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BONEBRIDGE (BCI 602)

Surgical Guide

AW52713_3.0 (English US)

Table of Contents

Surgical Guide

For the BCI 602 Implant

This guide describes the surgical procedure for the implantation of the osseointegrated Bone Conduction Implant BCI 602 step by step. It contains information about the use of related surgical tools and compatible devices as well as perioperative patient management.

The information in this guide is a reference for surgeons and healthcare professionals supporting the implantation of the BCI 602. It should be used together with the instructions for use accompanying the BCI 602 implant. For information on current indications, contraindications, warnings, precautions and possible adverse events refer to the instructions for use for the BCI 602 implant.

Introduction

The BONEBRIDGE is an osseointegrated bone conduction implant system for individuals with conductive or mixed hearing loss as well as for those suffering from single-sided deafness. The BCI 602 is part of the BONEBRIDGE system.

The BONEBRIDGE system consists of an external part, the audio processor, and an implanted part, the bone conduction implant. The audio processor is worn over the implant and kept in place by magnetic attraction. It contains two microphones, a digital signal sound processor and a battery.

The BCI 602 consists of a magnet, surrounded by the receiver coil, the transition and the Bone Conduction – Floating Mass Transducer (BC-FMT) with electronics in a hermetic housing. Power and information from the audio processor are sent transcutaneously to the BCI 602. The BC-FMT vibrates in a controlled manner, specific to each patient's hearing needs. The BCI 602 is implanted into the temporal bone. When the implant is in position and receives stimulation from the externally worn audio processor, it causes the bone to vibrate and thus stimulates the inner ear.

The BC-FMT is 18.2 mm in diameter and requires a maximum drill depth of 4.5 mm. An overview of the BCI 602 and its dimensions is shown in Figure 1.

Surgeons and audiologists work together selecting candidates for implantation. Thorough audiological and medical evaluations need to be performed and reviewed in conjunction with candidacy information provided in the instructions for use of the BCI 602. Before surgery, candidates are counselled about the risks and benefits of a BONEBRIDGE implantation. Best outcomes are achieved by accurate candidate selection and proper counselling of the patient in order to achieve realistic expectations.

The audio processor can be activated as soon as the swelling of the skin has reduced. An audiologist programs the audio processor to the patient's particular hearing needs. The patient typically wears the audio processor all day, immediately after activation.

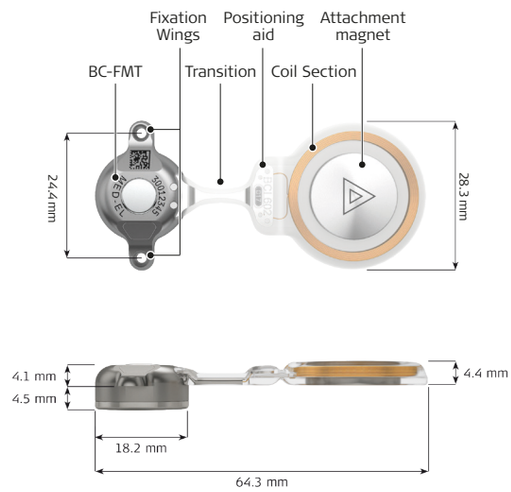

Figure 1: BCI 602 overview and dimensions

Surgical Tools and Accessories

Most instruments needed for implantation of the BCI 602 are included in a standard micro-instruments set. The BCI 602 Implant Kit contains a single-use screwdriver and cortical screws. The BCI 602 Implant Kit is shipped together with the BCI 602 Sizer Kit.

For challenging anatomies, the BCI 602 Lifts (1mm) are available separately. The Skin Flap Gauge 7 is an optional reusable surgical tool to estimate the thickness of the skin flap and should be ordered separately prior to the first procedure.

BCI 602 Implant Kit

The BCI 602 implant is shipped in a sterile tray, which additionally contains a single-use screwdriver and three cortical screws for an easy fixation of the BC-FMT.

Surgical Screwdriver (SD 2)

The surgical screwdriver (crosstip) is 113 mm in length and has a diameter of 16 mm. For easier handling, the top section is rotatable. The surgical screwdriver is a single-use tool.

Figure 2: Surgical Screwdriver (SD 2)

Cortical Screws

Every implant is delivered with three cortical screws in screw holders. Each screw is made of titanium alloy and is 5 mm in length. The two self-drilling cortical screws have a diameter of 1.6 mm. The emergency screw (blue surface) has a diameter of 1.9 mm.

Figure 3: Two self-drilling cortical screws and one emergency screw (larger diameter, blue surface)

BCI 602 Sizer Kit

The BCI 602 Sizer Kit is used to support a BCI 602 implantation. It contains the Footprint-Sizer (FP-Sizer), the Transducer-Sizer (T-Sizer) and a handle. It is for single use only and shipped in sterile condition. The BCI 602 Sizer Kit can be used before opening the main implant package.

FP-Sizer

The FP-Sizer represents the footprint of the implant. It is used to mark the position of the implant on the skin and bone.

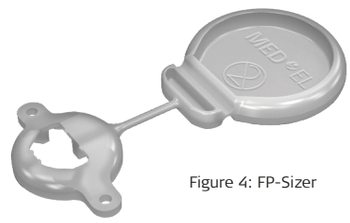

Figure 4: FP-Sizer

T-Sizer

The T-Sizer represents the part of the BC-FMT which needs to be recessed into the bone. It can be used to mark the outline of the BC-FMT on the skull bone and to check if the required depth of the bone bed is already reached.

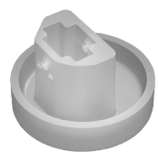

Figure 5: T-Sizer

FP- and T-Sizer Assembly

The FP-Sizer connected to the T-Sizer represents the geometry of the whole implant. The Footprint- and Transducer-Sizer Assembly is used to determine if the fixation wings are in flat contact with bone.

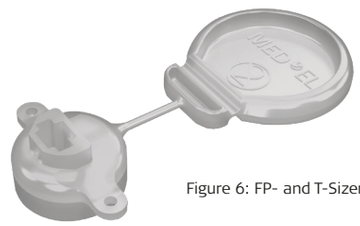

Figure 6: FP- and T-Sizer Assembly

Handle

The handle can be assembled to the T-Sizer for convenient handling.

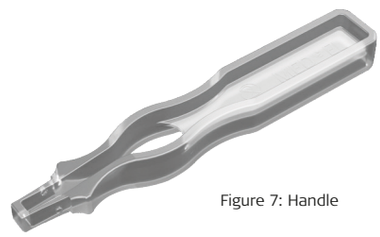

Figure 7: Handle

BCI 602 Lifts (1mm)

The BCI 602 Lifts (1mm) are used if the drilling depth for the bone bed cannot be reached due to anatomical reasons or if an uneven skull surface has to be compensated for.

The package contains four BCI 602 Lifts (1mm), two self-drilling cortical screws and one emergency screw.

BCI 602 Lifts (1mm)

The four BCI 602 Lifts (1mm) are identical and they are 1mm in size. Two BCI 602 Lifts (1mm) can be used with the Footprint- and Transducer-Sizer Assembly. Two BCI 602 Lifts (1mm) are intended to be used with the implant if necessary.

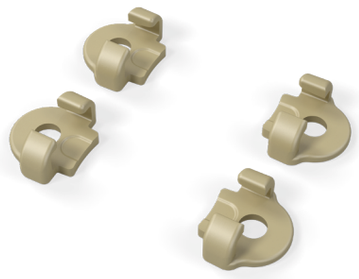

Figure 8: BCI 602 Lifts (1mm)

Cortical Screws

The self-drilling cortical screws and the emergency screw are identical to the ones in the BCI 602 Implant Kit.

Skin Flap Gauge 7

The optional Skin Flap Gauge 7 is used to estimate the thickness of the skin flap over the coil section of the implant to achieve optimal magnetic attachment and signal transmission of the external audio processor. It is made of stainless surgical steel and is delivered non-sterile. Therefore it has to be cleaned, disinfected and sterilized before use and each reuse. More details can be found in the instructions for use provided with the Skin Flap Gauge 7.

Figure 9: Skin Flap Gauge 7

General Surgical Considerations

The implantation of a BCI 602 requires the drilling of a bone bed for the BC-FMT. For secure fixation, two self-drilling cortical screws are used. The coil section of the implant is placed below the periosteum in a tight periosteal pocket. Neither further drilling nor fixation is necessary for the coil section of the implant. Surgery is performed under general anesthesia. It is performed either on an outpatient or inpatient basis.

General Precautions

The surgery follows standard otologic practice and includes the normal risk of major ear surgery as well as risks associated with general anesthesia.

It is recommended not to remove the BCI 602 from its sterile packaging until the bone bed is prepared and the device is ready to be placed. For preparation of the bone bed, the BCI 602 FP-Sizer and T-Sizer are used.

Preoperative CT Scan

A preoperative CT scan is required to determine whether the patient's anatomy is adequate to enable placement of the BCI 602 implant. The scanning is performed to establish that the volumetric requirements of the BCI 602 can be met. These are as follows:

The BCI 602 is placed in the temporal bone. Implantation requires sufficient bone mass to create a bone bed for the BC-FMT with a diameter of 18.2 mm and a drilling depth of 4.5 mm without exposing the dura or sigmoid sinus. In addition, there must be adequate bone mass adjacent to the recess for the BC-FMT for the implant screws which have an penetration depth of 4 mm.

In cases where this depth cannot be reached, the BCI 602 Lifts (1mm) should be used, which reduce drilling depth to 3.5 mm and penetration depth of the screws to 3 mm.

Registration Form

The registration form contained in the packaging should be completed and returned promptly to MED-EL. A returned registration form ensures traceability of the implant and secures warranty rights.

Surgical Steps

The implant surgery described and illustrated below is performed on a right ear. The procedure is divided into six surgical steps:

STEP 1: Preparation

Open the BCI 602 Sizer Kit, remove the FP-Sizer from its sterile packaging and bring it into the surgical field. Place the FP-Sizer on the patient's skin and mark the outline of the desired position of the implant.

As illustrated in Figure 10, the best position for the coil section of the implant is posterior and superior to the ear canal, angled approximately 45°. The coil section of the implant should be oriented in a way that the audio processor does not touch the pinna. For placement of the coil section, also consider other patient-specific factors, for example the use of glasses and hats.

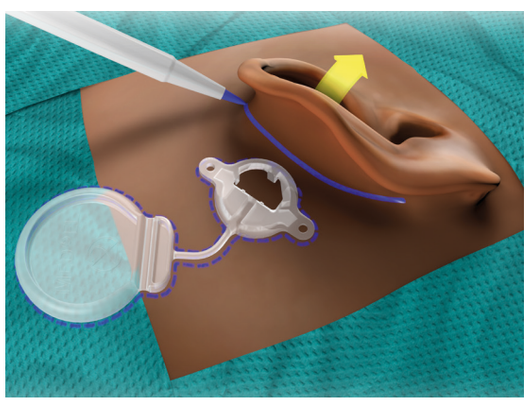

Figure 10: Positioning the FP-Sizer and planning the incision

Depending on anatomical conditions, the BC-FMT might be placed in different positions in the temporal bone. In order to always achieve proper positioning of the coil section, the implant can be bent at its transition, max. ±90° in the horizontal plane and max. −30° in the vertical plane as shown in Figure 11.

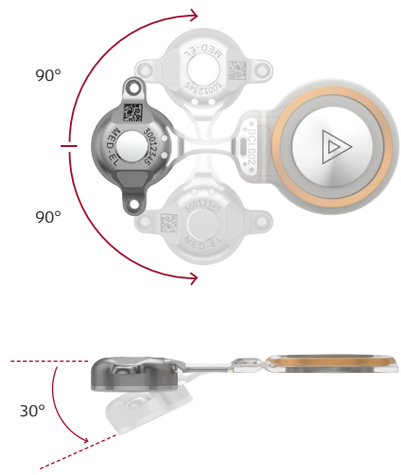

Figure 11: Possible bending angles of the BCI 602

STEP 2: Incision

Mark the incision at least 5 mm away from the desired implant position to minimize the risk of device extrusion and post-operative infection. The incision only needs to be large enough to allow placement of the implant and to drill the bone bed for the BC-FMT.

First infuse the incision site with a vasoconstriction agent and then create the incision. It is recommended to perform a double layer incision. Therefore make an anteriorly-based pericranial fascia incision. The portion of the pericranial flap overlying the coil section of the implant may be incised, but the anterior portion of the flap must be preserved to provide a continuous tissue layer over the BC-FMT of the implant. Hemostasis is achieved with monopolar or bipolar electrocautery.

CAUTION

Do not use monopolar electrocautery once the BCI 602 is in the surgical field or if the patient already has an active implant on the other side.

STEP 3: Preparation of a Periosteal Pocket

Prepare a tight periosteal pocket to accommodate the coil section of the BCI 602 using the Footprint-Sizer. For proper signal transmission and fixation of the audio processor, the flap must not exceed a thickness of 7 mm. Evaluate the thickness of the portion of the flap over the coil section, for example by using the Skin Flap Gauge 7.

STEP 4: Creation of the Bone Bed for the BC-FMT

The optimal position of the bone bed for the BC-FMT as well as the position of the two cortical screws depends on the individual anatomy. It is recommended to preoperatively determine the best position by analyzing the CT scan or similar.

Mark the position of the BC-FMT on the bone with the help of the T-Sizer (see Figure 12). To simplify the use of the template, assemble the handle to the T-Sizer. Make sure that the pins on the handle fit into the pin holes on the T-Sizer. To disassemble, press the lower part of the handle together and pull apart.

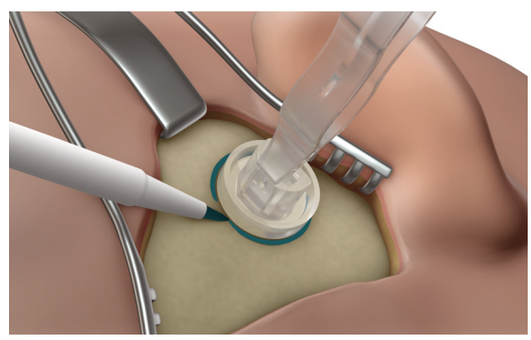

Figure 12: Marking the position of the BC-FMT using T-Sizer and handle

Use standard otologic burrs to create the bone bed. Use the T-Sizer to check the drilling depth during preparation of the bone bed as shown in Figure 13.

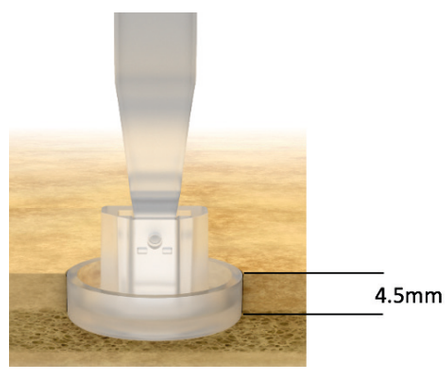

Figure 13: Checking the drilling depth using T-Sizer and handle

If the BCI 602 Lifts (1mm) are not used, the bone bed needs to be 4.5 mm in depth. Make sure the fixation wings are in flat contact with bone. To verify the contact, connect the T-Sizer to the FP-Sizer. The handle can be used for convenient handling. It might be helpful to bend the coil section of the Footprint- and Transducer-Sizer Assembly during creation of the bone bed as shown in Figure 14 (A). To check if the fixation wings are in flat contact with bone, use a surgical instrument like a needle as shown in Figure 14 (B).

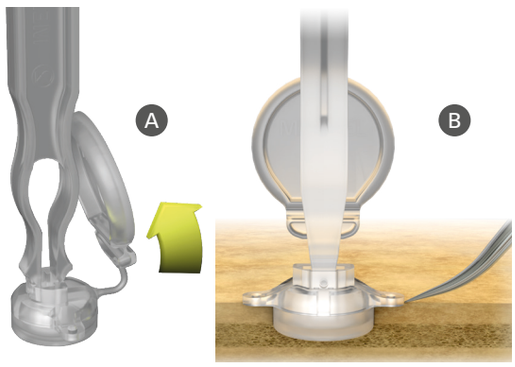

Figure 14: FP-Sizer: Bending the transition of the FP-Sizer (A) Checking flat contact of the FP-Sizer with a needle (B)

NOTE: All vibrations of the transducer are transmitted to the bone via the two screws. Therefore it is not implicitly necessary to have a tight bone bed.

If it is anatomically not possible to drill a bone bed of 4.5 mm depth, use the BCI 602 Lifts (1mm) to reduce the drilling depth to 3.5 mm. Attach the BCI 602 Lifts (1mm) to the fixation wings of the FP-Sizer (see Figure 15 (A)) and check the flat contact between the BCI 602 Lifts (1mm) and the bone as shown in Figure 15 (B).

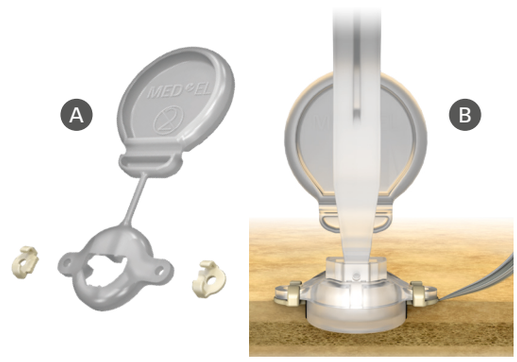

Figure 15: Attaching the BCI 602 Lifts (1mm) to the FP-Sizer (A) Checking flat contact with a needle (B)

In special anatomical conditions, a single BCI 602 Lift (1mm) can be used in order to e.g. compensate a strong curvature of the temporal bone as shown in Figure 16.

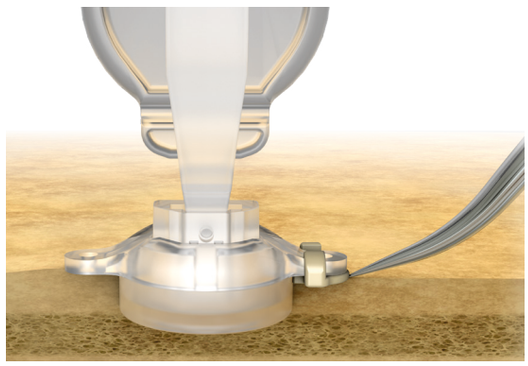

Figure 16: Using a single BCI 602 Lift (1mm) for curvature compensation

STEP 5: Fixation of the BCI 602

Remove the BCI 602 from its sterile package and bring it into the surgical field. Care should be taken when handling the implant. Do not allow any portion of the implant to make contact with surgical drapes, sponges, or towels. Keep in mind that the implant contains magnets and may be attracted to other magnetic devices or surfaces in the operating room.

CAUTION
Do not use monopolar electrocautery once the BCI 602 is in the surgical field or if the patient already has an active implant on the other side.

In case the BCI 602 Lifts (1mm) are used, slide them onto the fixation wings as shown in Figure 17.

Figure 17: Attaching the BCI 602 Lifts (1mm) to the BCI 602

Arrange the BCI 602 over the surgical site and carefully bend it according to the final position required. Keep in mind that the implant can be bent max. ±90° in the horizontal plane and max. −30° in the vertical plane. Note the correct holding position during bending as shown in Figure 18.

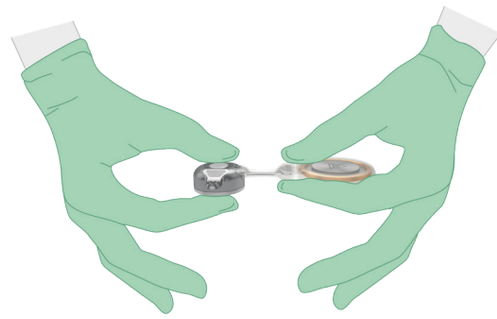

Figure 18: Bending the BCI 602

CAUTION
Avoid bending the transition of the BCI 602 multiple times. Avoid bending angles greater than those given.

Place the coil section of the implant in the periosteal pocket in a way that the ⚠ symbol on the magnet is facing towards the skin. Hold the implant at the positioning aid between forefinger and thumb while carefully pushing it into the periosteal pocket. The coil section should reside under the desired position previously marked on the skin. Then place the BC-FMT into the prepared bone bed. Make sure there is no soft tissue between fixation wings and bone.

Use the provided screwdriver to fix the implant to the bone with the supplied self-drilling cortical screws. First secure both screws loosely and then tighten them securely. For optimal power transmission to the bone, as well as for MRI safety reasons, it is mandatory to always use two screws and to fully countersink the screw heads into their designated position as shown in Figure 19. This is achieved by placing the screws perpendicular to the cortical bone.

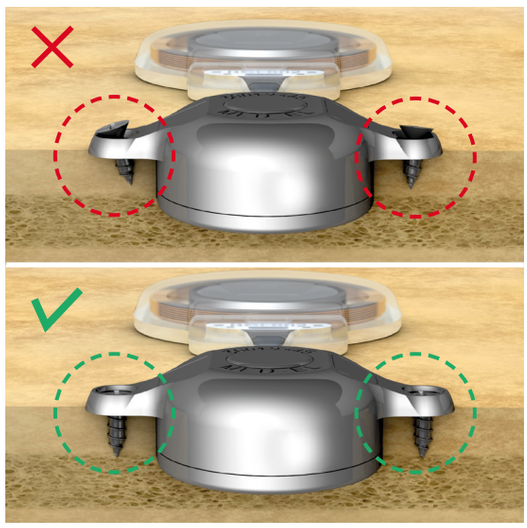

Figure 19: Fully countersink both screws

In case a self-drilling screw does not bite adequately, use the provided emergency screw (blue surface) in the existing screw hole.

NOTE: In case of dense cortical bone, creating a starter hole with a 1mm diamond burr is recommended.

STEP 6: Closure

Visually inspect the BC-FMT and palpate it to ensure a proper fixation without any slack. Ensure that the coil section of the implant is in its desired position.

Depending on the incision, close the wound in layers and take care to avoid contact with the implanted BCI 602 during the closure process. Clean the incision area and apply wound dressing to the wound site.

CAUTION

Do not use monopolar electrocautery once the BCI 602 is in the surgical field or if the patient already has an active implant on the other side.

Appendices

MED-EL Surgical Videos

Please contact your local MED-EL office or distributor for the latest MED-EL surgical videos or visit the MED-EL Professional Website (www.medel.com/pro).

MED-EL Contacts

To contact MED-EL, please visit the website www.medel.com/contact-med-el.

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