

VORP 503

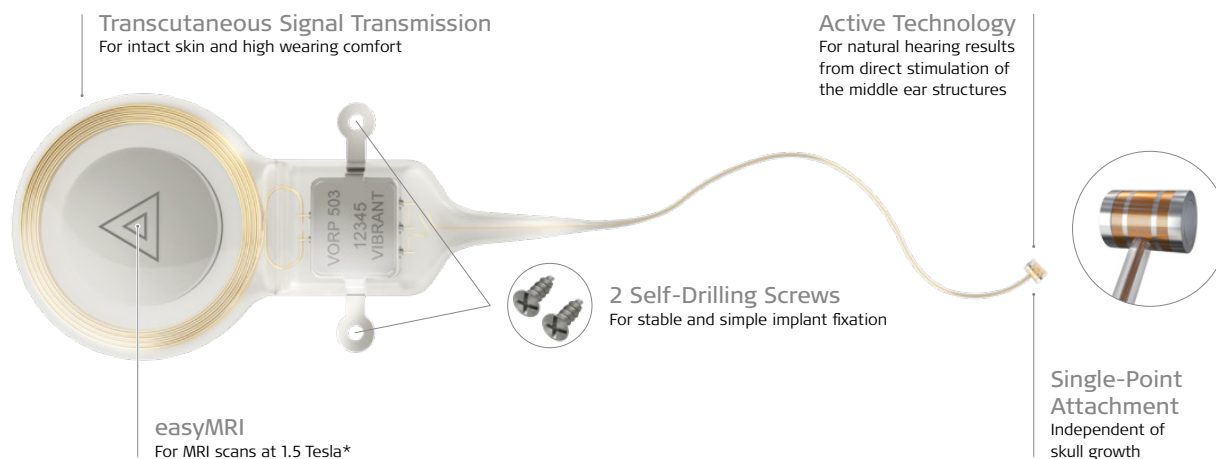
Active Middle Ear Implant
VIBRANT SOUNDBRIDGE System



hearLIFE

VORP 503 Active Middle Ear Implant

Hear Naturally, Feel Free



Satisfied Users

- Active stimulation of the middle ear structures produces a natural listening experience
- Transcutaneous signal transmission keeps skin intact
- An unobstructed auditory canal and lightweight audio processor ensure maximum wearing comfort and hearing throughout the day

Flexible Implantation

- Suitable Couplers for different anatomies and types of hearing loss
- Standardized coupling to various middle ear structures
- Self-drilling screws allow stable and simple implant fixation
- Single-point FMT attachment simplifies fixation and makes the implant independent of skull growth

Future-Orientated

- Extremely reliable
- Very low incidence of complications¹
- easyMRI: users have peace of mind while undergoing MRI scans*
- Compatible with current and next-generation audio processors: users can switch to the latest signal processing without any problems



easyMRI Magnet Technology Designed for MRI

Three in every four people will need an MRI scan in the next 10 years.²

VIBRANT SOUNDBRIDGE allows quick, hassle-free MRI scans at 1.5 T.*

The magnet technology used in our implants was specially designed for MRI.

* The SOUNDBRIDGE VORP 503 implant is MR conditional. Recipients with the SOUNDBRIDGE VORP 503 implant may be safely MRI scanned at 1.5 Tesla following the conditions detailed in the instructions for use.



Surgical flexibility and standardized coupling

Choosing the Right Couplers

Flexibility during surgery is important—therefore we developed various Couplers that allow the FMT (Floating Mass Transducer) to be coupled to appropriate middle ear structures which suit specific anatomies and pathologies.



Vibroplasty-CliP-Coupler and Stapes-SH-Coupler

- For standardized coupling to the head of stapes
- Coupler choice depends on anatomical conditions



RW-Soft-Coupler

- Fixing the FMT to the round window
- Anatomically optimized shape (dimensions: 1.5 x 1 mm)



Incus-SP-Coupler

- For fixing the FMT to the short process of incus with posterior epitympanotomy
- No posterior tympanotomy required
- 35% shorter surgery time³
- Distance from facial nerve and chorda tympani

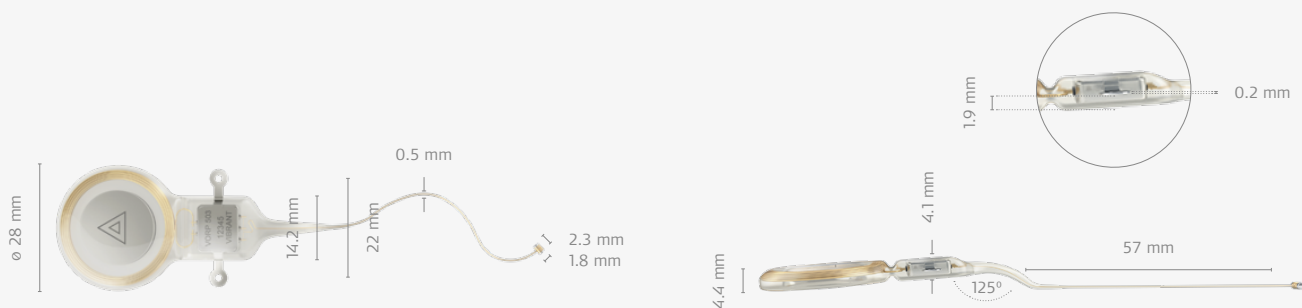


Incus-LP-Coupler

- For fixing the FMT to the long process of incus with posterior tympanotomy
- Simple coupling without crimping

Technical Data

VIBRANT SOUNDBRIDGE System



VORP 503

Contents of Implant Kit

- 1 VORP 503 middle ear implant
- 3 self-drilling cortical screws
- 1 single-use screwdriver

Weight

- 10.6 g

Materials in Contact With Tissue

- Implant: medical grade silicone elastomers, titanium, medical grade epoxy
- Screws: titanium alloy Ti 6Al 7Nb

Recommended Bone Bed Depth for Demodulator

- 1.9 mm

Safety Features

- Overvoltage protection

MRI Conditions

- MR-conditional at 1.5 Tesla*

Screw Penetration in Bone

- 3.5 mm (max.)

Maximum Immersion Depth

- 50 m in salt water (6 bar)

Biocompatible in Accordance With ISO 10993-1

Latex-Free**

Delivered Sterile

Not for Reuse

Vibroplasty Couplers

Incus-SP-Coupler

- For placement onto the short process of the incus
- Material in contact with tissue: titanium grade 5 ELI (ASTM F136)
- Contents of kit: 1 Coupler, 1 holding frame, 1 retainer

Incus-LP-Coupler

- For placement onto the long process of the incus
- Material in contact with tissue: titanium grade 5 ELI (ASTM F136), titanium grade 2 (ASTM F67)
- Contents of kit: 1 Coupler, 1 holding frame, 1 retainer

RW-Soft-Coupler

- For placement onto the round window membrane
- Material in contact with tissue: Medical silicone and silicone gel
- Contents of kit: 2 Couplers, 1 holding frame, 2 retainers

Vibroplasty-Clip-Coupler

- For placement onto the stapes head
- Material in contact with tissue: titanium grade 2, titanium grade 1
- Contents of kit: 1 Coupler

Stapes-SH-Coupler

- For placement onto the stapes head
- Material in contact with tissue: Titanium Grade 2 (ASTM F67) and Titanium Grade 5 (ASTM F136)
- Contents of kit: 1 Coupler, 1 holding frame, 1 retainer

Find frequency response curves for SOUNDBRIDGE VORP 503 on go.medel.pro/vorp503-fr-re



1 KlieB, M. K., Ernst, A., Wagner, J. and Mittmann, P. (2018), The development of active middle ear implants: A historical perspective and clinical outcomes. Laryngoscope Investigative Otolaryngology, 3: 394-404. doi: "https://doi.org/10.1002/liao.2.215" 10.1002/liao.2.215

2 Based on OECD data for Germany, 2014

3 Schraven, S. P.; Rak, K.; Cebulla, M.; Radeloff, A.; Grossmann, W.; Hagen, R.; Mlynski, R. (2018): Surgical Impact of Coupling an Active Middle Ear Implant to Short Incus Process. Otolology & Neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otolology and Neurotology, 39, p. 688-692

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** Where "latex-free" means "not made with latex" in accordance with the latest FDA "Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex" guideline, 2014

Please find detailed information and specific conditions for use for each product in the respective instructions for use.