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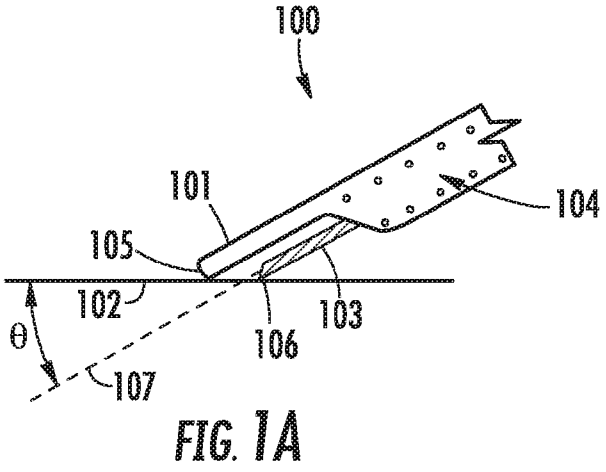

FIG. 1A

(57) Abstract: The disclosure is generally related to medical devices, systems, and methods. In particular embodiments, implant applicators may be provided for subdermally inserting an implant. In some aspects, an applicator may include a housing defining a body of the applicator, and a cannula coupled with the housing and extending distally from the body of the applicator. In some embodiments, a cannula guide may extend from the body of the applicator and may help a user align the applicator at a desired angle relative to the skin surface prior to insertion of the cannula into the skin. The applicator may further include a skin guide that limits skin buckling against the applicator housing during cannula insertion into the skin. The cannula may have an implant holding section where an inner surface of the cannula is inwardly indented such that the inner surface of the cannula friction fits with an implant.

WO 2017/019631 A1

SUBDERMAL APPLICATOR

CROSS-SECTION TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 62/196,998 filed July 25, 2015 and U.S. Provisional Application No. 62/278,428 filed January 13, 2016, the full disclosures of which are incorporated herein by reference in their entirety for all purposes.

BACKGROUND OF THE DISCLOSURE

[0002] The present disclosure is generally related to medical devices, systems, and methods. In particular embodiments, implant applicators may be provided for subdermally inserting an implant.

[0003] Implants capable of long term drug delivery, and designed for insertion under the skin of a human or animal are being used in multiple therapeutic applications. Despite their long history of use, there are still occasional problems with incorrect placement of such implants under the skin. In part, this may be due to erroneous handling of the implant applicators used to insert the implants under the skin. Accordingly, further improvements may be had with implant applicators.

SUMMARY OF THE DISCLOSURE

[0004] The present disclosure is generally related to medical devices, systems, and methods. In particular embodiments, implant applicators may be provided for subdermally inserting an implant. Optionally, in some embodiments, the implant applicators may be used for inserting a rod-like implant containing a therapeutic agent under the skin of a patient (e.g., human or animal).

[0005] In some aspects of the present disclosure, an implant applicator may be provided. The applicator may be for subdermally inserting an implant in a human or animal. The applicator may include a housing. A cannula may be provided with a distal tip, a longitudinal axis, and an insertion length extending from the housing in a distal direction. The applicator may include a cannula guide extending from the housing in the distal direction. The cannula guide may have a distal end and may be cantilevered over at least part of the insertion length of the cannula. The distal tip of the cannula and the distal end of the cannula guide may be aligned along a line oriented at an angle between 15 and 45 degrees with the longitudinal axis of the cannula.

[0006] In some embodiments, a handle section may be located on the housing and may be located proximal to the cannula guide. The handle section may have a width substantially larger than the diameter of the cannula. The handle may have a width between 0.5 inches – 1.25 inches in certain embodiments.

[0007] Embodiments may include a skin guide that is located on the housing at a site of entrance of the cannula into the housing. The skin guide may have a beveled section at an angle between 20 and 60 degrees with the longitudinal axis of the cannula.

[0008] In some embodiments, the cannula guide, the handle section, and the skin guide may be integrated with the housing into a single unit with functionally different sections.

[0009] In another aspect, an applicator for subdermally inserting an implant in a human or animal may be provided that includes a housing and a cannula having a longitudinal axis and an insertion length extending from the housing in a distal direction. A cannula guide may be provided that extends from the housing in a distal direction. The cannula guide may have a distal end and may be cantilevered over at least part of the insertion length of the cannula. The distal end of the cannula guide may be flattened along a line oriented at an angle between 15 and 45 degrees with the longitudinal axis of the cannula.

[0010] In still further aspects an implanter may include a housing defining a body of the applicator, a cannula coupled with the housing and extending distally from the body of the applicator. The cannula may have a distal tip, a longitudinal axis, and an insertion length. A cannula guide may extend from the body of the applicator. The cannula guide may have a distal end that is distal relative to the distal tip of the cannula and above the distal tip of the cannula. "Above" should be understood to refer to a higher level when the device is positioned for use. The distal end of the cannula guide may be distal relative to the distal tip of the cannula and above the distal tip of the cannula such that a straight line between the distal end of the cannula guide and the distal tip of the cannula forms an angle between 15 degrees and 45 degrees with the longitudinal axis of the cannula.

[0011] In some embodiments, the straight line between the distal end of the cannula guide and the distal tip of the cannula may form an angle between 20 degrees and 40 degrees with the longitudinal axis of the cannula. Optionally the straight line between the distal end of the cannula guide and the distal tip of the cannula forms an angle between 25 degrees and 35 degrees with the longitudinal axis of the cannula.

[0012] In some embodiments, an applicator is provided that includes a housing defining a body of the applicator. A cannula may be coupled with the housing and may

extend distally from the body of the applicator. The cannula may have a distal tip, a longitudinal axis, and an insertion length. A cannula guide may extend from the body of the applicator. The cannula guide may have a distal end that is distal relative to the distal tip of the cannula and above the distal tip of the cannula. The distal end of the cannula guide may include a beveled surface that is beveled at an angle between 15 degrees and 45 degrees with the longitudinal axis of the cannula.

[0013] Optionally, the beveled surface may be at an angle between 20 degrees and 40 degrees with the longitudinal axis of the cannula. In some embodiments, the beveled surface is at an angel between 25 degrees and 35 degrees with the longitudinal axis of the cannula.

[0014] In certain embodiments, an applicator may include a housing defining a body of the applicator and a cannula coupled with the housing and extending distally from the body of the applicator. The cannula may have a distal tip, a longitudinal axis, and an insertion length. A cannula guide may extend from the body of the applicator. The cannula may extend from a distal surface of the body of the applicator. The distal surface of the body of the applicator may define a skin guide having a surface at an angle between 20 degrees and 60 degrees with the longitudinal axis of the cannula. In some embodiments, the surface of the skin guide may be at an angle between 35 and 45 degrees with the longitudinal axis of the cannula.

[0015] In some embodiments, the cannula of any of the described applicators may be slideably coupled with the housing and may be retractable proximally into the body of the housing.

[0016] Optionally, an obdurator may be provided that extends into the cannula from a proximal end of the cannula. The obdurator may be fixedly attached to the housing such that the cannula may move proximally relative to the obdurator during retraction of the cannula proximally into the body of the housing.

[0017] A user actuator may be provided that is operably coupled with the cannula and slidable in a proximal direction in a track of the applicator which may retract the cannula in the proximal direction.

[0018] A safety lock mechanism may be provided that is operably coupled with the user actuator. The safety lock mechanism may include a deformable protrusion that extends into a slot in the housing to bias the user actuator against moving in the proximal direction. The safety lock mechanism may be user moveable in the track of the applicator in the proximal direction to deform the protrusion of the safety lock mechanism such that the

protrusion is urged out of the slot in the housing. When the protrusion is urged out of the slot in the housing, the user actuator may be unlocked for movement in the proximal direction.

[0019] In some embodiments, the slot may extend from the track in a direction transverse to the track.

[0020] In some aspects, an implant delivery system may be provided. the implant delivery system may include an applicator described herein and where the cannula includes an implant holding section where an inner surface of the cannula is inwardly indented. An implant may be provided that is friction fit within the implant holding section of the cannula.

[0021] In some aspects an implant delivery system may include an applicator described herein and the implant disposed within the cannula of the applicator. A cannula guard may be disposed over the distal tip of the cannula and may be removable therefrom. The cannula guard may include a push rod that extends proximally (from the inner surface of the guard) into the distal tip of the cannula when the cannula guard is disposed over the distal tip of the cannula so as to prevent the implant from escaping from within the cannula.

[0022] In some embodiments, the implant may be constructed of a metal material. Optionally, the implant may be made of a titanium material and may be configured to deliver one or more drugs to a patient once implanted.

[0023] Embodiments of the disclosure covered by this disclosure are defined by the claims below, not this summary. This summary is a high-level overview of various aspects of the disclosure and introduces some concepts that are further described in the Detailed Description section below. This summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used in isolation to determine the scope of the claimed subject matter. The subject matter should be understood by reference to appropriate portions of the entire specification of this patent, any or all drawings, and each claim.

[0024] The disclosure will be better understood upon reading the following description and examining the figures which accompany it. These figures are provided by way of illustration only and are in no way limiting on the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Further details, aspects, and embodiments of the disclosure will be described by way of example only and with reference to the drawings. In the drawings, like reference numbers may be used to identify like or functionally similar elements. Elements in the

figures may be illustrated for simplicity and clarity and have not necessarily been drawn to scale.

[0026] Figure 1A illustrates an exemplary applicator and its alignment with a surface of a skin according to some embodiments of the disclosure.

[0027] Figure 1B illustrates the exemplary applicator of Figure 1A further modified with cannula guide having a beveled distal end according to some embodiments of the disclosure.

[0028] Figure 2A illustrates another exemplary applicator according to some embodiments of the disclosure that is repositioned relative to the skin surface after initial insertion of the cannula into the skin.

[0029] Figure 2B illustrates the exemplary applicator of Figure 2A inserted into the skin a desired insertion distance.

[0030] Figure 3A and Figure 3B illustrate another exemplary applicator with an obdurator according to some embodiments.

[0031] Figure 4 illustrates another exemplary applicator with a cannula guard according to some embodiments.

[0032] Figure 5 illustrates an exemplary needle lock mechanism that may be used with embodiments of the applicator.

[0033] Figure 6A shows a side view of an implant holder section of an exemplary cannula that may be used with embodiments of the applicator.

[0034] Figure 6B shows a top view of the cannula shown in Figure 6A.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0035] In the context of this disclosure, the term "distal" refers to an orientation towards a patient, and the term "proximal" refers to an orientation towards a user of the device.

[0036] When subdermally inserting an implant through the skin of a patient, it may be important to position the cannula at a preferred angle relative to the skin surface prior to penetrating the skin with the cannula in order to insert an implant correctly under the skin of the patient. Failure to do so may lead to incorrect placement of the implant under the skin. In some embodiments, the preferred angle may be between 15 and 45 degrees, more preferably between 20 and 40 degrees (e.g., between 25-35 degrees or the like). To this end, at least some embodiments of the applicators described herein may include a cannula guide that helps a user align and position the applicator at the desired angle relative to the skin

surface prior to insertion of the cannula into the skin and insertion of the implant. In certain embodiments, the cannula guide may extend at least in part over the cannula and may be connected with a housing of the applicator. Optionally, a portion of the housing of the applicator may form or otherwise define the cannula guide. Put in another way, the cannula guide may be integrated into the housing of the applicator.

[0037] Embodiments of the applicator may further include a housing that defines a body of the applicator. The cannula and the cannula guide may extend distally from the body of the applicator. The body of the applicator may define a handle section of the applicator. In some embodiments, a distal surface of the body from which the cannula extends may define a skin guide. Optionally, the cannula guide, the handle section, and the skin guide may be integrated with the housing into a single unit with functionally different sections.

[0038] Figure 1A illustrates an exemplary applicator 100 and its alignment with a surface of a skin 102 according to some embodiments of the disclosure. The exemplary applicator 100 may include a cannula guide 101 and a cannula 103, each extending distally from a body 104 of the applicator 100.

[0039] Cannula guide 101 may be cantilevered over cannula 103 and may extend beyond cannula 103 such that a distal end 105 of cannula guide 101 is distal relative to the distal tip 106 of cannula 103. In some embodiments, a straight line between the distal end 105 of cannula guide 101 to the distal tip 106 of cannula 103 may form an angle θ with a longitudinal axis 107 of the cannula 103. Angle θ may be between 15 degrees and 45 degrees in some embodiments. In certain embodiments, angle θ may be between 20 and 40 degrees (e.g., 25-35 degrees or the like). During use of the applicator 100, a medical practitioner may place the device 100 on the skin 102 of a patient, as illustrated in Figure 1A, with the tip 106 of cannula 103 and the distal end 105 of cannula guide 101 touching skin 102, for the purpose of positioning cannula 103 at a preferred angle (e.g., 15-45 degrees) relative to the skin surface 102.

[0040] Figure 1B illustrates the exemplary applicator 100 of Figure 1A further modified with cannula guide 101 having a beveled distal end 105a according to some embodiments of the disclosure. In some embodiments, as illustrated in Figure 1B, the distal end 105a of cannula 101 may be flattened or beveled at an angle θ between 14 and 45 degrees with the longitudinal axis 107 of cannula 103. In some embodiments, this angle θ may be between 25 and 35 degrees. During use of the device 100a, a medical practitioner may place the device on skin 102 of a patient, as illustrated in Figure 1B, with the flattened or beveled distal end 105a of cannula guide 101 touching skin 102, thereby positioning cannula 103 at a

desired angle for penetrating skin 102. In some embodiments, cannula guide 101 may be slightly shorter than shown in Figure 1B with respect to cannula 103 and may not be positioned on skin 102 during alignment, but may be held above the skin surface 102. In such embodiments, cannula guide 101 may, by virtue of the shape of the flattened end, be used as a visual indicator to position cannula 103 at the desired angle relative to skin 102. In some embodiments, the guide 101 may be 0.1 – 0.5 inches above the cannula 103.

[0041] Figure 2A illustrates exemplary applicator 200 according to some embodiments of the disclosure that is repositioned relative to the skin surface 205 after initial insertion of the cannula 204 into the skin 205. Figure 2B illustrates the exemplary applicator 200 of Figure 2A inserted into the skin 205 a desired insertion distance. As illustrated in Figure 2A and 2B, handle section 201 may be defined by a housing 202 of the device 200. The handle 201 may be located proximal to the cannula guide 203 on a main body of applicator 200. Handle section 201 may have a width that is substantially larger than the diameter of cannula 204 and may be ergonomically shaped to provide a user sufficient grip on the device 200 to perform the steps necessary for insertion of the implant under the skin 205. As illustrated, handle section 201 may include protrusions that may further enhance a medical practitioners grip on the device 200 during deployment of the implant. During insertion of the implant under the skin 205, a user may grip the device 200 by handle section 201, and place cannula 204 and cannula guide 203 on or above the skin 205 of a patient at a desired angle, as described above. Next, as illustrated in Figure 2A, the user may penetrate the skin 205 with cannula 204, and may thereafter or simultaneously angle the device 200 down to a position where the cannula 204 is approximately parallel the surface of the skin 205. In a continuation of these movements, and as illustrated in Figure 2B, the user may then advance the device 200 in a distal direction relative to the skin 205, to insert cannula 204 with the implant under the skin 205 to a desired depth for positioning of the implant.

[0042] In some embodiments, skin guide 206 may be provided at a site where the cannula 204 extends from the housing 202. The skin guide 206 may be defined by a distal surface of the main body of the housing 202. The skin guide 206 may be angled in a way that facilitates sliding of the skin 205 under the housing 202. The skin guide 206 may have a beveled configuration with a beveled surface at an angle between 20 and 60 degrees to the longitudinal axis 207 of the cannula 204 to guide the skin 205 of a patient underneath the device 200 during insertion of the cannula 204, and to reduce the risk of painful skin 205 buckling against the housing 202 during the insertion of cannula 204.

[0043] Figure 3A and Figure 3B illustrate another applicator 300 with an obdurator 306 according to some embodiments. In addition to handle 301 (on the main body of implanter 300, defined by housing 302), cannula 303, and cannula guide 304, some embodiments may further include an obudrator 306 and cannula retractor mechanism 308. Obdurator 306 may be disposed within at least a part of cannula 303 from a proximal end of cannula 303 and may be provided proximal to implant 307 in cannula 303. Cannula retractor mechanism 308 may comprise any desired motion transfer mechanism, such as a direct connection, a geared system, a system comprising levers and or hinges, a spring-loaded system, etc. In the illustrated embodiment, the cannula retractor mechanism 308 includes a user actuator 310 mechanically coupled with the cannula 303.

[0044] In combination, cannula retractor mechanism 308 and obdurator 306 may be employed by a user to retract cannula 303 from underneath skin 309, while keeping implant 307 stationary at the desired position under skin 309 with obdurator 306. Accordingly, in some embodiments, the cannula 303 may be retracted proximally relative to the housing 302 such that a portion (or the entirety) of the cannula 303 may be retracted therein. A user may retract the cannula 303 by sliding the user actuator 310 in a track of the applicator 300 in the proximal direction. With the user actuator 310 mechanically linked to the cannula 303, the cannula 303 will also move in the proximal direction relative to the housing 302 during movement of the user actuator 310 in the proximal direction. The obdurator 306 may be fixed within housing 302 such that during cannula 303 retraction, the cannula 303 moves proximally relative to the obdurator 306. Additionally, during cannula 303 retraction, the proximal end of the implant 307 may engage with a distal end of the obdurator 306 which may keep the implant 307 in a preferred location under the skin 30 during cannula 303 retraction.

[0045] Figure 4 illustrates another exemplary applicator 400 with a cannula guard 410 according to some embodiments. The cannula guard 410 may be configured to cover a distal end of cannula 403 when the applicator 400 is packaged or when the applicator 400 is handled prior to use to limit accidental injury from the distal end of the cannula 303 prior to applicator use for inserting the implant 307. The cannula guard 410 may be dimensioned to slide over the distal end of the cannula 403. In some embodiments, an internal push rod 411 may extend from an internal surface of the distal end of cannula guard 410 in the proximal direction. The internal push rod 411 may extend into the distal end of the cannula 403 a distance which may hold the implant 307 at a preferred location within the cannula 403 prior to removal of cannula guard 410 and insertion of implant 407. In some embodiments,

implant 407 may be secured in cannula 403 between push rod 411 of cannula guard 410 and a distal end of obdurator 406 that extends into cannula 403 from a proximal end of cannula 403.

[0046] Figure 5 illustrates an exemplary needle lock mechanism 500 that may be used with embodiments of the applicator described herein. The needle lock mechanism 500 may be used to prevent premature deployment of the implant (e.g., implant 407) from the implanter. In some embodiments the needle lock mechanism 500 comprises a locking element 501 and a sliding finger grip 502 (e.g., user actuator). The sliding finger grip 502 may be configured to be slideable (e.g., in a track) in the proximal direction for retraction of the cannula into the housing 506 as described above. The locking element 501 may be braced against the sliding finger grip 502 and may have a flexible or deformable distal protrusion 503 which extends into or may be slid into a groove or slot 504 on the housing 506. When the protrusion 503 extends into the slot 504, the locking element 501 may bias the user actuator 502 against moving in the proximal direction along the track. When the user wants to disengage the locking element 501, the user may slide the locking element 501 proximally away from the user actuator 502 which deforms the flexible distal protrusion 503 and withdraws it from the groove 504. Thereafter, the finger grip 502 may be slid freely in the proximal direction along the track. In some embodiments, the locking element 501 may or may not slide in the same track as the sliding finger grip 502. In some embodiments, the groove 504 may extend from the track in a direction transverse to the track.

[0047] The implant may be secured in the cannula in various manners. For instance, in some embodiments, the implant may be secured by a friction-fit engagement. Figure 6A shows a side view of an implant holder section of an exemplary cannula 601 that may be used with embodiments of the applicator to friction fit an implant held therein. Figure 6B shows a top view of the cannula 601 shown in Figure 6A. As illustrated in Figure 6A and Figure 6B, the cannula 601 may have an implant holder section 602 where an inner surface of the cannula 601 may protrude inwardly, producing an area where the lumen of the cannula reduces in size. As illustrated in Figure 6A, the section 602 with the reduced lumen size may form a friction fit with the implant 603, thus securing the implant 603 within the cannula 601 prior to insertion. In some embodiments, the reduced lumen size may be produced by a cut into the wall of cannula 601 which bends the cannula 601 inward.

[0048] During use of an exemplary embodiment of the device, e.g., applicator 400 as shown in FIG. 4, a user may first remove the device from a packaging material (not shown).

[0049] After preparation of the skin site of the patient, the user holds the device by handle section 402, removes needle guard 410 and places the device on the skin under the correct angle, aided by cannula guide 401. The user then penetrates the skin with cannula 403 and angles the device to a position substantially parallel to the skin, thereby lifting the skin of the patient slightly up. The user then moves the entire device forward, thereby inserting cannula 403 under the skin to the desired distance. Movement of the device over the skin is facilitated by skin guide 408. Once the desired insertion depth is achieved, the user moves fingergrip 404 of cannula retractor mechanism 405 in an appropriate manner, for instance by sliding the fingergrip 404 in a proximal direction. Any desired manipulation of fingergrip 404 may be employed, including sliding, rotating, using a push button, etc.

[0050] Cannula retractor mechanism 405 retracts cannula 403 in a proximal direction, removing cannula 403 from underneath the skin. Contrary to cannula 403, obdurator 406 is in a fixed position in housing 409. Therefore, implant 407 is held in a stationary position underneath the skin, while cannula 403 is being retracted. Finally, obdurator 406 is removed from underneath the skin (e.g., by moving applicator 400 proximally), and the skin incision made by cannula 403 may be closed with a steristrip.

[0051] The subject matter of the present invention is described here with specificity, but the claimed subject matter may be embodied in other ways, may include different elements or steps, and may be used in conjunction with other existing or future technologies.

[0052] This description should not be interpreted as implying any particular order or arrangement among or between various steps or elements except when the order of individual steps or arrangement of elements is explicitly described. Different arrangements of the components depicted in the drawings or described above, as well as components and steps not shown or described are possible. Similarly, some features and sub-combinations are useful and may be employed without reference to other features and sub-combinations. Embodiments of the invention have been described for illustrative and not restrictive purposes, and alternative embodiments will become apparent to readers of this patent. Accordingly, the present invention is not limited to the embodiments described above or depicted in the drawings, and various embodiments and modifications may be made without departing from the scope of the claims below.

CLAIMS

What is claimed is:

1. An applicator for subdermally inserting an implant in a human or animal, the applicator comprising:

a housing defining a body of the applicator;

a cannula coupled with the housing and extending distally from the body of the applicator, the cannula having a distal tip, a longitudinal axis, and an insertion length;

a cannula guide extending from the body of the applicator, the cannula guide having a distal end that is distal relative to the distal tip of the cannula and above the distal tip of the cannula;

wherein the distal end of the cannula guide is distal relative to the distal tip of the cannula and above the distal tip of the cannula such that a straight line between the distal end of the cannula guide and the distal tip of the cannula forms an angle between 15 degrees and 45 degrees with the longitudinal axis of the cannula.

2. The applicator of claim 1, wherein the straight line between the distal end of the cannula guide and the distal tip of the cannula forms an angle between 20 degrees and 40 degrees with the longitudinal axis of the cannula.

3. The applicator of claim 2, wherein the straight line between the distal end of the cannula guide and the distal tip of the cannula forms an angle between 25 degrees and 35 degrees with the longitudinal axis of the cannula.

4. An applicator for subdermally inserting an implant in a human or animal, the applicator comprising:

a housing defining a body of the applicator;

a cannula coupled with the housing and extending distally from the body of the applicator, the cannula having a distal tip, a longitudinal axis, and an insertion length;

a cannula guide extending from the body of the applicator, the cannula guide having a distal end that is distal relative to the distal tip of the cannula and above the distal tip of the cannula; and

wherein the distal end of the cannula guide comprises a beveled surface that is at an angle between 15 degrees and 45 degrees with the longitudinal axis of the cannula.

5. The applicator of claim 4, wherein the beveled surface is at an angle between 20 degrees and 40 degrees with the longitudinal axis of the cannula.

6. The applicator of claim 5, wherein the beveled surface is at an angel between 25 degrees and 35 degrees with the longitudinal axis of the cannula.

7. An applicator for subdermally inserting an implant in a human or animal, the applicator comprising:

a housing defining a body of the applicator;

a cannula coupled with the housing and extending distally from the body of the applicator, the cannula having a distal tip, a longitudinal axis, and an insertion length;

a cannula guide extending from the body of the applicator; and

wherein the cannula extends from a distal surface of the body of the applicator and wherein the distal surface of the body of the applicator defines a skin guide having a surface at an angle between 20 degrees and 60 degrees with the longitudinal axis of the cannula.

8. The applicator of claim 7, wherein the surface of the skin guide is at an angle between 35 and 45 degrees with the longitudinal axis of the cannula.

9. The applicator of claim 7 or 8, wherein the housing forms the cannula guide, the body, and the skin guide.

10. The applicator of any of the above claims, wherein the cannula is slideably coupled with the housing and may be retracted proximally into the body of the housing.

11. The applicator of claim 10, further comprising an obdurator extending into the cannula from a proximal end of the cannula, wherein the obdurator is fixedly attached to the housing such that the cannula moves proximally relative to the obdurator during retraction of the cannula proximally into the body of the housing.

12. The applicator of claim 10 or 11, further comprising a user actuator operably coupled with the cannula and slidable in a proximal direction in a track of the applicator to retract the cannula in the proximal direction.

13. The applicator of claim 12, further comprising a safety lock mechanism operably coupled with the user actuator, the safety lock mechanism including a deformable protrusion that extends into a slot in the housing to bias the user actuator against

moving in the proximal direction, and wherein the safety lock mechanism is user moveable in the track of the applicator in the proximal direction to deform the protrusion of the safety lock mechanism such that the protrusion is urged out of the slot in the housing thereby unlocking the user actuator for movement in the proximal direction.

14. The applicator of claim 13, wherein the slot extends from the track in a direction transverse to the track.

15. An implant delivery system for subdermally inserting an implant in a human or animal, the implant delivery system comprising:

the applicator of any of claims 1-14, wherein the cannula comprises an implant holding section where an inner surface of the cannula is inwardly indented; and

an implant friction fit within the implant holding section of the cannula.

16. An implant delivery system for subdermally inserting an implant in a human or animal, the implant delivery system comprising:

the applicator of any of claims 1-14;

the implant disposed within the cannula; and

a cannula guard disposed over the distal tip of the cannula and removable therefrom, the cannula guard including a push rod that extends proximally into the distal tip of the cannula when the cannula guard is disposed over the distal tip of the cannula.

17. The implant delivery system of claim 15 or 16, wherein the implant comprises a metal material.

18. The implant delivery system of claim 17, wherein the implant comprises a titanium material.

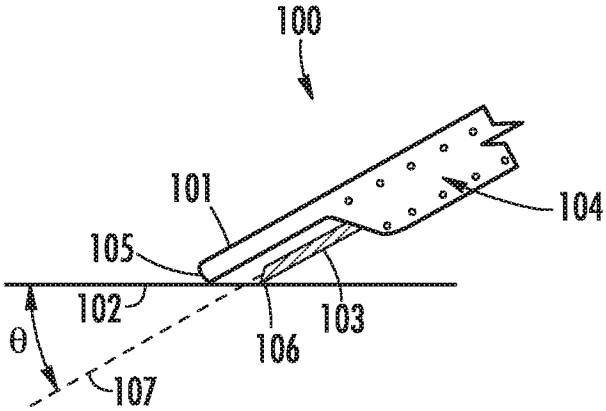

FIG. 1A

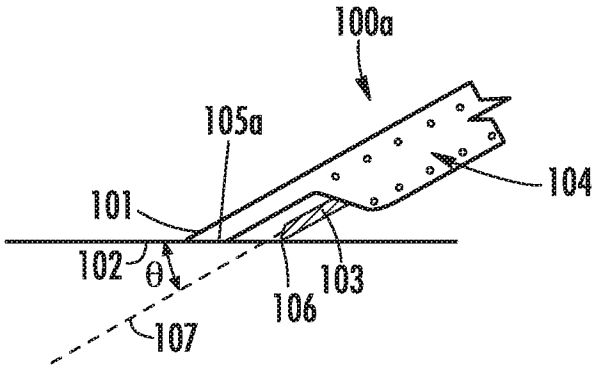

FIG. 1B

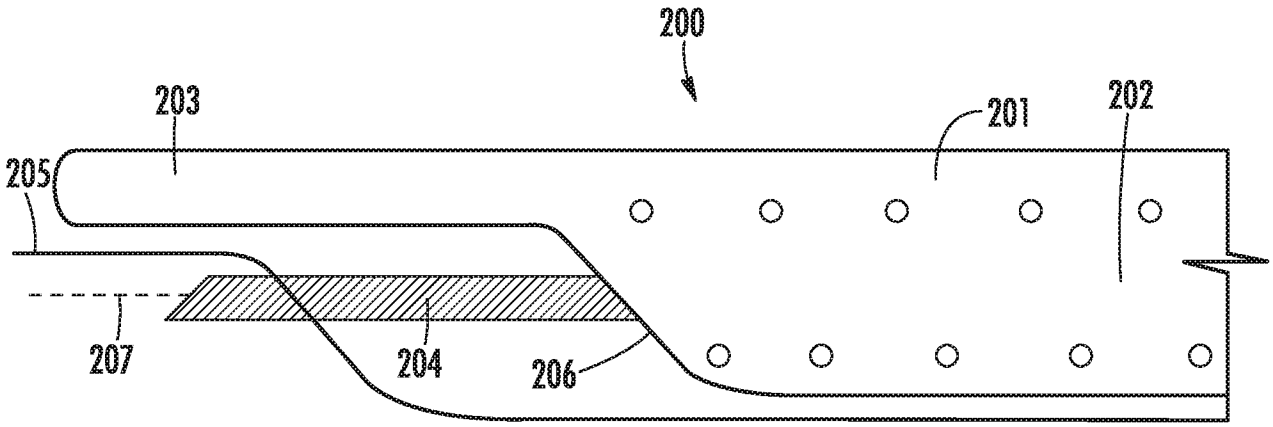

FIG. 2A

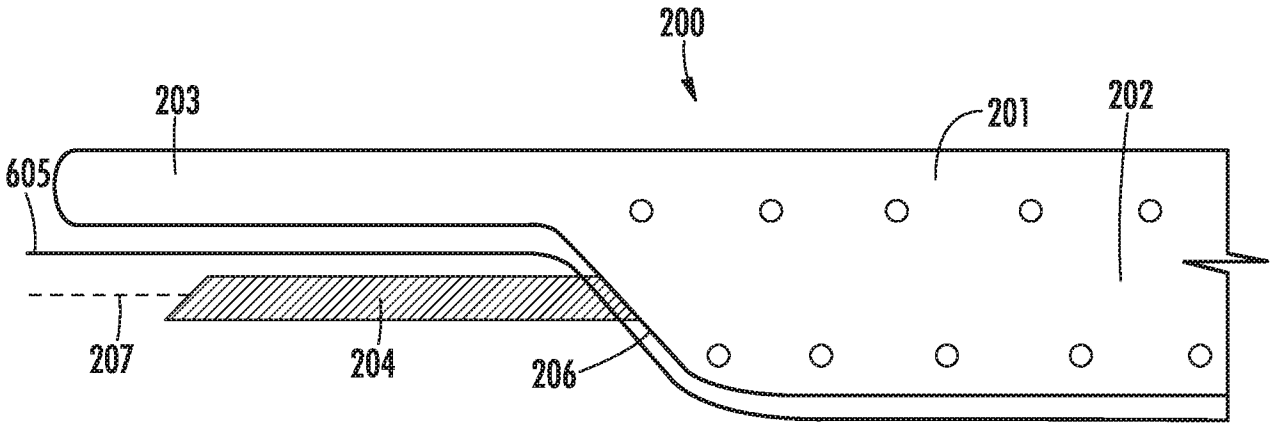

FIG. 2B

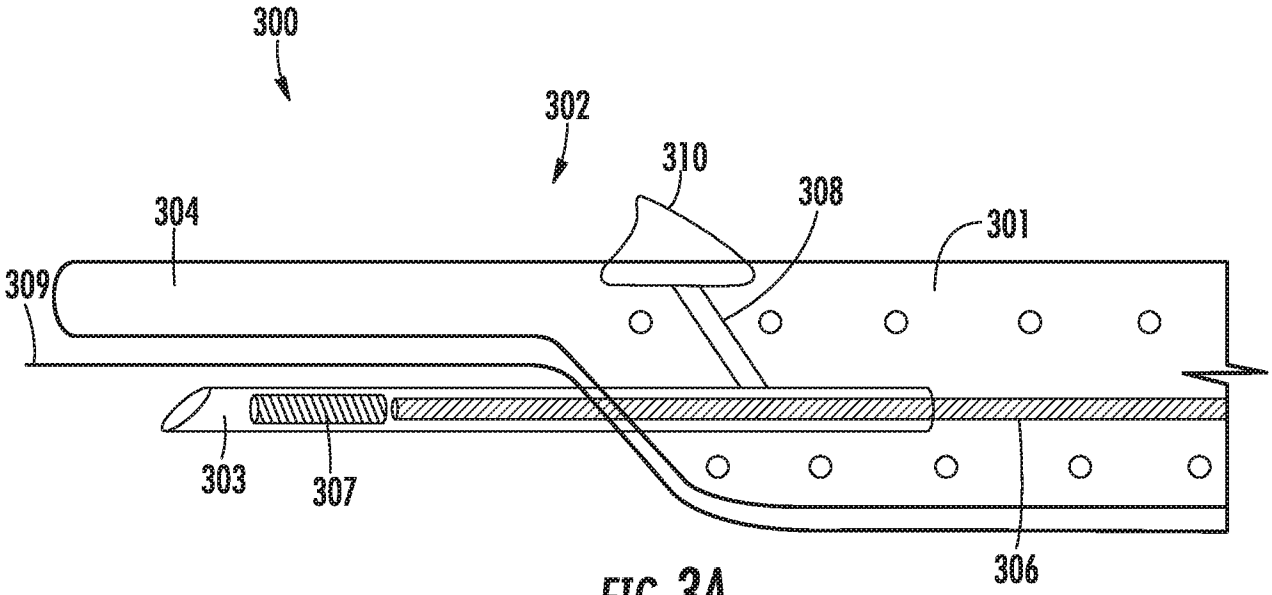
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FIG. 3A

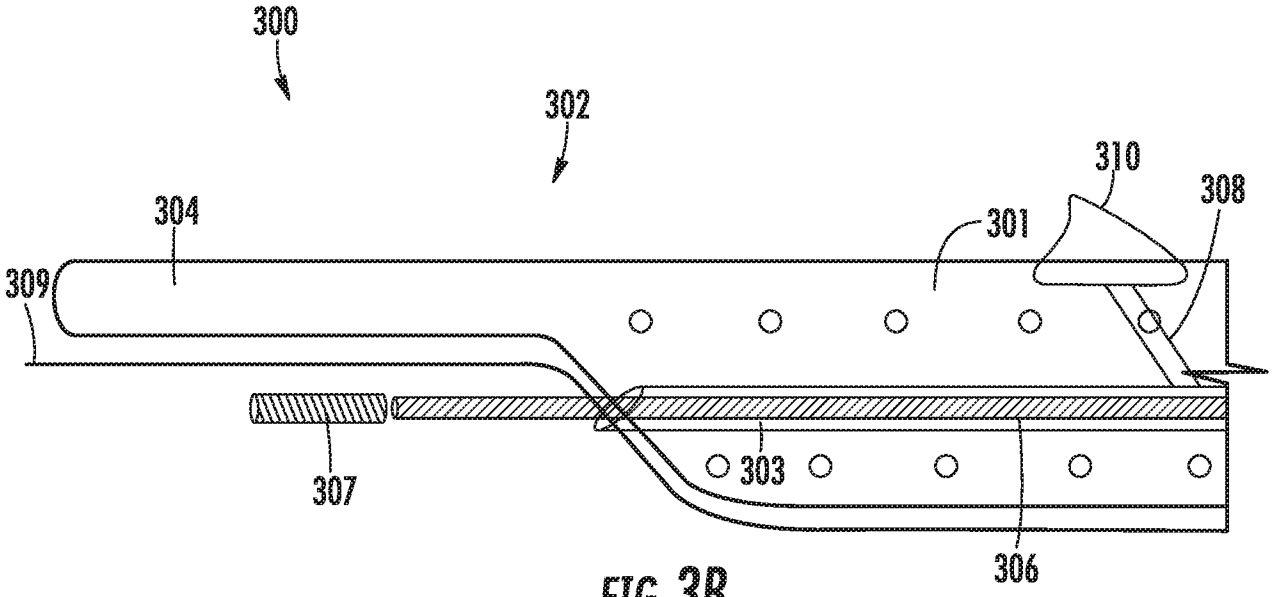
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FIG. 3B

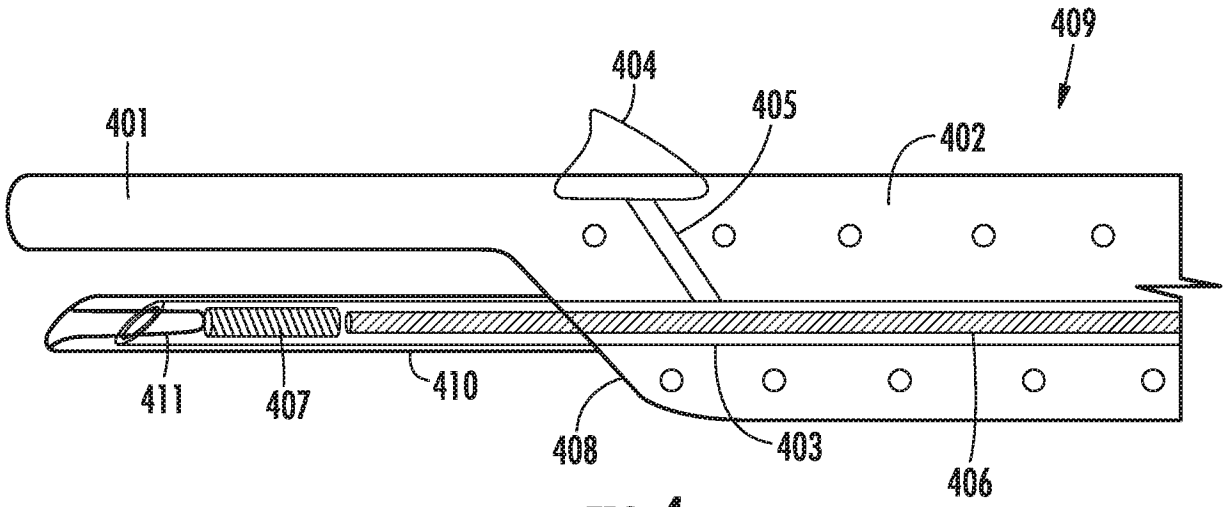

FIG. 4

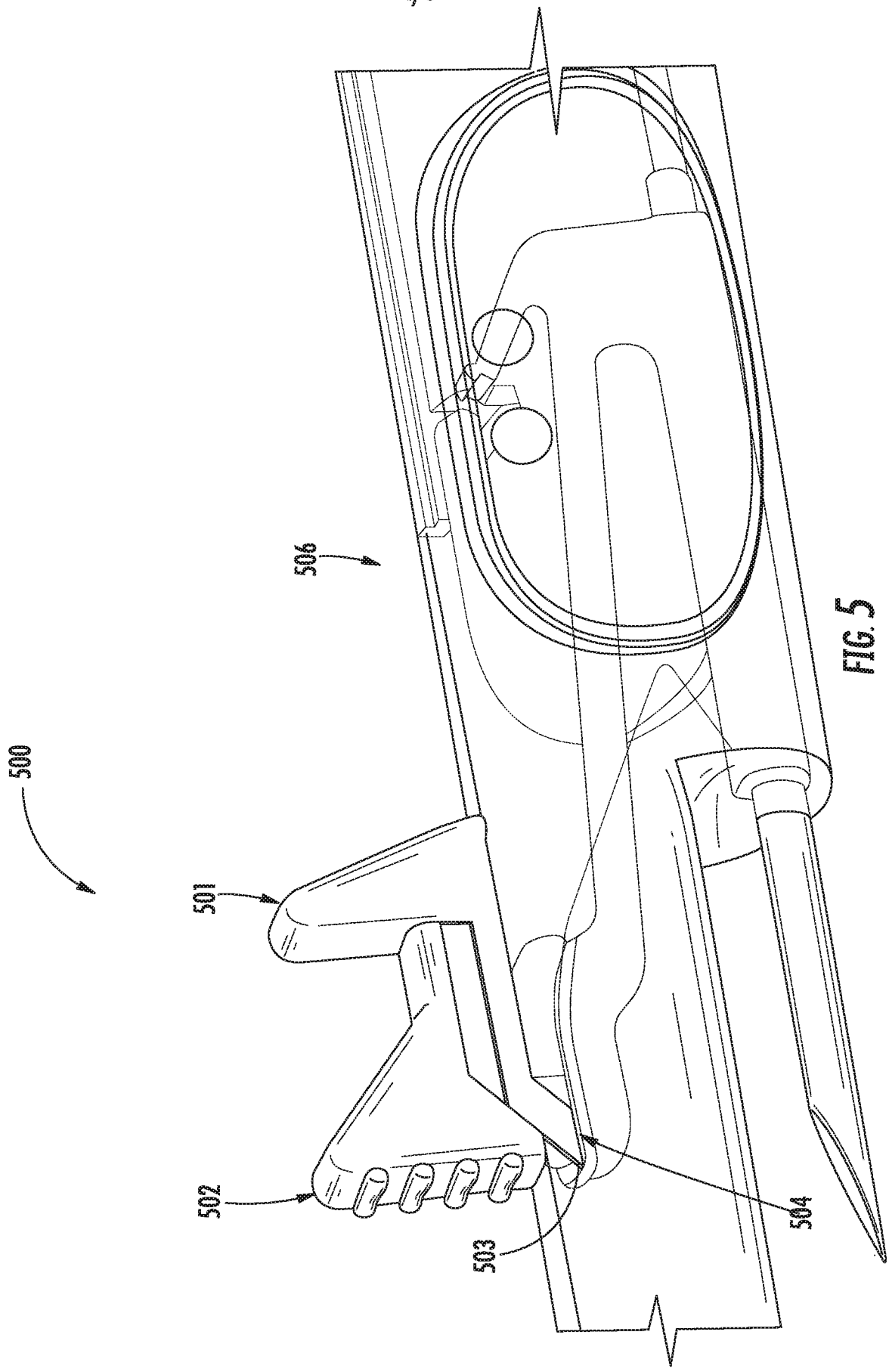

FIG. 5

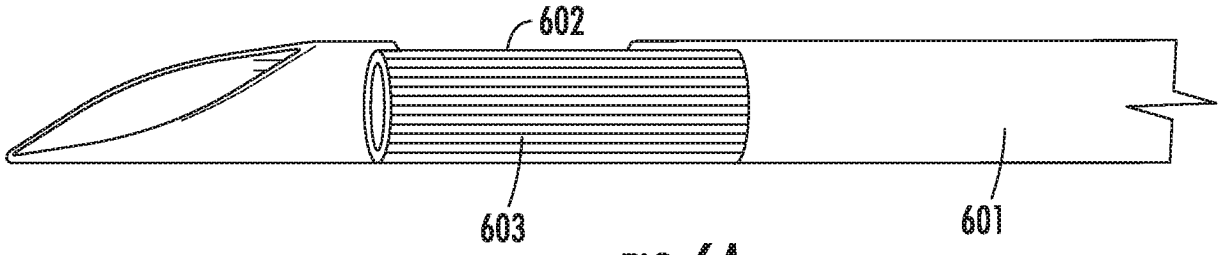

FIG. 6A

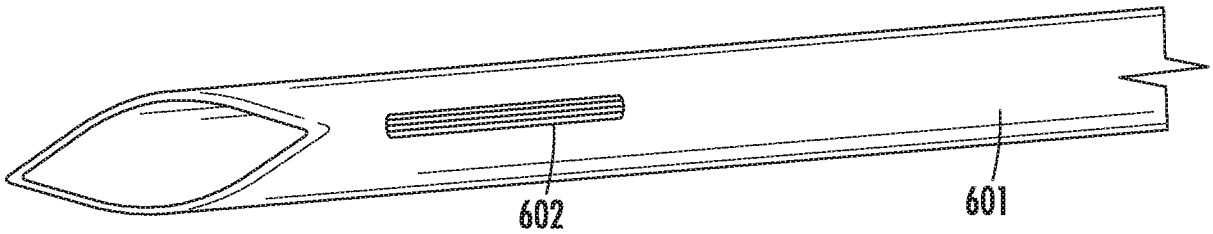

FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/043928

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 A61M37/00
ADD.

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)
A61B 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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/036465 A1 (GLUKHOVSKY ARKADY [US] ET AL) 11 February 2010 (2010-02-11) paragraphs [0024], [0037] - [0046]; figure 8	1-6, 15-18
Y	WO 98/13091 A1 (AMERICAN HOME PROD [US]) 2 April 1998 (1998-04-02) pages 6-13; figures 1-5	1-6, 15-18
Y	WO 2011/112916 A1 (SID TECHNOLOGIES LLC [US]; TSALS IZRAIL [US]; EVANS CHRISTOPHER [US];) 15 September 2011 (2011-09-15) paragraphs [0046] - [0086]; figures 1A-8B	1-6, 15-18
Y	WO 2014/137901 A1 (SID TECHNOLOGIES LLC [US]) 12 September 2014 (2014-09-12) paragraph [0049]; figure 7	1-6, 15-18

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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	Date of mailing of the international search report
23 September 2016	25/11/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Dydenko, Igor

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/043928

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 324 854 A (WEESE WILFRED W) 13 June 1967 (1967-06-13) columns 3-4; figures 1-5 -----	1-6, 15-18
A	EP 0 596 161 A1 (TEXAS INSTRUMENTS INC [US]; TEXAS INSTRUMENTS HOLLAND [NL]) 11 May 1994 (1994-05-11) column 3; figures 1,2 -----	1,4

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2016/043928

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010036465 A1	11-02-2010	CA 2732751 A1	11-02-2010
		EP 2320993 A1	18-05-2011
		US 2010036465 A1	11-02-2010
		US 2013310846 A1	21-11-2013
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		ES 2575546 T3	29-06-2016
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		DE 69224386 D1	12-03-1998
		DE 69224386 T2	18-06-1998
		EP 0596161 A1	11-05-1994

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2016/043928

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6(completely); 15-18(partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6(completely); 15-18(partially)

an applicator for subdermally inserting an implant in a human or animal, the applicator comprising:a housing defining a body of the applicator;a cannula coupled with the housing and extending distally from the body of the applicator, the cannula having a distal tip, a longitudinal axis, and an insertion length;a cannula guide extending from the body of the applicator, the cannula guide having a distal end that is distal relative to the distal tip of the cannula and above the distal tip of the cannula;wherein the distal end of the cannula guide is distal relative to the distal tip of the cannula and above the distal tip of the cannula such that a straight line between the distal end of the cannula guide and the distal tip of the cannula forms an angle between 15 degrees and 45 degrees with the longitudinal axis of the cannula.

1.1. claims: 4-6(completely); 15-18(partially)

an applicator for subdermally inserting an implant in a human or animal, the applicator comprising:a housing defining a body of the applicator;a cannula coupled with the housing and extending distally from the body of the applicator, the cannula having a distal tip, a longitudinal axis, and an insertion length;a cannula guide extending from the body of the applicator; andwherein the cannula extends from a distal surface of the body of the applicator and wherein the distal surface of the body of the applicator defines a skin guide having a surface at an angle between 20 degrees and 60 degrees with the longitudinal axis of the cannula.

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2. claims: 7-14(completely); 15-18(partially)

an applicator for subdermally inserting an implant in a human or animal, the applicator comprising:a housing defining a body of the applicator;a cannula coupled with the housing and extending distally from the body of the applicator, the cannula having a distal tip, a longitudinal axis, and an insertion length;a cannula guide extending from the body of the applicator; andwherein the cannula extends from a distal surface of the body of the applicator and wherein the distal surface of the body of the applicator defines a skin guide having a surface at an angle between 20 degrees and 60 degrees with the longitudinal axis of the cannula.
