# MED-EL Hearing Implants MRI Safety Status Overview



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## MED-EL Hearing Implants MRI Safety Status Overview

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)
COCHLEAR IMPLANTS	Mi1200 SYNCHRONY Mi1200 SYNCHRONY PIN Mi1210 SYNCHRONY ST Mi1250 SYNCHRONY 2 Mi1250 SYNCHRONY 2 PIN	MR Conditional	0.2T	Transmit: No restrictions Receive: No restrictions	Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg)	no specific orientation is required	optional	yes
			1.0T 1.5T			supine, prone or side position with the head kept straight (max. 30° head tilting to the side)		
			ЗT	Transmit: Local head and multi-channel Body Coils must not be used. Receive: No restrictions	Normal Operating Mode Head SAR: 1.6 W/kg Body SAR for locations <35 cm from the top of the head: 1.0 W/kg Body SAR for loactions ≥35 cm from the top of the head: 2.0 W/kg	supine, prone or side position with the head kept straight (max. 30° head tilting to the side)		
		MR Conditional	0.2T	Transmit: No restrictions Receive: No restrictions	Normal Operating Mode (Head SAR: 3.2 W/kg, Body SAR: 2.0 W/kg)	no specific orientation is required	no	
	Mi1000 CONCERTO PIN SONATATI <sup>100</sup>		1.0T 1.5T			supine, prone or side position with the head kept straight	Elastic bandage wrapped around the head at least 3 times	no
	PULSARci <sup>100</sup> C40+ C40	MR Conditional	0.2T	Transmit: No restrictions Receive: No restrictions	Normal Operating Mode (Head SAR: 3.2 W/kg, Body SAR: 2.0 W/kg)	no specific orientation is required	no	
			1.0T 1.5T			supine, prone or side position with the head kept straight	Elastic bandage wrapped around the head at least 3 times	no
AUDITORY BRAINSTEM IMPLANTS	Mi1200 SYNCHRONY ABI Mi1200 SYNCHRONY PIN ABI	MR Conditional	0.2T	Transmit: No restrictions Receive: No restrictions	Normal Operating Mode (Head SAR: 3.2 W/kg, Body SAR: 2.0 W/kg)	no specific orientation is required		
			1.0T 1.5T			supine, prone or side position with the head kept straight (max. 30° head tilting to the side)	no	yes
	Mi1000 CONCERTO ABI Mi1000 CONCERTO PIN ABI	MR Conditional	0.2T	Transmit: No restrictions Receive: No restrictions	Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg)	no specific orientation is required	no	no
			1.0T 1.5T			supine, prone or side position with the head kept straight	Elastic bandage wrapped around the head at least 3 times	
		SARci <sup>100</sup> ABI + ABI MR Conditional	0.2T	Transmit: No restrictions Receive: No restrictions	Normal Operating Mode (Head SAR: 3.2W/kg, Body SAR: 2.0W/kg)	no specific orientation is required	no	
	PULSARci <sup>100</sup> ABI C40+ ABI		1.0T 1.5T			supine, prone or side position with the head kept straight	Elastic bandage wrapped around the head at least 3 times	no
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: 3.2 W/kg, Body SAR: 2.0 W/kg)	straight head orientation	no	no
	VIBRANT SOUNDBRIDGE Vibrating Ossicular Prosthesis (VORP 502x)	MR Unsafe	n/a	n/a	n/a	n/a	n/a	n/a
BONE CONDUCTION IMPLANTS	BONEBRIDGE Bone Conduction Implant (BCI 601)	MR Conditional	<u>≤</u> 1.5T	No restrictions	No restrictions	No restrictions	no	no

Valid for MRI scans of all body regions.

Verify the implant variant/model via the patient ID/user ID card or contact the implanting clinic.

Some implant models may not be released for distribution in all countries.

Please contact your local MED-EL representative for information on current product availability in your country.

## MED<sup>®</sup>EL

### OTHER ELIGIBILITY CRITERIA

Before entering the scanner room, all external components of the implant system must be removed.

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.

Before entering the scanner room, all external components of the implant system must be removed.

MRI scan not earlier than 6 months post implantation. 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.

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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.

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www.medel.com/ isi-cochlearimplant-systems



www.medel.com isi-vorp-503



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