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.

If these conditions or instructions are not followed, injury to the patient and/or damage to the implant may occur. Any questions or concerns should be clarified with the manufacturer prior to conducting an MRI examination by contacting Oticon Medical at mri.ci@oticonmedical.com

Before the MRI examination

Step 1: Check the patient’s data information
Most of the information can be found on the Patient ID card, otherwise contact the treating physician.

- Verify if the patient is unilaterally or bilaterally implanted:
  - Unilateral
  - Bilateral

- Determine the patient’s model(s) of implant(s):
  - Neuro Zti
  - Digisonic® SP range (Digisonic® SP, Digisonic® SP EVO, Digisonic® SP ABI, Digisonic® SP Binaural)

- Verify the delay since the last date of implantation:
  - More than 6 months
  - Less than 6 months. The patient must have been implanted at least 6 months prior to the MRI examination. In which case, please contact Oticon Medical at mri.ci@oticonmedical.com

Step 2: Determine the static magnetic field strength needed

- 1.5 Tesla > Compatible with Digisonic® SP range. Compatible with Neuro Zti implant with or without magnet in place. We recommend removing the magnet in the case of MRI examinations in the head region, to minimise the artefacts created.

- 3 Tesla > Not compatible with Digisonic® SP range. Compatible with Neuro Zti implant without the magnet. Magnet removal is required (refer to Step 4 for the procedure).
If the patient is eligible for the MRI:

**Step 3: Inform the patient of the potential side effects**
- Pain and discomfort may occur during the MRI examination
- Auditory sensation may occur during the MRI examination
- Demagnetisation of the implant magnet could occur due to the static magnetic field if the magnet is kept in place during the examination
- With the Neuro Zti implant: even if extremely unlikely, magnet displacement/dislodgement may occur and the magnet will need to be replaced

**Step 4: Manage the magnet removal for the Neuro Zti implant, if required**
(for 3 Tesla MRI or to reduce artefact size at 1.5 Tesla):
1. Order a dummy magnet (M80179) or 2 dummy magnets in the case of bilateral patients
2. Order a Neuro Zti magnet extractor (M80177) and a new magnet (M80178) or 2 magnets for replacement in the case of bilateral patients
3. Schedule the pre-MRI surgery with the cochlear implant surgeon to remove the magnet*
4. Schedule the post-MRI surgery with the cochlear implant surgeon to insert a new magnet*

**Day of the MRI examination**

**Step 5: Prepare the patient**
- Ensure the magnet has been carefully removed if required
- Remove all external components before entering the MRI room
- A compression bandage must be placed on the patient’s head to provide better support and prevent the implant from moving during the examination (Fig 1.). A folded gauze can be placed over the implant site to increase pressure on the implant. The bandage should cover the implant site and the implant should be placed in the middle of the bandage. The bandage should be wrapped around the head at least three full times. No specific type of bandage is required.
- Determine the anatomic area which requires a scan
  - Head > Head coil in receive mode can be used
  - Body > Body coil in transmit/receive mode can be used
- Correctly position the patient in the MRI scanner

For all MRI examinations requiring the patient’s head is to be placed in the centre of the tunnel, and position the patient in a supine position (Fig 2.). It is imperative that this position is applied at least 30 cm before the beginning of the tunnel.

**Step 6: Ensure the MRI machine is correctly set-up in “normal operating mode”**
Max. 3.2 W/kg for Head SAR, 2.0 W/kg for Whole-Body SAR

**Step 7: Perform the MRI examination**

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*The magnet removal/placement procedure for the surgeon is described in the Neuro Zti Instructions for Use (downloadable at www.oticonmedical.com/mri).*