Instructions for Use
0006223_Rev02 — 2026-02
EN

Stapes Prostheses

Clippable Stapes Prostheses and Accessories

Soft CliP

NiTiFLEX

CliP Piston àWengen

CliP Piston MVP

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36028797850630027 —02.03.2026 12:32

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/stp1.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), ++EHKM0217K (Soft CliP Hook)
International addresses:	https://www.kurzmed.com/en/contact.html

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

1.4 Safety-related Changes

Document number	Edition date	Safety-related Changes
0006223_ 01	2025-10	Complete revision
0006223_ 02	2026-02	None

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 15]

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)
Soft CliP Hook (accessory)	1 x instrument

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 / Soft CliP Hook (accessory)	The product is not sterile. Packaging: Bag with ziplock + outer packaging (folding box)

6 Product Description

6.1 General information

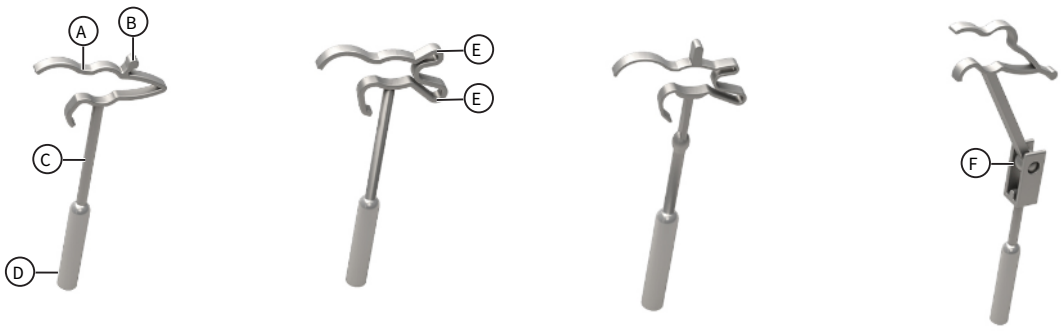


Illustration 1: Stapes prostheses, from left to right: CliP Piston àWengen, Soft CliP, NiTiFLEX, CliP Piston MVP

A Clip
B Pin
C Shaft
D Piston
E Loops
F Ball joint

[Specifications, page 15]

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
Soft CliP Hook (accessory)	The Soft CliP Hook is designed for pushing the clippable band of the stapes prothesis onto the long process of the incus (applicable for Soft CliP / NiTiFLEX).

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 Piston àWengen Soft CliP CliP Piston MVP	100% titanium	Patient	Standard
Stapes prosthesis NiTiFLEX	Clip: 100% nitinol Shaft + piston: 100% titanium	Patient	Standard

Accessories: [Specifications, page 15]
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 12]
Soft CliP Hook		[Place prostheses with loops (Soft CliP, NiTiFLEX), page 9]

[Specifications, page 15]

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]

[Compatibility of Accessories, page 16]

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.
Soft CliP Hook (accessory)	The Soft CliP Hook is used to push the Soft CliP or NiTiFLEX Stapes Prosthesis onto the long process of the incus.

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 (NiTiFLEX)
- 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 / Soft CliP Hook (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.
- 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:

⚠ 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, Soft CliP Hook:

⚠ 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.

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.

13.1 Required Equipment and Materials

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

- KURZ Meter (accessory)
- Hooklet, 0.2 mm diameter, e.g. Soft CliP Hook (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.

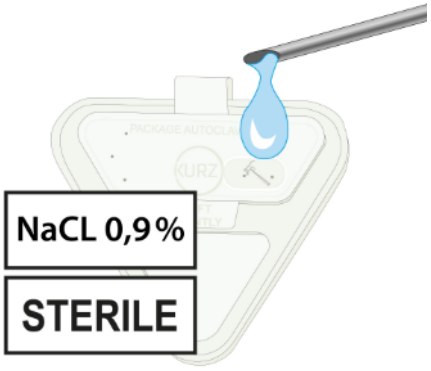
13.3 Choosing the Prosthesis

⚠ WARNING

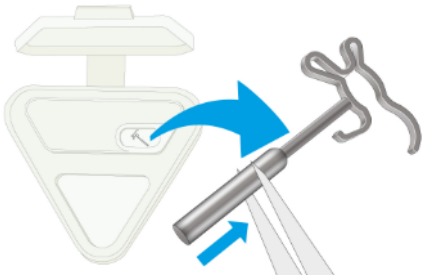
- Always select the length of the prosthesis according to the anatomical and functional conditions.
  Otherwise there are risks to the health of your patient. In addition, the hearing result may be affected.

The manufacturer recommends using the KURZ Meter to determine the required size of the prosthesis.
[Using the KURZ Meter, page 12]
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.

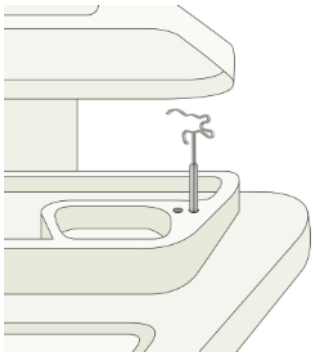
13.4 Preparing the Prosthesis



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 piston.



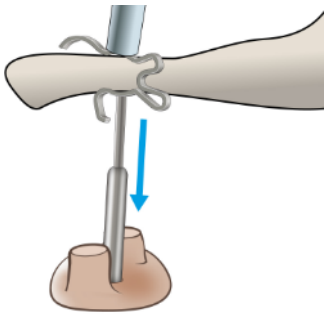
4. If necessary, place the prosthesis in one of the receptacles in the protective packaging (diameter 0.4 mm/0.6 mm) until it is transported to the middle ear.

13.5 Placing the Prosthesis

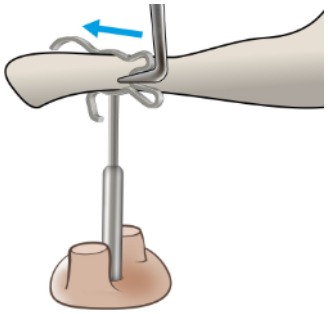
⚠ WARNING

- Completely seal the opening to the inner ear after insertion of the stapes prosthesis.
  Otherwise, a risk of a perilymphatic fistula exists.
- When fixing the prosthesis to the malleus handle (not possible with all prostheses):
  Ensure that the prosthesis is not in direct contact with the tympanic membrane. Cover the prosthesis against the tympanic membrane with a graft.
  Otherwise, a risk of tympanic membrane perforation exists.

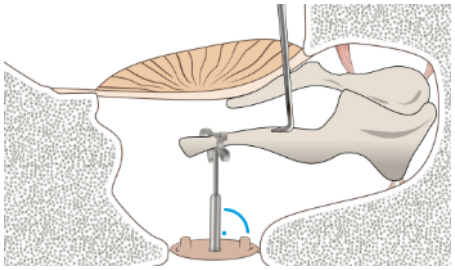
13.5.1 Place prostheses with loops (Soft CliP, NiTiFLEX)



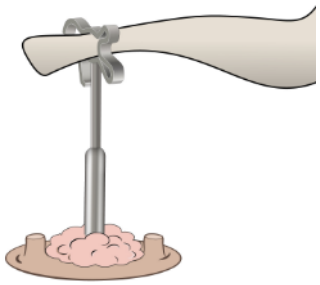
1. Insert the end of the prosthesis piston into the opening to the inner ear.
2. Place the prosthesis over the long processus of the incus so that the long processus of the incus is in the opening of the clip.



3. Slide the clip onto the long processus of the incus so that the long processus of the incus is in the extension of the clip. To do so, place a little hook between the two loops and slide the prosthesis in the desired direction.
The manufacturer recommends using Soft CliP Hook.



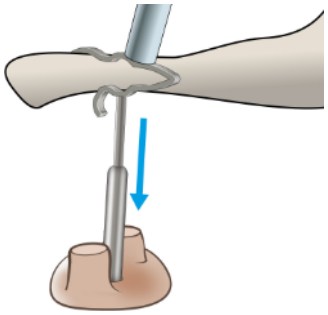
4. Check the fit of the prosthesis:
The piston must be perpendicular to the stapes base plate / oval window and must not exert any tension on the surrounding structures.
The clip must not have any play on the long processus of the incus, but it must not constrict the long processus of the incus either.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



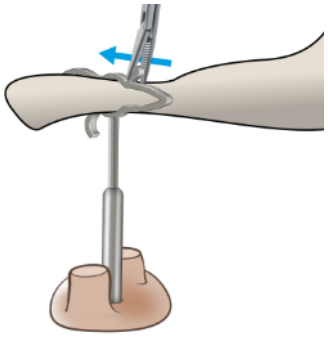
5. Seal the opening to the inner ear with a suitable graft (e.g. connective tissue).

Alternative placement technique for NiTiFLEX: [Place prostheses with a pin (CliP Piston àWengen, NiTiFLEX), page 10]

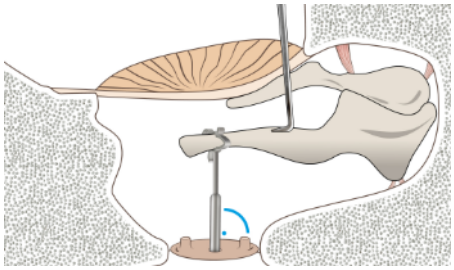
13.5.2 Place prostheses with a pin (CliP Piston àWengen, NiTiFLEX)



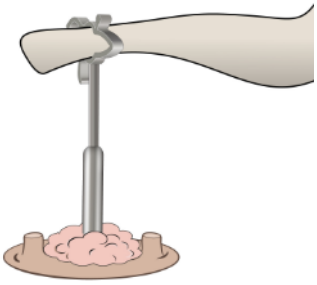
1. Insert the end of the prosthesis piston into the opening to the inner ear.
2. Place the prosthesis over the long processus of the incus so that the long processus of the incus is in the opening of the clip.



3. Slide the clip onto the long processus of the incus so that the long processus of the incus is in the extension of the clip. To do so, attach a suitable instrument (e.g. micro-ear forceps) to the pin and slide the prosthesis in the desired direction.



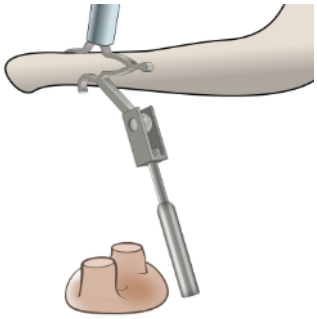
4. Check the fit of the prosthesis:
   The piston must be perpendicular to the stapes base plate / oval window and must not exert any tension on the surrounding structures.
   The clip must not have any play on the long processus of the incus, but it must not constrict the long processus of the incus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



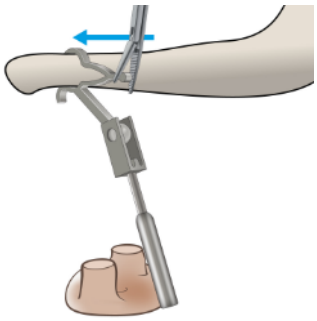
5. Seal the opening to the inner ear with a suitable graft (e.g. connective tissue).

Alternative placement technique for NiTiFLEX: [Place prostheses with loops (Soft CliP, NiTiFLEX), page 9]

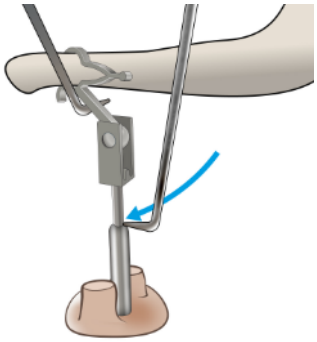
13.5.3 Place the CliP Piston MVP



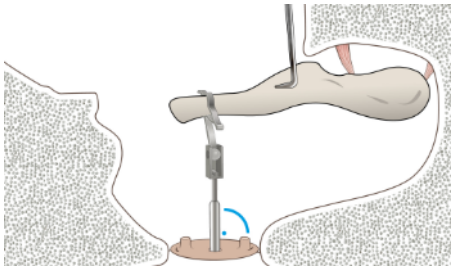
1. Place the prosthesis over the malleus handle with the malleus handle in the opening of the clip.



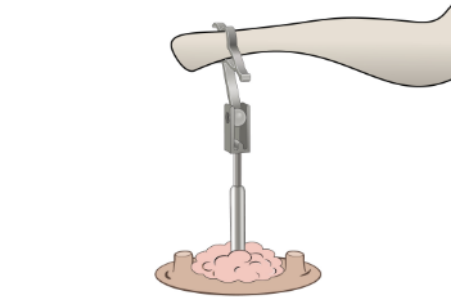
2. Slide the clip onto the malleus handle until the malleus handle is in the extension of the clip. To do so, attach a suitable instrument (e.g. micro-ear forceps) to the pin and slide the prosthesis in the desired direction.



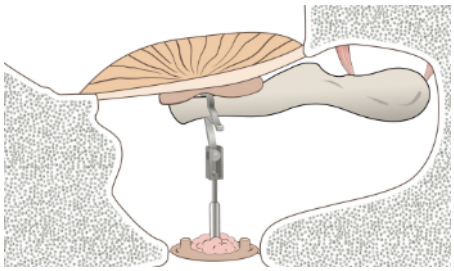
3. Using two little hooks, insert the end of the prosthesis piston into the opening to the inner ear.



4. 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 clip should not have any play on the malleus handle, nor should it constrict the malleus handle. If the prosthesis cannot be securely fixed: Remove the prosthesis and select another prosthesis.
   ATTENTION: To check, do not touch the clip itself, just gently manipulate the ossicles.



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



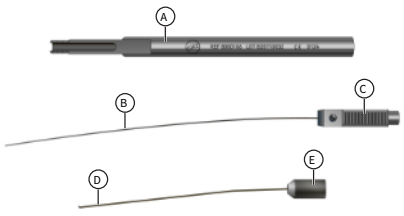
6. Cover the prosthesis with a graft (cartilage disc) against the tympanic membrane.

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

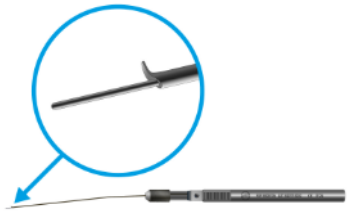
- The product is not sterile. Process the product before first and any further application.
  This is the only way to ensure the product is germ-free and functional. Process in accordance with the processing instructions document. [Additional Information, page 4]



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 2: KURZ Meter, components

13.6.1 Assembling the KURZ Meter



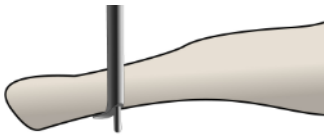
1. Insert the probe into the tube.
2. Insert the handle with slider of the probe into the receptacle on the handle until it stops.
3. Screw the union nut on the tube finger-tight onto the handle until it stops. To do this, turn the union nut clockwise.

13.6.2 Determining the Required Prosthesis Size

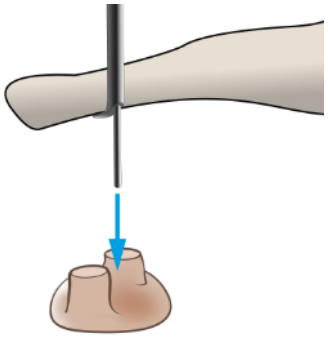
⚠ WARNING

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

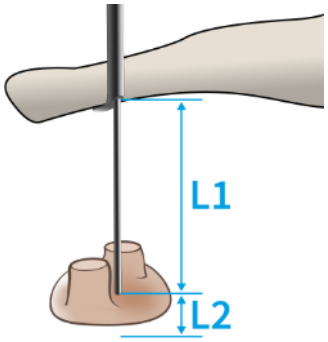
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.
Initial state: The slider is at the proximal stop. The tube is flush with the probe.



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



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 long processus of the incus/malleus handle and 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 15]

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

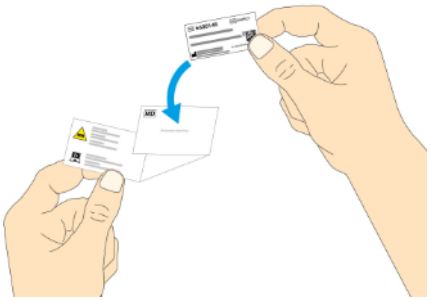
⚠ WARNING

- 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

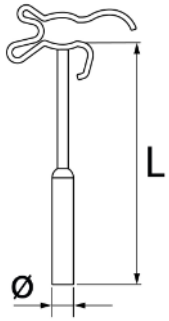
Soft CliP			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
	3.50	1006 203	1006 253
	3.75	1006 204	1006 254
	4.00	1006 205	1006 255
	4.25	1006 206	1006 256
	4.50	1006 207	1006 257
	4.75	1006 208	1006 258
	5.00	1006 209	1006 259
	5.50	1006 211	1006 261
	6.00	1006 213	1006 262
Width of the clip: 0.25 mm			

Table 2: Soft CliP

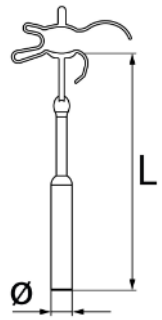
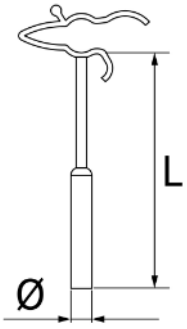
NiTiFLEX			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
	3.50	1007 203	1007 253
	3.75	1007 204	1007 254
	4.00	1007 205	1007 255
	4.25	1007 206	1007 256
	4.50	1007 207	1007 257
	4.75	1007 208	1007 258
	5.00	1007 209	1007 259
	5.50	1007 211	1007 261
	6.00	1007 213	1007 263
Width of the clip: 0.25 mm			

Table 3: NiTiFLEX

CliP Piston àWengen			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
	3.50	1006 803	1006 853
	3.75	1006 804	1006 854
	4.00	1006 805	1006 855
	4.25	1006 806	1006 856
	4.50	1006 807	1006 857
	4.75	1006 808	1006 858
	5.00	1006 809	1006 859
	5.50	1006 811	1006 861
	6.00	1006 813	1006 863

CliP Piston àWengen			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
Width of the clip: 0.25 mm			

Table 4: CliP Piston àWengen

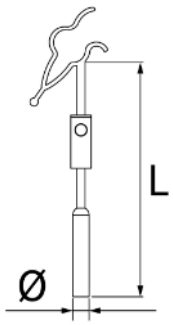
CliP Piston MVP			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
	5.00	1006 708	1006 758
	5.25	1006 709	1006 759
	5.50	1006 710	1006 760
	5.75	1006 711	1006 761
	6.00	1006 712	1006 762
	6.25	1006 713	1006 763
	6.50	1006 714	1006 764
Width of the clip: 0.25 mm			

Table 5: CliP Piston MVP

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
	Soft CliP Hook	8000 127	Stainless steel, surgical quality	Suitable for processing, Tip: 0.2 mm

Table 6: Accessories

19.3 Compatibility of Accessories

	KURZ Meter	Soft CliP Hook
Soft CliP	Yes	Yes
NiTiFLEX	Yes	Yes
CliP Piston àWengen	Yes	No
CliP Piston MVP	Yes	No