

## PRECAUTIONS FOR MEDICAL PROCEDURES

### Neurostimulation or diathermy

Neurostimulation or diathermy must not be carried out in the area of the implant since it could lead to current induction at the electrodes. This may damage the implant and/or the surrounding tissue.

### Electrosurgery and other treatment with electrical current

Monopolar electrosurgical instruments must not be used in the head and neck area close to the cochlear implant. Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of the cochlear implant. Such currents may damage the implant and/or the surrounding tissue. In general remove your OPUS 2 audio processor from your head any time a medical treatment is given in which an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire Cochlear Implant System during the initial stages of the treatment.

### Ultrasound

Therapeutic ultrasound treatment should not be applied close to the cochlear implant as the implant may inadvertently concentrate the ultrasound field and cause harm.

### Electroconvulsive therapy

Electroshock or electroconvulsive therapy should not be used in patients with cochlear implants. Such therapy may damage the implant and/or the surrounding tissue.

### Radiation Therapy

The MED-EL Cochlear Implants are robust against radio-therapeutic irradiation of up to a total ionization dose of 240 Gray. MED-EL external components need to be taken off during irradiation. Therapeutic ionising radiation in general may damage electronic components of your Cochlear Implant System and such damage may not be immediately detected.

In order to minimize the risk of tissue necrosis due to local overdose, during radiotherapeutic treatments, the implant should not be placed in the direct radio-therapeutic beam.

### Magnetic Resonance Imaging (MRI)

MRI is possible in patients with cochlear or auditory brainstem implants only with specified models of MRI machines. Evidence has been provided for these implants to pose no known hazard in magnetic field strengths of 0.2 T, 1.0 T and 1.5 T (without surgical removal of the internal magnet) when the following safety recommendations and guidelines are adhered to. The physician/MRI operator should always be informed that a patient is a cochlear implant or an auditory brainstem implant user and that special safety recommendations and guidelines have to be followed:

**Safety recommendations and guidelines for MRI scanning:**

- MRI scanner with static magnetic field strength of 0.2 T, 1.0 T or 1.5 T only. No other field strengths are allowed. (When using other field strengths, injury to the patient and/or damage to the implant are possible.)
- MRI scan not earlier than 6 months post implantation. (Performing an MRI at an earlier stage may result in implant displacement and/or damage to the implant)
- A minimum thickness of the bone underneath the implant magnet of 0.4mm is required in order to withstand forces of 5 N (equals a gravitational force of about 0.5 kg) or up to 9 N for the C40 cochlear implant. (In an MRI scanner torque forces act on the implant magnet, exerting rotational pressure: the device will try to turn to line up with force lines. The resulting forces on the edges of the implant are counterbalanced by the cranial bone and the skin flap. Bone underneath the implant magnet should be thick enough to withstand these exerting forces.)
- Patients with mechanically damaged implants must not undergo MRI. (Ignoring this guideline could result in injury to the patient.)

**Safety Guidelines:**

- Before patients enter any MRI room all external components of the implant system (audio processor and accessories) must be removed. For field strengths of 1.0 T or 1.5 T a supportive head bandage must be placed over the implant. A supportive head bandage may be an elastic bandage wrapped tightly around the head at least three times (refer to Fig. A). The bandage shall fit tightly but should not cause pain.



Fig. A: Head bandage to support fixation of the implant

- Head orientation: The longitudinal axis of the head must be parallel to the main magnetic field of the scanner. For example this is the case when the patient is in a supine position with the head kept straight. (The patient should not turn or bend his/her head to the side; otherwise partial demagnetization of the implant magnet is possible.)
- Sequences in Normal Operating Mode shall be used only! During the scan patients might perceive auditory sensations such as clicking or beeping. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory sensations can be reduced by selecting sequences with lower specific absorption rate (SAR) and slower gradient slew rates.

## General precautions and warnings

- Image artifacts are to be expected (refer to Fig. B).

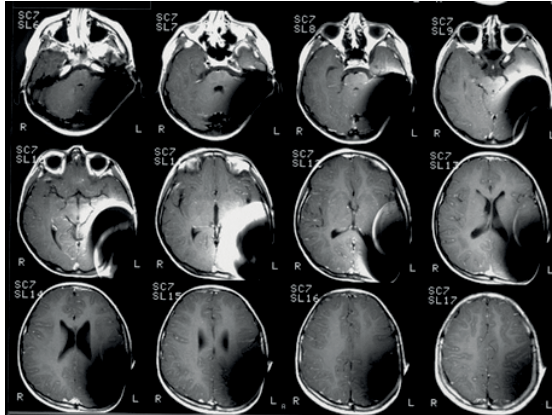


Fig. B: MR images obtained with a 1.5 T scanner (8 year old child)

- The above instructions should also be followed if areas of the body other than the head are to be examined (e.g. knee, etc.). When lower extremities are to be examined, it is recommended that the patient's legs are positioned in the scanner first to minimize any risk of weakening the implant magnet.
- The above instructions also apply for patients with bilateral cochlear implants or bilateral auditory brainstem implants.

If the conditions for MR safety and the Safety Guidelines are not followed, injury to the patient and/or damage to the implant may result!

### Other treatments

The effects of a number of treatments are unknown, e.g. radioactive radiation (cobalt, linear accelerator) or electrical examinations in the dental area. Please contact your clinic.

### Ear infections

Infections in the implanted ear must be treated promptly by a physician who will prescribe antibiotics as necessary. Prophylactic use of antibiotics is recommended for all patients unless medically contra-indicated. The surgeon should prescribe adequate dosing for each patient's condition. Please inform your CI centre of such infections.

### Electrical lice combs

Cochlear implant users should not use these devices.

### Meningitis vaccine and prevention

Bacterial meningitis is rare but has the potential to be serious. The risk of contracting meningitis after your CI surgery can be reduced by the meningitis vaccine, by using antibiotics before and after CI surgery and by using the surgical technique recommended by MED-EL. As with all cochlear implant surgery, preventative antibiotic usage is recommended for all patients unless medically contra-indicated. Talk to your surgeon about this. Your surgeon should prescribe adequate antibiotic dosing for you or your child and should check your or your child's immunisation status before your implant surgery.