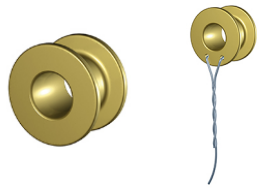
Patient Information Document
0005941 _Rev01 — 2024-05
EN

VENTILATION TUBES

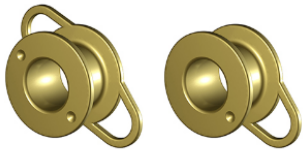
Ventilation Tubes

Tuebingen Type Ventilation Tube



Diabolo Type Ventilation Tube

Long-Term Ventilation Tube with Eyelets



Minimal Type Ventilation Tube

Trocar Ventilation Tube

CE 0124

HEINZ KURZ GMBH
TUEBINGER STR. 3
72144 DUSSLINGEN
GERMANY

9007199979346571 —28.05.2024 09:52

1 Dear Patient,

You have been given an implant of the type KURZ Ventilation Tube. For your own safety, please read this Patient Information Document carefully and keep it somewhere safe. If you have any questions about your implant, please contact the physician who treats you.

2 About this Document

2.1 Symbols Glossary

Symbol	Description
	MR conditional
	MR unsafe
	Catalog number
	Batch code
	Unique Device Identification (UDI)
	Manufacturer
	Patient name
	Date of implantation
	Name of the implanting healthcare institution / provider
	Patient information website

Table 1: Symbols Glossary

2.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of your general condition or your death.

2.3 Additional Information

Download link for the Patient Information Document:[1)]	www.kurzmed.com/en/pi/vnt.html
This patient information is based on the following instructions for use:	0005951_Rev01
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

[1)] Updated on an ongoing basis.

The catalog number and batch code for your implant can be found on your implant card.

For Australia: 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 you live. https://www.tga.gov.au/

3 What you need to pay attention to

⚠ 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.

1. Always carry your implant card with you. Show your implant card and this Patient Information Document to your treating physician before undergoing diagnostic or therapeutic procedures.
2. Contact your doctor if you experience one or more of the following symptoms: Earache, feeling of pressure or itching in the ear, bleeding from the ear, hearing loss
3. Stick to the appointments you make with your treating physician for follow-up examinations and observe their instructions for any necessary follow-up measures.

ATTENTION: Your KURZ Ventilation Tube must be monitored regularly by your attending physician. Be sure to keep your appointments for these follow-up examinations and follow your physician's advice on the necessary aftercare measures. This is especially true when the intended lifetime of your KURZ Ventilation Tube has been reached ([Expected Lifetime, page 3]).

4 Product Description

4.1 General information

Ventilation tubes are small, almost tube-shaped implants that are inserted into the tympanic membrane. With the help of ventilation tubes, the middle ear can be ventilated and fluids that accumulate in the middle ear can drain away (drainage).
[Specifications, page 5]

4.2 Materials with Potential Patient Contact

[Specifications, page 5]

5 Intended Use

5.1 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

5.2 Expected Lifetime

Expected lifetime of the product: 5 years
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.

6 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

7 Combining with Other Procedures

⚠ WARNING

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

7.1 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).

7.2 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

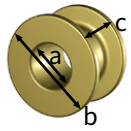
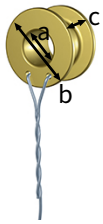
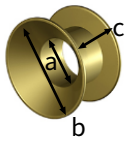
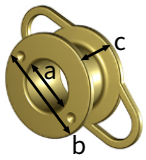
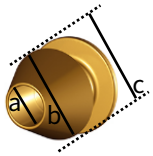
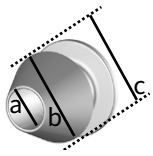
8 Other Residual Risks

Beyond the listed safety instructions, possible complications and side effects, no further significant residual risks are known.

9 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

10 Specifications

	MR	REF	Material	a / b / c [mm]
Tuebingen Type Ventilation Tubes				
	MR	1015 001	Gold-platinum	1,25 / 2,55 / 1,60
		1015 003		1,50 / 2,80 / 1,60
		1015 010	Silver, gold-plated	1,25 / 2,55 / 1,60
		1015 012		1,50 / 2,80 / 1,60
		1015 036	Titanium	1,00 / 2,00 / 1,60
		1015 030		1,25 / 2,55 / 1,60
		1015 032		1,50 / 2,80 / 1,60
	MR	1015 002	Gold-platinum Stainless steel	1,25 / 2,55 / 1,60
		1015 004		1,50 / 2,80 / 1,60
		1015 011	Silver, gold-plated Stainless steel	1,25 / 2,55 / 1,60
		1015 013		1,50 / 2,80 / 1,60
		1015 031	Titanium Stainless steel	1,25 / 2,55 / 1,60
		1015 033		1,50 / 2,80 / 1,60
Diabolo Type Ventilation Tubes				
	MR	1015 051	Gold-platinum	0,75 / 1,60 / 0,70
		1015 053		1,25 / 2,55 / 1,50
		1015 055		1,80 / 2,80 / 1,50
Long-Term Ventilation Tubes with Eyelets				
	MR	1015 064	Gold-platinum	1,50 / 2,80 / 1,60
		1015 065		
Trocar Ventilation Tubes				
	MR	1015 074	Silver, gold-plated	1,25 / 2,5 / 2,8
	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	Ø innen: 0,60 mm Ø außen: 0,90 mm Länge: 6 mm