

## 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 G<sup>2</sup>/cm (185 T<sup>2</sup>/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    |           |           |
|                                                                                     |                                                                                     |                             |           |           |           |           |