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MR Information

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Dear Medical Professional:

Heinz Kurz GmbH Medizintechnik manufactures implants for surgeons specializing in otorhinolaryngology. 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 Medizintechnik

Regulatory Affairs

CTO

GENERAL INFORMATION

Currently all available

- **Passive Middle Ear Implants for Tympanoplasty and Stapedioplasty**
- **Implants for Rhinology, Ophthalmology 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.

A safe MR scan is **not possible for all Ventilation tubes**.
There are some Ventilation Tubes which are

MR UNSAFE others are

MR Conditional.

Please make sure in case of MR scanning with Ventilation Tubes that the complete information about the implant is available. If the Reference Number (REF Number) of the Ventilation Tube is unknown or unclear, **do not perform a MR scan.**

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 Tympanoplasty

Non-clinical testing has demonstrated the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

REF Number	Brand Name	Material
1002020 / 1002010	TTP VARIAC / VARIO System Partial	Pure Titanium
1002023 – 1002033	Duesseldorf Type Bell	Pure Titanium
1002073 – 1002080	München^{LMU} Bell Partial Prothesis	Pure Titanium
1002223 – 1002230	TTP Tuebingen Type Bell	Pure Titanium
1002250 – 1002257	CliP Partial Prosthesis	Pure Titanium
1002350 – 1002357	CliP Partial FlexiBAL	Pure Titanium
1002423 – 1002430	Malleus Notch Prosthesis (MNP) Partial	Pure Titanium
1002473 – 1002480	Bell Partial Vincent	Pure Titanium
1002610 / 1002612	Angular Prosthesis	Pure Titanium
1002615 / 1002617	Angular CliP Prosthesis	Pure Titanium
1002620	Incus Bridge Prosthesis (IBP)	Pure Titanium
1004020 / 1004010	TTP VARIAC / VARIO System Total	Pure Titanium
1004034 – 1004049	Duesseldorf Type Aerial	Pure Titanium
1004074 – 1004089	München^{LMU} Aerial Total Prothesis	Pure Titanium
1004234 – 1004249	TTP Tuebingen Type Aerial	Pure Titanium
1004434 – 1004449	Malleus Notch Prosthesis (MNP) Total	Pure Titanium
1004458 – 1004462	Regensburg Type Prosthesis	Pure Titanium
1004478 – 1004494	Aerial Total Vincent	Pure Titanium
1004930 / 1004975	Ω Connector / Spider	Pure Titanium

Not all products might be available in all countries.

- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified in Section 1.2.

Under the scan conditions defined above, the Tympanoplasty Prostheses listed in the table above are expected to produce a maximum temperature rise of 2.8°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 6 mm from the Tympanoplasty Prosthesis when imaged with a gradient echo pulse sequence and a 7.0 tesla MRI system.

Section 1.2. – Additional MRI Safety Instructions

- Body coil only was used for testing as a worst-case assumption.

Section 2.1 MRI Safety Information Stapedioplasty

Non-clinical testing has demonstrated the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

REF Nummer	Artikel	Material
1006003 - 1006051	Matrix Stapes Prosthesis	Pure Titanium
1006053 - 1006081	Skarzynski Stapes Prosthesis	Pure Titanium
1006263 - 1006291	MatriX SlimLine Stapes Prosthesis	Pure Titanium
1006103 - 1006120; 1006153 - 1006170	K-Piston Stapes Prosthesis	Pure Titanium
1006203 - 1006211; 1006253 - 1006261	Soft-CliP Stapes Prosthesis	Pure Titanium
1006523 - 1006529	LCP Stapes Prosthesis	Pure Titanium
1006543 - 1006565	Bucket Type Stapes Prosthesis	Pure Titanium
1006600 - 1006602; 1006650 - 1006652	Angular Piston Stapes Prosthesis	Pure Titanium
1006708 - 1006713; 1006758 - 1006763	CliP-Piston MVP Stapes Prosthesis	Pure Titanium
1006803 - 1006811; 1006853 - 1006861	CliP-Piston àWengen Stapes Prosthesis	Pure Titanium
1006960	MRP Stapes Prosthesis	Pure Titanium
1007103 - 1007111; 1007153 - 1007161	NiTiBOND Stapes Prosthesis	PureTitanium / Nitinol
1007203 - 1007211; 1007253 - 1007261	NiTiFLEX Stapes Prosthesis	PureTitanium / Nitinol

Not all products might be available in all countries.

- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified in Section 2.2

Under the scan conditions defined above, the Stapedioplasty Prostheses listed in the table above are expected to produce a maximum temperature rise of 2.9°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Stapedioplasty Prosthesis when imaged with a gradient echo pulse sequence and a 7.0 tesla MRI system.

Section 2.2. – Additional MRI Safety Instructions

- Body coil only was used for testing as a worst-case assumption.

Section 3.1 MRI Safety Information Ventilation Tubes 1

MR UNSAFE

Following products are MR UNSAFE:

REF Number	Brand Name	Material
1015002/ 1015004	Tuebingen Type Ventilation Tubes with wire	Gold-Platinum / Stainless Steel
1015011/ 1015013	Tuebingen Type Ventilation Tubes with wire	Gilded Silver / Stainless Steel
1015031/ 1015033	Tuebingen Type Ventilation Tubes with wire	Pure Titanium / Stainless Steel
1015072	Minimal Type Ventilation Tube	Gold coated Stainless Steel

Not all products might be available in all countries.

Do not perform a MR scan with these implants.

Section 4.1 MRI Safety Information Ventilation Tubes 2

Non-clinical testing has demonstrated the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

REF Number	Brand Name	Material
1015001 / 1015003	Tuebingen Type Ventilation Tubes	Gold-Platinum
1015010 / 1015012	Tuebingen Type Ventilation Tubes	Gilded Silver
1015020 / 1015022	Tuebingen Type Ventilation Tubes	Titanium coated
1015030 / 1015032 / 1015036	Tuebingen Type Ventilation Tubes	Pure Titanium
1015051 / 1015053 / 1015055	Beveled Type Ventilation Tubes	Gold-Platinum
1015064 / 1015065	Ventilation Tubes Long Term	Gold-Platinum
1015074	Trocar Ventilation Tubes (TVT)	Gilded Silver
1015075	Trocar Ventilation Tubes (TVT)	Pure Titanium

Not all products might be available in all countries.

- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified in Section 4.2

Under the scan conditions defined above, the Ventilation Tubes listed in the table above are expected to produce a maximum temperature rise of 2.6°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the Ventilation Tube when imaged with a gradient echo pulse sequence and a 7.0 tesla MRI system.

Section 4.2 – Additional MRI Safety Instructions

- Body coil only was used for testing as a worst-case assumption.

Section 5.1 MRI Safety Information Rhinology

Non-clinical testing has demonstrated the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

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.

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- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified in Section 5.2

Under the scan conditions defined above, the Implants listed in the table above are expected to produce a maximum temperature rise of 3.4°C after 15 minutes of continuous scanning.

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

Section 5.2 – Additional MRI Safety Instructions

- Body coil only was used for testing as a worst-case assumption.

Section 6.1 MRI Safety Information Laryngology

Non-clinical testing has demonstrated the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

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.

- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 3500 Gauss/cm (35 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified in Section 6.2

Under the scan conditions defined above, the implants listed in the table above are expected to produce a maximum temperature rise of 4.2°C after 15 minutes of continuous scanning.

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

Section 6.2 – Additional MRI Safety Instructions

- Body coil only was used for testing as a worst-case assumption.

7.1 MRI Safety Information Ophthalmology

Non-clinical testing has demonstrated that the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

REF Number	Brand Name	Material
4001002 - 4001010	Upper Eyelid Implant	Gold
4007002 - 4007010	Upper Eyelid Implant	Platin-Iridium

Not all products might be available in all countries.

- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 10000 Gauss/cm (100 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified in Section 7.2

Under the scan conditions defined above, the implants listed in the table above are expected to produce a maximum temperature rise of 3.3°C after 15 minutes of continuous scanning.

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

Section 7.2 – Additional MRI Safety Instructions

- Body coil only was used for testing as a worst-case assumption.