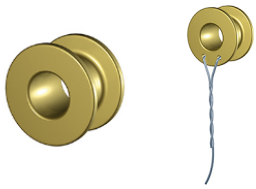
Instructions for Use
0005951_Rev01 — 2024-05
EN

VENTILATION TUBES

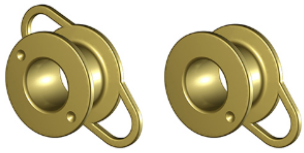
Ventilation Tubes

Tuebingen Type Ventilation Tube



Diabolo Type Ventilation Tube

Long-Term Ventilation Tube with Eyelets



Minimal Type Ventilation Tube

Trocar Ventilation Tube

Trocar Handle

MD ONLY CE 0124

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721813003 —24.05.2024 11:34

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
	Sterilized using irradiation
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	MR conditional
	MR unsafe
	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

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.

⚠ CAUTION

Non-compliance may result in light or moderate injuries or a light or moderate deterioration of the general condition of the patient, user, or a third party.

1.3 Additional Information

Download link for these Instructions for Use:[1)]	www.kurzmed.com/en/ifu/vnt.html
Download link for the Patient Information Document:[1)]	www.kurzmed.com/en/pi/vnt.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):	++EHKM0037H
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/vnt.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
0005951_ Rev01	2024-05	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 Package Contents

Ventilation tube:

- 2 x 5 ventilation tube (Trocar Ventilation Tube: Each on one disposable trocar)
- 10 x product label

Trocar handle:

- 1 x trocar handle
- 1 x Processing Instruction (REF 0001770)

5 Packaging and Sterility

Ventilation tube:

The product is sterile (sterilized by radiation).

Each ventilation tube is contained in a tube in its own blister. Each 5 blisters form a blister strip. The scope of delivery includes 2 blister strips. The ventilation tubes can be removed individually.

Trocar handle:

⚠ 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. For processing, please refer to the Processing Instructions (REF 0001770).

6 Product Description

6.1 General information

[Specifications, page 10]

6.2 Structure and Operation

The ventilation tube is inserted into the tympanic membrane. With its almost tubular structure, the ventilation tube maintains the patency of the incision site in the tympanic membrane and allows the tympanic cavity to be ventilated or drained. The ventilation tube is kept in place by its design (e.g. flanges).
With Tuebingen, Diabolo and Long-Term type ventilation tubes, a paracentesis is performed before placement.
With tympanic tubes of the Trocar Ventilation Tube and Minimal Type Ventilation Tube types, the tympanic membrane is incised when the ventilation tube is placed. With ventilation tubes of the Minimal Type Ventilation Tube type, this is achieved by the self-cutting tip of the ventilation tube. Ventialtion tubes of the Trocar Ventilation Tube type are supplied on a trocar, which is used to incise the tympanic membrane.

6.3 Materials with Potential Patient Contact

[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

Trocar Ventilation Tube: KURZ Trocar Handle (trocar holder) made of stainless steel, resterilisable; use is mandatory.
[Specifications, page 10]

6.5 Other Devices to be Used in Combination with the Device

Apart from the equipment and materials required for implantation, the product KURZ Ventilation Tube is not intended to be used in conjunction with any other products.

7 Intended Use

7.1 Intended Purpose

KURZ Ventilation tubes Tubes are small implants for the ventilation and/or drainage of the middle ear, which are inserted into the tympanic membrane, creating a passage between middle ear and outer auditory canal.
Tuebingen Type Ventilation Tube / Diabolo Type Ventilation Tube / Long-Term Ventilation Tube: Placement after paracentesis.
Trocar Ventilation Tube: Placement without prior paracentesis, by means of the disposable trocar the ventilation tube is supplied with.
Minimal Type Ventilation Tube: Placement without prior paracentesis. Primarily serves to ventilate the middle ear.
Trocar Handle: The Trocar Handle is a passive, reusable device which is used intraoperatively to hold the Trocar Ventilation Tube by connecting the Trocar Handle to the disposable trocar the Trocar Ventilation Tube is supplied with.

7.2 Indications

- Recidivating seromucous otitis media
- Tympanic cavity effusion of other origins

7.3 Contraindications

- Known allergy to the respective material
- Otitis media favourably influenced by pharmacotherapy / for which paracentesis is sufficient for treatment
- High jugular vein bulb
- Clinical history with tympanoplasty
- Glomus tumor
- Cholesteatoma
- Trocar Ventilation Tube: Flat tympanic cavity (amongst others retraction of the tympanic membrane, adhesions)
- Minimal Type Ventilation Tube: Flat or filled tympanic cavity (amongst others retraction of the tympanic membrane, adhesions)

7.4 Patient Target Group

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

- Infants and young children
- 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

Ventilation tube:

Expected lifetime of the product: 5 years

Trocar handle:

The lifetime of the product depends on the operating conditions and the associated wear.

Please refer to the processing instructions (REF 0001770).

ATTENTION: The expected lifetime is the time that the manufacturer expects the product to be safe and perform its function. The actual application duration may deviate from this and is at the discretion of your attending physician.

7.7 Intended Place of Use

- Operating theatre
- Treatment room
- Examination room (outpatient care)

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 intended purpose mentioned.

9 Possible Complications and Side Effects

Complications and injuries can occur during and after the procedure.

- Skin irritations or allergies
- Product occlusion
- Premature rejection of the ventilation tube
- Permanent tympanic membrane perforation after the end of the therapy
- Infections, if external bacteria gain access to the middle ear via the ventilation tube
- Myringosclerosis
- Tympanic sclerosis
- Cholesteatoma formation, e.g. due to epithelium entry during paracentesis / tympanic ventilation tube insertion
- Medial dislocation of the tympanic ventilation tube
- Otorrhea
- Migration of the ventilation tube into the tympanic cavity
- Adhesion of the ventilation tube
- Hearing loss and long-term complications such as atrophy and retraction

10 Combining with Other Procedures

⚠ WARNING

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

10.1 Tuebingen Type with Wire, Minimal Type

⚠ WARNING

- The product is not MRI-safe and must not be used in MR fields.
  The possible consequences of the application of non-MRI safe products in MR-fields include: Heating of the product, electromagnetic discharges, consequential damages caused by the application of force to the product, interferences in the imaging (also in the surrounding tissue).

10.2 Tuebingen Type without Wire, Diabolo Type, Long-Term Ventilation Tubes, Trocar Ventilation Tubes

⚠ WARNING

- 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 original packaging.
Store the product in a dry place and protect it from sunlight.

12 Processing

Ventilation tube:

⚠ 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.

Trocar handle:

⚠ 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. For processing, please refer to the Processing Instructions (REF 0001770).

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.

Ensure the presence of hygienic / sterile conditions needed for the intervention.
Insert tympanic ventilation tubes into the anteroinferior (ai) or posteroinferior (pi) quadrant of the tympanic membrane.

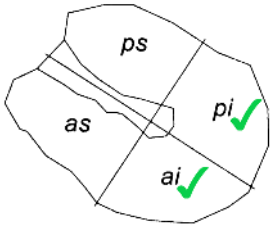


Illustration 1: Application site in the tympanic membrane

13.1 Tuebingen Type, Diabolo Type, Long-Term Ventilation Tubes

Placement is performed after paracentesis.

13.1.1 Required Equipment and Materials

Suitable inserter instrument (alligator jaw forceps or similar).

13.1.2 Product Preparation

1. Select a suitable product (shape and size).
2. Carefully remove the product from the sterile packaging.

13.1.3 Product Placement

1. Grasp the ventilation tube with the insertion instrument. Observe the direction of implantation.
2. Insert the ventilation tube through the paracentesis opening and position the ventilation tube correctly.
3. Tympanic ventilation tubes with wire: Shorten the wire after successful insertion and form an eyelet at the end of the wire to avoid skin irritations. The wire serves to retrieve the tympanic ventilation tube, if it slides too far into the tympanic cavity during implantation.

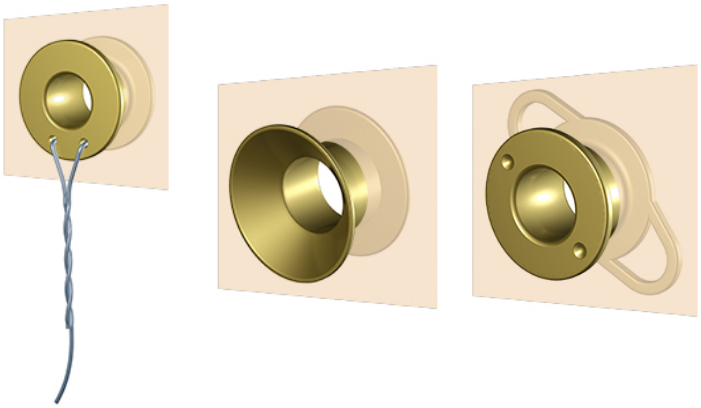


Illustration 2: Implantation direction: Front = external auditory canal, back = tympanic cavity

13.2 Trocar Type Ventilation Tubes

13.2.1 Required Equipment and Materials

- KURZ Trocar Handle (REF 8000 143) [Specifications, page 10]

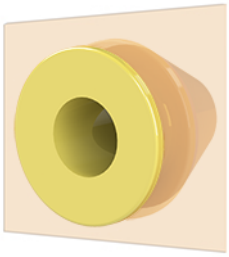
13.2.2 Product Preparation

1. Carefully remove the ventilation tube with trocar from the sterile packaging.
2. Screw the trocar onto the KURZ Trocar Handle.

The manufacturer recommends applying sterile saline solution between the ventilation tube and the trocar to facilitate handling.

Illustration 3: Ventilation tube on trocar, screwed onto the trocar handle

13.2.3 Product Placement



1. Perforate the tympanic membrane at the desired position using the tip of the trocar (without prior paracentesis) and place the ventilation tube.
2. Remove the trocar from the ventilation tube. The ventilation tube remains in its position.

Illustration 4: Front = external auditory canal, back = tympanic cavity

13.3 Minimal Type Ventilation Tubes

13.3.1 Required Equipment and Materials

Suitable inserter instrument (alligator jaw forceps or similar).

13.3.2 Product Preparation

1. Carefully remove the product from the sterile packaging.

13.3.3 Product Placement

1. Grasp the ventilation tube with the insertion instrument. Observe the direction of implantation.
2. Perforate the tympanic membrane at the desired position using the cutting tip of the ventilation tube (without prior paracentesis) and place the ventilation tube.
   ATTENTION: The flange of the ventilation tube points downwards.

Illustration 5: Front = external auditory canal, back = tympanic cavity

13.4 Removal of the product

⚠ WARNING

- Do not use the wire to remove the product after successful treatment.
  Otherwise there is a risk of injury for the patient.

Active removal of the product is usually not necessary, as the product is usually expelled spontaneously after a few weeks. [Possible Complications and Side Effects , page 6]
If there is no spontaneous rejection: Grasp the product with a suitable tool and remove it.

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 strong fluctuations of the ambient pressure (e.g., diving, taking headers into the water, explosions).
  Otherwise there is a risk of injury to the the ossicles / the vestibular system, possibly leading to a sense-of-hearing or vestibular disorder.
- Do not expose the patient to microwave radiation.
  Otherwise there are risks to the health of the patient.

ATTENTION: Fill out the implant card and give it to the patient.

16 Follow-up measures after removal of the product

- Regular monitoring of the tympanic membrane, especially in patients with an increased risk of secondary cholesteatoma, for early detection of this potential complication

17 Disposal

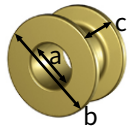
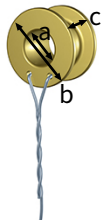
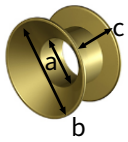
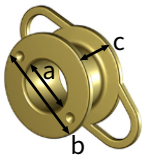
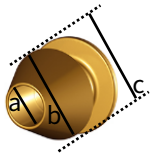
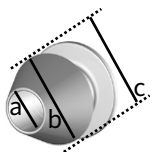
⚠ WARNING

- 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.

⚠ CAUTION

- Minimal Type Ventilation Tube, trocar of the Trocar Ventilation Tube: The product has points / sharp edges. For disposal, pack the product in a suitable stable container.
  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.

	MR	REF	Material	a / b / c [mm]	Property
Tuebingen Type Ventilation Tubes					
	MR	1015 001	Gold-platinum	1,25 / 2,55 / 1,60	Size 1
		1015 003		1,50 / 2,80 / 1,60	Size 2
		1015 010	Silver, gold-plated	1,25 / 2,55 / 1,60	Size 1
		1015 012		1,50 / 2,80 / 1,60	Size 2
		1015 036	Titanium	1,00 / 2,00 / 1,60	Size 0
		1015 030		1,25 / 2,55 / 1,60	Size 1
		1015 032		1,50 / 2,80 / 1,60	Size 2
	MR	1015 002	Gold-platinum Stainless steel	1,25 / 2,55 / 1,60	Size 1 with wire
		1015 004		1,50 / 2,80 / 1,60	Size 2 with wire
		1015 011	Silver, gold-plated Stainless steel	1,25 / 2,55 / 1,60	Size 1 with wire
		1015 013		1,50 / 2,80 / 1,60	Size 2 with wire
		1015 031	Titanium Stainless steel	1,25 / 2,55 / 1,60	Size 1 with wire
		1015 033		1,50 / 2,80 / 1,60	Size 2 with wire
Diabolo Type Ventilation Tubes					
	MR	1015 051	Gold-platinum	0,75 / 1,60 / 0,70	Size 0
		1015 053		1,25 / 2,55 / 1,50	Size 1
		1015 055		1,80 / 2,80 / 1,50	Size 2
Long-Term Ventilation Tubes with Eyelets					
	MR	1015 064	Gold-platinum	1,50 / 2,80 / 1,60	1 eyelet
		1015 065			2 eyelets
Trocar Ventilation Tubes					
	MR	1015 074	Silver, gold-plated	1,25 / 2,5 / 2,8	On a trocar (Stainless steel, MR unsafe, will be removed after placement) 
	MR	1015 075	Titanium, medical grade	1,25 / 2,5 / 2,8	
Minimal Type Ventilation Tubes					
	MR	1015 072	Stainless steel, medical grade, gold-plated	Inner Ø: 0,60 mm Outer Ø: 0,90 mm Length: 6 mm	Self-cutting
Trocar Handle					
	MR	8000 143	Stainless steel	Length: 120 mm Ø 1,8 mm / 3,0 mm	Non sterile

19 Implant Card

1. Print out the form with the implant cards and cut out the individual implant cards.
2. Stick one enclosed sticker (product label) on the back of each implant card.
   ATTENTION: The sticker displays, among other things, the batch number of the product. It is therefore important for the traceability of the product that the ventilation tube used and the sticker come from the same packaging.
3. Complete the missing data (patient name, facility name, implantation date).

Implant Card Ventilation Tubes

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www.kurzmed.com/en/pi/vnt.html

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