Instructions for Use

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EN

Tympanoplasty Prostheses

Partial prostheses, variable length

Accessories

TTP®-VARIAC System Partial

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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
	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/tym5.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
0005956_ 01	2024-10	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 13]

4 Scope of Delivery

TTP-VARIAC System Partial (Tympanoplasty Prosthesis + AC Sizer System Partial)	1 x tympanoplasty prosthesis 1 x Sizer Disk 1 x implant card 4 x product label
Accessories: Titanium Tweezers/Micro Scissors/ Cutting Forceps/Titanium Micro Closing Forceps/Instrument Tray (Tray TTP-VARIAC)	1 x instrument/instrument tray (Tray TTP-VARIAC) 1 x processing instructions

5 Packaging and Sterility

TTP-VARIAC System Partial (Tympanoplasty Prosthesis + AC Sizer System Partial)	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)
Accessories: Titanium Tweezers/Micro Scissors/ Cutting Forceps/Titanium Micro Closing Forceps/ Instrument Tray (Tray TTP-VARIAC)	The product is not sterile. Packaging: Bag with ziplock + outer packaging (folding box); Instrument tray: Bags with snap lock only

6 Product Description

6.1 General information

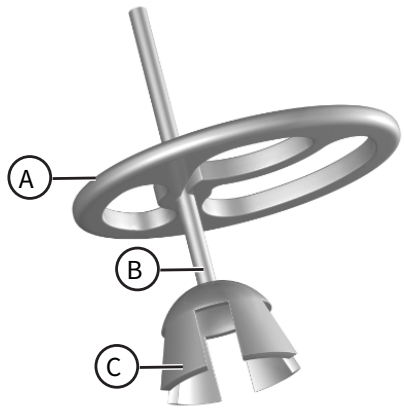


Illustration 1: Tympanoplasty Prosthesis

A Fenestrated head plate with locking mechanism

B Shaft with variable length

C Foot of prosthesis: Expandable bell with 4 slots (2 wider slots for positioning on the stapes legs and the stapedius tendon)

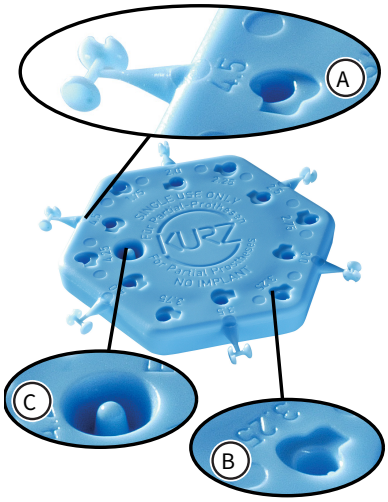


Illustration 2: AC Sizer System Partial

A Detachable sizers of different lengths, with size indication
Recesses for shortening the prosthesis to the determined length

B Recesses, intermediate sizes

C Cone for expanding the bell

[Specifications, page 13]

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 Partial	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. The disc is used to adjust the length of KURZ TTP-VARIAC Partial / Total prostheses prior to insertion.

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 Partial: [Specifications, page 13]

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

System accessories for TTP-VARIAC System Partial:

Accessories	Figure	REF	Material	Intended Use
Titanium Tweezers		8000136	Titanium	The Titanium Tweezers are a passive, reusable device which is used intraoperatively and non-invasively during a tympanoplasty procedure to handle the KURZ Tympanoplasty prostheses.
Micro Scissors		8000172	Stainless steel	The Micro Scissors are a passive, reusable device which is used intraoperatively and non-invasively to cut the sizer from the AC Sizer System Total / Partial.
Titanium Micro Closing Forceps		800137	Titanium	The Titanium Micro Closing Forceps are a passive, reusable device which is used intraoperatively and non-invasively to fix the headplate of a KURZ TTP VARIAC prosthesis to the shaft, after the length is adjusted.
Cutting Forceps		8000171	Stainless steel	The Cutting Forceps are a passive, reusable device which is used intraoperatively and non-invasively to cut off the protruding part of the shaft of a KURZ TTP VARIAC prosthesis after the length is adjusted and the headplate is fixed.
Instrument Tray (Tray TTP-VARIAC)		8000173	Stainless steel	The Tray TTP-VARIAC Set is a reusable device used to hold the KURZ VARIAC Set instruments during transport, sterilization and storage.

Other 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

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 Partial	The AC Sizer System Partial is a passive, sterile, single use device. The sizer is used for intraoperative and surgically invasive determination of the length of the KURZ Partial Tympanoplasty prostheses by temporarily inserting the sizer into the implant site. The AC Sizer System Partial features a cone for expanding the bell-shaped end of the KURZ Partial prostheses before implantation. The AC Sizer System Partial is used for non-invasive adjustment of KURZ TTP-VARIAC System Partial prostheses before implantation.

Accessories: [Accessories, page 6]

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 Partial	Single-use product - lifetime corresponds to the duration of the procedure.
Accessories: Titanium Tweezers / Micro Scissors / Cutting Forceps / Titanium Micro Closing Forceps/ Instrument Tray (Tray TTP-VARIAC)	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.

Instruments (titanium tweezers, micro scissors, cutting forceps, closing forceps), instrument tray (Tray TTP-VARIAC):

⚠ 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.
System accessories for TTP-VARIAC System Partial:

- AC Sizer System Partial
- Titanium Tweezers
- Micro Scissors
- Cutting Forceps
- Titanium Micro Closing Forceps
- Instrument Tray (Tray TTP-VARIAC)

The manufacturer recommends using the following products:

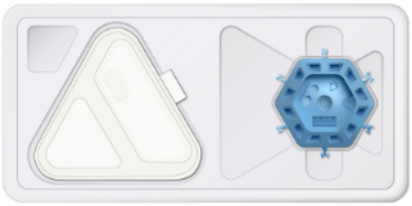
- KURZ Precise Cartilage Knife Set (REF 8000 155)
- Cartilage Forceps Schimanski Design (REF 8000 193)

13.2 Preparation of the Patient

As usual for a type III tympanoplasty.

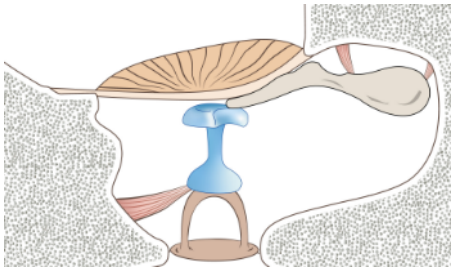
13.3 Determining the Prosthesis Length

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
In this process, take into account the thickness of the graft to cover the head plate of the prosthesis.



1. Open the sterile packaging and remove the sizer disk.

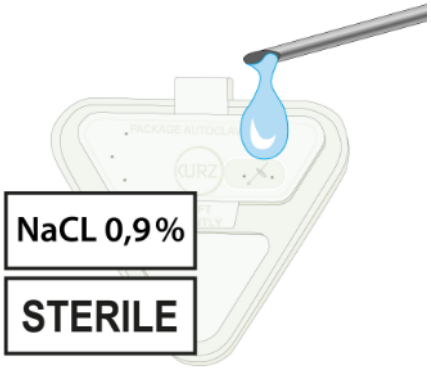
2. Hold the selected sizer with an appropriate microsurgical instrument (e.g. suction device) and cut with micro scissors.



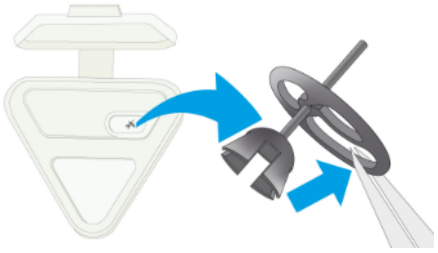
3. Place the bell-shaped base of the sizer on the stapes head.
   ATTENTION: The size specification corresponds to the absolute length of the respective sizer and the corresponding prosthesis.
   When determining the required length, take into account the thickness of the graft used to cover the head plate.
4. 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.

13.4 Unpacking the Prosthesis



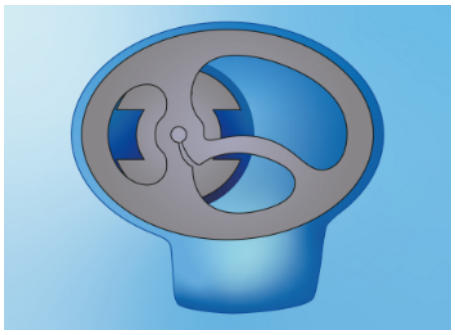
1. Apply drops of sterile saline solution on the openings of the protective packaging. In this process, ensure that the perforations in the lid are also coated in saline solution so that liquid can penetrate the protective packaging.



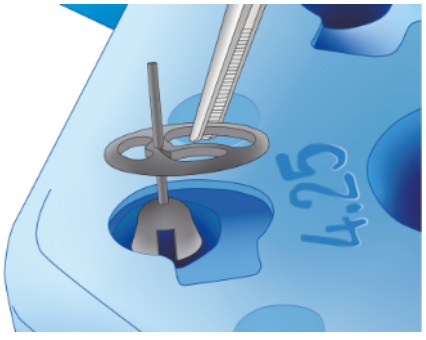
2. Carefully remove the prosthesis from the protective packaging. ATTENTION: Do not grasp the prosthesis by the shaft to avoid bending the prosthesis.

13.5 Adjusting the Length of the Prosthesis

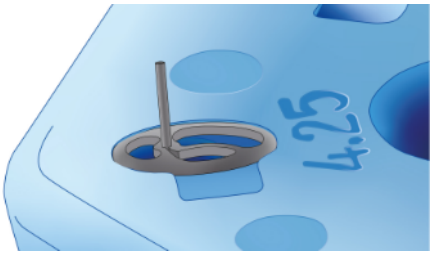
1. Choose the recess in the sizer disk that matches the appropriate sizer. There are recesses between the sizers in the respective intermediate sizes.



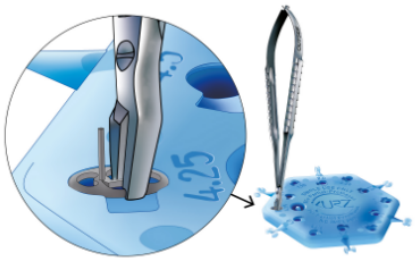
2. Use the titanium tweezers adjust the prosthesis so that the two wider slots in the foot of the prosthesis face towards the edge and the centre of the sizer disk and the two narrower slots each face towards the sides.

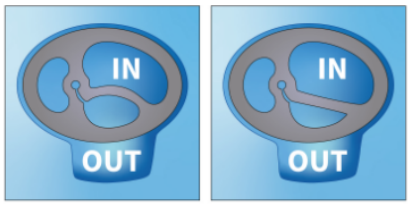


3. Insert the prosthesis in this orientation, foot first, into the recess until it will go no further. The prosthesis slides into the recess on the guide rails.



4. Slide down the head plate of the prosthesis on the shaft of the prosthesis until the head plate has been completely inserted and is flush in the intended recess.





5. Use closing forceps to close the head plate lock. For this purpose, position the limb of the closing forceps marked OUTSIDE in the recess provided on the outside of the head plate. Position the limb of the closing forceps marked INSIDE on the inside of the head plate. Carefully close the closing forceps fully. This straightens the bracket in the head plate and fixates the position of the head plate in relation to the shaft.

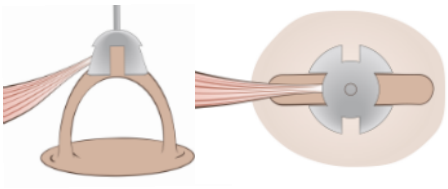
6. Use cutting forceps to cut off the protruding part of the shaft.
ATTENTION: For technical reasons, it is not possible to cut the shaft so it is completely flush. The remaining protrusion helps stabilise the graft position. Take into account the length of the protrusion when choosing the graft.

13.6 Placing the Prosthesis

13.6.1 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.



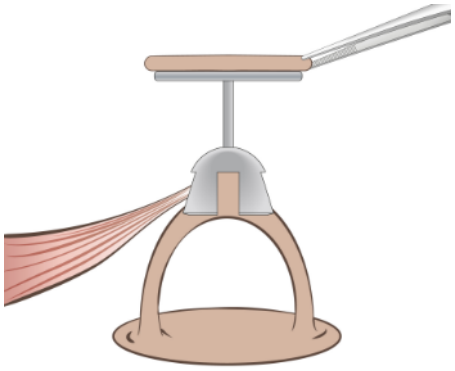
1. Position the prosthesis on the stapes head. To do this, position the prosthesis so that the stapes legs are each in one of the wide slots. The stapedius tendon is also in one of the wide slots.
   If required: Expand the bell of the prosthesis using the sizer disk. For this purpose, carefully press the bell of the prosthesis onto the cone of the sizer disk using a suitable surgical instrument.
2. Adjust the prosthesis to the stapes head.
   ATTENTION: Ensure that the prosthesis is firmly positioned on the stapes head.
3. 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.

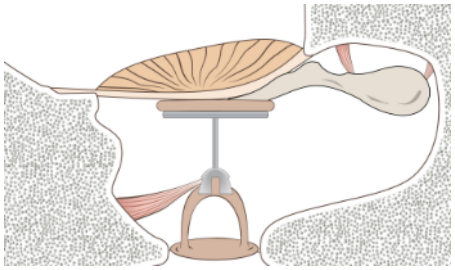
13.6.2 Linking the Head Plate to the Tympanic Membrane/Malleus Handle

⚠ 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.

Then check the fit of the prosthesis.

13.6.3 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.

13.7 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: 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 8]
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.

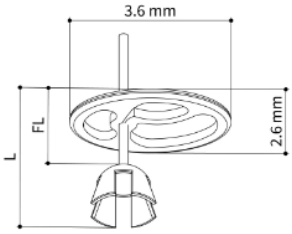
16 Disposal

⚠ 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

TTP-VARIAC System Partial REF 1002020	Name	Material	Properties
	Tympanoplasty Prosthesis	Titanium	Variable length: Overall length L: 1.75 - 4.50 mm Functional length FL: 0.75 - 3.50 mm Adjustable in 0.25 mm increments
	AC Sizer System Partial	Kunststoff	6 sizers (total length 2.0 / 2.5 / 3.0 / 3.5 / 4.0 / 4.5 mm) 12 recesses to adjust length: 1.75 - 4.50 mm total length in 0.25 mm increments