Instructions for Use

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EN

OMEGA CONNECTOR
and Sizer OMEGA CONNECTOR (accessory)

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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 with protective packaging inside
	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
	Grüner Punkt: Dual recycling system in Germany

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

Download link for these Instructions for Use:[1)]	www.kurzmed.com/en/ifu/tym6.html
Download link for the Patient Information Document:[1)]	www.kurzmed.com/en/pi/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
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
International addresses:	https://www.kurzmed.com/en/contact.html

[1)] Updated on an ongoing basis.

1.4 Safety-related Changes

Document number	Edition date	Changes
0005957_ 01	2024-10	Complete revision

2 Important Safety Information

⚠ WARNING

- Before using the product: Read the Instructions for Use for the product and for all products used in combination. Follow and save the Instructions for Use.
  Otherwise there are risks for 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 10]

4 Scope of Delivery

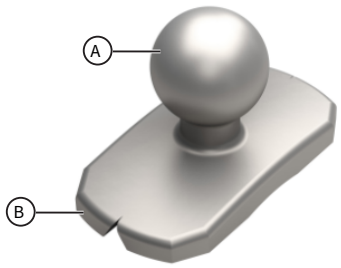
OMEGA CONNECTOR (Tympanoplasty Prosthesis)	1 x prosthesis 1 x implant card 4 x product label
Sizer OMEGA CONNECTOR (accessory)	1 x sizer 1 x processing instructions

5 Packaging and Sterility

OMEGA CONNECTOR (Tympanoplasty Prosthesis)	The product is sterile (sterilized by radiation). Packaging: Single sterile packaging with protective packaging (small tube) on the inside.
Sizer OMEGA CONNECTOR (accessory)	The product is not sterile. Packaging: Bag with ziplock + outer packaging (folding box)

6 Product Description

6.1 General Information



A Micro ball joint: Connecting part to the hollow stamp of a KURZ total prosthesis

B Base plate: Longitudinal milling on the bottom side to compensate for unevenness of the stapes foot plate

Illustration 1: OMEGA CONNECTOR

[Specifications, page 10]

6.2 Structure and Operation

OMEGA CONNECTOR (Tympanoplasty Prosthesis)	Prostheses which are inserted to partially or completely replace middle ear structures involved in sound conduction.
Sizer OMEGA CONNECTOR (accessory)	A sizing tool which is used to determine whether the stapes footplate can accommodate the OMEGA CONNECTOR prosthesis.

6.3 Materials with Potential Patient Contact

The following table lists all implant materials that the user or patient may come into contact with during application.

Product (part)	Material	Contact person
OMEGA CONNECTOR (Tympanoplasty Prosthesis)	100% titanium	Patient

Sizer OMEGA CONNECTOR : [Specifications, page 10]

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

	Sizer OMEGA CONNECTOR [Checking available Space on Stapes Footplate, page 8] [Specifications, page 10]

6.5 Other Devices to be Used in Combination with the Device

The OMEGA CONNECTOR is intended for use in conjunction with KURZ total prostheses with a hollow circular foot.

Compatibility: [Specifications, page 10]

7 Intended Use

7.1 Intended Purpose

OMEGA CONNECTOR (Tympanoplasty Prosthesis)	KURZ middle ear prostheses are intended for the partial or total surgical replacement of the ossicular chain of the human middle ear. The objective is the restoration of the mechanical transfer of sound from the tympanic membrane to the oval window of the cochlear with the least impairment of hearing.

Sizer OMEGA CONNECTOR (accessory)	The Sizer OMEGA CONNECTOR is a passive, reusable device which is used intraoperatively and surgically invasive by inserting it transiently into the implant site to determine whether there is sufficient space for placing the KURZ OMEGA CONNECTOR.

7.2 Indications

- Chronic otitis media with functional impairment of the ossicular chain
- Traumatic injury to the ossicular chain
- Congenital malformations of the middle ear
- Revision surgery due to inadequate hearing improvement (e.g., due to dislocation of a previously implanted prosthesis)

7.3 Contraindications

- Known sensitivity or allergy to titanium
- Complications or sequelae of unresolved otitis media, such as intracranial abscess, meningitis, lateral sinus thrombosis, malignancies, or patient-specific systemic disease
- Acute middle ear inflammation
- 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 all genders

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 (otorhinolaryngology)

7.6 Expected Lifetime

OMEGA CONNECTOR (Tympanoplasty Prosthesis)	No product-specific restrictions. Regular check-ups are needed.
Sizer OMEGA CONNECTOR (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

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

10 Combining with Other Procedures

OMEGA CONNECTOR (tympanoplasty prosthesis)

⚠ 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.
- Do not expose the patient to microwave radiation.
  Otherwise there are risks to the health of the 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, electromagnetic 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

OMEGA CONNECTOR (tympanoplasty prosthesis)

⚠ 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.

Sizer OMEGA CONNECTOR:

⚠ 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.

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 a suitable suction device or with appropriate forceps or tweezers.
  Otherwise the function of the prosthesis may be impaired.

Ensure the presence of hygienic / sterile conditions needed for the intervention.
It is placed as part of a type III tympanoplasty (ossicular reconstruction).
Perform the intervention under appropriate visual supervision.
ATTENTION: Also observe the instructions for use of the KURZ total prosthesis used.

13.1 Required Equipment and Materials

As usual for a type III tympanoplasty.

- Compatible KURZ total prosthesis [▸Specifications, page 10]
- Sizer OMEGA CONNECTOR

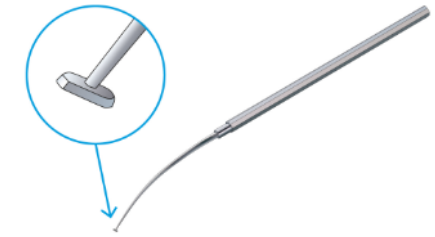
13.2 Preparation of the Patient

As usual for a type III tympanoplasty.
Endaural or retroauricular access to the middle ear.

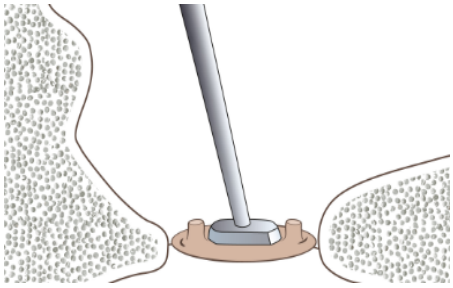
13.3 Checking available Space on Stapes Footplate

⚠ WARNING

- Only use the OMEGA CONNECTOR if there is sufficient space on the stapes footplate. Always use the Sizer OMEGA CONNECTOR to determine the available space.
  Otherwise necroses/migration of the prosthesis/dizziness may occur.

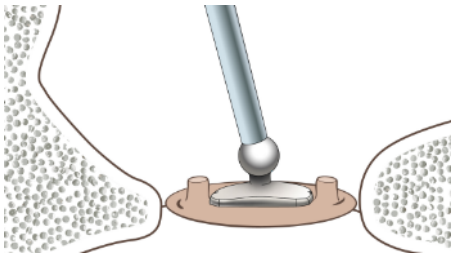


1. Hold the sizer's test head in the oval gap between the two bases of the stapes crura.
   ATTENTION: The test head must fit between the bases of the stapes crura without having to apply tension to the stapes crura. In this process, the test head must fully rest on the stapes footplate.
2. Remove the sizer.



ATTENTION: The sizer is intended solely for checking the available space and it is not intended for implantation.

13.4 Placing the OMEGA CONNECTOR



1. Open the sterile packaging and the protective packaging. Carefully remove the OMEGA CONNECTOR from the protective packaging. For this purpose, hold the OMEGA CONNECTOR at the ball joint with a suitable suction device.
2. Use a suitable suction device at the bases of the stapes crura to position the OMEGA CONNECTOR on the stapes footplate. Ensure that the OMEGA CONNECTOR does not exert tension on the bases of the stapes crura and that the OMEGA CONNECTOR does not protrude beyond the stapes footplate.OMEGA CONNECTOR.

13.5 Placing the KURZ Total Prosthesis

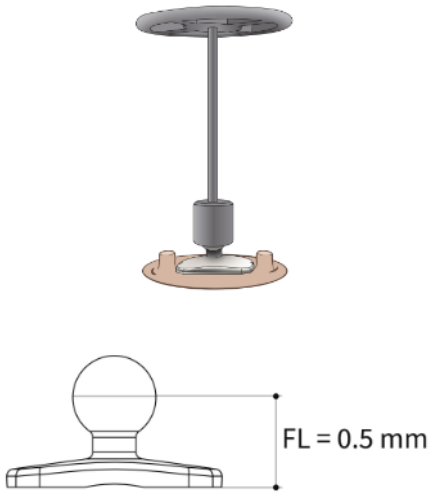


Illustration 2: OMEGA CONNECTOR: Functional length FL

1. Then position the KURZ total prosthesis on the OMEGA CONNECTOR. For this purpose, position the hollow stem of the total prosthesis on the micro ball joint of the OMEGA CONNECTOR.

ATTENTION: When choosing the required length of the total prosthesis also take into account the functional length of the OMEGA CONNECTOR (= 0.5 mm).

13.6 Removing the Prosthesis

OMEGA CONNECTOR and KURZ total 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

The instruction to the patient must include:

⚠ 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

ATTENTION: Fill out the implant card and give it to the patient.
Stick one of the product labels provided into the designated box on the implant card. Complete all other boxes.
The implant card must be presented at every radiological examination.

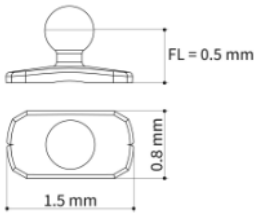
16 Disposal

⚠ 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.
  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 Specifications

	Name	REF	Material	Properties
	OMEGA CONNECTOR Tympanoplasty Prosthesis	1004 930	Titanium	Functional lenght FL: 0,5 mm Compatible KURZ total prostheses: • TTP®-Tuebingen AERIAL Total • Duesseldorf AERIAL Total • MunichLMU Total • MNP Malleus Notch Total • TTP® -VARIAC System
	Sizer OMEGA CONNECTOR	8000 555	Stainless steel (stainless instrument steel)	Non sterile Suitable for re-sterilising