

BCI 602

Active Bone Conduction Implant
BONEBRIDGE System

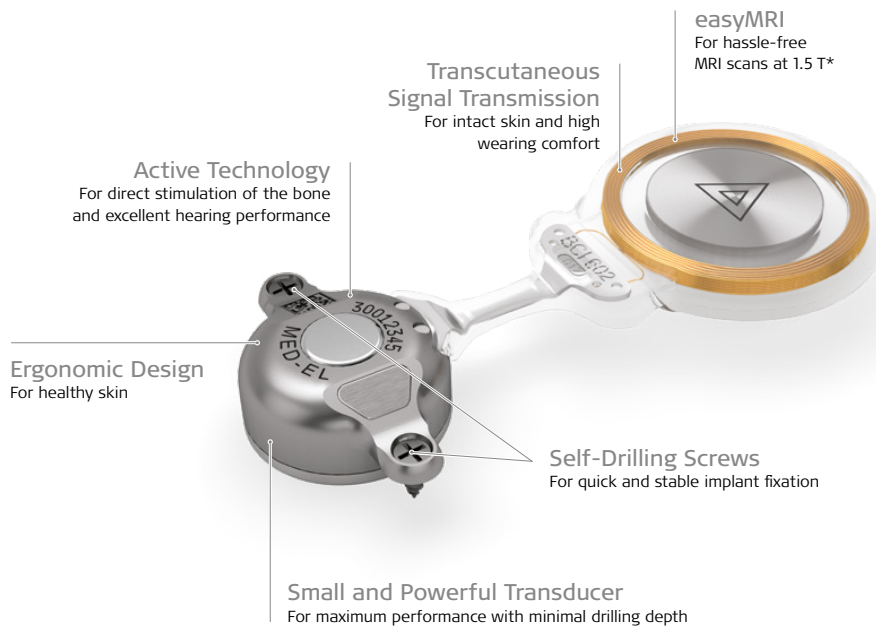


reddot award 2019
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hearLIFE

BCI 602 Active Bone Conduction Implant

Always A Step Ahead



easyMRI—Magnet technology made for MRI

3 out of 4 people will need an MRI in the next 10 years.** With BONEBRIDGE, it's possible to have quick and hassle-free MRI scans.* The magnet technology in BONEBRIDGE was specially developed for MRIs and is covered by our life-long MRI guarantee.****



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

Straightforward Surgery

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

Efficient Workflow

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

* The BONEBRIDGE bone conduction implant is MR conditional. Recipients with BONEBRIDGE 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.

**** The terms and conditions of the MRI guarantee can be found at <https://go.medel.com/mri-guarantee-terms>

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 are not dampened by skin.
- High wearing comfort: The implant is placed under intact skin. The audio processor is kept 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.

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?

BCI 602 Lifts and BCI 602 Sizer Kit

BCI 602 Lifts

The BCI 602 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

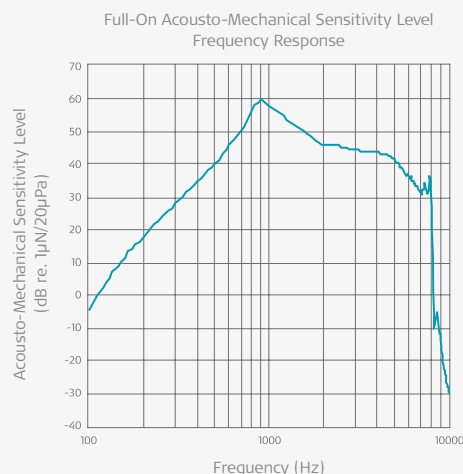
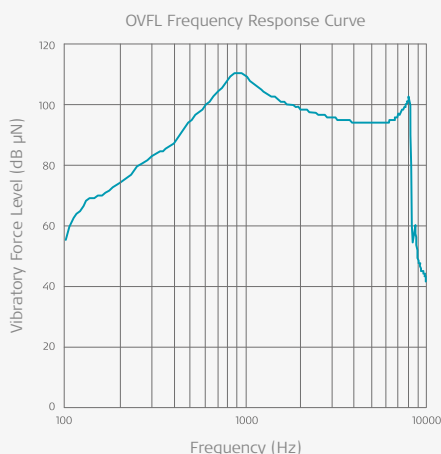
BCI 602 Sizer Kit

The BCI 602 Sizer Kit is delivered sterile with the implant, so that you have everything you need for surgery.

- Intuitive handling
- Time-saving for an efficient workflow



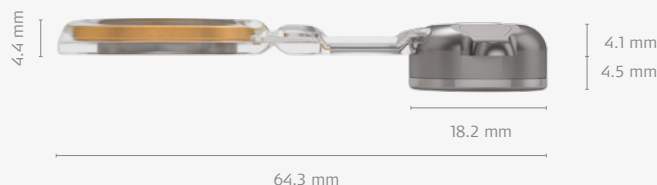
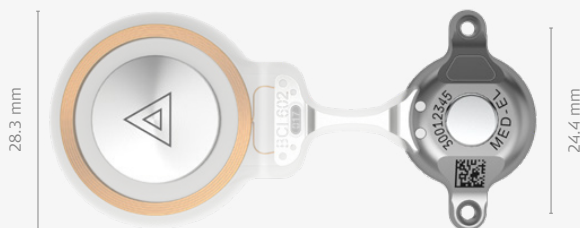
Frequency Response Curves for BCI 602 Implant With SAMBA 2 BB



Technical Data

BONEBRIDGE System

Actual Size



BCI 602 Implant

Implant Kit Contents

- 1 BCI 602 Bone Conduction Implant
- 3 Cortical Screws (Osseointegration 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 ELI (in accordance with ASTM F 136-12)
- Screws: Titanium alloy Ti6Al7Nb

Screwdriver

- Polyoxymethylene (POM), martensitic stainless steel (1.4197)

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

Not for Reuse

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

Not for Reuse

BCI 602 Sizer Kit

Kit Contents

- 1 Footprint Sizer
- 1 Transducer Sizer
- 1 Handle

Materials in Contact With Tissue

- Footprint Sizer
- Purell HP372P Polypropylene (PP)
- Transducer Sizer
- Purell HP372P Polypropylene (PP)
- Handle
- Tritan MX731

Biocompatible in Accordance
With ISO 10993-1

Latex-Free***

Delivered Sterile

Not for Reuse

Find frequency response
curves for BONEBRIDGE on
go.medel.pro/bci602-fr-re



*** "Latex-free" means here "not made with latex" in accordance with the current FDA Guidelines "Recommendations for Labeling 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.

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