First Choice in Passive Middle Ear Implants

KURZ

For more than 30 years now, KURZ has stood for ground-breaking developments in the middle ear prosthetics with its implants, instruments and ventilation tubes.

HIGH-TECH FOR THE MIDDLE EAR

When the company founder Heinz Kurz started with a small golden ventilation tube in 1974, no one could foresee that KURZ implants would one day set the standards for middle ear prostheses and instruments worldwide. Today KURZ products are highly innovative, high-tech works of art, designed to comply with the smallest tolerances and material thicknesses.

From the beginning, the proximity to local universities was an important locational advantage for our company, as well as the density of highly specialized companies in southwest Germany. To this day, KURZ prostheses are manufactured exclusively at our locally owned and operated manufacturing facility with support from competent partners.

WORLDWIDE REPRESENTATION

We supply surgeons and clinics worldwide via a broad network of distribution partners and have an American based subsidiary Kurz Medical Inc. Attention to detail is important in the care and handling of our products and therefore we believe in supporting the market place with the highest level of sophistication and professional ethics. KURZ hosts several clinical and academic training seminars globally conducted by leading specialists in middle ear surgery.

ENTHUSIASM FOR TECHNOLOGY

In our developmental efforts, we work closely with leading national and international scientists, surgeons and engineers. Our collective know-how, tireless creativity and inquisitive minds, focus on the realization of implant designs that are comparable to functional anatomy in hopes of providing our patients with the best possible hearing results whom our products are made for.

KURZ Middle Ear Prostheses

WELL-ESTABLISHED KNOWLEDGE OF THE MIDDLE EAR

The aim of reconstructing the ossicular chain is to create the natural function as closely as possible and conduct the incoming acoustic signal to the inner ear with minimal loss. The complex mechanics of acoustic sound transmission places high demands on the development of implants and calls for well-established knowledge of the middle ear. Furthermore, prostheses must have properties that facilitate implantation for the surgeon and help to minimize risks.

SOLUTIONS FOR EVERY SITUATION

KURZ covers the entire range of implants required for tympanoplasty and stapes surgery. In addition, the product line is rounded off by precision otological instruments and ventilation tubes.

INNOVATIVE DESIGNS AND MATERIALS

Innovative KURZ product designs and materials have set new standards in middle ear prosthetics throughout the world. For example, length adjustable prostheses can be shortened to a Functional Length of 0.75 mm. Clip prostheses standardize coupling to the incus or stapes. New types of ball-joint designs counterbalance the natural movements of the tympanic membrane and anatomically adapted bells create a secure connection to the stapes head. Furthermore, finely balanced weight distribution provides the prostheses with intraoperative stability.

These developments are based not only on well-established anatomical understanding but also on the latest results of scientific research and extensive test series. KURZ prostheses are available in numerous types and offer ideal solutions also in challenging anatomical situations.

MR information is available on www.kurzmed.com

IMPLANT MATERIALS AND PROCESSING

UTMOST CARE AND HIGHEST PRECISION

In order to achieve best possible results, the elegant design of the KURZ prostheses often probes the limits of feasibility. The manufacturing process of these prostheses requires highest precision and utmost care. Stringent inspections furthermore ensure compliance with highest quality standards.

INTENSIVE CLEANING PROCESS

All KURZ prostheses undergo an intensive cleaning process. The result is an extremely pure surface. This contributes toward ensuring irritation-free contact with the sensitive mucosa and helps to prevent inflammations and granulomas which can develop as a result of residues or dirt particles.

HIGH DEMANDS TO BE MET BY MATERIALS

For the production of their prostheses, KURZ uses only high-quality, clinically tested material: Due to its excellent biocompatibility titanium has since decades proven its worth as implant material. In addition, KURZ employs innovative nitinol variants which offer numerous clinically unique benefits.

MR SAFETY TESTS

MR safety tests also cover the compatibility of KURZ prostheses, as long-term implants, with potential future Tesla strengths (up to 7.0 T). For further MR-related information, see www.kurzmed.com

NITINOL

Nitinol was discovered in 1958 by the Naval Ordnance Laboratory (USA). 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.

Nitinol can assume different properties: As a shape memory alloy, the metal is malleable and returns to its pre-programed state when heated. The NiTiBOND® makes use of this closing effect.

Nitinol can also be produced in a superelastic configuration. These properties have been utilized in the design of the NiTiFLEX. The clip attachment exhibits extreme spring elasticity and gently couples to the long process of the incus.

TITANIUM

KURZ uses only high-quality (ASTM F67, medical grade), pure titanium for its prostheses. The properties of this material grade are ideally suited due to its rigidity, weight and technical manufacturing possibilities. The biocompatibility of this metal is also suitable for long-term applications.

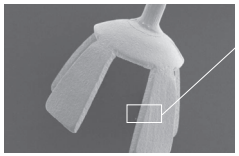
Thanks to its low mass, titanium is particularly suitable for the use in middle-ear prosthetics. Compared to other materials, it minimizes losses in connection with the transmission of sound energy. Moreover, the material is extremely resistant to deformation, while at the same time it can, if required, be adapted to individual anatomical situations by bending.

References:
Wirsching K., Lehle K., Jacob P., Gleich O., Strutz J., Kwok P.
Influence of Surface Processing on the Biocompatibility of Titanium.
Materials 2011, 4(7), 1238-1248; doi: 10.3390/ma4071238

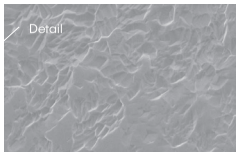
PURE TITANIUM (ASTM F67): CHEMICAL COMPOSITION

Element	Grade 1	Grade 2	Grade 3	Grade 4
Titanium (Ti)	99.48	99.31	99.19	98.94
Nitrogen (N)	0.03	0.03	0.05	0.05
Carbon (C)	0.10	0.10	0.10	0.10
Hydrogen (H)	0.0125	0.0125	0.0125	0.0125
Ferrite (Fe)	0.20	0.30	0.30	0.50
Oxygen (O)	0.18	0.25	0.35	0.40

Maximum cut-off grades in % (m/m)



**BELL after cleaning.
50 times magnification
(KURZ Prosthesis)**



**Titanium surface after cleaning.
1000 times magnification
(KURZ Prosthesis)**

STAPES PROSTHESES

PORTFOLIO OF OPTIONS

One critical step in stapes surgery is the coupling of the prosthesis to the long process of the incus. KURZ meets this requirement with solutions for various needs and schools.

CRIMPING – EXTREMELY GENTLE MODELING

Wide, perforated or exceptionally elegant loops in KURZ crimp prostheses facilitate modeling around the long process of the incus. This gentle but stable coupling supports good transmission of the incoming acoustical signal as well as protects the sensitive mucosa.

CLIPPING – SUPERELASTIC BANDS

A standardized form of coupling is provided by KURZ clip prostheses. Initial practical experience has shown that the superelastic nitinol band of the NiTiFLEX reduces the application force required when placed on to the incus. The contact-free zones are also designed to ensure that vascular nutrition of the surrounding structures is undisturbed.

HEATING – SHAPE MEMORY EFFECT

KURZ only uses pure titanium or titanium-nitinol combinations. Nitinol can have various characteristics: In addition to the superelastic properties, KURZ also uses the more traditional shape memory version of nitinol in their NiTiBOND® prosthesis. When heated with the aid of a laser, the NiTiBOND® loop closes in its pre-defined shape. The result is a more atraumatic, standardized coupling.

OPTIMAL SOLUTIONS FOR REVISION SURGERY

KURZ also offers solutions for revision surgery. The CliP® Piston MVP with its micro ball joint and extra long malleus CliP® creates a direct, adaptable and standardized connection between the malleus and stapes footplate. The Angular Piston stabilizes coupling between a shortened incus and the inner ear when bone resorption has occurred.

MR SAFETY

MR safety tests for future potential Tesla levels (e.g. 7.0 T) are performed on the KURZ prostheses, making them long-term implants.

To protect the surrounding tissue and prevent the risk of adhesions, the stem of KURZ stapes prostheses is rounded. In addition, all KURZ implants are available in standard sizes making shortening redundant.

12 p.d. atitikimas:"*MR tinkamas iki 7 teslų*"

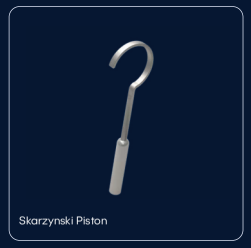
CRIMPING


MatriX


MatriX Slimline


MatriX Offset


K-Piston


Skarzynski Piston


Angular Piston

CLIPPING


NiTiFLEX


Soft CliP®


CliP® Piston àWengen


CliP® Piston MVP

HEATING


NiTiBOND®

CLIP® PISTON MVP STAPES PROSTHESIS
FOR MALLEOVESTIBULOPEXY

CLIP TECHNOLOGY PROVEN IN THE LONG TERM

The CliP Piston MVP is designed for malleus to footplate revision stapes surgery. Long term usage shows that the CliP easily standardizes consistent coupling to the neck of the malleus.

12 p.d. atitikimas: -jungiantis plaktuko rankeną su kilpos papėde per rutulio tipo sąnarį

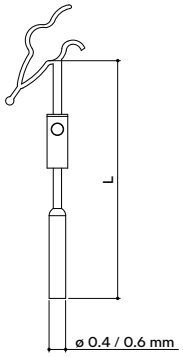
BALL JOINT PROSTHESIS FOR MALLEOVESTIBULOPEXY

The extra long dimensions with an integrated ball joint simplify the complicated off axis positioning of traditional malleus to footplate implants. The ball joint additionally allows for the piston to be centered in the fenestration reducing tangential friction.

POSTOPERATIVE STABILITY

After adaptation of the implant the ball joint remains stable. The risk of postoperative dislocation is accordingly reduced.

Developed in close collaboration with Prof. Dr. Häusler, Bern University Canton Hospital, Switzerland.



CliP Piston MVP
Material:
Pure Titanium (ASTM F67 Medical Grade)
Diameter: 0.4/0.6 mm
Band loop width: 0.25 mm

LENGTH L (mm) Ø 0.4 mm	REF
5.00	1006 708
5.25	1006 709
5.50	1006 710
5.75	1006 711
6.00	1006 712
6.25	1006 713
6.50	1006 714

LENGTH L (mm) Ø 0.6 mm	REF
5.00	1006 758
5.25	1006 759
5.50	1006 760
5.75	1006 761
6.00	1006 762
6.25	1006 763
6.50	1006 764

12 p.d. atitikimas: *"fiksuoto ilgio: 6 mm, distalinė implanto dalis: 0,4 mm diametro"*
12 p.d. atitikimas: *"0,4 mm ir diametro distalinė implanto dalis"*

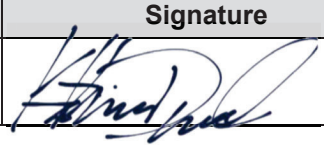
12 p.d. atitkimas:"*titaninis*"

CE 0124

Technical Data Sheet (TDS) CliP Piston MVP

Release process

Creator	Role	Date	Signature
Zanette, Catrin	RA-Manager	2024-09-23	

Reviewer	Role	Date	Signature
Düwel, Kathrin	RA-Manager	2024-09-23	

Approver	Role	Date	Signature
Zanette, Catrin	RA-Manager	2024-09-23	

Abstract

The document summarizes various information regarding the product that may be relevant for registrations.

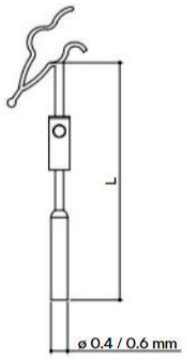
General Information

Change history

Date	Rev.	Change	Changes
2019-11-07	02	Ä191102	New creation
2021-06-23	03	Ä210622	Kontinuierliche Anpassung TDS an Vorlage P03F23
2024-09-12	04	Ä240912	Adaption to P03F23 Rev08

Technical Data Sheet (TDS) CliP Piston MVP

Technical Data Overview

Product name:	CliP Piston MVP	Technical Drawing:	Picture:
Manufactured by:	Heinz Kurz GmbH Tübinger Strasse 3 72144 Dusslingen, Germany		
CE Mark release:	30.04.2004		
Medical Device Class according to MDD:	Class IIb Rule 8		
Medical Device Class according to MDR:	Class IIb Rule 8		
Notified Body:	Dekra Certification GmbH (0124)		
Medical Device Class Australia:	Class IIb Rule 3		
Medical Device Class Brazil:	Class III Rule 8		
Medical Device Class Canada:	Class III Rule 1		
Medical Device Class Japan:	N/A not registered in Japan		
Medical Device Class USA:	Class II (ETB)		
Technical Specification:			
Material:	Pure Titanium ASTM F67 Gr. 2, Gr. 4		
Weight:	3,2 mg – 4,9 mg		
Rationale for the qualification of the product as a medical device:	The product is a medical device according to Medical Device Directive 93/42/EEC Article 1 point 2. The product qualifies as “Medical Device” under treatment, alleviation of, or compensation for, an injury or disability purpose per Article 2-Definition in MDR EU 2017/745		
Device description:	Middle ear implants for stapedioplasty		
Principles of operation and mode of action:	Prostheses which are inserted to partially or completely replace middle ear structures involved in sound conduction.		
Explanation of novel features:	No novel features		
Description, including non-devices intended to be used in combination:	There are no devices or non-devices intended to be used in combination		
Human or animal tissues or cells:	No human or animal cells are used		
Absorbable or dispersable substances introduced into the human body:	No absorbable or dispensable substances are introduced into the human body		
Delivery Status:	Sterile 12 p.d. atitkimas: Sterilus (simbolis ant pakuotės)		
Sterilization Method:	Gamma-Radiation		
Shelf life:	Shelf-life 6 ½ years after sterilization		
Resterilization / Reprocessing:	The prosthesis is intended for one-time use only. Reprocessing / resterilization is not permitted. 12 p.d. atitikimas: "*vienkartinis*"		
Packaging:	Prosthesis Packaging consists of: - primary packaging: Triangular box (PP) - sterile barrier packaging: Tyvek + GAG-PET 500 µm - Non-sterile storage packaging including Instructions for Use and Implant Card		
Storage:	Store in a dry place at room temperature in the unopened original package. Each prosthesis bears a batch number and an expiration date and may not be used after that date.		

Technical Data Sheet (TDS) CliP Piston MVP

Product affiliation:	Productfamily A
Intended use:	KURZ middle ear prostheses are intended for the partial or total surgical replacement of the ossicular chain of the human middle ear. The objective is the restoration of the mechanical transfer of sound from the tympanic membrane to the oval window of the cochlear with the least impairment of hearing.
Indication for use:	The following underlying diseases may lead to an indication of a passive middle-ear prosthesis for recontraction of the human auditory ossicular chain. - Otosclerosis / congenital stapes fixation - Malformation of the middle ear with fixed foot plate - Revision surgery due to inadequate hearing improvement, e. g. due to dislocation of a (previ-ously implanted) prosthesis
Contraindications:	- Allergy to titanium - Situations where conservative treatment approaches are adequate - Acute middle ear inflammation that can result in dislocation of the prosthesis - Acute and chronic infectious diseases - General wound healing impairments - Important! Any opening-up of the inner ear (such as perforation of the footplate of the stapes, partial or complete removal of the stapes, partial or complete removal of the stapes footplate (stapedio-plasty)) is contraindicated in cases of inflammation in the acoustic meatus and / or the middle ear due to the risk of inflammatory process spreading into the inner ear.
Possible Complications:	Possible adverse effects / injuries may occur during or after the surgery. Fine bone structures are Touched and mobilized as part of the surgical procedure and this may result in surgically induced trauma or infection. Such damage may be irreversible or correctable only through revision surgery. - Postoperative dislocation of the prosthesis - Incus necrosis - Recurrent or postoperative middle ear inflammation - Vertigo - Labyrinthine hearing loss following intraoperative trauma - Tissue irritation, scar formation, granuloma - Perilymphatic fistula - Perforation of the tympanic membrane - Inner ear damage up to and including deafness (Surditas) - Tinnitus - Irritation or even damage to the facial nerve up to and including paresis of the facial nerve (e. g. intraoperative injury of the chorda Tympani) - Incus subluxation - Floating footplate - Lack of hearing improvement
Warnings:	The patient must be informed by the physician about the following aspects. It is not permissible to expose patients with metal implants to microwave radiation. Strong fluctuations of the ambient pressure (immersion, diving headfirst into water, explosions, fireworks, etc.), sports (e. g. types of contact sports), as well as sauna (during the healing phase) can damage the middle-ear struc-tures and/or lead to disturbances of the sense of hearing and equilibrium, and are therefore to be avoided. **Intraoperative** Unintentional bending of the implant must be absolutly avoided when removing it from the primary packaging, since this may cause defective functioning of the implant itself. Extreme care must be taken in the selection of the prosthesis length for the implantation to prevent later problems such as implant dislocation or the occurrence of inner ear symptoms, such as vertigo, for example. **Postoperative** Should a granuloma or a perilymphatic fistula develop after surgery, appropriate medical proce-dures must be initiated immediately.
Accessories:	N/A no accessories
Intended patient population, patient selection criteria:	- Children and young people - Adults - Patients of any gender
Intended User:	Physician specialized in ENT surgery
MRI:	MR Conditional at 1.5 T; 3.0 T and 7.0 T, for detailed information please refer to the MR Information on www.kurzmed.com.
GMDN Code:	35690 “A sterile device intended to be implanted for the functional reconstruction of segments of the ossicular chain (mallues, incus, and/or stapes bones) to facilitate the conduction of sound waves from the tympanic membrane to the inner ear. It is designed to treat conductive hearing

Technical Data Sheet (TDS) CliP Piston MVP

	loss from traumatic or surgical injury, otosclerosis, congenital fixation of the stapes, or chronic middle ear disease. The device is typically in the form of a tube made of metal [e.g., stainless steel, titanium (Ti)], polymers, or a combination of these materials."		
EMDN Code:	P020101 " MIDDLE EAR IMPLANTS"		
MDT Code:	2001 "Devices manufactured using metal processing" 2011 "Devices which require packaging, including labelling"		
MDS Code:	1005 "Devices in sterile condition"		
MDN Code:	MDN: 1102 "Non-active osteo- and orthopaedic implants"		
MDA Code:	MDA: Not applicable, no active device		
Basic UDI-DI:	++EHKM0027F		
UDI-DI:			
REF	**Dimention:** Diameter / length in mm	**GTin (Bar-Code)**	**HIBC (Data-Matrix)**
1006708	0,4 / 5,00	14250368830709	+EHKM100670818
1006709	0,4 / 5,25	14250368830716	+EHKM100670919
1006710	0,4 / 5,50	14250368830723	+EHKM100671011
1006711	0,4 / 5,75	14250368830730	+EHKM100671112
1006712	0,4 / 6,00	14250368830747	+EHKM100671213
1006713	0,4 / 6,25	14250368830754	+EHKM100671314
1006714	0,4 / 6,50	14250368830839	+EHKM100671415
1006758	0,6 / 5,00	14250368830761	+EHKM10067581D
1006759	0,6 / 5,25	14250368830778	+EHKM10067591E
1006760	0,6 / 5,50	14250368830785	+EHKM100676016
1006761	0,6 / 5,75	14250368830792	+EHKM100676117
1006762	0,6 / 6,00	14250368830808	+EHKM100676218
1006763	0,6 / 6,25	14250368830815	+EHKM100676319
1006764	0,6 / 6,50	14250368830822	+EHKM10067641A

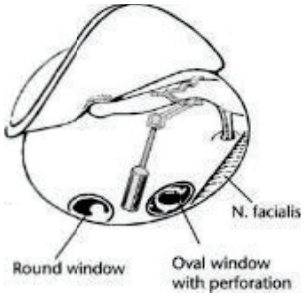
Clipping
CliP® Piston MVP

12 p.d. atitikimas: *"distalinė implanto dalis apvali"*

- Malleovestibulopexy - revision surgery when the incus is eroded and attachment to the malleus is necessary instead
- Unique ball-joint to bridge the challenging angle between Malleus and Stapes footplate

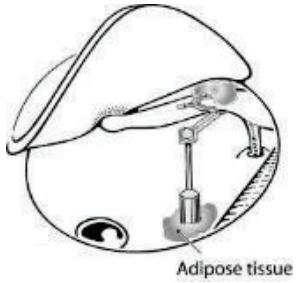
12 p.d. atitikimas: *"sąnarys judrus"*

- A prosthesis with standardized clipping in contrast to a crimping prostheses that is difficult to attach
- The most sold length is 6mm



Step 1


Step 2



Step 3

12 p.d. atitikimas:*"sterilus (simbolis ant pakuotės)"*
12 p.d. atitikimas:*"vienkartinis (pažymėta simboliu)"*

HEINZ KURZ GMBH

Mittelohrimplantat
Middle ear implant
Mellemøreimplantat
implant d'oreille moyenne
Εμφύτευμα μέσου ωτός
Impianto per l'orecchio medio
Middenoorimplantaat
Mellomøreimplantat
Implante do ouvido médio
Implante de oído medio
Mellanöronimplantat
Vidusauss implants
Vidurinės ausies implantas
Stredoušný implantát
Vsadek za srednje uho
Středoušní implantát
Implant de ureche medie
Implantat srednjeg uha

CliP Partial Prosthesis
Titanium
0.2 x 2.5 mm

REF 1002253

LOT 2214070

2027-12-01

(01)14250368810435(17)271201(10)2214070

HIBC +EHKM10022531/$$3271201221407 0K

Chirurgisches Implantat
Surgical Implant
Implant Chirurgical
Implante Quirúrgico
Impianto Chirurgico
Хирургический имплантат

12 p.d. atitikimas: "- *ant pakuotės pažymėta produkto galiojimo laikas*"

HEINZ K MBH

Mittelohrimplantat
Middle ear implant
Mellemøreimplantat
implant d'oreille moyenne
Εμφύτευμα μέσου ωτός
Impianto per l'orecchio medio
Middenoorimplantaat
Mellomøreimplantat
Implante do ouvido médio
Implante de oído medio
Mellanöronimplantat
Vidusauss implants
Vidurinės ausies implantas
Stredoušný implantát
Vsadek za srednje uho
Středoušní implantát
Implant de ureche medie
Implantat srednjeg uha

MRP Malleus Replacement Prosthesis
Titanium
0.8 x 3.0 mm

REF 1006960

LOT 2216090

2028-06-01

(01)14250368820885(17)280601(10)2216090

HIBC +EHKM10068601/$$3280601 22160

KURZ

Chirurgisches Implantat
Surgical Implant
Implant Chirurgical
Implante Quirúrgico
Impianto Chirurgico
Хирургический имп