

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 movable within or adjacent to, and relative to, the handle portion. 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 a patient at an implantation site.

[0005] The system also includes a placement guide having a first surface and a pilot-tube. The pilot-tube includes 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, a longitudinal central axis arranged relative to the first surface at either or both of a second distance and an angle. The placement guide is configured to guide the placement cannula within the tissue to effect implantation of the implant to a determined placement depth beneath the outer surface of the skin of the patient. 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 device for use with a placement tool is provided and includes a first surface and a pilot-tube having a central longitudinal axis. The tube includes a proximal end configured to receive the distal end of a placement cannula for delivering an implant into tissue and a distal end spaced apart from the proximal end at a first distance. The longitudinal axis arranged relative to the first surface at either or both of a second distance and an angle and the placement guide are configured to guide a placement cannula of a placement tool within the tissue to effect implantation of the implant at a determined placement depth beneath the outer surface of the skin of the patient. 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;

- the placement guide is configured to provide a placement depth of the implant of about 0.5 mm to about 4.5 mm, about 1 mm to about 4 mm, preferably about 1.5 mm to about 3 mm, beneath the outer surface of the skin of the patient;
- the pilot-tube is configured to receive and guide the placement cannula into tissue; and
- at least one of the rigidity of the guide, the first distance, the second distance and the angle are configured to guide the placement cannula and deliver the implant at the determined placement depth.

[0012] The placement guide is generally configured to allow substantially free rotation of the cannula within the pilot-hole/pilot-tube of the placement guide. During an implant placement procedure, this feature may permit the practitioner to conveniently, safely, and accurately create a placement tract through tissue by nimbly rotating the cannula through the tissue, without, or with minimal inhibition from the guide. It was discovered that placements of implants using systems with the described placement guides occurred with minimal or no harm, and with minimal or no bruising, to patients.

[0013] Such harm and bruising to patients may otherwise occur during placements of implants made, for example, with more cumbersome placement tools, such as a “one-piece placement tool,” having a fixed guide portion, and a cannula that cannot freely rotate relative to the fixed guide. Placements of implants with such cumbersome one-piece placement tools, having a fixed guide portion, and a cannula that cannot freely rotate relative to the fixed guide, proceed with restricted motion of the cannula, due to the fixed nature of the tool. Restricted motion of the cannula, during an insertion procedure, can result in excessive or misdirected force being used to create a placement tract through tissue which may result in harm and/or bruising to the patient.

[0014] By contrast, the presently described systems have a placement guide configured to permit substantially free rotation of the cannula within the pilot-hole/pilot-tube of the placement guide which may permit rotation of the cannula independently from the guide and, thus, relatively nimble maneuvering of the placement tool/system. During insertion of the cannula into an 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 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 of a cannula in the presently described placement tool occurs independently of the placement guide, which remains substantially still on the outer surface of skin at the incision site and thus does not pull tissue at the incision site back and forth. Free rotation of the cannula in the presently described placement tool, within the pilot tube of the placement guide, may permit the practitioner to gradually ease the cannula through tissue, even fibrous connective tissue, with optimal control of the cannula's insertion path. Thus, the presently described placement tool and placement guide may allow for convenient, safe and accurate placement of the cannula into tissue. The presently described placement tool and placement guide may also mitigate difficulties encountered upon insertions of implants into different types of tissue among patients.

[0015] In some embodiments, an implant removal tool is provided which includes a first arm, a second arm configured at least during use to be spaced apart from, and substantially parallel to, the first arm, a first opening arranged at a distal end of the first arm, and a second opening arranged at a distal end of the second arm. As used herein, the term "substantially parallel" with respect to first and second arms means that the first and second arms need not be perfectly parallel; rather, the first and second arms may be oriented substantially parallel to one another, for example, when the device is in an open orientation, prior to use, causing the first and second openings to generally point away from one another. Alternatively, the first and second arms are also oriented substantially parallel to one another when the device is in a closed orientation, during use when the arms are brought together, causing the first and second openings to generally point towards one another.

[0016] The first opening is configured to corral or otherwise capture a first end of an implanted implant, and the second opening is configured to corral or otherwise capture a second end of the implanted implant. The tool may also include a locking device configured to maintain the distance between the first arm and second arm as the arms are brought together and reach the user's desired spacing. The locking device permits the user/practitioner to carry out subsequent steps (*e.g.*, incision and/or removal of the implant from the incision) hands-free with respect to the removal tool. In some embodiments, an implant removal tool is provided for removing an implant from intraepidermal, subepidermal, intradermal, subdermal, intracutaneous, and/or subcutaneous tissue.

19. The placement guide of claim 17, 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 palpitation of an area of the outer surface of skin around the site at which the implant is being inserted.
20. The placement guide of claim 17, 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.
21. The placement guide of claim 17, 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.
22. The placement guide of claim 17, wherein the pilot-tube is configured to receive and guide the placement cannula into tissue.
23. The placement guide of claim 17, wherein the placement guide is made from a material that is translucent or substantially clear.
24. The placement guide of claim 17, wherein the pilot-tube is configured at an incline relative to the underside of the guide.
25. The placement guide of claim 17, wherein the placement guide cannot readily be flexed or bent, length-wise or width-wise, by a user.