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

BRAND NAME	MATERIAL	REF NUMBER
Matrix Stapes Prosthesis	Pure Titanium	1006003 - 1006051
Matrix Offset Stapes Prosthesis	Pure Titanium	1006032 - 1006037
Skarzynski Stapes Prosthesis	Pure Titanium	1006053 - 1006081
MatriX SlimLine Stapes Prosthesis	Pure Titanium	1006263 - 1006291
K-Piston Stapes Prosthesis	Pure Titanium	1006103 - 1006120
Soft-CliP Stapes Prosthesis	Pure Titanium	1006153 - 1006170
LCP Stapes Prosthesis	Pure Titanium	1006203 - 1006211
Bucket Type Stapes Prosthesis	Pure Titanium	1006253 - 1006261
Angular Piston Stapes Prosthesis	Pure Titanium	1006523 - 1006529
CliP-Piston MVP Stapes Prosthesis	Pure Titanium	1006543 - 1006565
CliP-Piston àWengen Stapes Prosthesis	Pure Titanium	1006600 - 1006602
MRP Stapes Prosthesis	Pure Titanium	1006650 - 1006652
NiTiBOND Stapes Prosthesis	PureTitanium / Nitinol	1006708 - 1006713
NiTiFLEX Stapes Prosthesis	PureTitanium / Nitinol	1006758 - 1006763

- 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 Stapedioplasty Prostheses listed in the table above are expected to produce a maximum temperature rise of 2.9°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the Stapedioplasty 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 STAPEDIOPLASTY

MIDDLE EAR INTELLIGENCE

WHAT IS STAPEDIOPLASTY?
The middle ear consists of three small bones: The malleus, the incus and the stapes. Stapedioplasty is a surgical technique to replace the stapes with a prothesis. The stapes is either removed entirely or partially, in which case a small whole is drilled into the remaining stapes footplate. A prosthesis is then attached to the incus and inserted into the footplate to connect the middle ear to the inner ear and enable the sound conduction.
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?
If the stapes cannot vibrate, the sound conduction to the inner ear is not possible anymore. The goal of this surgery is to replace the stapes with a prosthesis to restore the hearing and the middle ear function.

IS THE PROCEDURE SAFE?
Stapedioplasty 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 performed through the ear canal. The defect of the ossicular chain is repaired with a prosthesis. The surgeon will remove the stapes and replace it with a prosthesis. 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 or nitinol for our stapediolasty prostheses. Nitinol is an alloy made up of titanium and nickel in roughly equal proportions. The materials are distinguished by good mechanical properties as well as high resistance to corrosion and a good biocompatibility. They are clinically tested materials 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. For patients with suspected nickel allergies an allergy test should be performed prior to surgery.

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.