VIBRANT SOUNDBRIDGE
Middle Ear Implant System
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* Wireless connectivity feature is available with the Siemens miniTek™. Sivantos is not responsible for the operation with the SAMBA or its compliance with safety and regulatory standards in operation with the SAMBA.

Pictures: eye5.at // Dannel Zangerl
The New Standard in Middle Ear Implants

As market leader in the development of middle ear implant technology, MED-EL's SOUNDBRIDGE Middle Ear Implant System now sees the evolution of the VORP implant, a new generation of Vibroplasty Couplers and the distinctive SAMBA Audio Processor. Building on its proven reliability, SOUNDBRIDGE’s direct drive technology is used to treat individuals with mild to severe sensorineural hearing loss as well as conductive and mixed hearing loss.

Re-shaping the Future of Middle Ear Implant Solutions
- VORP 503 is MR Conditional at 1.5 Tesla
- Improved VORP design and handling
- New generation of Vibroplasty Couplers—offering new and more flexible coupling possibilities
- SAMBA Audio Processor—with an award winning design and cutting edge hearing technology
The key to this advancement has been the successful co-operation between global surgical expertise and MED-EL's research and development in technology. The underlining concept for the newly designed VORP and Vibroplasty Couplers is to provide medical professionals with the most advanced technology for precise and flexible middle ear surgical solutions.

COMPONENTS

VORP 503—Numerous Innovations
This new generation of the VORP is now MR Conditional at 1.5 Tesla enabling users to undergo MRI scans, if required in the future. With the improved design of the VORP comes a thinner body, optimized geometry and adjusted conductor link length. The implant can now be securely placed via fixation wings on both sides of the demodulator, using self-drilling screws. Due to this new fixation method, less drilling for the implant is required and the implant can be secured quickly and efficiently.

The new implant is MR Conditional at 1.5 Tesla.
**Floating Mass Transducer™ (FMT)—More Surgical Flexibility**

The FMT, the core of SOUNDBRIDGE’s technology, has become more flexible in its application, as the updated design sees the complete removal of the attachment clip and therefore eliminates the need to choose between a left or right version. The FMT, to be coupled with the most appropriate Vibroplasty Coupler, ensures an optimal solution for each individual case.

**Vibroplasty Couplers—Optimal Coupling**

The new Vibroplasty Couplers have been further architected and designed with simplicity in surgical handling and optimized coupling to the middle ear structures. The new range of Couplers which offer wider flexibility and surgical efficiency, now include:

For sensorineural hearing loss:
- Incus-SP-Coupler—new coupling option on the short process of the incus without posterior tympanotomy, away form facial nerve and chorda tympani.
- Incus-LP-Coupler—crimp-free attachment of the FMT onto the long process of the incus

For conductive and mixed hearing loss:
- RW-Soft-Coupler—Round Window Vibroplasty with less drilling and more standardized round window coupling
- Vibroplasty-CliP-Coupler—standardized stapes head coupling
With 20 years of experience in developing, innovating and collating the satisfaction of users, the SOUNDBRIDGE system continues to be the most successful middle ear implant on the market. Its success is due to the unique technology, with the Floating Mass Transducer (FMT) being the core component of the implant.

**Single Point Attachment**
The FMT is placed on a vibratory structure of the middle ear and stimulates it directly. This direct drive technology provides users with improved hearing quality and improved speech understanding. It is the only middle ear implant system that features a single point attachment which makes it independent of skull growth and therefore suitable for implantation in adults and children alike.

“*The audio processor of the SOUNDBRIDGE is light and comfortable. I must admit, I often forget that I’m wearing a hearing device at all.*”

*Ramona (SOUNDBRIDGE user)*
The Surgery—Functional and Time-saving

IMPLANT FIXATION
With the VORP’s new design, the wings allow the implant to be securely fixed into the mastoid bone using self-drilling screws and the single-use screwdriver, which are supplied in the implant kit. This reduces the amount of drilling needed when creating a bone-bed for the demodulator and also eliminates the need to use sutures for fixation.

VIBROPLASTY COUPLER AND FMT ASSEMBLY
The new range of Couplers are supplied with a holding frame and retainer which ensure a smart and precise way of creating an FMT and Coupler assembly. There is no longer the need to use forming forceps for crimping the FMT during surgery as the new assemblies are simply pushed on to the chosen middle ear structure. Depending on the individual case, the VORP 503 can be used with any Vibroplasty Coupler.

VIBROPLASTY - OPTIMIZING SURGICAL SOLUTIONS
The SOUNDBRIDGE is implanted using Vibroplasty. This is the name given to the treatment of hearing loss via vibratory stimulation in the middle ear. With the development of improvements to the implant design and the creation of the new Vibroplasty Couplers, the system now provides professionals with new and more flexible coupling possibilities.
SOUNDBRIDGE is indicated for use in patients who have mild to severe hearing loss and cannot achieve success or adequate benefit from conventional hearing aids. The diagram below shows that SOUNDBRIDGE can be a good solution for the following audiological and medical conditions.

SOUNDBRIDGE is indicated for use in patients who have either:

- Mild to severe sensorineural hearing loss and suffer from a medical condition in the ear canal and can therefore not use conventional hearing aids.

  or

- Conductive or mixed hearing loss and have experienced failed revision tympanoplasty or malformations.
The Solution for Different Kinds of Hearing Loss

Sensorineural Hearing Loss
- SOUNDBRIDGE is the only hearing solution for patients suffering from chronic disease in the ear canal.
- It can be implanted through the mastoid into the middle ear which means that the ear canal remains free.
- In 18 studies with over 400 patients, SOUNDBRIDGE has shown to be an effective treatment for sensorineural hearing loss in its indication criteria.

Mixed Hearing Loss
- SOUNDBRIDGE bypasses the middle ear issues and provides direct amplification to the inner ear. When the air-bone gap is greater than 25-30dB direct stimulation of the inner ear is more effective and provides better outcomes compared to conventional hearing aids.*

Conductive Hearing Loss
- SOUNDBRIDGE is a possible solution for patients who may suffer from e.g. atresia from birth.
- By implanting SOUNDBRIDGE, patients can still then undergo outer ear reconstruction.

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SAMBA brings with it a new wave of hearing technology for SOUNDBRIDGE and BONEBRIDGE users. It offers them versatility with wireless connectivity options*. SAMBA can be connected to external devices via Bluetooth or telecoil. This enables the signal from a mobile phone, MP3 player, FM system or assistive listening device to be transmitted wirelessly and with no loss of quality to the audio processor. With its award winning design, the user is offered a sleek, elegant and contemporary audio processor with the ability to choose a cover colour which discreetly matches the hair or one of the new designs, to make an expressive individual statement.

**Professionals also benefit from:**
- Fewer audio processor variants simplifying the ordering and distribution process
- Data-logging which provides information about the usage of SAMBA
- Faster fitting due to the self-learning system of SAMBA
- The Vibrogram which provides a standardized fitting procedure for SOUNDBRIDGE and BONEBRIDGE

**Activation**
After approximately 8 weeks when the patient's skin has healed from the surgery, the system can be activated.

**With SAMBA users benefit from:**

- Wireless Connectivity*
- Individual Design
- Speech Tracking
- Adaptive Directional Microphones
- Simple Control and Handling With Remote Control
- Up to 5 Individual Adaptable Programs
- Intelligent Sound Adapter
Users Choose Their Individual SAMBA Style

Basic package
SAMBA comes with the following 9 interchangeable covers:

- Silver Grey
- Light Blond
- Golden Sand
- Simply Black
- Glossy Black
- Terra Brown
- Mahogany
- Dark Chocolate
- Tweed

More information at www.medel.com/samba

Design covers
These 12 individual SAMBA design covers can be ordered separately:

- Playtime
- Coral
- Very Berry
- Intarsia
- Driftwood
- Space
- Glossy Anthracite
- Safari
- Kilt
- Night Sky
- Glossy Blue
- Melody
SAMBA Features

Intelligent Sound Adapter—SAMBA Adapts to Users’s Listening Habits
SAMBA distinguishes between different listening situations, for example, in noisy environments, music, speech in quieter environments, and automatically adjusts to the most appropriate setting.

In addition, the audio processor learns and recognizes the adjustments which the users manually set themselves in specific listening environments. For example, when a user always readjusts the volume in a quieter environment, SAMBA will recognize it and save it. Overtime, the system will automatically adjust and change the setting. This not only saves the user from having to manually adjust their SAMBA but also proves time-efficient for them and cost-efficient for professionals as there should naturally be a reduction in fitting sessions.

Wireless Connectivity®—Linking Users to the World Around Them
SAMBA offers wireless connectivity via Bluetooth or telecoil and plugs into external devices. Through this new feature users can connect to their mobile phones, MP3 players, FM systems or other wireless devices without losing any quality of sound. This new function is possible by using the Siemens miniTEK™ remote control which can be ordered separately. MED-EL support services can provide users with further information as to which is best for them.

SAMBA Remote Control—in Control With the Push of a Button
Users can simply control the volume and change between programs with the easy-to-operate remote control, which is supplied with SAMBA.

Individual Adaptable Programs—Customizing the Hearing Experience
SAMBA can offer the user up to 5 different programs for different listening situations which can be customized to suit their individual hearing needs (in loud environments or TV and music).

Adaptive Directional Microphones—Minimizes Background Noise
The adaptive directional microphones automatically detect and minimize background noise. This feature is particularly useful in situations where the noise can be louder, for example, in a restaurant. With SAMBA, users can effortlessly take part in conversations with background noise from behind or to the side being automatically omitted.

Speech Tracking—Razor-sharp Speech Feature
With this particular program SAMBA can automatically recognize the direction from which speech is coming from and sets the orientation of the microphones accordingly. It therefore optimizes the focus on speech and users can naturally tune in to others speaking, be it from behind, to the side or in front.
SOUND EXPERIENCE WITH SAMBA

SAMBA is fitted using the latest SYMFIT software which standardizes the procedure for SOUNDBRIDGE. SAMBA can be fitted using the battery-pill or by using the wireless option. Vibrograms can be created for the SOUNDBRIDGE system.
MED-EL SPORTS HEADBAND—COMFORT AND SUPPORT FOR AN ACTIVE LIFESTYLE

The MED-EL Sports Headband provides comfort and security for sports and many other vigorous activities. With the headband, users need not worry about the audio processor shifting out of place or falling off. The audio processor can stay securely in place over the implant thanks to the specially-designed pockets within the headband. The breathable microfiber material also protects the audio processor from sweat and moisture.

The MED-EL Sports Headband is available in black and comes in four different sizes (XS, S, M and L). The headband can be ordered via www.medel.com/skinfit-en or by contacting your MED-EL representative.
FAQs

What are the main innovations of the new SOUNDBRIDGE system?
- Implant is MR Conditional at 1.5 Tesla
- New Vibroplasty Couplers:
  - Incus-SP-Coupler—new coupling on short process of the incus. No need to create posterior tympanotomy, away from facial nerve and chorda tympani.
  - Incus-LP-Coupler—coupling to the long process of the incus without crimping.
  - RW-Soft-Coupler—standardized round window coupling with less drilling.
  - Vibroplasty-CliP-Coupler—standardizing stapes-head coupling.
- Improved design and handling of the VORP 503 implant—quicker fixation with self-drilling screws.
- SAMBA Audio Processor—adaptive signal processing and wireless connectivity* option.

Is the new SOUNDBRIDGE MR safe?
The new SOUNDBRIDGE is MR Conditional at 1.5 Tesla. The patented magnet technology limits interference with the magnetic field in the MRI scanner. This gives users the possibility to still benefit from MRI scans if required in the future. Always remove the audio processor before entering the MRI area.

What are the target groups for the SOUNDBRIDGE system?
Candidates with sensorineural or conductive and mixed hearing losses as shown below.

| Sensorineural hearing loss (plus pathology in the ear canal) | Mixed hearing loss (after middle ear surgery) | Conductive hearing loss (e.g. atresia) |

What are the advantages of a clip-free and orientation free FMT?
The VORP 503’s new design means there is no left and right versions. The implant can be used for both sides and surgeons can choose which Vibroplasty Coupler to use.

Which Vibroplasty Coupler should be used?
- Sensorineural
  - Incus-SP-Coupler—new coupling option
  - Incus-LP-Coupler—improved coupling, no crimping

- Conductive and mixed hearing losses
  - RW-Soft-Coupler—standardized RW coupling, less drilling
  - Vibroplasty-CliP-Coupler—standardizing stapes-head coupling

What are the advantages of a self-learning signal processing system?
The user can now experience optimized hearing benefit in all listening environments. With the Intelligent Sound Adaptor SAMBA adapts to users’ listening habits and distinguishes between different listening environments. The audio processor learns and recognizes the adjustments which users manually set themselves in specific listening environments. Additionally, it logs usage and sound environment of the audio processor.

What wireless connectivity options are available with SAMBA?
To enable users to use wireless connectivity* options, they can independently choose the Siemens miniTEK*. This allows them to use mobile phones, MP3 players, FM systems or other audio devices via Bluetooth, telecoil, or direct input.

How much maintenance is required with the new SOUNDBRIDGE system?
There is no maintenance required apart from changing the battery in the SAMBA Audio Processor and the battery in the remote control. Users can also change the SAMBA covers if they wish, as a choice of colours and designs are available.
MED-EL—A TRUSTED PARTNER
Meet MED-EL

At MED-EL, our goal is to overcome hearing loss as a barrier to communication and quality of life worldwide. Based in Innsbruck, Austria, MED-EL has over 1,500 employees and is present in more than 100 countries.

For nearly 40 years, MED-EL founders Ingeborg and Erwin Hochmair have been pioneering cochlear implant research. As a company, MED-EL has been driving innovation in the field of hearing implants for more than 20 years.

Let us know if you have any questions.