**Instructions for Use**
0006225_Rev04 — 2026-04
EN

# Stapes prosthesis

## Heat-reactive Stapes Prostheses and Accessories

## NiTiBOND

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45035997128688011 —20.04.2026 15:42

## Table of Contents

## 1 About this Document

### 1.1 Symbols Glossary

| Symbol | Description |
|---|---|
|  | Caution: Consult Instructions for Use |
|  | Caution! |
|  | Fragile; handle with care |
|  | Do not use if package is damaged |
|  | Keep away from direct sunlight |
|  | Keep dry |
|  | Use-by date |
|   | Sterilized using irradiation |
|  | Do not reuse |
|  | Do not resterilize |
|  | Single sterile barrier system |
|  | Single sterile barrier system with protective packaging inside |
|  | Single sterile barrier system with protective packaging outside |
|   | MR conditional |
|   | Medical device |
|   | Catalog number |
|   | Batch code |
|   | Unique Device Identification (UDI) |
|   | Quantity per packaging unit |
|  | Manufacturer |
|  | Date of manufacture |
|   | (USA) Caution: Federal Law restricts this device to sale by or on the order of a physician. |
|  | Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling). |
|  | Patient name |
|   | Date of implantation |
|  | Name of the implanting healthcare institution / provider |
|  | Patient information website |

*Table 1: Symbols Glossary*

### 1.2 Safety Information Marking

**⚠ WARNING**

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

**NOTICE**

Product damage or other damage may occur in case of non-compliance.

### 1.3 Additional Information

This document is available in electronic form on the manufacturer's website. If required, a printed copy of this document can be requested from the manufacturer.

| | |
|---|---|
| Download link for these Instructions for Use:[1)] | www.kurzmed.com/en/ifu/stp3.html |
| Download link for the processing instructions: [1)] | https://www.kurzmed.com/en/ifu/reprocessing.html |
|  Download link for the Patient Information Document:[1)] | www.kurzmed.com/en/pi/stp.html |
| Disclaimer for the availability of the SSCP | As a general rule: The SSCP will only be made available after the product has been authorised in accordance with REGULATION (EU) 2017/745 (MDR). The implementation described here does not apply until the corresponding module of the Eudamed database comes into force. Until then, the SSCP is available at the following download link: www.kurzmed.com/en/sscp/stp.html |
| Summary of Safety and Clinical Performance (SSCP): [1)] | https://ec.europa.eu/tools/eudamed To search for the product-specific SSCP, enter the basic UDI-DI of the product. |
| Basic UDI-DI (device identifier): | ++EHKM0027F |
| Accessories: Basic UDI-DI (device identifier): | ++EHKM0207H (KURZ Meter), ++EHKM0277X (Tray KURZ Meter) |
| International addresses: | https://www.kurzmed.com/en/contact.html |

[1)] Updated on an ongoing basis. Other language versions are also available there.

For the complete UDI (UDI-PI) please refer to the product label.

### 1.4 Safety-related Changes

| Document number | Edition date | Safety-related Changes |
|---|---|---|
| 0006225_ 01 | 2025-10 | Complete revision |
| 0006225_ 02 | 2026-02 | None |
| 0006225_ 03 | 2026-03 | Deleted: Information on the closing temperature |
| 0006225_ 04 | 2026-04 | Added:<br>WARNING: Apart from the specific provisions on MRI safety, the following applies: Do not expose the product to diagnostic or therapeutic electromagnetic radiation.<br>WARNING: If the prosthesis closes under the influence of heat before it is in the correct position: Discard the prosthesis and use a new prosthesis. Do not advance the prosthesis onto the incus in the closed state or re-open the prosthesis.<br>Note on heat generation during closure of the prosthesis |

## 2 Important Safety Information

**⚠ WARNING**

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use.
  Otherwise there are risks to the health of your patient.
- Do not disassemble or modify the product.
  Otherwise there are risks to the health of your patient.

ATTENTION: In case that any serious incident has occurred in relation to the device the incident should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

## 3 Product Codes / REF

[ Specifications, page 14 ]

## 4 Scope of Delivery

| | |
|---|---|
| Stapes prosthesis | 1 x stapes prosthesis<br>1 x Thermo Dummy<br>1 x implant card<br>4 x product label |
| KURZ Meter (accessory) | 1 x instrument<br>1 x Instrument Tray (Tray KURZ Meter) |

## 5 Packaging and Sterility

| | |
|---|---|
| Stapes prosthesis | The product is sterile (sterilized by radiation).<br>Packaging: Single sterile barrier system with protective packaging inside (prosthesis and Thermo Dummy in plastic triangular box with fixation and in hard blister) + outer packaging (folding box). |
| KURZ Meter (accessory) | The product is not sterile.<br>Packaging: Bag with ziplock + outer packaging (folding box) |

## 6 Product Description

### 6.1 General information

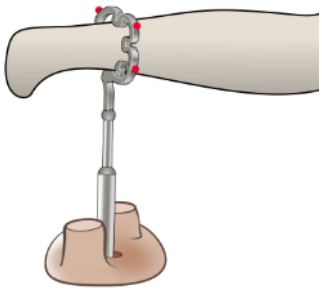


*Illustration 1: NiTiBOND in situ, with spots for laser application (red)*

The supplied thermo dummy simulates the heat-reactive properties of the NiTiBOND prosthesis, allowing the user to check and adjust the laser power settings required to close the NiTiBOND prosthesis.

[ Specifications, page 14 ]

### 6.2 Structure and Operation

| | |
|---|---|
| Stapes prosthesis | Prostheses which are inserted to partially replace middle ear structures involved in sound conduction. |
| KURZ Meter (accessory) | The KURZ Meter is designed to determine the required length of the KURZ stapes prosthesis by measuring the distance between the stapes footplate to the long process of the incus/ handle of the malleus |

### 6.3 Materials with Potential Patient Contact

The following table lists all materials of the implant with which the user or the patient has contact during use, either for every application ("standard") or in case of a damage to the product ("potentially").

| Product (part) | Material | Contact person | Type of contact |
|---|---|---|---|
| Stapes prosthesis | Clip: 100% nitinol<br>Shaft + piston: 100% titanium | Patient | Standard |

Accessories: [ Specifications, page 14 ]

Not made with natural rubber (latex).

No products made with natural rubber (latex) are used in the production process.

ATTENTION: Do not use the product if the patient has known intolerances / allergies to the materials used.

### 6.4 Accessories

| | | |
|---|---|---|
| KURZ Meter |  | [ Using the KURZ Meter, page 11 ] |

[ Specifications, page 14 ]

### 6.5 Other Devices to be Used in Combination with the Device

With the exception of equipment and materials required for implantation, the product is not intended for use in conjunction with any other products.

[ Required Equipment and Materials, page 8 ]

## 7 Intended Purpose

### 7.1 Intended Purpose

| | |
|---|---|
| Stapes prosthesis | KURZ stapes prostheses are intended for the partial surgical replacement of the ossicular chain of the human middle ear. The objective is the restoration of the mechanical transmission of sound from the incus/ malleus to the inner ear to restore/ improve hearing. |
| KURZ Meter (accessory) | The KURZ Meter is used to determine the required length of the KURZ stapes prosthesis. |
| Tray KURZ Meter (accessory) | The Tray KURZ Meter is a reusable device used to hold the KURZ Meter during sterilization and storage. |

### 7.2 Indications

Conductive hearing loss due to stapes foot plate fixation (e.g., due to otosclerosis, tympanosclerosis, congenital / other malformations)

### 7.3 Contraindications

- Known sensitivity or allergy to titanium
- Known allergy or sensitivity to nickel-titanium alloys
- Inflammation or infections of the middle ear / of the external auditory canal
- Impaired wound healing

### 7.4 Patient Target Group

The product is suitable for use in the following patient groups:

- Children and youth
- Adults
- Patients of any gender

### 7.5 Intended User

The intended user is a physician with experience in treating similar cases with this product or with comparable products or a physician with the following specialty:

- ENT surgeon

### 7.6 Expected Lifetime

| | |
|---|---|
| Stapes prosthesis | No product-specific restrictions.<br>Regular check-ups are needed. |
| KURZ Meter (accessory) | Frequent processing has little impact on these instruments. The end of the product lifetime is usually based on wear and tear as well as damage from use. Please refer to the processing instructions. |

### 7.7 Intended Place of Use

- Operating theatre

It is the responsibility of the user to decide on a case-by-case basis which precautions must be taken for any complications that may arise.

### 8 Expected Clinical Benefit

According to the clinical evaluation, the product can be used safely and effectively for treatment according to the indications mentioned.

### 9 Possible Complications and Side Effects

- Postoperative dislocation of the prosthesis
- Incus necrosis/ erosion
- Recurrent or postoperative middle ear inflammation
- Dizziness / Vertigo
- Tissue irritation, scar formation, granuloma
- Perilymphatic fistula
- Tympanic membrane perforartion
- Inner ear damage up to and including deafness (Surditas)
- Chorda tympani damage
- Injury to the facial nerve (including paresis / palsy)
- Bleeding
- Incus subluxation
- Tinnitus
- *Floating footplate*

### 10 Combining with Other Procedures

Stapes prostheses:

**⚠ WARNING**

- Laser therapy, argon plasma coagulation, high-frequency surgery, and other procedures, the effect of which is due to heat: Do not use those methods directly on the product.
  Otherwise, injury to the tissue and product damage are possible.
- Apart from the specific provisions on MRI safety, the following applies: Do not expose the product to diagnostic or therapeutic electromagnetic radiation.
  Otherwise there are risks to the health of your patient.
- The product is MRI conditional. Use the product in MRI fields only as per specification.
  Possible consequences of using the product in MRI fields outside the specifications include: Heating of the product, electrostatic discharges, consequential damages caused by the application of force to the product, errors in the imaging (also in the surrounding tissue)

For important information about MRI see:
http://www.kurzmed.com/de/mr-information.html

### 11 Shelf Life and Storage

For date of expiry, see the product label.
Store the product in unopened original packaging.
Store the product in a dry place and protect it from sunlight.

### 12 Processing

Stapes prostheses, Thermo Dummy:

**⚠ WARNING**

- Single use product: Do not process (e.g., clean, disinfect, sterilize), resterilize or reuse the product.
  This is the only way to ensure the product is germ-free and functional. Due to the mechanical properties of the product, processing or resterilization could lead to material degradation.

KURZ Meter, Tray KURZ Meter:

**⚠ WARNING**

- The product is not sterile. Process the product before first and any further application.
  This is the only way to ensure the product is germ-free and functional. Process in accordance with the processing instructions document. [ ▸Additional Information, page 4 ]

## 13 Application Instructions

**⚠ WARNING**

- Do not use the product if the packaging or the product is damaged or expired.
  This is the only way to ensure the product is germ-free and functional.
- Only remove the product from storage packaging immediately before use. When the product is removed from the packaging, observe the relevant hygienic regulations.
  Otherwise there are risks to the health of your patient.
- NiTiBOND must not be placed using the *vein graft technique*.
  Otherwise there are risks to the health of your patient.

**NOTICE**

- Always grasp, transport and manipulate the prosthesis with appropriate forceps or tweezers. Ensure that the prosthesis shaft is not inadvertently deformed or the prosthesis is not damaged in any other way.
  Otherwise the function of the prosthesis may be impaired.

Ensure the presence of hygienic / sterile conditions needed for the intervention.
Placement takes place as part of a stapedotomy/stapedectomy.
Perform the intervention under appropriate visual supervision. When doing so, ensure that the potential heat development through the endoscope does not lead to premature closure of the prosthesis.
ATTENTION: Each type of laser generates a different laser beam and therefore a different energy input. Therefore, the required laser settings for activation of the NiTiBOND stapes prosthesis must be determined prior to use. This can be done using the Thermo Dummy or on the basis of documented empirical data.
Use a focused beam and direct it exclusively at spots 1 to 3.
In vitro studies show that CO2lasers generate a large laser beam and can therefore result in a high energy input.

### 13.1 Required Equipment and Materials

As usual for stapedotomy/stapedectomy.

- Laser for heat application [ ▸Application Instructions, page 8 ]

The manufacturer recommends using the following products:

- KURZ Meter (accessory)

### 13.2 Preparation of the Patient

**⚠ WARNING**

- Adjust the opening created during the stapedotomy/stapedectomy to the diameter of the prosthesis piston. The piston must not exert any tension on the surrounding structures.
  Otherwise there are risks to the health of your patient.

As usual for stapedotomy/stapedectomy.
Endaural or retroauricular access to the middle ear.

### 13.3 Choosing the Prosthesis

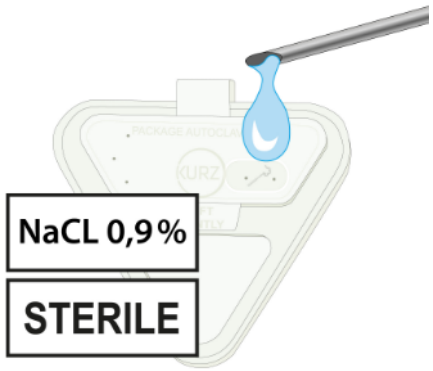
**⚠ WARNING**

- Always select the length of the prosthesis according to the anatomical and functional conditions.
  Otherwise there are risks to the health of your patient. In addition, the hearing result may be affected.

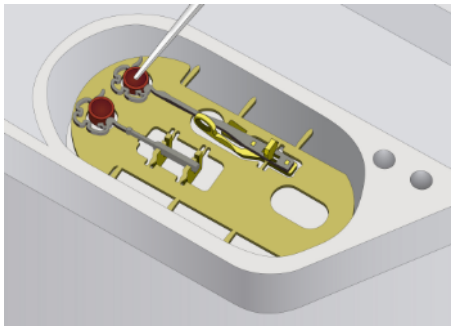
The manufacturer recommends using the KURZ Meter to determine the required size of the prosthesis.
[ ▸Using the KURZ Meter, page 11 ]
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.

## 13.4 Preparing the Prosthesis

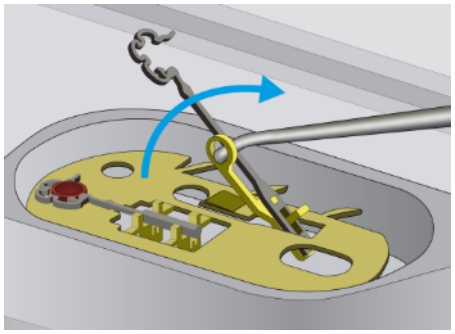
### 13.4.1 Open the sterile packaging



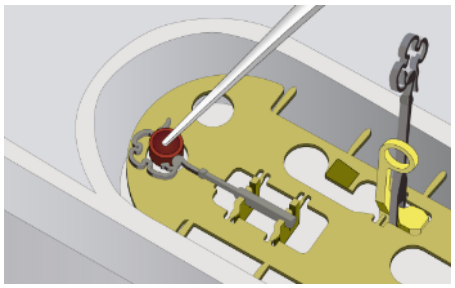

1. Open the sterile packaging.
2. Apply drops of sterile saline solution on the openings of the protective packaging. In this process, ensure that the perforations in the lid are also coated in saline solution so that liquid can penetrate the protective packaging.



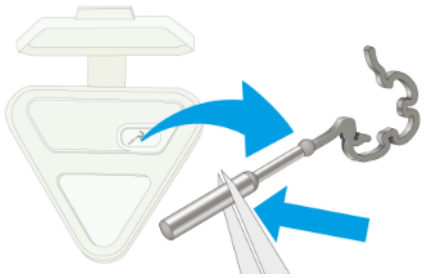
3. Press the locking pin of the Thermo Dummy all the way down using a pointed instrument.



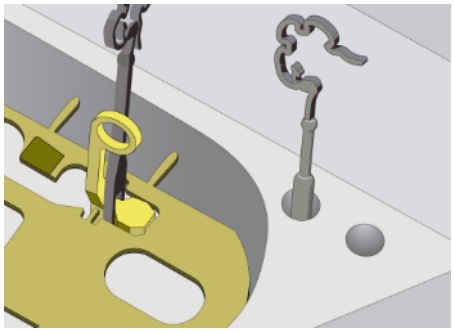
4. Insert a suitable instrument into the eyelet on the Thermo Dummy and align the Thermo Dummy until it engages in a vertical position.
5. Calibrate the laser using the Thermo Dummy. [ Calibrating the Laser with the Thermo Dummy, page 10 ]



6. Use a pointed instrument to push the locking pin of the prosthesis all the way down.



7. Carefully remove the prosthesis from the protective packaging.
   ATTENTION: Grasp the prosthesis by the piston.



8. If necessary, place the prosthesis in one of the receptacles in the protective packaging (diameter 0.4 mm/0.6 mm) until it is transported to the middle ear.

### 13.4.2 Calibrating the Laser with the Thermo Dummy

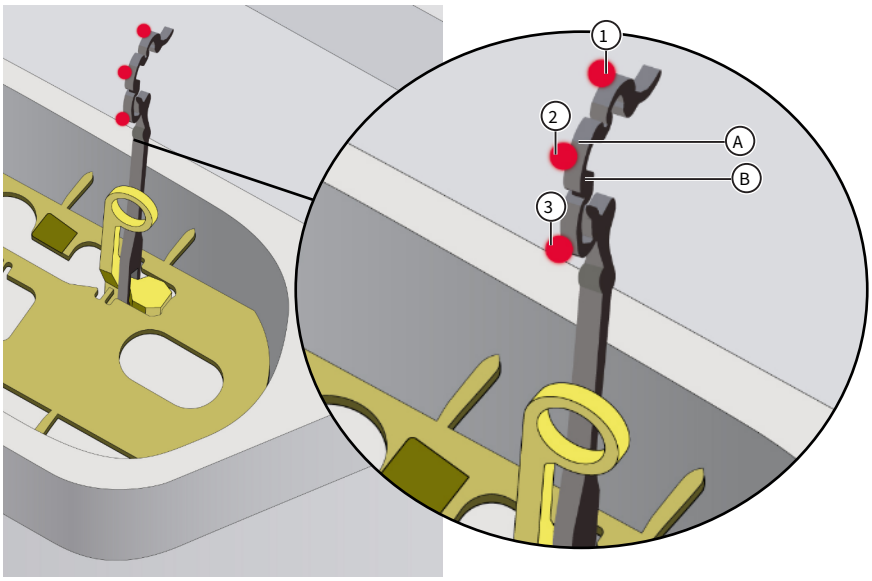



*Illustration 2: Thermo Dummy: Calibrating the Laser*

| | | | |
|---|---|---|---|
| 1 | Spot 1 | A | Heat-reactive area |
| 2 | Spot 2 | B | Incus contact area (applies only to the prosthesis, not to the Thermo Dummy) |
| 3 | Spot 3 | | |

The Thermo Dummy is used to determine the optimum power setting for the laser. The Thermo Dummy has the same closing properties as the prosthesis:

- To close, apply heat to the spots (spots 1 to 3) using the laser.
- By default, the spots should be activated in the sequence Spot 1, Spot 2, Spot 3. Depending on the geometry of the incus, a different sequence may be required.
- The manufacturer recommends applying a low laser power first and gradually increasing it as required.
- Several laser shots can be applied per spot.
- The closing procedure cannot be reversed.

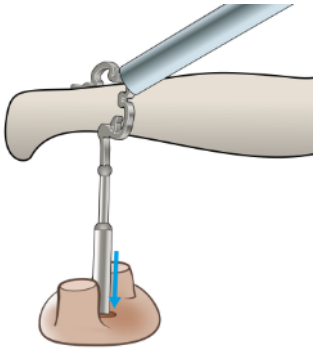
ATTENTION: The Thermo Dummy is not intended for use on the patient.

## 13.5 Placing the Prosthesis

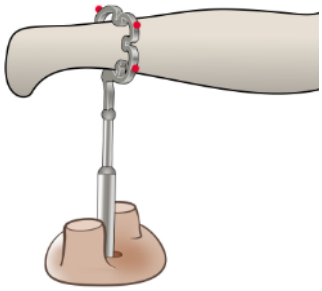
**⚠ WARNING**

- If the prosthesis closes under the influence of heat before it is in the correct position: Discard the prosthesis and use a new prosthesis.
  Do not advance the closed prosthesis onto the incus or attempt to reopen the prosthesis.
  Otherwise there are risks to the health of your patient.
- Apply the laser exclusively to the spots (spots 1 to 3). Use a focused beam.
  Otherwise there are risks to the health of your patient.
- Completely seal the opening to the inner ear after insertion of the stapes prosthesis.
  Otherwise, a risk of a perilymphatic fistula exists.

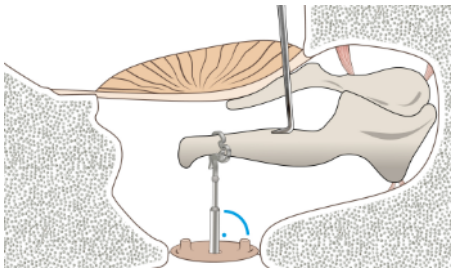
ATTENTION: If intraoperative flushing is required: Use only body-warm fluids to avoid impairing the thermoactive properties of the prosthesis.



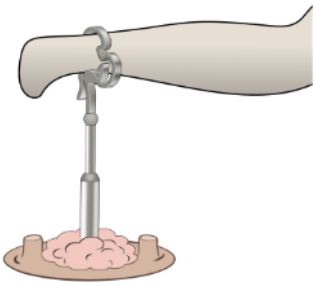
1. Insert the end of the prosthesis piston into the opening to the inner ear and place the prosthesis loop over the long processus of the incus.



2. Close the loop around the long processus of the incus. To do this, apply heat to spots 1 to 3 using a laser.
   ATTENTION: Make sure that there is as little liquid as possible in the area of the thermoactive zones, as liquid can affect the required laser power.



3. Check the fit of the prosthesis:
   The piston must be perpendicular to the stapes base plate / oval window and must not exert any tension on the surrounding structures.
   The loop must not have any play on the long processus of the incus, but it must not constrict the long processus of the incus either. If the prosthesis cannot be securely fixed: Remove the prosthesis and select another prosthesis.
   ATTENTION: To check, do not touch the loop itself, just gently manipulate the ossicles.



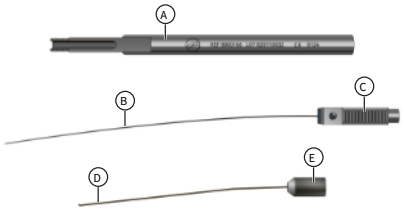
4. Seal the opening to the inner ear with a suitable graft (e.g. connective tissue).

### 13.6 Using the KURZ Meter

This section describes how to use the KURZ Meter to determine the required prosthesis size.
[ Choosing the Prosthesis, page 8 ]

**WARNING**

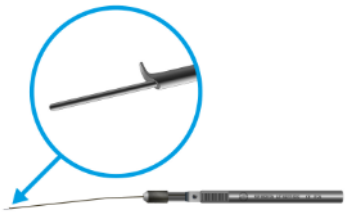
- The product is not sterile. Process the product before first and any further application.
  This is the only way to ensure the product is germ-free and functional. Process in accordance with the processing instructions document. [ Additional Information, page 4 ]




A Handle, with scale (on the side)
B Probe (straight), with handle with slider
C Handle with slider
D Tube (angled), with union nut
E Union nut

*Illustration 3: KURZ Meter, components*

### 13.6.1 Assembling the KURZ Meter



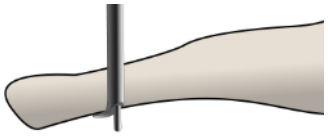
1. Insert the probe into the tube.
2. Insert the handle with slider of the probe into the receptacle on the handle until it stops.
3. Screw the union nut on the tube finger-tight onto the handle until it stops. To do this, turn the union nut clockwise.

### 13.6.2 Determining the Required Prosthesis Size

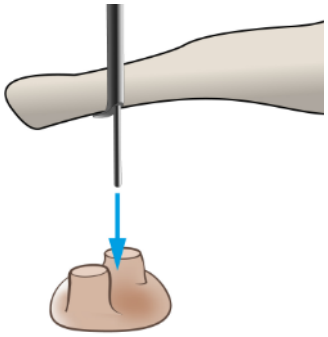
**⚠ WARNING**

- Do not insert the probe tip into the opening to the inner ear.
  Otherwise, there is a risk of injury to the inner ear.

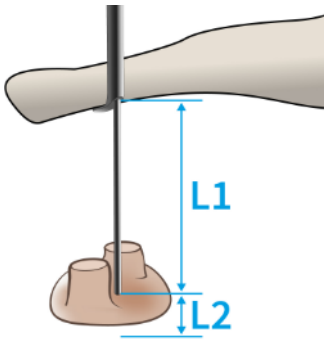
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.
Initial state: The slider is at the proximal stop. The tube is flush with the probe.



1. Place the stop hook at the end of the tube medial to the long processus of the incus.



2. Gently move the slider distally to advance the probe tip to the stapes footplate/oval window.
   Make sure that the KURZ Meter is perpendicular to the stapes footplate/oval window.




3. Once the tip of the probe touches the stapes footplate/is level with the oval window:
   Read the distance $L_1$ on the scale on the handle of the KURZ Meter.
4. Determine the required prosthesis size $L = L_1 + L_2$.
   $L_1$ = measured distance between the long processus of the incus and the stapes footplate/oval window
   $L_2$ = desired immersion depth of the piston in the opening to the inner ear
5. Remove the KURZ Meter.
6. Select the appropriate prosthesis size. [ Specifications, page 14 ]

## 13.7 Removing the Prosthesis

The prosthesis is intended to remain in the body. However, should it nevertheless be necessary to remove the prosthesis:
Before removing the prosthesis: Loosen any adhesions.
Follow-up treatment at the discretion of the treating physician.

## 14 Aftercare

- Follow-ups as indicated by the treating physician.

## 15 Instructing the Patient

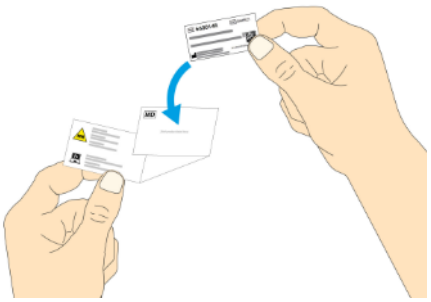
**⚠ WARNING**

- Protect the auditory canal from water penetration.
  Otherwise there is a risk of inflammation / infection of the middle ear.
- Avoid severe fluctuations in ambient pressure (e.g. diving, jumping head first into water, explosions).
  Failure to do so may result in injury to the tympanic membrane/ossicles, which can lead to hearing and balance disorders.

ATTENTION: Also inform the patient about the consequences of combining with other procedures.
[ ▸Combining with Other Procedures, page 7 ]
Implant card: [ ▸Implant Card, page 13 ]

## 16 Implant Card

ATTENTION: Complete the implant card before the patient is discharged from hospital and give it to the patient.



1. Stick one of the product labels provided into the designated box on the implant card. Complete all other sections.

The implant card must be presented at every radiological examination.

## 17 Disposal

**⚠ WARNING**

- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk. Dispose of the product in accordance with procedures for hazardous waste in hospitals.
  Otherwise there is a risk of infection for the user and for third parties.

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

## 18 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.
Due to biological and individual differences, no product is 100% effective under all circumstances.
**Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.**
The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.
If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.
If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.
Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.

All claims based on the consequences of non-compliance with the Instructions for Use, including specified indications, contraindications, warnings, instructions, application, storage and off-label use, as well as the consequences of a combination with third-party products are excluded.
Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.
No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.

## 19 Specifications

### 19.1 Stapes Prostheses

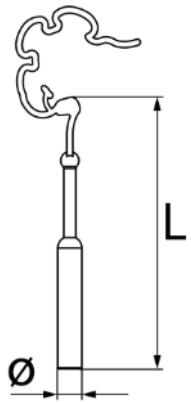
| NiTiBOND | | | |
|---|---|---|---|
| | L [mm] | Ø 0.4 mm REF | Ø 0.6 mm REF |
|  | 3.50 | 1007 103 | 1007 153 |
| | 3.75 | 1007 104 | 1007 154 |
| | 4.00 | 1007 105 | 1007 155 |
| | 4.25 | 1007 106 | 1007 156 |
| | 4.50 | 1007 107 | 1007 157 |
| | 4.75 | 1007 108 | 1007 158 |
| | 5.00 | 1007 109 | 1007 159 |
| | 5.50 | 1007 111 | 1007 161 |
| | 6.00 | 1007 113 | 1007 163 |
| Including the Thermo Dummy (Nitinol ) | | | |
| Width of the loop: 0.25 mm | | | |

*Table 2: NiTiBOND*

### 19.2 Accessories

| Accessories | | | | |
|---|---|---|---|---|
| | Name | REF | Material | Properties |
|  | KURZ Meter | 8000 106 | Stainless steel, surgical quality | Reprocessable, included Tray KURZ Meter |
|  | Tray KURZ Meter | 8000 174 | Stainless steel, surgical quality | Reprocessable, sold separately |

*Table 3: Accessories*