MED-ELin kuuloistutteet ja MRI

Sisäkorvaistute :

Aina ennen kuvausta tulisi ottaa yhteyttä laitevalmistajaan.
Täytä mukana tuleva kaavake ja toimita se päätoimistoomme Insbruckiin, sieltä tulee lupa ja tarkemmat ohjeet kuvaukselle.

Jos tulee ns. Kiire kuvantaminen, voidaan se pakottavissa olosuhteissa tehdä alla olevan kaavakkeen ohjeiden mukaan.

Välikorvaistute, Vibrant Soundbridge :
MRI –kuvantamista ei suositella, tutkimukset ovat vielä käynnissä.
Suomessa käyttäjiä toistaiseksi hyvin vähän.

Luujohtaistute, Bonebridge :
MRI –sopiva 1,5T asti, kuvaan toki tulee suuri artefakta.

MED-EL

MRI Examination Request Form

Please complete and return this form to MED-EL, Fuerstenweg 77a, A-6020 Innsbruck Austria
or FAX to +43-512-272708

NOTE: MED-EL recommends using a MRI only when other diagnostic procedures (i.e. CT, PET, etc.) are not applicable. To avoid the loss of warranty coverage, this form must be completed by the referring physician in cooperation with the respective radiology department and reviewed and approved by MED-EL PRIOR to performing the MRI examination. The guidelines outlined on this form must be explicitly followed. If assistance with this form is needed, please contact MED-EL @ +43-512-288889-100.

Patient Identification (name or other ID):	Implant Serial Number(s):	Date of Implantation (minimum 6 months ago):
Date of birth:	Left ear: Right ear:	Left ear: Right ear:

MRI Equipment Manufacturer:	Model Number/Serial Number:	Field Strength:	Exact Anatomical Location of Examination:

Clinician or Radiology Department Person who can be contacted by MED-EL: Name and position (Title): Telephone #: Fax #

Name of the Clinic / Radiology Department:

Address:

General Information:

A.) The following MRI Equipment may currently be used with MED-EL CI Patients (see Guidelines):

1.) 0.2 Tesla Extremity MR Systems.

2.) Open 0.2 Tesla devices.

3.) 1.0 and 1.5 Tesla devices.

4.) For other field strengths, contact MED-EL for consultation and alternatives.

B.) With spin echoes, signal voids are encountered within a radius of approximately 50mm around the implant. Geometrical distortions within a distance of 12cm are smaller than 1mm. Even when using gradient echoes, the contralateral side of the head can be displayed without artifacts.

C.) An important consideration concerns the torque acting on the magnet in the CI. In a magnetic field longitudinal to the body, this torque induces a force that tries to twist the implant against the skin. The magnitude of the torque is proportional to the magnetic field strength. For a 1.5 Tesla device, the torque corresponds to a maximum force of 9N (i.e. the force corresponds to the weight of a 0.9kg mass), which pulls on the edge of the implant. To exclude possible small amount of demagnetization of the CI-Magnet it may be considered to perform MRI at lower field strengths than 1.5 Tesla.

CAUTION! The CAUTIONS and GUIDELINES provided below are applicable regardless of the examined body part:

MRI DEVICES WITH FIELD STRENGTHS IN THE RANGE BETWEEN 0.2 AND 1.0 TESLAs SHALL NOT BE USED

(i.e. 0.2T < Prohibited Field Strength Range < 1.0T)! Their Larmor frequencies closely match the CI transmission frequency, which may permanently damage the implant during the examination.

GUIDELINES:

PREPARATION FOR THE MRI EXAMINATION:

1.) To ensure appropriate fixation of the CI, MED-EL recommends that you contact the implanting surgeon to obtain information concerning the bone bed and fixation of the CI (i.e. surgical suture material, bone pate', etc.).

2.) The bone layer under the CI should have a minimum thickness of approximately 0.4 mm. When there is any doubt about the bone thickness or in the case of children under the age of 12 years old, a CT should be performed to determine actual bone thickness.

3.) The prospective MRI Patient should have been implanted for a minimum of 6 months.

OVER

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GUIDELINES (cont'd):

THE MRI EXAMINATION:

A.) All external parts of the CI system must be removed. For an extremity MR System, the head must be a minimum of 10cm away from the MR magnet during the examination.

B.) For 1.0 and 1.5 Tesla MRI devices, a pressure bandage around the patient's head is required. MED-EL also recommends the use of a pressure bandage for 0.2 Tesla MRI devices. (See Figure 1 below)

C.) When using 1.0 and 1.5 Tesla MRI devices, the implant plane shall not deviate by more than 10° from the magnetic field direction in order to prevent excessive demagnetization of the CI magnet. Implant orientation can be estimated by placing the transmitter on the head outside the bore. The transmitter coil plane is then in parallel to the implant plane. Ideally, the magnetic field direction of the MRI device should be in parallel with the implant plane. Remove the transmitter before moving the patient into the bore.

D.) When using 0.2 Tesla MRI devices, the patient must be in a correctly oriented side position. The correct orientation is ascertained by holding the patient's transmitter in the static field of the MRI device and orienting it such that it does not "flip-over." The patient's orientation should be relative to this stable transmitter orientation. Remove the transmitter before performing the MRI examination. With the 0.2 Tesla Open device, sequences containing RF pulses with a Gaussian envelope (i.e. Fast Spin Echo (FSE)) must not be used.

Important: The correctly oriented side position is the only position where the implant is not subjected to torque or RF during the examination.

E.) Minimum RF Pulse Duration at 50% amplitude: sinc-envelope = 670µs (overall duration = 2560µs)

Gaussian envelope = 270µs

Important: With shorter pulse durations, the induced voltage in the receiver circuit may damage the implant.

F.) To prevent excessive heating of the CI during a MRI examination, avoid sequences with high SAR strain (e.g. Half Fourier RARE, or with short echo spacing (FSE), a high number of layers (SE, FSE), and/or a short Repetition Time TR (SE, FSE)). Never run sequences in the "first level operating mode."

Figure 1:

Supportive fixation of the implant by external bandages. A medium-hard piece of rubber or other suitable object (approximately 2 - 3cm thick) placed against the skin over the site of the CI may be used to maximize stability.

STATEMENT OF UNDERSTANDING:

This MRI examination approval is being requested by the undersigned with the understanding that all recommended guidelines from MED-EL will be followed during the performance of the MRI examination and that failure to comply with these recommendations may 1) adversely affect the Patient and/or MED-EL Cochlear Implant, and 2) void the warranty. In addition, the undersigned agrees to provide MED-EL with a copy of the scans for MRIs performed on the head of CI patients. This MRI examination will be conducted with the informed consent of the patient.

Physician's Name/Signature: _____ Date: _____

Radiologist or Other Name/Signature: _____ Date: _____

APPROVALS:

_____ Date: _____
MED-EL Technical Director

_____ Date: _____
MED-EL RA Manager/Safety Officer