Surgical Procedure Guidelines for Baha® 5 SuperPower

Surgical considerations
Surgery for the Baha 5 SuperPower System follows the standard Baha surgical techniques for Baha Attract System and Baha Connect System. However, the BI300 Implant needs to be placed more posteriorly to allow sufficient clearance between the sound processing unit and the actuator unit. The steps outlined in this guide will help ensure correct placement of the BI300 Implant for use with the Baha 5 SuperPower. This guide complements the existing Surgical guides for Baha Attract System and Baha Connect System.

Additional considerations
For candidates where a progressive hearing loss may be anticipated, consider placing the BI300 Implant according to these guidelines, to help ensure that an upgrade to a Baha 5 SuperPower would be possible, if and when it’s needed.

Surgical procedure for Cochlear Baha Connect System
Cochlear Baha BIA400 Implant System
Before surgery: Identify and mark the implant site with the non-sterile blue Indicator for Baha 5 SuperPower, Baha Connect System. Remove the Indicator before the patient is transferred to the sterile field. Prepare the patient as for any surgical procedure, i.e. sterilize the incision area. Local or general anesthesia can be used for adult patients. When children undergo Baha surgery, general anesthesia is most often used.

NOTE: The surgical template is provided non-sterile and is not meant for use in the sterile field and should be discarded after a single use.

STEP 1 Prepare the site
A • Mark the incision, generally 20-30 mm long, following the direction of the hair line, and 10 mm away from the implant site. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.
B • Measure the tissue thickness before local anesthesia is injected.
C • Measure the tissue thickness. A thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler should be used. Inject local anesthesia. The amount of injection should be limited for minimal distortion of tissue thickness. If surgery is performed under general anesthesia, 1-2 ml of local anesthesia is generally sufficient.

***NOTE: Be sure not to depress the tissue when measuring.

D • Select the appropriate abutment length based on the measured tissue thickness. See the table for suggested abutment selection guide.

***NOTE: When in doubt, select the longer abutment.

E • The coating is intended to be in contact with the tissue. In a few patients, the coating may be slightly visible. This will not impact the outcome.

STEP 2 Make the incision
F • Use a scalpel to make an incision down to the periosteum.
G • Open up the incision using a self retaining retractor. Make a cruciate incision (6 x 6 mm square) in the periosteum to expose enough bone for the implant flange and raise the edges with the raspatorium.

***NOTE: The use of cautery, particularly monopolar, should be minimized where possible.
STEP 3 Drill with the guide drill

- Use the drill indicator and abundant irrigation during all drilling procedures.
- Begin drilling with the guide drill with 3 mm spacer (2000 rpm).
- Move the burr up and down to ensure visual inspection and that coolant reaches the tip of the drill.
- Check the bottom of the hole repeatedly for bone.
- If there is adequate bone thickness, remove the white spacer and continue drilling to a depth of 4 mm.

STEP 4 Drill with the widening drill

- Widen the hole with the relevant widening drill (2000 rpm).
- Move the widening drill up and down during drilling to ensure that coolant reaches the tip of the drill.
- Create a small countersink in the bone. The widening drill is designed to allow early recognition when countersinking is complete.

STEP 5 Place the implant and abutment

- Pick up the implant and abutment using the abutment inserter.
- Place the implant without irrigation until the first threads of the implant are well within the bone. Once the implant is in the bone, continue with irrigation. If unsure about the bone quality, start the torque low and increase if needed.

<table>
<thead>
<tr>
<th>Bone quality</th>
<th>Suggested torque</th>
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</thead>
<tbody>
<tr>
<td>Compact bone</td>
<td>40-50 Ncm</td>
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</table>

STEP 6 Close and suture

- Use a biopsy punch Ø 5 mm to punch a hole in the skin next to the incision, exactly over the abutment.

- **NOTE:** Avoid stretching the skin and ensure that the sutures do not pull the skin in an unnatural way. Increased tension in the skin, and the resulting push/pull forces, could lead to discomfort around the abutment.

- Ensure that the skin edges around the abutment do not create an unwanted pocket around the abutment.
- Carefully ease the skin over the abutment.
- Suture the incision. The sutures should stabilise both the skin and the underlying tissue during the healing.

STEP 7 Attach the healing cap

- Apply a thin, low or non-adherent dressing and attach the healing cap with plug.
- Remove the dressing, sutures and healing cap 10-14 days post-op. If not healed, apply a new dressing and a new healing cap.

- **NOTE:** Avoid using a thick dressing underneath the healing cap, as this may cause unwanted compression of the soft tissue during healing. In order to obtain a good seal between the hydroxyapatite-coating and the full thickness of the surrounding tissue, a stress-free interface without tissue compression should be maintained at all times, especially during the healing phase. Avoid using ribbon gauze.
Surgical Procedure for Cochlear Baha Attract System

BI300 Implants & BIM400 Implant Magnet

Before surgery: Identify and mark the implant site with the non-sterile white Indicator for Baha 5 SuperPower, Baha Attract System. Remove the Indicator before the patient is transferred to the sterile field. Prepare the patient as for any surgical procedure, i.e. sterilize the incision area. Local or general anesthesia can be used for adult patients. When children undergo Baha surgery, general anesthesia is most often used.

NOTE: The surgical template is provided non-sterile and is not meant for use in the sterile field and should be discarded after a single use.

STEP 1 Prepare the site

A. Use the Indicator for Baha Attract to mark the location of the magnet.
B. Mark the C-shaped incision anterior of the position of the magnet, at least 15 mm from the edge of the magnet. The length of the incision can be extended for easier access.
C. Before local anesthesia is injected, measure the soft tissue thickness in three positions (anterior magnet edge, middle of magnet, posterior magnet edge). A thin hypodermic needle, a clamp and a ruler should be used. Ensure not to depress the tissue when measuring. If the soft tissue is thicker than 6 mm, soft tissue reduction will be a must later in the procedure. Inject local anesthesia with adrenalin around the implant site.

STEP 2 Make the incision

E. Use a scalpel to make an incision down to the periosteum. Retract soft tissue posteriorly and superiorly via blunt dissection. The temporalis is retracted superiorly down to the periosteum.
F. Open up the incision using self-retaining retractors. Place the Implant magnet template on the periosteum to ensure good positioning of the implant magnet in relation to the incision and the bone. Mark the selected position of the implant on the periosteum with a pen or the sharp tip on the Implant magnet template.
G. Make a cruciate incision (6 mm square) in the periosteum to expose enough bone for the implant flange. Raise the edges with the raspatorium.

STEP 3 Drill with the guide drill

Be certain to drill at an angle perpendicular to the bone surface. The drill indicator verifies correct drill orientation.

G. Begin drilling with the guide drill with 3 mm spacer (2000 rpm). Ensure there is abundant irrigation during all drilling procedures.
H. Move the burr up and down to ensure visual inspection and that coolant reaches the tip of the drill.
I. Check the bottom of the hole repeatedly for bone.
J. If there is adequate bone thickness, remove the white spacer and continue drilling to a depth of 4 mm.

STEP 4 Drill with the widening drill

Be certain to drill at an angle perpendicular to the bone surface.

I. Widen the hole with the relevant widening drill, 3 or 4 mm (2000 rpm). Ensure abundant irrigation during all drilling procedures.
J. Move the widening drill up and down during drilling to ensure that coolant reaches the tip of the drill.
K. Create a small countersink in the bone. The widening drill is designed to allow early detection when countersinking is complete.
STEP 5  Place the implant

- Change the drill program to a low-speed setting and select the correct torque according to the bone quality. Pick up the implant using the Implant inserter.
- Place the implant without irrigation until the first threads of the implant are inserted in the bone. Once the first threads of the implant are in the bone, continue with irrigation.
- Place the bone bed indicator on the implant and gently hand tighten it to the implant threads by turning the top knob. Make sure that it is properly tightened. Rotate it clockwise to ensure it does not touch the bone. This will allow sufficient clearance for the correct mounting of the Implant magnet.
- If the bone bed indicator touches soft tissue, remove the tissue. If the bone bed indicator touches bone, remove excessive bone, by exposing the bone in that area. Polish the bone using a standard otological high-speed drill. Check repeatedly that sufficient bone has been removed using the bone bed indicator.
- When sufficient bone has been removed, put the periosteum back over the area and, if necessary, suture it in place.

STEP 6  Attach the implant magnet

- Pick up the implant magnet and place it in the conical connection of the implant. Verify the internal screw is protruding over the magnet surface before tightening the screw with the screwdriver. This will ensure a proper connection. Make sure the arrow on the Implant magnet is orientated towards the top of the patient’s head. Hand tighten the screw with the Unigrip screwdriver, while holding the magnet with your fingers.
- Continue to tighten to 25 Ncm with the Machine screwdriver Unigrip and the Multi wrench with ISO adapter, while holding the magnet with your fingers.
- Evaluate the thickness of the flap using the Soft tissue gauge. Always move the gauge sideways over the entire flap. Do not compress the flap. It should fit loosely in the soft tissue gauge to verify correct tissue thickness.

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**NOTE:** If local anesthesia has been infiltrated in the soft tissue, this can increase the flap thickness and affect the results when the thickness of the flap is measured.

- If the skin flap is thicker than 6 mm, carefully thin the flap until it fits loosely in the Soft tissue gauge.

STEP 7  Close and suture

- Place the flap over the Implant magnet and suture. Be sure to suture the deep layer to the periosteum, or suture the skin to the periosteum and back to the skin. Do not suture over the Implant magnet where pressure will later be applied.
- Apply a pressure dressing over the wound for 24-48 hours.

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**NOTES:** Do not remove the sutures before the incision is sufficiently healed. Do not fit the Sound Processor Magnet before the wound is sufficiently healed.

Not everyone with hearing loss is a candidate for a Baha. All surgical procedures include an element of risk, and it is impossible to guarantee success. For complete information regarding the risks and benefits of a Baha procedure, please refer to the Instructions for use for the Baha implant available at [www.Cochlear.com/US/BahaIndications](http://www.Cochlear.com/US/BahaIndications)