

# **MSAC application 1803**

**Implantation of an active middle ear implant (Vibroplasty) for treatment of mixed and conductive hearing loss**

## **Application for MBS eligible service or health technology**

### **HPP Application number:**

HPP200239

### **Application title:**

Implantation of an active middle ear implant (Vibroplasty) for treatment of mixed and conductive hearing loss

### **Submitting organisation:**

MED-EL IMPLANT SYSTEMS AUSTRALASIA PTY LTD

### **Submitting organisation ABN:**

38161162385

## **Application description**

### **Succinct description of the medical condition/s:**

An active middle ear implant (aMEI) is intended for individuals with mild to moderate mixed (MHL) or conductive (CHL) hearing loss, who cannot achieve success or adequate benefit from surgical therapy or bone-conduction devices, or cannot wear traditional hearing aids due to medical reasons.

### **Succinct description of the service or health technology:**

The service is for the implantation of an aMEI (Vibroplasty) for the treatment of adults, adolescents and children with mild to moderate mixed or conductive hearing loss as indicated above.

The technology used in the service is the VIBRANT SOUNDBRIDGE (VSB), which is currently the only aMEI available in Australia.

The VSB is comprised of two main components:

1. Internal implanted component, the VORP 503, which is coupled to a vibratory structure of the middle ear via the FMT in a procedure named Vibroplasty; and
2. External audio processor (AP) containing a power source (battery), microphone, and digital signal processor.

The AP is held to the patient's head via magnetic attraction to the implant magnet.

The signal from the AP is transmitted to the implant and transformed into mechanical vibrations, which are then transduced to the cochlea by the FMT, thus restoring the natural hearing pathway.

## Application contact details

**Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?**

Applicant

**Are you applying on behalf of an organisation, or as an individual?**

Organisation

**Applicant organisation name:**

MED-EL IMPLANT SYSTEMS AUSTRALASIA PTY LTD

## Application details

**Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?**

No

**Which list/schedule will the other health technologies be listed on? (if 'Yes' above)**

**Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?**

New

## Relevant MBS items

**Please select any relevant MBS items.**

MBS item number	Selected reason type
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**What is the type of service or health technology?**

Therapeutic

## PICO sets

Implantation of aMEI (Vibroplasty) for C/MHL

### Population

**Describe the population in which the proposed health technology is intended to be used:**

Patients above the age of 5 years with conductive (CHL) or mixed (MHL), mild to moderate hearing loss who cannot achieve success or adequate benefit from surgical therapy or bone-conduction devices or cannot wear traditional hearing aids due to medical reasons.

**Select the most applicable Medical condition terminology (SNOMED CT):**

Mild to moderate hearing loss

### Intervention

**Name of the proposed health technology:**

Vibrant SOUNDBRIDGE

### Comparator

**Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:**

1. Prescribed List (PL) group 02.01.09 - Implantable Piezoelectric Bone Conduction Hearing System (all components), i.e.  
Active transcutaneous BCIs:  
Cochlear Osia system, including other healthcare resources:
  - Audiometry testing AC and BC thresholds and speech recognition
  - Programming of the audio processor (first fitting)
  - Aftercare and re-fitting (if necessary)
2. Other bone-conduction systems listed under PL group 02.01.04 - Implantable Bone Conduction Hearing System, i.e.  
Active transcutaneous BCIs:  
BONEBRIDGE System (BCI 602 kit + SAMBA 2 BONEBRIDGE audio processor)
  - Audiometry testing AC and BC thresholds and speech recognition

- Programming of the audio processor (first fitting)
- Aftercare and re-fitting (if necessary)

## Outcomes

**Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:**

multiple outcomes stated, please refer relevant section in attached PICO Set (1) document

## Proposed MBS items

**Proposed item:**

AAAAA

**MBS item number (where used as a template for the proposed item):**

41617

**Category number:**

THERAPEUTIC PROCEDURES

**Category description:**

SURGICAL OPERATIONS

**Proposed item descriptor:**

Active middle ear implant, partially implantable, insertion of, via Vibroplasty, for patients with:

- (a) mixed or conductive hearing loss; and
- (b) no success or adequate benefit from surgical therapy or bone conduction devices; or
- (c) cannot wear traditional hearing aids.

**Proposed MBS fee:**

\$2,138.30

**Indicate the overall cost per patient of providing the proposed health technology:**

\$17,803.60

**Please specify any anticipated out of pocket expenses:**

\$56.00

**Provide any further details and explain:**

anticipated out of pocket expenses are per year for batteries for the audio processor (estimation based on 8 cards of batteries per year at \$7/card) anticipated out of pocket costs are for per yea/year batteries for audio processor (estimation based on 8 cards of batteries per year at \$7/card)

NA

**How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):**

no funding; occasionally state-base funding via hospital or self-funded by patients

**Claims**

**In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?**

Superior

**Please state what the overall claim is, and provide a rationale:**

Claim: aMEIs can provide true binaural hearing.

Rationale: Because the FMT of the proposed health technology is located close to the target cochlea, it can provide selective stimulation of one single cochlea. There is no risk of cross stimulating the contralateral side. This is a huge advantage over BCIs, which cannot selectively stimulate one single cochlea. Selective stimulation is paramount for true binaural hearing and improved localization abilities.

**Estimated utilisation**

**Estimate the prevalence and/or incidence of the proposed population:**

TBC

**Provide the percentage uptake of the proposed health technology by the proposed population:**

**Year 1 estimated uptake (%):**

TBC

**Year 2 estimated uptake (%):**

TBC

**Year 3 estimated uptake (%):**

TBC

**Year 4 estimated uptake (%):**

TBC

**Estimate the number of patients who will utilise the proposed technology for the first full year:**

TBC

**Will the technology be needed more than once per patient?**

Yes, multiple times

**Over what duration will the health technology or service be provided for a patient? (preferably a number of years):**

life of the patient

**Optionally, provide details:**

The health technology is expected to be implanted once per affected ear and remain implanted for the life of the patient.

**What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):**

0

**Optionally, provide details:**

The health technology is expected to be implanted once per affected ear and remain implanted for the life of the patient.

## Consultation

**List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.**

### **Entity who provides the health technology/service**

- THE AUSTRALIAN SOCIETY OF OTOLARYNGOLOGY HEAD & NECK SURGERY LIMITED
- AUDIOLOGY AUSTRALIA LTD
- INDEPENDENT AUDIOLOGISTS AUSTRALIA

### **Entity who may be impacted by the health technology/service**

- INDEPENDENT AUDIOLOGISTS AUSTRALIA
- THE AUSTRALIAN SOCIETY OF OTOLARYNGOLOGY HEAD & NECK SURGERY LIMITED
- AUDIOLOGY AUSTRALIA LTD

### **Entity relevant to the proposed service/health technology**

- CICADA QLD INC.

## Regulatory information

**Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?**

Yes

**Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?** *(if 'Yes' above)*

Yes

**Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**



Class III

**Please enter all relevant ARTG IDs:**

<b>ARTG ID</b>	<b>ARTG name</b>
389014	Vibrating Ossicular Prosthesis – VORP 503 Implant Kit - Partially-implantable middle ear implant system
353970	Samba 2 Audio Processor - Partially-implantable middle ear implant system sound processor
446331	SYMFIT - Hearing aid fitting/programming application software

**Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?**

No

**Provide details:** *(if 'Yes' above)*

The intended purpose in this application is covered by the intended purpose of the ARTG listing. However, the indication range in this application is narrower than the ARTG which includes individuals with mild to severe hearing loss. This application includes individuals with mild to moderate hearing loss.