BCI 602
Active Bone Conduction Implant
BONEBRIDGE System
BCI 602 Active Bone Conduction Implant
Always A Step Ahead

- Active Technology
  For direct stimulation of the bone and excellent hearing performance
- Transcutaneous signal transmission ensures intact skin and high wearing comfort
- Ergonomic design keeps skin healthy
- Compatible with current and future audio processor generations, so users can easily switch to the latest signal processing technology

Happy Users

- Active stimulation of the bone delivers exceptional hearing performance
- Transcutaneous signal transmission ensures intact skin and high wearing comfort
- Ergonomic design keeps skin healthy
- Compatible with current and future audio processor generations, so users can easily switch to the latest signal processing technology

- Minimal drilling depth (3.5-4.5 mm) for straightforward surgery
- Self-drilling screws provide a safe and stable implant fixation

Straightforward Surgery

- All implant-specific surgical equipment is delivered with the implant
- No resterilisation of surgical equipment necessary
- Surgery possible under local anaesthetic

Efficient Workflow

- BONEBRIDGE recipients may be safely MRI scanned at 1.5 Tesla following the conditions detailed in the instructions for use.
- Based on OECD data for Germany, 2014.

easyMRI—Magnet technology made for MRI
3 out 4 people will need an MRI in the next 10 years.**
With BONEBRIDGE, it’s possible to have quick, safe, and hassle-free MRI scans.* The magnet technology in our implants was specially developed for MRIs.

- No surgery
- No discomfort
- No hearing downtime

* BONEBRIDGE recipients may be safely MRI scanned at 1.5 Tesla following the conditions detailed in the instructions for use.
** Based on OECD data for Germany, 2014.
Why Choose an Active Bone Conduction Implant?

An active bone conduction implant generates the vibrations itself and transmits them directly to the bone. That has several advantages:

- Excellent hearing performance via efficient energy transmission: Vibrations don’t have to pass through skin or other tissue, and so aren’t dampened before they reach the bone.
- High wearing comfort: The implant is placed completely under intact skin. The audio processor is kept comfortably in place over the implant using magnets.
- Discreet hearing solution: The audio processor is small and light, as it only contains the battery and microchip. The transducer is contained within the implant.

Only an active bone conduction implant can combine these three benefits in one device. The BCI 602 is a second-generation active bone conduction implant, developed with years of experience. This makes it the most advanced active bone conduction implant available—why would you choose anything else for your patients?
The BCI Lifts can be used to reduce the drilling depth from 4.5 mm to 3.5 mm.

- Reduced drilling depth
- More flexibility during surgery
- More options for asymmetrical anatomies

The BCI Sizer Kit makes it easier to prepare for implantation. The kit is delivered sterile with the implant, so that you have everything you need for surgery.

- Intuitive handling
- Delivered sterile for immediate use
- Time-saving for an efficient workflow
Selection Criteria for BONEBRIDGE

BONEBRIDGE uses bone conduction to help people with conductive or mixed hearing loss, or single-sided deafness, to hear. Bone conduction works by sending sound waves to the cochlea through the bones of the skull, bypassing any blockages in the outer or middle ear.

Conductive or Mixed Hearing Loss

- Permanent conductive or mixed hearing loss with bone conduction thresholds within the red area of the diagram
- 5 years old or above
- Suitable anatomy for BONEBRIDGE implantation
- Absence of retrocochlear or central auditory processing disorders
- Adequate motivation and realistic expectations

Single-Sided Deafness

- Permanent sensorineural hearing loss in the affected ear with hearing thresholds within the shaded area of the diagram
- Normal hearing in the contralateral ear with hearing thresholds within the shaded area of the diagram
- 5 years old or above
- Suitable anatomy for BONEBRIDGE implantation
- Absence of retrocochlear or central auditory processing disorders in the contralateral ear
- Adequate motivation and realistic expectations

Frequency Response Curves for BCI 602 Implant with SAMBA 2 BB
## Technical Data

### BCI 602 Implant

**Implant Kit Contents**
- 1 BCI 602 Bone Conduction Implant
- 3 Cortical Screws (Osteointegration of the screws is not required):
  - 2 Self-Drilling Standard Screws 1.6 x 5 mm (silver)
  - 1 Emergency Screw 1.9 x 5 mm (blue)
- 1 Surgical Screwdriver SD 2 (single-use)

**Weight**
Approx. 20 g

**Materials in Contact with Tissue**
Implant: Medical grade silicone elastomer, titanium grade 5 EU (in accordance with ASTM F 136-12)
Screws: Titanium alloy Ti6Al7Nb

**Screwdriver**
Polyoxymethylene (POM), martensitic stainless steel (1.4977)

**MRI Conditions**
MR Conditional at 1.5 Tesla
Details at medel.com/important-safety-information

**Maximum Diving Depth**
50 m in salt water (6 bar)

**Biocompatible in accordance with ISO 10993-1**
Latex-free
Delivered sterile

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### BCI 602 Lifts (1mm)

**Kit Contents**
- 4 BCI 602 Lifts (1 mm)
- 3 Cortical Screws
  - 2 Self-Drilling Standard Screws 1.6 x 5 mm, 1 Emergency Screw 1.9 x 5 mm

**Materials in Contact with Tissue**
PEEK

**Biocompatible in accordance with ISO 10993-1**
Latex-free
Delivered sterile

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### BCI 602 Sizer Kit

**Kit Contents**
- 1 Footprint Sizer
- 1 Transducer Sizer
- 1 Handle

**Materials in Contact with Tissue**
Footprint Sizer
Purell HP2 Polypropylene (PP)
Transducer Sizer
Purell HP372P Polypropylene (PP)
Handle
Tritan MX731

**Biocompatible in accordance with ISO 10993-1**
Latex-free
Delivered sterile

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*** “Latex-free” means here “not made with latex” in accordance with the current FDA Guidelines “Recommendations for Labeling of Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex”, 2014.

Please find detailed information and specific conditions for use for each product in the respective instructions for use.