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MRI Safety Information

for the HiRes™ Ultra 3D Cochlear Implant

Labeling symbols and their meanings:

	The external components of the HiResolution™ Bionic Ear System are MR Unsafe and must be removed before entering a room containing an MRI scanner.
	The implant components of the HiRes™ Ultra 3D cochlear implant are MR conditional.

The HiRes Ultra 3D cochlear implants have a specifically designed magnet that allows safe MRI scanning with the magnet in place, without angular restrictions of the head, surgical removal of the magnet or a bandaging protocol.

MRI Warnings

Do not allow patients with a HiRes cochlear implant to be in the area of an MRI scanner unless the following conditions have been met:

- The external sound processor and headpiece must be removed before entering a room containing an MRI scanner.
- Verify that the implant, or both implants if bilaterally implanted, are compatible for conducting an MRI before proceeding. Failure to do so can lead to device movement, device damage, magnet movement, patient discomfort, or trauma and pain to the patient.

NOTE: MRI procedures are contraindicated for CLARION (C1 and CII) cochlear implant recipients. For information regarding MRI use with HiRes 90K, HiRes 90K Advantage, and HiRes Ultra cochlear implants, please contact Advanced Bionics Technical Support.

NOTE: MRI safety was evaluated only for the HiRes Ultra 3D. Interactions between non-Advanced Bionics implants and the HiRes Ultra 3D during MRI are unknown.

- The recommended minimum duration of time post implant surgery prior to undergoing an MRI scan is 2 to 4 weeks in order to allow any inflammation to subside.
- An MRI scan is not recommended if the patient has a fever.

Caution:

- During the MRI procedure, you may experience pain, pressure, or discomfort. If this occurs, please notify your physician.
- Please consult with your physician prior to an MRI to determine if the benefits of an MRI are worthwhile over other imaging techniques.



MRI Safety Information:

Testing has demonstrated that the HiRes Ultra 3D cochlear implant is MR Conditional. Unilateral and bilateral recipients

with this device with magnet in place can be safely scanned in a horizontal closed bore quadrature coil MR system meeting the following conditions:

MRI Field Strength	1.5T	3.0T
Maximum Spatial Field Gradient	20 T/m	
RMS Gradient Field	34.4 T/s	
Peak Slew Rate	200 T/m/s	
Maximum whole body averaged SAR	2.0 W/kg	2.0 W/kg
Maximum head averaged SAR	3.2 W/kg	2.6 W/kg

When tested under scan conditions defined above, the HiRes Ultra 3D cochlear implant produced a maximum temperature rise of $<3^{\circ}\text{C}$ after 15 minutes of continuous scanning.

NOTE: During the scan, patients might perceive auditory sensations. Adequate counseling of the patient is advised prior to performing the MRI. The likelihood and intensity of the auditory sensations can be reduced by selecting sequences with a lower Specific Absorption Rate (SAR) and slower gradient slew rates.

NOTE: For cases that would clinically benefit from reduced device artifact (for example, some head or neck scans), the internal magnet is surgically removed and possibly replaced with a Temporary Non-Magnetic Plug before the recipient undergoes an MRI procedure. The HiRes Ultra 3D cochlear implant can withstand 5 replacement cycles.

In MRI testing, the measured range of device image artifact radius extending from the HiRes Ultra 3D cochlear implant for spin and gradient echo sequences and all imaging planes are provided in Table A and Table B.

Table A: Artifact at 3.0T MRI Field Strength

Implanted	Magnet	Artifact Range
Unilaterally	In Place	5.5 - 6.9 cm
	Removed	1.4 - 4.2 cm
Bilaterally	In Place	6.1 - 7.4 cm
	Removed	1.9 - 6.9 cm

Table B: Artifact at 1.5T MRI Field Strength

Implanted	Magnet	Artifact Range
Unilaterally	In Place	4.1 - 6.5 cm
	Removed	2.4 - 3.2 cm
Bilaterally	In Place	5.7 - 8.2 cm
	Removed	3.4 - 4.1 cm

For additional information regarding the use of an MRI scanner with a HiRes Ultra 3D cochlear implant, please contact Advanced Bionics Technical Support at technical-services@advancedbionics.com or visit www.advancedbionics.com/mri.