IMPORTANT USER INFORMATION – KURZ PROSTHESES FOR STAPEDIOPLASTY (NiTiBOND)

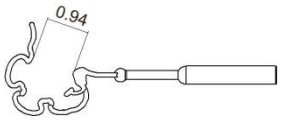
USA **Read carefully before clinical use!**

Product Description
KURZ middle ear prostheses are intended for ossicular replacement to restore functionality to the middle ear in cases of pathological changes of the sound transmission system. The NiTiBOND Stapes Prosthesis acts as a bridge between the long process of the incus and the base of the stapes, with the piston extending into the perilymphatic space of the inner ear. The loop consists of nickel-titanium alloy (Nitinol), while the piston and the shaft are made of pure titanium.

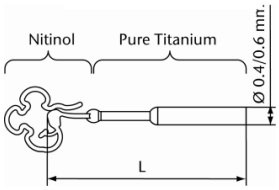
Diameter and Lengths

Ø 0,4mm		Ø 0,6mm	
REF	**L (mm)**	**REF**	**L (mm)**
1007 103	3.50	1007 153	3.50
1007 104	3.75	1007 154	3.75
1007 105	4.00	1007 155	4.00
1007 106	4.25	1007 156	4.25
1007 107	4.50	1007 157	4.50
1007 108	4.75	1007 158	4.75
1007 109	5.00	1007 159	5.00
1007 111	5.50	1007 161	5.50

Open Position



Closed Position



Purpose
The KURZ NiTiBOND Stapes Prosthesis provides a partial replacement of the human ossicular chain when surgically indicated (see below). The objective is to transmit the greatest amount of sound energy possible to the inner ear without loss along the mechanical path.

Indications
Before a decision is made to implant a prosthesis, the patient's complete medical history must be reviewed:
- Otosclerosis (stapedial fixation) / congenital stapedial fixation
- Malformation of the middle ear
- Traumatic injury to the ossicular chain
- Revision surgery to correct inadequate hearing improvement, e.g. through dislocation of a prosthesis

Contraindications and Possible Risks
- Allergy to nickel, titanium, or nickel-titanium alloys (nitinol): A preoperative allergy test is recommended to minimize the risk of an allergic reaction. In patients with a known allergy to nickel, titanium, or nickel-titanium alloys (nitinol), do NOT use an implant containing these materials.
- Cases in which conservative treatment methods (e.g. a hearing device) are adequate.
- Acute middle ear inflammation which can lead to labyrinthitis or prosthesis dislocation.
- Inflammation of the auditory canal increases the risk of spreading infective foci into the middle or inner ear.
- If the ear undergoing surgery is the sole hearing source for the patient, there is a risk of complete bilateral deafness. In individual cases, this must be discussed between patient and physician.
- Acute and chronic infectious diseases
- General wound healing disorders
- Patients with alcohol, drugs, or nicotine abuse

Possible Complications and Adverse Events
Adverse events or injuries can occur during or after the intervention. Extremely fine bony structures are manipulated and moved as part of the surgical procedure which can lead to iatrogenic trauma or an infection. These injuries may be irreversible or only correctable with revision surgery.
- Postoperative implant dislocation or fracture
- Necrosis or erosion in the vicinity of the contact zones (incus)
- Recurrent middle ear inflammation
- Inner ear injury, including deafness
- Perilymphatic fistula
- Tinnitus
- Tissue irritation, scar formation, granulomas
- Dizziness
- Tympanic perforation
- Irritation or even damage to the facial nerve, including facial paralysis

Intolerance reactions such as granuloma formation and implant rejection, or interaction with medications are not known to date. In such cases, the prosthesis must be removed using conventional surgical procedures.

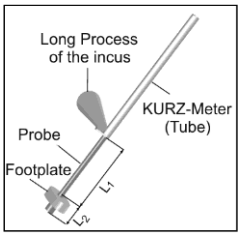
Warnings – Precautions

Intraoperative
Unintentional bending must be avoided during removal of the implant from the primary package; otherwise functional damage to the implant may occur. The middle ear structures must be manipulated as gently as possible. Prevention of injury to the inner ear must be ensured, especially in the region of the stapes and the oval window. Extreme care must be taken with the selection of the prosthesis length to reduce the risk of postoperative complications such as implant dislocation or the occurrence of inner ear symptoms, e.g. dizziness.

Postoperative
If a granuloma or perilymphatic fistula occurs postoperatively, initiate the required medical response immediately. Pay attention to appropriate hygiene of the treated ear.

Measurement of Prosthesis Length

LProsthesis = L1 + L2
L1 = Measured distance
L2 = Immersion depth* (Piston)
*The determination of the immersion depth L2 of the prosthesis is subject to the decision of the surgeon.



KURZ-Meter
(REF: 8000 106)

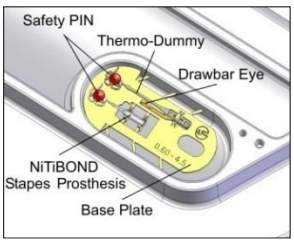


Figure 1 Overview – Contents

Recommended Instrumentation
KURZ measuring device (REF 8000 106) to determine the required length.
Titanium forceps (REF 8000 136) for removing and handling the prosthesis.
Instead of the KURZ instruments general surgical ENT instruments can be used.

Handling / Use / Implantation
Important: Use only surgical laser for heat application.

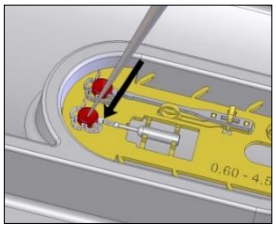


Figure 2 Remove Safety Pin
Push the Safety Pin downward with a pointed instrument until implant and Thermo-Dummy are released.

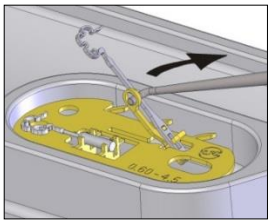


Figure 3 Raising the Thermo-Dummy
Raise the Thermo-Dummy by the eye with a small hook or forceps until it locks into upright position.

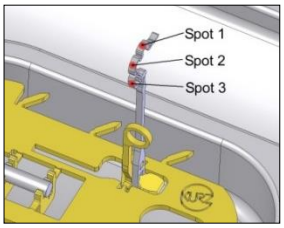


Figure 4 Laser Calibration
Calibrate the laser that will be used for heat application. The Thermo-Dummy is not an implant; it is intended exclusively for the determination of the exact power level required to close the NiTiBOND Stapes Prosthesis. Start with the lowest laser power settings on Spot 1 and gradually increase the laser power. The correct laser power settings are established when movement of the loop is generated by the heat application. Use this power setting and proceed with Spot 2 and 3 to completely close the Thermo-Dummy. Once the Thermo-Dummy is closed it cannot be used again for determination of the correct laser settings.

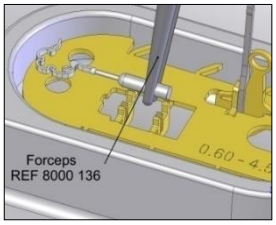


Figure 5 Prosthesis Removal
Remove the NiTiBOND Stapes Prosthesis with the titanium forceps. Make sure to grasp it at the midpoint of the piston to avoid prosthesis damage.

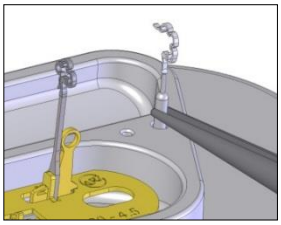


Figure 6 "Parking"
"Park" the implant in one of the customized slots within the primary box (Ø 0.4 / 0.6 mm) to facilitate transfer to the middle ear.

Implantation:

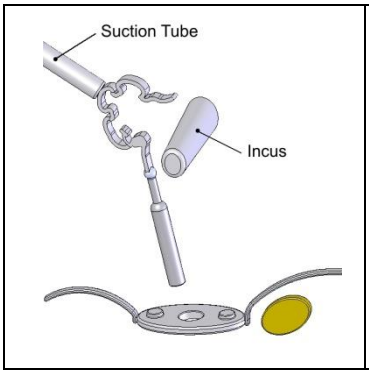


Figure 7 Transfer to the Middle Ear
Transfer from the primary package and insertion of the prosthesis into the middle ear should be performed, if at all possible, with a thin suction tube or fine micro forceps. Carefully apply the suction tube or micro forceps to the prosthesis loop.

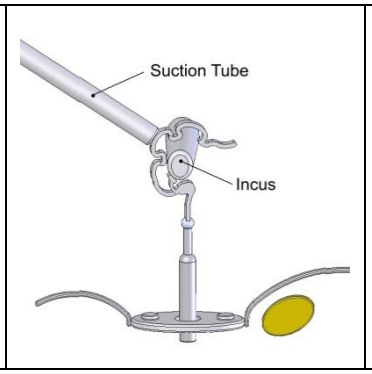


Figure 8 Suspension on the Incus
Mount the prosthesis on the stapes foot plate by inserting the piston into the prepared opening/perforation. Then carefully slide the loop over the long incus process.

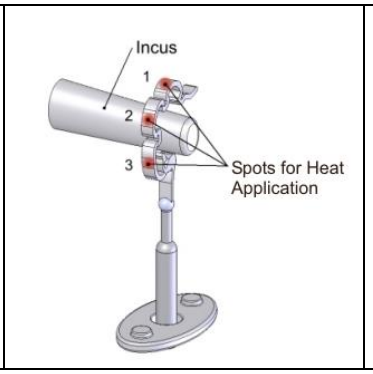


Figure 9 Laser Heat Application
Apply the laser heat sequentially to Points 1, 2 and 3 (red spots) to close the loop around the incus for an effective and safe implant connection.

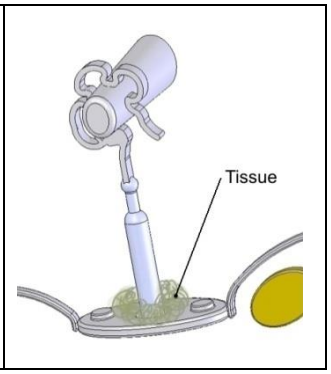


Figure 10 Sealing the Stapes Prosthesis
If at all possible, insert the prosthesis upright into the perforation on the stapedial base plate. Seal the perforation with tissue around the piston.

Laser Procedure: observe the sequence "Spot 1" – "Spot 2" – "Spot 3" during laser application! The setting should be equivalent to the result obtained during laser calibration (see Figure 4). However, due to different incus shapes, variations in the laser application sequence may be necessary. The laser heat setting for closing the loop starts with an As temperature ~55°C (131°F) and ends with Af ~ 70°C (158°F). The unique geometry of the thermal block assures that the heat does not reach the incus mucosa under normal circumstances.

Attention!
If implantation of the prosthesis is performed under local anesthesia (LA), the patient can be startled by the noise created during laser application. The patient should be forewarned of this to prevent unforeseeable head movements resulting in potential injury to the middle ear.
If after closure of the loop rinsing is necessary for whatever reason, it should ONLY be done with solutions at body temperature.

MRI Information

MR Conditional
Non-Clinical testing has demonstrated the NiTiBOND to be MR Conditional.

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It can be scanned safely under the following conditions:
- static magnetic field of 1.5T, 3.0T or 7.0T only.
- spatial gradient field of 30 T/m and less (3000 G/cm) or less
- for 1.5T[1], 3T[1] and 7T[1] field strengths "normal operating mode" only with a maximum whole-body averaged (WBA) SAR of 2 W/kg and a head-averaged (HA) SAR of 3.2 W/kg for 15 minutes continuous scanning.

[1]Extrapolation to head coil; body coil only was used for testing as a worst-case assumption.

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

Derived from non-clinical testing the worst case object produced a temperature rise of less than 1.9°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 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.

Derived from non-clinical testing the worst case object produced a temperature rise of less than 2.9°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 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.

Derived from non-clinical testing the worst case object produced a temperature rise of less than 0.4°C at a maximum head averaged specific absorption rate (SAR) of 2.0 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.

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.

Warning:
The physician must inform the patient about the following: Patients with metallic implants are not to be subjected to microwave radiation. Severe variations in ambient pressure (scuba diving, diving head-first, explosions, fireworks, etc.) can damage the middle ear structures and/or cause hearing loss and/or equilibrium disorder and should be avoided.

Sterility:
KURZ middle ear prostheses are provided sterile. The prostheses are sterilized with gamma radiation in a strictly controlled cycle with sterility validation testing for each batch. Inspect package for punctures or other damage prior to surgery. Open storage package directly before surgery to prevent contamination. Upon withdrawal, observe the usual instructions for asepsis.

Resterilization/ Reprocessing:
The prosthesis is intended for one-time use only. Reprocessing / resterilization is not permitted.

Storage:
Storage conditions in unopened original packaging: Store in a dry place at room temperature, protected from direct sunlight. Brief fluctuations of temperature and humidity are permissible. Each prosthesis bears a batch number and an expiration date and may not be used after that date.

Documentation
It is recommended by the manufacturer to record the LOT-Number and Type of Prosthesis in the patient´s medical record, operative record and implant pass by applying the adhesive labels.

Sale Restriction: US Federal Law restricts KURZ prostheses to sale by or on the order of a physician.

Manufacturer
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USA: Kurz Medical Inc., 70 Chestnut Street, Shrewsbury, MA 01545-USA, Phone: 508.841.5900, Fax: 508.519.2672, Toll Free: 866.449.8020, Customer Service: orders@kurzmed.com

Version: DMS 0001011_Rev.02-1 - 9501246

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SYMBOLS

	Manufacturer		Item number
	Expiration date		Batch code
	Sterilized using irradiation		Do not use if package is damaged
	Keep away from sunlight		Do not resterilize
	Do not reuse!		Single sterile barrier system
	Store in a dry place		Single sterile barrier system with protective packaging inside
	Consult instructions for use		Single sterile barrier system with protective packaging outside
	Fragile, handle with care		Medical device
			Caution