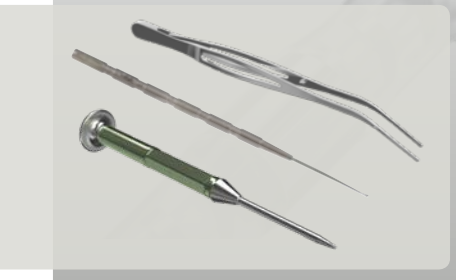
COCHLEAR IMPLANT SYSTEM

Surgical Manual

Neuro Zti cochlear implant range



Designed for a future of sounds

oticon MEDICAL

CONTENTS

"Note": *indicating a note/tip.*

"Caution": *Potential hazard that could result in patient/user temporary injury or hospitalisation if not avoided.*

"Warning": *Potential hazard that could result in patient/user serious injury or death if not avoided.*

INTRODUCTION

Before implanting the Neuro Zti implant, the physician shall become familiar with the technical specifications of the Neuro Zti device and the associated surgical techniques.

This surgical manual is intended for healthcare professionals to offer guidance on how to perform the Neuro Zti implant surgery including planning and preparation. This guide presents one surgical procedure but other surgical approaches could be more appropriate and adapted accordingly to the medical judgement of the physician. Distribution to any other recipient is prohibited.

However, this manual should not replace the comprehensive training a physician should have received and the careful reading of the following documents is still required:

- The Neuro Zti Instructions for Use: provides information on the Neuro Zti implant including the technical specifications with all of the associated indications, contradictions and warnings on medical interventions.
- The Surgical Tool Instructions for Use: provides information on the sterile and non-sterile surgical tools including the technical specifications.
- The Pre-disinfection, Cleaning and Sterilisation Instructions for Use: provides information for cleaning, and sterilisation for the surgical tools, to assure that these items are correctly handled and can be reused at a later stage.

Results will vary based on several factors. Not all patients are candidates for this product and/or procedure.

Oticon Medical (NEURELEC) reserves the right to make changes to the design, characteristics and models without prior notice. The only warranty Oticon Medical (NEURELEC) makes, is the express written warranty extended on the sale or rental of its products.

Warning: *If information is incomplete or ambiguous or should you have any question or concern about the information provided, please contact the Oticon Medical Customer Service or the local Oticon Medical distributor.*

Note: *All Instructions for Use are available on the Oticon Medical website.*

PATIENT JOURNEY

The patient journey begins at their assessment and evaluation. A diagnosis will be performed by trying hearing aids and if the trial remains unsuccessful, the multi disciplinary team in conjunction with local medical guidelines, will determine the patient's cochlear implant candidacy.

Cochlear implants are designed for people with severe to profound perceptive hearing loss, who experience limited benefits from appropriately fitted hearing aids. Today's cochlear implants are designed to offer speech understanding in all types of sound environments depending on the person's own ability.

Once the patient has decided to go ahead for a cochlear implantation, they will receive the surgery, and then support of a multi disciplinary team via post surgery appointments and a recovery period. It can take six to twelve months, or in some cases longer, before the patient fully adjusts to their cochlear implant and during the process the hearing experience can gradually be improved and adjusted.

PATIENT JOURNEY

Patient selection

A series of tests and assessments are carried out by the implantation team to evaluate whether a cochlear implant system is suitable for the patient. These include:

- Detailed audiology assessment of the auditory capacities and auditory nerve function
- Various medical examinations to check the patient's general health condition
- CT scan and/or an MRI of the inner ear
- Psychological assessment of the patient's and/or family's motivation for implantation and expectations
- Speech and language assessment to measure the patient's language aptitude and ability to lip-read

Treatment schedule

If the patient is considered to be eligible for a cochlear implantation, several steps are required before, during and after the surgery. The times below are recommended, however, the exact times will be determined by the physician on a case-by-case basis.

Steps	Time	Associated documentation
Surgery		
Implantation	D-day	• Neuro Zti Instructions for Use • Surgical tool Instructions for Use • Implantation registration form*
Recovery period	1 month after surgery	
Activation and rehabilitation		
Activation and first fitting of the sound processor	1 month after surgery	• Product registration*
Speech therapy rehabilitation	From 1 month after surgery Recurrence: Every week	
Routine follow-up		
Fitting of the sound processor	From 1 month after surgery Recurrence: Every month	• Genie Medical CI Installation Guide • Genie Medical CI Fitting Guide • CI-Link Programming system Instructions for Use
Fitting of the sound processor	From 2nd year after surgery Recurrence: Every 6 months	• Genie Medical CI Fitting Guide • CI-Link Programming system Instructions for Use

**To be returned to Oticon Medical within 15 days for the activation of the warranty.*

Patient preparation for surgery

Prior to implantation, patients will not only be informed of the benefits of a cochlear implant, but also of its potential risks:

Risks related to the surgery

- Normal risks associated with surgery and general anaesthesia, risks increase in some patients with certain medical conditions.
- Complications associated to surgical procedure, such as skin irritation, infection, inflammation, epidural or subdural haematoma, pain, swelling, wound healing complications, CSF leakage, perilymphatic fistula, facial nerve injury leading to transient, or permanent facial nerve paralysis[1].
- Meningitis can occur in rare cases but can result in serious illness. Patients should be appropriately counselled regarding this risk. Prior to cochlear implant surgery, the physician should check the candidate's immunity to both bacterial and viral meningitis. Certain pre-existing conditions may increase the risk of meningitis such as certain congenital malformation of the inner ear[2].

Risks related to the device

- Once the implant is in place, the risk of revision surgery or device explantation still exists in case of device failure, a decrease of device performance or for other medical reasons.
- Loss of residual hearing associated with the electrode array insertion.
- Transient vertigo or dizziness, persistent pain or discomfort, numbness, transient or permanent taste disturbance.
- Facial nerve stimulation, or increased pre-existing tinnitus.
- Unusual pain.
- Perception of uncomfortable sound sensations can lead to a reduction in the number of active electrodes.
- Device may result in uncomfortable, intermittent or non-auditory sensations.
- Electrode array misplacement or magnet displacement.
- Screw migration, electrode array migration, or receiver migration.
- Receiver extrusion, electrode array extrusion, or magnet extrusion.
- Implant rejection, or foreign body reaction.

In the operating room the patient is prepared as for conventional ear surgery with the incision area sterilised.

The patient is placed in a supine position on the implantation side that gives optimal access to the skull bone.

Local or general anaesthesia may be used. After the patient has been anaesthetised, the incision area should be shaved for approximately 3 to 4 cm behind the retro-auricular fold on the implantation. It is always recommended to try to remove as little hair as possible for cosmetic reasons.

Unless contraindicated, it is possible to proceed, from the beginning of the procedure and after placement of the sterile fields, to an infiltration in the incision line with an adrenaline solution (or epinephrine).

[1]Neuromonitoring is recommended, particularly if the facial nerve may be at greater risk, such as, congenital temporal bone anomalies and revision surgeries.

[2]Vaccination recommendations are available on the Centres for Disease Control and Prevention website, www.cdc.gov

SURGICAL STEPS

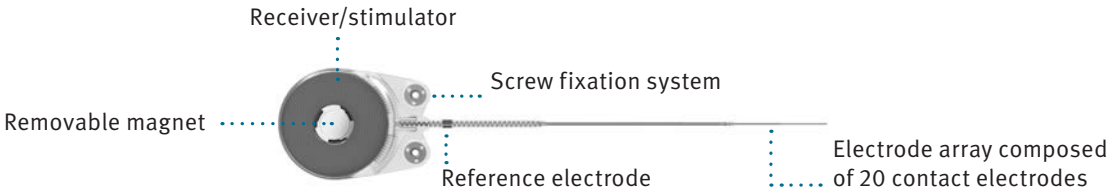
The preparation procedure involves selecting the patient for surgery, selecting the appropriate implant, as well as, preparing the operating room for surgery.

The surgical steps and medical recommendations listed in this chapter are intended to support the surgeon to implant the Neuro Zti implant.

Determining the optimal Neuro Zti implant version

The Neuro Zti implant is available with 2 different versions of electrode array: the EVO and the CLA.

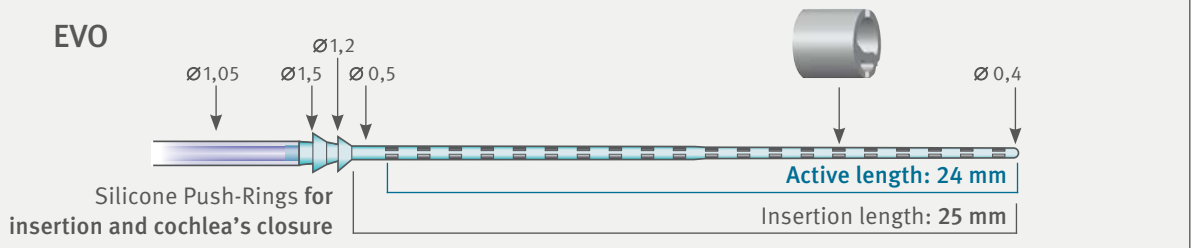
Neuro Zti implant overview



Below are some detailed information for the selection of the most suitable array for the surgery.

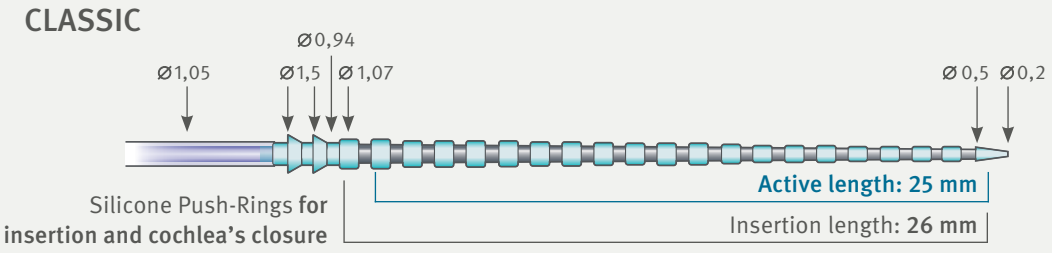
Note: *It is recommended to perform a scan before the implantation to check the integrity of the cochlea and easily choose the implant version to use.*

- The **EVO** electrode array is thin and flexible, with a smooth surface, designed to preserve the fragile structure of the cochlea (typical cochlea, residual hearing, etc.)



All measurements are in mm.

- The **CLA** (stands for CLASSIC) electrode array has a stiffness profile that is designed for typical and difficult insertions (ossified cochlea, fibrosis, etc.)



Electrodes and silicone rings' sizes are progressively reduced along the array. All measurements are in mm.

Determining the position of the receiver

Before conducting the incision for the skin flap, it is recommended to determine the optimal position of the implanted system.

Determine the incision line's position

It is recommended to allow sufficient space between the incision and the implant. The implant's receiver needs to be under the temporal muscle and far enough from the auricle of the ear (about 2 cm) to ensure:

- No overlapping with the sound processor
- That the spiral reinforcement of the implant lead remain flat (the part from the end of the receiver)
- No risk of extrusion
- No post-operative infection
- No interference

Mark the incision line and the receiver's position

Using the Neuro processor indicator*

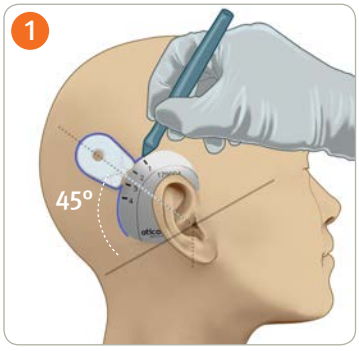
To determine the positioning of the implant and of the sound processor, the Neuro Zti implant indicator (M80180, included in the Neuro Zti packaging) shall be used along with the Neuro processor indicator (179994, to be ordered separately).

The bottom edge of the Neuro Zti implant indicator fixation system shall be positioned against the external edge of the Neuro processor indicator (Figure 1). They must not overlap.

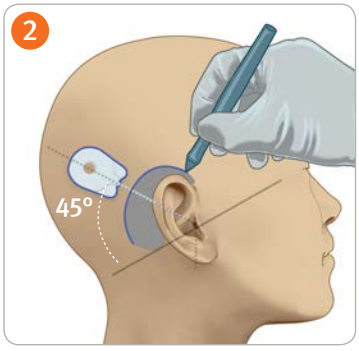
The silicone tail of the implant indicator can be used as a guide and placed on one or between two markers of the Neuro processor indicator. The markers help to position the implant at the desired angle.

Angles in respect to the orbitomeatal line:
Marker 1 = 60°, Marker 2 = 50°, Marker 3 = 40°, Marker 4 = 30°
We recommend an angle of 45° to the orbitomeatal line which is between the 2. and 3. markers.

Use a sterile skin marker, if desired, to mark the position of the implant receiver and the shape of the Neuro processor indicator.



Note: *By having the four markers (1,2,3,4) on both sides, the Neuro processor indicator has been designed to ensure symmetry when conducting bilateral implantations.*



Using the processor indicator

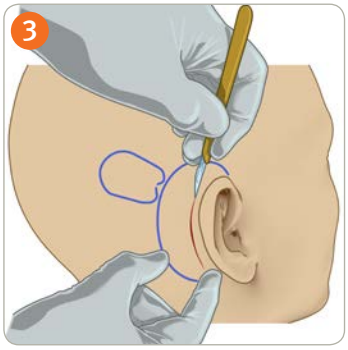
To determine the positioning of the implant and of the sound processor, the Neuro Zti implant indicator (M80180, included in the Neuro Zti packaging) shall be used with the processor indicator (M80176, to be ordered separately).

**Availability is subject to a CE marking, local registration and commercial availability. More information on local availability can be obtained from your local Oticon Medical office.*

The bottom edge of the Neuro Zti implant indicator fixation system shall be positioned far enough from the processor indicator (Figure 2). Ideally, the distal part of the implant body should be positioned approximately 80 mm posterior and superior to the auditory meatus, on a naturally flat surface. In this position, the optimal distance of 15 mm between the proximal part of the implant's receiver and the posterior edge of the processor indicator is achieved.

We recommend an angle of 45° to the orbitomeatal line, the silicone tail of the implant indicator can help to position the implant at the desired angle.

Measuring the skin thickness and performing the incision



Before performing the incision and the skin starts to swell, ensure the skin flap thickness is respected.

Warning: *Skin flap thickness shall be up to 8 mm.*

This range will ensure:

- Optimal signal transmission
- An effective magnetic hold
- Power consumption

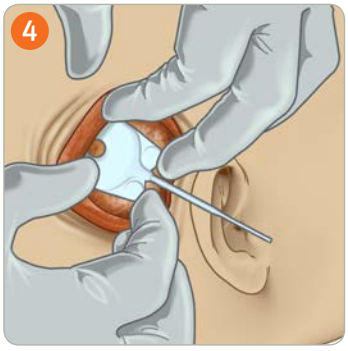
If the skin is too thick a skin flap reduction might be required.

Performing a sufficient incision (Figure 3) to enable:

- Good access through the facial recess
- Optimal placement of the implant
- Easy access to the fixation inserts while holding the screwdriver perpendicular to the screws

Warning: *Monopolar surgical instrument must not be used in case a cochlear implant has already been placed. Bipolar electrosurgical instrument could be used as long as it is not near or in contact with the implant.*

Determining the final position of the receiver



First, the silicone Neuro Zti implant indicator should slide inside the periosteal pocket (Figure 4) to prepare and ensure an easy progression of the Neuro Zti implant receiver.

Note: *The Neuro Zti implant shall only be inserted into its final position after previous use of the Neuro Zti silicone implant indicator as described above.*

Use a sterile marker to mark the position on the bone as well as the final position of the electrode channel.

In some cases, flattening the bone may be required to ensure the receiver remains flat on the bone for a good fixation.

Completing the standard surgical procedure

Drill mastoidectomy

Performing a standard cortical mastoidectomy by starting along the temporal line with a cutting burr.

Note: *To properly position and protect the reinforced part of the electrodes array lead, the mastoid cavity shall not have any sharp edges and a channel (or groove) should be formed deep enough to hold the array (approximately 2 mm).*

Posterior tympanotomy

Proceeding to the posterior tympanotomy to approach the middle ear and access the round window.

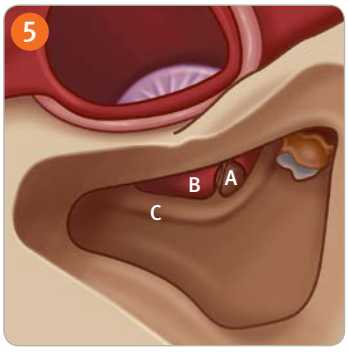
Note: *It is important to use constant irrigation when drilling further between the facial nerve and the chorda tympani, to avoid thermal damage to the nerves.*

Identify the stapes and the stapedius tendon, the promontory and the round window niche (Figure 5).

Then, ensure an adequate exposure of the round window membrane (remove the bone overhang or the false membrane as needed).

The tympanic membrane and the ear canal are not to be disturbed during the surgical procedure.

According to the anatomical conditions and preferences of the surgeon, the introduction of the electrode array can be done either by the round window or by a cochleostomy.



A. Stapes and stapedius tendon
B. Round window niche
C. Facial nerve

Positioning the receiver

Handling the implant

Warning: *The implant should remain in the inner blister pack until completing the standard surgical procedure up until reaching the round window/cochleostomy.*

Do not use sharp surgical instruments which could damage the electrode array. We recommend opening the inner sterile blister pack only at the time when it is needed.

Warning: *Before implanting, ensure the implant is not damaged. Avoid touching and/or bending the electrode array.*

Orientation of the implant

The side of the Neuro Zti implant indicating “Bottom” and all markings of the implant shall be placed against the skull and shall not be visible.

Bottom
Side of the receiver in contact with the skull.

Up
Side of the receiver in contact with the tissue.

Reference electrode

Note: *The titanium plate contains important information that identifies the implant.*

Before attaching the implant receiver to the skull, the reference electrode which is situated on the implant toroid must remain on the mastoid where it must lie flat.

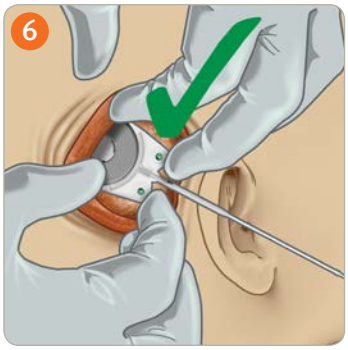
Note: *The reference electrode must not be placed under the bone, but must stay in contact with the tissue in order to conduct the eCAP measurement.*

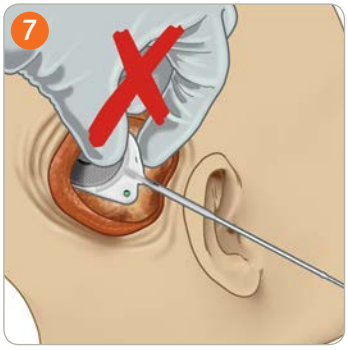
Insertion of the receiver

The receiver should be gently placed into the periosteal pocket (Figure 6) previoulsy prepared with the Neuro Zti implant indicator.

Slide it in by slowly pushing the flexible wings with two fingertips or an atraumatic tool.

Warning: *Do not push in by bending or twisting the silicone wings (Figure 7).*





Fixation of the implant

Caution: *The implant has to be secured with the screw fixation system.*

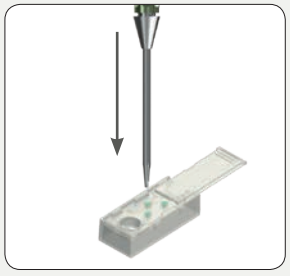
No milling of the bone is needed for the implant bed as the Neuro Zti has a flat skull facing side and a screw fixation system.

Warning: *It is always recommended to fix the Neuro Zti once in place with the two self-tapping screws provided in the packaging to prevent any possible displacement or migration, which could create stress and possibly damage the electrode array.*

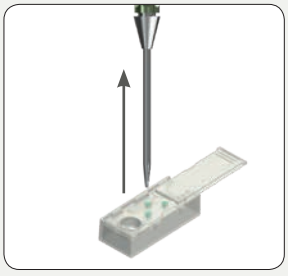
Using the screw fixation system

Removing the screws from the sterile box

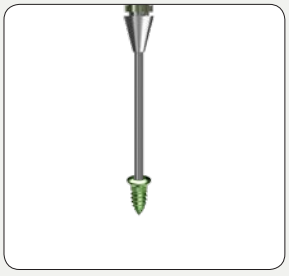
Open the sterile box by sliding the upper cap.



Insert the screwdriver into the screw using a firm axial pressure. (M80173 can be ordered separately).

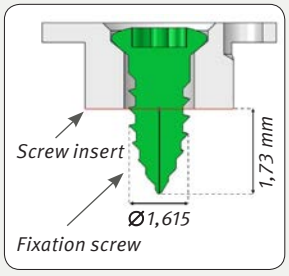


Slowly withdraw the screw from the box.

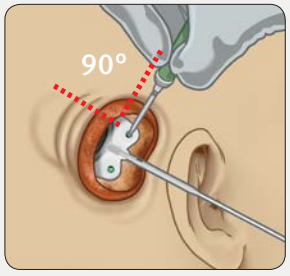


The screw is now attached to the screwdriver and can be used.

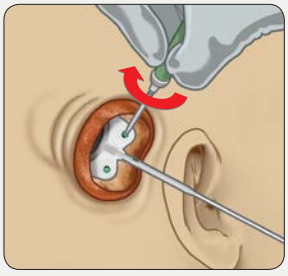
Fixing the screws into the bone



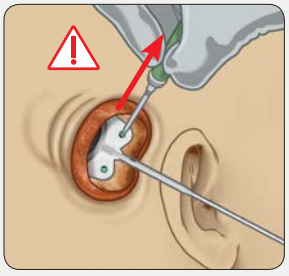
Position the first screw into one of the fixation system's titanium inserts. Penetration depth: 1,73 mm



Hold the screwdriver vertically (90°) to the implant axis for fixation.



Slowly tighten the screw by using a firm axial pressure with the palm of the hand on the top of the screwdriver. At least 4 turns are needed.

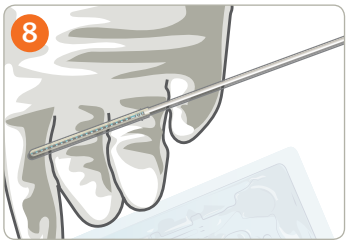


Stop when more resistance is felt. Disengage the screwdriver from the screw and check that it is secured.

Repeat the same procedure for the second screw.

Note: *It is important to stop as soon as more resistance is felt as self-tapping screws continue to turn perpetually and generate a bigger hole which will not ensure proper fixation.*

Inserting the electrode array



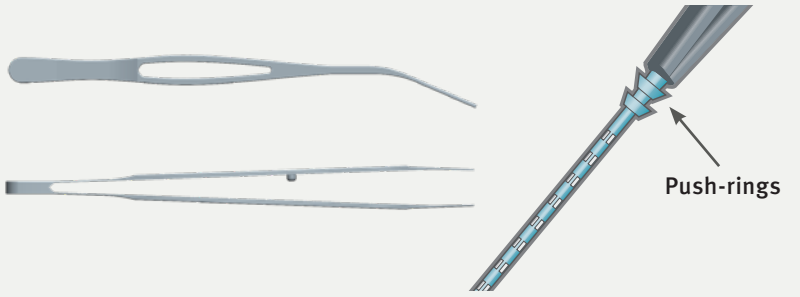
Warning: *Carefully remove the protective tubing of the electrode array before insertion (Figure 8).*

Slowly insert the electrode array to follow the cochlear spiral within the scala tympani when inserted. Guide the tip of the electrode array towards the base of the scala tympani using the Oticon Medical adapted tool.

For both versions of electrode array (CLA or EVO), there are 20 full band electrodes which do not require any specific rotating angle.

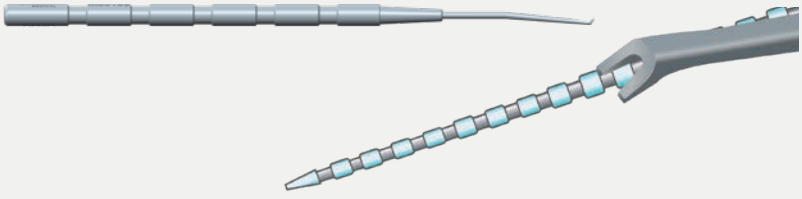
Note: *To ensure a smooth insertion or in case of difficult anatomy, a probe-array (M80181) could be used before the insertion of the Neuro Zti^{CLA} implant.*

Surgical tools compatibility



Insertion forceps (M80175)

- Designed to insert the EVO electrode array.
- Help guiding the electrode array by holding it above the first extra-cochlear silicone ring.



Insertion fork (M80306)

- Designed to insert the CLA electrode array.
- Facilitate the insertion by positioning the tip of the insertion fork between the silicone rings along the array, in order to apply an axial force.

Finish insertion by using the silicone extra-cochlear push ring as reference. Once insertion is complete, the ring should close the round window/cochleostomy access.

Caution: *In this case, closure of the cochlea could be done according to the preference of the surgeon (fascia, fresh blood, bone wax, etc.).*

Warning: *The electrode array shall be inserted with minimal insertion force. If resistance is felt before reaching the silicone ring, the insertion shall be stopped to avoid damaging the structure of the cochlea.*

Performing the intraoperative measurement

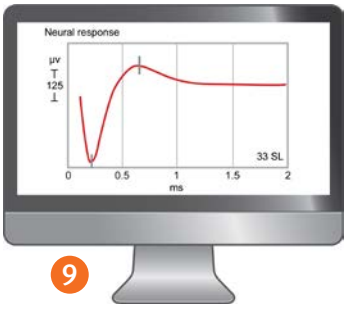
Warning: *The intraoperative measurement shall be done before or after closure to ensure the implanted device is functioning properly (Figure 9).*

Intraoperative objective measurements are obtained with the sound processor antenna coil placed in a sterile sheath and positioned on top of the implant receiver.

Note: *Do not touch or press the external coil while performing the measurements.*

Note: *During objective measures in the operating room, the connection to the implant might fail if the skin thickness is below 4 mm. In this case, use the Neuro Zti implant indicator as a spacer above the skin flap, to increase the distance between the sound processor antenna and the implant stimulator.*

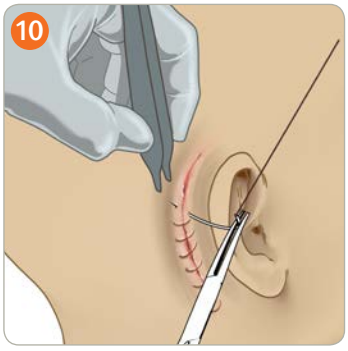
Perform the impedance testing and eCAP measurements to check the integrity of the electrodes. Refer to the Genie Medical CI Fitting Guide for instructions about the performance of the objective measurements.



Performing the closure

Performing the closure layer by layer (Figure 10).

- 1st layer: Muscle and periosteum › This soft tissue layer is important as it directly covers the receiver and the mastoid cavity.
- 2nd layer: Subcutaneous tissue
- 3rd layer: Skin



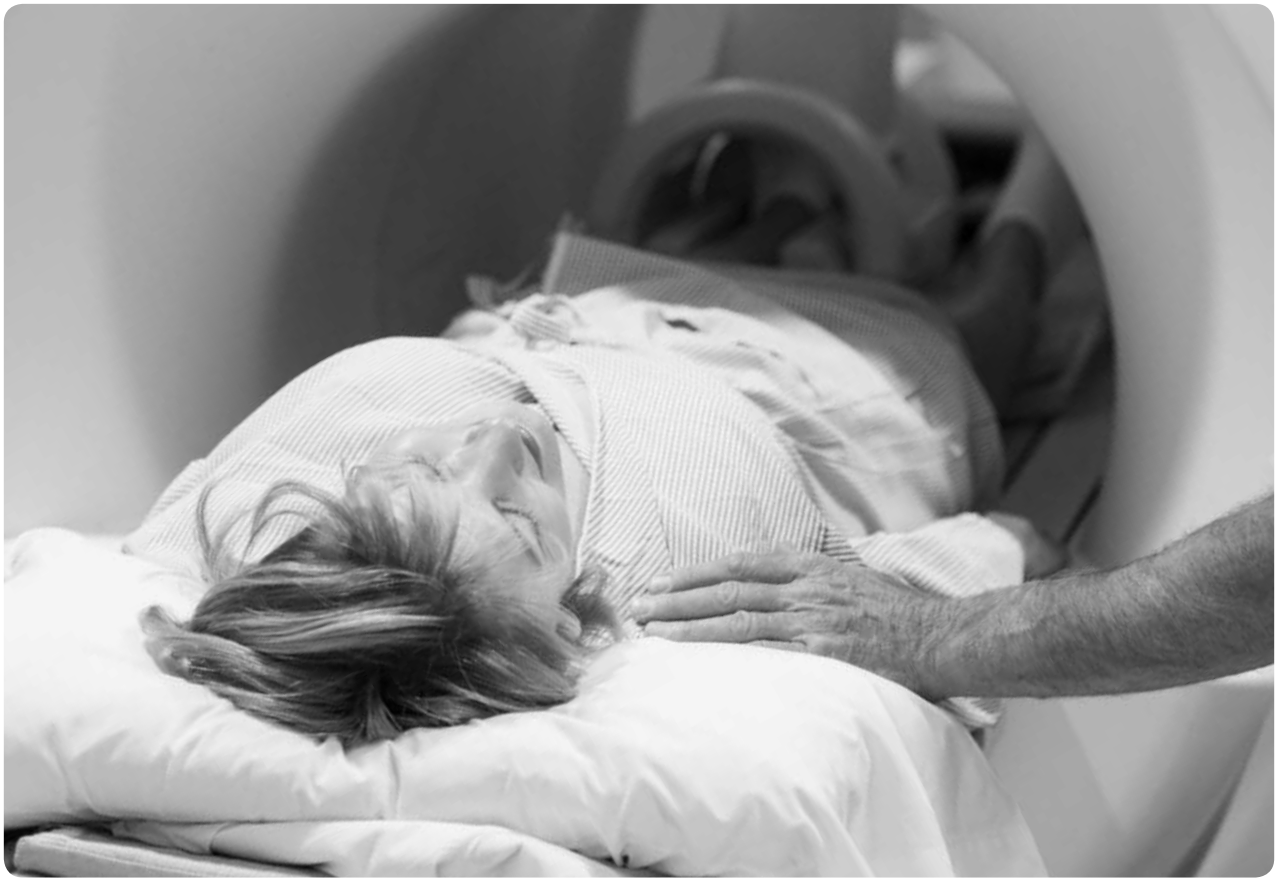
Performing imaging

It is recommended to perform a scan (Cone Beam CT or x-ray) to check the position of the electrodes in the cochlea.

Note: *After the surgery, the Implantation registration form provided in the packaging must be filled in and signed by the medical team and returned to Oticon Medical within 15 days after the surgery to register and activate the warranty of the implant.*

AFTERCARE

After the implantation, several aftercare steps must take place such as the activation and fitting in order to optimise the patient's individual requirements. While part of the treatment takes place in a clinical environment, the patient also has to learn and adjust to the new hearing sensations in their own personal time.



Patient monitoring

Recovery period

After the operation, the patient is required to stay in the hospital as long as advised by the medical professionals.

The healing period lasts around 3 to 5 weeks. During this period the patient can resume normal activities, however the patient will be unable to hear.

Activation

After the recovery period, the patient receives their sound processor for the activation and the fitting audiologist will adapt the sound processor to the physiology of the user.

Using the dedicated fitting software, the audiologist creates a “sound map”. This determines the individual’s limits for each electrode to make hearing as clear and comfortable as possible.

Routine follow-up

After cochlear implantation, improvements in hearing are linked to the efforts made by the user and their families. Speech therapy, rehabilitation programmes and attending all sound processor fitting sessions are highly recommended. Initially, fitting sessions are scheduled regularly, but they become less frequent once settings are optimised. At a later stage, fewer appointments are required to monitor the progress and fine tuning of the patient.

Specific medical intervention

Most medical interventions and examinations are still possible but users may have to remove the external part of the implant system. In spite of the few medical restrictions, cochlear implant users are still strongly advised to contact the implantation centre before any surgical intervention or medical examination, as for example, for a magnetic resonance imaging (MRI).

Magnetic Resonance Imaging (MRI) procedure

Prior to obtaining an MRI scan, the patient has to contact their treating physician. Any decision to authorise an MRI scan remains a medical decision balancing the risk of damage against the benefit of information provided by the MRI scan.

Any questions or concerns should be clarified with the manufacturer prior to conducting an MRI examination.

Warning: *If these conditions or instructions are not followed, injury to the patient and/or damage to the implant may occur.*

In the event that the magnet needs to be removed (e.g due to MRI at 3 Tesla (T), or if it is needed to reduce artefacts etc.), the below procedure needs to be followed:

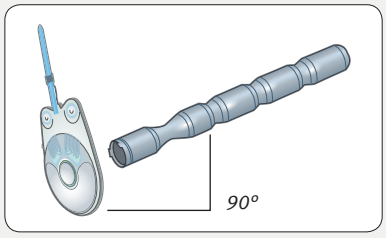
Step 1: Make an incision and expose the magnet

Make a small incision to access the magnet. Cut any fibrosis tissue to expose the magnet. The decision on optimal incision size and location should be done on a case by case basis, aiming to minimise the probability of skin-flap complications.

In order to avoid damage to the electrode array, incisions anterior to the receiver (over the toroid) are not recommended. Incision shall be made next to the implant receiver.

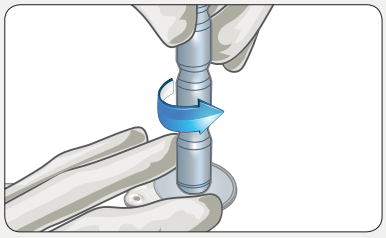
Warning: *The receiver needs to be well stabilised using your fingers while removing the magnet.*

Step 2: Remove the magnet

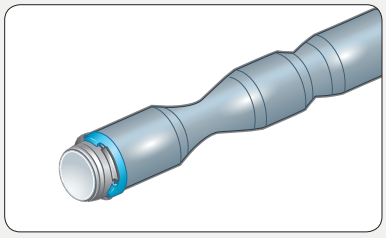


When using the magnet extractor tool, place it facing the magnet to extract.

In order to use the magnet extractor tool 90º access is required as regards the primary plane of the receiver.

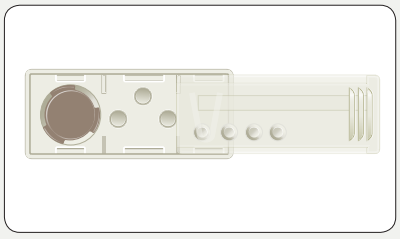
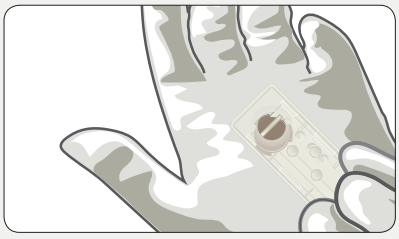


To grab the magnet placed in the implant receiver, insert the three hooks from the magnet extractor tool into the three corresponding grooves in the magnet and lock the magnet extractor tool by slightly turning to the left (counter-clock-wise) while stabilising the receiver with your fingers.The magnet will be released from the implant by turning counter-clockwise and pulling it.

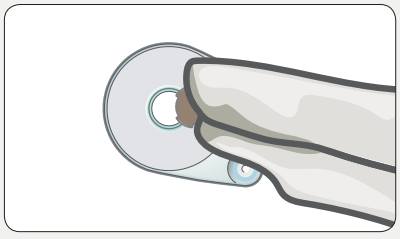
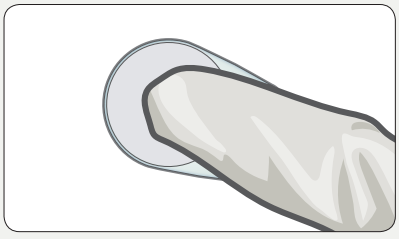


Note: *The magnet extractor tool is magnetic at the point of contact to ease the extraction.*

Step 3: Replace the magnet with the dummy


Remove the dummy from the sterile packaging.

By using a finger, place the dummy at the centre of the implant receiver until it is in place.

Note: *The dummy magnet is now in place and cannot be removed without the magnet extractor tool.*

Step 4: Close incision according to best surgical practice

Note: *When using a dummy magnet the cochlear implant recipient should be informed that the external sound processor can no longer be kept in place on the head if no headband is used to maintain the antenna or until a new magnet (with magnetic casing) is in place.*

Dummy removal and magnet replacement intervention
To replace the magnet, follow the same procedure explained in the “Magnet removal procedure” section. Instead of replacing the magnet with a dummy magnet (M80178) place a new magnet (M80179).

Note: *Wait until incision is healed prior to wearing the external sound processor.*

This procedure would be indicated also if a patient’s magnet was demagnetised following repeated MRI at 1.5T.

Patient requisites

- All external components of the implant system (sound processor and accessories) must be removed from the head of the patient.
- If the recipient is a bilateral Neuro Zti recipient, the same procedures outlined in this document must also be followed for the contralateral implant.

Explantation

Explantation of cochlear implants are unlikely events which require an additional surgery. Explantation may occur in the following cases:

- Device failure (e.g: head trauma, inherent to the device)
- Medical or surgical complication (e.g: wound or flap problems)
- Electrodes extrusion, magnet extrusion, or removable magnet extrusion
- Electrodes migration, device displacement, or removable magnet displacement.

If malfunction of the Neuro Zti cochlear implant is suspected, the system must be examined with the help of Oticon Medical clinical support. If malfunction of the implant is confirmed and the medical team decides to explant, it is important to contact Oticon Medical, and request an explantation kit (Ref: M80183) in order to return the explanted system and making it available for examination.

Illustrations and images in this manual are not to scale.

Date of last review: 02-2019

NOTES

Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world's largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advances in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with users' needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.

CE 0459

196822UK - version A

Oticon Medical
NEURELEC
2720 Chemin Saint-Bernard
06220 Vallauris
France
TEL: +33 (0) 4 93 95 18 18 – FAX: + 33 (0) 4 93 95 38 01
info@oticonmedical.com

oticon MEDICAL | Because sound matters

www.oticonmedical.com