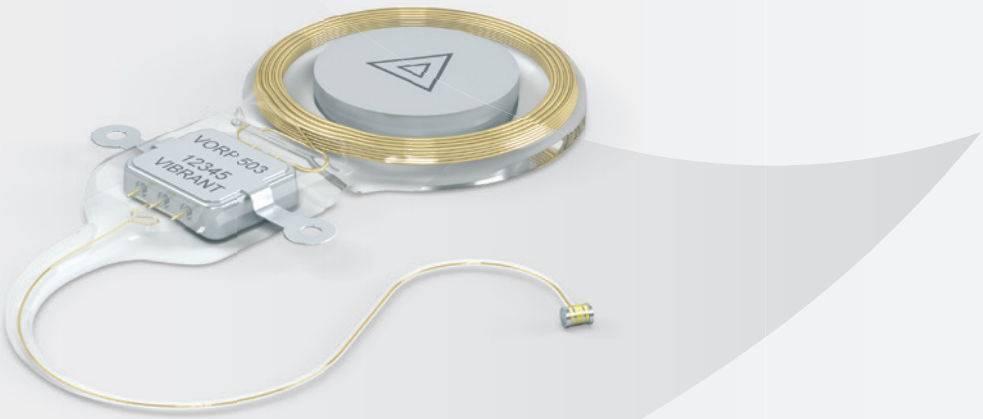
For Professionals

MED EL

VORP 503

Active middle ear implant

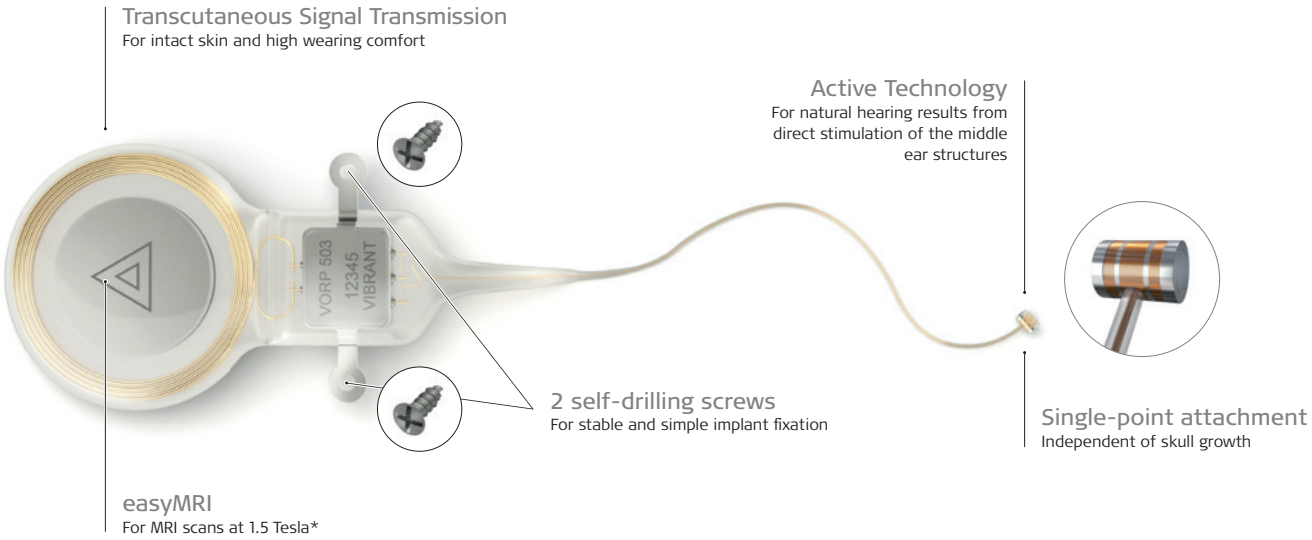
VIBRANT SOUNDBRIDGE System



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 complications[1]
- 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 specially designed for MRI

3 in every 4 people will need an MRI scan in the next 10 years.[2] The VIBRANT SOUNDBRIDGE allows quick, safe and comfortable MRI scans at 1.5 T.* The magnet technology used in our implants was specially designed for MRI.

- No surgery
- No discomfort
- No hearing downtime

* 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.

VIBRANT SOUNDBRIDGE for sensorineural hearing loss

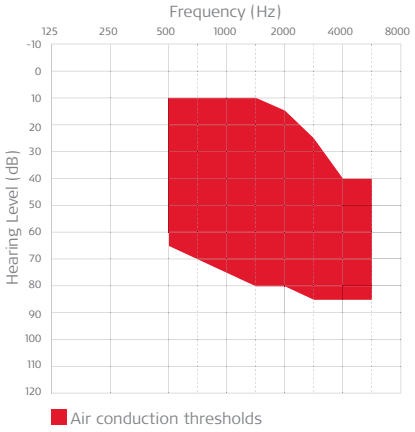
Hearing without conventional hearing aids

Conventional hearing aids are typically used for minor to severe sensorineural hearing loss, but many users don't wear their hearing aids because they are unhappy with the hearing they offer or find them uncomfortable. VIBRANT SOUNDBRIDGE is the perfect alternative that offers people the opportunity to hear again – they can benefit from a natural hearing experience, an unobstructed auditory canal and high wearing comfort, allowing them to hear throughout the day.

Benefits

- Simple surgery
- Very good hearing results[1]
- High user satisfaction[3]

Indication criteria



- Sensorineural hearing loss with stable air conduction thresholds that fall within the red area in the chart
- Age 5 years or older
- Normal middle ear functions as shown by audiometric thresholds and impedance measurements
- Speech audiometry curve adequate to the respective PTA with speech understanding of at least 50% at MCL with headphones in open-set word test
- Improvement of speech understanding through amplification possible
- Absence of retrocochlear and central auditory disorders
- Adequate motivation and realistic expectations

Which Couplers for sensorineural hearing loss?

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 hearing loss indications and anatomies.

For sensorineural hearing loss, the following Couplers are available:

Incus-SP-Coupler

- For fixing the FMT to the short limb of incus with atticotomy
- No posterior tympanotomy required
  - 35% shorter surgery time[4]
  - Distance from facial nerve and chorda tympani

Incus-LP-Coupler

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

VIBRANT SOUNDBRIDGE for conductive and mixed hearing loss

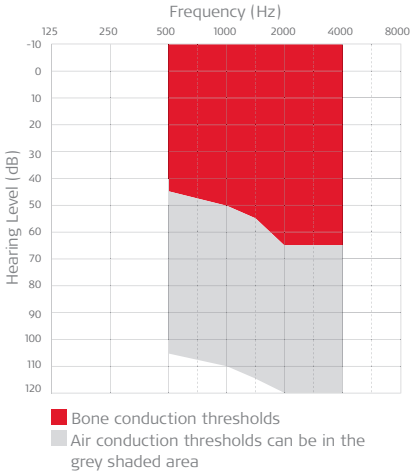
Direct, side-specific stimulation for complex anatomies

Conductive and mixed hearing loss often involves complex anatomies, meaning that bone conduction solutions are frequently used. However, if direct, side-specific stimulation promises better results for the user, the VIBRANT SOUNDBRIDGE is an efficient alternative solution, with Couplers that offer various options and maximum flexibility to suit individual anatomies.

Benefits

- Allows coupling for various middle ear anatomies
- Easy to use in comparison with other active middle ear implants
- Very good hearing results

Indication criteria



- Conductive or mixed hearing loss with stable bone conduction thresholds that fall within the red area in the chart
- Age 5 years or older
- Absence of active middle ear infections
- Ear anatomy that allows the FMT (Floating Mass Transducer) to be positioned on a suitable middle ear vibratory structure
- Improvement of speech understanding through amplification possible
- Absence of retrocochlear and central auditory disorders
- Adequate motivation and realistic expectations

Which Couplers for conductive and mixed hearing loss?

For treating conductive and mixed hearing loss, the following Couplers are available:

RW-Soft-Coupler

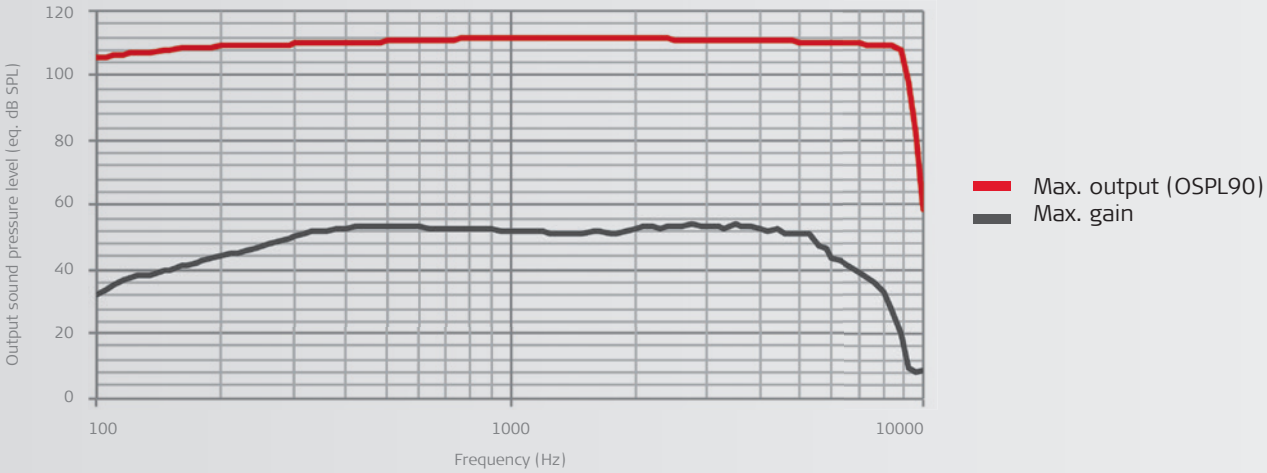
- Fixing the FMT to the round window
- Anatomically optimized shape (dimensions: 1.5 x 1 mm)

Vibroplasty-CliP-Coupler

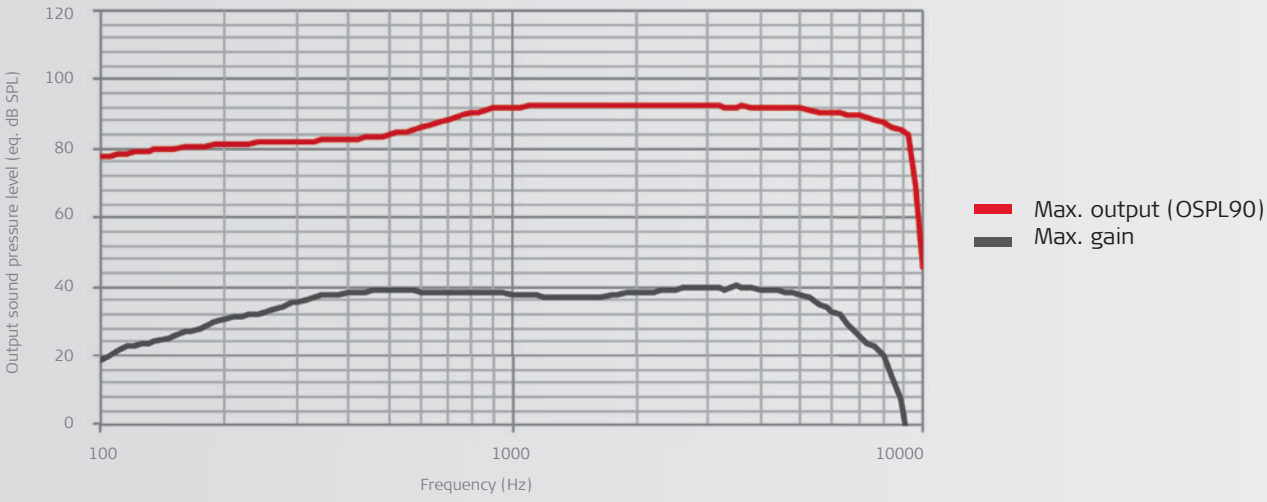
- For standardized coupling to the head of stapes

Output curves

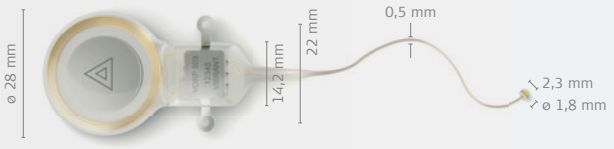
Output curves for VIBRANT SOUNDBRIDGE System with SAMBA Hi

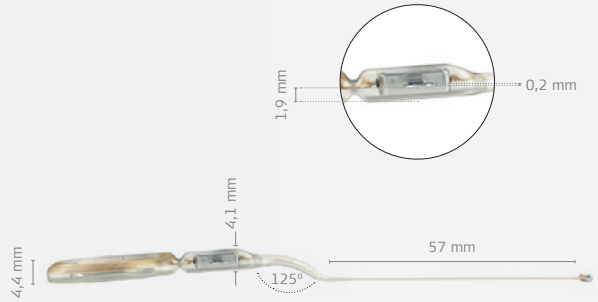


Output curves for VIBRANT SOUNDBRIDGE System with SAMBA Lo



Technical data





VORP 503

Contents of implant kit
1 VORP 503 middle ear implant
3 self-drilling cortical screws (1.6 x 4 mm)
1 single-use screwdriver

Weight
10.6 g

Material 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
For details see medel.com/important-safety-information

Screw penetration in bone
3.5 mm (max.)

Maximum immersion depth
50 m in salt water (6 bar)

Biocompatible according to ISO 10993-1
Latex-free**
Delivered sterile

Vibroplasty Couplers

Incus-SP-Coupler
- for sensorineural hearing loss
- 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 sensorineural hearing loss
- 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 conductive and mixed hearing loss
- material in contact with tissue: Medical silicone and silicone gel
- Contents of kit: 2 Couplers, 1 holding frame, 2 retainers

Vibroplasty-CliP-Coupler
- for conductive and mixed hearing loss
- material in contact with tissue: titanium grade 2, titanium grade 1
- Contents of kit: 1 Coupler

[1] Kließ, 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: HYPERLINK «https://doi.org/10.1002/lio2.215» 10.1002/lio2.215
[2] Based on OECD data for Germany, 2014
[3] Han JJ, Rhee J, Song JJ, Koo JW, Choi BY. Clinical predictors for satisfaction with incus vibroplasty: a preliminary study. European archives of oto-rhino-laryngology : official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery. 2018;275(2):371-378.
[4] 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. Otology & Neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology, 39, p. 688-692

** Here, "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.

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