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**MR Information**Date: 2011 May 02nd**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 implants 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 | CIiP Partial Prosthesis | Pure Titanium |
| 1002350 - 1002357 | CIiP Partial FlexiBAL | Pure Titanium |
| 1002423 - 1002430 | Malleus Notch Prosthesis (MNP) Partial | Pure Titanium |
| 1002610 / 1002612 | Angular Prosthesis | Pure Titanium |
| 1002615 / 1002617 | Angular CIiP 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 head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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 2.2°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 object 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 object 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 implants are MR Conditional.

| REF Number | Brand Name | Material |
|--------------------------------------|--------------------------------------|-------------------------|
| 1006103 - 1006120; 1006153 - 1006170 | 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 head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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 2.2°C (with a background temperature increase of ≈ 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 3.6°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 object produced a temperature rise of less than 0.4°C (with a background temperature increase of ≈ 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 implants 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 head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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 implants 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 59 T/m and less (5900 G/cm) (value extrapolated)
- maximum whole body or head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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 ≈ 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 ≈ 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 ≈ 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:

| 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 |

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 implants 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 46 T/m and less (4600 G/cm) (value extrapolated)
- maximum whole body or head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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 implants 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 55 T/m and less (5500 G/cm) (value extrapolated)
- maximum whole body or head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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 implants 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 59 T/m and less (5900 G/cm) (value extrapolated)
- maximum whole body or head¹ averaged specific absorption rate (SAR) of
 - < 2.0 W/kg (1.5 T; transmit / receive Body coil; transmit / receive Head¹ coil)
 - < 1.4 W/kg (3.0 T; transmit / receive Body coil; transmit / receive Head¹ 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

¹Extrapolation 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.