

IMPLANT PLACEMENT AND REMOVAL SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 62/170,561, filed June 3, 2015, and entitled “Subcutaneous Implant Placement System,” and U.S. Provisional Patent Application No. 62/170,994, filed June 4, 2015, and entitled “Subcutaneous Implant Placement System.” The present application incorporates herein by reference the disclosures of all of the above-referenced applications in their entireties.

FIELD OF THE INVENTION

[0002] Embodiments of the present disclosure relate to systems, methods and devices for placing and removing an implant at/from a determined depth beneath an outer surface of skin.

SUMMARY OF SOME OF THE EMBODIMENTS

[0003] Some embodiments of this disclosure present systems, methods and devices which guide placement of implants at a determined depth within tissue, beneath the outer surface of skin, as well as for the removal of the implants from within tissue, such as intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue. Systems, methods and devices herein can be adapted for placement of implants to any determined depth. In some embodiments, the determined depth of the implant upon placement is about 0.5 mm to about 4.5 mm, about 1 mm to about 4 mm, about 1.5 mm to about 3 mm, beneath an outer surface of skin of a patient, such as a human patient. In some embodiments, systems, methods and devices are provided to guide placement of implants into or among intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue depths.

[0004] According to a first aspect, a system for placing an implant is provided which comprises a placement tool including a handle portion and a placement cannula. The cannula has a length, a proximal end arranged near the handle portion and a distal end opposite

the proximal end, and is configured to deliver the implant within a tissue of a patient via an incision in the skin of the patient at an implantation site.

[0005] The system also includes a placement guide comprising a first surface configured to be disposed adjacent to a surface of the skin of the patient at the implantation site and a pilot-tube. The pilot-tube comprising a proximal end configured to receive the distal end of the placement cannula, a distal end spaced apart from the proximal end at a first distance, and a longitudinal central axis arranged relative to the first surface at either or both of a second distance and an angle, wherein the placement guide is configured to guide the placement cannula within the tissue to effect implantation of the implant at a predetermined placement depth beneath the outer surface of the skin of the patient such that opposite ends of the implant are placed at a determined depth that is substantially the same, and wherein the placement cannula is movable relative to the placement guide, either within or adjacent to the pilot-tube. During insertion of the cannula into the incision, prior to release of the implant from the cannula, the handle portion and cannula can be rotated by a practitioner, in clockwise and counterclockwise directions, *e.g.*, back and forth within a span or range of between about 9 o'clock to about 3 o'clock, about 10 o'clock and about 2 o'clock, or about 11 o'clock to about 1 o'clock, relative to the central longitudinal axis of the pilot-tube on the placement guide. Rotation in this manner, while the placement guide remains substantially stationary, without rotating, on the outer surface of the skin of the patient, may promote controlled and proper progression of the cannula into the tissue of the patient beneath the outer surface of skin. Thus, in some embodiments, the placement guide is configured to allow substantially free rotation of the cannula within the pilot-tube of the placement guide. In some embodiments, a system is provided for placing an implant into and/or among intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue.

[0006] In such systems (and other embodiments), one and/or another of the following features may be included:

- at least one of the first distance, the second distance and the angle are configured to guide the placement cannula and deliver the implant at the determined depth beneath the outer surface of the skin of the patient;

- the placement guide further comprises a visualization window or opening which extends along a length and a width of the placement guide and which is configured to enable visualization and/or palpitation of an area of skin around the site at which the implant is being inserted;

pressure to the incision, applying an adhesive to at least one side of the incision, and closing the incision; and

- the determined depth is about 0.5 mm to about 4.5 mm, about 1 mm to about 4 mm, about 1.5 mm to about 3 mm, beneath the outer surface of the skin of the patient.

[0009] In some embodiments for placing an implant, both ends of the implant are placed at a determined depth that is substantially the same, resulting in a substantially level placement of the implant. In other words, each end of the implant is placed at a determined depth that is within about 0.5 mm, about 0.4 mm, about 0.3 mm, about 0.2 mm, or about 0.1 mm of the other end.

[0010] According to a second aspect, a placement guide for use with a placement tool is provided and includes a first surface configured to be disposed adjacent to a surface of the skin of the patient at the implantation site and a pilot-tube. The pilot tube includes a proximal end configured to receive a distal end of a placement cannula of the placement tool for delivering an implant into tissue, a distal end spaced apart from the proximal end at a first distance, and a longitudinal axis therethrough from the proximal end to the distal end. The longitudinal axis is arranged relative to the first surface at either or both of a second distance and an angle, wherein at least one of the second distance or the angle of the placement guide are configured to guide the placement cannula of the placement tool within the tissue to effect implantation of the implant beneath the outer surface of the skin of the patient such that opposite ends of the implant are placed at a determined depth that is substantially the same, and wherein the pilot tube is configured to permit rotation of the placement cannula within the pilot tube. In some embodiments, the placement guide is made from a material (*e.g.*, medical-grade plastic) that is translucent or substantially clear. In some embodiments, the placement guide is substantially rigid. For example, in some embodiments, the placement guide is sufficiently rigid that it cannot be substantially flexed, warped or bent, length-wise and/or width-wise, by a user during normal usage. In some embodiments, a placement guide device is provided for use with a placement tool. In some embodiments, a placement guide device is provided for placing an implant into and/or among intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue.

[0011] The placement guide, according to some embodiments, may include one and/or another of the following features:

- a visualization window or opening which extends along a length and a width of the first surface and configured to enable visualization and/or palpitation of an area of skin around the site at which the implant is being inserted;

Claims:

1. A system for placing an implant, comprising:
 - a placement tool comprising
 - a handle portion, and
 - a placement cannula having a length, a proximal end arranged near the handle portion and a distal end opposite the proximal end, the placement cannula configured to deliver the implant within a tissue of a patient via an incision in the skin of the patient at an implantation site; and
 - a placement guide comprising
 - a first surface configured to be disposed adjacent to a surface of the skin of the patient at the implantation site and
 - a pilot-tube, comprising a proximal end configured to receive the distal end of the placement cannula, a distal end spaced apart from the proximal end at a first distance, and a longitudinal central axis arranged relative to the first surface at either or both of a second distance and an angle;

wherein the placement guide is configured to guide the placement cannula within the tissue to effect implantation of the implant at a predetermined placement depth beneath the outer surface of the skin of the patient such that opposite ends of the implant are placed at a determined depth that is substantially the same, and

wherein the placement cannula is movable relative to the placement guide, either within or adjacent to the pilot-tube.
2. The system of claim 1, wherein at least one of the first distance, the second distance, and the angle of the longitudinal central axis of the pilot-tube relative to the first surface of

the placement guide are configured to guide the placement cannula for the delivery of the implant at the determined placement depth.

3. The system of claim 1, wherein the determined placement depth is about 0.5 mm to about 4.5 mm beneath the outer surface of the skin of the patient.

4. The system of claim 1, wherein the placement guide further comprises a visualization window or opening, wherein the visualization window or opening extends along a length and a width of the placement guide and is configured to allow visual observation and/or palpation or touch of an area of an outer surface of skin around the implantation site.
5. The system of claim 1, wherein the placement guide further comprises a visualization opening, wherein the visualization opening extends along a length and a width of the placement guide and is configured to allow visual observation and palpation or touch of an area of an outer surface of skin around the implantation site.
6. The system of claim 1, wherein the implant is an osmotic mini-pump.
7. The system of claim 1, configured to permit the placement cannula to rotate within the pilot-tube.
8. A method for placing an implant, comprising:
providing a placement system according to claim 1.
9. The method of claim 8, further comprising at least one of:
loading the implant into the distal end of the placement cannula;
creating an incision in the skin at an implantation site;
arranging the placement guide at the implantation site, such that the distal end of the pilot-tube is aligned with the incision;
inserting the distal end of the loaded placement cannula in the proximal end of the pilot-tube;
moving the placement cannula relative to the pilot-tube until at least a part of the handle portion is proximate the proximal end of the pilot-tube such that the distal end of

the placement cannula is guided farther into the incision and into the tissue beneath and/or adjacent the incision;

releasing the implant from the placement cannula;

removing the placement cannula from the skin of the patient; and

removing the placement guide from the skin of the patient.

10. A placement guide for use with a placement tool, the placement guide comprising:
- a first surface configured to be disposed adjacent to a surface of the skin of the patient at the implantation site; and
 - a pilot-tube comprising
 - a proximal end configured to receive a distal end of a placement cannula of the placement tool for delivering an implant to tissue, a distal end spaced apart from the proximal end at a first distance, and a longitudinal axis therethrough from the proximal end to the distal end,
- wherein the longitudinal axis is arranged relative to the first surface at either or both of a second distance and an angle,
- wherein at least one of the second distance or the angle of the placement guide is configured to guide the placement cannula of the placement tool within the tissue to effect implantation of the implant beneath the outer surface of the skin of the patient such that opposite ends of the implant are placed at a determined depth that is substantially the same, and
- wherein the pilot tube is configured to permit rotation of the placement cannula within the pilot tube.

11. The placement guide of claim 10, wherein the pilot-tube is configured to permit rotation of the placement cannula within the pilot-tube.
12. The placement guide of claim 10, further comprising a visualization window or opening that extends along a length and a width of the first surface and configured to enable visual observation and/or palpation or touch of an area of the outer surface of skin around the site at which the implant is being inserted.
13. The placement guide of claim 12, wherein the visualization window or opening has a length that extends beyond the tip of the cannula when the cannula is inserted into, and fully extended through, the pilot-tube.
14. The placement guide of claim 10, wherein the placement depth is from about 0.5 mm to about 4.5 mm beneath the outer surface of the skin of the patient.
15. The placement guide of claim 10, wherein the pilot-tube is configured to receive and guide the placement cannula into tissue.
16. The placement guide of claim 10, wherein the placement guide is made from a material that is translucent or substantially clear.
17. The placement guide of claim 10, wherein the pilot-tube is configured at an incline relative to the first surface.
18. The placement guide of claim 10, wherein the placement guide cannot readily be flexed or bent, length-wise or width-wise, by a user.

19. The system of claim 1, wherein the placement cannula is movable within and relative to the handle portion.