THE FOLLOWING PRODUCTS ARE MR CONDITIONAL:

MRI SAFETY INFORMATION STAPEDIOPLASTY		
1006003-1006051	Matrix Stapes Prosthesis	Pure Titanium
1006053-1006081	Skarzynski Stapes Prosthesis	Pure Titanium
1006263-1006291	MatriX SlimLine Stapes Prosthesis	Pure Titanium
1006103-1006120 1006153-1006170	K-Piston Stapes Prosthesis	Pure Titanium
1006203-1006211 1006253-1006261	Soft-CliP Stapes Prosthesis	Pure Titanium
1006523-1006529	LCP Stapes Prosthesis	Pure Titanium
1006543-1006565	Bucket Type Stapes Prosthesis	Pure Titanium
1006600-1006602 1006650-1006652	Angular Piston Stapes Prosthesis	Pure Titanium
1006708-1006713 1006758-1006763	CliP-Piston MVP Stapes Prosthesis	Pure Titanium
1006803-1006811 1006853-1006861	CliP-Piston äWengen Stapes Prosthesis	Pure Titanium
1006960	MRP Stapes Prosthesis	Pure Titanium
1007103-1007111 1007153-1007161	NiTiBOND Stapes Prosthesis	Pure Titanium / Nitinol
1007203- 1007211 1007253- 1007261	NiTiFLEX Stapes Prosthesis	Pure Titanium / Nitinol

Not all products might be available in all countries.
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 in Section 2.2.

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.

Section 2.2. - Additional MRI Safety Instructions
• Body coil only was used for testing as a worst-case assumption. 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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PATIENT INFORMATION LEAFLET – KURZ PROSTHESES FOR STAPEDIOPLASTY

RhinoSurgical | MEDICAL DEVICE SPECIALISTS

KURZ
MIDDLE EAR INTELLIGENCE

WHAT IS STAPEDIOPLASTY?

Stapedioplasty is a surgical technique “stapedectomy” a surgery to remove a small bone, called the stapes, from the middle ear. This surgery is done when the tissue around the stapes hardens and prevents the stapes from working correctly and causes conductive hearing loss. The doctor replaces the stapes with an implant or prosthesis. The aim of reconstructing this 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 repair the defect, but also to eradicate the disease from the middle ear and restore hearing and 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 either performed through the ear canal or through the skin at the back of the ear. The hole in your ear drum or middle ear bone is repaired using a graft taken from your own tissue around the ear. A dressing called an ear wick is left inside the 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 an hour to 90 minutes and involves replacing the defective bone with an implant.

WHAT IMPLANT MATERIALS ARE USED?

KURZ uses only high-quality (ASTM F67, medical grade), pure titanium and Nitinol. Nitinol, the alloy is made up of nickel and titanium in roughly equal proportions. It is distinguished by good mechanical properties as well as high resistance to corrosion. These are clinically tested materials, with numerous clinically unique 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. In such cases, for patients with Nickel allergy or Polyethylene glycols (PEGs)
- 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

- 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

AT HOME AFTER THE OPERATION.

Your doctor may recommend one week off work after the operation to give your body the best chance of recovery. 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.

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 in charge 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 (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.

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 because of the implant included magnetic field interactions, heating, induced electrical currents, and possible artefacts.

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) is unknown or unclear, do not perform a MR scan. Please check below or with your Doctor.