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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 / Quality Assurance

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# Tympanoplasty

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Tympanoplasty Prostheses are MR Conditional.

REF Number	Brand Name	Material
1002020 / 1002010	TTP VARIAC / VARIO System Partial	Pure Titanium
1002023 - 1002033	Duesseldorf Type Bell	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
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
1004234 - 1004249	TTP Tuebingen Type Aerial	Pure Titanium
1004434 - 1004449	Malleus Notch Prosthesis (MNP) Total	Pure Titanium
1004458 - 1004462	Regensburg Type Prosthesis	Pure Titanium
1004930 / 1004975	Ω Connector / Spider	Pure Titanium

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)

for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing the worst case Prosthesis produced a temperature rise of less than 2.2°C (with a background temperature increase of ≈ 1.7°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case Prosthesis produced a temperature rise of less than 3.5°C (with a background temperature increase of ≈ 3.2°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case Prosthesis produced a temperature rise of less than 0.3°C (with a background temperature increase of ≈ 0.3°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.

# Stapedioplasty

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Stapedioplasty Prostheses are MR Conditional.

REF Number	Brand Name	Material
1006103 - 1006112; 1006153 - 1006162	K-Piston Stapes Prosthesis	Pure Titanium
1006203 - 1006211; 1006253 - 1006261	Soft CliP Prosthesis	Pure Titanium
1006523 - 1006529	Lenticle Cup Prosthesis	Pure Titanium
1006600 - 1006602; 1006650 - 1006652	Angular Piston Prosthesis	Pure Titanium
1006708 - 1006713; 1006758 - 1006763	CliP Piston MVP	Pure Titanium
1006803 - 1006811; 1006853 - 1006861	CliP Piston àWengen	Pure Titanium
1006960	Malleus Replacement Prosthesis (MRP)	Pure Titanium
1007103 - 1007111; 1007153 - 1007161	NiTiBOND Stapes Prosthesis	Pure Titanium / Nitinol

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)
 for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing the worst case Prosthesis produced a temperature rise of less than 2.2°C (with a background temperature increase of  $\approx$  2.0°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case Prosthesis produced a temperature rise of less than 3.6°C (with a background temperature increase of  $\approx$  3.2°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case Prosthesis produced a temperature rise of less than 0.4°C (with a background temperature increase of  $\approx$  0.4°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.

# Ventilation Tubes 1

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Ventilation Tubes are MR Conditional.

REF Number	Brand Name	Material
1015020 / 1015022	Tuebingen Type Ventilation Tubes	Titanium coated
1015030 / 1015032 / 1015036	Tuebingen Type Ventilation Tubes	Pure Titanium
1015075	Trocar Ventilation Tubes (TVT)	Pure Titanium

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing of the worst case object produced a temperature rise of less than 2.0°C (with a background temperature increase of  $\approx$  1.7°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 3.2°C (with a background temperature increase of  $\approx$  3.2°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 0.3°C (with a background temperature increase of  $\approx$  0.3°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.

# Ventilation Tubes 2

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Ventilation Tubes are MR Conditional.

REF Number	Brand Name	Material
1015001 / 1015003	Tuebingen Type Ventilation Tubes	Gold-Platinum
1015010 / 1015012	Tuebingen Type Ventilation Tubes	Gilded Silver
1015051 / 1015053 / 1015055	Beveled Type Ventilation Tubes	Gold-Platinum
1015064 / 1015065	Ventilation Tubes Long Term	Gold-Platinum
1015074	Trocar Ventilation Tubes (TVT)	Gilded Silver

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing the worst case object produced a temperature rise of less than 2.0°C (with a background temperature increase of  $\approx$  1.7°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 3.2°C (with a background temperature increase of  $\approx$  3.2°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 0.3°C (with a background temperature increase of  $\approx$  0.3°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.

## Ventilation Tubes 3



**MR unsafe**

**Following products are MR unsafe:**

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

# Rhinology

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Ventilation Tubes are MR Conditional.

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

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing the worst case object produced a temperature rise of less than 2.4°C (with a background temperature increase of  $\approx$  2.0°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 4.3°C (with a background temperature increase of  $\approx$  2.9°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 1.1°C (with a background temperature increase of  $\approx$  0.4°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.

# Laryngology

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Ventilation Tubes are MR Conditional.

REF Number	Brand Name	Material
5001000 - 5001003	TVFMI	Pure Titanium
5002010 - 5002014	Trachea support ring	Pure Titanium

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing the worst case object produced a temperature rise of less than 2.4°C (with a background temperature increase of  $\approx$  2.0°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 5.3°C (with a background temperature increase of  $\approx$  2.9°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 1.4°C (with a background temperature increase of  $\approx$  0.4°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.

# Ophthalmology

For estimated WBA SAR extrapolation a temperature increase limit of 2°C was used



MR Conditional

Based on rationale and worst case analysis about the static magnetic field, the spatial gradient magnetic field and RF heating, following Ventilation Tubes are MR Conditional.

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

It can be scanned safely under the following conditions:

- static magnetic field of 7 Tesla or less with
- spatial gradient field of 45 T/m and less (4500 G/cm) (value extrapolated)
- maximum whole body or head<sup>1</sup> averaged specific absorption rate (SAR) of
  - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head<sup>1</sup> coil)
  - < 2.0\* W/kg (7.0 T; transmit / receive Head coil)for 15 minutes of continuous scanning.

(These SAR data are based on rationale and worst case analysis).

\*Recommendation: limit of normal operating mode

<sup>1</sup>Extrapolation to head coil; body coil (1.5T / 3.0T; transmit / receive Body coil) only was used for testing as a worst-case assumption.

The following MR Labeling information about RF heating are based on rationale and worst case analysis.

In non-clinical testing the worst case object produced a temperature rise of less than 2.4°C (with a background temperature increase of  $\approx$  2.0°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 1.5 Tesla Intera Philips Medical Systems (Software: Release 10.6.2.5, 2006-03-10) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 4.1°C (with a background temperature increase of  $\approx$  2.9°C) at a maximum whole body averaged specific absorption rate (SAR) of 2.5 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 3 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR A30) MR Scanner.

In non-clinical testing the worst case object produced a temperature rise of less than 0.5°C (with a background temperature increase of  $\approx$  0.4°C) at a maximum head averaged specific absorption rate (SAR) of 2.1 W/kg assessed by calorimetry for 15 min. of continuous MR scanning in a 7 Tesla Magnetom Trio Siemens Medical Solutions (Software: Numaris/4, syngo MR B15) MR Scanner.

No other RF heating testing than 1.5, 3 and 7 Tesla only was performed.

General notice: The whole body or head averaged SAR is inappropriate to scale exact local temperature increases. Local SAR can deviate and result in much higher values than the WBA-SAR software displayed.

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.