Patient Information Document

0005961_Rev03 — 2026-03

EN

Tympanoplasty Prostheses

Total Prostheses, Partial Prostheses, Angled Prostheses, MRP Malleus Replacement, OMEGA CONNECTOR

MR CE 0124

HEINZ KURZ GMBH
TUEBINGER STR. 3
72144 DUSSLINGEN
GERMANY

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1 Dear Patient,

You have been given an implant of the type KURZ Tympanoplasty 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

This patient information document applies to the following products:	• TTP Tuebingen BELL Partial • Duesseldorf BELL Partial • MunichLMU BELL Partial • MNP Malleus Notch Partial • CliP Partial Dresden • CliP Partial FlexiBAL • TTP VARIAC System Partial • TTP Tuebingen AERIALTotal • Duesseldorf AERIAL Total • MunichLMU AERIAL Total • MNP Malleus Notch Total • Regensburg Total • TTP VARIAC System Total • Angular Plester • Angular CliP • OMEGA CONNECTOR • MRP Malleus Replacement
 Download link for the Patient Information Document:[1)]	www.kurzmed.com/en/pi/tym.html

This patient information is based on the following instructions for use:	0005958_Rev03 / 0005952_Rev03 / 0005954_Rev02 / 0005955_Rev02 / 0005956_Rev02 / 0005957_Rev02 / 0005959_Rev02
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/tym.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):	++EHKM0017D

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

For the complete UDI (UDI-PI) please refer to the product label.

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

For Australia: 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 you live. https://www.tga.gov.au/

3 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
3. 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.

4 Product Description

4.1 General

Tympanoplasty prostheses are small prostheses that replace parts of the ossicular chain in the middle ear and thus enable sound to be conducted from the tympanic membrane to the inner ear.

Most tympanoplasty prostheses consist of a head plate, a shaft and a foot.

The head plate is attached to the tympanic membrane (and sometimes also to the malleus). Depending on the type, tympanoplasty prostheses replace the stapes partially (partial prostheses) or completely (total prostheses). In partial prostheses, the foot of the prosthesis sits on the stapes head, in total prostheses the foot of the prosthesis sits on the stapes footplate.

Angled prostheses are a special form: They do not have a head plate that rests against the tympanic membrane, but instead have straps with which they are attached to the long process of the incus.

The malleus replacement prosthesis MRP Malleus Replacement and the OMEGA CONNECTOR can also be implanted to optimally position or stabilise the tympanoplasty prosthesis.

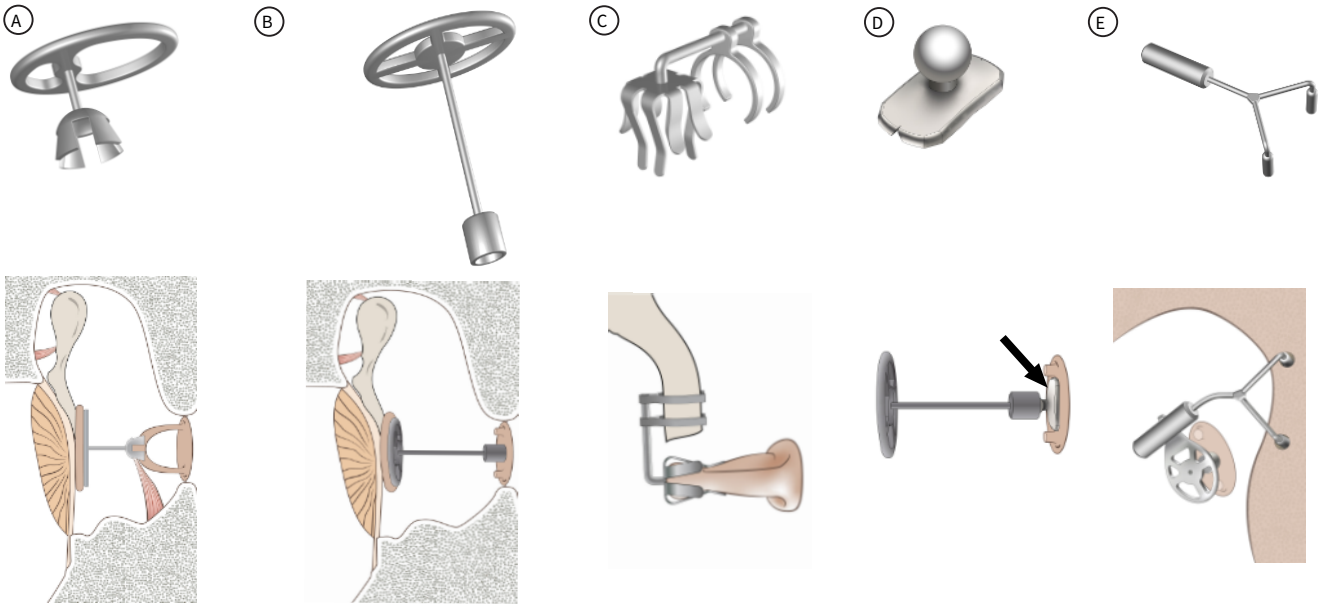

Illustration 1: Tympanoplasty Prostheses

A Partial prosthesis, here: Type BELL with bell-shaped base for coupling to the stapes head

B Total prosthesis for coupling with the stapes footplate

C Angled prosthesis, here: Type CliP with straps for attachment to the long process of the incus and clip for coupling to the stapes head

D OMEGA CONNECTOR (arrow), with total prosthesis

E MRP Malleus Replacement, here: With partial prosthesis MNP Malleus Notch Partial

For details of your implant, please refer to the product label in your implant card.

4.2 Materials

Titanium

5 Intended Use

5.1 Patient Target Group

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

- Children and youth
- Adults
- Patients of any gender

5.2 Expected Lifetime

No product-specific restrictions.
Regular check-ups are needed.

6 Possible Complications and Side Effects

- Implant migration
- Implant extrusion
- Lateralisation of the implant
- Sensorineural hearing loss
- Infection
- Dizziness
- Periprosthetic fibroses
- Periprosthetic cholesteatom formation

7 Combining with Other Procedures

⚠ 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.
- Apart from the specific provisions on MRI safety, the following applies: Do not expose the product to diagnostic or therapeutic electromagnetic radiation.
  Otherwise there are risks to the health of your patient.
- 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

8 Other Residual Risks

Beyond the listed safety instructions, possible complications and side effects, no further significant residual risks are known.

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.