

Stapes Prosthesis



Bucket Type



HEINZ KURZ GMBH
TUEBINGER STR. 3
72144 DUSSLINGEN
GERMANY

1 Dear Patient,

You have been given an implant of the type KURZ Stapes Prosthesis. For your own safety, please read this Patient Information Document carefully and keep it somewhere safe. If you have any questions about your implant, please contact the physician who treats you.

2 About this Document

2.1 Symbols Glossary










Symbol	Description
	MR conditional
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

2.2 Safety Information Marking

WARNING

Non-compliance may result in serious injuries, serious deterioration of your general condition or your death.

2.3 Additional Information

	www.kurzmed.com/en/pi/stp.html
Download link for the Patient Information Document: ¹⁾	
This patient information is based on the following instructions for use:	0006227_Rev01

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

The catalog number and batch code for your implant can be found on your implant card.

3 Important Safety Information

WARNING

- Read these instructions carefully, adhere to them and save them. Otherwise there are risks to your health.

4 What you need to pay attention to

WARNING

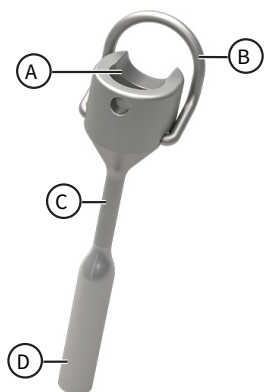
- Protect the auditory canal from water penetration. Otherwise there is a risk of inflammation / infection of the middle ear.
1. Always carry your implant card with you. Show your implant card and this Patient Information Document to your treating physician before undergoing diagnostic or therapeutic procedures.
 2. Contact your doctor if you experience one or more of the following symptoms: Earache, hearing loss / deafness, dizziness, tinnitus

- Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.

ATTENTION: Your implant must be monitored regularly by your attending physician. Be sure to keep your appointments for these follow-up examinations and follow your physician's advice on the necessary aftercare measures.

5 Product Description

5.1 General information



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

Illustration 1: Bucket Type

[▶ Specifications, page 4]

5.2 Materials with Potential Patient Contact

Product (part)	Material	Contact person	Type of contact
Stapes prosthesis	100% titanium	Patient	With every use

6 Intended Purpose

6.1 Patient Target Group

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

- Children and youth
- Adults
- Patients of all genders

6.2 Expected Lifetime

Stapes prosthesis	No product-specific restrictions. Regular check-ups are needed.
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7 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*

8 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>

9 Follow-up measures after removal of the product

The product is basically intended to remain in the body, but can be removed if necessary. In this case the follow-up treatment is at the discretion of the treating physician.

10 Specifications

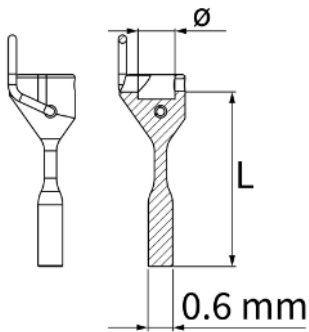
Stapes Prosthesis Bucket Type			
	L [mm]	Bucket Ø 0.9 mm REF	Bucket Ø 1.0 mm REF
	4.00	1006 543	1006 563
	4.25	1006 544	1006 564
	4.50	1006 545	1006 565
Ø Piston: 0.6 mm			

Table 2: Stapes Prosthesis Bucket Type