Cochlear[™] Baha[®] System

Cochlear® Hear now. And always

Surgical procedure guidelines for Baha® 5 SuperPower

Surgical considerations

The steps outlined in this guide will help ensure correct placement of the Cochlear Bl300 Implant for use with the Cochlear Baha® 5 SuperPower Sound Processor. In general, surgery for the Baha System with Baha 5 SuperPower follows the standard Baha surgical techniques for either the Baha Connect System or Baha Attract System. However, when using the Baha 5 SuperPower, the Bl300 Implant needs to be placed more posteriorly to allow sufficient clearance between the sound processing unit and the actuator unit. This guide complements the existing Surgical guides for Baha Connect System and Baha Attract System.



Additional considerations

For candidates where a progressive hearing loss may be anticipated and another Baha sound processor will be initially fitted, 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 Baha Connect System

Using the Cochlear Baha BIA400 Implant and Abutment

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.





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.
- Measure the tissue thickness before local anesthesia is injected.

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.



Be sure not to depress the tissue when measuring.

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

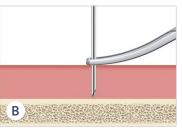


When in doubt, select the longer abutment.

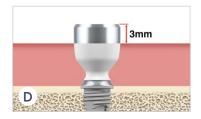
The DermaLock™ hydroxyapatite (HA) coating is intended to be in contact with the tissue. In a few patients, the HA coating may be slightly visible. This will not impact the outcome.

STEP 2 and onwards, follow the standard DermaLock surgical procedure, see P1974272, Baha DermaLock Surgery Guide and P1974269, Baha DermaLock FAST Surgery Quick Guide.





Approximate tissue thickness (mm)	Abutment length (mm)
3 or less	6
4-5	8
6–7	10
8-9	12
10-11	14
12 or more	14 with
С	soft tissue thinning



Surgical procedure for 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

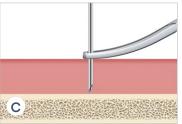
The surgical template is provided non-sterile and is not meant for use in the sterile field and should be discarded after a single use.

STEP 1 Prepare the site

- A Use the Baha Indicator 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.
- 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 and onwards, follow the standard Baha Attract surgical procedure, see P2001601, Baha Attract System Surgery Guide and P1974270, Baha Attract Surgery Quick Guide **Cochlear Americas** 10350 Park Meadows Drive Lone Tree, CO 80124 USA Telephone: 1 303 790 9010 Support: 1800 483 3123

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In the United States and Canada, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

The content of this guideline is intended as a guide for information purposes only and does not replace or remove clinical judgment or the professional care and duty necessary for each specific recipient case. The information has been prepared with reference to the best information available at the time of preparation. However, no assurance is given that the information is entirely complete or accurate in every respect. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise. This guideline does not address all elements of standard practice and accepts that individual clinicians are responsible to:

- advise recipients of their choice and ensure informed consent is obtained prior to delivering care
- provide care within scope of practice, meet all legislative requirements and maintain standards of professional conduct
- apply standard precautions, and additional precautions as necessary, when delivering care
- document all care in accordance with mandatory and local requirements.

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