

MRI Safety Information

MR Conditional	
	Non-clinical testing has demonstrated that implants of the type Upper Eyelid Implant are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury.
Product name	Upper Eyelid Implant
REF	4007 002 – 4007 010
Manufacturer	HEINZ KURZ GMBH TUEBINGER STR. 3 D—72144 DUSSLINGEN Deutschland https://www.kurzmed.com mailto:info@kurzmed.de
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Location of MRI safety information	www.kurzmed.com/de/mr-information.html

Parameter	Notes
Static Magnetic Field Strength (B_0)	1.5 T / 3.0 T / 7.0 T
Maximum Spatial Field Gradient	40 T/m (4000 gauss/cm)
RF Transmit Coil Type	Any RF transmit coil may be used.
RF Receive Coil Type	Any receive RF coil can be used.
Maximum Whole-Body SAR or Head-SAR (specific absorption rate) Extrapolation to head coil; body coil was only used for testing as a worst-case assumption	1,5 T: < 0.9 W/kg (Device-Specific RF Operating Conditions) 3 T: < 1.0 W/kg (Device-Specific RF Operating Conditions) 7 T: ≤ 2 W/kg (Normal Operating Mode) No in vitro in vivo translation has been performed, therefore in vitro measurement results are considered only.
Scan Duration	Maximum continuous scan duration of 15 min
MR Image Artefact	MR image quality is compromised if the area of interest is in the same or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

