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(54) Title: ALIGNMENT OF A NEEDLE IN AN INTRADERMAL INJECTION DEVICE

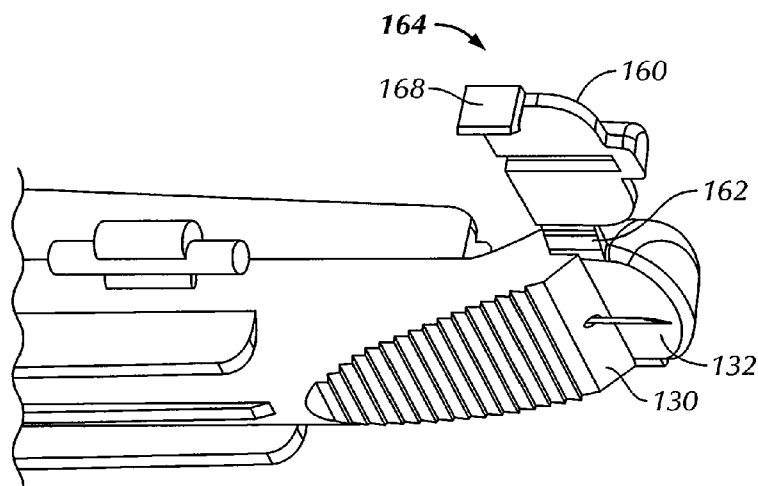


FIG. 8A

(57) Abstract: An adapter device (100, 200) for use in combination with a syringe (20) to form an assembly (10) for delivering an intradermal injection. The adapter device comprises a body (110, 210) which is connectable to the syringe. A second primary skin contacting surface (232) is positioned at a distal end (126, 226) of the body. At least one support element (140, 150, 240) is connected to the body. With the assembly in an assembled condition, the at least one support element supports a needle cannula (24) connected to the syringe. The needle cannula is supported by the at least one support element intermediate a base (26) and a tip (28) of the needle cannula. At least a terminal portion of the needle cannula extends axially in a direction substantially parallel to at least a planar portion of the second primary skin contacting surface.



TITLE OF THE INVENTION

[0001] Alignment of a Needle in an Intradermal Injection Device

BACKGROUND OF THE INVENTION

5 [0002] The invention relates to devices for delivery of intradermal injections generally, and more particularly to an adapter device combinable with a standard syringe to form an assembly for delivery of an intradermal injection.

[0003] Intradermal injections are used for delivering a variety of diagnostic and treatment compositions into a patient. Substances may be injected intradermally for diagnostic testing, such as
10 to determine a patient's immunity status against tuberculosis and the status of allergic diseases. Vaccines, drugs and other compounds may also be delivered intradermally. In many instances, intradermal delivery is preferred because it generally requires a smaller volume dose of the diagnostic or treatment compound than other delivery techniques. An intradermal injection is made by delivering the substance into the epidermis and upper layer of the dermis. There is considerable
15 variation in the skin thickness, both between individuals and within the same individual at different sites of the body. Generally the outer skin layer, or the epidermis, has a thickness between 500-200 microns and the dermis, the inner and thicker layer of the skin, has a thickness between 1.5-3.5 mm.

[0004] Making intradermal injections is difficult and generally requires an experienced nurse or medical professional. Incorrect placement of the tip of the needle cannula leads to a failed injection.
20 The placement of the needle tip deeper than about 3.0 mm has the potential of delivering the injection into the subcutaneous region, where the intradermal dosage may be insufficient. Incorrect placement of the needle cannula may also puncture the skin again after being inserted into dermis, with the delivered compound being lost on the surface of the skin. Injection is often followed by a jet effect, with the compound exiting the injection site through the needle puncture track. The jet
25 effect is even more pronounced for injections through a needle placed perpendicular to the injection site and in particular for shallow delivery. The success of intradermal injections is often determined by the experience of the healthcare professional. The preferred intradermal injection technique (using a standard needle) requires the healthcare professional to stretch the skin, orient the needle bevel to face upward, and insert a short bevel needle cannula at an angle of around 10-15 degrees,
30 assuring that 2 to 3 mm of the needle cannula are located in the skin. The needle tip ends up positioned in the dermis or close to epidermis boundary. The compound is slowly injected into the

skin of the patient, forming a blister or wheal. The insertion of the needle at an incorrect angle and/or depth results in a failed intradermal injection. Intradermal (ID) injection has been considered for immunization in the past, but has generally been rejected in favor of more reliable intramuscular or subcutaneous routes of administration because of the difficulty in making a successful ID injection.

[0005] Administration into the region of the intradermal space has been routinely used in the Mantoux tuberculin test, in which a purified protein derivative is injected at a shallow angle to the skin surface using a 27 or 30 gauge needle and a standard syringe. The technique is known to be quite difficult to perform and requires specialized training. A degree of imprecision in the placement of the injection results in a significant number of false negative test results. As a result, the Mantoux approach has not led to the use of intradermal injection for systemic administration of substances, despite the advantage of requiring smaller doses of substances.

[0006] There have been attempts to develop devices that would assure a precise needle penetration depth during ID injection which tends to vary due to tissue compliance, penetration angle, skill level and other factors. These are detailed in US Patent Numbers 4,393,870 and 6,200,291 and US Published Patent Applications Numbers 2003/0093032 and 2004/0147901. These devices employ complex constructions that tension the skin by vacuum, expanding the mounting surface prior to the needle insertion.

[0007] Alchas *et al.* developed a unique intradermal needle assembly for the delivery of compounds into the intradermal space by penetrating the dermis perpendicularly to its surface. A limiter supporting the needle is placed on the skin, the needle inserted, and the compound delivered. The penetration depth is in the 0.5 to 3 mm range, with a device limiter setting the penetration depth. There is a broad range of patents, issued and pending, defining different features of the system. U.S. Patent Numbers 6,494,865, 6,569,123, 6,689,118, 6,776,776, and U.S. Patent Publication Number 2003/0199822 describe such systems. The main limitation of the systems developed by Alchas *et al.* is the broad range of deposit depth due to assembly tolerances, needle bevel and the variations in skin properties. Another concern is back flow through the needle channel from the deposit pool to the surface of the skin due to a short direct channel formed by the needle. The jet effect further limits the performance when a shallow delivery is attempted.

[0008] Shielding and disposal of the contaminated needle cannula is a primary concern upon completion of an injection. It is preferable to cover the contaminated needle as soon as the intradermal injection is completed. A number of different approaches to shielding the contaminated

needle are discussed in U.S. Patent Numbers 4,631,057; 4,747,837; 4,801,295; 4,998,920; 5,053,018; 5,496,288; and 5,893,845.

[0009] The lack of suitable devices to accomplish reproducible delivery to the epidermal and dermal skin layers has limited the widespread use of the ID delivery route. Using conventional devices, ID injection is difficult to perform, unreliable and painful to the subject. There is thus a need for devices and methods that will enable efficient, accurate and reproducible delivery of agents to the intradermal layer of skin.

[0010] WIPO Patent Application Publication WO/2008/131440 ("the '440 publication") discloses devices and methods for intradermal administration of diagnostic and therapeutic agents, vaccines and other compounds into the dermal layer of the skin. The '440 publication is incorporated herein by reference in its entirety. The devices and the methods simplify the ID injection process and increase the consistency of the placement of the needle tip in the dermal space close to the skin surface allowing for a shallow cannula placement in the dermis. Furthermore, the devices and methods broaden the number of sites suitable for ID injection and make successful ID injections possible with limited training.

[0011] The applicability of devices disclosed in the '440 publication would be substantially broadened with design improvements allowing for improved placement depth of the cannula in the dermis. Furthermore, a design facilitating the ease of device and syringe merger would be of a substantial benefit. The improvements facilitating the ID injection using one hand and other features would also be beneficial for the use of ID devices and methods. There is thus a need for improvements to devices and methods for efficient, accurate and reproducible delivery of agents to the intradermal layer of skin.

BRIEF SUMMARY OF THE INVENTION

[0012] Briefly stated, in a first aspect the invention is an adapter device for use in combination with a syringe to form an assembly for delivering an intradermal injection. The adapter device comprises a body which is connectable to the syringe. A second primary skin contacting surface is positioned at a distal end of the body. At least one support element is connected to the body. With the assembly in an assembled condition, the at least one support element supports a needle cannula connected to the syringe. The needle cannula is supported by the at least one support element intermediate a base and a tip of the needle cannula. At least a terminal portion of the needle cannula

extends axially in a direction at least substantially parallel to at least a planar portion of the second primary skin contacting surface.

[0013] Preferably, the adapter device further comprises a first primary skin contacting surface positioned at the distal end of the body. The first primary skin contacting surface is positioned at an angle to the second primary skin contacting surface between approximately 100 degrees and approximately 165 degrees.

[0014] Further preferably the adapter device body is formed in a first portion and a second portion, the portions being rotatably connectable. A first support element is connected to the first portion and a second support element connected to the second portion. The first and second support elements support the needle cannula along a plane passing through a centerline of the syringe.

[0015] Alternatively, the adapter device may preferably include a single support element connected to the body, wherein the support element supports the needle cannula at a point offset from a syringe centerline in one of a plane at least substantially perpendicular to the planar portion of the second primary skin contacting surface or a plane at least substantially parallel to the planar portion of the second primary skin contacting surface.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0016] The foregoing summary, as well as the following detailed description of the invention, will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings embodiments which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown.

[0017] In the drawings:

[0018] FIG. 1 is a lower side perspective view of an assembly of an adapter device and a syringe in accordance with a preferred embodiment of the present invention;

[0019] FIG. 2 is an enlarged side elevational view of a distal end of the adapter device shown in FIG. 1;

[0020] FIG. 3 is an upper side perspective view of the adapter device of FIG. 1, shown with two rotatably connected portions in an open position;

[0021] FIG. 4 is an enlarged upper rear perspective view of the distal end of the adapter device of FIG. 3;

[0022] FIG. 5 is an upper side perspective view of the adapter device of FIG. 3, shown with a fixed needle syringe installed;

[0023] FIG. 6A is a schematic representation of a side elevational view of a first needle cannula alignment technique capable of being incorporated into the adapter device of FIG. 1;

5 [0024] FIG. 6B is a schematic representation of an end view of the needle cannula alignment technique of FIG. 6A;

[0025] FIG. 7A is a schematic representation of a side elevational view of a second needle cannula alignment technique capable of being incorporated into the adapter device of FIG. 1;

10 [0026] FIG. 7B is a schematic representation of an end view of the needle cannula alignment technique of FIG. 7A;

[0027] FIG. 8A is a lower side perspective view of the distal end of the adapter device of FIG. 1, shown with a safety shield in a first, open position;

[0028] FIG. 8B is an upper side perspective view of the distal end of the adapter device of FIG. 8A, with the safety shield shown in a second, closed position;

15 [0029] FIG. 9 is a side elevational view of an adapter device in accordance with a second preferred embodiment of the present invention, shown with a fixed needle syringe in axial alignment in preparation for assembly with the adapter device;

[0030] FIG. 10 is a rear perspective view of the adapter device and syringe of FIG. 9, shown in an assembled condition;

20 [0031] FIG. 11A is a schematic representation of a side view of a third needle alignment technique, capable of being incorporated into the adapter device of FIG. 9;

[0032] FIG. 11B is a schematic representation of an end view of the needle alignment technique of FIG. 11A;

25 [0033] FIG. 12A is a schematic representation of a top plan view of a fourth needle alignment technique, capable of being incorporated into the adapter device of FIG. 9; and

[0034] FIG. 12B is a schematic representation of an end view of the needle alignment technique of FIG. 12A.

DETAILED DESCRIPTION OF THE INVENTION

30 [0035] Certain terminology is used in the following description for convenience only and is not limiting. The words “right”, “left”, “lower”, “upper”, “horizontal” and “vertical” designate directions in the drawings to which reference is made. The words “inwardly” and “outwardly” refer to directions toward and away from, respectively, the geometric center of the adapter device and

designated parts thereof. Unless specifically set forth herein, the terms “a”, “an” and “the” are not limited to one element but instead should be read as meaning “at least one”. The terminology includes the words noted above, derivatives thereof and words of similar import.

[0036] Referring to the drawings, shown in FIG. 1 is a first presently preferred embodiment of an adapter device 100 for use in combination with a syringe 20 to form an assembly 10 for delivering an intradermal injection. The adapter device 100 comprises a body 110 connectable to the syringe 20. In this first embodiment, the body 110 is formed in a first portion 120 and a second portion 122, the portions 120, 122 being rotatably connectable by one or more hinges 124 and inter-engaging connector tabs 125 and receiving holes 127 (see FIG. 3). The body is preferably formed using conventional polymeric materials, for example polypropylene, using conventional fabrication techniques, for example, injection molding. Other materials and fabrication techniques could also be used.

[0037] The body 110 may be sized and shaped to accept any type of syringe 20, for example a fixed needle style syringe 30 (see FIG. 5), or a Luer lock style syringe (not illustrated) or other standard syringes. The syringe 20 has a centerline 22. A needle cannula 24 (see FIG. 2) is typically disposed along the centerline 22, but could alternatively be positioned offset from the centerline 22. At a first, proximal end, the needle cannula 24 has a base 26 (see FIG. 9), at which the needle cannula joins a supporting hub. At a second, distal end, the needle cannula 24 a terminal portion 27 of the needle cannula, including a tip 28 (see FIG. 9), is inserted into a patient receiving the intradermal injection.

[0038] With continued reference to FIG. 1, the body 110 has a body centerline 112, which is preferably, but not necessarily, coincident with the syringe centerline 22. The body further comprises a second primary skin contacting surface 132 positioned at a distal end 126 of the body 110. The second primary skin contacting surface 132 is preferably, as illustrated, in its entirety a planar surface. Alternatively, the second primary skin contacting surface 132 could comprise both a planar surface forming only a portion of the second primary skin contacting surface 132, with a remaining portion of the second skin contacting surface being non-planar. In this first preferred embodiment, the second primary skin contacting surface 132 is at least generally parallel to the syringe centerline 22 and adapter body centerline 112. Alternatively, as will be discussed in further detail below with respect to an alternative preferred embodiment, at least the planar portion of the second primary skin contacting surface 132 could be inclined either up or down relative to the syringe and body centerlines 22, 112.

[0039] Preferably, the adapter body 110 further comprises a first primary skin contacting surface 130 positioned at the distal end 126 of the body 110. With reference to FIG. 2, preferably the first and second primary skin contacting surfaces 130, 132 are positioned at an angle 134 between approximately 100 degrees and approximately 165 degrees. The first primary skin contacting surface 130 includes an opening 136 (see FIG. 1) through which the needle cannula 24 extends through the first primary skin contacting surface 130.

[0040] Like the second primary skin contacting surface 132, the first primary skin contacting surface is preferably planar in its entirety, as illustrated, but alternatively could comprise both a planar portion and a non-planar portion (not illustrated).

[0041] Note that the first primary skin contacting surface 130 is optional. Alternatively, the opening 136 could be enlarged to such an extent as to effectively eliminate the first primary skin contacting surface 130. This alternative configuration is not illustrated in the drawings.

[0042] With reference again to FIG. 1, the body 110 is further preferably provided with opposing finger flanges 170 to facilitate handling of the assembly 10 during the injection process.

Preferably, a first finger flange 170a is connected to the first body portion 120 and a second finger flange 170b is connected to the second body portion 122. Further preferably, the finger flanges 170 are aligned along a central axis 172 which is at least substantially perpendicular to the planar portion of the second primary skin contacting surface 132.

[0043] With reference now to FIG. 4, the adapter body 110 is provided with at least one support element connected to the body 110. In the embodiment illustrated in FIG. 4, a first support element 140 and a second support element 150 are provided. The first support element 140 is connected to the first portion 120 and the second support element 150 is connected to the second portion 122. As will be discussed more fully below, a single support element can be provided in an alternative embodiment. With the assembly 10 in an assembled condition, the first and second support elements 140, 150 support the needle cannula 24 connected to the syringe 20. The needle cannula 24 is supported at a point or along a line positioned intermediate the needle cannula base 26 and the tip 28.

[0044] The support elements 140, 150 function to align at least the terminal portion 27 of the needle cannula 24 primarily relative to the second primary skin contacting surface 132 such that at least the terminal portion 27 of the needle cannula 24 extends axially in a direction substantially parallel to at least the planar portion of the second primary skin contacting surface 132. As noted above in the background section, controlling the depth into the skin of an intradermal injection is critical to the success of the injection. It is therefore critical to properly align at least the terminal

portion 27 of the needle cannula 24 relative to the second primary skin contacting surface 132, as variation of needle cannula 24 alignment relative to the second primary skin contacting surface 132 translates directly into variation of depth of the intradermal injection.

[0045] The need for alignment is driven by the normal tolerance of the angularity of the needle cannula 24 resulting, for example, from manufacturing variability or post-manufacturing deformation of the needle cannula. Any needle cannula possesses an angularity tolerance from its base to its tip. Taking the base as a reference point, this angularity tolerance forms a cone of positional uncertainty increasing in its radial extent in a linear manner from base to tip. For example, a two degree tolerance on angularity for a 1 inch long needle results in a circular zone of positional uncertainty at the tip having a radius of $\text{acrtan}(2^\circ) = 0.035$ inches.

[0046] Note further that providing a support intermediate the hub and tip in effect stiffens the needle cannula 24, reducing the tendency of the needle cannula 24 to deflect during the injection process (such deflection thus increasing the difficulty in ensuring the intradermal injection is delivered at the proper depth). The intermediate support thus provides an additional advantage in that a smaller diameter (and more flexible) needle cannula 24 may be used, in view of the enhanced stiffness resulting from the intermediate support.

[0047] With reference now to FIG. 5, to form the assembly 10, the syringe 20 is placed within a receiving cavity formed in each of the two portions 120, 122. The two portions 120, 122 are then rotated into engagement, such that connecting tabs 125 engage receiving holes 127 to secure the body 110 to the syringe 20.

[0048] With reference again to FIG. 4 as well as to FIGS. 6A and 6B, a first needle alignment technique is based on providing opposing, axially-offset first and second support elements 140, 150 having respective V-groove portions 142, 152. FIGS. 6A and 6B schematically illustrate that the needle cannula 24 is captured between the first and second support element V-groove portions 142, 152 such that the needle cannula 24 is aligned along the syringe centerline 22 to be substantially parallel with at least the planar portion of the second primary skin contacting surface 132. Note that if the needle cannula 24 is nominally positioned at an intended offset from the syringe centerline, the support elements 140, 150 would be configured to accommodate that intended offset. Such an offset configuration would be atypical for a syringe however. But generally speaking, the first and second support elements 140, 150 support the needle cannula 24 along a plane 146 passing through the syringe centerline 22. The first primary skin contacting surface 130 is omitted in FIG. 6B (as well as FIG. 7B discussed below) for clarity.

[0049] With reference now to FIGS. 7A and 7B, in an alternative embodiment, the first and second support elements 140, 150 could be provided with planar portions 144, 154 directly supporting the needle cannula 24 in the assembled condition. The planar portions 144, 154 are axially aligned (that is, aligned along the body centerline 112). Note that in this second alignment technique the needle cannula 24 is supported only in the “y” (or “vertical”) direction (as indicated in FIGS. 7A and 7B), as opposed to being supported in both the “y” and “z” directions (as indicated in FIGS. 6A and 6B) when the first alignment technique is used. Thus, with the second alignment technique of FIGS. 7A and 7B, there is uncertainty associated with the position of the needle cannula 24 in the z direction (that is, the direction parallel to the second primary skin contacting surface 132). This is of no consequence to the injection process, as it is variability in alignment of the needle cannula 24 in the y direction that is critical to the depth and resulting success of the intradermal injection.

[0050] With reference now to FIGS. 8A and 8B, the adapter device 100 may further comprise a safety shield 160. The safety shield 160 is preferably connected to the body 110 by a living hinge 162 for rotation between a first position 164 exposing the tip 28 of the needle cannula 24 and a second position 166 covering the tip 28 of needle cannula 24. The safety shield 160 is preferably held in the second position 166 by a resiliently flexible catch 168.

[0051] With reference now to FIG. 9, a second presently preferred embodiment adapter device 200 is, like the first embodiment adapter device 100, intended for use in combination with a syringe 20 to form an assembly 10 for delivering an intradermal injection. The adapter device 200 comprises a body 210 connectable to the syringe 20. The body 210 is preferably formed in one piece as an integral, unitary component. The body 210 is preferably formed using conventional polymeric materials, such as polypropylene, using conventional fabrication techniques, for example, injection molding. Other known conventional materials and fabrication techniques could also be used.

[0052] Like the first embodiment body 110, the second embodiment body 210 may be sized and shaped to accept any type of syringe 20, for example a fixed needle style syringe 30 shown in FIG. 9, or a Luer lock style syringe (not illustrated) or other standard syringes.

[0053] The body 210 has a body centerline 212, which, in the assembled condition, is preferably, but not necessarily, coincident with the syringe centerline 22. The body further comprises a second primary skin contacting surface 232 positioned at a distal end 226 of the body 210. Similarly to the first embodiment body 110, the second primary skin contacting surface 232 is preferably, as illustrated, in its entirety a planar surface. Alternatively, the second primary skin

contacting surface 232 could comprise both a planar surface forming only a portion of the second primary skin contacting surface 232, with a remaining portion of the second skin contacting surface being non-planar. In one embodiment, as illustrated in FIG. 9, the second primary skin contacting surface 232 is at least generally parallel to the syringe centerline 22 and adapter body centerline 212.

As discussed below relative to a third alignment technique illustrated in FIGS. 11A and 11B, at least the planar portion of the second primary skin contacting surface 232 could be inclined either up or down relative to the syringe and body centerlines 22, 212.

[0054] Preferably, the second embodiment adapter body 210 further comprises a first primary skin contacting surface 230 positioned at the distal end 226 of the body 210. As with the first embodiment adapter device 100, preferably the first and second primary skin contacting surfaces 230, 232 are positioned at an angle 234 (see FIG. 11A) between approximately 100 degrees and approximately 165 degrees. The first primary skin contacting surface 230 includes an opening 236 (illustrated only schematically in FIG. 11A) through which the needle cannula 24 extends through the first primary skin contacting surface 230. Note that the opening 236 must be sized sufficiently large to accommodate deflection of the needle illustrated schematically in FIGS. 11A and 12A.

[0055] Like the second primary skin contacting surface 232, the first primary skin contacting surface 230 is preferably planar in its entirety, as illustrated, but alternatively could comprise both a planar portion and a non-planar portion (not illustrated).

[0056] Note as before with the first embodiment adapter device 100, that the first primary skin contacting surface 230 is optional. Alternatively, the opening 236 could be enlarged to such an extent as to effectively eliminate the first primary skin contacting surface 230. This alternative configuration is not illustrated in the drawings.

[0057] The second embodiment adapter body 210 is formed to receive the syringe 20 in a sideways motion. Stated otherwise, the body 210 includes side openings 214, including a syringe barrel side opening 216, a syringe hub portion side opening 218, and a needle cannula side opening 220. The syringe 20 can thus be assembled with the second embodiment adapter device 200 in a direction substantially perpendicular to body centerline 212.

[0058] With reference now to both FIG. 9 and FIG. 10, the adapter body 210 is formed at least in part as a C-shaped tube 222 having gripping tabs 224. As best seen in FIG. 10, the gripping tabs 224 retain the syringe barrel 32 within the C-shaped tube 222. As the artisan skilled in the art of injection molding will appreciate, to facilitate the molding fabrication process, openings 225 are preferably provided to allow opposing molds to form the body 210, including the gripping tabs 224.

[0059] With continued reference to FIG. 9, the body 210 is further preferably provided with a pair of opposing finger flanges 270 to facilitate handling of the assembly 10 during the injection process. Like the first embodiment finger flanges 170, first and second finger flanges 270a and 270b are configured to facilitate one-handed handling of the adapter device 200 during an injection. Also like the first embodiment finger flanges 170, the second embodiment finger flanges 270 are aligned along a central axis 272 which is at least substantially perpendicular to the planar portion of the second primary skin contacting surface 232. Note that either style of finger flange 170, 270 could be utilized in either the first or second adapter device embodiment 100, 200.

[0060] Before proceeding further with the detailed description of the invention, it should be noted relative to the schematic representations of needle alignment techniques to be discussed herein below that the simple linear deflected shapes schematically illustrated do not accurately reflect the actual deflected shape of the needle cannula 24, which of course will vary depending on the support conditions and flexure characteristics of the actual needle cannula 24 (for example, stiffness of the needle hub, material of the needle cannula 24, and diameter of the needle cannula 24). Accordingly, the simplified linear shapes shown should be understood to be mere approximations.

[0061] With reference now to FIGS. 11A and 11B, the adapter body 210 preferably comprises a single support element 240 connected to the body 210. With the assembly 10 in an assembled condition, the single support element 240 supports the needle cannula 24 connected to the syringe 20. The needle cannula 24 is supported at a point 290 positioned intermediate the needle cannula base 26 and the tip 28. As with the first embodiment adapter device 100, the support element 240 functions to align the needle cannula 24 primarily relative to the second primary skin contacting surface 232 such that at least the terminal portion 27 of the needle cannula 24 extends axially in a direction substantially parallel to at least the planar portion of the second primary skin contacting surface 232. In general, the single support element 240 supports the needle cannula 24 at a support point 290 which is offset from the syringe centerline 22 in either (a) a plane substantially perpendicular to the planar portion of the second primary skin contacting surface 232 or (b) a plane substantially parallel to the planar portion of the second primary skin contacting surface.

[0062] More particularly, as illustrated schematically in FIGS. 11A and 11B, a third needle alignment technique is based on providing the single support element 240 having a planar portion 242. With the syringe 20 and second embodiment adapter device 200 fully assembled, the planar portion 242 positions the needle cannula 24 at a known support angle 280 relative to the syringe centerline 22. More particularly, the single support element 240 supports the needle cannula 24 at the support point 290 which is offset from the syringe centerline 22 in a vertical plane 248

substantially perpendicular to the planar portion of the second primary skin contacting surface 232. The offset can be either toward the second primary skin contacting surface 232, or away from it (that is, either in a positive or negative y direction, (the y direction being as indicated in FIGS 11A and 11B)).

5 [0063] In order to appropriately control the depth of the injection, the planar portion of the second primary skin contacting surface 232 is inclined relative to the syringe centerline 22 at a non-zero angle 282 (nominally equal to angle 280), such that the planar portion of the second primary skin contacting surface 232 is oriented substantially parallel to the terminal portion 27 of the needle cannula proximate the tip 28. The support angle 280 and the non-zero angle 282 are thus formed in
10 the vertical plane 248 (illustrated in FIGS. 11A and 11B as the x-y plane) that is at least substantially perpendicular to the second primary skin contacting surface 232. Note that the non-zero angle 282 is inclined in a positive y direction if the support angle 280 is similarly inclined in a positive y direction (as illustrated in FIG. 11A), but if the support angle 280 were inclined in a negative y direction (not illustrated), the non-zero angle 282 would likewise be inclined in a
15 negative y direction (not illustrated).

[0064] Recall that the simple linear deflected shape schematically illustrated does not accurately reflect the actual deflected shape of the needle. Accordingly, the actual optimal angle at which the second primary skin contacting surface should be inclined to the syringe centerline 22 to accomplish as nearly as possible parallelism between the terminal portion 27 of the needle and the planar
20 portion of the second primary skin contacting surface 232 may not be angle 280, but rather an angle approximately equal to support angle 280. In practice, the non-zero angle 282 may exceed the support angle 280 due to the fact that the needle cannula 24 will leave the hub along the syringe centerline 22 and then be deflected at support point 290.

[0065] With reference to FIG. 11B, the needle cannula 24 is captured first by a ramp portion 246
25 which guides the needle cannula 24 to the planar portion 242 during the process of assembling the syringe 20 with the adapter device 200. A ramp design is needed in view of the uncertainty of where the needle cannula 24 is initially positioned. The ramp 246 extends sufficiently far from the syringe centerline 22 such that the cone of uncertainty of where the needle cannula 24 is initially positioned is captured within the ramp portion 246. Note that the ramp portion 246 must terminate,
30 and the planar portion 242 begin at a point at or beyond the cone of positional uncertainty such that when the needle cannula 24 is in its final supported position, the support point 290 falls along the planar portion 242.

[0066] Note that FIG. 11B illustrates assembly of the syringe 20 with the adapter 200 in a direction along the z axis (that is, "side insertion" along the horizontal axis). This same third alignment technique could be applied to an adapter (not illustrated) which receives the syringe in a direction along the y axis (that is, "bottom insertion" along the vertical axis). The needle cannula 24 will be deflected in a manner substantially similar to that illustrated in FIG. 11A, but in a negative y direction rather than a positive y direct. The planar portion of the second primary skin contacting surface 232 would likewise be inclined in a negative y direction. The planar support surface 242 would be positioned below the syringe centerline 22 such that the support point 290 would fall at or outside of the cone of positional uncertainty. In this embodiment (not illustrated), two opposing ramps 246 could be provided to "funnel" the needle cannula 24 into position along a relatively narrow planar support surface 242, or alternatively the planar support surface 242 could be sufficiently broad to ensure contact with the needle cannula 24, irrespective of the needle cannula's initial position within the cone of positional uncertainty.

[0067] With reference now to FIGS. 12A and 12B, in a fourth needle cannula alignment technique, the support point 290 is offset from the syringe centerline 22 in a horizontal plane 250 substantially parallel to the planar portion of the second primary skin contacting surface 232 (illustrated in FIG. 12A to be the x-z plane). In contrast to the third alignment technique, in the fourth alignment technique the planar portion of the second primary skin contacting surface 232 is oriented substantially parallel to the syringe centerline 22. In this fourth alignment technique, the support angle 280 is thus formed in the horizontal plane 250 that is at least substantially parallel to the second primary skin contacting surface 232. FIG. 12B illustrates that a single support element 240 having a V-groove portion 244 is used with this fourth needle cannula alignment technique. Similar to the concept behind sizing of the ramp portion 246 of the third alignment technique, the V-groove portion 244 is sized to capture the needle cannula 24 no matter where it is located within the cone of positional uncertainty associated with the expected range of angular straightness tolerance of the needle cannula 24.

[0068] As with the third alignment technique, it would be possible to reorient the V-groove portion 244 from a side insertion configuration (illustrated in FIGS. 12A and 12B) to a bottom insertion configuration (not illustrated), wherein the V-groove portion 244 is rotated 90 degrees, and the offset occurs in the vertical plane 248, which is at least substantially perpendicular to the horizontal plane 250. With such a reorientation, it would of course be necessary to also modify the orientation of the planar portion of the second primary skin contacting surface 232 relative to the

syringe centerline 22, such that the terminal portion of the needle cannula 24 is substantially parallel to the planar portion of the second primary skin contacting surface 232 in the assembled condition.

[0069] Rather than incorporating the V-groove portion 244 illustrated, alternatively two opposing inclined ramp portions (corresponding to opposing sides of the V-groove portion 244)

5 could be provided, but rather than joining together at the vertex, the opposing sides could join opposing sides of a slot (not illustrated). The width of the slot could be slightly larger than the diameter of the needle cannula 24, to allow the needle cannula 24 to slide within the slot (not illustrated). The closed end of the slot would be positioned along the syringe centerline 22. Thus, the slot (not illustrated) would extend from approximately from where the vertex of the V-groove
10 portion 244 would fall in the illustrated embodiment (see FIG. 12B) to the syringe centerline 22. Depending upon its initial position within the cone of positional uncertainty, the needle cannula 24 would be positioned at some point within the slot after assembly of the syringe 20 with the adapter device 200.

[0070] It will be appreciated by those skilled in the art that changes could be made to the
15 embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

CLAIMS

That which is claimed is:

1. An adapter device (100, 200) for use in combination with a syringe (20) to form an assembly (10) for delivering an intradermal injection, comprising:
 - 5 a body (110, 210) connectable to the syringe;
 - a second primary skin contacting surface (132, 232) positioned at a distal end (126, 226) of the body; and
 - at least one support element (140, 150, 240) connected to the body,
 - wherein:
 - 10 with the assembly in an assembled condition:
 - the at least one support element supports a needle cannula (24) connected to the syringe, with the needle cannula supported by the at least one support element intermediate a base (26) and a tip (28) of the needle cannula, and
 - at least a terminal portion (27) of the needle cannula proximate the tip extends
 - 15 axially in a direction at least substantially parallel to at least a planar portion of the second primary skin contacting surface.
2. The adapter device of claim 1, further comprising a first primary skin contacting surface (130, 230) positioned at the distal end of the body and further positioned at an angle (134, 234) to
20 the second primary skin contacting surface between approximately 100 degrees and approximately 165 degrees.
3. The adapter device of claim 1, wherein the syringe is a fixed needle style syringe (30).
- 25 4. The adapter device of claim 1, wherein the syringe is a Luer lock style syringe.
5. The adapter device of claim 1 further comprising a safety shield (160) connected to the body by a living hinge (162) for rotation between a first position (164) exposing the tip of the needle cannula and a second position (166) covering the tip of needle cannula.
30
6. The adapter device of claim 1, further comprising a pair of finger flanges (170, 270) connected to the body wherein the finger flanges are aligned along a central axis (172, 272) that is at

least substantially perpendicular to a plane containing at least the planar portion of the second primary skin contacting surface.

7. The adapter device of claim 1, wherein:

the body is formed in a first portion (120) and a second portion (122), the portions being rotatably connectable;

a first support element (140) is connected to the first portion and a second support element (150) is connected to the second portion, and

the first and second support elements support the needle cannula along a plane passing through a centerline (22) of the syringe.

8. The adapter device of claim 7, wherein portions (144, 154) of the first and second support elements supporting the needle cannula in the assembled condition are planar and the first and second support elements are axially aligned.

9. The adapter device of claim 7, wherein the portions (142, 152) of the first and second support elements supporting the needle cannula in the assembled condition are V-shaped grooves and the first and second support elements are axially offset.

10. The adapter device of claim 1, wherein:

a single support element (240) is connected to the body, and

the single support element supports the needle cannula at a point (290) offset from a syringe centerline (22) in one of a plane (248) at least substantially perpendicular to the planar portion of the second primary skin contacting surface or a plane (250) at least substantially parallel to the planar portion of the second primary skin contacting surface.

11. The adapter device of claim 10, wherein the point offset from the syringe centerline is in the plane substantially perpendicular to the planar portion of the second primary skin contacting surface, and the planar portion of the second primary skin contacting surface is inclined relative to the syringe centerline at a non-zero angle (282) such that the planar portion of the second primary skin contacting surface is oriented substantially parallel to the terminal portion of the needle cannula proximate the tip.

12. The adapter device of claim 10, wherein the point offset from the syringe centerline is in the plane substantially parallel to the planar portion of the second primary skin contacting surface and the planar portion of the second primary skin contacting surface is oriented substantially parallel to the syringe centerline.

5

13. The adapter device of claim 10, wherein the non-zero angle at least equals an expected range of angular straightness tolerance of the needle cannula.

14. The adapter device of claim 10, wherein the body is formed at least in part as a C-shaped tube (222) to provide an opening (216) for receiving at least a portion of a barrel of the syringe.

10

15. The adapter device of claim 10, wherein a portion (242) of the single support element engaging the needle cannula is planar and the non-zero angle is formed in the plane (248) that is at least substantially perpendicular to the second primary skin contacting surface.

15

16. The adapter device of claim 10, wherein a portion (244) of the support element engaging the needle cannula has a V-groove shape and the non-zero angle is formed in the plane (250) that is at least substantially parallel to the second primary skin contacting surface.

20

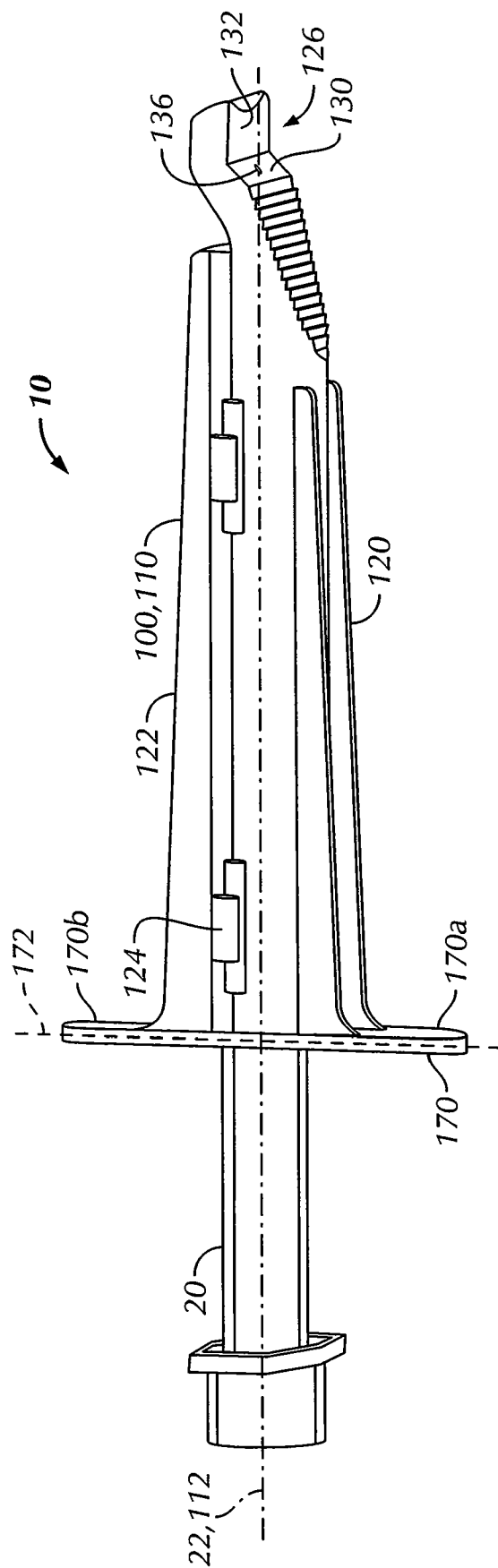


FIG. 1

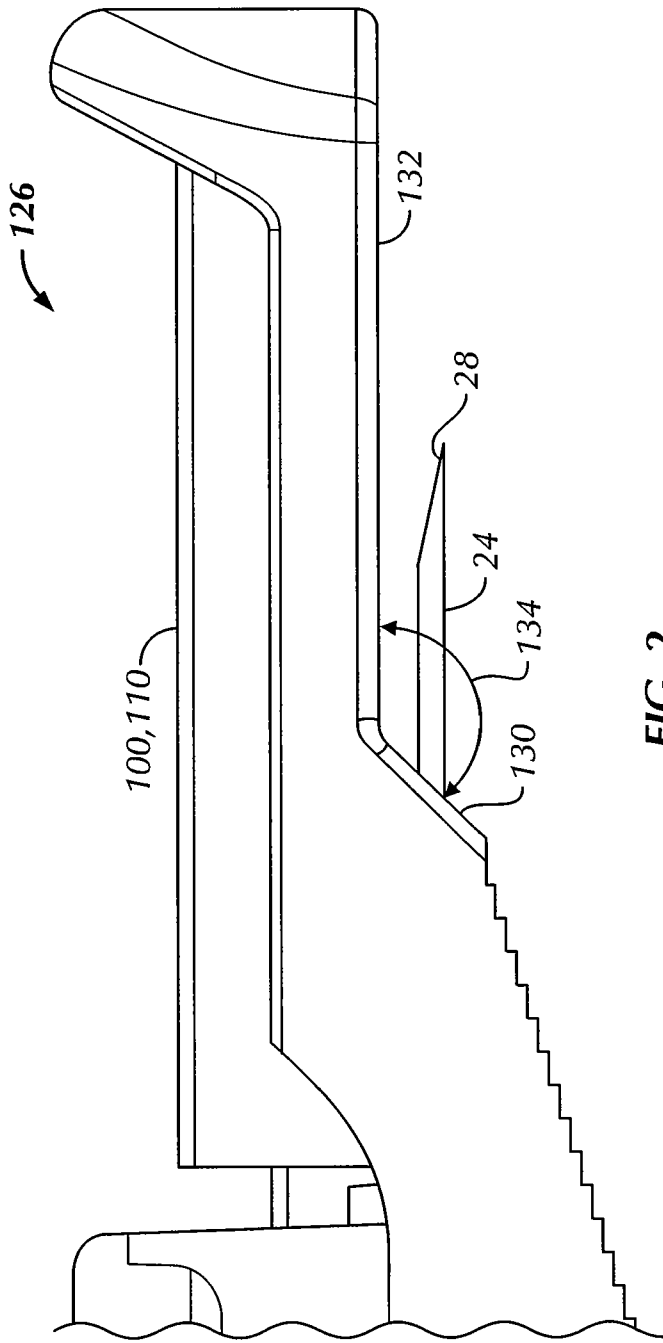


FIG. 2

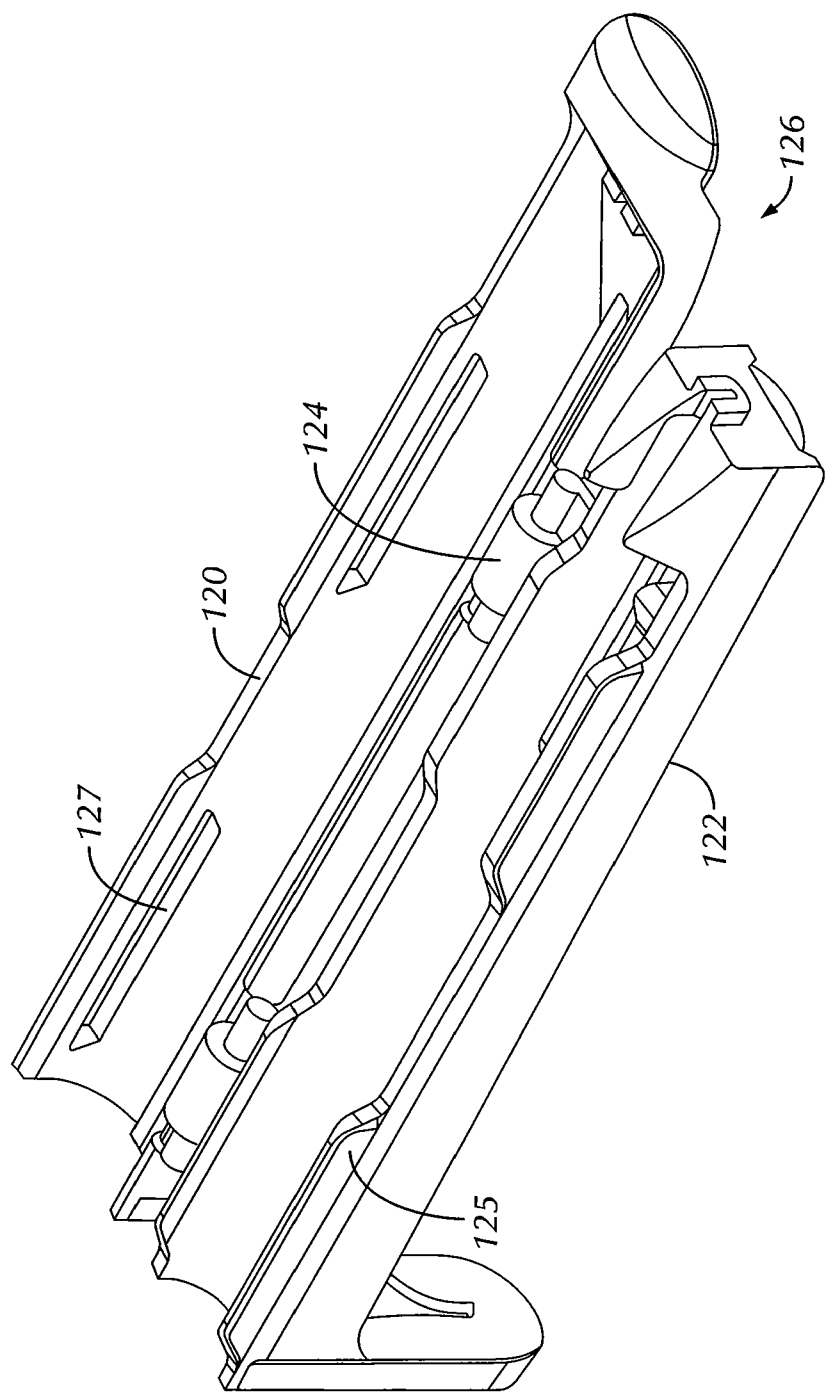


FIG. 3

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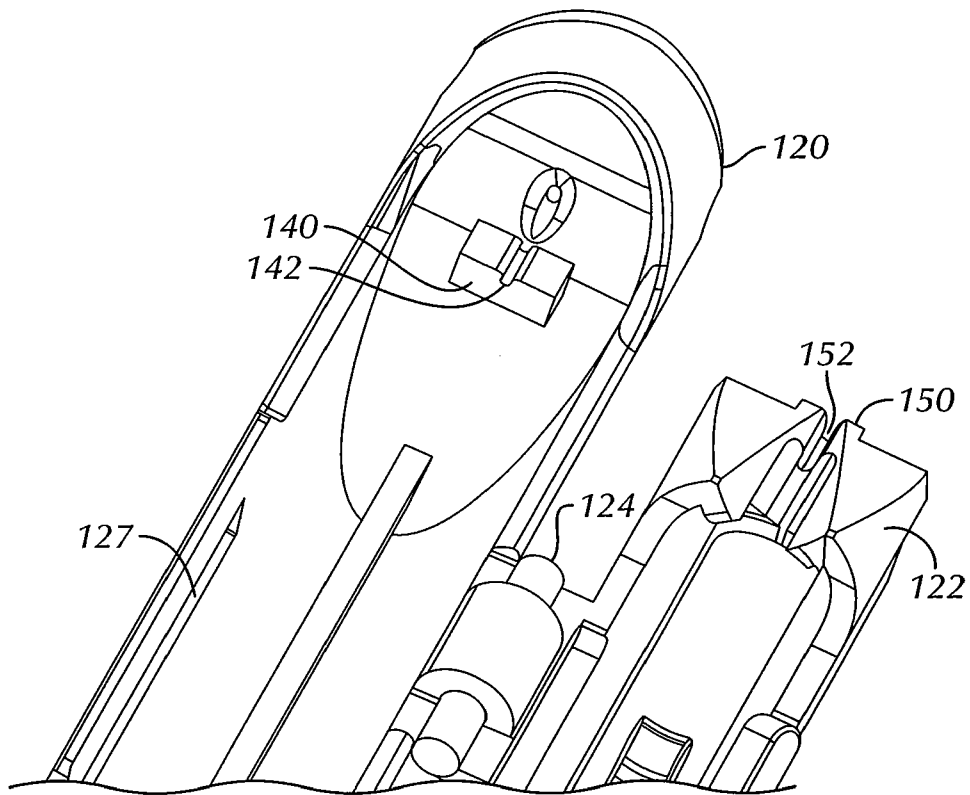


FIG. 4

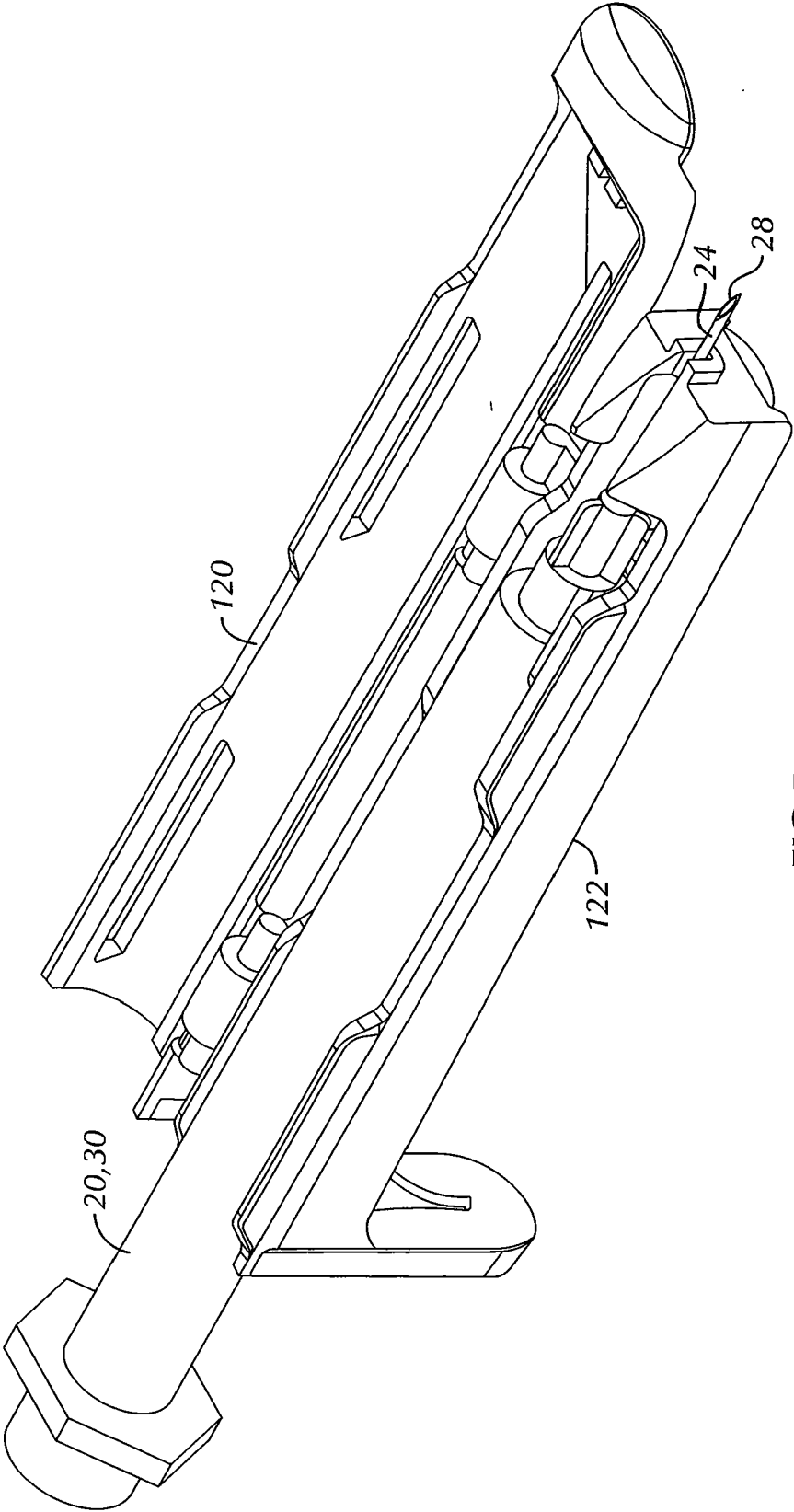
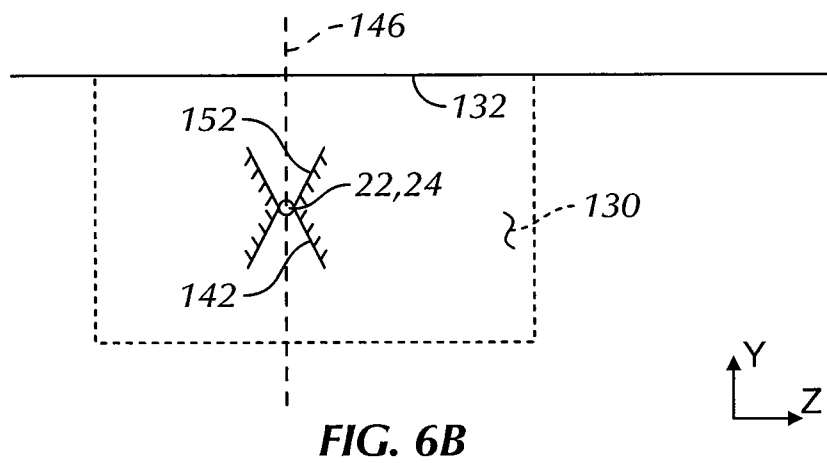
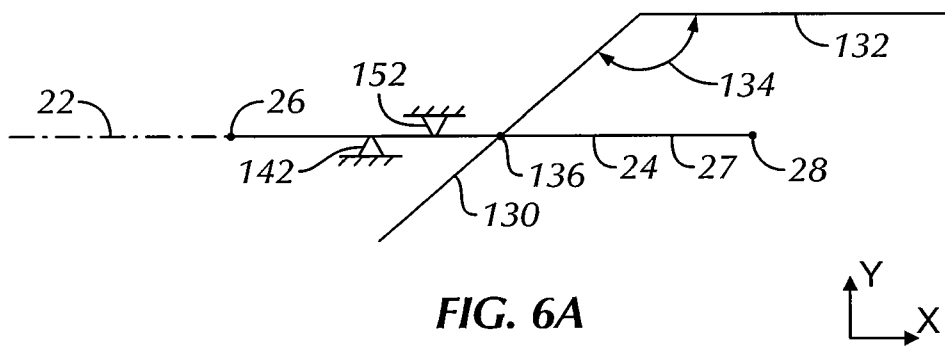
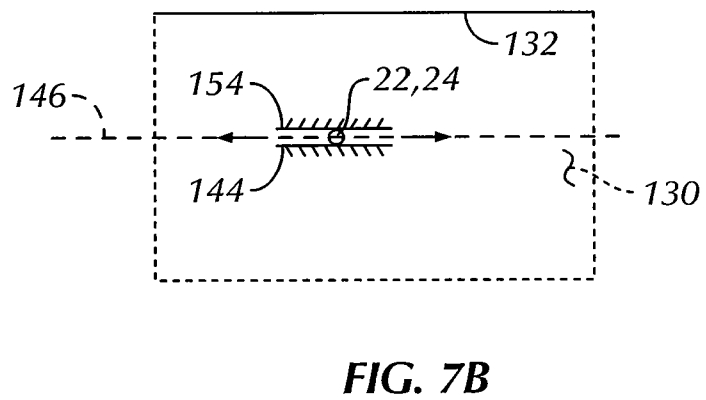
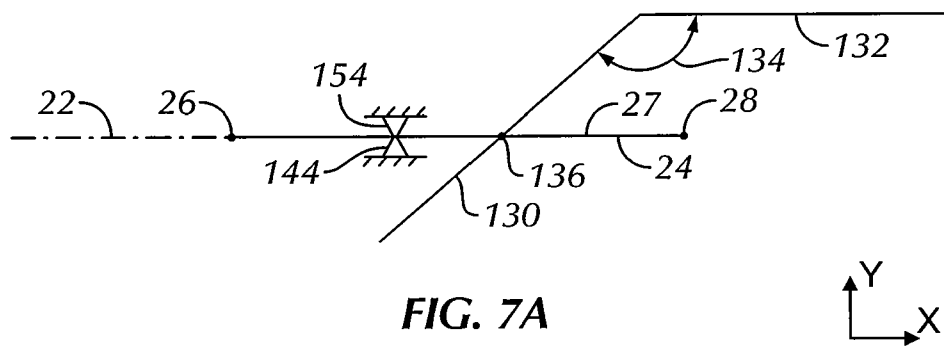


FIG.5

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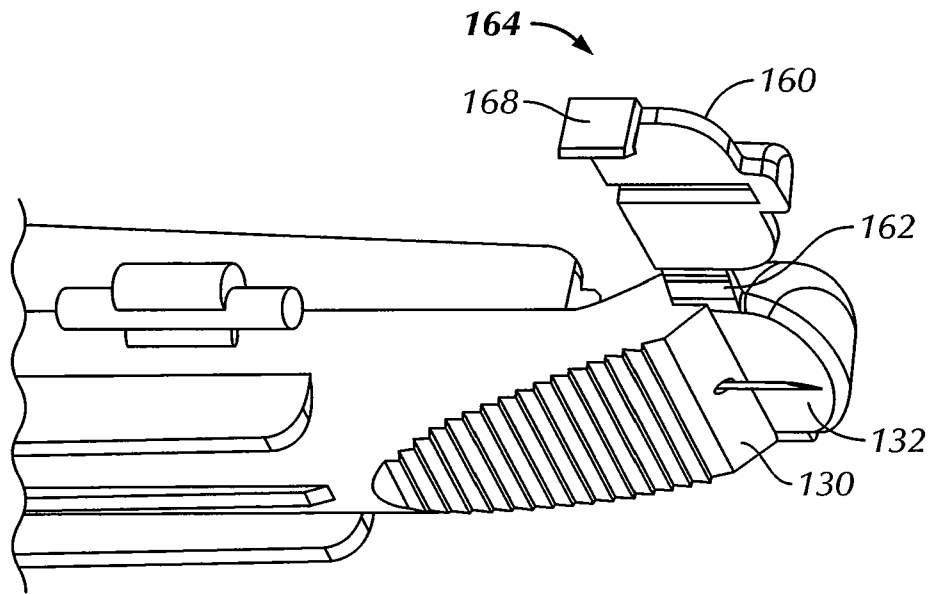


FIG. 8A

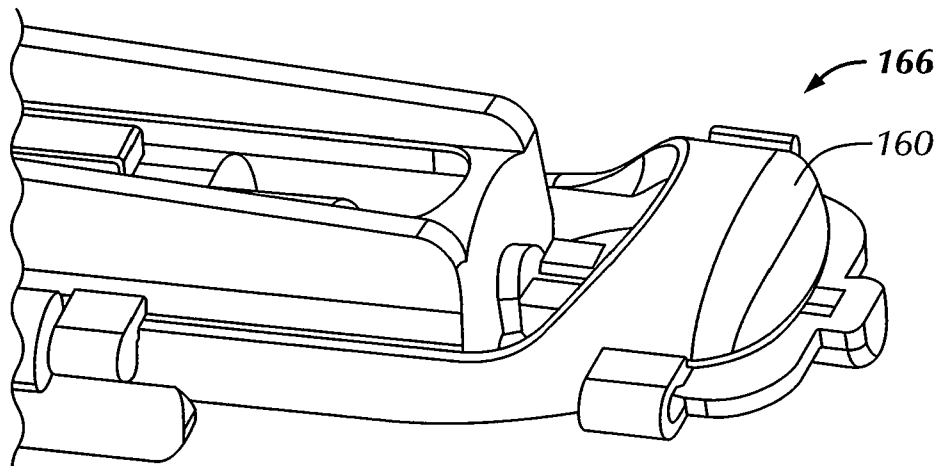


FIG. 8B

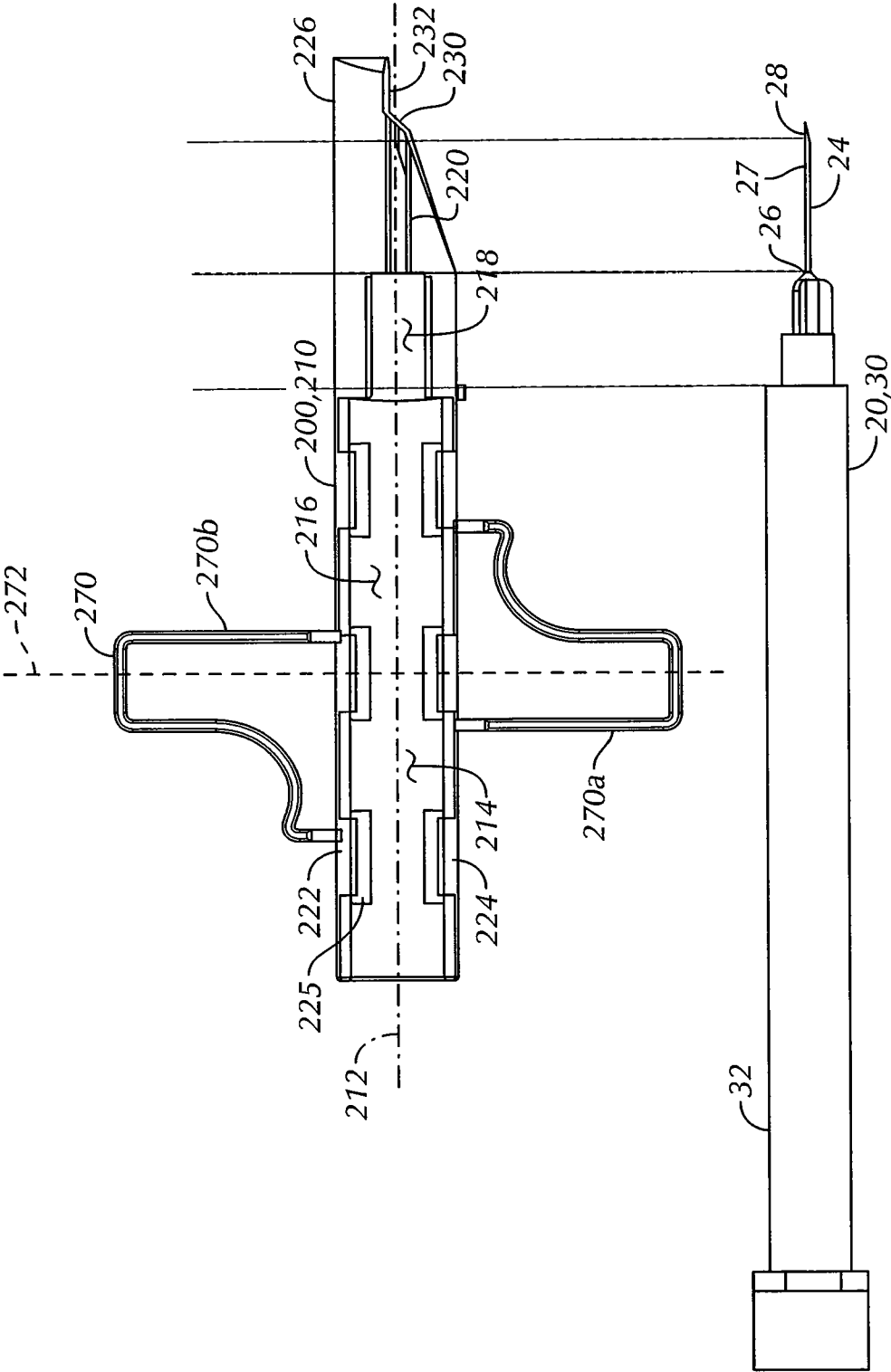


FIG. 9

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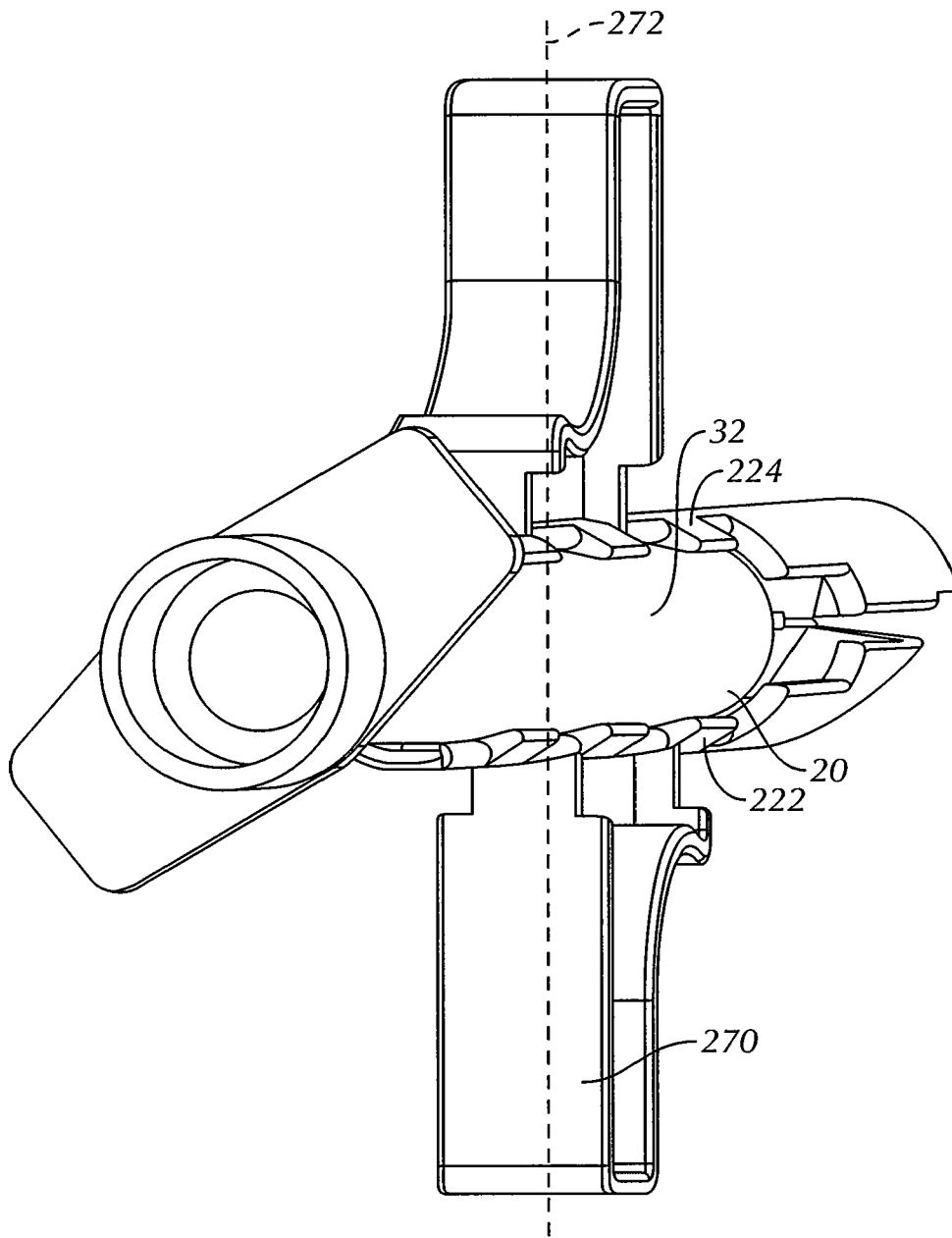


FIG. 10

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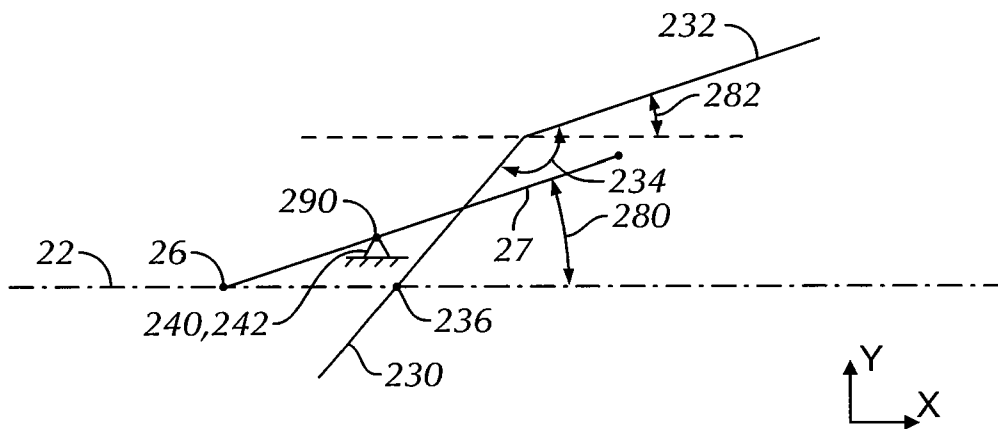


FIG. 11A

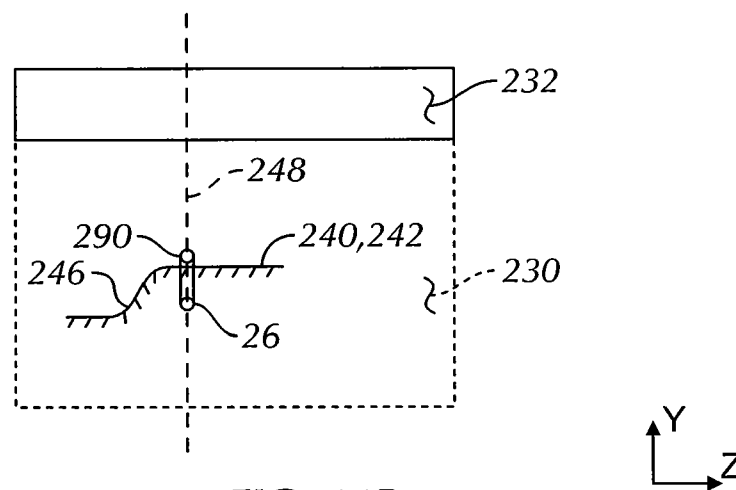


FIG. 11B

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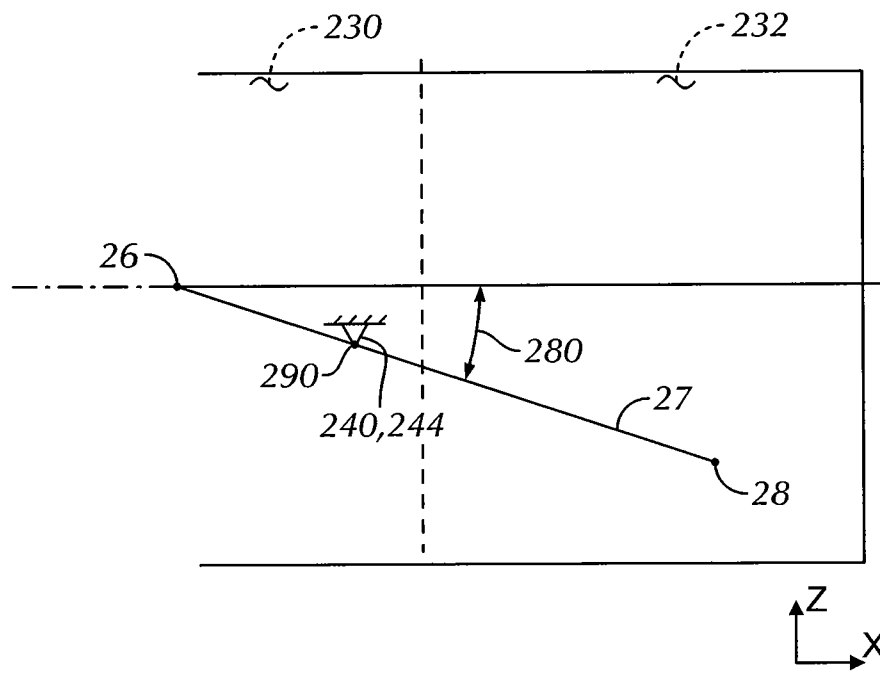


FIG. 12A

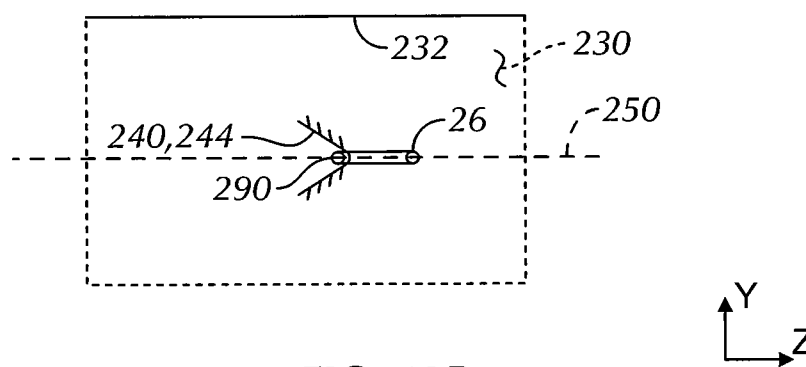


FIG. 12B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/066960

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/32 A61M5/42 A61M5/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/131440 A1 (SID TECHNOLOGIES LLC [US]; PROGRAM FOR APPROPRIATE TECHNO [US]; TSALS) 30 October 2008 (2008-10-30) cited in the application like application, but no separate needle support; sliding safety shield 230 ; page 7, line 8 - page 8, line 31	1-6
A	US 2002/193744 A1 (ALESI DANIEL E [US] ET AL) 19 December 2002 (2002-12-19) abstract	5
A	US 5,437,640 A (SCHWAB LOUIS [US]) 1 August 1995 (1995-08-01) abstract	1

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

15 March 2010

Date of mailing of the international search report

29/03/2010

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Authorized officer

Manschot, Jan

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2009/066960

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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