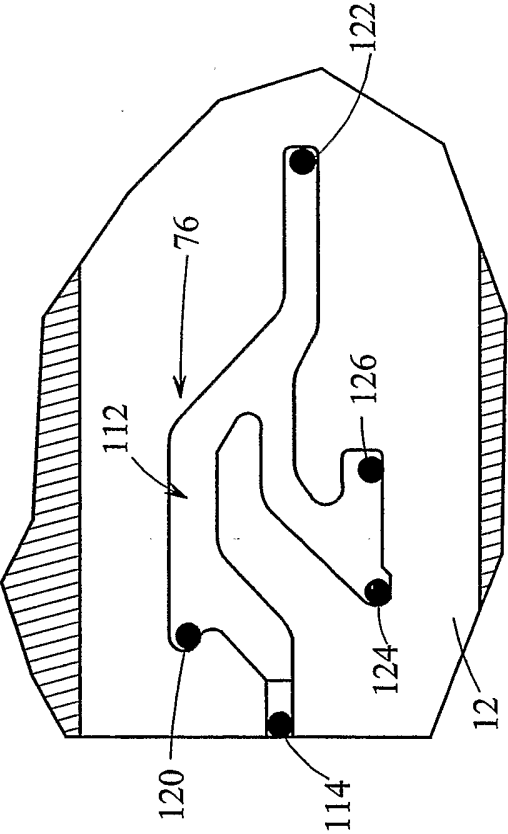


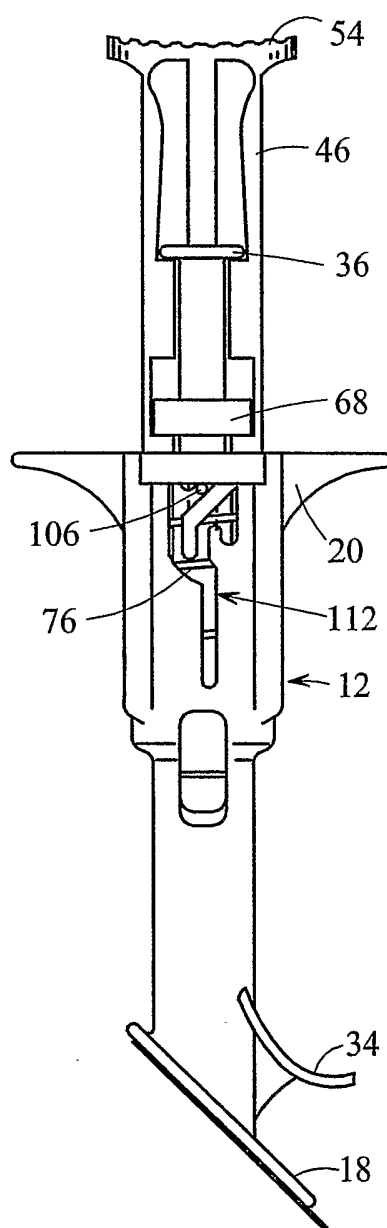
FIG. 10





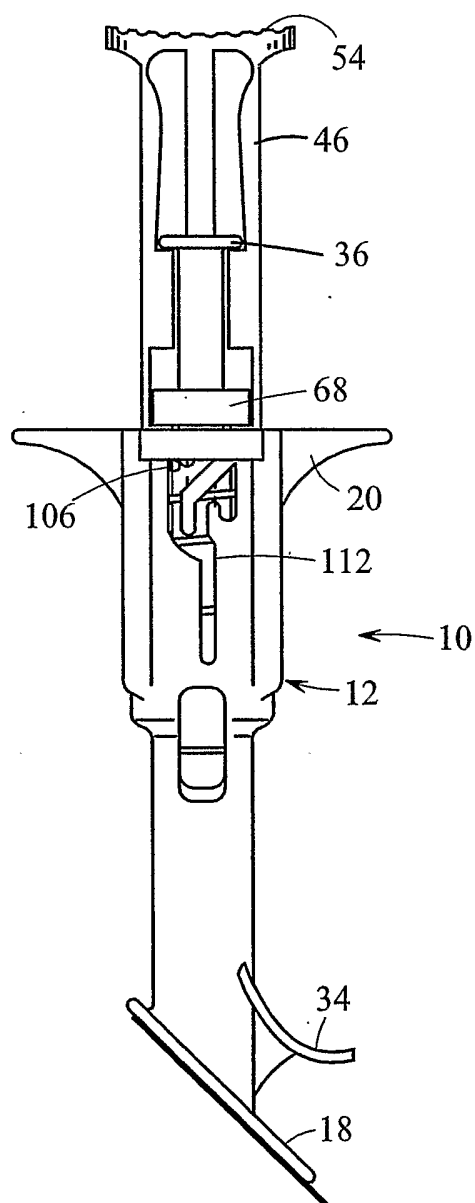
8/16

FIG. 13



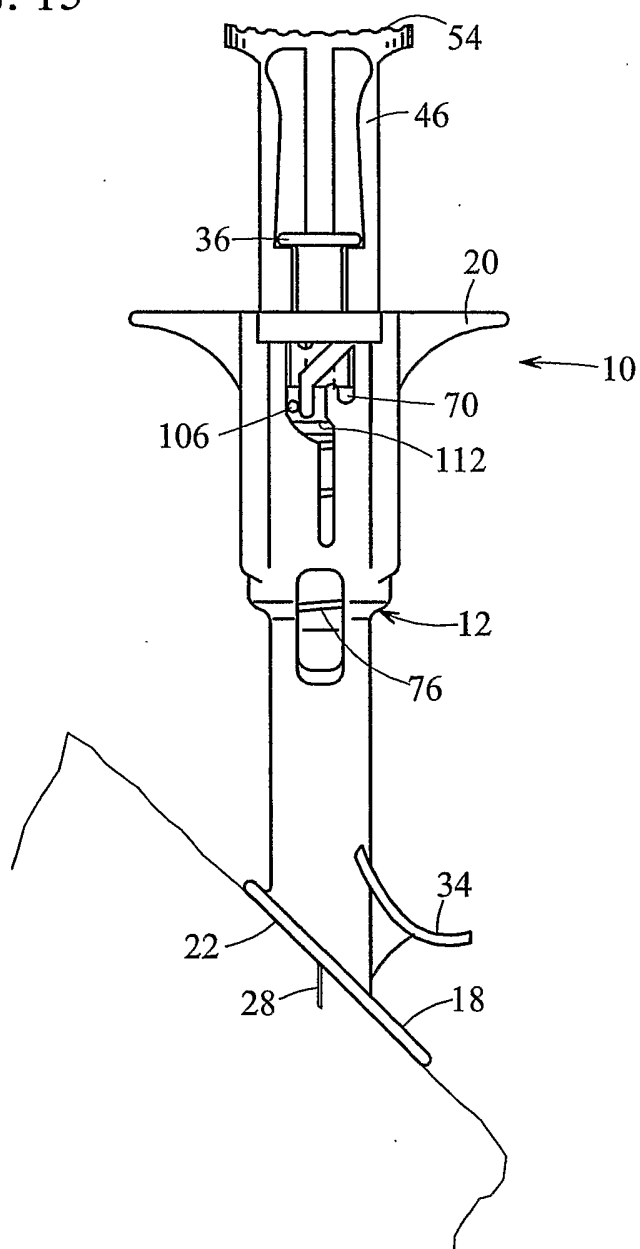
9/16

FIG. 14



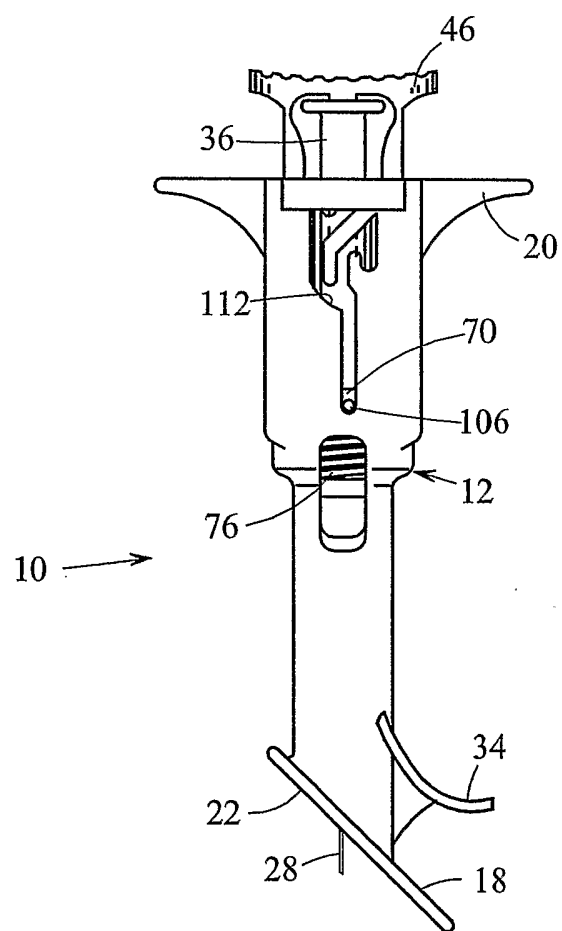
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FIG. 15



11/16

FIG. 16



12/16

FIG. 17

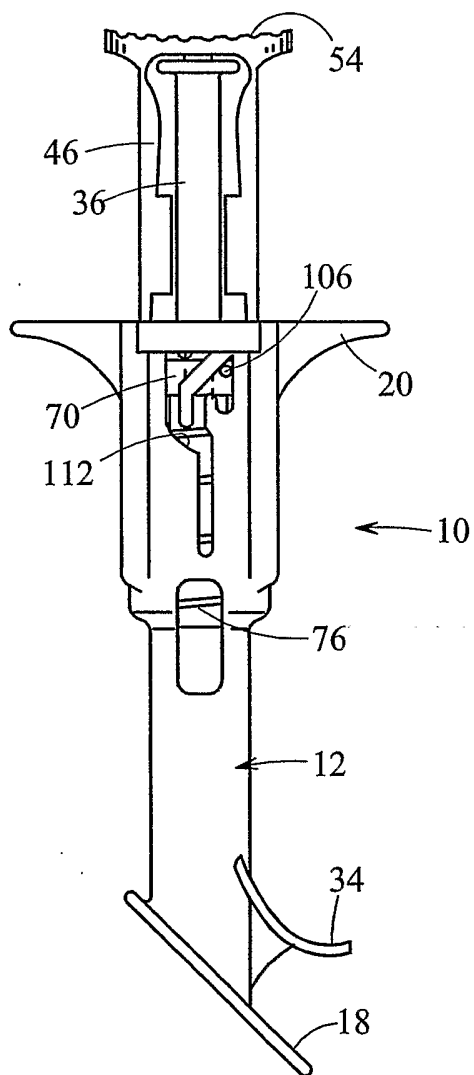


FIG. 19

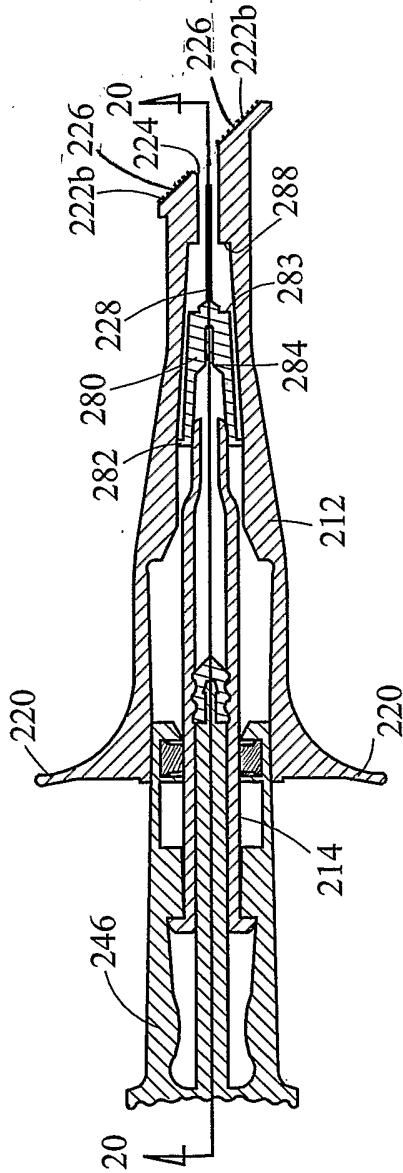


FIG. 18

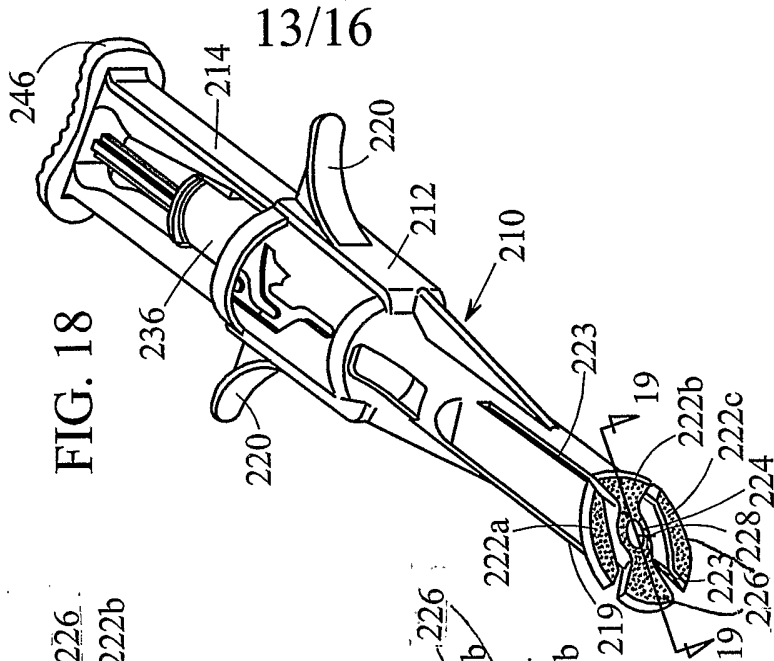
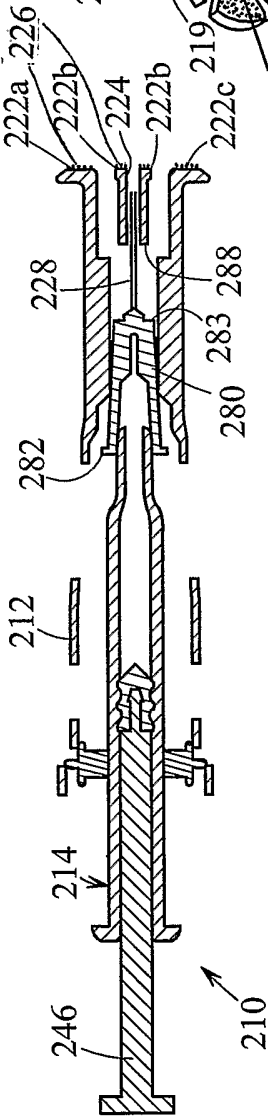
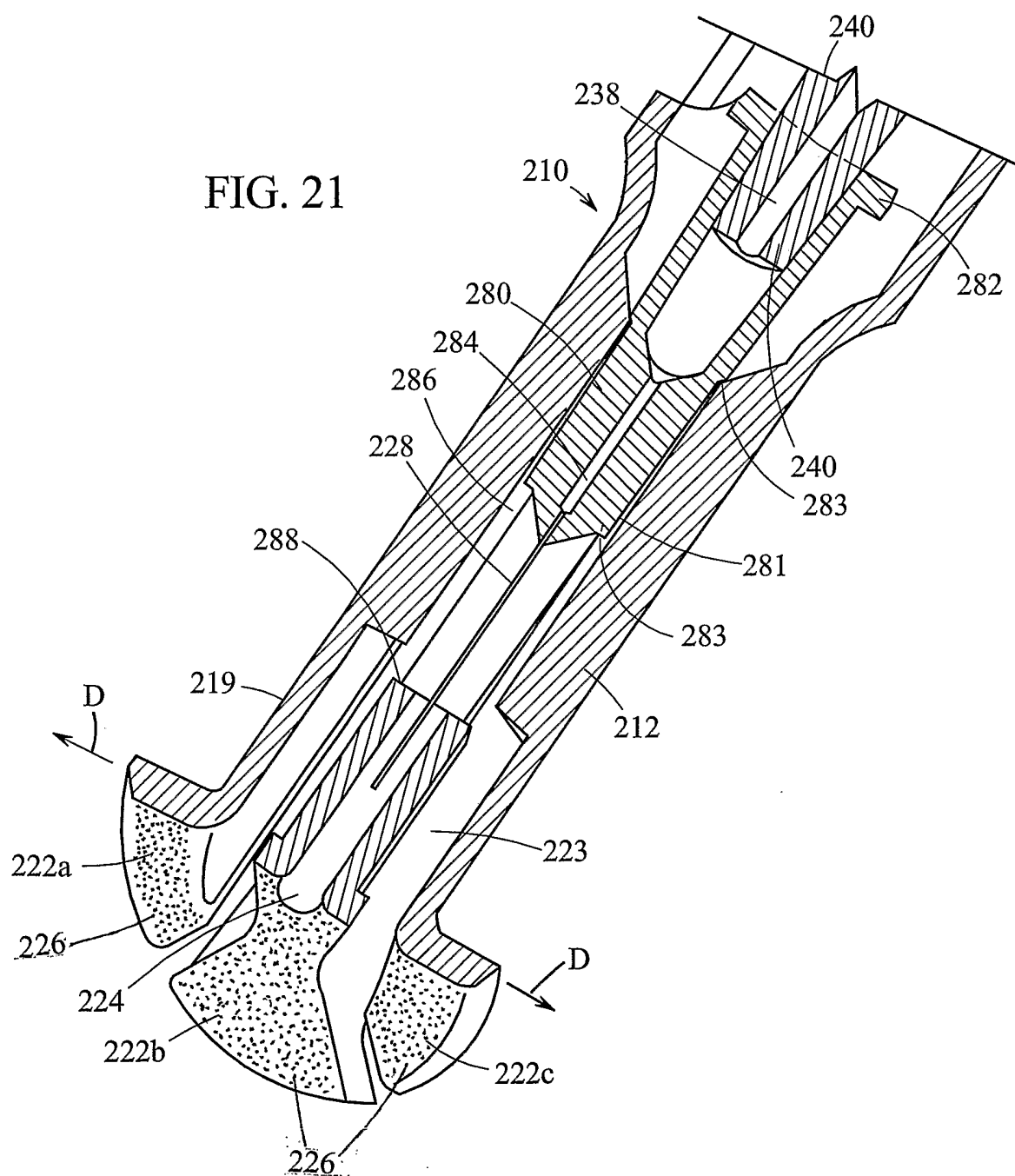


FIG. 20



14/16

FIG. 21



15/16

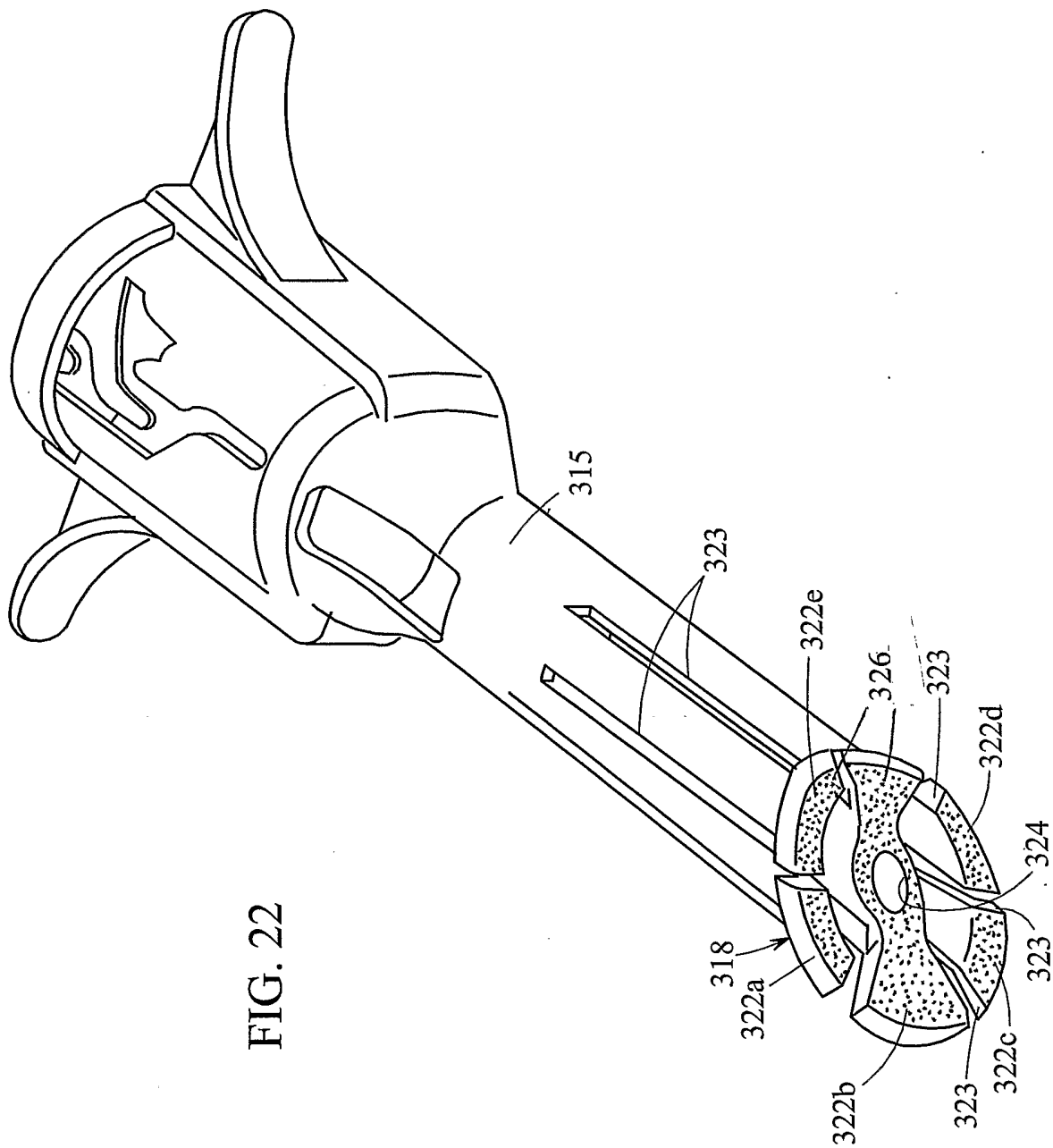


FIG. 22

16/16

FIG. 23

