THE FOLLOWING PRODUCTS ARE MR UNSAFE:

BRAND NAME	MATERIAL	REF NUMBER
Tuebingen Type Ventilation Tubes with wire	Gold-Platinum / Stainless Steel	1015002 / 1015004
Tuebingen TypeType Ventilation Tubes with wire	Gilded Silver / Stainless Steel	1015011 / 1015013
Tuebingen Type Type Ventilation Tubes with wire	Pure Titanium / Stainless Steel	1015031 / 1015033
Minimal Type Ventilation Tube	Gold Coated / Stainless Steel	1015072

Do not perform a MR scan with these implants.

THE FOLLOWING PRODUCTS ARE MR CONDITIONAL:

BRAND NAME	MATERIAL	REF NUMBER
Tuebingen Type Ventilation Tubes	Gold-Platinum	1015001 / 1015003
Tuebingen Type Ventilation Tubes	Gilded Silver	1015010 / 1015012
Tuebingen Type Ventilation Tubes	Titanium coated	1015020 / 1015022
Tuebingen Type Ventilation Tubes	Pure Titanium	1015030 / 1015032 / 1015036
Beveled Type Ventilation Tubes	Gold-Platinum	1015051 / 1015053 / 1015055
Ventilation Tubes Long Term	Gold-Platinum	1015064 / 1015065
Trocar Ventilation Tubes (TVT)	Gilded Silver	1015074
Trocar Ventilation Tubes (TVT)	Pure Titanium	1015075

Non-clinical testing has demonstrated the products listed are MR Conditional. They can be scanned safely under the following conditions listed beneath this table.

- Static magnetic field of 1.5 T, 3.0 T, or 7.0 T.
- Maximum spatial gradient field of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode)
- Follow the additional MRI Safety Instructions as specified. (Body coil only was used for testing as a worst-case assumption).

Under the scan conditions defined above, the Ventilation Tubes listed in the table above are expected to produce a maximum temperature rise of 2.6°C after 15minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 8 mm from the Ventilation Tube when imaged with a gradient echo pulse sequence and a 7.0 tesla MRI system.

See www.kurzmed.com for detailed MRI Safety Information.

IMPORTANT INFORMATION

Please remember that this leaflet is intended as general information only. It is not definitive. We aim to make the information as up to date and accurate as possible, but please be warned that it is always subject to change. Please, therefore, always check specific advice on the procedure or any concerns you may have with your doctor. After reading this information if there any questions you would like to ask, please ask your nurse or doctor.
Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration https://www.tga.gov.au/reporting-problems.

This information is available in electronic formats on request.

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11/2020-DMS_0004748_Rev.01

PATIENT INFORMATION LEAFLET - KURZ VENTILATION TUBES

Type Tuebingen, Type Diabolo, and all Type Long Term

MIDDLE EAR INTELLIGENCE

WHAT ARE KURZ VENTILATION TUBES OR GROMMETS?
Ventilation Tubes are tiny tubes (see front picture) which have a hole through the middle and look similar to a cotton reel.

WHY DO I NEED THEM?
Usually because you have either a condition called 'Glue Ear' or recurrent ear infections. Glue Ear is a condition where glue-like fluid prevents sound vibration from passing through the middle ear to the inner ear from where the sounds are transmitted to the brain.

WHAT CAUSES GLUE EAR?
The causes are not always clear, problems with the Eustachian tube, repeated ear infections and allergies are all associated with Glue Ear. It can occur after a cold.

WHAT DO KURZ VENTILATION TUBES OR GROMMETS DO?
Ventilation Tubes are inserted into the ear drum allowing air to pass into the middle ear and hence prevent the formation of further glue-like fluid.

PURPOSE
The purpose of a ventilation tube is to ventilate and / or drain the tympanic cavity. Thus, the pathologically changed mucous tissue of the middle ear can regenerate and serious changes of the middle ear can be avoided. Ventilation tubes of the types Tübingen, Diabolo and Long-Term allow temporary ventilation of the middle ear and/or drainage of the middle ear by surgical incision (paracentesis) into the tympanic membrane.

HOW LONG DO VENTILATION TUBES STAY IN THE EAR?
This varies between individuals and with the type of Ventilation Tube used. Short term: approx. 1-6 Months. Long term: approx.: 6 Months and longer (has to be removed surgically). It is hoped that during this time the Eustachian tube will have recovered its normal function.

CONTRAINDICATIONS
- Known allergy to the respective materials.
- Patients with otitis media reacting positively to drug therapy, and patients with otitis media for whom, from a medical point of view, the physician considers paracentesis alone sufficient.
- Glomus tumor.
- High jugular bulb.

SIDE EFFECTS, INTERACTIONS
- Skin irritations or allergies. In such cases, the ventilation tube is to be removed following the well-known surgical procedures.
- Early extrusion of the ventilation tube.
- Permanent perforation of the tympanic membrane after completion of the treatment.
- Damage to the ossicular chain in case of implantation in the tympanic membrane at the wrong place.
- Infections when bacteria penetrate from outside into the middle ear via the ventilation tube.
- Cholesteatoma formation due to epithelial carryover during parcentesis / insertion of a vent tube.
- Myringosclerosis / Tympanosclerosis
- Medial displacement of the vent tube.

HOW LONG WILL I BE IN HOSPITAL?
You will be admitted as a 'day case' so you will not need to stay in hospital. The operation may, in some cases, be performed under local anaesthetic.

WHEN CAN I GO BACK TO WORK?
You may return to work after one day off. It should be possible to return to work the following day in the case of a local anaesthetic. As this is determined by individual influence factors, the physician in charge will discuss your hospital stay and return to work with you.

AT HOME AFTER THE OPERATION

1. You may be prescribed eardrops for the first few days.
2. For the first three weeks keep the ear canal dry. When washing your hair, you should use an ear plug e.g. cotton wool smeared with Vaseline. This is because soapy water can irritate the ear. After three weeks still take care whilst washing your hair and bathing.
3. Surface swimming is usually permitted after one month with the ear canal(s) protected by ear plugs. It may also be advisable to wear a swimming hat.
4. Please be sure to follow any instructions given by the clinic and keep any follow-up appointment made by the hospital or doctor.

HAND HYGIENE
In the interests of patient safety, hand hygiene is a very important factor in controlling infection. Patients are encouraged to clean their hands well.

WARNING
The ventilation tube forms a passage between middle ear and outer auditory canal. Thus, pathogenic germs can reach the middle ear by means of water or air. Therefore, the auditory canal ought to be appropriately protected.

Severe variations in ambient pressure (scuba diving, diving headfirst, explosions, etc.) are to be avoided, as they can result in injuries of the tympanic membrane and / or the remaining ossicles and, as a consequence in auditory and equilibratory dysfunctions. After insertion of a ventilation tube with retention wire, the wire should be shortened and – if possible – bent into a loop in order to avoid irritations of the acoustic meatus skin. The retention wire is not intended for removal after successful treatment (risk of trauma!) but for retainment in case the tube slips too far into the tympanic cavity.

MRI SAFETY INFORMATION
KURZ manufactures implants for surgeons specializing in otorhinolaryngology. These are designed for permanent implantation in the patient. Examinations with magnetic resonance imaging (MRI) techniques are employed increasingly for all types of diagnostic purposes.

Patients with metallic implants may not be exposed to microwave irradiation. Potential hazards that MR imaging may have as a result of the implant included magnetic field interactions, heating, induced electrical currents, and possible artefacts. Patients with "Minimal tubes" made of gold-plated steel must not be exposed to magnetic resonance imaging (MR), the "Ventilation tubes" must be removed before such examination.

MRI CLASSIFICATIONS

MR UNSAFE

MR CONDITIONAL

MR UNSAFE means it is not possible for magnetic resonance imaging (MRI).

MR Conditional means that non-clinical testing has demonstrated that the implant can be scanned safely under specific conditions. Scanning under different conditions may result in severe patient injury.

Details on the MR conditions for each Implant are given on the following page. If the (REF Number) of the Ventilation Tube is unknown or unclear, do not perform a MR scan. Please check below or with your Doctor.