

Inspiring for Splendid Healthcare

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MIDDLE EAR IMPLANTS

OSSEOUS

Surgical Implants



EON

Inspiring for Splendid Healthcare®
MEDITECH
PVT. LTD.



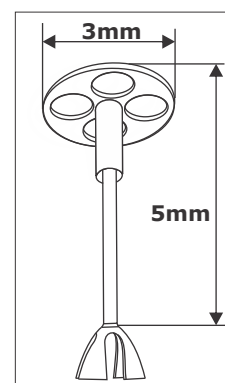
Tita-Prosthesis type Partial Vario Campana (PORP)

Tita-Prosthesis type Partial Vario Campana consists of two units, one being the Disk-Cylinder and the other being the Campana cup with the radial shaft. It is used for Partial ossicular chain reconstruction.

It is a replacement for the Malleus & Incus as it connects the Tympanic Membrane and the Head of the Stapes.

Design Benefits

- ✦ The length of the shaft at the end of the Campana cup can be cut as per the requirement and then inserted into the cylinder on the disc (Fig). Thus only one Tita-prosthesis type Partial Vario Campana is needed for a particular Partial ossicular reconstruction.
- ✦ Four symmetrical holes on the disc enhance the surgeon's view of the middle ear cavity.
- ✦ Offers best possible length selection.
- ✦ Campana shaped cup offers lowest risk of dislocation.
- ✦ Radial outer facing disk minimizes risk of Tympanic Membrane injury.
- ✦ Optimally roughened surface on outer face of disk and inside of cup ensure firm placement of prosthesis.
- ✦ MRI Compatible.



Material: CP Titanium Medical Grade ASTM F 67

Shaft Diameter: 0.3mm, Disk Diameter: 3.0mm

L (Functional Length) 5.00mm to 1.75mm

REF Number	Description	No. Of Units/Box
E1101	Tita-Prosthesis type partial Vario Campana with removable head, and it can be trimmed from 5.00 mm to 1.75 mm using Osseous Cutter (REF : EI01) (PORP)	1 Unit, Gamma Sterile



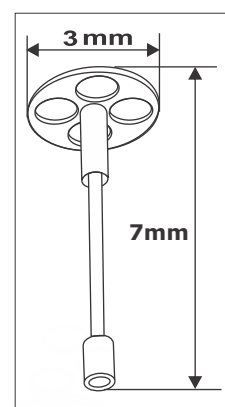
Tita-Prosthesis type Total Vario Cask (TORP)

Tita-Prosthesis type Total Vario Cask consists of two units, one being Disk-Cylinder and the other being cask shaped head with radial shaft. It is used for Total Ossicular chain reconstruction.

It is a replacement for the complete ossicular chain as it connects the Tympanic Membrane and the Footplate of the Stapes (at the Oval Window).

Design Benefits

- ✦ The length of shaft at the end of the Cask head can be cut as per the requirement and then inserted into the cylinder on the disc (Fig). Thus only one Tita-prosthesis type Total Vario Cask is needed for a particular total ossicular reconstruction.
- ✦ Four symmetrical holes on the disc enhance the surgeon's view of the middle ear cavity.
- ✦ Offers best possible length selection.
- ✦ Stable design with cask shaped head offers lowest risk of dislocation.
- ✦ Radial outer facing disk minimizes risk of Tympanic Membrane injury.
- ✦ Optimally roughened surface on outer face of disk and inner side of Cask to ensure firm placement of prosthesis.
- ✦ MRI Compatible.



Material: CP Titanium Medical Grade ASTM F 67

Shaft Diameter: 0.3mm, Disk Diameter: 3.0mm

L (Functional Length) 7.00mm to 3.00mm

REF Number	Description	No. Of Units/Box
E1102	Tita-prosthesis type Total Vario Cask with removable head, and it can be trimmed from 7.00 mm to 3.00 mm using Osseous Cutter (REF : EI01) (TORP)	1 Unit, Gamma Sterile



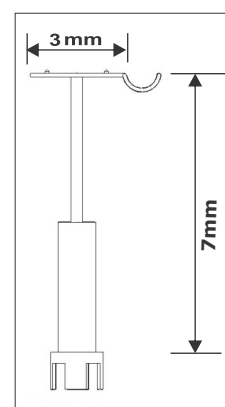
Titanium Universal Middle Ear Prosthesis

Titanium Universal Middle Ear Prosthesis consists of three units, one being the Disk with hook and shaft, second being a cup with connecting shaft and third being connector for both above parts.

It is the complete ossicular chain as it connects the Tympanic Membrane and stapes head or the footplate of the stapes (at the oval window).

Design Benefits

- ✦ The length of the shaft with Disk can be cut as per requirement and inserted into connector. The same way, shaft with the cup is also inserted to make Partial version. Thus only one implant is needed for a partial or total ossicular reconstruction.
- ✦ Maximum open parts of the disc enhance the surgeon's view of the middle ear cavity.
- ✦ Offers best possible length selection.
- ✦ PTFE connector is a joint between the prosthesis upper part and Cup for partial version or it is the ending part in the total version.
- ✦ Disk Hook can be used to clamp the malleus handle.
- ✦ Optimally roughened surface on outer face of disk and inside of cup ensure firm placement of prostheses.
- ✦ MRI Compatible.



Material: CP Titanium Medical Grade & Virgin PTFE

Shaft Dia: 0.3mm, Disk Dia: 3.0mm and connector Dia 0.8mm

L (Functional Length) 7.00mm to 3.00mm

REF Number	Descriptions	No. Of Units/Box
E1138	Titanium Universal Middle Ear Prosthesis and it can be trimmed from 7.00 mm to 3.00 mm using Osseous Cutter (REF : EI01)	1 Unit, Gamma Sterile



TitaHAp prosthesis type Vario Partial (PORP)

TitaHAP Prosthesis type Vario Total (TORP)

A thin layer of Hydroxyapatite (HAP) is coated onto the top surface of Disk-Cylinder for better fixation of Disk to Tympanic Membrane (TM).

The HAP coating gives a firmer grip of the prosthesis to the TM. It acts as an intermediate layer between TM and the Titanium Disk. The prosthesis has the conducting capabilities of Titanium and excellent flexibility that gives more comfort to surgeons.

Design Benefits

- ✦ Favorable fixation with TM (Fibroblast cell fixation within HAP pores).
- ✦ Light weight compare to conventional HAP prostheses.
- ✦ Excellent biocompatibility.
- ✦ No need for Cartilage placement between prosthesis and TM.
- ✦ Least risk of extrusion due to HAP coating.
- ✦ Provides good flexibility.
- ✦ Good visibility during implantation of prosthesis on Capitulum/footplate.

Material: CP Titanium Medical Grade & Hap

HAP Coating thickness: 35um ± 5um.

Adhesion of HAP with Titanium: ≥ 15MPa



HAP Coating



PORP



TORP

REF Number	Description	No. Of Units/Box
E1207	TitaHAp prosthesis type Vario Partial (PORP)	1 Unit, Gamma Sterile
E1208	TitaHAp prosthesis type Vario Total (TORP)	1 Unit, Gamma Sterile



Fluoroplastic Middle Ear Prosthesis

Fluoroplastic Partial Prosthesis (PORP)



Design Benefits

- ✦ Much Biocompatible with biological tissues.
- ✦ Easily Trimmable from 5.00mm-2.00mm in length.
- ✦ Conventional Design.

Material: Fluoroplastic

REF Number	Shaft Diameter OD/ID	Disk Diameter	Functional Length	Total Length	No. Of Units/Box
E2133	1.8/1.20 hollow , partially	3.00	5.00-2.00	5.00	1 Unit, ETO Sterile

Fluoroplastic Total Prosthesis (TORP)



Design Benefits

- ✦ Much Biocompatible with biological tissues.
- ✦ Easily Trimmable from 7.00mm-3.00mm in length.
- ✦ Conventional Design.

Material: Fluoroplastic

REF Number	Shaft Diameter	Disk Diameter	Functional Length	Total Length	No. Of Units/Box
E2134	0.8	3.00	7.00-3.00	7.00	1 Unit, ETO Sterile

All dimensions are in mm



Fluoroplastic Middle Ear Prostheses

Fluoroplastic Offset Partial Prosthesis (PORP)



Design Benefits

- ✦ Offset PORP is allowing surgeon's visibility of the superstructure of stapes during surgery.
- ✦ The position of the shaft permits a direct, rather than angled stapes to tympanum placement.
- ✦ Easily Trimmable from 5.00mm-2.00mm in length.

Material: Fluoroplastic

REF Number	Shaft Diameter OD/ID	Functional Length	Total Length	No. Of Units/Box
E2141	1.8/1.20 hollow , partially	5.00-2.00	5.00	1 Unit, ETO Sterile

Fluoroplastic Offset Total Prosthesis (TORP)



Design Benefits

- ✦ Offset TORP aids the surgeon for better visualization of the footplate.
- ✦ The position of shaft permits a direct, rather than angled, union between footplate and tympanic membrane.
- ✦ Easily Trimmable from 7.00mm-3.00mm in length.

Material: Fluoroplastic

REF Number	Shaft Diameter	Functional Length	Total Length	No. Of Units/Box
E2142	0.8	7.00-3.00	7.00	1 Unit, ETO Sterile

All dimensions are in mm

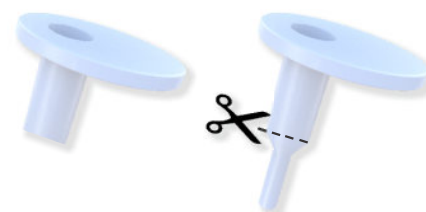


Fluoroplastic Universal Middle Ear Prosthesis - Offset Fluoroplastic Universal Middle Ear Prosthesis - Centered

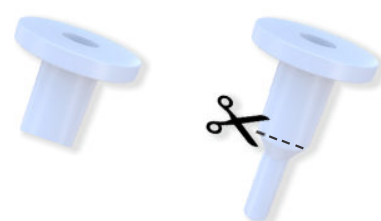
Both the Fluoroplastic Universal Middle Ear Prostheses are having partially cannulated shafts, which allow usage as Total prosthesis from Tympanic membrane to Footplate and Partial prosthesis from Tympanic membrane to stapes head as well. Only one Universal Middle Ear prosthesis requires in case of both total or Partial prostheses requirements.

Design Benefits

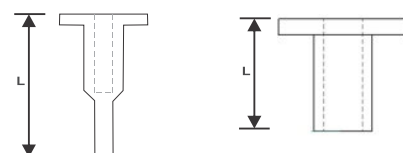
- ✦ Only one Universal prosthesis is required for a surgery as the length can be cut as per requirement.
- ✦ Offset prosthesis is allowing surgeon's visibility of the superstructure of stapes or footplate during surgery.
- ✦ Stable design provides maximum sound output.
- ✦ Offers best possible length selection.
- ✦ In case of Offset prosthesis, the position of shaft permits a direct, rather than angled, union between footplate or stapes head and tympanic membrane.
- ✦ Centered prosthesis is conventional design.
- ✦ Both prostheses are Much Biocompatible with biological tissues.



Universal Middle Ear Prosthesis - Offset



Universal Middle Ear Prosthesis - Centered



Material: Fluoroplastic

In case of TORP - Shaft OD 0.8 mm

In case of PORP - Shaft ID 1.20 mm

REF Number	Description	No. Of Units/Box
E2139	Fluoroplastic Universal Middle Ear Prosthesis - Offset L (Functional Length) 7.00 mm to 2.00 mm	1 Unit, ETO Sterile
E2140	Fluoroplastic Universal Middle Ear Prosthesis - Centered L (Functional Length) 7.00 mm to 2.00 mm	1 Unit, ETO Sterile



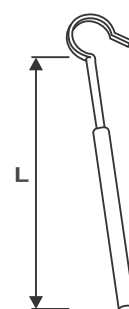
Tita-prosthesis Piston type Loop

Tita-PTFE Vario Piston type Loop

Both Stapes Pistons consist of a flat band loop and a shaft, used for Stapedioplasty surgery. These prostheses are connected between "Long Process" of Incus and the Footplate. In Malleus Stapedioplasty, the piston requires to be bent at the neck and this titanium loop easily facilitates this requirement which is not possible in the commonly used Teflon piston.

Design Benefits

- ✦ Only one Piston is required for a Stapedioplasty surgery as the length can be cut as per requirement.
- ✦ Malleable enough to facilitate bending at the neck for Malleus Stapedioplasty.
- ✦ Stable design provides maximum sound output.
- ✦ Offers best possible length selection.
- ✦ Easy loop introduction.
- ✦ Low risk of osteo-necrosis.
- ✦ Tita-PTFE Piston can be easily cut due to PTFE shaft.
- ✦ Tita Piston is MRI Compatible.
- ✦ Both Pistons can be trimmed by using Osseous Cutter (REF : EI01).



Material: CP Titanium Medical Grade & Fluoroplastic
Shaft Diameter 0.4 mm

REF Number	Description	No. Of Units/Box
E1103	Tita-prosthesis Piston type Loop L (Functional Length) 7.00mm to 3.50mm	1 Unit, Gamma Sterile
E4119	Tita-PTFE Vario Piston type Loop L (Functional Length) 7.00mm to 4.00mm	1 Unit, Gamma Sterile



Super Titanium Vario Piston type Loop

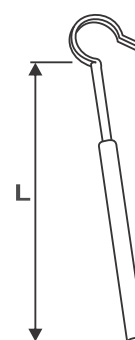
Super Tita-PTFE Vario Piston type Loop

Super Titanium is a kind of material which can be bent and twisted but it always returns to its original shape. Unique flat loop design of Super Titanium material provides self crimping (elastic properties) attachment to Incus and also provides uniform attachment of loop around total periphery of Incus which reduces the risk of compressive necrosis. A superelastic property of loop reduces the surgical process time and crimping difficulties.

Design Benefits

- ✦ More elastic titanium material for self crimping effect.
- ✦ Elastic self crimping loop shortens the time of surgery.
- ✦ Stable design provides maximum sound output.
- ✦ Reduced risk of osteo-necrosis.
- ✦ Super Titanium Piston is MRI Compatible.
- ✦ Super Tita-PTFE Piston can be easily cut due to PTFE shaft.
- ✦ Simplified loop introduction to Incus by easy downward movement.
- ✦ Both Pistons can be trimmed by using Osseous Cutter (REF : EI01).

Material: CP Titanium Medical Grade & Fluoroplastic
Shaft Diameter: 0.4mm



REF Number	Description	No. Of Units/Box
E9131	Super Titanium Vario Piston type Loop L (Functional Length) 7.00mm to 3.50mm	1 Unit, Gamma Sterile
E9132	Super Tita-PTFE Vario Piston type Loop L (Functional Length) 7.00mm to 4.00mm	1 Unit, Gamma Sterile



Super Elastic NITINOL Vario Piston type Loop

Super Elastic NITINOL-PTFE Vario Piston type Loop

NiTiNOL is Nickel (Ni) and Titanium (Ti) both as alloy accidentally discovered by two researchers at the Naval Ordinance Laboratory (NOL) and thus the material named NiTiNOL. The properties of NiTiNOL provides easy bending and twisting of prosthesis.

Design Benefits

- ✦ Alternative choice for NiTiNOL shape memory users who are concerned about heating the Incus.

Self crimping to long process of Incus

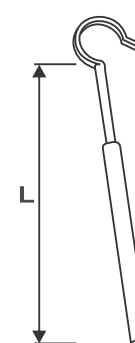
- ✦ Surgeons who enjoy crimp free pistons finds solution with Super Elastic NITINOL Loop. The loop closes softly, uniformly around long process of incus which minimizes the risk of incus necrosis. Superelastic property reduces the time of surgery.

Minimum force required to fit

- ✦ It can be easily fit to long process of incus by applying a simple vertical force.
- ✦ Super Elastic NITINOL-PTFE Piston can be easily cut because of PTFE shaft.
- ✦ Both Pistons can be trimmed by using Osseous Cutter (REF : EI01).

Material: NiTiNOL & Fluoroplastic

Shaft Diameter: 0.4 mm



REF Number	Description	No. Of Units/Box
E5120	Super Elastic NITINOL Vario Piston type Loop L (Functional Length) 7.00 mm to 3.50 mm	1 Unit, Gamma Sterile
E8130	Super Elastic NITINOL-PTFE Vario Piston type Loop L (Functional Length) 7.00 mm to 4.00 mm	1 Unit, Gamma Sterile

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Loop attachment procedure to Incus

FOR

Super Titanium Vario Piston type Loop

Super Tita-PTFE Vario Piston type Loop

Super Elastic NiTiNOL Vario Piston type Loop

Super Elastic NiTiNOL-PTFE Vario Piston type Loop

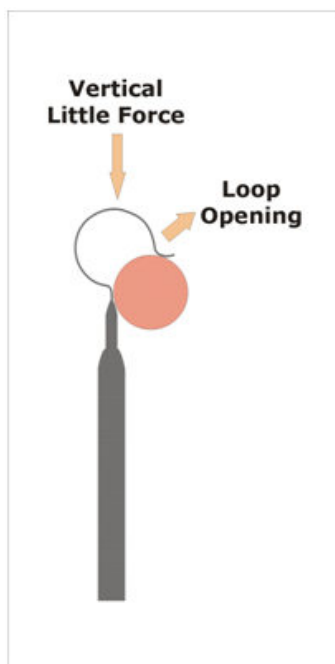


Figure 1

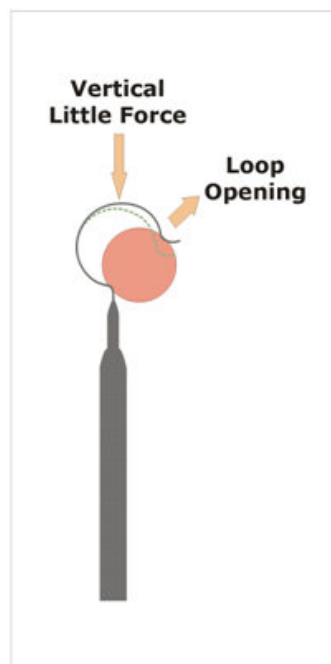


Figure 2

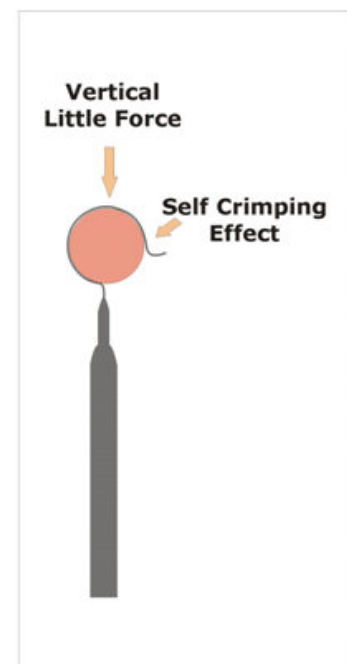


Figure 3

1. The loop attaches to Incus by applying an easy Vertical little force which opens loop. (Figure 1).
2. The loop will be opened (Figure 2) and again it returns to its original shape due to its elastic properties. (Figure 3).



Clip Stapes Piston- Titanium

Clip means a flexible device which holds objects in place. This principle used in Clip Stapes piston is one of the most efficient and effective solution for stapedioplasty. Clip Stapes piston simply clipped on the "Long process" of incus and does not encircle the incus so improves the vascular supply of incus.



Design Benefits:

- ✦ Clip shape like loop provides secure attachment on Incus.
- ✦ Improves the vascular supply of Incus.
- ✦ No need to crimp piston.
- ✦ Reduces risk of osteo-necrosis.
- ✦ Clip Stapes Piston is MRI Compatible.
- ✦ Eliminates the process of stapes piston fixation.
- ✦ Maximizes hearing result because of clip loop is not encircled the Incus.
- ✦ Reduces the surgical process time and crimping difficulties.
- ✦ Pistons can be trimmed by using Osseous Cutter (REF : EI01).

Material: CP Titanium Medical Grade

Shaft Diameter: 0.4mm

L (Functional length) 7.00mm to 3.5mm

REF Number	Description	No. Of Units/Box
E1121	Clip Stapes Piston- Titanium L (Functional Length) 7.00mm to 3.5mm	1 Unit, Gamma Sterile

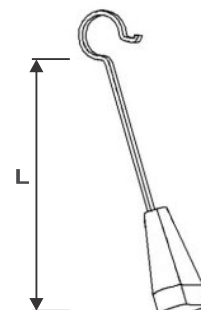


Titanium Stapes Piston with Integrated PTFE Shoe

Titanium Stapes Piston with Integrated PTFE Shoe is connected between "Long Process" of incus and the footplate. PTFE Shoe is larger in size which covers maximum place of Footplate of the Stapes(at the oval

Design Benefits:

- ✦ Larger size of PTFE shoe gives more stability.
- ✦ PTFE resists integration.
- ✦ Stable design gives maximum sound output.
- ✦ Reduces risk of extrusion.
- ✦ Titanium Stapes Piston with Integrated PTFE Shoe is MRI compatible.
- ✦ Easy to handle and insert into the Stapes Footplate.
- ✦ Easily trimmable with surgical knife.



Material: CP Titanium Medical Grade & Fluoroplastic

Shaft Diameter: 0.4mm

L (Functional length) 7.00mm to 3.5mm

REF Number	Description	No. Of Units/Box
E1122	Titanium Stapes Piston with Integrated PTFE Shoe L (Functional Length) 7.00mm to 3.5mm	1 Unit, Gamma Sterile

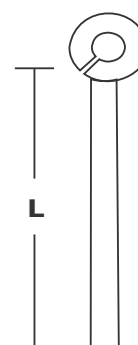


Fluoroplastic Stapes Piston

Using smooth jaw alligator forceps, the piston loop can be expanded with a pick to slip over the Incus.

Design Benefits

- ✦ "Plastic memory" provides secure closure.
- ✦ Easily Trimmable with scissor or cutting tool from 6.00mm-3.50mm length.
- ✦ Much Biocompatible with biological tissues.
- ✦ Conventional design for easy attachment with Long Process of Incus.



Material: Fluoroplastic (PTFE)

Shaft Diameter: 0.4mm ,0.5mm, 0.6mm

L (Functional length): 6.00mm to 3.50mm

REF Number	Piston Diameter	Loop Inner Diameter	Functional Length	Total Length	No. Of Units/Box
E2127	0.5	0.60	3.50-6.00	6.00	1 Unit, ETO Sterile
E2128	0.4	0.60	3.50-6.00	6.00	1 Unit, ETO Sterile
E2129	0.6	0.60	3.50-6.00	6.00	1 Unit, ETO Sterile

All dimensions are in mm



OSSEOUS MIDDLE EAR IMPLANTS - A Practical Method

- ✦ To obtain optimal adhesion of disk-cylinder and cup (Campana/Cask) with radial shaft, a drop of human blood should be introduced into the cylinder of the Disk and/or placing the drop on the radial shaft of the cup (Campana/Cask) before fixation.
- ✦ It is suggested that the Tympanic Membrane be underplayed with a cartilage tissue where the Osseous Middle Ear Implant comes in contact with it, so as to prevent direct contact with TM and thus reducing the chances for extrusion to a bare minimum.
- ✦ After implantation of Osseous Middle Ear Implants, the external auditory canal should be tamponed as normal.
- ✦ Post-operative infection or insufficient Middle Ear ventilation may cause a dislocation of the implants resulting in hearing loss. We recommend intake of oral antibiotics for a minimum of ten days and waiting for valsalva-maneuvers for a minimum of three weeks after surgery.

LOOK OUT FOR!!!!

Conditions in which Stapedioplasty and Ossiculoplasty surgery **should not be performed.**

1. Chronic Otitis Media.
2. Unhealthy Mucosa.
3. Unhealthy and unaerated Middle Ear.
4. Mobile Stapes.
5. Patient with poor ventilation (High risk of implants extrusion).
6. Persisting adhesion of the middle ear membrane.