Medical Procedures
for MED-EL Implant Systems
This manual provides important instructions and safety information for MED-EL Implant System users who have to undergo a medical procedure (e.g. MRI).

As an implant user, you might have questions about undergoing further medical procedures. Your medical team may also want more information about any special considerations for implant users. This guidance provides information that will help prevent damage to your implant and injury to yourself. Please share this information with your healthcare provider.

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Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Generally remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.
- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.
- 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. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.
- Ultrasonic therapy and imaging must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL 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 radiotherapeutic beam.
- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.
Magnetic Resonance Imaging (MRI) Safety Information

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Patients implanted with a MED-EL Cochlear Implant may be safely scanned with a MRI system without surgical removal of the internal magnet when adhering to the conditions for safe scanning listed below. The implant has a specially designed magnet which allows safe MRI scanning with the magnet in place, and there is no need to remove the implant magnet. The implant magnet can be surgically removed if needed to avoid imaging artifacts. The physician/MRI operator should always be informed that a patient is a MED-EL Cochlear Implant user and that the conditions for safe scanning below must be followed.

Non-clinical testing has demonstrated that the MED-EL Cochlear Implant is MR Conditional. A patient with this implant can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5T or 3.0T
- Maximum spatial field gradient of 2,900 G/cm (29 T/m)
- For 1.5T systems (see Table 1):
  - Only sequences in Normal Operating Mode with a maximum head Specific Absorption Rate (SAR) of 3.2 W/kg.
- For 3.0T systems (see Table 1):
  1. For head scans and scans with a landmark location that is less than 35 cm from the top of the head the MR system must be able to provide a SAR limit prediction that allows fractional SAR display.
2. Sequences in Normal Operating Mode only with the following SAR restrictions:
   a. For head scans: Maximum average head SAR must not exceed 1.6 W/kg (50% of maximum head SAR).
   b. For landmark locations less than 35 cm from the top of the head: Maximum whole-body SAR must not exceed 1.0 W/kg.
   c. For landmark locations at least 35 cm away from the top of the head: Maximum whole-body SAR must not exceed 2.0 W/kg.

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<th>MRI field strengths</th>
<th>Average head SAR</th>
<th>Average whole-body SAR</th>
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<td>Landmark location ≥35 cm from the top of the head</td>
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<td>1.5T</td>
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<td>2.0 W/kg</td>
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Table 1: Specific Absorption Rate (SAR levels)

For 1.5 T scans under the conditions listed above, the implant is expected to produce a maximum temperature rise of less than 2 °C during 15 minutes of continuous MR scanning.

For 3.0 T scans under the conditions listed above, the implant is expected to produce a maximum temperature rise of less than 3 °C during 15 minutes of continuous MR scanning.

- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed from the head.
- Head transmit coils or multichannel transmit coils must not be used with a 3.0 T MR system.
- The patient should be lying on his/her back with the head aligned parallel to the long axis of the scanner. The head should not be tilted more than 30 degrees from the axis of the scanner. The patient should be advised not to tilt his/her head to the side; otherwise torque is exerted onto the implant magnet which might cause pain. For scans requiring a head coil, the head coil will maintain a proper head orientation. For scans without a head coil, appropriate padding that will prevent the head from tilting more than 30 degrees must be used.
- Testing has demonstrated that migration or magnet displacement will not occur when scanned under these conditions. For field strengths of 1.5 T and 3.0 T, an optional supportive head bandage may be placed over the implant, for instance using an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage shall fit tightly, but should not cause pain.
• The implant must not be damaged mechanically, electrically or in any other way.
• In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this additional implant must be met.
• 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 a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
• The magnet can be removed to reduce image artifacts. If the magnet is not removed, image artifacts are to be expected (refer to Figure 2 and Figure 3). The artifacts extend approximately 10 cm (3.9”) in radius around the device in a Spin Echo scan.
• The exchange of the magnets with the Non-Magnetic Spacer and vice versa has been tested for at least five repetitions.
• 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.

If the conditions for safe scanning listed above are not followed, injury to the patient and/or damage to the implant may result!
Figure 1: Head bandage to support fixation of the implant

Figure 2: Image artifacts of a spin echo sequence in axial view arising in a 1.5T scanner. The left picture shows the artifacts obtained with the implant magnet in place, whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.

Figure 3: Image artifacts of a spin echo sequence in axial view arising in a 3.0T scanner. The left picture shows the artifacts obtained with the implant magnet in place, whereas the right picture illustrates the image artifacts when the implant magnet is replaced with the Non-Magnetic Spacer.
Interference with other equipment, robustness of the device in special medical or diagnostic environments

- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.

- Generally remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.

- Any necessary ionizing radiation therapy should be carefully considered and the risk of damage to the MED-EL implant has to be carefully weighed against the medical benefit of such therapy.

- Electroshock or electroconvulsive therapy in the head and neck region must not be used. Such therapy may damage the implant and/or the surrounding tissue.

- 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. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.

- Ultrasonic therapy and imaging must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.

- MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL 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 radiotherapeutic beam.

- Other treatments: The effects of a number of treatments are unknown, e.g. electrical examinations in the dental area. Please contact your clinic.
Magnetic Resonance Imaging (MRI) Safety Information

| ☓ | The external components of the MED-EL Cochlear Implant System (audio processor and accessories) are MR Unsafe and need to be removed prior to scanning. |
| ☑ | The implant components of the MED-EL Cochlear Implant System are MR Conditional. |

Non-clinical testing has demonstrated that MED-EL Cochlear Implants are MR Conditional. They can be safely scanned under the following conditions:

0.2 or 1.5 Tesla:

**Conditions:**
- Bone thickness underneath the implant magnet of at least 0.4mm. Bone thickness must be determined using CT images.
- Static magnetic field of 0.2T or 1.5T
- Spatial gradient field of up to 8T/m (800 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2W/kg and a maximum head averaged SAR of 3.2W/kg
- Implantation performed at least 6 months ago
- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed.
- The implant is not damaged mechanically, electrically or in any other way.
Additional MRI safety information for 0.2 or 1.5 Tesla scanning:

- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly, but should not cause pain.
- Head orientation: In case of 1.5T systems, 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.
- 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 a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- 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.
- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise <2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.
Figure 1: Head bandage to support fixation of the implant

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)
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- Instruments used in electrosurgery can produce high-frequency voltages which may induce currents in the electrodes of implantable devices. Such currents may damage the implant and/or the surrounding tissue. Monopolar electrosurgical instruments must not be used in the head and neck region. If bipolar electrosurgical instruments are used, the tips of the cautery must be kept at least 5 mm away from the reference electrodes on the stimulator housing and any contacts of the active electrode.
- Generally remove your external components (e.g. audio processor and accessories) from your head when undergoing medical treatment where an electrical current is passed through your body, or at least carefully observe the correct functioning of your entire MED-EL Implant System during the initial stages of the treatment.
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### 0.2 or 1.5 Tesla:

**Conditions:**
- Bone thickness underneath the implant magnet of at least 0.4mm. Bone thickness must be determined using CT images.
- Static magnetic field of 0.2T or 1.5T
- Spatial gradient field of up to 8T/m (800 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2W/kg and a maximum head averaged SAR of 3.2 W/kg
- Implantation performed at least 6 months ago
- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed.
- The implant is not damaged mechanically, electrically or in any other way.
Additional MRI safety information for 0.2 or 1.5 Tesla scanning:

- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly, but should not cause pain.
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- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise <2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.
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• 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. This applies also to iontophoresis and any current inducing medical and/or cosmetic treatment.

• A diagnostic level of ultrasonic energy of up to 500 W/m² within the range of 2 MHz to 5 MHz does not cause any damage to the implant.

• MED-EL Cochlear Implants are robust against 240 Gy ionizing radiation dose under 6 MV photon beam (pulsed radiation from a linear accelerator) with a field size FS = 30 cm × 30 cm, source to surface distance SSD = 100 cm, depth = 0.8 cm in a 30 cm × 30 cm × 15 cm perspex phantom. MED-EL external components need to be taken off during irradiation. Therapeutic ionizing radiation in general may damage electronic components of your MED-EL 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 radiotherapeutic beam.

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Additional MRI safety information for 0.2 or 1.5 Tesla scanning:

- Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).
- A supportive head bandage must be placed over the implant before entering the scanner room. This may be an elastic bandage wrapped tightly around the head at least three times (refer to Figure 1). The bandage needs to fit tightly, but should not cause pain.
- Head orientation: In case of 1.5T systems, 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.
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- In non-clinical testing and electromagnetic in-vivo computer simulations, the implant produced a maximum temperature rise <2 °C during 15 minutes of continuous MR scanning in the Normal Operating Mode at a maximum whole-body averaged SAR of 2.0 W/kg and a maximum head averaged SAR of 3.2 W/kg.
Figure 1: Head bandage to support fixation of the implant

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)
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**Conditions:**
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- Static magnetic field of 0.2T or 1.5T
- Spatial gradient field of up to 8T/m (800 G/cm)
- Only sequences in Normal Operating Mode with a maximum whole-body averaged Specific Absorption Rate (SAR) of 2W/kg and a maximum head averaged SAR of 3.2W/kg
- Implantation performed at least 6 months ago
- Before patients enter any MRI room, all external components of the implant system (audio processor and accessories) must be removed.
- The implant is not damaged mechanically, electrically or in any other way.
Additional MRI safety information for 0.2 or 1.5 Tesla scanning:

• Large image artifacts are to be expected. The size and shape of the image artifacts depend on the MRI sequence. The artifacts extend approximately 10 cm (3.9 in.) in radius around the device in a Spin Echo scan (refer to Figure 2).

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• Head orientation: In case of 1.5T systems, 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.

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Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)
Symbols

- **MR Conditional**
- **MR Unsafe**
- **Manufacturer**

Please visit us at http://www.medel.com/us/isi-cochlear-implant-systems/

Help and assistance are always available from your local office. Please refer to the accompanying Contact Sheet for your local office.
USA Distributor
MED-EL Corporation, USA
2511 Old Cornwallis Road, Suite 100
Durham, NC 27713, USA
implants.us@medel.com

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician.