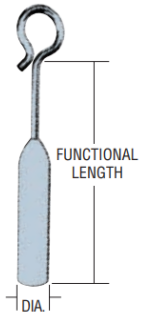
Stapes Pistons and Ossicular chain prostheses and MRI Safety

www.mrisafety.com

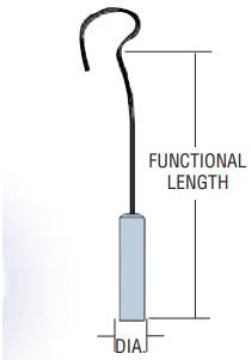
Commonly used Stapes Prostheses/Pistons



SMart Pistons
Nitinol/Fluoroplastic

Cat. No.	Piston Diameter	Functional Length
70142168	0.4 mm	3.50 - 5.25mm*
70145920	0.5 mm	3.75 mm
70145921	0.5 mm	4.00 mm
70145922	0.5 mm	4.25 mm
70145923	0.5 mm	4.50 mm
70145924	0.5 mm	4.75 mm
70145925	0.6 mm	3.75 mm
70145926	0.6 mm	4.00 mm
70145927	0.6 mm	4.25 mm
70145928	0.6 mm	4.50 mm
70145929	0.6 mm	4.75 mm
70145930	0.8 mm	3.75 mm
70145931	0.8 mm	4.00 mm
70145932	0.8 mm	4.25 mm
70145933	0.8 mm	4.50 mm
70145934	0.8 mm	4.75 mm

*Trimmable



SMart Malleus to Footplate Pistons
Nitinol/Fluoroplastic

Cat. No.	Piston Diameter	Functional Length
70142037	0.6 mm	5.5 mm
70142038	0.6 mm	6 mm
70142039	0.6 mm	6.5 mm

Nitinol and fluoroplastic

Safe to 3T MRI

The Big Easy™ Piston Straight Design

Developed in conjunction with Jack M. Kartush, MD - Farmington Hills, MI

Product#	Material	SD	SL	L
1156601	Platinum & Titanium	0.5	1.25	4.00
1156602	Platinum & Titanium	0.5	1.25	4.25
1156603	Platinum & Titanium	0.5	1.25	4.50
1156604	Platinum & Titanium	0.5	1.25	4.75

Safe for MRI to 1.5T

Platinum

Commonly Used Ossicular Chain Prostheses

Kurz Medical

TTP-VARIAC® SYSTEM
Adjustable Length Prostheses

MAXIMUM VARIABILITY

The tension-sensitive annular ligament of the stapes footplate plays a key role in reconstruction of the ossicular chain: If undesirable pretension develops here, it can have a critical effect on the postoperative hearing outcome. Short prosthetic solutions as short as 0.75 mm Functional Length are available to counteract against unintentional tension.

HIGH-PRECISION PATENTED SYSTEM

The TTP-VARIAC System provides variability that is unique throughout the world: It is comprised of two variable-length titanium prostheses (one Partial, one Total) and the multifunctional AC^{sizer} Disk. With the aid of different sizes of Sizer attached to the latter the surgeon can determine the required length of prosthesis with precision. On account of the patented clamping mechanism directly within the head plate the implant can be shortened to a Functional Length of up to 0.75 mm and the head plate can be fixed to the stem securely.

PROVEN BENEFITS OF KURZ TYMPANOPLASTY PROSTHESES

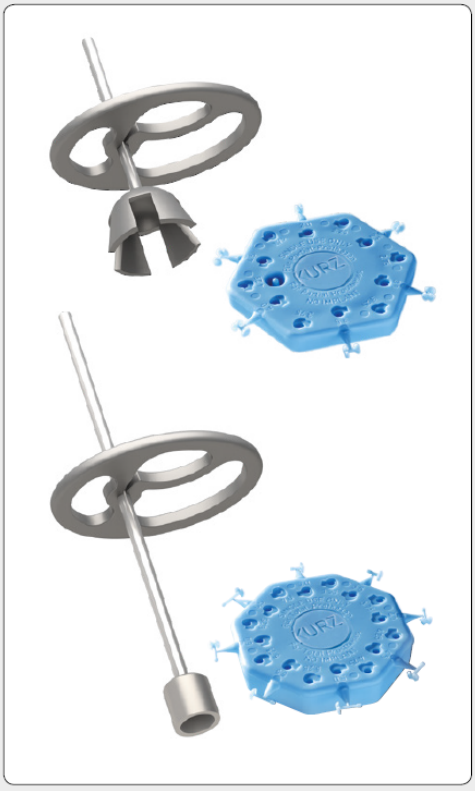
Like all KURZ prostheses, the TTP-VARIAC System has proven benefits: The elegant design and a fenestrated head plate provide maximum intraoperative visibility. The partially roughened surface improves stability.

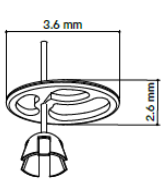
TWO PROSTHESES FOR ALL LENGTHS

The high flexibility of the TTP-VARIAC System ensures not only the most appropriate length in each case. It also makes a major contribution to the optimization of inventory levels. One ideal addition to the total prosthesis model is the OMEGA CONNECTOR (see page 18-19).

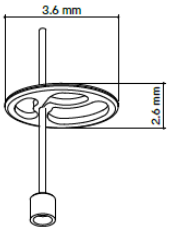
Developed in close collaboration with Tuebingen University ENT Clinic, Germany.

Voss, S. E., Nakajima, H. H., Huber, A. M., & Shera, A. C. (2013). Function and Acoustics of the Normal and Diseased Middle Ear. In Puria, S., Fay, R. R. & Popper, A. (Eds). The Middle Ear. Science, Otosurgery, and Technology. Chapter 4. New York, Heidelberg, Dordrecht, London: Springer.





TTP-VARIAC System
Partial Prosthesis
Material:
Pure Titanium (ASTM F67
Medical Grade)
Shaft Diameter: 0.2 mm



TTP-VARIAC System
Total Prosthesis
Material:
Pure Titanium (ASTM F67
Medical Grade)
Shaft Diameter: 0.2 mm

ITEM	REF
TTP-VARIAC System Partial (Prosthesis and Sizer-Disk) Adjustable Length 1.75 - 4.50 mm (in 0.25 mm increments) Functional Length (FL) 0.75 - 3.50 mm	1002 020
TTP-VARIAC System Total (Prosthesis and Sizer-Disk) Adjustable Length 3.0 - 7.0 mm (in 0.25 mm increments)	1004 020

The TTP-VARIAC System Total Prosthesis is compatible with the OMEGA CONNECTOR (REF 1004 930).

Neudert M., Bornitz M., Lasurashvili N., Schmidt U., Beleites T., Zahnert T.: Impact of Prosthesis Length on Tympanic Membrane's and Annular Ligament's Stiffness and the Resulting Middle Ear Sound Transmission. Otology & Neurotology: HYPERLINK "http://journals.lww.com/otology-neurotology/toc/2016/10000" October 2016, Volume 37, Issue 9 p e369-e376. Doi: 10.1097/MAO.0000000000001064

Ω CONNECTOR

OPTIMIZED FIT

In total ossicular reconstruction, movements of the tympanic membrane can alter the implant position on the stapes footplate. This risk may be reduced by using the OMEGA CONNECTOR together with a total prosthesis. The OMEGA CONNECTOR is designed to compensate for tympanic membrane movements and provide additional stability.

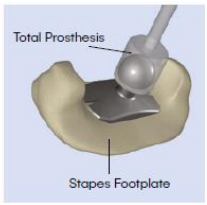
FLEXIBLE JOINT CONNECTION

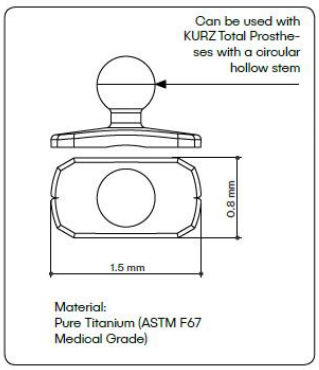
With sufficient footplate access, the OMEGA CONNECTOR increases the medial surface contact of a total prosthesis. The micro ball joint connects with the cannulated stem of the KURZ total prosthesis. In this way it accommodates drum to head plate angles without prosthesis manipulations.

STABLE CONNECTION

An aspiration tip is ideally used to place the OMEGA CONNECTOR first into the middle ear. The cupped medial end of the total prosthesis is assembled with the OMEGA in situ. A snug and stable fit between the two prostheses makes fixation with adhesive unnecessary. The undersurface of the shoe has a longitudinally milled recess to compensate for footplate irregularity.

Developed in close collaboration with Dr. med. G. Schmid, Reutlingen, Germany.





Material:
Pure Titanium (ASTM F67 Medical Grade)

ITEM	FL (mm)	REF
OMEGA CONNECTOR	0.5 mm	1004 930

FL: Functional Length

CLIP® PARTIAL PROSTHESIS DRESDEN TYPE

STANDARDIZED COUPLING FOR MORE SAFETY

The special feature of the CliP Partial Prosthesis Dresden is its spring-loaded fastening mechanism: The CliP standardizes coupling to the stapes head and thus enhances safety for a good postoperative outcome.

SECURE FIT

The elastic CliP ensures a secure fit on the stapes head. Especially in the case of extensive eardrum reconstructions this stability is a major advantage.

EXTREMELY ELEGANT

KURZ implants are designed in such a way that they largely simulate the fine biological structures of the auditory ossicle chain. KURZ addresses this challenge with prosthesis geometries that are extremely fine and push back the limits of feasibility. Their manufacturing process requires the utmost care and precision.

THE ORIGINAL

Over a decade of clinical use including numerous scientific studies confirm the unique benefits of the CliP Partial Prosthesis Dresden – the original among the clip prostheses.

CliP Partial Prosthesis in-situ

CliP Partial Prosthesis
Dresden
Material:
Pure Titanium (ASTM F67
Medical Grade)
Shaft Diameter: 0.2 mm

LENGTH L (mm)	FL (mm)	REF
1.75	0.75	1002 250
2.00	1.00	1002 251
2.25	1.25	1002 252
2.50	1.50	1002 253
2.75	1.75	1002 254
3.00	2.00	1002 255
3.25	2.25	1002 256
3.50	2.50	1002 257

FL: Functional Length

Special sizes upon request.

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.

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

Not all products might be available in all countries.

- 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 1.2.

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.

Grace Medical

Offset ALTO Concise Partial

Ref. #	Material	Head Size	Adjustable Length	Distal End
650-075	Titanium	2.50mm x 3.50mm	0.75mm to 5.75mm	1.45mm cup

Centered ALTO Concise Partial

Ref. #	Material	Head Size	Adjustable Length	Distal End
655-075	Titanium	3.00mm	0.75mm to 5.75mm	1.45mm cup

Centered ALTO Byte Partial

Ref. #	Material	Head Size	Adjustable Length	Distal End
655B	Titanium	3.00mm	2.25mm to 5.60mm	Adjustable

*May not be available in all countries

Offset Nano ALTO Byte Partial

Ref. #	Material	Head Size	Adjustable Length	Distal End
654	Titanium	1.50mm x 2.50mm	2.25mm to 5.60mm	Adjustable

*May not be available in all countries

Silverstein ALTO Total w/ Tack

Ref. #	Material	Head Size	Adjustable Length	Distal End Dia.
601	Titanium	2.50mm x 3.50mm	2.50mm to 7.00mm	0.8mm

Designed in conjunction with Herb Silverstein, MD, Sarasota, FL

Dornhoffer Footplate Shoe

Ref. #	Material	Length	Width	Height	ID
636-080	Titanium	1.40mm	1.09mm	1.14mm	0.8mm

Designed in conjunction with John Dornhoffer, MD, Little Rock, AR
Compatible with all Titanium Shaft Totals

Table 2: MR Conditional

Device Family	Family Product Number(s)	Device Material(s)
ALTO Partial and Total Prostheses	6XX, 612-001L, 612-002R	Titanium, HA, Silicone
ALTO Concise	650-075, 655-075	Titanium, Silicone
K-Helix Prostheses	756-XXX, 757-XXX	Titanium
Strasnick Prostheses	220-XXX, 270-XXX	Titanium, Silicone
Precise and other Ossicular Prostheses	280, 280M, 602-XXX, 652-XXX, 700-XXX, 705-XXX, 706-XXX, 707-XXX, 708-XXX, 709-XXX, 720-XXX, 750-XXX, 751-XXX, 752-XXX, 765-XXX, 770-XXX	Titanium, HA, Silicone
Stapes Prostheses-Piston	409-XXX, 410-XXX, 412-XXX, 413-XXX, 415-XXX, 417-XXX, 418-XXX, 419-XXX, 440-XXX, 442-XXX, 443-XXX, 452-XXX, 453-XXX, 454-XXX, 456-XXX, 460-XXX, 461-XXX, 462-XXX, 463-XXX, 465-XXX, 466-XXX, 467-XXX, 468-XXX, 469-XXX, 470-XXX, 471-XXX, 472-XXX, 473-XXX	"Titanium, Platinum, Stainless Steel, Nitinol, Fluoroplastic"
Stapes Prostheses-Buckets	420-XXX, 421-XXX, 422-XXX, 423-XXX, 424-XXX, 425-XXX, 426-XXX, 427-XXX, 428-XXX, 430-XXX, 431-XXX, 432-XXX	Titanium, Nitinol
Partial and Total Prostheses	200 through 208, 250 through 258, 220-800	Titanium, HA, Silicone
Foot Plate Shoes	636-XXX, 638-XXX	Titanium
ISJ and SRP	755, 758-XXX	Nitinol, Fluoroplastic

(XX = 00 through 99) (XXX = 000 through 999, i.e. Product number 190-XXX means all products ranging from 190-000 through 190-999)

Imaging at 7 Tesla or Less

Non-clinical testing has demonstrated that patients with these specific Grace Medical ossicular implants can undergo MRI safely, immediately after implantation under the following conditions:

- Static magnetic field of 7-Tesla or less
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 4 –W/kg for 15 minutes of scanning (i.e., per pulse sequence).