The BONEBRIDGE™ Bone Conduction Implant System
a new era in bone conduction stimulation
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
• The Bonebridge is a cosmetically appealing solution. The implant is completely invisible under the skin. The audio processor can be discretely worn under the hair
• The Bonebridge is the first active hearing implant where no surgical access to the middle ear is necessary

Indications for the Bonebridge:
• Conductive & mixed hearing loss
• Single sided deafness
Breakthrough technology with the 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 Amadé BB audio processor. The Amadé BB contains two microphones, a digital signal processor and a battery.

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). 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 the BONEBRIDGE™?

When selecting a candidate for the Bonebridge system, the following criteria and aspects should be recognized. Firstly, they must be 18 years of age or older. Then the candidate’s audiological state and medical background needs to be considered.

**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 Amadé BB 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.
Sound experience with the Amadé BB

With the Amadé audio processor (model BB), the Bonebridge system offers state-of-the-art signal processing. Together with direct bone conduction, this is the basis for superior results.

With the Amadé BB, users benefit from:

• Wind Noise Reduction
• Choice of 3 different programs
• Directional Microphone
• Sound Smoothing
• Speech and Noise Management

Wind noise reduction
Amadé BB users have the freedom of being outside or in the city, whilst still having the ability to hear sounds clearly. This intelligent technology constantly monitors the environment for wind noise, which, when detected, is automatically softened and allows improved hearing.

Choice of programs
The Amadé BB allows the user to be in control of each listening situation. It offers the choice of three different programs which can be adapted for different personal preferences. Whether in a restaurant, out with friends or in a meeting, the Amadé BB supports the flexibility to select the right program for the listener’s comfort.

The Amadé BB is easy to handle. By simply using the push button, the user can switch between programs effortlessly.

Directional microphone
The feature of dual microphone technology with directional mode reduces interference from the back and the side. This feature is beneficial in noisy situations, such as at parties or in restaurants and allows the user to understand the immediate conversation more clearly and distinctly.

Sound smoothing
Even when loud or unexpected sound occurs, the Amadé BB isolates sudden noises and reduces them without interfering with speech signals. This technology softens annoying noises, allowing the user to relax and enjoy daily life.

Speech and noise management
The Amadé BB distinguishes between speech and background noise. It focuses on speech and automatically identifies and reduces background noise, without affecting important speech signals.
Fitting the Amadé BB

The Amadé BB is based on the proven Amadé platform used with the Vibrant Soundbridge middle ear implant but optimized for bone conduction. As quickly as two to four weeks after surgery, the Amadé BB can be fitted depending on the healing of the skin flap above the implant. As soon as the swelling has reduced the activation of the Bonebridge can be started.

Using the SYMFIT Fitting Software the eight compression channels of the Amadé BB can be optimally fitted for the individual patient’s needs. The 16-frequency bands allow fine-tuning of the gain.
**Wide frequency range**
The audio processor supports frequencies up to 8000 Hz and is therefore not only able to represent speech signals in high quality but also other musical and environmental sounds.

**Microphone system**
The microphone system in the Amadé BB audio processor can be set to omnidirectional or directional mode. The user is free to focus on sound differently according to each listening situation.

**Magnet strengths**
The magnets are provided in five different strengths and for each patient the most suitable can be selected. Changing the magnet is easy and no tools are required.

**Choice of colours**
The Amadé BB is available in four different colours, providing users with the best option of matching their hair colour. This enables the audio processor to be hidden discreetly and comfortably under the hair.
Countries where MED-EL Hearing Implant Systems have been implanted (as of 2012)
MED-EL Medical Electronics headquartered in Innsbruck is a leading provider of hearing implants worldwide. The company founded by Dr. Ingeborg and Prof. Erwin Hochmair is one of the pioneers of the industry. The world’s first micro-electronic multi-channel cochlear implant developed by the two scientists was first implanted in a patient as early as 1977. The cochlear implant marked a milestone in medical history as it, for the first time, was and remains the first replacement of a human sense, the sense of hearing. Today, MED-EL offers the widest range of implantable solutions to treat the various causes and degrees of hearing loss. MED-EL’s main objective is to overcome hearing loss as a barrier to communication, opening up a world of sound to people around the world. Consistently high levels of investment in research and development fuel the pipeline of innovative hearing implant solutions, ensuring the company’s dynamic future.

**Research & Development: Safeguarding the future with innovations**

Since its founding, MED-EL has continuously invested in research and development. New standards, innovations, and industry “firsts” demonstrate the company’s consistent commitment. Research activity at MED-EL is driven by the development of new hearing implant technologies, the constant improvements made in cooperation with medical scientists and researchers, as well as breakthroughs in the field of neurostimulation.

**The world of sound: Wide range of hearing implant systems**

MED-EL currently offers the widest range of hearing implant systems in the world and more than half of the users are children. Every day people around the world are given the gift of hearing with the help of a product from MED-EL. The company’s solutions are distinguished by performance, ease of use and reliability.

**Technology leader: Set on a growth path**

MED-EL has 28 branches with implantations carried out in 96 countries and employs approximately 1,200 people worldwide. 700 are based at the company’s headquarters in Innsbruck, Austria, where R&D and production are located. 96% of the hearing implants are exported and purchased by roughly 1,300 ORL-clinics worldwide. MED-EL is an owner-managed private company.
BoneBridge™ users describe their initial impressions

A completely new and really beautiful awareness of life
With the Bonebridge, I have finally taken the opportunity to become a hearing participant in life again. It is only now that I notice everything that I had not perceived for years. My head first had to become accustomed to the numerous impressions and sounds once again, but it is an indescribably fantastic feeling. The handling of the audio processor is ultra simple and the volume of sound much greater than with hearing aids. I can even hear fine tones like the sound of the wind or the ticking of a clock again.

Petra, Germany

I am so happy that I opted for the Bonebridge
The operation is so easy; the colour of the audio processor is inconspicuously matched to my hair colour and therefore an excellent cosmetic result. A great benefit is also that the auricle remains free. The sound quality is natural. All in all everything went very well and positively for me. My quality of life has improved enormously and I am so happy that I have made this decision.

Karin, Germany

The best sound quality that I have experienced in 60 years
I opted for the Bonebridge because the implantable part of the Bonebridge lies completely under the skin. I wore a double-sided pair of bone spectacles for 50 years and thought I was being well treated, but the Amade audio processor has shown that there was room for improvement. I was surprised at how well the communication is working and am really happy that the Amade audio processor and the Bonebridge have been developed.

Hartmut, Germany

With the Bonebridge, I feel much more actively involved in life
Since I received the hearing implant, music has played an increasingly important role in my life because I can hear it more intensively and louder. What pleases me the most: When I get into my car in the morning and can turn on the music and hear everything much more intensively and clearly! This makes me feel so happy! I feel like a new person since the day my Bonebridge was activated.

Daniela, Austria
Data Sheet

**Dimensions Amadé BB**
- Diameter: 29.1 mm
- Height: 8.8 mm
- Weight: ≤ 8 g

**Dimensions BCI**
- Length: 69 mm, width: 28.6 mm, thickness: 4.5 mm

**Dimensions BC-FMT**
- Diameter: 15.8 mm
- Thickness: 8.7 mm

**Product category**  
Amadé BB (Audio Processor)

**Signal processing**  
8 AGC channels
16 frequency bands

**Frequency range**  
250 – 8000 Hz

**Variants**  
Amadé BB

**Styles available**  
Left and right

**Power supply**  
Single Zinc-Air #675 or equivalent
Low battery warning

**Magnets**  
Five magnet strengths

**Material**  
PC, polyester

**Fitting software**  
Connexx software with SYMFIT database

**Colour range**  
Dark Chocolate
Terra Brown
Golden Sand
Silver Grey

**Enhanced features**  
Three different programs
Directional Microphone
Wind Noise Reduction
Sound Smoothing
Speech and Noise Management

**Product category**  
BCI 601 Implant Kit

**Styles available**  
The implant can be used for either side

**Materials**  
Silicone
Titanium

**Contents of Implant Kit**  
- Coil-Sizer (C-Sizer)
- Transducer-Sizer (T-Sizer)
- Cortical screws (2 regular screws, 1 emergency screw)
- Drill bit with stopper
- Bone Conduction Implant (BCI 601)

**Indications:**  
18 years or older.

**AUDIOLOGY**
- Conductive or mixed hearing loss with a mild inner ear component. Indicated by audiometric testing with the bone conduction thresholds better than or equal to 45 dB HL at 500 Hz, 1 kHz, 2 kHz and 3 kHz
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 needed apart from changing the battery in the Amadé BB audio processor.

Is the Bonebridge MRI safe?
The Bonebridge is MRI conditional up to 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 Amadé BB before the MRI.

What is new about the Amadé BB?
The system is based on the proven Amadé platform used with the Vibrant Soundbridge middle ear implant but optimized for the Bonebridge. Therefore the Amadé BB is only to be used with the Bonebridge BCI.

- Severe to profound sensorineural hearing loss in the ipsilateral ear, while the contralateral ear has normal hearing. Air conduction in the contralateral ear should be equal to or better than 20 dB HL measured at 500 Hz, 1 kHz, 2 kHz and 3 kHz.
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