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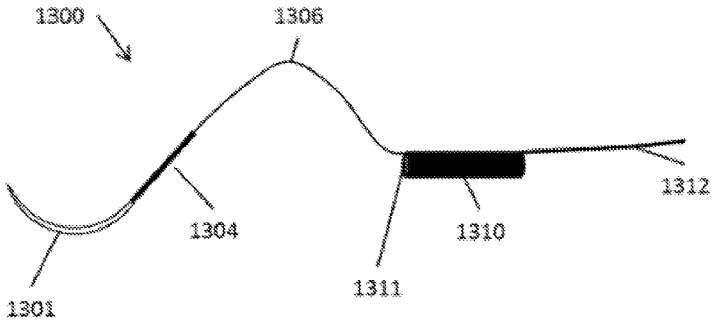

Fig. 6

(57) Abstract: A stapedius muscle recording electrode arrangement is described having one or more wire electrodes with an inner conducting wire covered by an outer layer of electrical insulation. There is an electrode opening in the electrical insulation that exposes underlying conducting wire. A curved needle has a tip configured for insertion into stapedius muscle tissue, and a base end coupled to the at least one wire electrode. The wire electrode and the needle are configured for insertion of the curved needle through the stapedius muscle tissue or between the stapedius muscle surface and the inner bony surface of the pyramidal eminence to embed the wire electrode in the stapedius muscle tissue or between the stapedius muscle surface and the inner bony surface of the pyramidal eminence for electrical interaction of the conducting wire at the electrode opening with the stapedius muscle tissue.

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TITLE

Stapedius Muscle Reflex Recording Electrode with a Sacrificial Part

[0001] This application claims priority from U.S. Provisional Patent Application 62/105,260, filed January 20, 2015, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present invention relates to an electrode configuration for insertion along or into the stapedius muscle.

BACKGROUND ART

[0003] A normal ear transmits sounds as shown in Figure 1 through the outer ear **101** to the tympanic membrane (eardrum) **102**, which vibrates the ossicles of the middle ear **103** (malleus, incus, and stapes). The stapes footplate is positioned in the oval window **106** that forms an interface to the fluid filled inner ear (the cochlea) **104**. Movement of the stapes generates a pressure wave in the cochlea **104** that stimulates the sensory cells of the auditory system (hair cells). The cochlea **104** is a long narrow duct wound spirally around its central axis (called the modiolus) for approximately two and a half turns. The cochlea **104** includes an upper channel known as the scala vestibuli, a middle channel known as the scala media and a lower channel known as the scala tympani. The hair cells connect to the spiral ganglion cells of the cochlear nerve **105** that reside in the modiolus. In response to received sounds transmitted by the middle ear **103**, the fluid-filled cochlea **104** functions as a transducer to generate electric pulses which are transmitted to the cochlear nerve **105**, and ultimately to the brain.

[0004] Hearing is impaired when there are problems in the ability to transduce external sounds into meaningful action potentials along the neural substrate of the cochlea **104**. To improve impaired hearing, auditory prostheses have been developed. For example, when the impairment is related to operation of the middle ear **103,** a conventional hearing aid or middle ear implant may be used to provide acoustic-mechanical stimulation to the auditory system in the form of amplified sound. Or when the impairment is associated with the cochlea **104**, a cochlear implant with an implanted stimulation electrode can electrically

stimulate auditory nerve tissue with small currents delivered by multiple electrode contacts distributed along the electrode.

[0005] Figure 1 also shows some components of a typical cochlear implant system, including an external microphone that provides an audio signal input to an external signal processor **111** where various signal processing schemes can be implemented. The processed signal is then converted into a digital data format, such as a sequence of data frames, for transmission into the implant **108**. Besides receiving the processed audio information, the implant **108** also performs additional signal processing such as error correction, pulse formation, etc., and produces a stimulation pattern (based on the extracted audio information) that is sent through an electrode lead **109** to an implanted electrode array **110**.

[0006] Typically, the electrode array **110** includes multiple electrode contacts **112** on its surface that provide selective stimulation of the cochlea **104**. Depending on context, the electrode contacts **112** are also referred to as electrode channels. In cochlear implants today, a relatively small number of electrode channels are each associated with relatively broad frequency bands, with each electrode contact **112** addressing a group of neurons with an electric stimulation pulse having a charge that is derived from the instantaneous amplitude of the signal envelope within that frequency band.

[0007] Figure 2 shows various functional blocks in a signal processing arrangement for producing electrode stimulation signals to electrode contacts in an implanted cochlear implant array according to a typical hearing implant system. A pseudo code example of such an arrangement can be set forth as:

```
Input Signal Preprocessing:
      BandPassFilter (input_sound, band_pass_signals)
Envelope Extraction:
      BandPassEnvelope (band_pass_signals, band_pass_envelopes)
Stimulation Timing Generation:
      TimingGenerate (band_pass_signals, stim_timing)
Pulse Generation:
      PulseGenerate (band_pass_envelopes, stim_timing, out_pulses)
```

The details of such an arrangement are set forth in the following discussion.

[0008] In the arrangement shown in Figure 2, the initial input sound signal is produced by one or more sensing microphones, which may be omnidirectional and/or directional. Preprocessor Filter Bank **201** pre-processes this input sound signal with a bank of multiple parallel band pass filters (e.g. Infinite Impulse Response (IIR) or Finite Impulse Response (FIR)), each of which is associated with a specific band of audio frequencies, for example, using a filter bank with 12 digital Butterworth band pass filters of 6th order, Infinite Impulse Response (IIR) type, so that the acoustic audio signal is filtered into some K band pass signals, U_1 to U_K where each signal corresponds to the band of frequencies for one of the band pass filters. Each output of sufficiently narrow CIS band pass filters for a voiced speech input signal may roughly be regarded as a sinusoid at the center frequency of the band pass filter which is modulated by the envelope signal. This is also due to the quality factor ($Q \approx 3$) of the filters. In case of a voiced speech segment, this envelope is approximately periodic, and the repetition rate is equal to the pitch frequency. Alternatively and without limitation, the Preprocessor Filter Bank **201** may be implemented based on use of a fast Fourier transform (FFT) or a short-time Fourier transform (STFT). Based on the tonotopic organization of the cochlea, each electrode contact in the scala tympani typically is associated with a specific band pass filter of the Preprocessor Filter Bank **201**. The Preprocessor Filter Bank **201** also may perform other initial signal processing functions such as and without limitation automatic gain control (AGC) and/or noise reduction and/or wind noise reduction and/or beamforming and other well-known signal enhancement functions. An example of pseudocode for an infinite impulse response (IIR) filter bank based on a direct form II transposed structure is given by Fontaine et al., *Brian Hears: Online Auditory Processing Using Vectorization Over Channels*, Frontiers in Neuroinformatics, 2011; incorporated herein by reference in its entirety.

[0009] The band pass signals U_1 to U_K (which can also be thought of as electrode channels) are output to an Envelope Detector **202** and Fine Structure Detector **203**. The Envelope Detector **202** extracts characteristic envelope signals outputs $Y_1, \ldots, Y_K$ that represent the channel-specific band pass envelopes. The envelope extraction can be

represented by $Y_k = LP(|U_k|)$, where |.| denotes the absolute value and LP(.) is a low-pass filter; for example, using 12 rectifiers and 12 digital Butterworth low pass filters of 2nd order, IIR-type. Alternatively, the Envelope Detector **202** may extract the Hilbert envelope, if the band pass signals $U_1, \ldots, U_K$ are generated by orthogonal filters.

[0010] The Fine Structure Detector **203** functions to obtain smooth and robust estimates of the instantaneous frequencies in the signal channels, processing selected temporal fine structure features of the band pass signals $U_1, \ldots, U_K$ to generate stimulation timing signals $X_1, \ldots, X_K$. The band pass signals $U_1, \ldots, U_k$ can be assumed to be real valued signals, so in the specific case of an analytic orthogonal filter bank, the Fine Structure Detector **203** considers only the real valued part of U_k. The Fine Structure Detector **203** is formed of K independent, equally-structured parallel sub-modules.

[0011] The extracted band-pass signal envelopes $Y_1, \ldots, Y_K$ from the Envelope Detector **202**, and the stimulation timing signals $X_1, \ldots, X_K$ from the Fine Structure Detector **203** are input signals to a Pulse Generator **204** that produces the electrode stimulation signals Z for the electrode contacts in the implanted electrode array **205**. The Pulse Generator **204** applies a patient-specific mapping function—for example, using instantaneous nonlinear compression of the envelope signal (map law)—That is adapted to the needs of the individual cochlear implant user during fitting of the implant in order to achieve natural loudness growth. The Pulse Generator **204** may apply logarithmic function with a form-factor C as a loudness mapping function, which typically is identical across all the band pass analysis channels. In different systems, different specific loudness mapping functions other than a logarithmic function may be used, with just one identical function is applied to all channels or one individual function for each channel to produce the electrode stimulation signals. The electrode stimulation signals typically are a set of symmetrical biphasic current pulses.

[0012] Figure 3 shows a portion of the middle ear anatomy in greater detail, including the incus **301** and the stapes **302**. The lenticular process end of the incus **301** vibrates the head **305** of the stapes **302**, which in turn vibrates the base **303** of the stapes **302** which couples the vibration into the inner ear (cochlea). Also connected to the head **305** of the

stapes **302** is the stapedial tendon **306** of the stapedius muscle situated within the bone of the pyramidal eminence **307**. When a loud noise produces an excessively high sound pressure that could damage the inner ear, the stapedius muscle reflexively contracts to decrease the mechanical coupling of the incus **301** to the stapes **302** (and thereby also reduce the force transmission). This protects the inner ear from excessively high sound pressures.

[0013] The tensing of the stapedius muscle when triggered by such high sound pressures is also referred to as the stapedius reflex. Medically relevant information about the functional capability of the ear may be obtained by observation of the stapedius reflex. Measurement of the stapedius reflex also is useful for setting and/or calibrating cochlear implants because the threshold of the stapedius reflex is closely correlated to the psychophysical perception of comfortable loudness, the so-called maximal comfort level (MCL). The stapedius reflex can be determined in an ambulatory clinical setting using an additional device, an acoustic tympanometer that measures the changes in acoustic impedance of the middle ear caused by stapedial muscle contraction in response to loud sounds.

[0014] To measure the stapedius reflex intra-operatively, it is known to use electrodes that are brought into contact with the stapedius muscle to relay to a measuring device the action current and/or action potentials generated upon a contraction of the stapedius muscle. But a reliable minimally-invasive contact of the stapedius muscle is difficult because the stapedius muscle is situated inside the bony pyramidal eminence and only the stapedial tendon is accessible from the interior volume of the middle ear.

[0015] Various intraoperative stapedius muscle electrodes are known from US 6,208,882, however, these only achieve inadequate contact of the stapedius muscle tissue (in particular upon muscle contraction) and are also very traumatizing. This reference describes one embodiment that uses a ball shape monopolar electrode contact with a simple wire attached to it. That would be very difficult to surgically position into a desired position with respect to the stapedius tissue and to fix it there allowing for a long-term atraumatic and stable positioning. Therefore the weakness of this type of electrode is that it does not qualify for chronic implantation. In addition, there is no teaching of how to

implement such an arrangement with a bipolar electrode with electrode contacts with sufficient space between each other to enable bipolar registration.

[0016] Some intraoperative experiments and studies have been conducted with hook electrodes that have been attached at the stapedius tendon or muscle. These electrode designs were only suitable for acute intra-operative tests. Moreover, some single hook electrodes do not allow a quick and easy placement at the stapedius tendon and muscle—the electrode has to be hand held during intra-operative measurements, while other double hook electrodes do not ensure that both electrodes are inserted into the stapedius muscle due to the small dimensions of the muscle and the flexibility of the electrode tips. One weakness of these intraoperative electrodes is that they do not qualify for chronic implantation.

[0017] German patent DE 10 2007 026 645 (incorporated herein by reference) discloses a two-part bipolar electrode configuration where a first electrode is pushed onto the stapedius tendon or onto the stapedius muscle itself, and a second electrode is pierced through the first electrode into the stapedius muscle. One disadvantage of the described solution is its rather complicated handling in the very limited space of the surgical operation area, especially manipulation of the fixation electrode. In addition, the piercing depth of the second electrode is not controlled so that trauma can also occur with this approach. Also it is not easy to avoid galvanic contact between both electrodes.

[0018] U.S. Patent Publication 20100268054 (incorporated herein by reference) describes a different stapedius electrode arrangement having a long support electrode with a base end and a tip for insertion into the target tissue. A fixation electrode also has a base end and a tip at an angle to the electrode body. The tip of the fixation electrode passes perpendicularly through an electrode opening in the support electrode so that the tips of the support and fixation electrodes penetrate into the target tissue so that at least one of the electrodes senses electrical activity in the target stapedius tissue. The disadvantages of this design are analogous to the disadvantages mentioned in the preceding patent.

[0019] U.S. Patent Publication 20130281812 (incorporated herein by reference) describes a double tile stapedial electrode for bipolar recording. The electrode is

configured to be placed over the stapedius tendon and a sharp tip pierces through the bony channel towards the stapedius muscle. The downside of this disclosure is again its rather complicated handling in the very limited space of the surgical operation area,

[0020] Various other stapedial electrode designs also are known, all with various associated drawbacks. A simple wire and ball contact electrode is very difficult to surgically position and to keep it atraumatically stabilized for chronic implantations. The penetrating tip of such a design must be stiff enough to pass through the bone tunnel, but if the tip is too stiff, it is difficult to bend and maneuver the wire into its position. And some stapedius muscle electrode designs are only monopolar electrodes (with a single electrode contact) and are not suitable for a bipolar arrangement with the electrode contacts with sufficient distance between each other to enable bipolar registration.

SUMMARY

[0021] Embodiments of the present invention are directed to stapedius muscle recording electrode arrangements having one or more wire electrodes with an inner conducting wire covered by an outer layer of electrical insulation. There are one or more electrode openings in the electrical insulation that exposes underlying conducting wire. In some embodiments an extended portion of the conducting wire may be uninsulated to ensure the galvanic contact of the wire with the stapedial muscle tissue. A curved needle has a tip configured for insertion into or along the stapedius muscle tissue, and a base end coupled to the at least one wire electrode. The wire electrode and the curved needle are configured for insertion of the needle along or through the stapedius muscle tissue to position the conductive wire along the stapedial muscle or its tendon or to embed the wire electrode in the stapedius muscle tissue for electrical interaction of the conducting wire with the stapedius muscle tissue.

[0022] In some specific embodiments, the curvature of the curved needle may be constant over the entire needle or it may vary from a relatively larger curvature radius towards the tip of the needle to a relatively smaller curvature radius towards the base end of the needle. There may be a transition section of non-metallic material or an isolated metallic wire that couples the base end of the curved needle to the at least one wire electrode. This transition section may be malleable. There may be a ball shaped electrode

contact at each electrode opening connected to the underlying conducting wire and extending out through the electrode opening above the outer layer of electrical insulation. There may be a drug eluting component incorporated into the electrical insulation and configured to release a therapeutic drug over time from the embedded at least one wire electrode into adjacent stapedius muscle tissue. In some embodiments there may be two wire electrodes configured for bipolar operation. The at least one wire electrode and the curved needle may possess a single shared longitudinal axis. And the curved needle may have a stiffness greater than that of the at least one wire electrode.

[0023] Embodiments of the present invention also include methods for embedding a stapedius muscle electrode along or into the stapedius muscle tissue of a patient. A stapedius muscle electrode according to any of the above arrangements is provided. An opening is drilled into the bone of the pyramidal eminence of the patient at least part way towards the underlying stapedius muscle. Then – if positioning of the electrode along (not within) the stapedial muscle is chosen - a tunneling instrument may be used to perform a tunnel between the opening drilled in the pyramidal eminence and the natural orifice of the stapedial tendon. The tunnel is created between the muscle and the inner bony surface of the pyramidal eminence. The tip of the curved needle is then inserted through the opening in the pyramidal eminence into the stapedius muscle. The curved needle is then directed into and through the tunnel and out of the natural orifice of the stapedial tendon or it is directed through the stapedius muscle into the stapedius tendon and out at the distal end (i.e. the end towards the stapes) of the stapedius tendon . The curved needle is pulled out along the outer surface of the stapedius tendon close to the head of the stapes to embed the at least one wire electrode and the electrode opening in the stapedius muscle or along the tunnel. Then the curved needle is separated from the at least one wire electrode or from the transition section. Opposite direction of electrode positioning is also possible.

[0024] The opening may have a diameter of 0.5 mm and the tunnel may have a diameter of 100-200 μm. The curved needle may be separated from the at least one wire electrode or from the transition section at the distal end of the stapedius tendon, or at a distance away from the distal end of the stapedius tendon so as to leave a section of the wire electrode to be secured against the pyramidal eminence to fix the at least one wire electrode into position embedded in the stapedius muscle or in the tunnel. This fixation

may be achieved by bending the wire over the bony rim of the pyramidal eminence.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] Figure 1 shows anatomical structures of a typical human ear.

[0026] Figure 2 shows various functional blocks in a signal processing arrangement for a typical cochlear implant system

[0027] Figure 3 shows detailed anatomy around the stapedius tendon in a human ear.

[0028] Figure 4 A-C shows stapedius electrode arrangements according to various specific embodiments of the present invention.

[0029] Figure 5 A-F shows various steps in implanting a stapedius electrode according to an embodiment of the present invention.

[0030] Figure 6 shows an alternative electrode arrangement.

[0031] Figure 7 shows an alternative electrode arrangement with a second recording electrode and a separate movable fixation element.

[0032] Figure 8 shows an alternative electrode arrangement with a second recording electrode mounted on a movable element.

DETAILED DESCRIPTION

[0033] Various embodiments of the present invention are directed to stapedius muscle recording electrode arrangements that use a simple inexpensive electrode (e.g. wire electrode) that is attached to a curved needle to be passed inside the pyramidal eminence between a surgically created opening in the pyramidal eminence and the natural orifice of the stapedial tendon.

[0034] Figure 4 A-C shows stapedius electrode arrangements **400** according to various specific embodiments of the present invention. As seen in the figures, there are one or

more wire electrodes **405** with an inner conducting wire covered by an outer layer of electrical insulation such as silicone. For example, the inner conducting wire may be 50 μ diameter platinum wire. In some specific embodiments, there may be a drug eluting component incorporated into the electrical insulation of the at least one wire electrode **405** and configured to release a therapeutic drug over time from the embedded at least one wire electrode **405** into adjacent stapedius muscle tissue. In each wire electrode **405** there is an electrode opening **406** in the electrical insulation that exposes underlying conducting wire to form an electrode contact for electrical interaction of the wire electrode **405** with the stapedius muscle tissue. The far end of the electrode wire **405** may be attached to any device for processing the recorded electrical potentials from the stapedius muscle.

[0035] In the embodiments shown in Figs. 4 A-C, the base end **403** of the curved needle **401** is coupled to the at least one wire electrode **405** by a transition section of suture material **404** that may be conductive or non-conductive; for example, 25 μ diameter platinum wire 1- 5 mm in length (e.g. 2.5 mm) may be used. Suture material **404** also may be malleable. In other specific embodiments, suture material may be omitted and the curved needle **401** may be directly coupled to at least one wire electrode **405**. Fig. 4A shows an embodiment with just one wire electrode **405** for monopolar operation. There is an electrode opening **406** for monopolar recording. The electrode opening **406** may have a length of 1- 10 mm (e.g. 8 mm) and along this length the entire wire surface may be uninsulated. Figs. 4 B-C show embodiments with two wire electrodes **405** configured for bipolar operation. In the embodiment shown in Fig. 4B, there are two electrode openings **406** that are offset from each other by an appropriate distance for bipolar recording. Fig. 4C shows an embodiment with ball-shaped electrode contacts at each electrode opening **406**, which are connected to the underlying conducting wire and extending out through the electrode opening **406** above the outer layer of electrical insulation that forms the outer surface of the at least one wire electrode **405**.

[0036] A curved needle **401** has a tip **402** configured for insertion into stapedius muscle tissue, and a base end **403** coupled to the at least one wire electrode **405** or to the transition section **404**. Typically, the curvature of the curved needle **401** may be constant over the entire needle or it may vary from a relatively larger curvature radius towards the tip of the needle to a relatively smaller curvature radius towards the base end of the needle. Further

a typical length of the curved needle may be 2-3 mm and a typical thickness may be 50-100 μm. The at least one wire electrode **405** and the curved needle **401** are configured for insertion of the needle **401** through the stapedius muscle tissue to embed the wire electrode **405** in the stapedius muscle tissue or through the tunnel. The at least one wire electrode **405** and the curved needle **401** may possess a single shared longitudinal axis. And the curved needle **401** may have a stiffness greater than that of the at least one wire electrode **405**.

[0037] Figures 5 A-F show various steps in implanting a stapedius electrode arrangement **400**. Initially as shown in Fig. 5A, the surgeon drills an opening **504** into the bone of the pyramidal eminence **501** of the patient's temporal bone, at least part way towards the underlying stapedius muscle **502**. Then – if positioning the electrode **400** along (not within) the stapedial muscle **502** is chosen - a tunneling instrument may be used to create a tunnel between the opening drilled in the pyramidal eminence **501** and the natural orifice of the stapedial tendon **503**. In this case the stapedius muscle **502** should first be dissected from the inner bony surface of the pyramidal eminence **501**. This can be achieved using the tunneling tool. Typically, the opening **504** may have a diameter of about 0.5 mm, and the diameter of the curved needle **401** and the at least one wire electrode **405** would be at least slightly smaller to fit into the opening **504**. The tip **402** of the curved needle **401** is inserted through the opening **504** in the pyramidal eminence **504** into the stapedius muscle **502**, as shown in Fig. 5B, or into the tunnel and then directed through the stapedius muscle **502** and into the stapedius tendon **503** or passing through the tunnel. In either case, the curved needle **401** exits at or near the distal end of the stapedius tendon **503**, as shown in Fig. 5C. The curved needle **401** is pulled out along the outer surface of the stapedius tendon **503** close to the head of the stapes to embed the at least one wire electrode **405** and the electrode opening **406** in the stapedius muscle **502** or along the tunnel.

[0038] Then once the wire electrode **405** has assumed its final position, as shown in Fig. 5D, the curved needle **401** is separated from the at least one wire electrode **405**, for example, by cutting. The curved needle **401** may be separated from the at least one wire electrode **405** right at the distal end of the stapedius tendon **503**, or at a distance away from the distal end of the stapedius tendon **503,** as shown in Fig. 5E, so as to leave a

section of the wire electrode **405** to be bent against the bony rim of the pyramidal eminence **501** to fix the position of the at least one wire electrode **405** that is embedded in the stapedius muscle or in the tunnel. In such an embodiment, the wire electrode **405** may still be easily explanted when necessary, as shown in Fig. 5F, simply by unbending the length that is coiled about the pyramidal eminence **501**.

[0039] In alternative embodiments an electrode arrangement **1300** as shown in Fig. 6 may be used. This electrode arrangement **1300** includes a curved needle **1301**, a transition section **1304** and a wire electrode **1306**. These components are comparable to the corresponding components described with reference to electrode arrangement **400** above. Here, the entire wire electrode **1306** is shown without insulation as a different example to the above. At the proximal end of wire electrode **1306**, a cylindrical section **1310** is attached. The cylindrical section **1310** may be made of any conductive biocompatible material and may typically have a length of 1-2 mm, corresponding to a typical length of an opening **504** into the bone of the pyramidal eminence **501** of the patient's temporal bone. Similarly, the thickness is typically about 0.5 to 1 mm, again corresponding to the thickness of the drilled opening **504**. The entire surface of the cylindrical section **1310** may be electrically insulated except the surface **1311** which may remain electrically conductive and which attaches to the wire electrode **1306**. During insertion of the electrode arrangement **1300**, surface **1311** may be advance into opening **504** far enough to attach to stapedius tissue. That way, the surface **1311** may increase the electrically conductive area and contribute to an increased sensitivity of the recording arrangement. The opposite end of cylindrical section **1310** may be attached to lead **1312**, which in turn may be attached to any device for processing the recorded electrical potentials from the stapedius muscle. As an alternative to the cylindrical form, section **1310** may have another geometrical form, e.g. it may have a ball shaped section.

[0040] Alternative embodiments of electrode arrangements (preferably bipolar recording arrangements), are shown in Figs. 7 and 8 where electrode arrangements **400** or **1300** may be used again, with other additional components. In Fig. 7, a separate electrically isolated conductor **1513** may have at its distal end a terminal port **1510** from which a recording electrode **1511** protrudes. Recording electrode **1511** may be inserted into stapedius tissue **502/503** through opening **504**. A movable hollow element **1512** formed, for example, as a

cylinder, may hold leads **1312** and **1513** in close proximity to each other and provide a fixation means for the entire electrode arrangement. Alternatively, as shown in Fig. 8, recording electrode **1611** may protrude directly from movable element **1610**. The size of the moveable element **1610** and the terminal port **1510** may be comparable to the opening **504** such that they can snuggly fit into the opening **504**. Alternatively, they may be larger in size such that the recording electrodes **1611** and **1511** may have a defined insertion depth into the stapedial tissue.

[0041] The electrode arrangements **400** or **1300** or the alternative arrangements shown in Figs. 7 and 8 may be part of a cochlear implant system or any other implantable system which can take advantage of a signal recorded from the stapedius muscle tissue. Branches **1312**, **1513**, **1613** or the far end of electrode wire **405** may be attached either directly to electronic circuitry within an implantable stimulator or it may be attached to an electrode branch as described e.g. in US3005216073, incorporated herein by reference.

[0042] For the monopolar recording configuration via electrode arrangements **400** or **1300** any reference electrode provided by the implantable device used may be exploited. Alternatively, a separate reference electrode, e.g. placed subperiosteally in the proximity of the ear may be used.

[0043] Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.

CLAIMS

What is claimed is:

1. A stapedius muscle electrode arrangement comprising:

at least one wire electrode having an inner conducting wire covered by an outer layer of electrical insulation with an electrode opening that exposes underlying conducting wire; and

a curved needle having:

i. a tip configured for insertion into contact with stapedius muscle tissue, and

ii. a base end coupled to the at least one wire electrode;

wherein the at least one wire electrode and the curved needle are configured for insertion of the needle through or along the stapedius muscle tissue to embed the at least one wire electrode into galvanic contact with the stapedius muscle tissue to provide for electrical interaction of the conductive wire with the stapedius muscle tissue.

2. The electrode arrangement according to claim 1, wherein a section of suture material couples the base end of the curved needle to the at least one wire electrode.

3. The electrode arrangement according to claim 1, further comprising:

a ball shaped electrode contact at each electrode opening connected to the underlying conducting wire and extending out through the electrode opening above the outer layer of electrical insulation.

4. The electrode arrangement according to claim 1, further comprising:

a drug eluting component incorporated into the electrical insulation and configured to release a therapeutic drug over time from the embedded at least one wire electrode into adjacent stapedius muscle tissue.

5. The electrode arrangement according to claim 1, wherein there are two wire electrodes configured for bipolar operation.

6. The electrode arrangement according to claim 1, wherein the at least one wire

electrode and the curved needle possess a single shared longitudinal axis.

7. The electrode arrangement according to claim 1, wherein the curved needle has a stiffness greater than that of the at least one wire electrode.

8. A method of embedding a stapedius muscle electrode into stapedius muscle tissue, the method comprising:

providing a stapedius muscle electrode arrangement including:

i. at least one wire electrode having an inner conducting wire covered by an outer layer of electrical insulation with an electrode opening that exposes underlying conducting wire; and

ii. a curved needle having a tip configured for insertion into stapedius muscle tissue, and a base end coupled to the at least one wire electrode;

drilling an opening into bone of the pyramidal eminence of the patient at least part way towards the underlying stapedius muscle;

creating a tunnel between the opening and a natural orifice of the stapedial tendon;

inserting the tip of the curved needle through the tunnel into the stapedius muscle;

directing the tip of the curved needle through the stapedius muscle into the stapedius tendon and out the distal end of the stapedius tendon;

pulling the curved needle out through the outer surface of the stapedius tendon to embed the at least one wire electrode and the electrode opening in the stapedius muscle; and

separating the curved needle from the at least one wire electrode.

9. The method according to claim 8, wherein a section of suture material couples the base end of the curved needle to the at least one wire electrode.

10. The method according to claim 8, further comprising:

a ball shaped electrode contact at each electrode opening connected to the underlying conducting wire and extending out through the electrode opening above the outer layer of electrical insulation.

11. The method according to claim 8, wherein a drug eluting component is incorporated

into the electrical insulation and configured to release a therapeutic drug over time from the embedded at least one wire electrode into adjacent stapedius muscle tissue.

12. The method according to claim 8, wherein there are two wire electrodes configured for bipolar operation.

13. The method according to claim 8, wherein the tunnel has a diameter of 0.5 mm.

14. The method according to claim 8, wherein the curved needle is separated from the at least one wire electrode at the distal end of the stapedius tendon.

15. The method according to claim 8, wherein the curved needle is separated from the at least one wire electrode at a distance away from the distal end of the stapedius tendon so as to leave a section of the wire electrode, and wherein the method further comprises securing the section of the wire electrode against the pyramidal eminence to fix the at least one wire electrode into position embedded in the stapedius muscle or along the outer surface of the stapedius muscle.

16. The method according to claim 15, where the fixation is achieved by bending of the wire over the bony rim of the pyramidal eminence between the tunnel and the natural orifice of the stapedial tendon.

17. The method according to claim 8, wherein the at least one wire electrode and the curved needle possess a single shared longitudinal axis.

18. The method according to claim 8, wherein the curved needle has a stiffness greater than that of the at least one wire electrode.

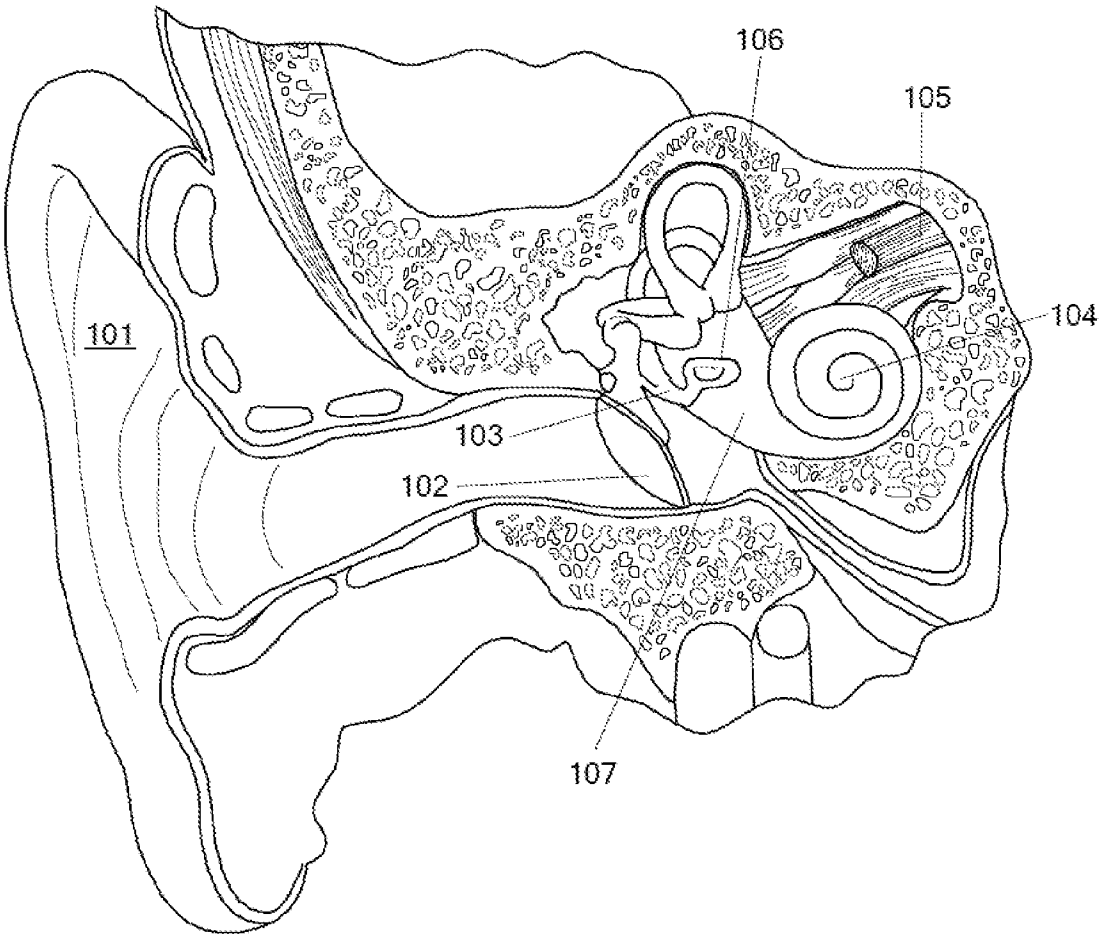


FIG. 1

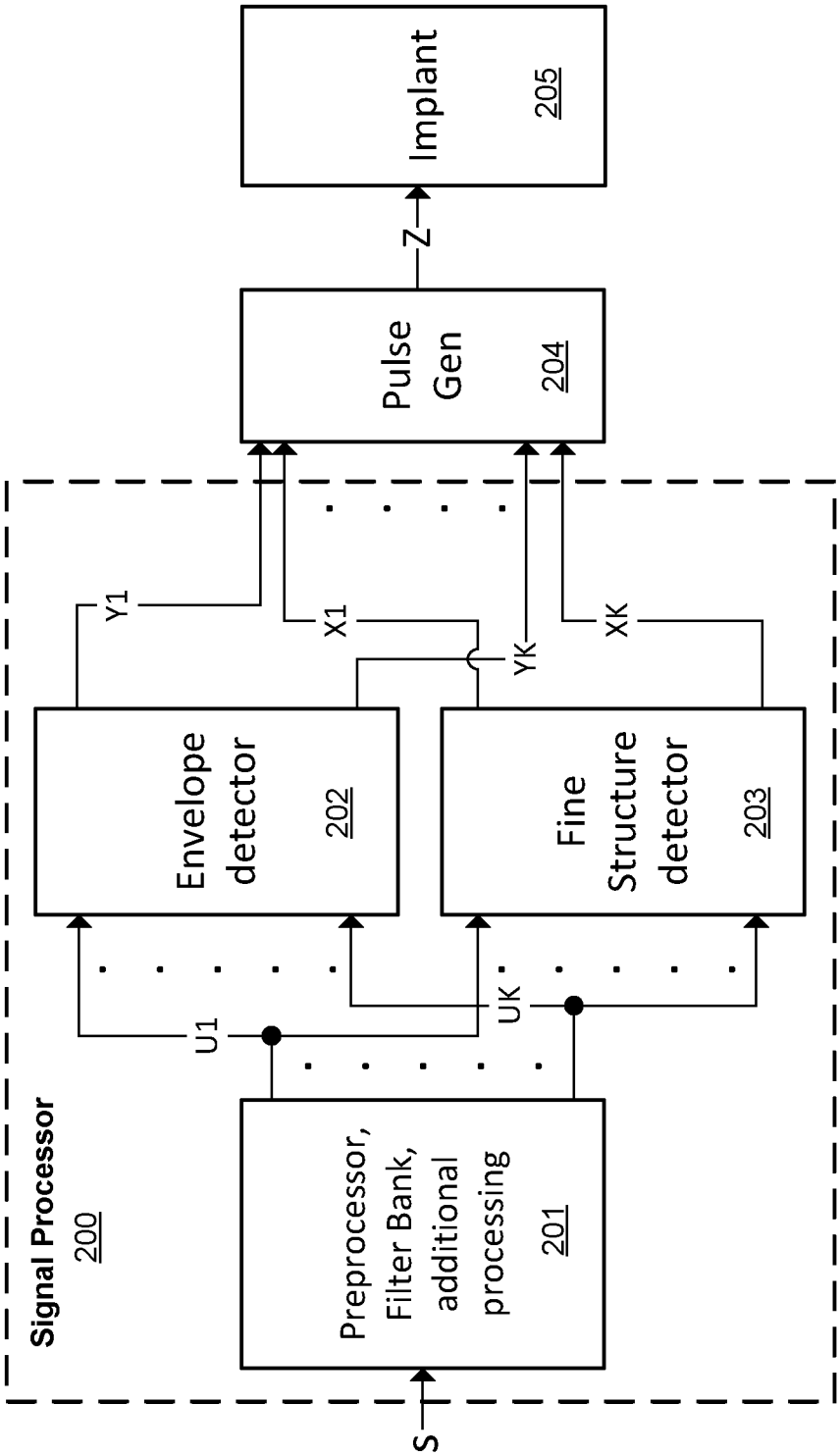

Implant
205
Z
Pulse Gen
204
Y1
X1
YK
XK
Envelope detector
202
Fine Structure detector
203
U1
UK
Preprocessor, Filter Bank, additional processing
201
Signal Processor
200
S

Fig. 2

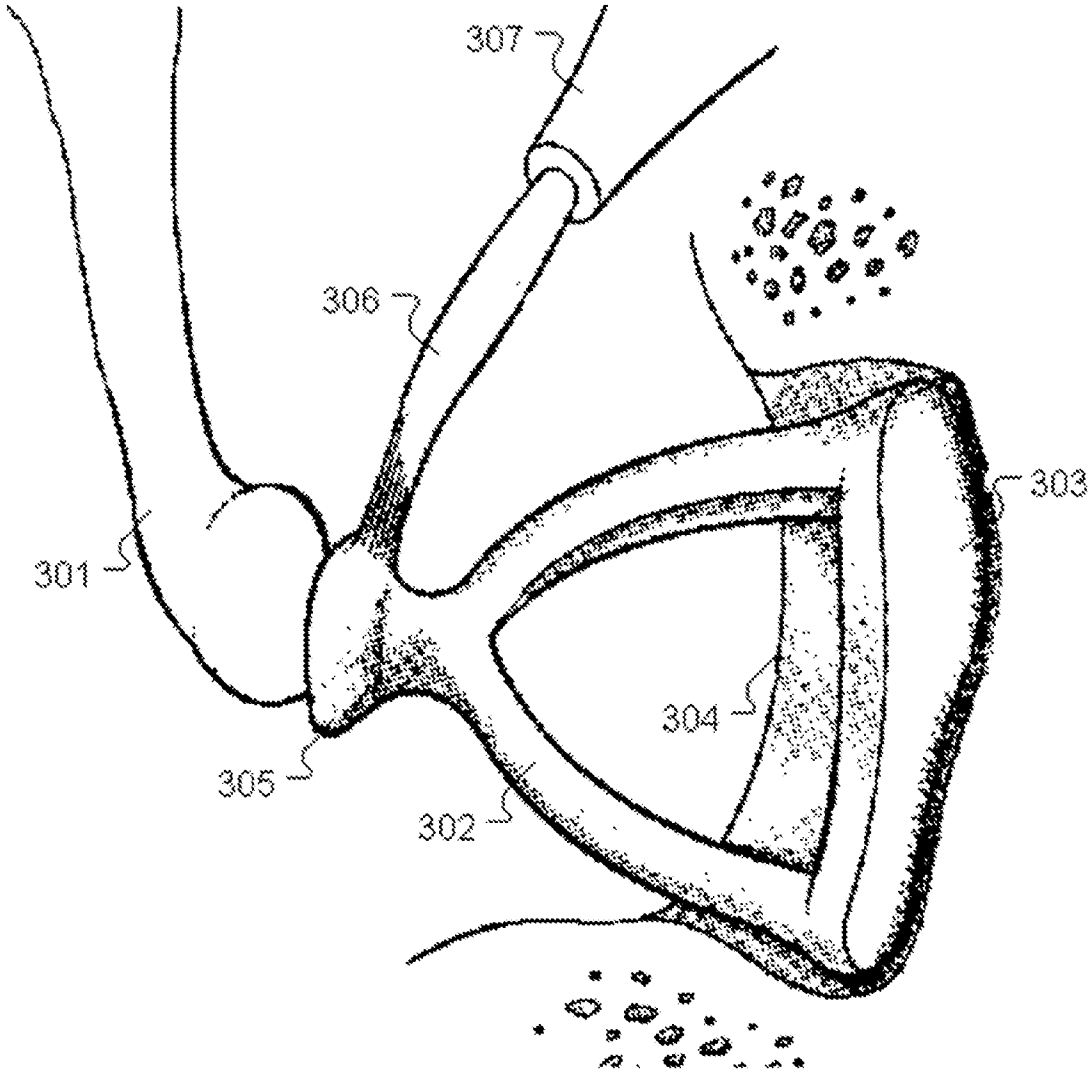


Fig. 3

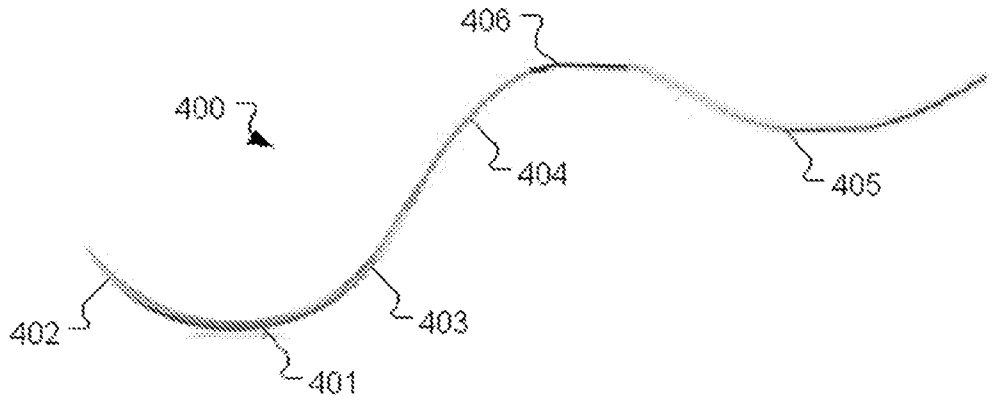


Fig. 4A

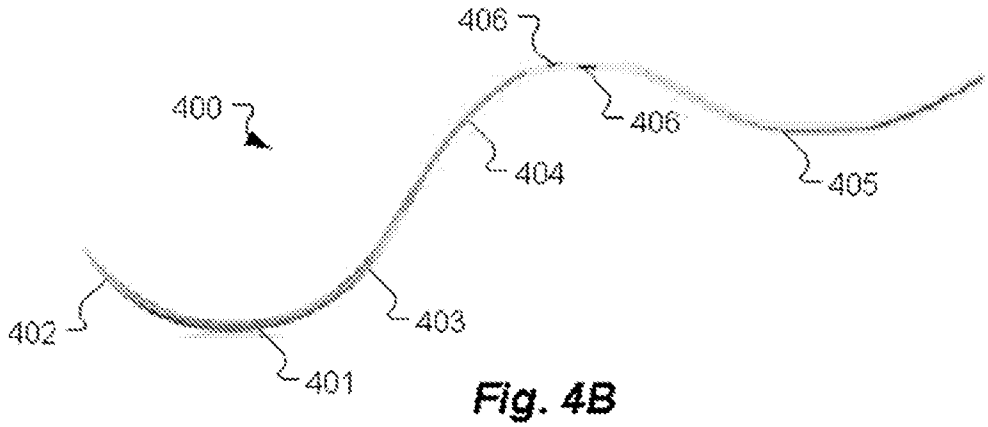


Fig. 4B

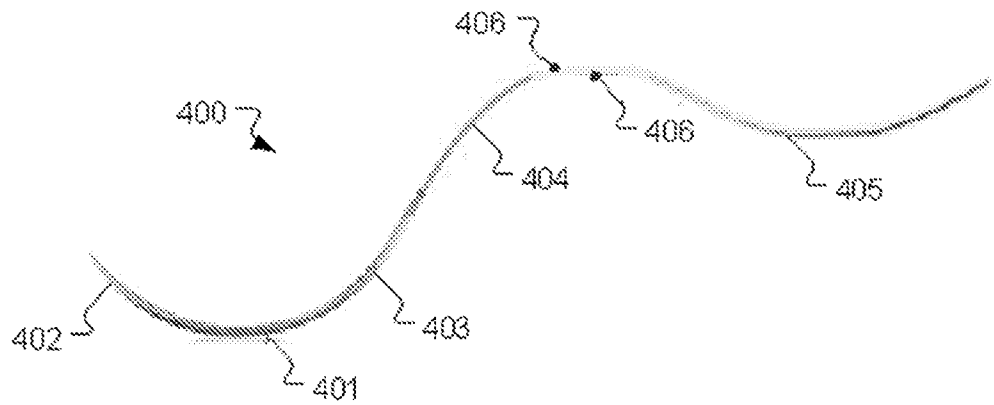


Fig. 4C

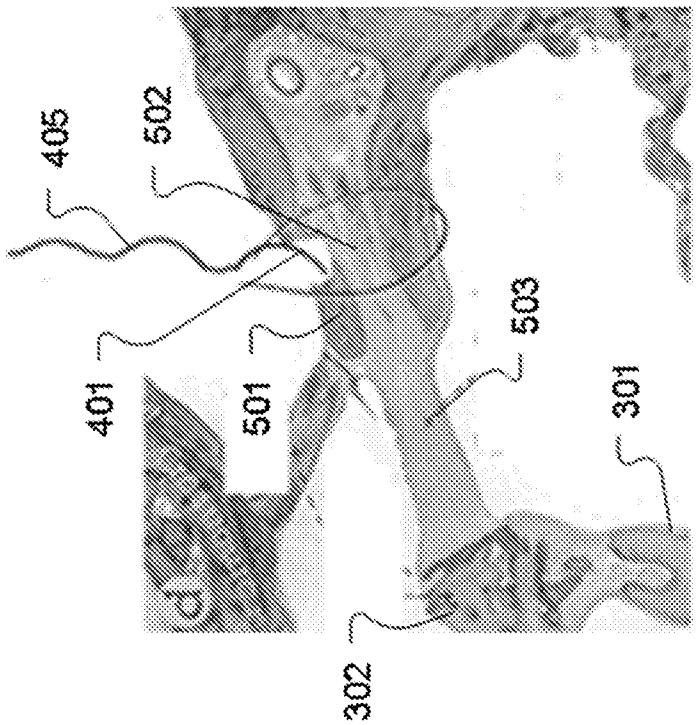


Fig. 5B

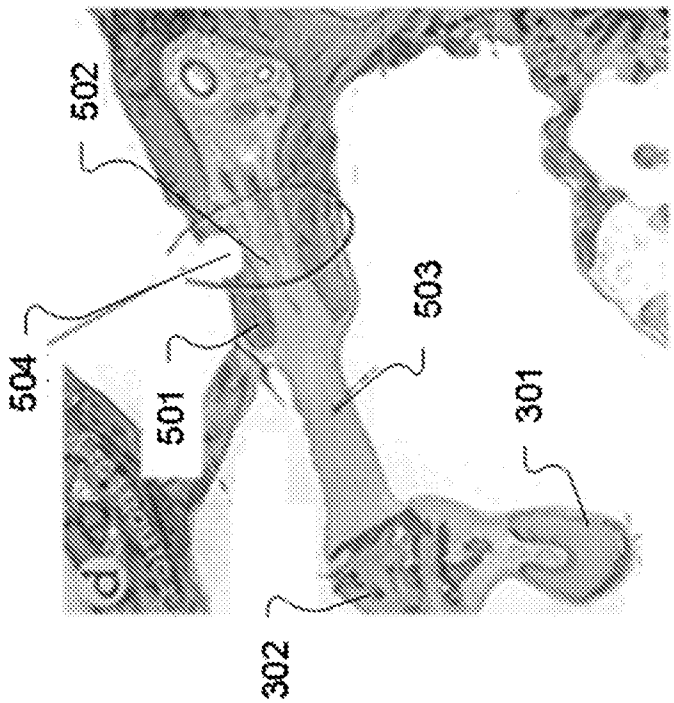


Fig. 5A

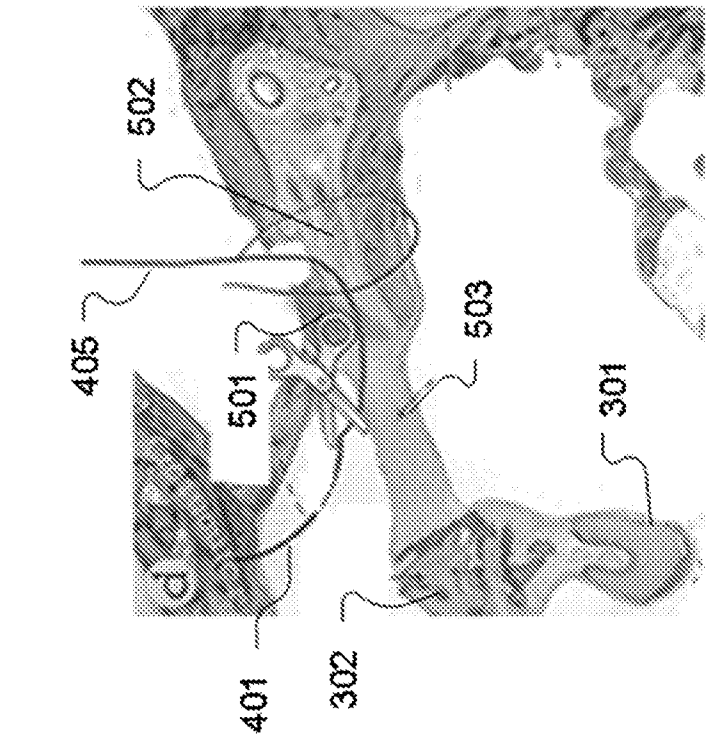


Fig. 5D

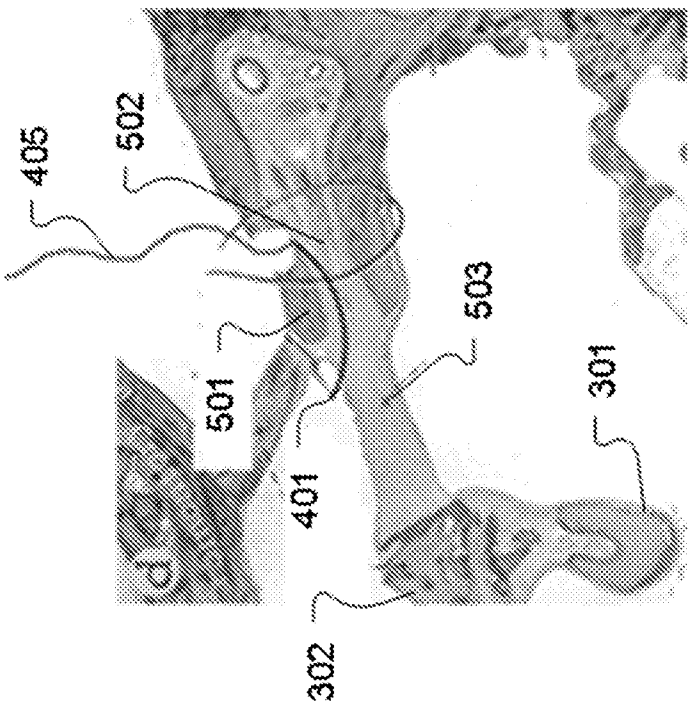


Fig. 5C

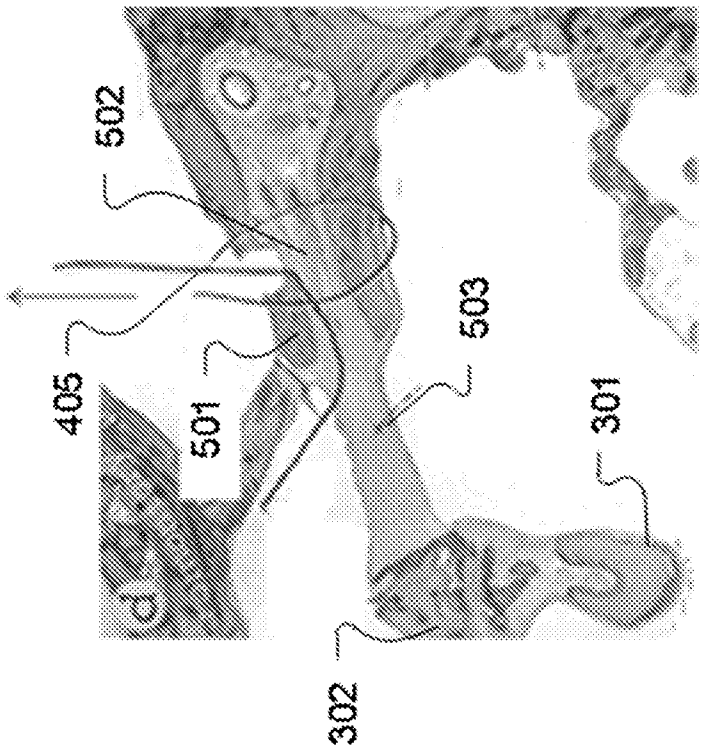


Fig. 5F

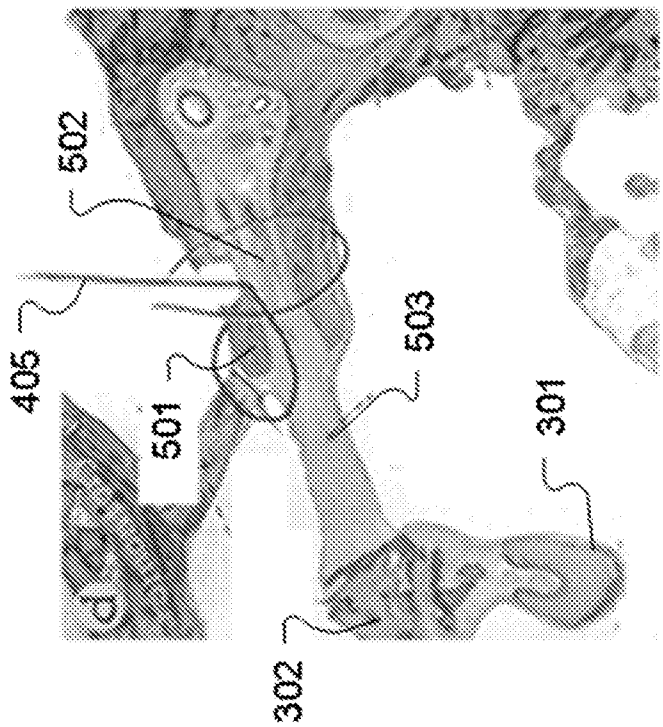
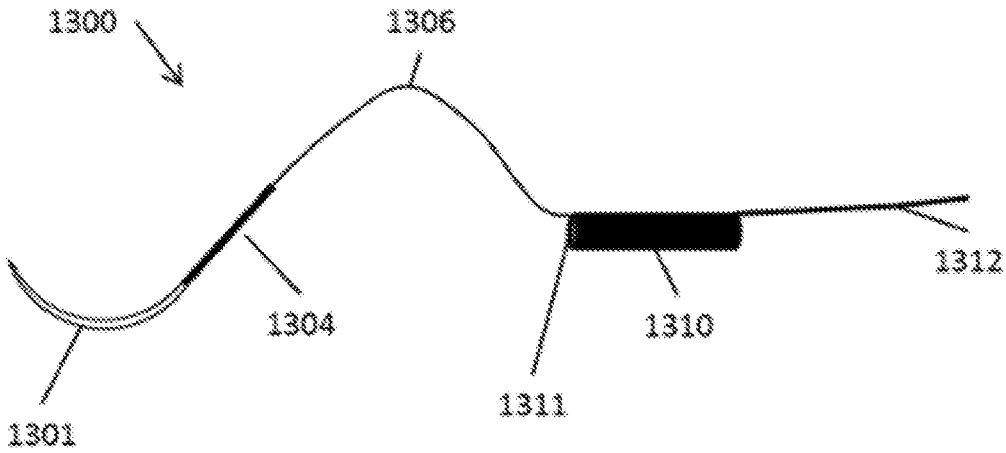


Fig. 5E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1311
1301

Fig. 6

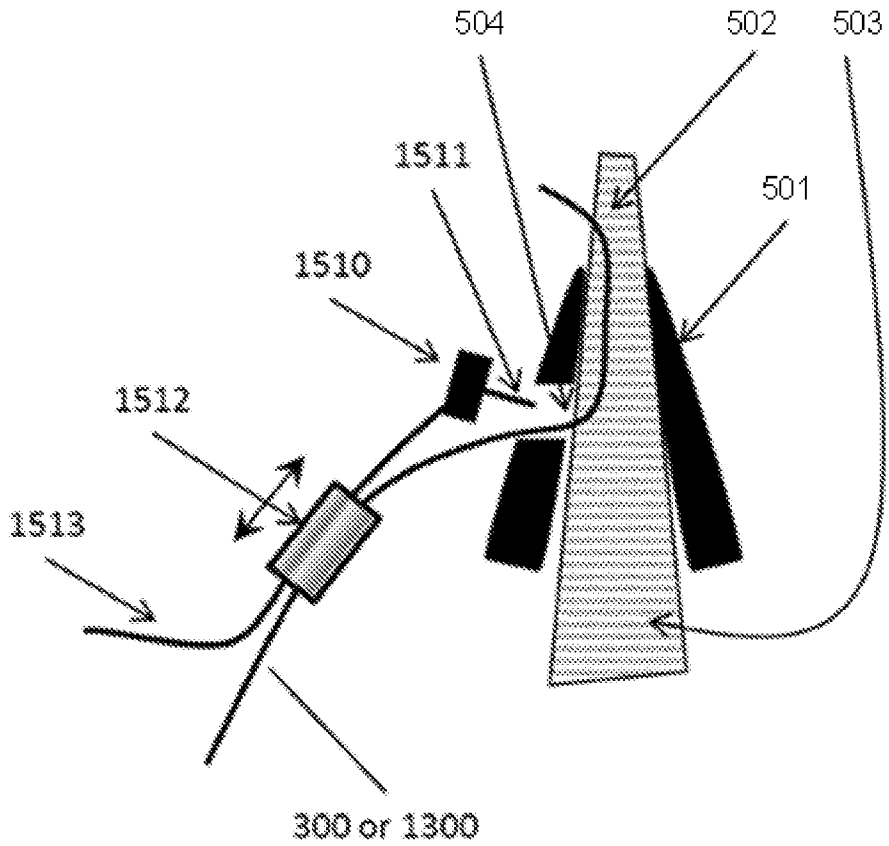
504
502
503
1511
501
1510
1512
1513
300 or 1300

Fig. 7

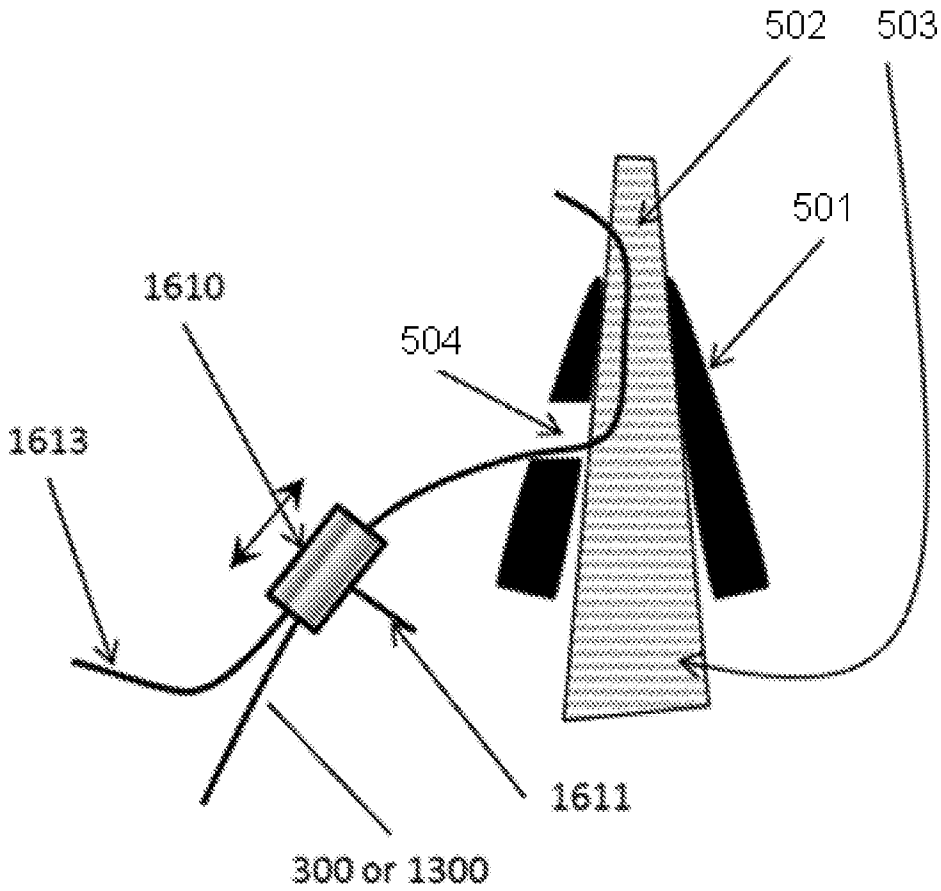

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/13821

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61N 1/00 (2016.01)
CPC - A61N 1/0541
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)
CPC: A61N 1/0541 IPC(8): A61N 1/00 (2016.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/379, 373, 546; 607/137, 136, 116, 57 CPC: A61N 1/0536, 1/05; A61B 5/8616, 5/8617 IPC: A61B 5/04 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google
Search Terms Used: lead, electrode%, curv*, arcuate, needle, ball, spher*, implantable, stapedius, steroid, drug, medication, medicament, insulat*, stapedial, bipolar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,341,226 A (PETERS) 27 July 1982 (27.07.1982) fig 1. 2. col 2, ln 52-66	1-2, 6-7
Y		4
X	US 2014/0243593 A1 (GOODE et al) 28 August 2014 (28.08.2014) fig 1A, para [0023], [0044]-[0045]	1, 5
Y		3
Y	US 6,208,882 B1 (LENARZ et al) 27 March 2001 (27.03.2001) fig 7, col 8, ln 16-30	3
Y	US 2003/0093138 A1 (OSYPKA et al) 15 May 2003 (15.03.2003) para [0025]	4
A	US 5,009,229 A (GRANDJEAN et al) 23 April 1991 (23.04.1991) entire document	1-7

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

* 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
25 April 2016 (25.04.2016)	19 MAY 2016
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/13821

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:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7, directed to a stapedius muscle electrode arrangement.

Group II: Claims 8-18 directed to a method of embedding an electrode into stapedius muscle tissue.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

----Continued on Supplemental Page----

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 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.:
1-7

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.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/13821

Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

SPECIAL TECHNICAL FEATURES

The invention of Group II includes the special technical feature of a method of embedding a stapedius muscle electrode into stapedius muscle tissue, the method comprising: drilling an opening into bone of the pyramidal eminence of the patient at least part way towards the underlying stapedius muscle;
creating a tunnel between the opening and a natural orifice of the stapedial tendon;
inserting the tip of the curved needle through the tunnel into the stapedius muscle;
directing the tip of the curved needle through the stapedius muscle into the stapedius tendon and out the distal end of the stapedius tendon;
pulling the curved needle out through the outer surface of the stapedius tendon to embed the at least one wire electrode and the electrode opening in the stapedius muscle, not required by Group I.

COMMON TECHNICAL FEATURES

Groups I and II are related as an apparatus (group I) and a method of using the apparatus (group II). The inventions of Groups I-II share the technical features of Claim 1. The apparatus is known in the prior art, as shown in US 4,341,226 A (PETERS).

Regarding claim 1, Peters discloses a stapedius muscle electrode arrangement (electrode arrangment taught capable of use in stapedius muscle) comprising:
at least one wire electrode having an inner conducting wire (14) covered by an outer layer of electrical insulation (16) with an electrode opening that exposes underlying conducting wire (opening shown in fig 1); and
a curved needle (22) having:
i. a tip (22a, fig 1) configured for insertion into contact with stapedius muscle tissue (intended use, tip capable of intended use), and
ii. a base end (22b) coupled to the at least one wire electrode (coupled by suture 18, fig 1, 2);
wherein the at least one wire electrode and the curved needle are configured for insertion of the needle through or along the stapedius muscle tissue to embed the at least one wire electrode into galvanic contact with the stapedius muscle tissue to provide for electrical interaction of the conductive wire with the stapedius muscle tissue (intended use, needle and electrode are capable of intended use).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.