

Information about MR compatibility of middle ear implants, stapes prostheses and ventilation tubes of SPIGGLE & THEIS Medizintechnik GmbH

Non-clinical testing has demonstrated that middle ear implants, stapes prostheses and ventilation tubes are MR conditional.



MR Conditional

A patient with this device can be safely scanned in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and **3 Tesla**, with
- Maximum spatial field gradient of 10,300 Gauss/cm (103 T/m)
- **Maximum force product of 185,000,000 G²/cm (185 T²/m)**
- Maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)

Physical testing of RF-induced heating has not been performed, since implant sizes are smaller than 2 cm and no other implants are used within a radius of 3 cm.

In non-clinical testing, the image artifact caused by the device extends approximately 8.61 mm from the “ventilation tube” when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.



Ventilation tubes with wire do not fall under the above criteria and are not suitable for MR examination.

We are happy to answer your individual questions regarding the MR compatibility of middle ear implants, stapes prostheses and ventilation tubes.

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REF article list MR compatibility:

	Middle ear implants made of Titanium					
	11100	11845	11942	12705	12805	12905
	11200	11847	11945	12710	12810	12910
	11300	11850	11947	12712	12812	12912
	11400	11855	11950	12715	12815	12915
	11500	11860	11955	12717	12817	12917
	11600	11865	11960	12720	12820	12920
	11830	11870	11965	12722	12822	12922
	11835	11930	11970	12725	12825	12925
	11840	11935	12100	12730	12830	12930
	11842	11940	12200	12735	12835	12935
	10000TP					
	Stapes prostheses made of Platinum/PTFE, Titanium, Nitinol/PTFE					
	10540425	10560475	10660425	10740450L	10740600M	10760450S
	10540450	10560600	10660450	10740450M	10740600S	10760475L
	10540475	10560900	10660475	10740450S	10760425L	10760475M
	10540600	10640425	10660700	10740475L	10760425M	10760475S
	10540900	10640450	10740425L	10740475M	10760425S	10760600L
	10560425	10640475	10740425M	10740475S	10760450L	10760600M
	10560450	10640700	10740425S	10740600L	10760450M	10760600S
	Ventilation tubes made of Titanium (without wire)					
	10076	10125	10125SC	101100		
	10100	10150		101125		
		Ventilation tubes with wire				
10100F		10125F	104100F	104150F		
101100F		10150F	104115F	104514F		
101125F			104125F			
	Ventilation tubes made of Silicone (without wire)					
	103000	103100	103200	103310		
	103010	103150	103300	103400		
	Ventilation tubes made of PTFE (without wire)					
	104100	104125	104200	104311		
	104115	104150	104210	104414		