THE FOLLOWING PRODUCTS ARE MR CONDITIONAL:
Non-clinical testing has demonstrated the products listed below are MR Conditional. They can be scanned safely under the following conditions listed beneath the table.

BRAND NAME	MATERIAL	REF NUMBER
TTP VARIAC / VARIO System Partial	Pure Titanium	1002020 / 1002010
Duesseldorf Type Bell	Pure Titanium	1002023 – 1002047
München^{LMU} Bell Partial Prothesis	Pure Titanium	1002073 – 1002080
TTP Tuebingen Type Bell	Pure Titanium	1002223 – 1002230
CliP Partial Prosthesis	Pure Titanium	1002250 – 1002274
CliP Partial FlexiBAL	Pure Titanium	1002350 – 1002368
Malleus Notch Prosthesis (MNP) Partial	Pure Titanium	1002423 – 1002430
Bell Partial Vincent	Pure Titanium	1002473 – 1002480
Angular Prosthesis	Pure Titanium	1002610 / 1002612
Angular CliP Prosthesis	Pure Titanium	1002615 / 1002617
Incus Bridge Prosthesis (IBP)	Pure Titanium	1002620
TTP VARIAC / VARIO System Total	Pure Titanium	1004020 / 1004010
Duesseldorf Type Aerial Prothesis	Pure Titanium	1004034 – 1004049
München^{LMU} Aerial Total Prothesis	Pure Titanium	1004074 – 1004089
TTP Tuebingen Type Aerial	Pure Titanium	1004234 – 1004249
Malleus Notch Prosthesis (MNP) Total	Pure Titanium	1004434 – 1004449
Regensburg Type Prosthesis	Pure Titanium	1004458 – 1004462
Aerial Total Vincent	Pure Titanium	1004478 – 1004494
Ω Connector / Spider	Pure Titanium	1004930 / 1004975

- 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 Tympanoplasty Prostheses listed in the table above are expected to produce a maximum temperature rise of 2.8°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 6 mm from the Tympanoplasty Prosthesis when imaged with a gradient echo pulse sequence and a 7.0 Tesla MRI system.

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

MRI CLASSIFICATIONS

MR CONDITIONAL

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.

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PATIENT INFORMATION LEAFLET – KURZ PROSTHESES FOR TYMPANOPLASTY

KURZ

MIDDLE EAR INTELLIGENCE

WHAT IS TYMPANOPLASTY?
Tympanoplasty is a surgical technique to reconstruct the ear drum (tympanic membrane) and/or middle ear bone. The aim of reconstructing the ossicular chain (=middle ear bones) is to create the natural function as closely as possible and conduct the incoming acoustic signal to the inner ear with minimal loss.

WHY DO I NEED THE SURGICAL PROCEDURE?
The goal of this surgical procedure is to eradicate the disease from the middle ear, repair the defect and restore hearing and the middle ear function.

IS THE PROCEDURE SAFE?
Tympanoplasty is a safe and effective procedure. Paramount to the success of the procedure is the preoperative assessment, good haemostasis intraoperatively, and thoughtful surgical planning with careful placement of the implant and graft by your Doctor.

HOW IS THE SURGERY PERFORMED?
The surgery is either performed through the ear canal or through the skin at the back of the ear. The defect of the ossicular chain is repaired with a prosthesis. The hole in your ear drum is repaired using a graft taken from your own tissue around the ear. A dressing called an ear wick is left inside the outer ear canal and is usually removed a few days after the surgery.

HOW LONG DOES THE SURGERY TAKE?
The surgery is usually performed under a general anaesthetic, it usually takes 1 to 2 hours and involves replacing the defective bone with an implant.

WHAT IMPLANT MATERIALS ARE USED?
KURZ uses only high-quality, pure titanium for our tympanoplasty prostheses. It is distinguished by good mechanical properties as well as high resistance to corrosion and a good biocompatibility. It is a clinically tested material with numerous benefits.

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.

CONTRAINDICATIONS
Known allergy to the respective materials. Patients reacting positively to drug therapy and patients for whom a conservative treatment is sufficient.

Acute middle ear infections that could dislocate the prosthesis. Acute and chronic infectious diseases. Patients with general wound healing impairments.

SIDE EFFECTS, INTERACTIONS
General complications such as nausea, vomiting, sore throat and drowsiness may occur because of the anaesthetic. Serious drug reactions related to the anaesthetic are considered very rare. Permanent perforation of the tympanic membrane after completion of the treatment.

Damage to the ossicular chain in case of implantation, graft failure or the tympanic membrane in the wrong place. Infections can occur both in the wound and in the middle ear when bacteria penetrate from outside into the middle ear.

Bleeding is common with a small amount of blood oozing onto the dressings, less often a haematoma can collect under the wound which may need to be drained with another procedure. Altered sensation of taste may occasionally occur. Loss of hearing - This is very rare and can vary from minor to severe
Damage to the facial nerve.

AT HOME AFTER THE OPERATION.
Keep your ear dry. You should avoid any strenuous activity, especially any heavy lifting for more than 2-3kg for two weeks after surgery. You may feel tired after your hospital stay so get as much rest as possible. Slowly increase your level of activity each day. Keep well hydrated. If sneezing, do so with your mouth open. Take regular analgesia as prescribed by your Doctor. Do not remove the ear pack or wick items in your ears and try not to ‚pop' your ears. If you notice discharge, swelling, hardness or redness on or around your wound or if you experience any other problems related to your surgery contact your Doctor as soon as possible. Smoking is not recommended. Follow the detailed information provided by your doctor closely.

WHEN CAN I GO BACK TO WORK?
Your Doctor will advise you when you may return to work. As this is determined by individual influence factors, the physician will discuss your hospital stay and return to work with you.

WARNING
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 (such as scuba diving, diving headfirst, explosions etc.) are to be avoided. They can result in injuries of the tympanic membrane and/or the remaining ossicles and, as a consequence, in auditory and equilibratory dysfunctions.

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 are 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.