BONEBRIDGE
Bone Conduction Implant System
A new era in bone conduction stimulation.

* 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 // Daniel Zangerl
BONEBRIDGE—The World’s First Active Bone Conduction Implant System

As a driving force behind new innovation combined with decades of experience in hearing implant technology, MED-EL proudly introduces the world’s first active bone conduction implant system – the BONEBRIDGE. With the BONEBRIDGE, MED-EL completes its family of hearing implant solutions.

With the successful development of this state-of-the-art system, patients can now benefit from:

- For decades semi-implantable, transcutaneous implants have proven successful and stable and have shown to go together with low complication rates.
- With the BONEBRIDGE transcutaneous technology proven in MED-EL cochlear implants and middle ear implants is now available for bone conduction stimulation.
- Intact skin device: the implant including the transducer is safely embedded under the skin. Therefore the risk of skin infection is very low and no continuous skin care is needed.
- Direct drive bone conduction together with state-of-the-art signal processing provides excellent audiological outcomes.
- BONEBRIDGE is MR-Conditional up to 1.5 Tesla, giving users the possibility to still benefit from MRI scans, if required in the future.
- BONEBRIDGE is a cosmetically appealing solution. The implant is completely invisible under the skin and the audio processor can be discretely worn under the hair. The covers of the new SAMBA audio processor can be interchanged. Users can choose a cover colour which discreetly matches the hair or one of the new designs, to make an expressive individual statement.
- BONEBRIDGE is the first active hearing implant where no surgical access to the middle ear is necessary.

BONEBRIDGE is available for adults and children aged 5 years or above and can be used for the following types of hearing loss:

- Conductive & mixed hearing loss
- Single-sided deafness
Breakthrough Technology
With BONEBRIDGE

Being the first active bone conduction implant, the BONEBRIDGE is a leap forward in bone conduction hearing system technology – a completely new and innovative type of hearing implant. It is the first active, intact skin hearing implant in bone conduction stimulation.

Components

The BONEBRIDGE is a semi-implantable system consisting of an implantable part, the BCI, and the externally worn SAMBA audio processor.

The BCI is the implantable part of the BONEBRIDGE and consists of a magnet surrounded by the receiver coil, the electronics (demodulator), a bendable transition and the innovative, highly efficient Bone Conduction - Floating Mass Transducer (BC-FMT).

Acoustic information from the audio processor is sent transcutaneously to the BCI. The BC-FMT vibrates the bone, the bone carries the vibration to the inner ear, where it is processed like normal sound.
Who is a Candidate for BONEBRIDGE?

When selecting a candidate for the BONEBRIDGE, the patient’s audiological state and medical background need to be considered. Furthermore, all candidates should be 5 years of age or older.

Audiological Aspects

Patients suffering from either:

- Conductive or mixed hearing loss as indicated by audiometric testing with bone conduction thresholds better than or equal to 45 dB HL at 500 Hz, 1 kHz, 2 kHz and 3 kHz
- Single-sided sensorineural deafness, that is severe-to-profound sensorineural deafness in one ear while the other ear has normal hearing (air conduction should be equal to or better than 20 dB HL measured at 500 Hz, 1 kHz, 2 kHz and 3 kHz)

Medical Indications

Candidates may have a history of:

- Revision tympanoplasty, ear canal stenosis or chronically draining ears where conventional hearing aids are not suitable due to poor wearability, feedback problems or poor sound quality
- Otosclerosis or tympanosclerosis that cannot be rectified to a sufficient extent by surgery, or wearing conventional hearing aids
- Congenital malformations where ear canals are absent and cannot be restored through conventional surgery
- Sudden deafness, acoustic neuroma or other reasons which cause severe to profound sensorineural hearing loss on one side
BONEBRIDGE Surgery

Placement and Fixation

The BC-FMT is positioned either in the sinodural angle or retrosigmoidal, depending on the anatomy and pathology of the patient. This is checked preoperatively via a CT scan analysis. The postoperative positioning of the SAMBA audio processor should also be considered.

Procedure

A bed for the BC-FMT is drilled and two fixation holes are drilled beside the bed. Once the implant is in place, the BC-FMT is fixed with two cortical screws. The receiver coil of the BCI is placed on the bone under the periosteum.

The surgery takes approximately 30 minutes to one hour and can be performed as an outpatient or inpatient procedure.

contained within the BCI Implant Kit is the implant itself, together with two templates (C-Sizer and T-Sizer), a single use drill bit and cortical titanium screws (two regular screws and one emergency screw).

Activation

The implant system can be activated as soon as the swelling of the skin flap above the implant has reduced. Osseointegration of any part of the BC-FMT is not needed for activating the system.

BCI Lifts & BCI Sizer Kit

As the anatomy can differ considerably between patients the use of BCI Lifts may be required when implanting the BONEBRIDGE. For patients who present a smaller skull or present more variable anatomy the BCI Lifts can help avoid uncovering the dura or sigmoid sinus, as less drilling depth is required.

Depth-Gauge-Handle
Depth-Gauge
Flat-Transducer-Sizer
Coil-Sizer
The SAMBA brings with it a new wave of hearing technology for BONEBRIDGE and VIBRANT SOUNDBRIDGE users. It offers them versatility in connecting via Bluetooth or telecoil to external devices such as mobile phones, FM systems or MP3 players.

**Individual Design**

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.

**reddot award 2014 winner**

With the SAMBA users benefit from:

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

Basic package
The SAMBA comes with the following 9 interchangeable covers:

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

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

More information at www.medel.com/samba
Intelligent Sound Adapter—SAMBA Adapts to User’s Listening Usage

The SAMBA distinguishes between different listening situations, for example, in noisy environments, music, conversations in a quiet environment etc. and automatically adjusts to the most appropriate setting. In addition, the audio processor learns and recognizes the adjustments which the user manually sets themselves in specific listening environments. For example, when a user always readjusts the volume in a quieter environment, the 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.

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 the 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 the 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.

Individual Adaptable Programs—Customizing the Hearing Experience

The SAMBA can offer the user up to 5 different programs for different listening situations which can be customized to suit their individual hearing needs (e.g. for noisy environments or for TV and music).

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 the SAMBA.

Wireless Connectivity—Linking Users to the World Around Them

The 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™ which can be ordered separately. MED-EL support services can provide users with further information as to which is best for them.
MED-EL Sports Headband

Comfort and Support for an Active Lifestyle

The new MED-EL Sports Headband provides comfort and security for sports and many other vigorous activities. With the MED-EL Sports Headband, there’s no need to worry about the audio processor shifting out of place or falling off. Now the audio processor is kept 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). It can be ordered at www.medel.com/skinfit-en or contact your MED-EL representative.
The SAMBA is fitted using the latest SYMFIT software which standardizes the procedure for the BONEBRIDGE. The SAMBA can be fitted using the battery pill or by using the wireless option. A Vibrogram can be created for the BONEBRIDGE system.

Professionals also benefit from:
- Fewer audio processor variants simplifying the ordering and distribution process
- Data-logging which provides information about the usage of the SAMBA
- Faster fitting due to the self-learning system of the SAMBA
- The Vibrogram which provides a standardized fitting procedure for the BONEBRIDGE
How does the BONEBRIDGE differ from other bone conduction devices (such as bone conduction hearing aids and bone anchored hearing aids)?

- Transcutaneous technology: the implant is safely embedded under the skin.
- Due to the fact that the implant is placed under intact skin there is minimal risk of skin infection and no continuous skin care is needed.
- Direct Drive Stimulation: Better sound quality because the implant is directly driving the bone.

What level of maintenance is needed with the BONEBRIDGE?

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.

Is the BONEBRIDGE MR safe?

The BONEBRIDGE is MR Conditional at 1.5 Tesla. It features a patented holding magnet that is force-neutral in the MRI. However, there will be an image artifact around the BCI. Always remove the SAMBA before the MRI.

Indications

- Patients must be 5 years or older

Audiology

- Conductive or mixed hearing loss as indicated by audiometric testing with bone conduction thresholds within the shaded area (as shown in diagram)
- Single-sided sensorineural deafness (air conduction in the contralateral ear should be equal to or better than 20 dBHL as shown in diagram)
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.

Please contact us if you have any further questions.