Instructions for Use
0005952_Rev02 — 2024-11
EN

Tympanoplasty Prostheses

Total Protheses, Fixed Length

Accessories

TTP®-Tuebingen AERIAL Total

Duesseldorf AERIAL Total

MunichLMU AERIAL Total

MNP Malleus Notch Total

Regensburg Total

MD ONLY CE 0124

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Table of Contents

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
	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/tym2.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
0005952_ 01	2024-10	Complete revision
0005952_ 02	2024-11	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 12]

4 Scope of Delivery

Tympanoplasty Prosthesis	1 x tympanoplasty prosthesis 1 x implant card 4 x product label
AC Sizer System Total (accessory)	10 x sizer disk
Malleus Handle Cavity Bending Pliers (Accessories)	1 x bending pliers 1 x processing instructions

5 Packaging and Sterility

Tympanoplasty 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)
AC Sizer System Total (accessory)	The product is sterile (sterilized by radiation). Packaging: Simple sterile barreir system + outer packaging (folding box)
Malleus Handle Cavity Bending Pliers (accessory)	The product is not sterile. Packaging: Bag with ziplock + outer packaging (folding box)

6 Product Description

6.1 General information

Illustration 1: AERIAL type total prostheses, from left to right: TTP-Tuebingen AERIAL Total, Duesseldorf AERIAL Total, MunichLMU AERIAL Total, MNP Malleus Notch Total

A Fenestrated head plate

B Shaft

C Foot: Stamp, hollow

D Fenestrated head plate with curved extension to accommodate the malleus handle

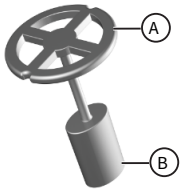


Illustration 2: Regensburg Total Type Total Prosthesis

A Fenestrated head plate with 2 recesses. The recesses mark the orientation of the foot.

B Foot: Stamp, solid, enlarged, oval

[Specifications, page 12]

Accessories: [Accessories, page 6]

6.2 Structure and Operation

Tympanoplasty Prosthesis	Prostheses which are inserted to partially or completely replace middle ear structures involved in sound conduction.
AC Sizer System Total (accessory) [Accessories, page 6]	Set of detachable dummy prostheses mounted on a disc, each corresponding in size to one of the tympanoplasty prostheses available. The dummy prostheses are used to determine the size of tympanoplasty prosthesis required.
Malleus Handle Cavity Bending Pliers (accessory) [Accessories, page 6]	A handheld instrument which uses mechanical force to create a concave indentation in the prosthesis headplate.

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

AC Sizer System Total: [Specifications, page 12]

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

AC Sizer System Total (accessory)		[Using the Sizer Disk, page 10]
Malleus Handle Cavity Bending Pliers (accessory)		[Using the Malleus Handle Cavity Bending Pliers, page 11]

[Specifications, page 12]
Other accessories (separate instructions for use):

- KURZ Precise Cartilage Knife Set (REF 8000 155)
- Cartilage Punch Set (REF 8000 200)
- Cartilage Forceps Schimanski Design (REF 8000 193)

6.5 Other Devices to be Used in Combination with the Device

Some tympanoplasty prostheses are compatible with other KURZ products. [Compatibility, page 13]
Apart from these and excluding the 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

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.
AC Sizer System Total (accessory)	The AC Sizer System Total is a passive, sterile, single use device. The sizer is used for intraoperative and surgically invasive determination of the length of the KURZ Total Tympanoplasty prostheses by temporarily inserting the sizer into the implant site.
Malleus Handle Cavity Bending Pliers (accessory)	The Malleus Handle Cavity Bending Pliers are a passive, reusable device which is used intraoperatively and non-invasively to bend an optional malleus handle cavity into the headplate of a KURZ Tympanoplasty prosthesis (TTP-Tuebingen, Duesseldorf)

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

Tympanoplasty Prosthesis	No product-specific restrictions. Regular check-ups are needed.
AC Sizer System Total (accessory)	Single-use product - lifetime corresponds to the duration of the procedure.
Malleus Handle Cavity Bending Pliers (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

Tympanoplasty 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.
- 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

Tympanoplasty prostheses, AC Sizer system:

⚠ 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.

Malleus Handle Cavity Bending Pliers:

⚠ 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. Always hold the prosthesis by the head plate for grasping and transport. 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 III tympanoplasty (ossicular reconstruction).
Perform the intervention under appropriate visual supervision.

13.1 Required Equipment and Materials

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

- AC Sizer System Total
- KURZ Malleus Handle Cavity Bending Pliers (if required for: TTP-Tuebingen AERIAL Total / Duessldorf AERIAL Total)
- KURZ Precise Cartilage Knife Set (REF 8000 155)
- Cartilage Forceps Schimanski Design (REF 8000 193)
- Cartilage Punch Set (REF 8000 200)

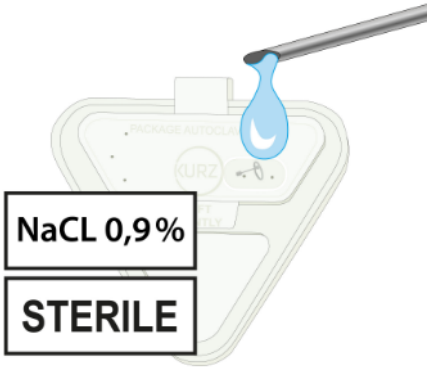
13.2 Preparation of the Patient

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

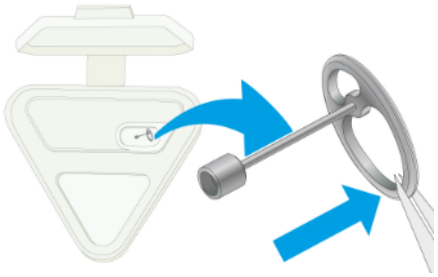
13.3 Choosing the Prosthesis

Always choose the length of the prosthesis according to the anatomical and functional conditions to achieve a good hearing result and to avoid complications. [Using the Sizer Disk, page 10]
If applicable: In this process, take into account the thickness of the graft to cover the head plate of the prosthesis.
When using OMEGA CONNECTOR: Also take into account the functional length of the OMEGA CONNECTOR (0.5 mm).

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.



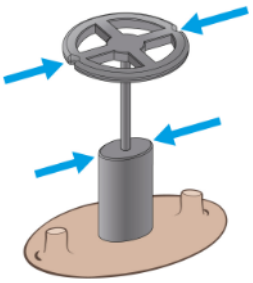
3. Carefully remove the prosthesis from the protective packaging. ATTENTION: Do not grasp the prosthesis by the shaft to avoid bending the prosthesis.

13.5 Placing the Prosthesis

13.5.1 Positioning the Prosthesis on the Stapes Footplate

When using OMEGA CONNECTOR: Also observe the OMEGA CONNECTOR instructions for use.

1. Position the prosthesis stem centrally on the stapes footplate.



2. The following applies to Regensburg Total: Adjust the prosthesis so that the recesses on the head plate are facing the bases of the stapes crura. The recesses indicate the orientation of the prosthesis' foot.

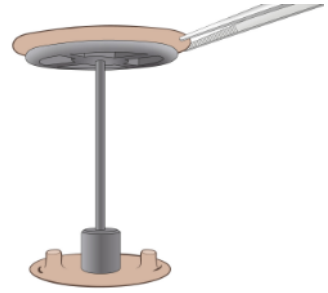
3. Optionally: Use a cartilage shoe (cartilage plate in a defined size and shape with central hole) to stabilise the base of the prosthesis. Use the KURZ cartilage punch (REF 8000200) to create the cartilage show (incompatible with Regensburg Total).
4. Adjust the prosthesis on the stapes footplate.
   ATTENTION: Ensure that the prosthesis is firmly positioned on the stapes footplate.
5. If required, carefully adapt the shape of the prosthesis to the anatomical structures. For this purpose, carefully bend the shaft.

Then link the head plate of the prosthesis with the tympanic membrane/malleus handle.

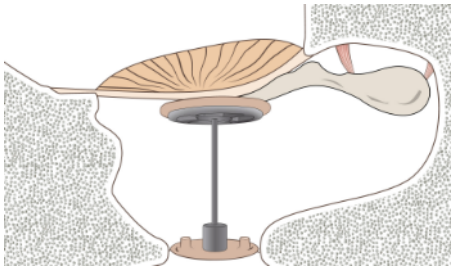
13.5.2 Linking the Head Plate to the Tympanic Membrane/Malleus Handle

⚠ WARNING

- Ensure that the head plate of the prosthesis is not in direct contact with the tympanic membrane. Cover the head plate opposite the tympanic membrane with a graft.
  Otherwise, there is a risk of tympanic membrane perforation.



1. Position the graft (cartilage disc, approx. 0.3 - 0.5 mm thick) on the head plate of the prosthesis. Ensure that the graft completely covers the head plate.



2. Link the head plate of the prosthesis with the tympanic membrane/with the malleus handle.
   TTP-Tuebingen AERIAL Total / Duessldorf AERIAL Total: If required, modify the head plate of the prosthesis for linking with the malleus handle. For this purpose, use the KURZMalleus Handle Cavity Bending Pliers only.
   [Using the Malleus Handle Cavity Bending Pliers, page 11]
3. MNP Malleus Notch Total: Link the curved extension of the head plate with the malleus handle.

Then check the fit of the prosthesis.

13.5.3 Checking the Prosthesis' Fit

1. Check whether the prosthesis causes tension in the tympanic membrane. If this is the case: Remove the implanted prosthesis and replace with a shorter prosthesis.
2. If the prosthesis used is too short: Remove the implanted prosthesis and replace with a longer prosthesis.
3. Close access to the middle ear.

13.6 Using the Sizer Disk

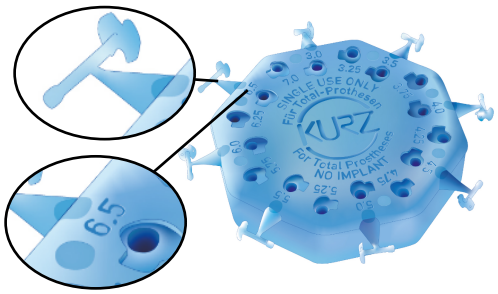
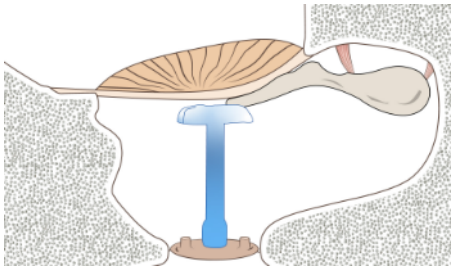


Illustration 3: AC Sizer System Total: 8 detachable sizers of different lengths, with size indication

1. Hold the selected sizer with an appropriate microsurgical instrument (e.g. suction device) and cut with micro scissors.



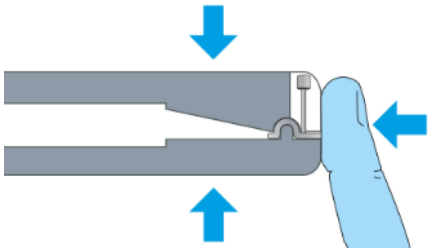
2. Place the foot of the sizer on the stapes footplate.
   ATTENTION: The size specification corresponds to the absolute length of the respective sizer.
   Take into account the thickness of the graft when determining the required length. When using OMEGA CONNECTOR: Also take into account the functional length of the OMEGA CONNECTOR (0.5 mm).
3. Remove the sizer from the middle ear after use.

ATTENTION: Sizers are exclusively used to determine the required prosthesis length and are not intended for implantation.

13.7 Using the Malleus Handle Cavity Bending Pliers

[Compatibility, page 13]

1. Grasp the prosthesis with fine tweezers and slide the foot of the prosthesis into the groove on the lower arm of the bending pliers. The head plate of the prosthesis is facing upwards. The short side of the head plate is laying flat.



2. Close the bending pliers. In this process, gently press your finger against the front of the bending pliers to prevent the prosthesis from slipping away. The cross brace presses the prosthesis into the groove, thus forming the recess for the malleus handle in the prosthesis.
3. Open the bending pliers and remove the prosthesis with the tweezers. If the prosthesis shaft has been deformed: Bend the shaft back to its original shape.

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 adhesions.
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 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

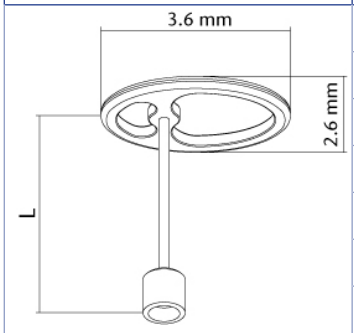
⚠ WARNING

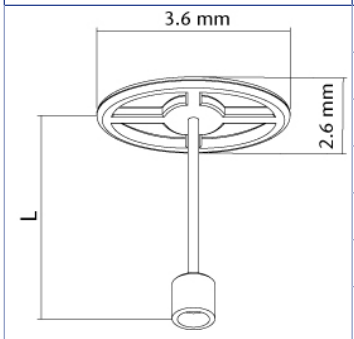
- The product was in contact with potentially infectious substances of human origin. Clean/pack the product for disposal according to the specific contamination risk.
  Otherwise there is a risk of infection for the user and for third parties.

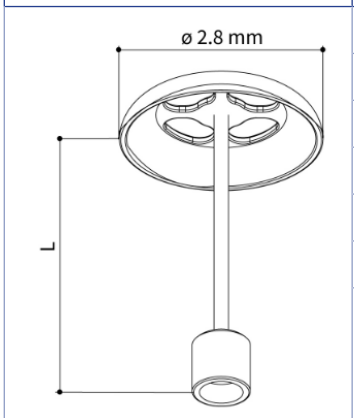
Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

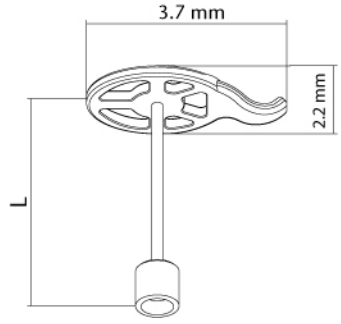
17 Specifications

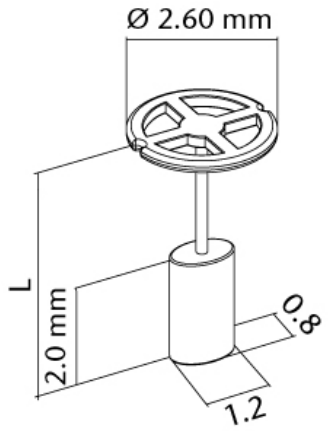
17.1 Tympanoplasty Prostheses

TPP-Tuebingen AERIAL Total	REF	L [mm]	REF	L [mm]	Properties
	1004 234	3.0	1004 241	4.75	Fenestrated head plate Foot: Stamp, hollow
	1004 235	3.25	1004 242	5.0	
	1004 236	3.5	1004 243	5.25	
	1004 237	3.75	1004 244	5.5	
	1004 238	4.0	1004 246	6.0	
	1004 239	4.25	1004 248	6.5	
	1004 240	4.5	1004 249	7.0	

Duesseldorf AERIAL Total	REF	L [mm]	REF	L [mm]	Properties
	1004 034	3.0	1004 041	4.75	Fenestrated head plate Foot: Stamp, hollow
	1004 035	3.25	1004 042	5.0	
	1004 036	3.5	1004 043	5.25	
	1004 037	3.75	1004 044	5.5	
	1004 038	4.0	1004 046	6.0	
	1004 039	4.25	1004 048	6.5	
	1004 040	4.5	1004 049	7.0	

MunichLMU AERIAL Total	REF	L [mm]	REF	L [mm]	Properties
	1004 074	3.0	1004 081	4.75	Fenestrated head plate Foot: Stamp, hollow
	1004 075	3.25	1004 082	5.0	
	1004 076	3.5	1004 083	5.25	
	1004 077	3.75	1004 084	5.5	
	1004 078	4.0	1004 086	6.0	
	1004 079	4.25	1004 088	6.5	
	1004 080	4.5	1004 089	7.0	

MNP Malleus Notch Total	REF	L [mm]	REF	L [mm]	Properties
	1004 434	3.0	1004 441	4.75	Fenestrated head plate with curved extension to accommodate the malleus handle Foot: Stamp, hollow
	1004 435	3.25	1004 442	5.0	
	1004 436	3.5	1004 443	5.25	
	1004 437	3.75	1004 444	5.5	
	1004 438	4.0	1004 446	6.0	
	1004 439	4.25	1004 448	6.5	
	1004 440	4.5	1004 449	7.0	

Regensburg Total	REF	L [mm]	REF	L [mm]	Properties
	1004 458	4.0	1004 461	4.75	Fenestrated head plate with 2 recesses. The recesses mark the orientation of the foot. Foot: Stamp, solid, enlarged, oval
	1004 459	4.25	1004 462	5.0	
	1004 460	4.5			

17.2 Accessories

	Name	REF	Material	Properties
	Malleus Handle Cavity Bending Pliers (Malleus Handle Cavity Bending Pliers)	8000109	Stainless steel, surgical quality	Suitable for processing
	AC Sizer System Total (10 x sizer disk)	8000550	Kunststoff	Per sizer disk: 8 sizers (3.0 / 3.5 / 4.0 / 4.5 / 5.0 / 5.5 / 6.0 / 6.5 mm)

17.3 Compatibility

	AC Sizer System Total REF 8000550	Malleus Handle Cavity Bending Pliers REF 8000109	MRP Malleus Replacement REF 1006960	OMEGA CONNECTOR REF 1004930
TPP-Tuebingen AERIAL Total	Yes	Yes	Yes [1)]	Yes
Duesseldorf AERIAL Total	Yes	Yes	Yes [1)]	Yes
MunichLMU AERIAL Total	Yes	No	No	Yes
MNP Malleus Notch Total	Yes	No	Yes	Yes
Regensburg Total	Yes	No	No	No

[1)] After modifying the head plate using the Malleus Handle Cavity Bending Pliers