Cochlear Implants

MED EL

Medical Procedures

for MED-EL CI/ABI Systems

AW33289_8.0 (English EU)

This manual provides important instructions and safety information for MED-EL CI/ABI System users who have to undergo a medical procedure (e.g. MRI). The authorisation of any medical procedure remains a medical decision balancing the risk of damage against the benefit provided.

As a CI/ABI 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 CI/ABI and injury to yourself. Please share this information with your healthcare provider.

Not all products in this document are currently approved or available in all countries. Please contact your local MED-EL representative for information on current product availability in your country.

In this document the general term "MED-EL Implant System" is used for all implant types. The specific implant name is identified in the header of the applicable section.

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

- 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.
- 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.
- Any necessary ionising 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.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL external components need to be taken off during irradiation. Therapeutic ionising radiation in general may damage electronic components of your MED-EL Implant System and such damage may not be immediately detected. In order to minimise 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) Caution

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

MRI is possible in patients with MED-EL implants only with specified models of MRI machines.

Evidence has been provided for this implant type to pose no known hazard in specified MRI environments (without surgical removal of the internal magnet) when adhering to the conditions and Safety Guidelines 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 regardless of the scanner field strength. The implant magnet can be surgically removed if needed to avoid imaging artefacts. The physician/MRI operator should always be informed that a patient is a MED-EL implant user and that special safety guidelines have to be followed:

MRI scanning is possible in consideration of the Safety Guidelines if the following conditions are fulfilled:

- MRI scanners with static magnetic field strengths of 0.2T, 1.0T, 1.5T or 3.0T only. No other field strengths are allowed. When using other field strengths, injury to the patient and/or damage to the implant are possible.
- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this implant need to be considered in addition.

Safety Guidelines:

- Before patients enter any MRI room, all external components of the MED-EL Implant System (audio processor and accessories) must be removed from the head. An optional supportive head bandage may 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 Figure 1). The bandage shall fit tightly, but should not cause pain.

- For all MRI systems (1.0T, 1.5T and 3.0T), the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side by more than 30 degrees from the long axis of the body otherwise torque will be exerted onto the implant magnet which might cause pain. In case of 0.2T scanners, no specific head orientation is required.
- For 0.2T, 1.0T and 1.5T scans (see Table 1), only sequences in "Normal Operating Mode" with a maximum Specific Absorption Rate (SAR) of 3.2W/kg for head scans and 2.0W/kg for whole body scans shall be used.
- For 3.0T scans the SAR limit must not exceed the SAR values for specific anatomic regions given in Table 1 to avoid any potentially dangerous heating at the electrode contacts. For the same reason head transmit coils or multi-channel transmit coils must not be used in case of a 3.0T MRI.

  For head examinations and examinations of the body that are less than 35cm from the top of the head, the MRI system must have the ability to set a reduced maximum specific absorption rate (SAR) or to display the estimated maximum SAR value.

  Sequences in Normal Operating Mode only with the following SAR restrictions:
  - For head scans: Maximum average head SAR must not exceed 1.6W/kg (50% of maximum head SAR).
  - For landmark locations less than 35cm from the top of the head: Maximum whole-body SAR must not exceed 1.0W/kg.
  - For landmark locations at least 35cm away from the top of the head: Maximum whole-body SAR must not exceed 2.0W/kg.

MRI field strengths	Average head SAR	Average whole-body SAR	
		Landmark location <35cm from the top of the head	Landmark location ≥35cm from the top of the head
0.2T	3.2W/kg	2.0W/kg	2.0W/kg
1.0T	3.2W/kg	2.0W/kg	2.0W/kg
1.5T	3.2W/kg	2.0W/kg	2.0W/kg
3.0T	1.6W/kg	1.0W/kg	2.0W/kg

Table 1: Specific Absorption Rate (SAR levels)

- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.

- In rare cases the patient might perceive a clicking sound upon entry in the MRI scanner tube.
- In rare cases temporary pain or discomfort may occur in the implant area during MRI even if all protocols and bandaging instructions are followed.
- The magnet can be surgically removed by pushing on the top side of the magnet so that it comes out at the bottom side of the implant to reduce image artefacts. If the magnet is not removed, image artefacts are to be expected (refer to Figure 2 and Figure 3).
- 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 MRI safety and the Safety Guidelines are not followed, injury to the patient and/or damage to the implant may result!

To reduce the likelihood and degree of patient discomfort, the patient should keep their head away from the scanner wall near the entrance of the scanner.

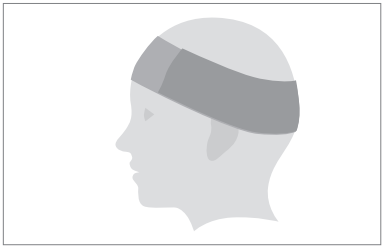

Figure 1: Head bandage to support fixation of the implant

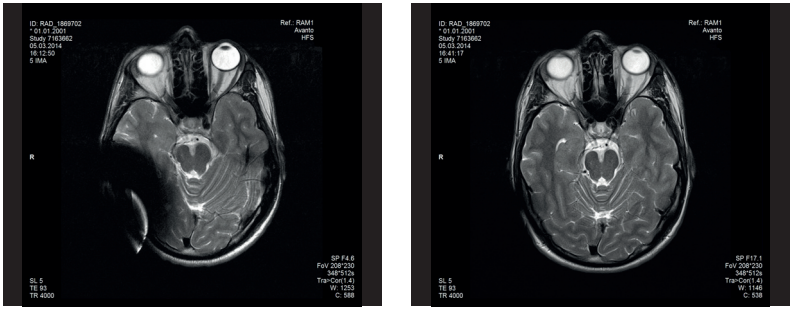

Figure 2: Image artefacts arising in a 1.5T scanner. The left picture shows the artefacts obtained with the implant magnet in place, whereas the right picture illustrates the image artefacts when the implant magnet is replaced with the Non-Magnetic Spacer.

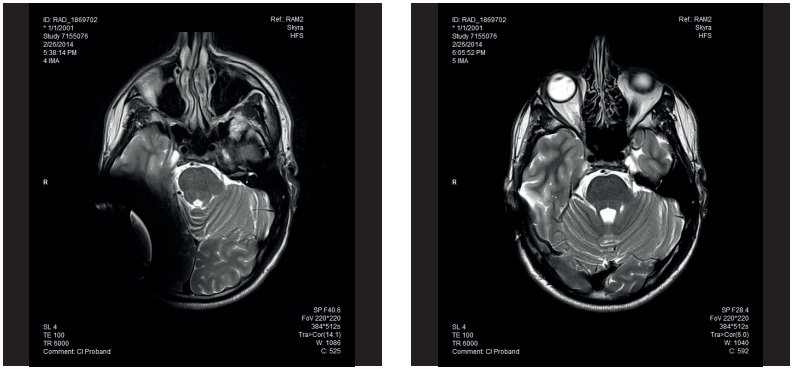

Figure 3: Image artefacts arising in a 3.0T scanner. The left picture shows the artefacts obtained with the implant magnet in place, whereas the right picture illustrates the image artefacts when the implant magnet is replaced with the Non-Magnetic Spacer.

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- Diagnostic ultrasound does not cause any damage to the implant.
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- In case of additional implants, e.g. a hearing implant in the other ear: MRI safety guidelines for this implant need to be considered in addition.

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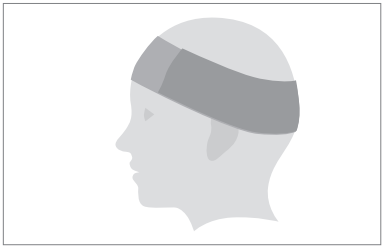

Figure 1: Head bandage to support fixation of the implant

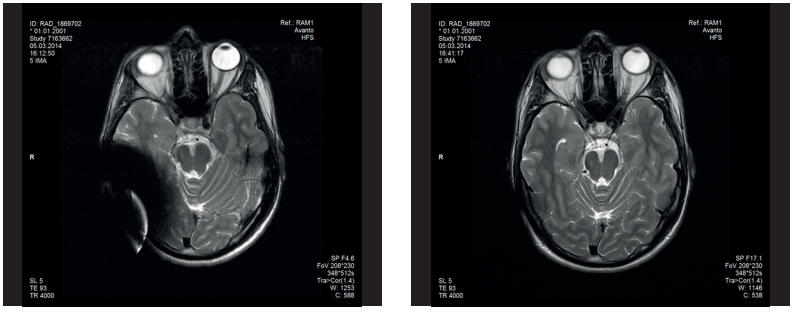

Figure 2: Image artefacts arising in a 1.5T scanner. The left picture shows the artefacts obtained with the implant magnet in place, whereas the right picture illustrates the image artefacts when the implant magnet is replaced with the Non-Magnetic Spacer.

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Safety Guidelines:

- Before patients enter any MRI room, all external components of the MED-EL Implant System (audio processor and accessories) must be removed. For field strengths of 1.0T or 1.5T, 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 Figure 1). The bandage shall fit tightly, but should not cause pain.
- In 1.0T and 1.5T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise demagnetisation of the implant magnet may be possible. In case of 0.2T scanners, no specific head orientation is required.

- Only sequences in Normal Operating Mode with a maximum Specific Absorption Rate (SAR) of 3.2 W/kg for head scans and 2.0 W/kg for whole body scans shall be used.
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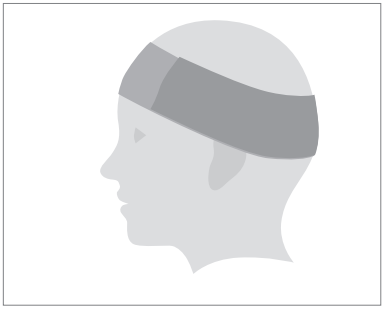

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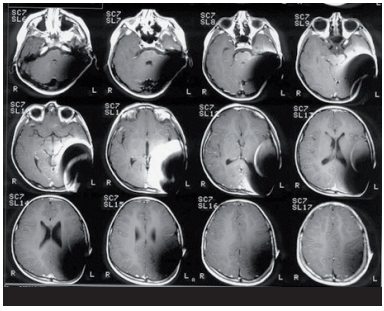

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)

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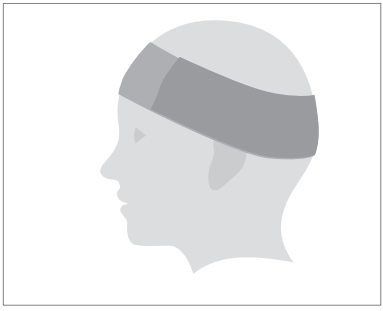

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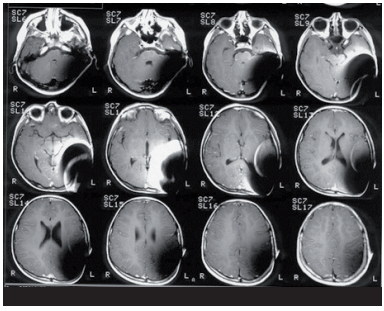

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)

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- 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 0.4 mm is required to withstand forces of 5 N (equals a gravitational force of about 0.5 kg). 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. The bone underneath the implant magnet should be thick enough to withstand these exerting forces.
- Patients with mechanically damaged implants (shattered implant housing) 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 MED-EL Implant System (audio processor and accessories) must be removed. For field strengths of 1.0T or 1.5T, 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 Figure 1). The bandage shall fit tightly, but should not cause pain.
- In 1.0T and 1.5T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise demagnetisation of the implant magnet may be possible. In case of 0.2T scanners, no specific head orientation is required.
- Only sequences in Normal Operating Mode with a maximum Specific Absorption Rate (SAR) of 3.2W/kg for head scans and 2.0W/kg for whole body scans shall be used.
- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
- In rare cases temporary pain or discomfort may occur in the implant area during MRI even if all protocols and bandaging instructions are followed.
- Image artefacts are to be expected (refer to Figure 2).
- 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 minimise any risk of weakening the implant magnet.
- The above instructions also apply to patients with bilateral MED-EL 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!

To reduce the likelihood and degree of patient discomfort, the patient should keep their head away from the scanner wall near the entrance of the scanner.

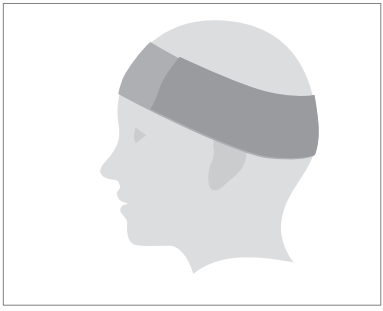

Figure 1: Head bandage to support fixation of the implant

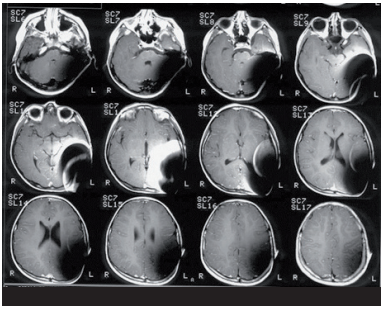

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)

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

- 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.
- 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 must be used, the tips of the cautery must be kept at least 3 cm away from the stimulator and all areas of the electrodes.
- Any necessary ionising 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.
- Diagnostic ultrasound does not cause any damage to the implant.
- Ultrasonic therapy must not be used in the area of the implant, as the implant may inadvertently concentrate the ultrasound field and cause harm.
- MED-EL external components need to be taken off during irradiation. Therapeutic ionising radiation in general may damage electronic components of your MED-EL Implant System and such damage may not be immediately detected. In order to minimise 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) Caution

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

MRI is possible in patients with MED-EL 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 0.2T, 1.0T and 1.5T (without surgical removal of the internal magnet) when adhering to the following safety recommendations and guidelines. The physician/MRI operator should always be informed that a patient is a MED-EL implant user and that special safety recommendations and guidelines have to be followed:

MRI scanning is possible in consideration of the Safety Guidelines if the following conditions are fulfilled:

- MRI scanners with static magnetic field strengths of 0.2T, 1.0T or 1.5T 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 0.4 mm is required to withstand forces of 5 N (equals a gravitational force of about 0.5 kg). 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. The bone underneath the implant magnet should be thick enough to withstand these exerting forces.
- Patients with mechanically damaged implants (shattered implant housing) 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 MED-EL Implant System (audio processor and accessories) must be removed. For field strengths of 1.0T or 1.5T, 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 Figure 1). The bandage shall fit tightly, but should not cause pain.
- In 1.0T and 1.5T MRI systems, the patient should be lying in the scanner in a supine, prone or side position with the head kept straight. The patient should be advised to not tilt their head to either side otherwise demagnetisation of the implant magnet may be possible. In case of 0.2T scanners, no specific head orientation is required.
- Only sequences in Normal Operating Mode with a maximum Specific Absorption Rate (SAR) of 3.2W/kg for head scans and 2.0W/kg for whole body scans shall be used.
- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
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- Image artefacts are to be expected (refer to Figure 2).
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- The above instructions also apply to patients with bilateral MED-EL implants.

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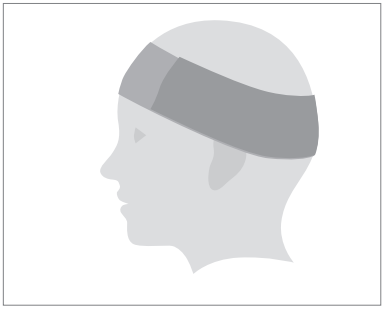

Figure 1: Head bandage to support fixation of the implant

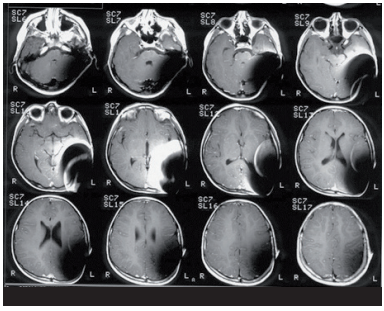

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)

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

- 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.
- 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 must be used, the tips of the cautery must be kept at least 3 cm away from the stimulator and all areas of the electrodes.
- Any necessary ionising 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 external components need to be taken off during irradiation. Therapeutic ionising radiation in general may damage electronic components of your MED-EL Implant System and such damage may not be immediately detected. In order to minimise 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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- A minimum thickness of the bone underneath the implant magnet of 0.4 mm is required to withstand forces of 5 N (equals a gravitational force of about 0.5 kg) or up to 9 N. 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. The bone underneath the implant magnet should be thick enough to withstand these exerting forces.
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- During the scan (temporarily) patients might perceive auditory sensations such as clicking or beeping as well as non-auditory sensations such as prickling, stinging or pain (slight). Adequate counselling of the patient is advised prior to performing the MRI. The likelihood and intensity of auditory and non-auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.
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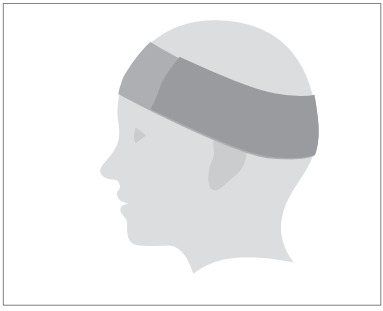

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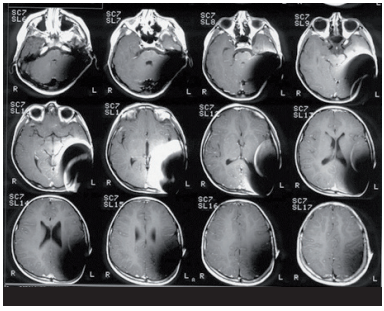

Figure 2: MR images obtained with a 1.5T scanner (8-year-old child)

Symbols

MR Conditional

MR Unsafe

Manufacturer

Please visit us at www.medel.com/isi

Help and assistance are always available from your local office.
Please refer to the accompanying Contact Sheet for your local office.

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