Cochlear Implant System

Neuro Zti Cochlear Implant
Instructions for Use

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CE 0459 *(2015)*

oticon MEDICAL

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

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

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

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.

This manual provides specific information to the surgical team involved in cochlear implant surgery.

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

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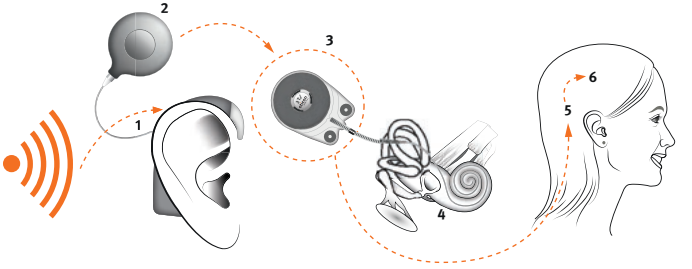
Description of the Neuro cochlear implant system

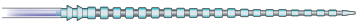
The Neuro cochlear implant system consists of an internal (implanted) and external part and can only be used with compatible accessories.



The external sound processor (1) is placed behind the ear and is connected to an antenna (2) which is placed over the implanted part (3). It acquires sound from the environment, digitally processes it and sends it wirelessly from the antenna (2) through the skin to the implanted part (3).

The internal implant (3) is surgically implanted under the skin and secured to the temporal bone behind the ear. It contains an electronic stimulator which distributes the sound to the electrodes placed in the cochlea (4).

Oticon Medical cochlear implant range

Neuro Zti^{CLA} Version (Ref: M80184) ^{CLA} stands for Classic	
Neuro Zti^{EVO} Version (Ref: M80185)	

Identification of the implant

In these Instructions for Use, versions of the Neuro Zti cochlear implant is mentioned only when required.

Bottom Side of the receiver in contact with the skull.

Upside of the receiver in contact with tissue.

Implant receiver marking:

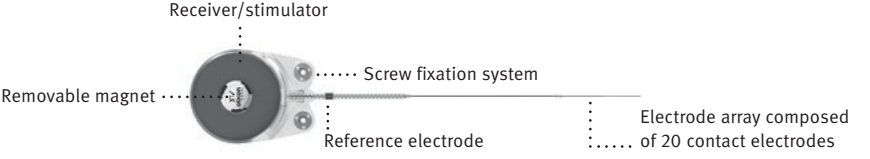
- Trademark of the manufacturer (Oticon Medical).
- Type of implant (model): The Neuro Zti^{CLA} or Neuro Zti ^{EVO} implant version.
- Serial number (SN): NZAxxxxx: (NZA) Neuro Zti^{CLA} version + (xxxxx) incremental number
  NZBxxxxx: (NZB) Neuro Zti^{EVO} version + (xxxxx) incremental number.
- “Bottom”: to specify the skull-facing side of the implant receiver.

Magnet marking:

- Trademark of the manufacturer (Oticon Medical).
- Batch number (LOT): YY-XXXXX (YY: Year – XXXXX: incremental number).
- 3T✓: "3T MR Conditional magnet, check MRI conditions before accessing MRI environment. The 3T MR conditional magnet will not be subject to magnet demagnetisation during 3T MRI exams

Main parts of the Neuro Zti implant

The Neuro Zti implant is a single-use device, which comes sterilized by ethylene oxide.
Refer to the "Data sheet" section in these Instructions for Use for detailed information on the performance characteristics and safety.



Compatibility
The Neuro Zti implant is compatible with the Neuro sound processors range and accessories specified in this manual.

Note: *Oticon Medical reports the reliability of its medical devices. Please refer to the reliability report available on the website www.oticonmedical.com.*

Intended use

The Neuro Zti implant is the implantable part of the Neuro Cochlear Implant System.

The Neuro Cochlear Implant System is intended to provide the opportunity to detect and recognise auditory information through electrical stimulation of the auditory nerve, for individuals with unilateral or bilateral severe-to-profound sensorineural hearing loss and who obtain limited benefit from appropriately fitted hearing aid(s). Limited benefit from appropriately fitted hearing aids is most commonly defined for post-lingually deafened adults as scoring 50% or less on a monosyllabic word recognition test, or 60% or less on an open set sentence recognition test.

Indications

The Neuro Zti cochlear implant is designed for adults and children of all ages who have unilateral or bilateral severe-to-profound sensorineural hearing loss, with limited benefit from appropriately fitted hearing aid(s). Limited benefit from appropriately fitted hearing aids is most commonly defined for post-lingually deafened adults as scoring 50% or less on a monosyllabic word recognition test, or 60% or less on an open set sentence recognition test.

Contraindications

The Neuro Zti Cochlear implant is not indicated in the following conditions:

- Hearing loss associated with auditory nerve and/or central auditory pathway lesions, malformation, or absence.
- Active external or middle ear infections or tympanic membrane perforation in the ear to be implanted.
- Absence of cochlea development.
- Anatomic abnormalities, preventing the placement of the chosen electrode array inside the cochlea.
- Psychological instability or unrealistic expectations regarding benefits.
- Allergy to implant materials (medical grade silicone, platinum-iridium, titanium).

Intended performance

In adult recipients with bilateral severe-to-profound hearing loss, sentence intelligibility scores measured one year after device activation in quiet are on average above 70%.

In adult recipients with bilateral hearing loss and older children (over 6-years-old):

- Detection of sounds (alerts, environmental sounds, music) at medium to loud levels (60 to 70 dB SPL).
- Understanding speech in the presence of moderate levels of noise (about 10 dB signal-to-noise ratio).
- In some cases, ability to have conversations over the phone.

In young children with bilateral hearing loss:
- Detection of sounds at medium to loud levels (alerts, environmental sounds, music).
- Development of language skills (speech production).
- Development of oral communication abilities and literacy (speech perception).

Bilateral implantation will usually maximise benefits for children, including the potential development of binaural hearing abilities, resulting in some patients in improved spatial sound perception and speech intelligibility in noise.

In patients with unilateral severe-to-profound hearing loss:
- In most cases, reduction of subjective tinnitus associated with unilateral hearing loss.
- In some cases, recovery of binaural hearing abilities with improvements of speech perception in difficult environments.

Note: *The Neuro Zti cochlear implant will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.*
- *In most cases, infrequent use of the device does not allow the user to obtain full benefit from it.*
- *The use of the device is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip-reading.*

Undesirable side effects

The candidate should be counselled on possible side effects, including the following:

Risks related to the surgery

- Normal risks associated with surgery and general anaesthesia; risks increase in some patients with certain medical conditions.
- Complications associated with the 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 and 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 immunisation status regarding bacterial and viral meningitis. Certain pre-existing conditions could increase the risk of meningitis, such as certain congenital malformations of the inner ear.[2]

[1] *Neuromonitoring is recommended, particularly where the facial nerve may be at greater risk, such as in the case of congenital temporal bone anomalies and revision surgeries (page 9).*

[2] *Vaccination recommendations are available on the Centers for Disease Control and Prevention website, http://www.cdc.gov. Local Public Health Agencies provide updated recommendations and information on national immunisation program.*

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, decrease of device performance or for 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, 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, magnet displacement.
- Screw migration, electrode array migration, receiver migration.
- Receiver extrusion, electrode array extrusion, magnet extrusion.
- Implant rejection, foreign-body reaction.

Note: *In the case of significant skin irritation, blistering, or signs of skin breakdown, use of the device should be suspended until the wound site can be assessed by the clinical CI caregivers.*

All these risks have been evaluated, and the materials and design of the implant have been chosen to minimise these risks (improved implant quality to reduce internal failures, screw fixation to prevent device displacement).

Hazards at implantation and during use could be avoided by using the device with precaution and by carefully following all the recommendations and warnings in these Instructions for Use (e.g. not dropping, immersing, or exposing the device to excessive heat).

Warning: *The healthcare professional should check the integrity of the material before use. Do not use the device if it is damaged in any way. Do not use if sterile packaging is damaged or already opened. The implant is a non-reusable sterile device and shall not be reused.*

Intended user profile

The device is intended to be implanted by a physician trained in cochlear implant surgery.

Warnings

- If any information is incomplete or ambiguous, or should you have any questions or concerns about the information provided, please contact Oticon Medical customer service or an Oticon Medical distributor.
- This device shall only be implanted by surgeons with adequate training in cochlear implantation. Clinical support is made available to assist during surgery.
- The device can only be dispensed to a patient after medical evaluation and under the agreement of a licensed physician (especially for children).
- Implantable device parts shall not be reused if they have been previously implanted in another patient.

Warnings to communicate to the patient

- The patient shall be informed of the benefits of a cochlear implant, but also of its possible undesirable side effects (refer to the “Undesirable side effects” section).
- Inform the patient that they must present the identification card prior to any medical examination or treatment.
- Advise the patient to carefully read the Instructions for Use supplied with his/her sound processor and the section relating to the warnings for use.
- The Neuro Zti implant has a removable magnet. Please advise the patient not to position a magnet on the head in the area of the implant receiver to avoid migration of the magnet.
- In case of failure or malfunction of the cochlear implant system, the patient should contact his/her implantation centre (for example, after undergoing an MRI diagnostic procedure).
- Patients are strongly advised against practising contact sports (rugby, boxing, American football etc.) as these activities could result in an impact force that may damage the implanted components.
- Do not dive below a depth of 20 m. Excess pressure may damage the implant. In addition, it is strongly recommended not to engage in professional deep-sea diving activities, as the implant is not guaranteed against repeated high pressure.
- Access to restricted areas: Patients should consult a physician before entering restricted areas (MRI examination room, walk-through metal detectors, 3D scanning booths, etc.).

Note: *The supplied identification card must be fully completed.*

Additional warnings specific to medical interventions/therapies

High-voltage electrical field:

- **Electrotherapy:** Electrotherapy may send currents of varying strengths. The use of high-voltage electrotherapy techniques is prohibited due to the risk of damage to the implant system. However, low-voltage electrotherapy may be considered if the electrodes are not placed in areas near the head or neck.
- **Electroconvulsive therapy:** Do not use electroconvulsive therapy as it can cause tissue damage in the cochlea or permanently damage the implant.
- **Defibrillation:** Sending several-thousand-volt electrical shocks through the body is not advised in a patient wearing a cochlear implant. Electrical shocks can cause tissue damage in the cochlea or permanently damage the implant.
- **Diathermy:** Medical diathermy using ultrasound, microwave or high-frequency currents cannot be considered on the area of the head and the neck. These treatments can cause cochlear tissue damage or permanent damage to the implant.
- **Neurostimulation:** Do not use neurostimulation directly over the cochlear implant. High currents induced into the electrode array can cause cochlear tissue damage or permanent damage to the implant.
- **Diagnostic tests or treatments using ultrasound:** The implant should not be exposed to therapeutic levels of ultrasonic energy. The device may inadvertently concentrate the ultrasonic field and be damaged.
- **Ionising radiation:** Ionising therapy may be used over the implant up to 112 grays.

- **Electrosurgery:** Do not use monopolar electrosurgical instruments on the head or neck, as doing so may induce currents and could cause damage to cochlear tissues or permanent damage to the implant. As soon as a cochlear implant is removed from its packaging in the operating room, any monopolar surgical systems shall be turned off to avoid any damage to the implant.
  – Bipolar electrosurgical instruments may be used on the patient's head and neck; however, they must not be in direct contact with the implant, nor be too close.

- **Non-Ionising electromagnetic radiation:**
  – MRI (Magnetic Resonance Imaging). To perform an MRI examination and get full MRI safety information, refer to the "MRI Safety Information" section in these Instructions for Use, visit **www.oticonmedical.com/mri** or contact Oticon Medical at **mri.ci@oticonmedical.com** or **+33 (0)4 93 95 18 18.**

- **Latest, up-to-date document version:**

Warning: *Please ensure that you always use the latest version of these Instructions for Use and MRI Checklist, available at:* ***www.oticonmedical.com/mri.***

Opening the Neuro Zti blister pack

A. Opening the first layer

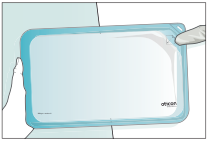
1

Non-sterile area

2

Non-sterile area

3



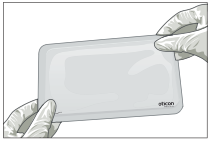
Non-sterile area | Sterile area

4

Non-sterile area | Sterile area

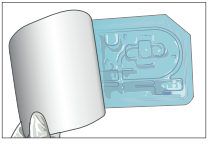
B. Opening the second layer

1



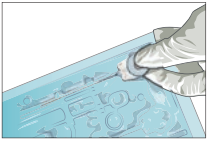
Sterile area

2



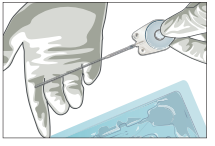
Sterile area

3



Sterile area

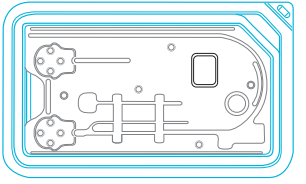
4



Sterile area

Neuro Zti pack content

- A sterile blister pack which includes: 1 Neuro Zti cochlear implant (Ref: M80184, Neuro Zti^{CLA} version; or Ref: M80185 Neuro Zti^{EVO} version), 1 small box with 3 self-tapping screws (Ref: M80174) (2 screws are used to attach the implant to the bone and 1 spare screw for replacement).



- An envelope which includes: 1 sterile Neuro Zti implant indicator (made of silicone) (Ref: M80180), which is used during the first steps of surgery to verify the correct positioning of the implant under the skin.

- An envelope with printed materials: Instructions for Use, Implantation Registration Form, Explantation Registration Form, Identification card for patient, labels for patient files.

Surgical instructions

Before implanting the Neuro Zti implant, the physician shall become familiar with the technical specifications and the surgical techniques for the Neuro ZTI device. Before implantation, patients shall be informed of the benefits of a cochlear implant, but also of its potential risks (refer to the "Undesirable side effects" section).

Warning: *Physicians must carefully read in advance these Neuro Zti cochlear implant Instructions for Use.*

Note: *Neither the physician or any person not authorised by Oticon Medical shall make changes to the implant design (such as removal of the fixation system). Unauthorised device modifications will void the warranty coverage.*

Surgical tools to use for a Neuro Zti cochlear implantation
(refer to the Neuro Zti Surgical Tool Instructions for Use):

Insertion fork *(designed for Neuro Zti^{CLA} version)*	M80306
Insertion forceps *(designed for Neuro Zti^{EVO} version)*	M80175
Neuro processor indicator	179994
Neuro Zti implant indicator	M80180
Neuro Zti screwdriver	M80173
Probe array (if needed – to be ordered separately)	M80181
Neuro Zti fixation screws	M80174

Warning: *Use only Oticon Medical surgical instruments to perform a cochlear implantation with a Neuro Zti implant.*

Surgical steps

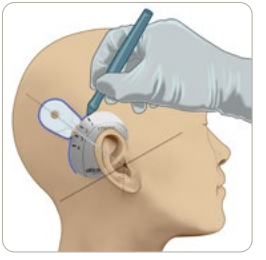
A. Determining the optimal Neuro Zti implant version

- The Neuro Zti^{CLA} (stands for CLASSIC) electrode array has a stiff profile which is designed for typical and difficult insertions (ossified cochlea, fibrosis, etc.).
- The Neuro Zti^{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.).

B. Determining the optimal position of the receiver

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

1. **Determine the position of the incision line**
   It is recommended to allow sufficient space between the incision and the implant. The receiver of the implant needs to be placed under the temporal muscle far enough from the auricle of the ear (about 2 cm).
2. **Mark the incision line and the position of the receiver**
   To determine the position of the implant and of the sound processor, the Neuro Zti Implant Indicator (M80180–included in the Neuro Zti package) shall be used along with the Neuro Processor Indicator (179994–to be ordered separately).



C. Measuring the skin thickness and performing the incision

Warning: *Skin flap thickness shall be up to 8 mm.*
If the skin is too thick, a skin flap reduction might be required.

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

D. Determining the final position of the receiver

In some cases, flattening the bone could be required to ensure the receiver remains flat on the bone for the best fixation. First, the Neuro Zti implant indicator (M80180) shall slide inside the periosteal pocket to prepare and ensure an easy progression and the correct positioning of the Neuro Zti implant receiver.

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

E. Completing the standard surgical procedure to access the cochlea

F. Positioning the receiver – Handling the implant

The implant shall be removed from the inner blister pack only after completing the standard surgical procedure up until the round window/cochleostomy.

Carefully read the instructions on how to open the implant sterile blister pack (refer to the "Opening the Neuro Zti blister pack" section). We recommend not to open the inner sterile blister pack before it is needed.

Warning: *Do not use sharp surgical instruments which could damage the electrode array.*

Warning: *The sterile state of the Neuro Zti implant shall be preserved throughout the different steps of surgery.*

Warning: *The Neuro Zti implant should be handled with care. The Neuro Zti shall be handled by holding the receiver of the implant and not the electrode array. Lifting or holding the Neuro Zti by the electrode array could cause damage to the array.*

Orientation of the implant

Warning: *The side of the Neuro Zti implant labelled "Bottom" and all markings of the implant shall be placed towards the skull and is thereby not visible.*

Note: *The bottom side of the implant contains important information which identifies the implant (refer to the "Identification of the implant" section).*

Before attaching the implant receiver to the bone, the reference electrode situated on the implant toroid shall be placed in a flat position and remain on the mastoid.

Caution: *The reference electrode must not be placed under the bone and must stay in contact with the tissue.*

Insertion of the receiver

- The receiver shall be gently placed into the periosteal pocket (previously 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.*

G. Fixation of the implant

Caution: *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 secure the Neuro Zti 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.*

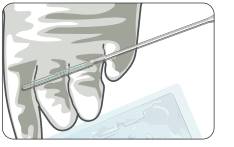
Follow the steps below to remove the screws from the sterile box:

- Open the sterile box by sliding the upper cap.
- Insert the screwdriver (M80173 – can be ordered separately) into the screw using a firm axial pressure.
- Slowly withdraw the screw from the box.
- The screw is now attached to the screwdriver and is now ready for use.

Position the first screw into one of the titanium inserts of the fixation system. It is recommended to hold the screwdriver vertical 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. Stop when more resistance is felt. Check that it is secure, then repeat the same procedure for the second screw.

H. Inserting the electrode array

Warning: *Carefully remove the protective tubing of the electrode array before insertion.*



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

Slowly insert the electrode array to follow the cochlear spiral within the scala tympani when inserted. Guide the tip of the electrode array toward the base of the scala tympani using the insertion fork (M80306) for the Neuro Zti^{CLA}, or the insertion forceps (M80175) for the Neuro Zti^{EVO}. Then, gradually advance the electrode array using minimal force. Finish insertion by using the silicone extracochlear push rings as a reference. Once insertion is complete, the rings shall block the round window/cochleostomy access.

Caution: *The electrode array must be secured to prevent the risk of migration. The fixation method and fixation points will depend on the surgical access and the surgeon's preferences.*

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

I. Performing the intraoperative objective measurements

Warning: *The intraoperative objective measurements shall be carried out before or after closure to ensure the implanted device is operating properly.*

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 on the external coil while performing the measurements.*

Note: *If the skin thickness is less than 4 mm, use the Neuro Zti implant indicator as a spacer on the receiver, above the skin flap.*

J. **Performing the closure**

K. **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.

L. **Registering the implant**

The Implantation Registration Form must be returned to Oticon Medical within 15 days of the implantation to register and activate the warranty of the implant.

Explantation

Warning: *The Neuro Zti cochlear implant could be explanted due to technical or medical reasons.*

Known medical reasons for explantation are:

- *antibiotherapy-resistant infection (e.g. Pseudomonas aeruginosa, staphylococci, meningitis, complication of cholesteatoma, mastoiditis or otitis media).*
- *cerebrospinal fluid leakage, skin flap complications, chronic pain.*
- *misplaced electrode array, implant or electrode array migration or extrusion;*
- *anomalous percept, dizziness, performance degradation, extracochlear stimulation;*
- *other health conditions requiring explantation (e.g. skull fractures, or cancer therapy).*

The system must be examined beforehand by the Medical team with help from Oticon Medical clinical support. After a common agreement, please order an explantation kit (Ref: M80183) to correctly return the intact explanted system for further examinations, as a special packing needs to be used for these types of shipments (diagnostic specimens shipment). The Neuro Zti implant needs to follow a special waste procedure.

If additional clarification is needed for the described procedures, please contact Oticon Medical customer service or your local distributor: info@oticonmedical.com.

MRI Safety Information

Magnetic Resonance Imaging (MRI) safety statement

All external components of the Oticon Medical cochlear implant system (BTE, antenna, accessories...) are MR Unsafe and need to be removed prior to MR imaging.	
The implanted components of the Oticon Medical cochlear implant system (Neuro Zti implants) are MR Conditional.	

Prior to undergoing an MRI scan, the patient shall contact their ENT 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: *Ensure you always use up-to-date MRI safety information available in these Instructions for Use and the MRI Checklist at* ***www.oticonmedical.com/mri,*** *or by directly contacting Oticon Medical at* ***mri.ci@oticonmedical.com.***

Non-clinical testing has demonstrated that the Neuro Zti cochlear implant is MR Conditional.

Warning: *If the conditions or instructions on this page are not followed, injury to the patient and/or damage to the implant may result.*

A patient with this implant can be safely scanned in an MR system under the following conditions, after checking for the patient's eligibility outlined in the "Magnet removal procedure" section below:

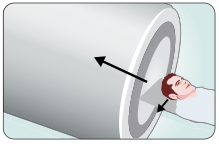
MRI Field Strength	Maximum average Head SAR	Maximum average Whole Body SAR	
		Distance (in B0 axis) between top of the head and center of MR scanner <= 30 cm	Distance (in B0 axis) between top of the head and center of MR scanner > 30 cm
1.5 Tesla	3.2 W/kg	2.0 W/kg	2.0 W/kg
3 Tesla	1.0 W/kg	0.6 W/kg	2.0 W/kg

MRI Field Strength	1.5 Tesla	3 Tesla
Maximum Spatial Field Gradient	20 T/m	15 T/m
Maximum switched gradient slew rate per axis	200 T/m/s	
Continuous MR scanning time	60 min	
Maximum temperature rises under conditions specified above	2.8˚C	4.0˚C

Warning: *If the conditions or instructions on this page are not followed, injury to the patient and/or damage to the implant may result.*

- Clinical system for hydrogen proton imaging (Horizontal field/cylindrical bore).
- Static magnetic field strengths 1.5T or 3T.
- Transmit head coils not allowed.
- Body coil can be used in Transmit/Receive mode. Transmit/Receive knee coils can be used. Receive-only coils can be used.
- For all MRI examinations which require placement of the head in the centre of the tunnel, position the patient in a supine position (Figure 1).

Figure 1



Current best practice is to lie the patient down on the MRI table outside of the MRI room, and to slowly move the patient near the entrance of the MRI tunnel.

In non-clinical testing, the magnetically induced displacement force and torque were tested, and no safety risk has been identified.

Caution: *A minimum healing period of 2 to 4 weeks after cochlear implant surgery is required before undergoing an MRI scan with the Neuro CI system. This period will allow for wound swelling to reduce to avoid causing any uncomfortable or painful sensation to the patient.*

Caution: *Demagnetisation of the implant magnet could occur due to static magnetic field. To reduce this risk, ensure to keep the longitudinal axis of the patient's head parallel to BO axis. 2.2% of magnet weakening is expected after one 3 Tesla MRI scan, and up to 3% after ten 3 Tesla MRI scans. If a significant magnet strength loss occurs, surgical intervention may be required to replace the implanted magnet.*

Caution: *It is possible that the patient might experience pain/discomfort, localised heating or auditory sensations during the MR Scan.*

Even if extremely unlikely, magnet dislodgement may occur, and the magnet will need to be replaced.

In non-clinical testing, the image artefact caused by the implant with and without magnet has been evaluated.

Caution: *You should expect to see artefacts, for example with spin echo sequences, as illustrated below. Artefact reduction can reach up to 30% with a spin echo sequence. Although magnet removal is not mandatory, the magnet can be taken out temporarily prior to the MRI examination to reduce the image artefacts.*

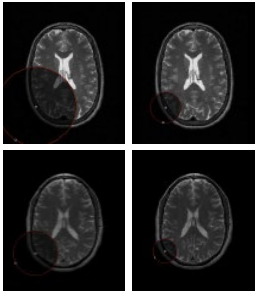


Image artefact area at 3T.
Left: with the magnet in place (**70.5 mm** – radius).
Right: with the magnet removed and a dummy in place (**28 mm** – radius).

Image artefact area at 1.5T.
Left: with the magnet in place (**46 mm** – radius).
Right: with the magnet removed and a dummy in place (**21.5 mm** – radius)

Magnet removal procedure (if required)

Caution: For patients who do not have a 3T MR Conditional magnet, the magnet shall be removed prior to the MRI exam at 3 Tesla strength to avoid any demagnetisation issues.
*3T MR Conditional magnets are specified by the **3T✓** symbol on the Patient ID card.*

MRI Strength	1.5 Tesla	3 Tesla
Recommended intervention if patient card has **3T✓ symbol**. For **bilateral** patients, the patient card must **have 3T✓ symbol** for **both.**	No magnet removal or surgery required.	**No magnet removal** or surgery required.
Recommended intervention if patient card(s) has at least **one magnet without 3T✓symbol.**		**Magnet removal/surgery** required prior to MRI examination.

The magnet may be removed prior to an MRI exam for MRI strengths at 1.5 or 3 Tesla to minimise image artefacts as outlined above.

Magnet removal or replacement is a surgical procedure and must take place following standard surgical practice to ensure sterility.

Required tools:
To extract the magnet of the Neuro Zti implant, the surgeon will need the three items mentioned below:

- **A Neuro Zti magnet extractor** (M80177) which can be ordered directly from Oticon Medical or the Oticon Medical local distributor. The tool is packed non-sterile, and should be sterilised before performing the surgery by following the Oticon Medical cleaning and sterilisation protocol. Refer to the Surgical tools Reprocessing Instructions for Use.

- **A Neuro Zti dummy magnet** (M80179). The dummy magnet is packed sterile, and shall be ordered directly from Oticon Medical or the Oticon Medical local distributor before performing a magnet extraction. The dummy magnet is a non-magnetic casing, which is used to avoid any harm caused by strong electromagnetic fields and to reduce artefact.

Caution: *The dummy magnet should be placed immediately after extracting the implant magnet in order to avoid the ingress of unwanted materials (blood, debris, etc.) into the magnet location on the implant.*

Note: *The cochlear implant recipient shall be informed that the processor antenna can no longer be kept in place on the head without the use of an external magnet system or a headband.*

- **A Neuro Zti magnet** (M80178) for replacement. The magnet is packed sterile, and shall be ordered from Oticon Medical or the Oticon Medical local distributor before performing any medical examination which requires a magnet extraction.

Step 1: Make an incision and expose the magnet

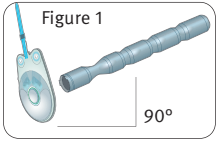
Make a small incision to access the magnet, and cut away any fibrosis tissue to expose the magnet. The decision about the optimal incision size and location should be made on a case-by-case basis, aiming to minimise the probability of skin flap complications.

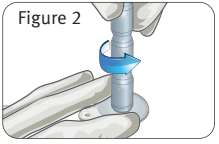
Warning: *To avoid potential damage to the electrode array, incisions anterior to the receiver (over the toroid) are not recommended. The incision shall be done next to the implant receiver.*

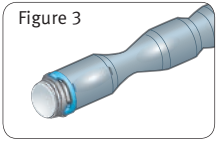
Step 2: Remove the magnet
When using the magnet extractor, place it facing the magnet to extract.
To use the magnet extractor tool, a 90° access is required towards the primary plane of the receiver (Figure 1).

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 (counterclockwise), while stabilising the receiver with your fingers (Figure 2).The magnet will be released from the implant by turning counterclockwise and pulling it.

Warning: *Carefully stabilise the receiver with your fingers whilst removing the magnet.*







Note: *The magnet extractor tool is magnetic at the point of contact to ease the extraction (Figure 3).*

Step 3: Replace the magnet with the dummy magnet
Remove the dummy from the sterile packaging (Figure 1). By using a finger, push the dummy into place in the centre of the implant receiver (Figure 2).

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

Figure 1

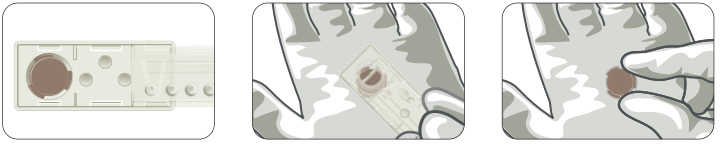
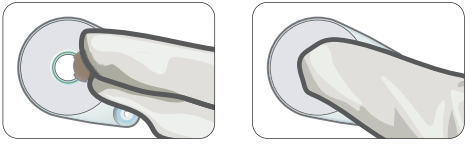


Figure 2



Step 4: Close the incision according to best surgical practice

Note: *When using a dummy magnet, the cochlear implant recipient shall 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

Follow the same procedure explained in the "Magnet removal procedure" section.

Magnet replacement

To replace the magnet, follow the same procedure explained in the "Magnet removal procedure" section. Instead of replacing the magnet with a dummy magnet (M80179), insert a new magnet (M80178).

Note: *Wait until the incision area is healed before wearing the external sound processor.*

Caution: *When replacing with a new magnet, only use a new magnet which has the 3T✓ symbol. In case of doubt, please contact* ***mri.ci@oticonmedical.com*** *or at* ***+33 (0)4 93 95 18 18.***

Patient requisites

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

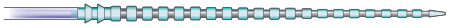
Data sheet – Neuro Zti cochlear implant specifications

Stimulation capacity	
Primary function	Electrical stimulation of the cochlea
Stimulation mode (depending on configuration)	Multi-mode grounding: combined stimulation with monopolar and common ground mode Monopolar for ECAP
Objective measurements	• Impedance measurement • Electrically evoked compound action potential ECAP

Mechanical properties	
Weight	11.5 g
Dimensions	Diameter: 30.5 mm Thickness for Neuro Zti Simulator/Receiver: ranging from 2.95 mm to 4.5 mm (edge to edge)
Volume	4.15 cm^3
Material in direct contact with human tissue	• LSR 40 shore A silicone • HCR 35 shore A & HCR 50 shore A silicone • Adhesive silicone • Platinum iridium 10% • Titanium grade 2 • Titanium grade 5
Receiver	Titanium grade 2 and Zirconia encapsulation
Insulation	Wire: Polytetrafluoroethylene (PTFE) and Polyester (PE) External tubing: Silicone (SI)

Performance characteristics	
Characteristics of output signal [Max 5 V]	Q: 2.2 to 230 nC, I: 220 uA to 2 mA, Δt: 10 us to 115 us
Impedance measurement	Normal values: 500 Ω – 7000Ω
Skin thickness	Up to 8 mm
Essential performance	Accuracy of the electrical stimulation (<10% at C level)
Stimulation frequency	Up to 47,500 pulses per second (software limited)
Transportation conditions	Temperature: -30°C to +60°C Relative humidity: 10% to 90% Atmospheric pressure: 70 kPa to 106 kPa
Storage conditions	Temperature: -30°C to +60°C Relative humidity: 10% to 90% Atmospheric pressure: 70 kPa to 106 kPa
Safety	
MRI safety level	Can be used in 1.5 and 3 Tesla field strength with magnet in place, subject to conditions outlined in section 'MRI Safety Information' above
Ionising radiation	Dose max. 112 grays
Methods recommended for determining the functionality of the system	Impedance measurement and integrity test (with collection equipment)
Operating pressure	Absolute pressure of 3 bars (corresponding to a diving depth of 20 metres)
Reference electrode	1 cylindrical ground electrode: 17 mm^2 Diameter: 2.1 mm Length: 2.5 mm
Automatic check	Implant identification

Neuro Zti^{CLA} (CLASSIC version)



Specifications and characteristics of the Neuro Zti^{CLA} electrode array	
Material components	Connecting wire: Platinum iridium 10% Stimulation electrodes: Platinum iridium 10%
Number of independent active electrodes	20
Insertion length	26 mm
Active length	25 mm
Dimensions	Active area: 0.39 mm^2 to 0.77 mm^2 Diameter at apex: 0.5 mm Diameter at base: 1.07 mm
Electrode contact pitch	Contact to contact spacing (centre): 1.2 mm
Reduced cochleostomy size	Diameter of 1 mm
General shape	Straight with shape conforming Straight: distance between electrodes and silicone, inferior to 0.1 mm
Shape at the apex	Rounded shape
Shape at the base	Diameter push rings: 2 x 1.5 mm
Insulation	Wire: Polytetrafluoroethylene (PTFE) and Polyester (PE) External tubing: Silicone (SI)

Neuro Zti^{EVO} (EVO version)

Specifications and characteristics of the Neuro Zti^{EVO} electrode array	
Material components	Connecting wire: Platinum iridium 10% Stimulation electrodes: Platinum iridium 10%
Number of independent active electrodes	20
Insertion length	25 mm
Active length	24 mm
Dimensions	Active area: 0.46 mm^2 to 0.60 mm^2 Diameter at apex: 0.4 mm Diameter at base: 0.5 mm
Electrode contact pitch	Contact to contact spacing (centre): 1.2 mm
Reduced cochleostomy size	Diameter of 0.8 mm
General shape	Straight with shape conforming Straight: distance between electrodes and silicone, inferior to 0.1 mm
Shape at the apex	Rounded shape
Shape at the base	Diameter push rings: 1 x 1.5 mm & 1 x 1.2 mm
Insulation	Wire: Polytetrafluoroethylene (PTFE) and Polyester (PE) External tubing: Silicone (SI)

Warranty terms and conditions

Important when implanting

1. Warranty period: The implant is guaranteed for 10 years from the date in which the receiver was implanted, as noted on the implantation registration sheet. Note that the implantation registration sheet must be signed by the surgeon and returned to Oticon Medical within 15 days after the surgery.
2. The implant is warranted to be free from defects in design or workmanship, and is subject to the warranty period defined in paragraph 1.
3. The warranty will be rendered null and void, in part or total, if the device is not implanted in accordance with instructions provided by Neurelec/Oticon Medical, who shall not be held liable, in the following cases:
   - The warranty shall also be void in the event of implant displacement, if the implant has not been attached using the screws (refer to the “Surgical instructions” section in these Instructions for Use).
   - When the implant has not been implanted before the “Use-by date” indicated on the protective packaging (and on the sterile pack).
   - In the event of alteration or voluntary or accidental mishandling, such as impact, exposing the implant to temperatures above +60°C or below -30°C, etc. (refer to the “Package: symbols and meanings” section in these Instructions for Use).
   - If the implant is used even though the sterile packaging has been damaged. The product is sterile and cannot be resterilised. Do not use if sterile packaging is damaged. Do not remove the implant from sterile packaging until needed. For shipping, the Neuro Zti outer pack should be packed in a strong and protective cardboard box.

4. Any dispute shall be subject to the exclusive jurisdiction of the courts of Nice, France.
5. The warranty of the device does not cover any misuse of the Neuro Zti cochlear implant before or during surgery, and the implant shall be handled with care.

Important when explanting

1. Neurelec/Oticon Medical shall not be held liable in the case of explantation due to medical problems (e.g. infection, electrode misplacement, contraindication, etc.).
2. Only explanted patients may receive the new implant under the terms of this warranty.
3. Oticon Medical shall be notified prior to any explantation when a malfunction has been observed.
4. The explanted implant must be returned to Oticon Medical within 15 days in the explantation kit obtained through Oticon Medical for an expert assessment, along with the completed medical device report and explantation registration sheet with details about the reason for the extraction.
5. Any implant which is explanted shall be technically examined to confirm that the new implant is still under warranty.
6. No compensation for damages will be paid regardless of the length of time or loss of use by the explanted patient.
7. Failure to comply with any of these clauses voids the warranty
8. The warranty consists of an outright exchange of the defective implant for an equivalent or a more recent generation device.
9. Exchanging an implant under the warranty shall not serve to extend the warranty period of the new implant, nor the replacement of the magnet with a new one.

Package: symbols and meanings

	Fragile; handle with care		**Caution:** Potential hazard that could result in patient/user temporary injury or hospitalisation if not avoided
	Sterilised using ethylene oxide		General symbol for recovery/recyclable Neuro Zti outer pack is made of 80% recycled materials and can be recycled
	Sterilised using steam sterilisation		Humidity limitation
	Single-use device; do not reuse		Temperature limitation
	Do not resterilise		Atmospheric pressure limitation
	Serial number		Use-by date
	Catalogue number		Date of manufacture
	Batch code		Manufacturer
	Prescription only		Do not use if the package is damaged

	MR conditional		Consult the instructions for use (print version)
	MR conditional		
3T✓	3T MR Conditional magnet, check MRI conditions before accessing MRI environments	 www.oticonmedical.com	Consult the instructions for use (e-IFU), can be downloaded at: **www.oticonmedical.com/mri**
	Warning: Potential hazard that could result in patient/user serious injury or death if not avoided		Indicating a note/tip
CE 0459		Marking for European Community with notified body number	

Pictures are not to scale and not contractually binding.

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