

MED-EL Hearing Implants MRI Safety Status Overview







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Full MRI safety information is available in the MRI section of the Medical Procedures Manual for CI/ABI, the IFU for Vibrating Ossicular Prosthesis and Bone Conduction Implant or at www.medel.com/isi

| IMPLANT CATEGORY | PRODUCT | MRI STATUS | STATIC MAGNETIC FIELD | RF COIL | Maximum sar | PATIENT/HEAD POSITION | HEAD BANDAGE REQUIREMENT | MAGNET REMOVABLE (In order to reduce image artifacts) | OTHER ELIGIBILITY CRITERIA | |
|-----------------------------------|---|----------------|-----------------------------|---|---|---|--|--|---|--|
| COCHLEAR IMPLANTS | Mi1200 SYNCHRONY Mi1200 SYNCHRONY PIN Mi1210 SYNCHRONY ST Mi1250 SYNCHRONY 2 Mi1250 SYNCHRONY 2 PIN | MR Conditional | 0.2T 1.0T 1.5T | Transmit: No restrictions Receive: No restrictions | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | no specific orientation is required supine, prone or side position with the head kept straight (max. 30° head tilting to the side) | optional | yes | Before entering the scanner room, all external components of the implant system must be removed. | |
| | | | 3T | Transmit: Local head and multi-channel Body Coils must not be used. Receive: No restrictions | Normal Operating Mode Head SAR: 1.6W/kg Body SAR for locations <35 cm from the top of the head: 1.0W/kg Body SAR for loactions ≥35 cm from the top of the head: 2.0W/kg | supine, prone or side position with the head kept straight (max. 30° head tilting to the side) | | | Before entering the scanner room, all external components of the implant system must be removed. For head examinations and examinations of the body that are less than 35 cm 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. | |
| | | | 0.2T | | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | no specific orientation is required | no | | Before entering the scanner room, all external components of the implant system must be removed. | |
| | Mi1000 CONCERTO Mi1000 CONCERTO PIN SONATATI ¹⁰⁰ | MR Conditional | 1.0T 1.5T | Transmit: No restrictions Receive: No restrictions | | supine, prone or side position with the head kept straight | Elastic bandage wrapped around the head at least 3 times | und the | | www.medel.com/ isi-cochlear- implant-systems |
| | | | 0.2T | | | no specific orientation is required | no | | MRI scan not earlier than 6 months post implantation. | |
| | PULSARCI ¹⁰⁰ C40+ C40 | MR Conditional | 1.0T 1.5T | Transmit: No restrictions Receive: No restrictions | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | supine, prone or side position with the head kept straight | Elastic bandage wrapped around the head at least 3 times | no | Bone thickness underneath the implant at least 0.4 mm. The implant must not be mechanically damaged. Before patients enter any MRI room, all external components of the implant system must be removed. | |
| AUDITORY BRAINSTEM IMPLANTS | | ٨ | 0.2T | | Named Opension Made | no specific orientation is required | | | | |
| | Mi1200 SYNCHRONY ABI Mi1200 SYNCHRONY PIN ABI | MR Conditional | 1.0T 1.5T | Transmit: No restrictions Receive: No restrictions | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | supine, prone or side position with the head kept straight (max. 30° head tilting to the side) | no | yes | Before entering the scanner room, all external components of the implant system must be removed. | |
| | Mi1000 CONCERTO ABI Mi1000 CONCERTO PIN ABI | MR Conditional | 0.2T | | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | no specific orientation is required | no | no | Before entering the scanner room, all external components of the implant system must be removed. | |
| | | | 1.0T 1.5T | Transmit: No restrictions Receive: No restrictions | | supine, prone or side position with the head kept straight | Elastic bandage wrapped around the head at least 3 times | | | www.medel.com/ |
| | | | 0.2T | | | no specific orientation is required | no | | MRI scan not earlier than 6 months post implantation. | isi-cochlear- implant-systems |
| | PULSARCI ¹⁰⁰ ABI C40+ ABI | MR Conditional | 1.0T 1.5T | Transmit: No restrictions Receive: No restrictions | Normal Operating Mode (Head SAR: 3.2 W/kg, Body SAR: 2.0 W/kg) | supine, prone or side position with the head kept straight | Elastic bandage wrapped around the head at least 3 times | no | Bone thickness underneath the implant at least 0.4 mm. The implant must not be mechanically damaged. Before entering the scanner room, all external components of the implant system must be removed. | |
| MIDDLE EAR IMPLANTS | VIBRANT SOUNDBRIDGE Vibrating Ossicular Prosthesis (VORP 503) | MR Conditional | 1.5T closed-bore | Transmit: Local head and neck coils must not be used. Receive: No restrictions | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | straight head orientation | no | no | Before entering the scanner room, all external components of the implant system must be removed. | www.medel.com/ isi-vorp-503 |
| | VIBRANT SOUNDBRIDGE Vibrating Ossicular Prosthesis (VORP 502x) | MR Unsafe | n/a | n/a | n/a | n/a | n/a | n/a | Patients implanted with the VORP 502 should not be subjected to MRI, and should not enter an MRI Suite or come into close proximity to other sources of strong magnetic fields. | www.medel.com/ isi-vorp-502 |
| BONE CONDUCTION IMPLANTS | BONEBRIDGE Bone Conduction Implant (BCI 601) | MR Conditional | ≤1.5T | No restrictions | No restrictions | No restrictions | no | no | Before patients enter any MRI room, all external components of the implant system must be removed. | www.medel.com/ isi-bci-601 |
| | BONEBRIDGE Bone Conduction Implant (BCI 602) | MR Conditional | 1.5T closed-bore | No restrictions | Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg) | No restrictions | no | no | Before patients enter any MRI room, all external components of the implant system must be removed. | ww.medel.com/ |