



Magnetic Resonance Imaging (MRI) Exam Instructions for Use

Neuro – The Cochlear Implant System

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MEDICAL

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MRI medical exam

Magnet removal is not required for magnetic field strengths at 1.5 Tesla. For magnetic field strengths greater than 1.5 Tesla magnet removal is required for MRI compatibility. In order to insure patient safety during an MRI exam and to prevent damage to the Neuro Zti, the following instructions must be understood and followed. Any questions or concerns should be clarified with the manufacturer prior to conducting an MRI exam with a patient implanted with the Neuro Zti.

MRI Strength	1.5 Tesla	3 Tesla
Recommended intervention	No surgery required, use standard head bandage	Remove magnet prior to MRI exam

Warnings:

1. All external cochlear implant components such as the BTE, antenna, audio streamers, cables and any other cochlear implant associated accessories are NOT compatible with MRI examination and must be removed prior to entering an MRI examination room. There is a risk that prolonged exposure to high strength magnetic fields could demagnetize the implanted magnet held by the Neuro Zti. To reduce the risk of demagnetization, care should be taken to keep the longitudinal axis of the patient's head parallel to the scanner's principal magnetic field. Loss of magnetization may interfere with antenna retention following an MRI

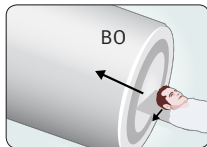
procedure. Should transcutaneous magnetic coupling become compromised, surgical intervention may be required to replace the implanted magnet following the procedures described below.

2. If the region of medical interest is likely to fall within the projected artifact produced by the Neuro Zti, the magnet may be removed prior to an MRI exam for MRI strengths at 1.5 Tesla to minimize artifacts.
3. It is possible that the medical region of interest may be obscured by artifacts produced by the Neuro Zti even with the implanted magnet removed.
4. It is possible that the patient may experience auditory sensations such as crackling, beeping and/or a humming sound during an MRI exam. The patient should be advised of this possibility and that it does not indicate device malfunction or damage.
5. If the patient is a bilateral Neuro Zti recipient, the same procedures outlined in this document must also be followed for the contralateral implant.
6. Head first: Technicians must slide the Neuro Zti recipient head first in the MRI machine independent of the anatomical region to be scanned. Caution: Entering feet first is contraindicated.
7. Note: To perform an MRI exam, the radiologist should fill out an exam form that can be found at www.oticonmedical.com. The form must be sent back for approval to the manufacturer that is mentioned on the cover before performing the MRI exam.

A. MRI exam with implanted magnet in place (at 1.5 Tesla) recommended guidelines for radiologists.

1. The patient must have been implanted with a cochlear implant at least 6 months prior to the MRI examination.
2. All external part or cochlear implant system accessories should be removed.
3. The patient must have a compression bandage applied to the head to secure the implant position.
4. For all MRI examinations requiring the head of the patient to be placed in the center of the tunnel, the position of the patient must be conformed to the 'usual position' (figure below). It is imperative that this position applies at least 30 cm before the beginning of the tunnel.

Note: When carrying out an MRI exam with a Neuro Zti cochlear implant, do not use the Head Coil Array.



'Usual Position' with nose up

B. MRI exam with magnet removal (3 Tesla)

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

Required tools:

In order to extract the magnet of the Neuro Zti implant, the surgeon will need to have the three elements mentioned below:

A Neuro Zti magnet extractor (M80177) that can be ordered directly from Oticon Medical or the local Oticon Medical distributor. The tool is packed non-sterile. It must be sterilized following Oticon Medical re-cleaning and sterilization protocol (M80330) before performing surgery.



A Neuro Zti dummy magnet (M8o178). The dummy magnet is packed sterile. It shall be ordered directly from Oticon Medical or Oticon Medical local distributor and before performing a magnet extraction. The dummy magnet is an empty titanium casing that does not hold any magnet in order to avoid any harm caused by strong electromagnetic field. The dummy magnet must be put in place after extracting the implant magnet in order to avoid the fibrosis to form into the implant.

Note: The cochlear implant recipient should be informed the processor antenna can no longer be kept in place on the head if no external magnet system or headband is used.

A Neuro Zti magnet (M8o179) for replacement. The magnet is packed sterile. It shall be ordered from Oticon Medical or Oticon Medical local distributor before performing any medical exam that requires a magnet extraction.

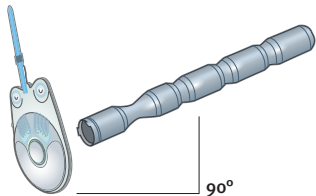
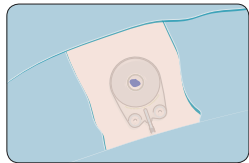


Step 1: Make an incision and expose the magnet.

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

In order to avoid potential damage to the electrode array, incisions anterior to the receiver (over the toroid) are not recommended. Incision should be made on the side of the implant receiver.

Note: A proper connection between the extractor tool and the magnet demands an angle of 90 degrees.



Step 2: Remove the magnet

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

In order to use the magnet extractor tool, 90 degree access with respect to the primary plane of the receiver is required (Figure 1).

To grab the magnet that is placed in the implant receiver, lock the extractor tool to the magnet by turning $\frac{1}{4}$ to the left (minimum 20° counter-clockwise) while stabilizing the receiver with your finger (Figure 2). The magnet will be released from the implant.

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

Figure 1

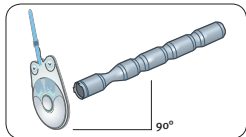
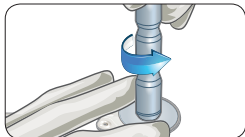
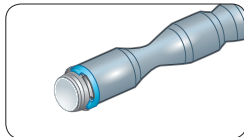


Figure 2



Hold with fingers,
lock the extractor tool and pull

Figure 3



Step 3: Replace magnet with dummy magnet

Remove the dummy from the sterile packaging (Figure 1). Using a finger, push the dummy at the center of the implant receiver until it stops. (Figure 2).

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

Figure 1

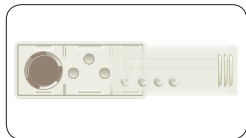
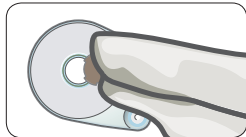


Figure 2



Step 4: Close incision according to best surgical practice

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

C. Dummy removal and magnet replacement intervention

Follow same procedures as in “B. MRI with magnet removal (3 Tesla)”.

D. Magnet replacement

To remove the magnet, follow procedure of “B. MRI Exam with magnet removal (3 Tesla)”. Instead of replacing the magnet with a dummy magnet (M80178); place a new magnet (M80179) instead.

This procedure would be indicated also if a patient’s magnet was demagnetised following repeated MRI at 1.5T or an accidental MRI at 3T that demagnetised a magnet.



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