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
The NiTiBOND Stapes Prosthesis manufactured by Heinz Kurz GmbH is 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 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 NiTiBOND

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.

<table>
<thead>
<tr>
<th>REF Number</th>
<th>Brand Name</th>
<th>Material</th>
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<tbody>
<tr>
<td>1007103 - 1007111;</td>
<td>NiTiBOND Stapes Prosthesis</td>
<td>Pure Titanium / Nitinol</td>
</tr>
<tr>
<td>1007153 - 1007161</td>
<td></td>
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</tbody>
</table>

- 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 NiTiBOND Stapes 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 NiTiBOND Stapes 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.