

Stapes Protheses

Crimpable Stapes Protheses and Accessories



MatriX



MatriX SlimLine



MatriX Offset



K-Piston



Skarzynski Piston



Angular Piston



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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/stp2.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), ++EHKM0227M (SteadyCrimP Forceps)
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
0006224_01	2025-10	Complete revision
0006224_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 14]

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

6 Product Description

6.1 General information

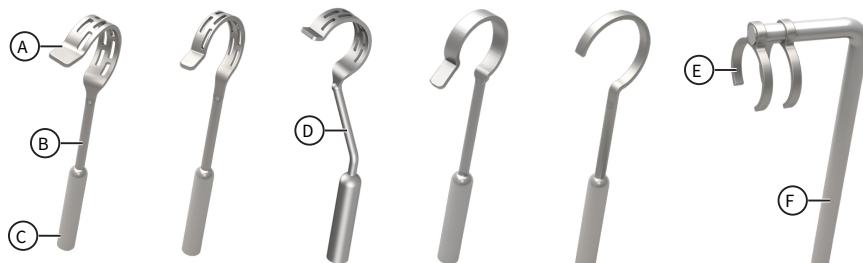


Illustration 1: Stapes prostheses, from left to right: Matrix, Matrix SlimLine, Matrix Offset, K-Piston, Skarzynski Piston, Angular Piston

- A Loop
- B Shaft
- C Piston
- D Offset shaft
- E Straps
- F Angled shaft

[▶ 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
SteadyCrimP Forceps (accessory)	The SteadyCrimP forceps are designed for fixing of stapes prostheses on the long process of the incus or on the 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 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 10]
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SteadyCrimP Forceps		[▶ Using SteadyCrimP Forceps, page 11] Assembly and disassembly: See processing instructions.
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[▶ 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.
SteadyCrimP Forceps (accessory)	The SteadyCrimP Forceps are used to fix a crimpable KURZ stapes prosthesis onto the long process of the incus or the handle of the malleus.

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 / SteadyCrimP Forceps (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 perforation
- 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, SteadyCrimp Forceps:

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.

- Closing forceps

The manufacturer recommends using the following products:

- KURZ Meter (accessory)
- SteadyCrimP Forceps (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.

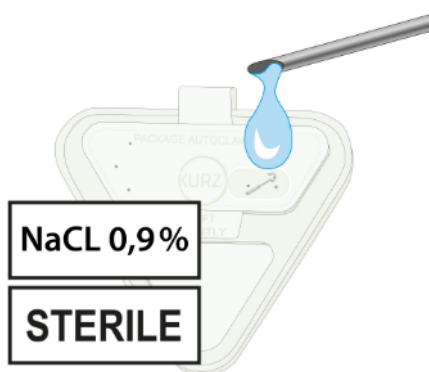
The manufacturer recommends using the KURZ Meter to determine the required size of the prosthesis.

[▶Using the KURZ Meter, page 10]

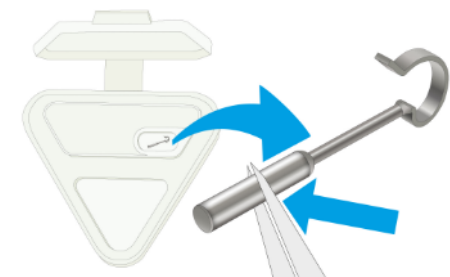
For MatriX Offset: Consider which ear the prosthesis is intended for when selecting. [▶Specifications, page 14]

ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.

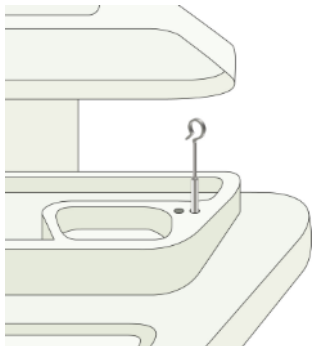
13.4 Preparing the Prosthesis



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 (Angular Piston: on the shaft).



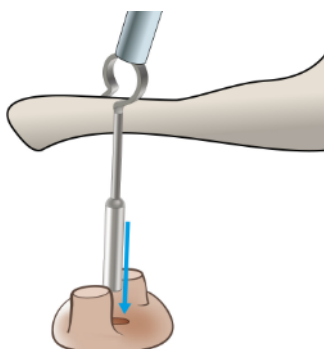
4. If necessary, place the prosthesis in one of the receptacles in the protective packaging (diameter 0.4 mm/0.6 mm) until it is transported to the middle ear.

13.5 Placing the Prosthesis

⚠ WARNING

- Crimp the stapes prosthesis in such a way that it does not have any play on the long processus of the incus or on the malleus handle.
Failure to do so may result in necrosis or erosion of the incus/malleus handle or migration of the stapes prosthesis.
- 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.

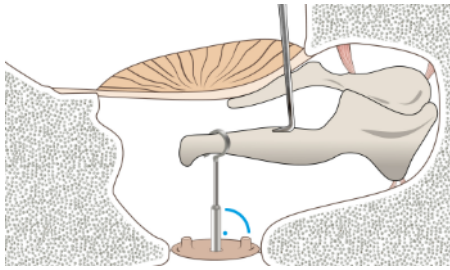
Depending on the size of the prosthesis, the prosthesis can be fixed to the malleus handle as an alternative to the procedure described here. The steps are the same.



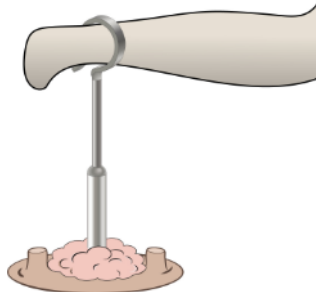
1. Place the loop/straps of the prosthesis on the long processus of the incus.
2. Using a suitable instrument, push down on the loop/straps until they fully enclose the long processus of the incus. When doing so, monitor the piston penetration into the opening to the inner ear.



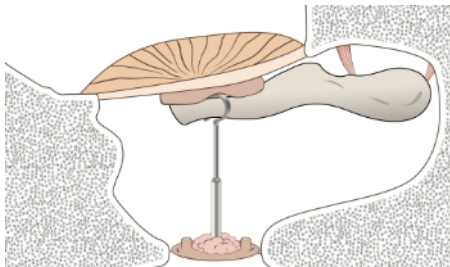
3. Close the loop/straps of the prosthesis with closing forceps.
The manufacturer recommends using SteadyCrimp forceps.
[▶ Using SteadyCrimP Forceps, page 11]



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 loop must not have any play on the long process of the incus, but it must not constrict the long process of the incus either. If the loop has play on the long process of the incus: Crimp the loop tighter.
ATTENTION: To check, do not touch the loop itself, just gently manipulate the ossicles.



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



6. When fixing the prosthesis to the malleus handle (not possible with all prostheses):
Cover the prosthesis with a graft (cartilage disc) against the tympanic membrane.

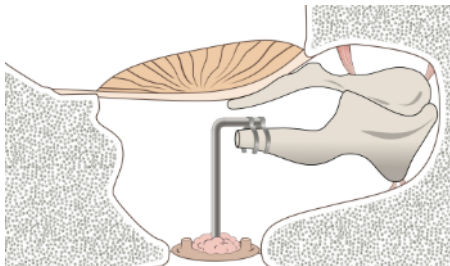


Illustration 2: Angular Piston in situ

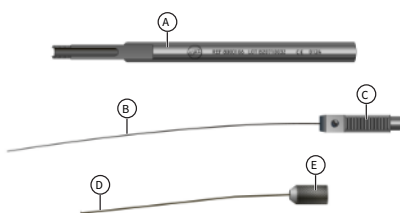
13.6 Using the KURZ Meter

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



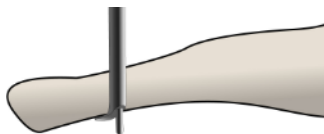
1. Insert the probe into the tube.
2. Insert the handle with slider of the probe into the receptacle on the handle until it stops.
3. Screw the union nut on the tube finger-tight onto the handle until it stops. To do this, turn the union nut clockwise.

13.6.2 Determining the Required Prosthesis Size

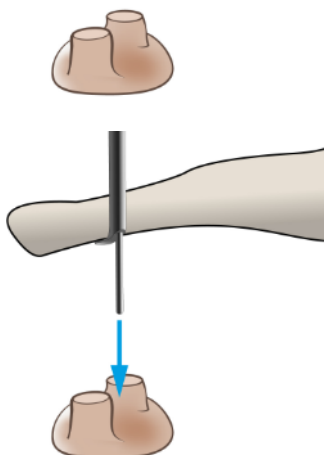
⚠ WARNING

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

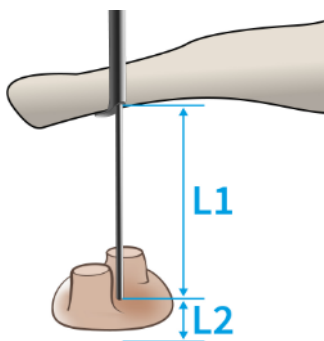
ATTENTION: The depth of the stapes prosthesis piston within the inner ear should be chosen at the discretion of the surgeon.
Initial state: The slider is at the proximal stop. The tube is flush with the probe.



1. Place the stop hook at the end of the tube medial to the long process 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 process 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 14]

13.7 Using SteadyCrimP Forceps

⚠ 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]

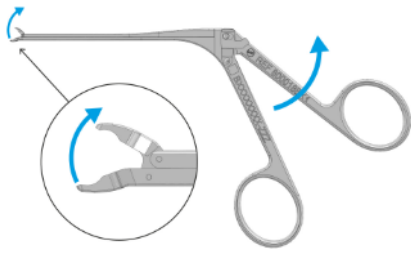
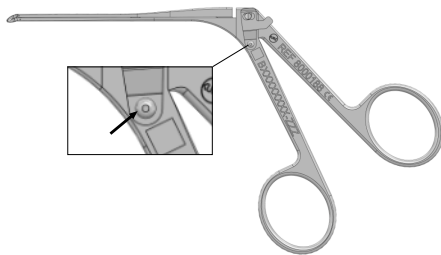


Illustration 4: SteadyCrimP Forceps

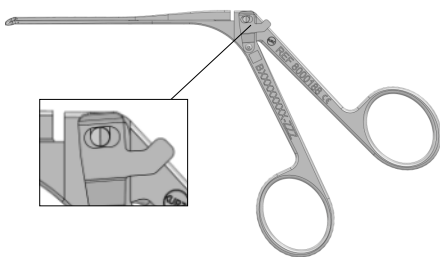
The jaws of the crimping forceps are used to crimp the stapes prosthesis around the corresponding anatomical structure. The crimping forceps are *reverse action* forceps: The jaw opens in the same direction as the handle is opened.

13.7.1 Carry out a function check

1. Make sure that the bolt is fully screwed into the thread.



2. Make sure that the lever is in the position shown.

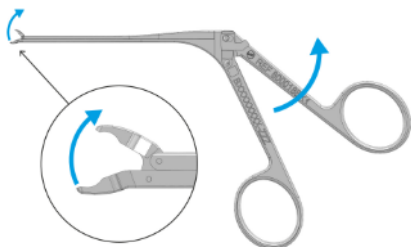


3. Try opening and closing the product.

ATTENTION: Do not move the lever.

If the product opens and closes smoothly, the product is ready for use. Otherwise, do not use the product.

13.7.2 Opening and closing SteadyCrimP



1. Grasp the crimping forceps. To do this, insert your thumb and index finger through the designated rings. Spread your thumb and index finger to open the handle. The jaws open in the same direction as the handle is opened.
2. Close the handle to close the forceps.

ATTENTION: Do not move the lever while using SteadyCrimP.

13.8 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.

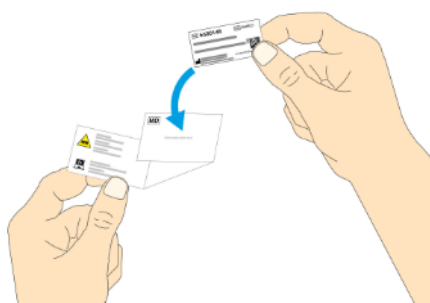
ATTENTION: Also inform the patient about the consequences of combining with other procedures.

[▶ 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

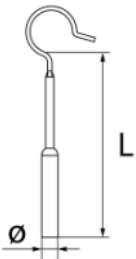
MatriX				
	L [mm]	Ø 0.4 mm REF	Ø 0.5 mm REF	Ø 0.6 mm REF
	3.50	1006 003	1006 023	1006 043
	3.75	1006 004	1006 024	1006 044
	4.00	1006 005	1006 025	1006 045
	4.25	1006 006	1006 026	1006 046
	4.50	1006 007	1006 027	1006 047
	4.75	1006 008	1006 028	1006 048
	5.00	1006 009	1006 029	1006 049
	5.25	1006 010	1006 030	1006 050
	5.50	1006 011	1006 031	1006 051
Width of the loop: 0.5 mm				

Table 2: MatriX

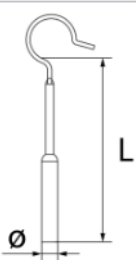
MatriX SlimLine				
	L [mm]	Ø 0.4 mm REF	Ø 0.5 mm REF	Ø 0.6 mm REF
	3.50	1006 263	1006 273	1006 283
	3.75	1006 264	1006 274	1006 284
	4.00	1006 265	1006 275	1006 285
	4.25	1006 266	1006 276	1006 286
	4.50	1006 267	1006 277	1006 287
	4.75	1006 268	1006 278	1006 288
	5.00	1006 269	1006 279	1006 289
	5.25	1006 270	1006 280	1006 290
	5.50	1006 271	1006 281	1006 291
Width of the loop: 0.3 mm				

Table 3: MatriX SlimLine

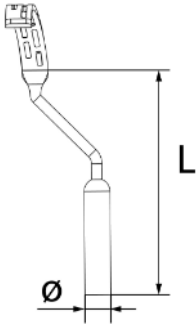
MatriX Offset			
	L [mm]	Left ear REF	Right ear REF
	4.50	1006 032	1006 035
	4.75	1006 033	1006 036
	5.00	1006 034	1006 037
Width of the loop: 0.5 mm Offset: 1.5 mm			

Table 4: MatriX Offset

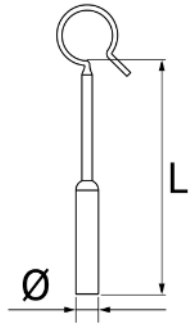
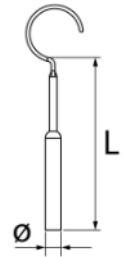
K-Piston			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
	3.50	1006 103	1006 153
	3.75	1006 104	1006 154
	4.00	1006 105	1006 155
	4.25	1006 106	1006 156
	4.50	1006 107	1006 157
	4.75	1006 108	1006 158
	5.00	1006 109	1006 159
	5.25	1006 110	1006 160
	5.50	1006 111	1006 161
	6.00	1006 112	1006 162
	7.00	1006 114	1006 164
	8.00	1006 116	1006 166
	9.00	1006 118	1006 168
	10.00	1006 120	1006 170
Width of the loop: 0.3 mm			

Table 5: K-Piston

Skarzynski Piston				
	L [mm]	Ø 0.4 mm REF	Ø 0.5 mm REF	Ø 0.6 mm REF
	3.50	1006 053	1006 063	1006 073
	3.75	1006 054	1006 064	1006 074
	4.00	1006 055	1006 065	1006 075
	4.25	1006 056	1006 066	1006 076
	4.50	1006 057	1006 067	1006 077
	4.75	1006 058	1006 068	1006 078
	5.00	1006 059	1006 069	1006 079
	5.50	1006 061	1006 071	1006 081

Skarzynski Piston				
	L [mm]	Ø 0.4 mm REF	Ø 0.5 mm REF	Ø 0.6 mm REF
Width of the loop: 0.2 mm				

Table 6: Skarzynski Piston

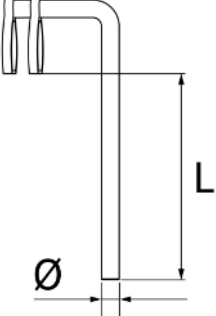
Angular Piston			
	L [mm]	Ø 0.4 mm REF	Ø 0.6 mm REF
	4.25	1006 600	1006 650
	4.50	1006 601	1006 651
	4.75	1006 602	1006 652

Table 7: Angular Piston

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
	SteadyCrimP Forceps	8000 188	Stainless steel, surgical quality	Suitable for processing

Table 8: Accessories