

## Information about MRI-Safety of SPIGGLE & THEIS-Implants

To guarantee safety to both patients and users regarding the behaviour of implants during MRI examinations, the Spiggle & Theis GmbH implants have been clinically tested <sup>(1)</sup> and evaluated. It can be concluded that the tested implants showed no measurable degree of warming under the magnetic strengths of 1.5 and 3.0 TF. Furthermore, the results proved that dislocation could not be expected where the implants had been suitably operatively secured.

As the majority of clinical issues can be resolved by the MRI imaging with 1.5 TF scanners, and the effective forces measurably stronger at 3.0 TF, the indications of a test using 3.0 TF should be strictly scrutinised due to the anatomically sensitive nature of the inner ear. In extreme cases it is advisable, from a radiological standing and for forensic reasons, to perform a computer tomography in advance in order to be able to rule out primary dislocation of the implant.

From the Spiggle & Theis GmbH perspective, it is not possible to grant a cross-the-board release for field strengths and the implants where we are first marketer regarding MRI examinations. This is due to the evolutionary development of the implant materials used, which correlate to the corresponding technological developments. We are however, happy to answer your individual questions concerning the MRI suitability of a specific implant.

<sup>(1)</sup> Verhalten von Titan-Mittelohrimplantaten bei 1,5 und 3 Tesla Feldstärke in der Magnetresonanztomographie

HC Bauknecht, C Jach, L Krug, T Schrom  
2008

<sup>(1)</sup>

Das Verhalten metallischer Mittelohrimplantate im Magnetfeld eines 7 Tesla starken Kernspintomographen\*

O. Schumacher, O. Michel  
2008

<sup>(1)</sup>

Wie verhalten sich metallhaltige Mittelohrimplantate in der Kernspintomographie?\*

How Do Metallic Middle Ear Implants Behave in the MRI?\*

P. Kwok, A. Waldeck, J. Strutz  
Laryngorhinootologie, 2003 Jan; 82 (1): 13-8

<sup>(1)</sup>

Einfluss der Magnetresonanztomographie auf Oberlidimplantate\*

Effects of magnetic resonance imaging fields on upper eyelid implants\*

T. Schrom, H. Bauknecht, A. Berghaus, H. Scherer  
HNO, 2005 Jan; 53: 741-746

\*On request we are sending these publications / documents – please contact our quality management.