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MR Information

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Dear Medical Professional:

Heinz Kurz GmbH manufactures implants for surgeons specializing in rhinology and laryngology. These are designed for permanent implantation in the patient.

Examinations with magnetic resonance imaging (MRI) techniques are employed increasingly for all types of diagnostic purposes. Potential hazards that MR imaging may have as a result of the implant included magnetic field interactions, heating, induced electrical currents, and possible artefacts.

**The MR Labeling information is based on rationale
and worst case analysis for every product group.**

For further information please contact,

Heinz Kurz GmbH

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GENERAL INFORMATION

Currently all available

- **Implants for Rhinology and Laryngology**

manufactured by Heinz Kurz GmbH are



MR Conditional.

MR Conditional means that non-clinical testing has demonstrated that the implant can be scanned safely under specific conditions. **Scanning under different conditions may result in severe patient injury.** Details on the MR conditions for each Implant are given on the following pages.

For details on MRI settings for each product please see the following pages.

Information for all products, listed by Reference Number and Product Name, is available on the following pages.

The MR information on the following pages is based on rationale and worst-case analysis for every product group. The MR information cannot be transferred to other products that are not listed in this document. If the REF number of the products is unknown or unclear do not perform a MR scan.



Section 1.1 MRI Safety Information Rhinology

Non-clinical testing has demonstrated that the products listed below are MR Conditional. A patient with these devices can be safely scanned in an MR system under the conditions specified below. Failure to follow these conditions may result in injury.

REF Number	Brand Name	Material
6002011 - 6002016	Breathe Implant àWengen	Pure Titanium
6002022	Dilatator Brusis	Pure Titanium

Not all products might be available in all countries.

The following MRI conditions apply:

- **Static magnetic field:** 1.5 T, 3.0 T, or 7.0 T
- **Maximum spatial field gradient:** 4,000 Gauss/cm (40 T/m)
- **RF transmit coil:** Any transmit RF coil may be used.
- **RF receive coil:** Any receive RF coil may be used.
- **Operating mode:** Normal Operating Mode and Device-Specific RF Operating Conditions
- **Maximum whole-body or head-averaged* SAR:**
 - **1.5 T:** < 1.1 W/kg (Device-Specific RF Operating Conditions)
 - **3.0 T:** < 1.0 W/kg (Device-Specific RF Operating Conditions)
 - **7.0 T:** ≤ 2 W/kg (Normal Operating Mode)**
- **Scan duration:** Maximum continuous scan duration of **15 minutes**

MR image quality is compromised if the area of interest is in the same area 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.

* Extrapolation to head coil; body coil only was used for testing as a worst-case assumption.

** No in vitro–in vivo translation has been performed; therefore, in vitro measurement results are considered only.

Section 1.2 – Additional MRI Safety Instructions

- **The body coil was used for testing as a worst-case assumption.**
- **Any transmit RF coil and any receive RF coil may be used, provided that the MRI conditions specified in Section 1.1 are met.**



Section 2.1 MRI Safety Information Laryngology

Non-clinical testing has demonstrated that the products listed below are MR Conditional. A patient with these devices can be safely scanned in an MR system under the conditions specified below. Failure to follow these conditions may result in injury.

REF Number	Brand Name	Material
5001000 - 5001003	TVFMI	Pure Titanium
5002010 - 5002014	Trachea Support Ring	Pure Titanium

Not all products might be available in all countries.

The following MRI conditions apply:

- **Static magnetic field:** 1.5 T, 3.0 T, or 7.0 T
- **Maximum spatial field gradient:** 4,000 Gauss/cm (40 T/m)
- **RF transmit coil:** Any transmit RF coil may be used.
- **RF receive coil:** Any receive RF coil may be used.
- **Operating mode:** Normal Operating Mode and Device-Specific RF Operating Conditions
- **Maximum whole-body or head-averaged* SAR:**
 - **1.5 T:** < 0.8 W/kg (Device-Specific RF Operating Conditions)
 - **3.0 T:** < 0.7 W/kg (Device-Specific RF Operating Conditions)
 - **7.0 T:** ≤ 2 W/kg (Normal Operating Mode)**
- **Scan duration:** Maximum continuous scan duration of **15 minutes**

MR image quality is compromised if the area of interest is in the same area 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.

* Extrapolation to head coil; body coil only was used for testing as a worst-case assumption.

** No in vitro–in vivo translation has been performed; therefore, in vitro measurement results are considered only.

Section 2.2 – Additional MRI Safety Instructions

- **The body coil was used for testing as a worst-case assumption.**
- **Any transmit RF coil and any receive RF coil may be used, provided that the MRI conditions specified in Section 2.1 are met.**