For Professionals

MED EL

BONEBRIDGE™
Information for Surgeons

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I. Information for Surgeons

The Information for Surgeons describes the Bone Conduction Implant (BCI 601), its surgical procedure, and the perioperative patient management methods. It is a reference for the surgeon implanting the BCI 601 and describes the procedures of how to install the device into the mastoid region. Key points and helpful references are found in the back with illustrations and graphics throughout the brochure.

Acknowledgements.
Special thanks to the following surgeons for their contributions in this information on the surgical technique of implanting the Bonebridge: Th. Lenarz, B. Schwab, R. Salcher (Hannover, Germany), I. Todt (Berlin, Germany), G. Sprinzl (Innsbruck, Austria), R. Hagen, R. Mlynski (Würzburg, Germany)

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I. Introduction

The Bonebridge (BB) is a bone conduction implant system for people with conductive and mixed hearing losses as well as for those suffering from single sided deafness (SSD).
The Bonebridge includes an external part, the audio processor, and an implanted part, the Bone Conduction Implant (BCI). The audio processor is worn on the head and contains two microphones, a digital signal processor, and a battery. The BCI consists of a receiver coil, a demodulator, and a transducer. Information from the audio processor is sent transcutaneously to the BCI so that the transducer (the Bone Conduction-Floating Mass Transducer, BC-FMT) vibrates in a controlled manner, specific to each patient's hearing needs. The BC-FMT is about 10 mm in height (with a drill depth of 8.7 mm), 15.8 mm in diameter and weighs about 10 g (see Fig. 1).

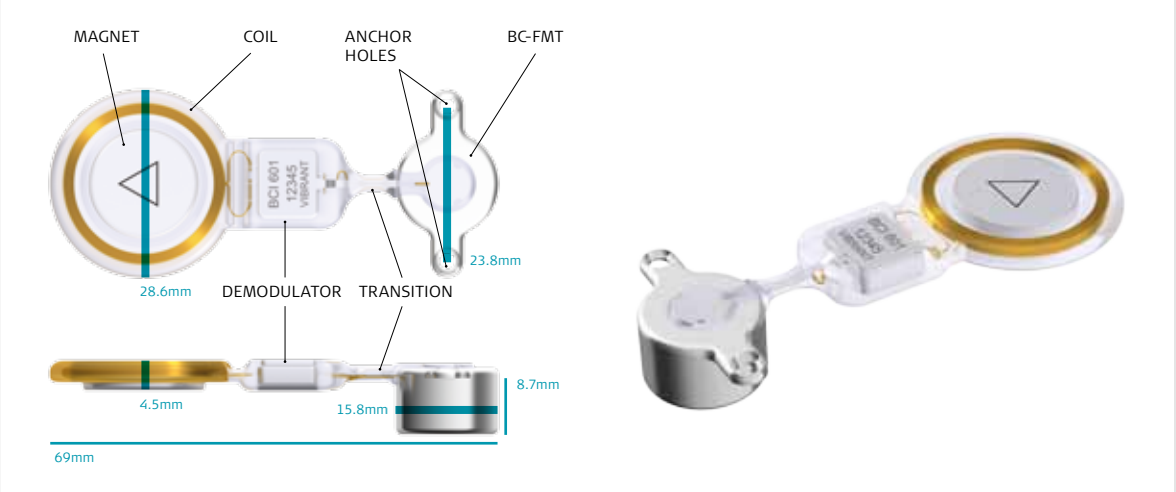


Figure 1: The BCI, seen from the top and the side.

The BCI is implanted in the mastoid and temporal region of the ear. When the implant is in position and is stimulated from the externally worn audio processor, it causes the bone to vibrate and stimulates the auditory system.
Surgeons and audiologists work together when selecting patients for implantation. Thorough audiologic and medical evaluations are performed and reviewed in conjunction with candidacy information. It is highly recommended to do a pre-operative CT scan that needs to be thoroughly analysed. Key points to be analysed are the thickness and consistency of the bone, the sigmoid sinus and the dura. Before surgery, patients are counselled about the risks and benefits of the Bonebridge implantation. Success is most likely when the patient is well selected and has realistic expectations of the BB's use.
Surgery lasts between 0.5 and 1 hour and is performed either on an outpatient or inpatient basis.
Since osseointegration of the screws is not needed, the processor can be programmed 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 for several hours a day, or all day, immediately after activation.
In this manual the surgical procedure is described for a right ear, unless otherwise mentioned.

Note: In this manual the surgical procedure is described for a right ear, unless otherwise mentioned.

II. Surgical tools

Specific instruments needed for the surgical installation of the BCI are provided in the implant package. The same surgical accessories are also available in a separate Surgical Tool Kit.
The generic surgical tools, Skin Flap Gauge 7 and the Torque Wrench Kit, have to be requested separately.

Tools shipped with the BCI or as Surgical Tool Kit (sterilized)

The BCI is shipped in one sterile tray, together with two single-use templates (the C-Sizer and the T-Sizer), two 2 mm cortical bone fixation screws, one 2.4 mm emergency screw, and one single-use drill bit.

A separate Surgical Tool Kit is also available with the same contents except for the implant itself.

Coil-Sizer (C-Sizer)

The C-Sizer, made of polypropylene, has three functions. delete and exchange with:

1. Determine optimum BCI placement on the head before incising the skin. An outline may be drawn to mark this position.
2. Outline the exact size of the seat before drilling.
3. Verify the size of the seat before placing the BCI.

Transducer-Sizer (T-Sizer)

The T-Sizer, made of titanium (the drill bit guide) and polypropylene (the body of the template), has three functions.

1. Outline the exact size of the seat before drilling.
2. Verify the size of the seat before placing the BCI.
3. Use as a drill guide to ensure the correct distance between the two anchor holes, as well as the correct orientation and depth of the anchor holes when used with the T-Sizer.

The C- and the T-Sizer can be connected to represent the complete BCI by inserting the bulge of the C-Sizer into the slot of the T-Sizer. They can only be connected in one direction.

Cortex screws

All supplied cortex screws have a length of 6 mm and are self tapping. The two regular cortex screws have an outer diameter of 2 mm and a golden surface finish. The emergency screw has an outer diameter of 2.4 mm and a blue surface finish.

Note: Adequate alternative screw lengths and/or titanium spacers may be used according to the patient's anatomy.

Drill bit

The supplied drill bit shall be used to drill the fixation points. Its diameter is 1.5 mm and it also has a PTFE-sleeve that ensures the correct depth when used together with the T-Sizer for drilling (3.9 mm).

Tools available separately

The use of the Skin Flap Gauge 7 and the Torque Wrench Kit is recommended. These tools are not included in the Kits and must be ordered separately.

Both tools are delivered non-sterile and have to be cleaned, disinfected and sterilized before use and each re-use according to the manufacturers instructions.

Skin Flap Gauge 7 (non sterile)

The Skin Flap Gauge 7, made of stainless surgical steel, is used to estimate the thickness of the skin flap over the BCI to ensure good attachment and signal transmission of the external audio processor.

Torque Wrench Kit (non sterile)

The Torque Wrench, made of stainless steel and titanium, consists of the body, the drive connection, and two exchangeable ratcheting mechanisms. The ratcheting mechanism is interposed between the body and the drive connection. The wrench includes a torque indicator (maximum torque is 32 Ncm) to facilitate precise tightening of screws. When turning the handle, the current torque is indicated on the scale at the end of the handle.

Unlike other torque wrenches, there is no clicking sound to indicate when enough force has been used.

Note: Exceeding the maximum torque of 32 Ncm will permanently impair the accuracy of the torque wrench.

CAUTION

ONCE THE WRENCH HAS BEEN OVERLOADED, IT MAY NOT BE USED AS A TORQUE WRENCH FOR SURGERY.

III. Surgery

The BCI is the implant portion of the Bonebridge system. It consists of the BC-FMT that is installed into the sinodural angle of the mastoid bone in a normal anatomy. The receiver coil of the BCI is installed under the skin in the post auricular area not more than 7 mm below the external surface of the skin. With screws, the BCI is securely fixated to the bone by the surgeon. The surgery is standard otologic practice for mastoid surgery with the additional step of securing the BCI. Because osseointegration is not needed, the patient can be activated as soon as the swelling of the skin is reduced.

General precautions

The BCI registration card, contained in the packaging, should be completed and returned promptly to VIBRANT MED-EL.
After anaesthesia has begun but before the sterile surgical field is prepared, determine the position of the BCI and incision. The position of the BC-FMT mainly depends on the anatomy of the patient and shall be determined according to the preoperative CT scan. Consider also the patient's use of eyeglasses or headwear when determining the position of the coil section of the BCI.

Overview

The following table provides a brief overview of the steps necessary to implant a BCI and points out the precautions of each step. For the demodulator and the coil section, no bed needs to be drilled.

Surgical steps	Main tasks	Pay attention to...
I. PREPARATION	• Shave hair • Mark BCI outline with T- and C-Sizer • Mark incision	• Position of BC-FMT and screws (depends on findings of CT scan) • Position of coil (consider patient's use of eyeglasses or headwear; transition of BCI can be bent ±90° in horizontal plane)
II. INCISION	• Incise and prepare skin flap • Place C- and T-Sizer • Estimate skin flap to ≤ 7 mm over coil section of BCI	• Skin flap integrity (Incision may impair blood supply of skin flap) • Place of incision (not over implant body, further posterior if auricle reconstruction is planned at later stage)
III. CREATION OF BONE BED FOR BC-FMT AND PERIOSTEAL POCKET FOR COIL	• Drill bone well in sinodural angle of mastoid • Check with T-Sizer • Elevate periosteum for coil section of the implant • Estimate skin flap thickness to ≤ 7 mm over coil section of BCI	• Correct position (depending on findings of CT scan) • Not damaging sigmoid sinus or dura (use diamond burr when drilling close to them)
IV. PREPARING BCI FIXATION	• Drill fixation points with drill bit provided, using T-Sizer as a guide	• Orientation/distance of fixation points (depending on findings of CT scan) • Not changing position of T-Sizer between drilling fixation hole 1 and 2
V. FIXATION OF THE BCI	• Remove BCI from sterile package • Arrange BCI over site • Place screws in anchor holes of BCI • Tighten screws with wrench	• Only use bipolar electrocautery once the implant is in surgical field • The BCI can be damaged by excessive bending • Not use torque > 32Ncm (other-wise bone can be damaged)
VI. CLOSURE	• Verify fixation of BC-FMT • Verify position of coil • Close skin flap in layers • Pressure dressing over the wound	• BC-FMT must be installed tightly

Surgical Steps

Step 1: PREPARATION

The CT scan needs to be evaluated to determine where to place the BC-FMT and the screws. In a normal anatomy, the BC-FMT should lie in the sinodural angle, where the interference with the sigmoid sinus and the dura is the least.

If the mastoid is already drilled out or if there is little space in the sinodural angle, the BC-FMT can be placed either behind the sinus or above the temporal line.

For the position of the screws a plane area on the bone should be chosen, taking into consideration the thickness and consistency of the bone, the position of the sigmoid sinus and the dura.

Shave the hair approximately 2 cm beyond the intended incision, removing the least amount of hair possible.

Remove the C- and T-Sizers from the sterile package and bring them into the surgical field.

Connect the C- and T-Sizer, place on the skin with the T-Tizer positioned to lay in the best position found during the CT analysis. The coil section of the implant should not lie under the auricle. Use a marking pen to trace the outer perimeter of the template on the scalp.

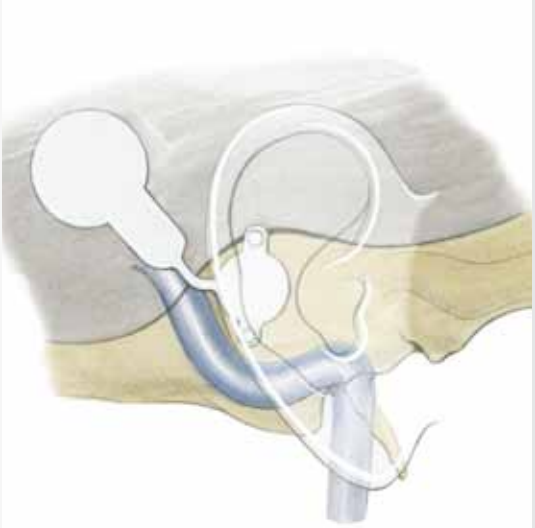


Figure 2: Position of BC-FMT is in sinodural angle. Exact position depends on findings of CT scan.

Mark the incision line at least 5 mm from the edge of the template to minimize the risk of device extrusion and postoperative infection. The incision only needs to be large enough to drill the seat for the BC-FMT of the BCI. Prepare the surgical field using standard procedures.

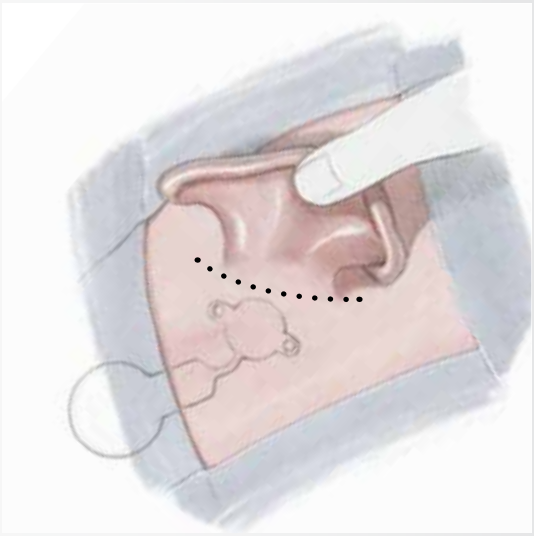
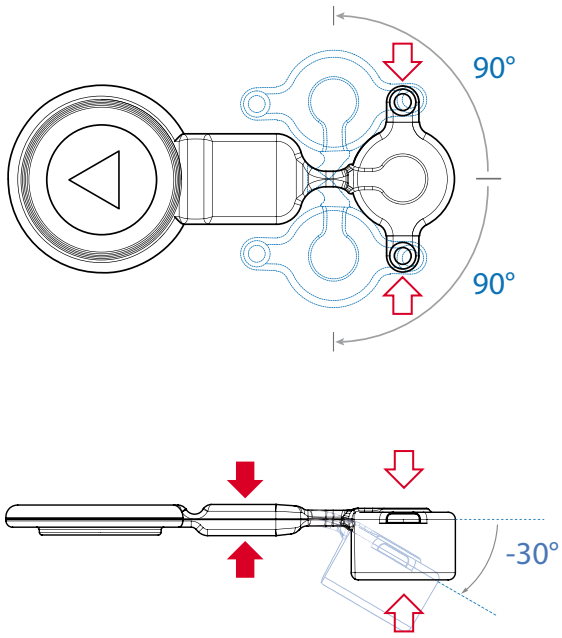


Figure 3: Position of BC-FMT is in sinodural angle. Exact position depends on findings of CT scan.

Note: BENDING OF THE BCI TRANSITION

The transition of the BCI may be bent ±90° in the horizontal plane and -30° in the vertical plane. Greater angles may cause a failure of the BCI due to wire breaks.



Step 2: INCISION

First infuse the incision site with a vasoconstriction agent and then make the incision.

If using a postauricular incision, incise the skin to the level of the temporalis fascia. Next, make an anteriorly-based pericranial fascia incision. The portion of the pericranial flap overlying the receiving coil and magnet may be excised, but the anterior portion of the flap must be preserved to provide a continuous tissue layer over the anterior portion of the demodulator and the BC-FMT. If using a small incision, a fascia incision approximately 1 cm anterior to the skin incision can be made.

In atresia cases, where a pinna reconstruction is planned at a later stage, the incision should be done further posteriorly, in such a way that the skin is healthy in the area where the pinna is to be reconstructed later. Haemostasis is achieved with monopolar or bipolar electrocautery. Note that only bipolar electrocautery should be used once the BCI is in the surgical field, or if the patient has an implant on the other side. Identify the mark on the skull and place the connected C- and T-Sizers.

Step 3: CREATION OF BONE BED FOR BC-FMT AND PERIOSTEAL POCKET FOR COIL

The position of the bone bed for the BC-FMT as well as the position of the fixation holes depends on the findings of the CT scan.

If the BC-FMT is placed in the **sinodural angle**, the reference points are the spine of Henley, the temporal line and the tip of the mastoid. Usually it is as close as possible to the EAC and as close as possible to the temporal line. If the BC-FMT is placed **behind the sinus,** the attachment of the digastric muscle and the mastoid tip are reference points. Use a standard otologic drill bit to create a bone bed in the sinodural angle of the mastoid. The implant needs to be recessed for 8.7 mm.

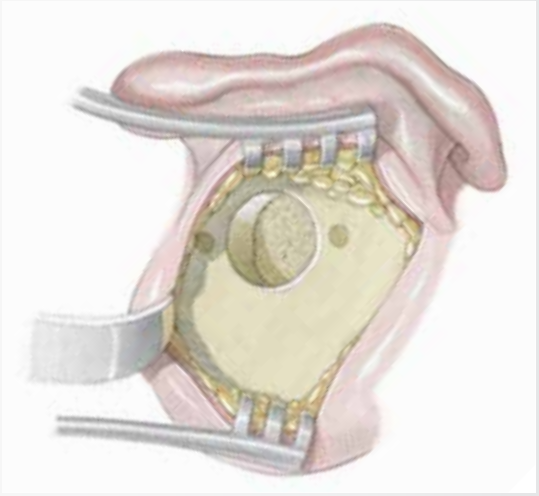


Figure 4a: Creation of bed for BC-FMT, considering position of fixation holes.

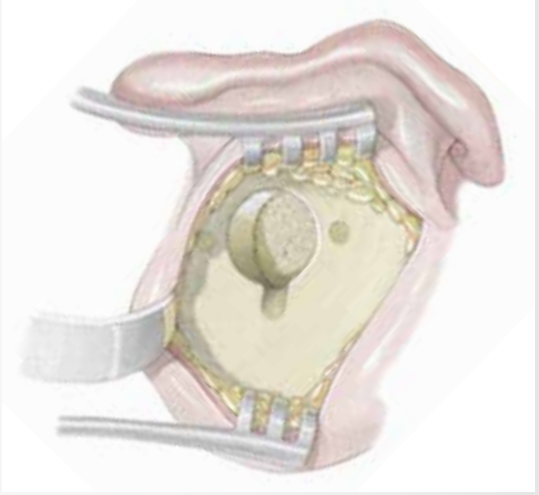


Figure 4b: With a very tight bed, additional bone should be removed where the transition exits the BC-FMT.

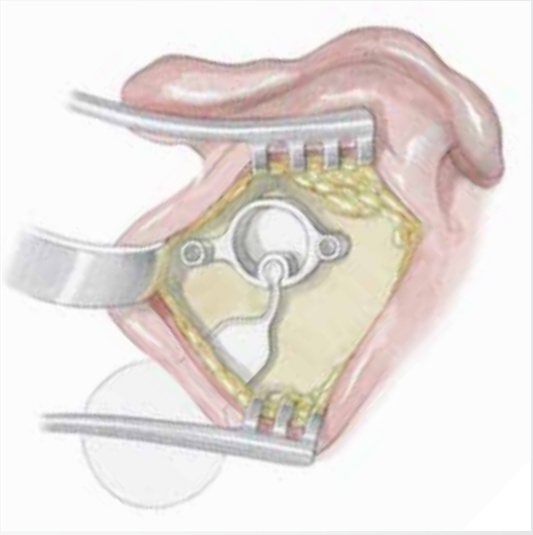


Figure 5: Verify the depth for the BC-FMT with the T-Sizer. For the demodulator of the implant, no bed needs to be drilled.

Special care should be taken when drilling close to the sigmoid sinus or the dura. When coming close to one of these structures, only a diamond burr shall be used to remove more bone. Titanium spacers may be used if a bed of 8.7 mm cannot be drilled.

Check with the T-Sizer whether sufficient bone has been removed.

In case of a very tight bone bed, a little bit of bone should be removed where the transition exits the BC-FMT.

Figure 6: The Skin Flap Gauge 7 is used to ensure that the flap covering the magnet fits loosely in the gauge and does not exceed 7 mm thickness.

Prepare a periosteal pocket to accommodate the coil and demodulator of the BCI, using the C-Sizer to check.

Evaluate the thickness of the portion of the flap over the magnet and receiving coil using the Skin Flap Gauge 7. Recall that the portion of the pericranial flap over the magnet and the receiving coil may be excised.

If the skin flap does not fit in the gauge loosely, carefully thin out the flap until it does. It is important to avoid thinning the flap too much as wound complications may occur.

To ensure proper transmission of the signal from the audio processor and proper attraction of the magnet, the total tissue thickness must not exceed 7 mm over the receiving coil.

Step 4: PREPARING BCI FIXATION

As mentioned above, the position of the fixation holes also depends on the findings of the CT scan.
Drill fixation points with the supplied drill bit with the stopper, using the T-Sizer as a guide. Using the T-Sizer prevents a drilling depth of more than 3.9 mm. The diameter of the drill bit holes is 1.5 mm.

CAUTION

DO NOT MOVE THE T-SIZER BEFORE BOTH FIXATION HOLES ARE DRILLED.

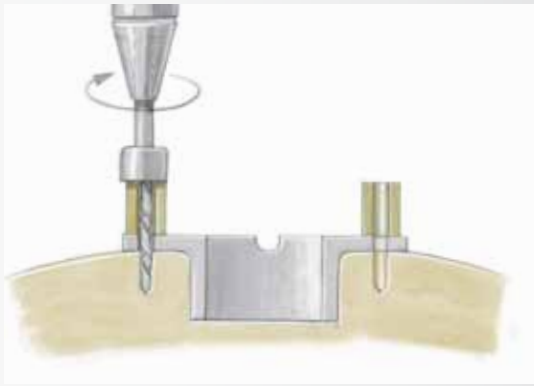


Figure 7: Using the T-Sizer when drilling the fixation holes prevents a drilling depth deeper than 3.9 mm.

Step 5: FIXATION OF THE BCI

Remove the BCI from its sterile package and bring it into the surgical field. VIBRANT MED-EL recommends that only the surgeon handles the device. Care should be taken when handling the BCI. Do not allow any portion of the BCI to contact surgical drapes, sponges, or towels. Keep in mind that the BCI contains magnets and may be attracted to other magnetic devices in the operating room.

CAUTION

ONCE THE BCI IS IN THE SURGICAL FIELD, MONOPOLAR ELECTROCAUTERY SHOULD NEVER BE USED.

Figure 8: The BCI is placed so that the triangle is facing upwards.

Arrange the BCI over the surgical site so that the magnet protrusion is towards the skull, with the triangle shape on the magnet facing towards the skin. Bend the transition of the implant according to the required final position.

Place the implant coil and the demodulator under the periosteum so that it resides under the desired external location of the audio processor position (previously marked) and the BC-FMT into the bed that has been prepared.

Carefully remove the screw from the implant package by firmly attaching it to the screwdriver. Place one regular cortical screw in each anchor hole of the BC-FMT. The regular screw has a diameter of 2 mm, a length of 6 mm, and a golden surface finish.

Assemble the torque wrench. The handle of the wrench will click into its final position. Use the wrench to firmly secure the screws into the mastoid by rotating the wrench clockwise until a secure fixation has been achieved.

Use the emergency screw (blue surface finish, diameter of 2.4 mm, 6 mm long) only if you did not achieve sufficient fixation with one of the regular screws.
There is no clicking sound to indicate when enough force has been used. For tightening the screws of the Bonebridge a force of about 10 Ncm is enough.

CAUTION

DO NOT EXCEED 32 Ncm TORQUE WHEN TIGHTENING THE SCREWS.

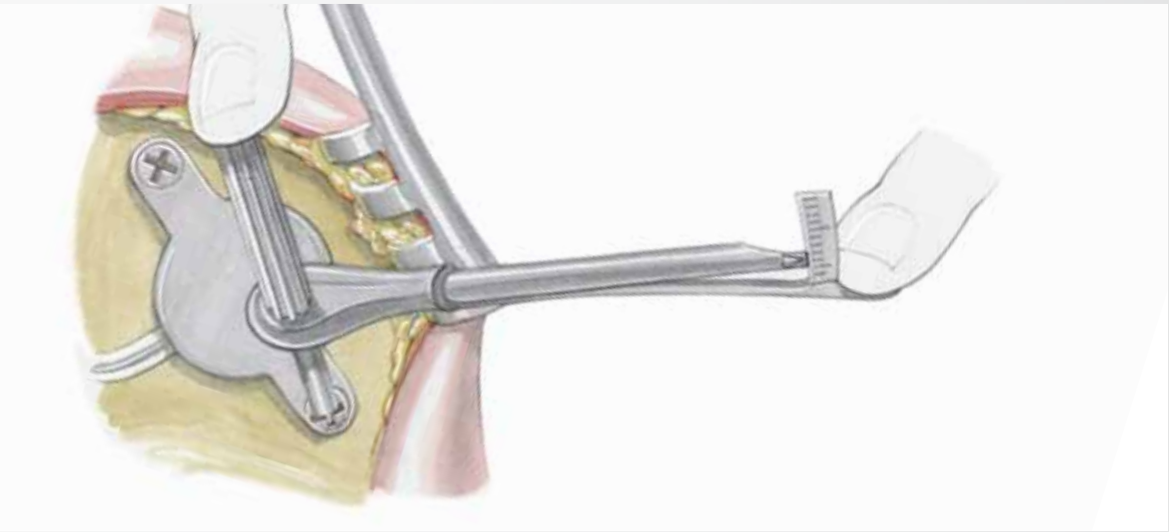


Figure 9: Usage of the supplied torque wrench to firmly secure the BC-FMT to the mastoid.
In case the screws are not adequate, alternative screw lengths can be used. The demodulator of the implant does not need to be sutured down. The fixation of the implant via the 2 screws is enough to hold the implant in place.

Step 6: CLOSURE

Inspect the BC-FMT under the microscope. Palpate the main body of the BC-FMT to make certain it is secure. The BC-FMT should be installed solidly and free from any minor slackness when palpated. Ensure that the receiver coil is in the desired position.

Close the scalp wound in layers, then suture the skin flap with a double layer closure, taking care not to make contact with the installed BCI during the closure process. Clean the incision area and apply a pressure dressing to the wound. When closure is achieved, the patient should be transferred to the recovery area and treated with standard recovery procedures.

CAUTION

MONOPOLAR ELECTROCAUTERY MUST NOT BE USED. TO ACHIEVE HEMOSTASIS, USE ONLY BIPOLAR ELECTRO-SURGICAL INSTRUMENTS AND ENSURE THAT THEY ARE NEVER IN CONTACT WITH THE BCI.

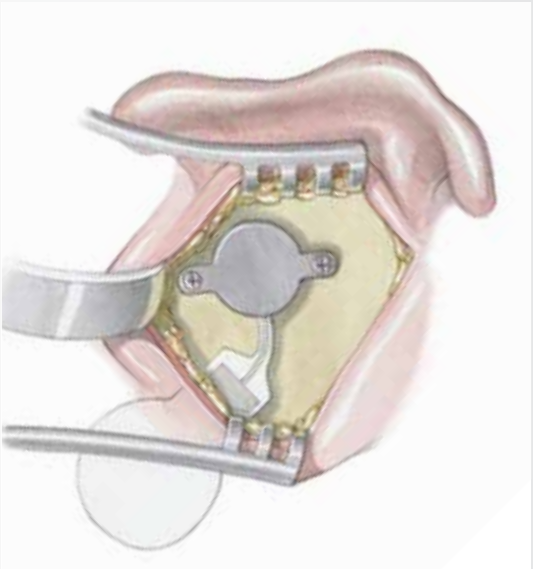


Figure 10: Final inspection of the tight implant position before closing the wound.

The watercolour drawings were created by Nikolaus Lechenbauer, a medical illustrator from Reutte, Austria.

Key Points

POSITION OF BCI

- Connect the C- and T-Sizer. Place the T-Sizer in the position according to the CT scan. In the sinodural angle, angle the C-Sizer approximately 45 degrees posterosuperiorly. With other approaches, find an appropriate position for the coil.

DRILL BONE BED FOR BC-FMT

- Drill the bone bed for the BC-FMT in the position according to the pre-operative CT scan. As per normal clinical practice, irrigation is recommended when drilling the bone bed. Take special care not to damage the sigmoid sinus or dura. Use the T-Sizer to check the depth and size of the bed.

DRILL FIXATION HOLES

- Drill the fixation holes with the drill bit supplied in the implant kit, and using the PTFE sleeve as well as the T-Sizer. Thus the drilling depth is limited to 3.9 mm.
- Do not move the T-Sizer between drilling the two fixation holes.

ENSURE PROPER SKIN FLAP THICKNESS

- The skin flap, including the temporalis fascia, must be measured with the Skin Flap Gauge 7.
- The total tissue thickness over the internal receiver must not exceed 7 mm. If the total thickness is greater than 7 mm, then the flap must be carefully thinned.

FIXATION OF THE BCI

- Carefully remove the screw from the implant package by firmly attaching it to the screwdriver. Place one regular cortical screw (golden surface finish) in each anchor hole of the BC-FMT.
- Use the emergency screw (blue surface finish) only if insufficient fixation occurred with one of the regular screws.
- Use the torque wrench to firmly secure the screws into the mastoid by rotating the wrench clockwise until secure fixation has been achieved.

REGISTRATION CARD

- The registration card, contained in the implant packaging, should be completed and returned promptly to VIBRANT MED-EL.

INITIAL ACTIVATION

- Since osseointegration of the screws is not needed, the audio processor can be programmed as soon as the swelling of the skin has reduced.

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