Instructions for Use
0006227_Rev01 — 2026-01
EN

Stapes Prostheses
and Accessories

Bucket Type

MD STERILE R ℞ ONLY

HEINZ KURZ GMBH
TUEBINGER STR. 3
72144 DUSSLINGEN
GERMANY

27021598620149515 —02.03.2026 13:08

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/stp4.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
International addresses:	https://www.kurzmed.com/en/contact.html

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

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 12]

4 Scope of Delivery

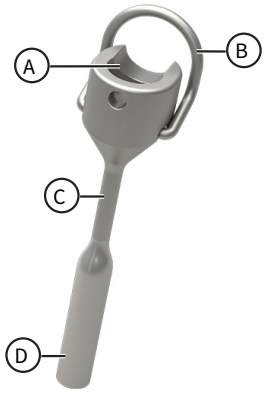
Stapes prosthesis	1 x stapes prosthesis 1 x implant card 4 x product label
KURZ Meter (accessory)	1 x instrument 1 x Instrument Tray (Tray KURZ Meter)

5 Packaging and Sterility

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

6 Product Description

6.1 General information



A	Bucket with holder for the incus
B	Safety wire
C	Shaft
D	Piston

Illustration 1: Bucket Type

[Specifications, page 12]

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	100% titanium	Patient	Standard

Accessories: [Specifications, page 12]

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 9]

[Specifications, page 12]

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 7]

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 mechan-

	ical 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
- 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. 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 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*

9 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.
- 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

10 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.

11 Processing

Stapes prostheses:

⚠ 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]

12 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.

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.
Suitable for placement using *vein graft technique*.
Perform the intervention under appropriate visual supervision.

12.1 Required Equipment and Materials

As usual for stapedotomy/stapedectomy.
The manufacturer recommends using the following products:

- KURZ Meter (accessory)

12.2 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.

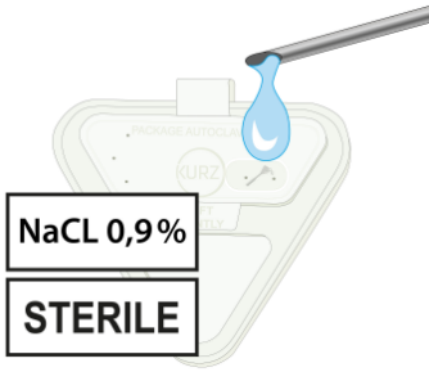
12.3 Choosing the Prosthesis

⚠ WARNING

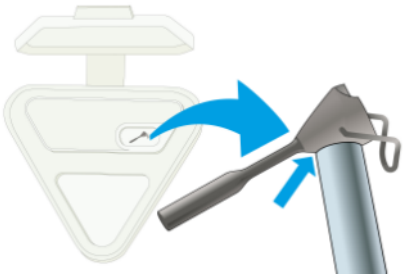
- Always select the length of the prosthesis according to the anatomical and functional conditions.
  Otherwise there are risks to the health of your patient. In addition, the hearing result may be affected.

The manufacturer recommends using the KURZ Meter to determine the required size of the prosthesis.
[Using the KURZ Meter, page 9]
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.

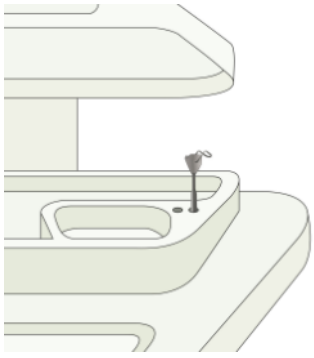
12.4 Preparing the Prosthesis



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. Carefully remove the prosthesis from the protective packaging.ATTENTION: Grasp the prosthesis by the bucket.
4. Make sure that the safety bracket is in the initial position. The bracket must point into the extension of the piston. The bracket must not be perpendicular to the piston.

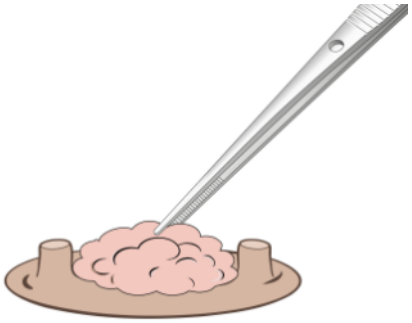


5. If necessary, place the prosthesis in one of the receptacles in the protective packaging (diameter 0.4 mm/0.6 mm) until it is transported to the middle ear.

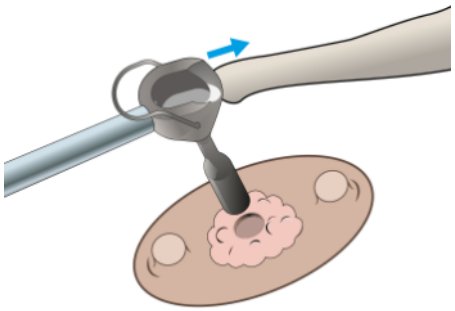
12.5 Placing the Prosthesis

⚠ WARNING

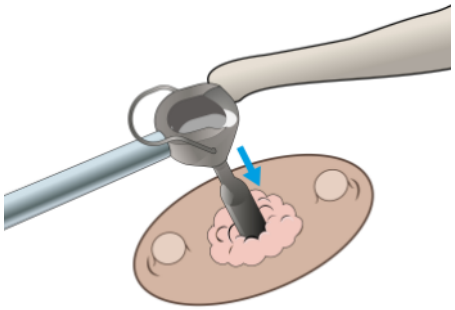
- Completely seal the opening to the inner ear after insertion of the stapes prosthesis.
  Otherwise, a risk of a perilymphatic fistula exists.



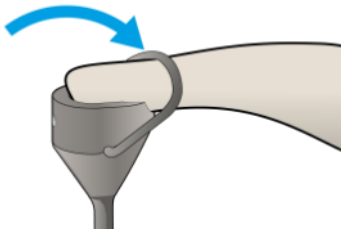
1. Apply the graft for the *vein graft technique*.



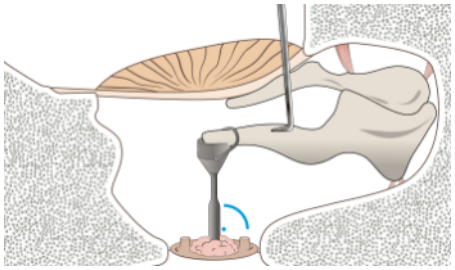
2. Position the prosthesis so that the receptacle opening faces the lenticular process and the piston is directly above the opening to the inner ear.



3. Insert the end of the prosthesis piston into the opening to the inner ear.



4. Move the prosthesis with a combined twisting and sliding motion so that the long processus of the incus slides into the receptacle.
5. Flip the safety bracket so that it passes over the long processus of the incus. Make sure that the safety bracket does not exert any pressure on the long processus of the incus.



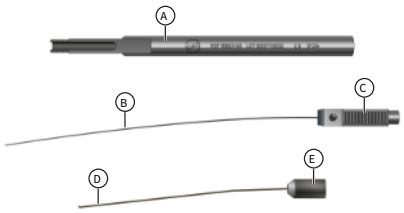
6. Check the fit of the prosthesis:
   The piston must be perpendicular to the stapes base plate / oval window and must not exert any tension on the surrounding structures.
   The bucket must not have any play on the long processus of the incus, but it must not constrict the long processus of the incus.
   If the prosthesis cannot be securely fixed: Remove the prosthesis and select another prosthesis.

12.6 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

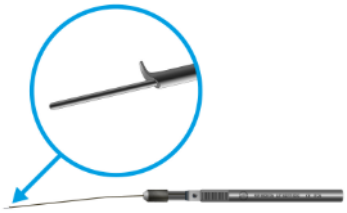
- The product is not sterile. Process the product before first and any further application.
  This is the only way to ensure the product is germ-free and functional. Process in accordance with the processing instructions document. [Additional Information, page 4]



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 2: KURZ Meter, components

12.6.1 Assembling the KURZ Meter



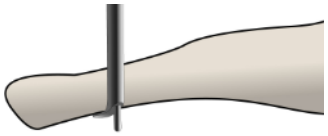
1. Insert the probe into the tube.
2. Insert the handle with slider of the probe into the receptacle on the handle until it stops.
3. Screw the union nut on the tube finger-tight onto the handle until it stops. To do this, turn the union nut clockwise.

12.6.2 Determining the Required Prosthesis Size

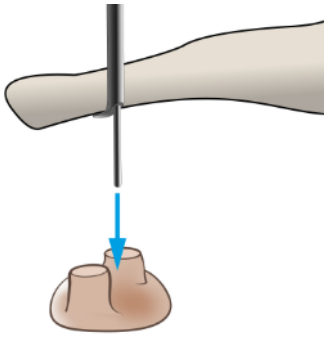
⚠ WARNING

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

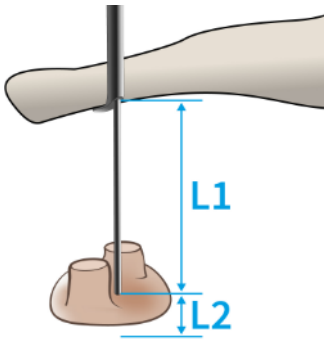
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.
Initial state: The slider is at the proximal stop. The tube is flush with the probe.



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 12]

12.7 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.

13 Aftercare

- Follow-ups as indicated by the treating physician.

14 Instructing the Patient

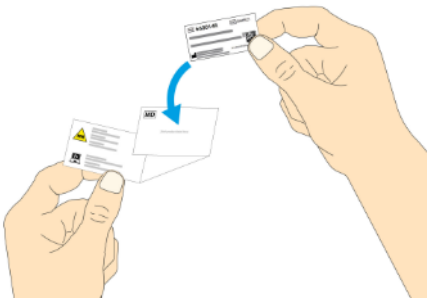
⚠ WARNING

- 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 11]

15 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.

16 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.

17 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.

18 Specifications

18.1 Stapes Prostheses

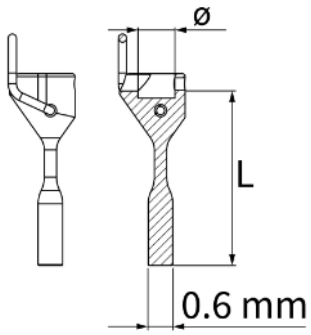
Stapes Prosthesis Bucket Type			
	L [mm]	Bucket Ø 0.9 mm REF	Bucket Ø 1.0 mm REF
	4.00	1006 543	1006 563
	4.25	1006 544	1006 564
	4.50	1006 545	1006 565
Ø Piston: 0.6 mm			

Table 2: Stapes Prosthesis Bucket Type

18.2 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