Instructions for Use
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EN

Tympanoplasty Prostheses

Angular Prostheses

Angular Plester

Angular CliP®

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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 re-use
	Do not resterilize
	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)
	HIBC: Health Industry Barcode
	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/tym3.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
0005954_ 01	2024-09	Complete revision

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 10]

4 Scope of Delivery

- 1 x tympanoplasty prosthesis
- 1 x implant card
- 4 x product label

5 Packaging and Sterility

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)

6 Product Description

6.1 General information

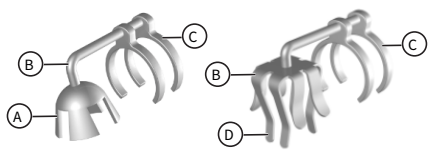


Illustration 1: Angular Plester, Angular CliP

A Foot of prosthesis: Bell with 4 slots (2 wider slots for positioning on the stapes arch and the stapedius tendon)

B Angled shaft

C Bands for attachment to the long process of the incus

D Foot of prosthesis: Clip with 8 teeth (2 x 2 short teeth for positioning on the stapes arch and on the stapedius tendon)

[Specifications, page 10]

6.2 Structure and Operation

Prostheses which are inserted to partially or completely replace middle ear structures involved in sound conduction.

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
Tympanoplasty Prosthesis	100% titanium	Patient

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

Accessories (separate instructions for use):

- KURZ Precise Cartilage Knife Set (REF 8000 155)
- Cartilage Forceps Schimanski Design (REF 8000 193)

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.

7 Intended Use

7.1 Intended Purpose

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.

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

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

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

⚠ 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

⚠ 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.

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. 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.
It is placed as part of a type II tympanoplasty (ossicular reconstruction).
Perform the intervention under appropriate visual supervision.

13.1 Required Equipment and Materials

As usual for a type II tympanoplasty.
The manufacturer recommends using the following products:

- KURZ Precise Cartilage Knife Set (REF 8000 155)
- Cartilage Forceps Schimanski Design (REF 8000 193)

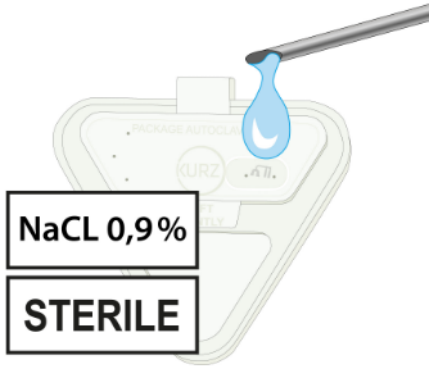
13.2 Preparation of the Patient

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

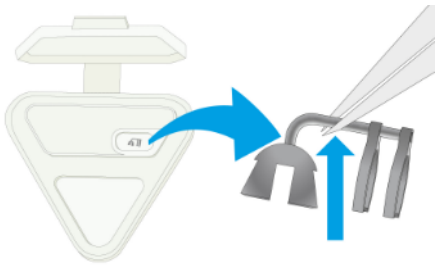
13.3 Choosing the Prosthesis

Always choose the length of the prosthesis according to the anatomical and functional conditions to achieve a satisfying hearing result and to avoid complications.

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.



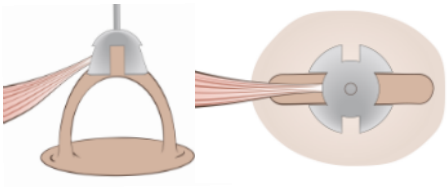
3. Carefully remove the prosthesis from the protective packaging. ATTENTION: Do not grasp the prosthesis by the shaft to avoid bending the prosthesis.

13.5 Angular Plester: Placing the Prosthesis

13.5.1 Positioning the prosthesis on stapes head

⚠ WARNING

- Ensure that the two wider slots of the prosthesis' foot are positioned at the stapes crura.
  Otherwise, there may be necroses/migration of the prosthesis.



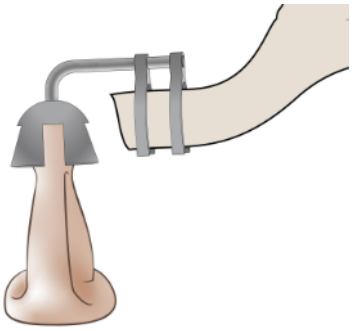
1. Position the prosthesis on the stapes head. To do this, position the prosthesis so that the stapes legs are each in one of the wide slots. The stapedius tendon is also in one of the wide slots.

2. Adjust the prosthesis to the stapes head.
   ATTENTION: Ensure that the prosthesis is firmly positioned on the stapes head.

13.5.2 Attaching the Prosthesis to the Long Processus of the Incus

⚠ WARNING

- Exercise utmost care when closing the straps.
  Otherwise there is a risk of damaging the ossicular chain.

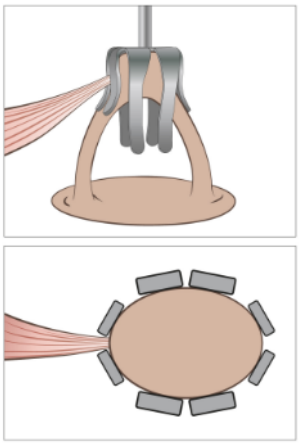


1. Position the straps on the long processus of the incus and close with micro forceps as far as necessary to secure the prosthesis to the long processus of the incus.
   ATTENTION: In this process, take utmost care to avoid damaging the ossicular chain.
2. Adjust the position of the prosthesis.
3. If prosthesis and the tympanic membrane will be in direct contact in the final position: Cover the prosthesis with a graft (cartilage disc) against the tympanic membrane.

Then: Close access to the middle ear.

13.6 Angular CliP: Placing the Prosthesis

13.6.1 Positioning the Prosthesis on the Stapes Head

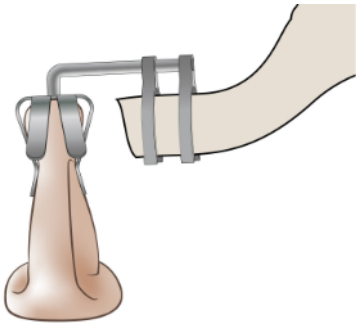


1. Position the prosthesis on the stapes head. For this purpose, adjust the prosthesis so that the short prongs rest against the stapes crura and the stapedius tendon runs between 2 short prongs.
2. Slide the prosthesis onto the stapes head. For this purpose, apply light pressure to the prosthesis.
   ATTENTION: Ensure that the prosthesis is securely positioned on the stapes head.
3. Adjust the prosthesis. For this purpose, manipulate the prosthesis with a fine needle or suction device.

13.6.2 Attaching the Prosthesis to the Long Processus of the Incus

⚠ WARNING

- Exercise utmost care when closing the straps.
  Otherwise there is a risk of damaging the ossicular chain.



1. Position the straps on the long processus of the incus and close with micro forceps as far as necessary to secure the prosthesis to the long processus of the incus.
   ATTENTION: In this process, take utmost care to avoid damaging the ossicular chain.
2. Adjust the position of the prosthesis.
3. If prosthesis and the tympanic membrane will be in direct contact in the final position: Cover the prosthesis with a graft (cartilage disc) against the tympanic membrane.

Then: Close access to the middle ear.

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:

1. Loosen adhesions.
2. Open the straps around the long processus of the incus to avoid injuries to the long processus of the incus.
3. For CliP type prostheses: Open the prongs to avoid injuring the stapes head.

Follow-up treatment at the discretion of the treating doctor.

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.

IMPORTANT: Also inform the patient about the consequences of combining with other procedures.
[Combining with Other Procedures, page 6]
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.

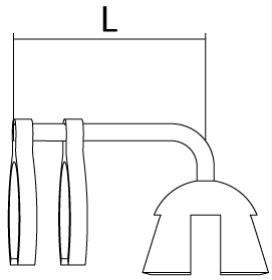
16 Disposal

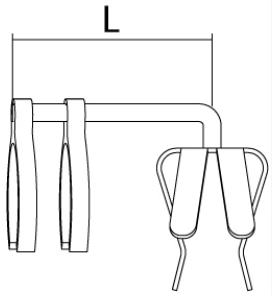
⚠ WARNING

- 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

Angular Plester	REF	L [mm]	Properties
	1002 610	2.25	Foot of prosthesis: Bell with 4 slots (2 wider slots for positioning on the stapes arch and the stapedius tendon) Angled shaft Bands for attachment to the long process of the incus
	1002 612	3.25	

Angular Clip	REF	L [mm]	Properties
	1002 615	2.25	Foot of prosthesis: Clip with 8 teeth (2 x 2 short teeth for positioning on the stapes arch and on the stapedius tendon) Angled shaft Bands for attachment to the long process of the incus
	1002 617	3.25	