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Electrode Insertion Tool

FIG. 1

An insertion tool for holding an electrode assembly for a medical implant is disclosed. The tool comprises an elongate body portion extending from a first end to a second end. An electrode assembly receiving region is located at the second end. The electrode assembly receiving region is adapted to support at least a portion of the electrode assembly in a substantially straight configuration, and includes a plurality of guide formations which are longitudinally spaced along the electrode assembly receiving region. The electrode assembly receiving portion may comprise a first proximal guide formation, a second distal guide formation longitudinally distal from the first guide formation and a third intermediate guide formation laterally offset from the first and second guide formations and located longitudinally intermediate the first and second guide formations.
COCHLEAR ELECTRODE INSERTION TOOL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from Australian Patent Application No. 201 1903898, filed on September 21, 2011.

BACKGROUND

Field of the Invention

[0002] The present disclosure relates generally to the field of insertion tools for medical implants, and more particularly, to

Related Art

[0003] One form of cochlear implant includes an external speech processor that communicates via radio frequencies with an implanted receiver connected to an electrode array. The electrode array includes an elongate array of longitudinally spaced and aligned electrode contacts disposed at its distal end. The electrode contacts transmit electrical signals directly to the auditory nerve endings in the cochlea (the inner ear), thereby bypassing damaged or lost hair cells. The cochlea has a 3-D helico-spiral structure defining a number of internal canals, including the scala tympani, or tympanic canal. The electrode array is generally inserted into the scala tympani via a cochleostomy or round window insertion.

[0004] The procedure for performing this task and ensuring that the electrode array is correctly positioned within the cochlear is a relatively difficult one requiring much skill and care by the surgeon. To correctly position the electrode array within the cochlea, a surgeon must first access the cochlea. This is typically done by performing a mastoidectomy and a posterior tympanotomy, followed by a cochleostomy to create an opening into the scala tympani of the cochlea into which the electrode array is to be inserted. The electrode array can alternatively be inserted through the round window. The tight spatial constraints of surgical sites result in both reduced manoeuvrability and visibility for the surgeon.
SUMMARY

[0005] In one aspect of the disclosed subject matter, an insertion tool for holding an electrode assembly for a medical implant is disclosed. The tool comprises an elongate body portion extending from a first end to a second end. An electrode assembly receiving region is located at the second end. The electrode assembly receiving region is adapted to support at least a portion of the electrode assembly in a substantially straight configuration, and includes a plurality of guide formations which are longitudinally spaced along the electrode assembly receiving region. The electrode assembly receiving portion may comprise a first proximal guide formation, a second distal guide formation longitudinally distal from the first guide formation and a third intermediate guide formation laterally offset from the first and second guide formations and located longitudinally intermediate the first and second guide formations.

[0006] In a further aspect of the disclosed subject matter, an insertion tool for inserting an elongate electrode assembly into a cochlea is disclosed. The tool comprises a proximal handle, an elongate shaft projecting from the handle, and an electrode assembly receiving region extending from a distal end of the shaft defining an opening for allowing the electrode assembly to be introduced into and released from the electrode assembly receiving region. The electrode assembly receiving region includes a plurality of guide formations which are longitudinally spaced along the electrode assembly receiving region. At least two of the guide formations are laterally offset from one another on either side of the electrode assembly receiving region.

[0007] There is still further provided an insertion tool for inserting an elongate electrode assembly into a cochlea. The tool is a reverse tweezer comprising a pair of first and second pincer arms biased into a closed position in which the elongate electrode assembly is held between the arms, and is movable into an open position to allow release of the electrode assembly. A plurality of guide formations extend from the first and second pincer arms and define in conjunction with the pincer arms when in the closed position a substantially straight
path, for receiving the electrode assembly. The guide formations include at least two longitudinally spaced guide formations on the first pincer arm and at least one guide formation on the second pincer arm, the guide formations being configured to cooperate to receive the electrode assembly.

[0008] As used herein, except where the context requires otherwise, the term "comprise" and variations of the term, such as "comprising", "comprises" and "comprised", are not intended to exclude further additives, components, integers or steps.

[0009] Further aspects of the present disclosed subject matter and further embodiments of the aspects described in the preceding paragraphs will become apparent from the following description, given by way of example and with reference to the accompanying drawings.
BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Illustrative embodiments of the disclosed subject matter are described herein with reference to the accompanying drawings, in which:

[0011] Figure 1 is a side view of an internal component of a typical cochlear implant showing the electrode assembly is a substantially straightened configuration;

[0012] Figure 2 is an enlarged side view of the curved electrode assembly of Figure 1;

[0013] Figure 3a is a side view of an embodiment of a cochlear electrode insertion tool;

[0014] Figure 3b is a detailed perspective view of the distal end of the cochlear electrode insertion tool of Figure 3a;

[0015] Figure 3c is a side view of the electrode assembly of Figure 2 fitted within and straightened by the cochlear electrode insertion tool of Figures 3a and 3b;

[0016] Figure 3d is a side view of the distal end of an alternative embodiment of the cochlear electrode insertion tool;

[0017] Figure 4a is a perspective view of a distal end of an embodiment of a cochlear electrode insertion tool;

[0018] Figure 4b is a perspective view of a distal end of an embodiment of the cochlear electrode insertion tool;

[0019] Figure 5a is a side view of an embodiment of a distal end of a cochlear electrode insertion tool;

[0020] Figure 5b is an end-view of the cochlear electrode insertion tool of Figure 5a;

[0021] Figure 6a is a perspective view of an embodiment of a reverse tweezer cochlear electrode insertion tool showing the open position;
Figure 6b is a perspective view of the reverse tweezer of Figure 6a shown in the closed position clasping an electrode assembly;

Figure 6c is an enlarged perspective view of the distal end of the insertion tool of Figures 6a and 6b;

Figure 7 is a front view of an alternative embodiment of a reverse tweezer cochlear electrode insertion tool; and

Figure 8 is a front view of an embodiment of reverse tweezer cochlear electrode insertion tool.
DETAILED DESCRIPTION

[0026] The following detailed description is provided with reference to cochlear implants. The disclosed subject matter may also have application to other types of implantable medical devices, and those skilled in the relevant arts will appreciate the application of the disclosed and other embodiments of the insertion tool described below to other implantable medical devices.

[0027] Surgical procedures, including the insertion of an electrode assembly of a cochlear implant, carry some risk. The electrode assembly needs to be accurately positioned at the round window, cochleostomy or other aperture for insertion. The initial part of the procedure is complicated by limited visibility and manoeuvrability. In addition, the electrode assembly tends to be difficult to manoeuvre to the insertion site.

[0028] The straightness and rigidity of electrode assemblies during locating the electrode assemblies to the insertion site is critical due to the small dimensions and tight spatial constraints of surgical sites. This is in contrast to the desire for a flexible electrode assembly once inside the cochlea. Traditional insertion tools, sheaths, and other straightening features that require larger diameter electrode assemblies, such as internal stylets, are undesirable as they result in a large outside profile, further reducing visibility thereby increasing the difficulty of the operation.

[0029] Aspects and embodiments of the insertion tool is described by way of example for use in the implantation of a perimodiolar electrode assembly. It should be understood to those skilled in the arts that embodiments of the insertion tool may be used with a variety of electrode assemblies including but not limited to straight electrode assemblies, perimodiolar electrode assemblies, mid-scala electrode assemblies and short electrode assemblies.

[0030] Figure 1 is a side view of a typical internal component 10 of a cochlear implant. The implant includes a stimulator/receiver unit 12 from which a stimulating lead assembly 14 extends. Stimulating lead assembly 14 includes a helix region 16, a transition region 18, an electrode
assembly 24 including a proximal region 20 and an intraxochlea region 22. Intraxochlea region 22 is configured for insertion into the scala tympani of the cochlea. A series of cochleostomy marker ribs 28 inform the surgeon how far electrode assembly 24 is inserted into the cochlea. An electrode array 26 disposed along intra-cochlear region 22 is formed of a plurality of electrode contacts 30 which are connected to stimulator/receiver unit 12 via signal pathways in stimulating lead assembly 14. It will be appreciated that the number of electrode contacts may vary.

[0031] An enlarged view of intra-cochlear portion 22 of electrode assembly 24 is illustrated in Figure 2. Electrode assembly 24 is manufactured in a pre-curved configuration, but is shown in the straightened position with stylet 34 inserted into a lumen 32 formed within electrode assembly 34. When electrode assembly 24 is straightened using stylet 34, the pre-curved electrode assembly resists the straightening force created by the stylet. As a result, electrode assembly 24 may have a bent shape as shown in Figure 2. Electrode assembly 24 may have general dimensions of a length of about 20mm from marker rib 28, and a diameter between 0.4mm to 0.8mm, tapering to a progressively smaller diameter towards the tip of electrode assembly 24.

[0032] Figure 3a is a side view of an embodiment of a cochlear electrode insertion tool 40. Figure 3b is a detailed perspective view of the distal end of the cochlear electrode insertion tool of Figure 3a. Figure 3c is a side view of the electrode assembly of Figure 2 fitted within and straightened by the cochlear electrode insertion tool of Figures 3a and 3b. Single post cochlear electrode insertion tool 40 includes a handle 42 and a rod 41 extending from the handle. Rod 41 has an intermediate offset portion 46 for enhancing in-line visibility and a distal portion 48 carrying an electrode assembly receiving region 50. Referring to Figure 3b, electrode assembly receiving region 50 includes a support shaft 44 which may be formed integrally with or separately from rod 41 and a pair of proximal guide formations 52 and 54 extending from support shaft 44 and laterally offset about the central axis 56 of electrode assembly receiving region 50. An intermediate guide formation 58 extends from support shaft 44 and is located in the same plane as guide formation 54, and a distal guide formation
60 extends from support shaft 44 and is located in the same plane as guide formation 52, and is both laterally and longitudinally offset from guide formation 58.

[0033] As best shown in Figure 3c, guide formations 52 and 54 are positioned to frictionally engage a portion of electrode assembly 24, with marker ribs 28 held securely, for example, via a friction fit between proximal guide formations 52 and 54. Intermediate guide formation 58 is positioned to prevent outward bowing of electrode assembly 24, with the silicone backing 36 pressing firmly against the inner surface of guide formation 58. Distal guide formation 60 in turn prevents inward curving of electrode assembly 24. Guide formations 58 and 60 are typically positioned at locations along electrode assembly 24 where the compressive forces of silicone backing 56 induce substantial curvature. As a result, electrode assembly 24 is further straightened, as is illustrated by a comparison of Figures 2 and 3c, in which electrode assembly 24 is substantially straight apart from a slight curvature towards its distal end beyond guide formation 58.

[0034] In operation, once electrode assembly 24 is fitted in position in the manner illustrated in Figure 3c, insertion tool 40 is then used to insert the electrode assembly partially into the cochlea for example, in collaboration with surgical forceps (commonly referred to as tweezers). The insertion tool is used to insert electrode assembly 24 up to a pre-determined distance, typically identified by markers 28. Thereafter, the tool can be readily disengaged from the electrode assembly using a slight lateral movement and the remainder of intra-cochlea region 22 may be inserted. By way of example, for a Contour Advance electrode assembly commercially available from Cochlear Limited, Sydney, Australia, the electrode assembly can be inserted using surgical tweezers and simultaneously retracting stylet 34. The insertion tool can maintain the electrode assembly in a rigid and substantially straight orientation for insertion into the cochlea using for example one hand, with the critical dimensions of the tool
being minimized. As a result, the surgeon's view into the cochleostomy is only minimally affected by the insertion tool during surgery.

[0035] It will be appreciated that electrode assembly receiving region 50 of the single leg tool may be implemented in a variety of configurations. For example, as is clear from Figure 3d, distal end 70 of an insertion tool may include multiple offset guide formations 72a, 72b, 72c and 72d, with a pair of proximal opposed guide formations 72e and 72f. A base 73 of the tool may be tapered in conformity with the electrode assembly.

[0036] Figure 4a shows an alternate embodiment of an electrode assembly receiving region having three longitudinally offset guide formations. The electrode assembly receiving region includes a proximal guide formations 152 and a distal guide formations 160 located longitudinally offset from and in substantially the same plane as guide formation 152. Guide formation 158 is longitudinally intermediate and laterally offset from the proximal guide formation 152 and the distal guide formation 160.

[0037] Figure 4b shows an alternate embodiment of electrode assembly receiving region having three offset guide formations. The electrode assembly receiving region includes two opposed proximal guide formations 252 and 254 and a distal guide formation 260 longitudinally offset from the proximal guide formations and in substantially the same plane as the proximal guide formation 252.

[0038] It should be understood to those of ordinary skill in the art that the support shaft and guide formations may take a number of different configurations. The guide formations may be tabs, posts, protrusions, arcuate sections and other suitable configurations. Support shaft 44 may take a number of configurations including a flat supporting surface substantially perpendicular to the guide formations as shown in Figure 3b or alternatively, may be in line with the guide formations, or travel from in-line to perpendicular to the guide formations. The support shaft may be formed of a rod, wire, arcuate section, mesh or other suitable structure.
[0039] Referring now to Figure 5a, a further embodiment of a distal portion 74 of a single post cochlear electrode assembly insertion tool has a semi-cylindrical configuration having a similar guide formation arrangement to that indicated in Figures 3a to 3c, and including distal guide formation 76a, intermediate guide formation 76b and proximal opposed guide formations 76c and 76d. As is clear from Figure 5b, the curved profile of the guide formations may be configured to retain the electrode array in a friction fit. The guide formations may also be configured to accommodate the tapered profile of the electrode assembly, with the proximal guide formations 76c and 76d being laterally spaced by a distance greater than the distal guide formations 76a and 76b.

[0040] Referring now to Figures 6a and 6b, another embodiment of a cochlear electrode assembly insertion tool 80 is shown in the form of a pair of reverse tweezers 82 having a handle in the form of outwardly biased arms 84 and 86 which are joined at 88 and are formed with cross-over bridges 90 and 92 at the opposite ends from which pincer limbs 94 and 96 extend. The pincer limbs 94 and 96 are as a result of the cross-over arrangement biased together and are separated in the manner illustrated in Figure 6a by exerting finger pressure on opposite sides of the arms 84 and 86. An electrode assembly support region 98, which is illustrated more clearly in Figure 6c, is formed towards the distal end of pincer arms 94 and 96, and is similar in overall configuration to the single post electrode receiving region of Figures 3a to 3c.

[0041] As is clear from Figure 6c, the pincer arm 96 is formed with a base 102 for receiving electrode assembly 24. Extending upwardly from the base is a proximal guide formation 104 and a distal guide formation 106 extends from the tip of the pincer arm 96. The pincer arm 94 is similarly formed with a proximal guide formation 110 and terminates in an intermediate tab 112. Pincer arm 94 may be planar, or may be formed with a strengthening rib which is co-planar with the base portion 102 of pincer arm 96. In operation, the reverse tweezers are pressed open and the electrode assembly is positioned on base portion 102, as is shown in Figure 6a. The reverse
tweezers are then released to allow them to close. The closing bias of the reverse tweezers is designed to be greater than the compression bias of the silicone backing, as a result of which the electrode assembly 24 is straightened in the manner illustrated in Figure 6b. Proximal guide formations 104 and 110 grip cochleostomy marker ribs 28, the intermediate guide formation prevents outward curvature of the silicone backing, and distal guide formation 106 prevents inward curvature. As was the case with the single post embodiment, various arrangements of guide formations such as tabs or posts may be provided to facilitate straightening of the electrode assembly without the bases contacting one another. Alternatively, the bases may be configured to overlap to provide greater versatility in handling electrode arrays of differing widths.

[0042] In addition, as is clear from embodiments illustrated in Figures 7 and 8 respectively, the pincer arms may have different profiles. Tweezer arm arrangement 114 in Figure 7 includes two half-bases 116 and 118 which in combination support the electrode assembly. The total width of the base or bases is sufficiently less than the width of the electrode array to ensure that sufficient straightening bias can be applied to the electrode assembly.

[0043] The embodiment 116 of Figure 8 shows a pair of pincer arms having curved guide formations 120 and 122 which locate around electrode assembly 24. The guide formations may include re-entrant portions indicated in broken outline at 124 and 126 to further hold the* array.

[0044] The cochlear electrode assembly insertion tools of the various embodiments may be formed from a metal such as 304 stainless steel. The tool may also be formed from a ceramic material using material such as alumina. Such a device will allow re-usability of the tool following surgical use and sterilisation. It is also envisaged that the tool may be disposable following use, and in this regard the tool may be made of a suitable plastics material such as PEEK, ABS, PMMA, polyimide, etc. In addition, the guide formations may have a surface finish that provides an increased frictional engaging ability.
An advantage of some embodiments of the reverse tweezer embodiments is that they can operate as both tweezers and as a straightening tool for straightening the electrode assembly.

There are a number of advantages associated with the insertion tools of at least some of the embodiments. The electrode assembly can be both held and inserted partially or fully with one hand. The narrow profile may reduce difficulties in viewing and manipulating during the operating procedure. The chances of electrode assembly insertion difficulties may be reduced due to the straightened configuration. Due to the reduction in manipulation and required force to insert the electrode assembly, damage to the apical pads may be reduced.
CLAIMS

1. An insertion tool for holding an electrode assembly, the tool comprising:
   an elongate body portion extending from a first end to a second end;
   an electrode assembly receiving region at the second end, the electrode receiving
   region adapted to support at least a portion of the electrode assembly in a substantially
   straight configuration, the electrode assembly receiving region including a plurality of guide
   formations which are longitudinally spaced along the electrode assembly receiving region.

2. An insertion tool of claim 1, wherein the electrode assembly receiving portion
   comprises a first proximal guide formation, a second distal guide formation longitudinally
   distal from the first guide formation and a third intermediate guide formation laterally
   offset from the first and second guide formations and located longitudinally intermediate
   the first and second guide formations.

3. An insertion tool of claim 2, wherein the electrode assembly receiving portion
   further comprises a fourth guide formation which is located laterally opposite to the first
   proximal guide formation.

4. An insertion tool of claim 3, wherein the first and fourth guide formations are
   operatively spaced apart by a distance which corresponds to a width of the electrode
   assembly.

5. An insertion tool of claim 3, wherein the guide formations are configured to
   frictionally engage with the electrode assembly.

6. An insertion tool of claim 1, wherein the guide formations comprise projecting guide
   tabs or posts.

7. An insertion tool of claim 6, in which the guide tabs or posts have electrode assembly
   contact surfaces which are substantially flat.
8. An insertion tool of claim 6, in which the guide tabs or posts are curved in conformity with the cross sectional shape of the electrode assembly.

9. An insertion tool of claim 1, in which the elongate body portion comprises a single elongate shaft.

10. An insertion tool of claim 1, in which the elongate body portion is formed with an intermediate kinked or offset portion.

11. An insertion tool of claim 1, in which the elongate body portion comprises a pair of first and second pincer arms and in which at least two guide formations extend from the first pincer arm and at least one guide formation extends from the second pincer arm.

12. An insertion tool of claim 11, in which the pair of pincer arms form part of a reverse tweezer arrangement in which a handle is formed with a pair of outwardly biased arms, the outwardly biased arms being joined to the pincer arms.

13. An insertion tool of claim 12, in which the pair of first and second pincer arms are biased so that the applying of a inwardly directed force to the handle increases the lateral distance between the guide formations on the first and second pincer arms.

14. An insertion tool of claim 11, in which the first pincer arm terminates in a guide formation, the second pincer arm terminates in a guide formation, and the first pincer arm is longer than the second pincer arm.

15. An insertion tool of claim 12, in which the pair of first and second pincer arms are biased so that the applying of a inwardly directed force to the handle increases the lateral distance between the guide formations on the first and second pincer arms.

16. An insertion tool of claim 11, in which the first pincer arm terminates in a guide formation, the second pincer arm terminates in a guide formation, and the first pincer arm is longer than the second pincer arm.
17. An insertion tool for inserting an elongate electrode assembly into a cochlea, the tool comprising:
   a proximal handle;
   an elongate shaft projecting from the handle;
   an electrode assembly receiving region extending from a distal end of the shaft
defining an opening for allowing the electrode assembly to be introduced into and released
from the electrode assembly receiving region, the electrode assembly receiving region
including a plurality of guide formations which are longitudinally spaced along the electrode
assembly receiving region, at least two of the guide formations being laterally offset from
one another on either side of the electrode assembly receiving region.

18. An insertion tool for inserting an elongate electrode assembly into a cochlea, the tool
comprising:
   a pair of first and second pincer arms biased into a closed position in which the
   elongate electrode assembly is held between the arms, and movable into an open position to
   allow release of the electrode assembly;
   a plurality of guide formations extending from the first and second pincer arms and defining
   in conjunction with the pincer arms when in the closed position a substantially straight path,
   for receiving the electrode assembly, the plurality of guide formations including at least two
   longitudinally spaced guide formations on the first pincer arm and at least one guide
   formation on the second pincer arm, the guide formations being configured to cooperate to
   receive the electrode assembly.