This guide is designed as a support tool for Baha® surgery. It is intended for operating room nurses, surgical staff, sterilization departments, wound care departments and anyone else involved in Baha surgery or related preparation and aftercare.

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This publication sets forth detailed recommended procedures for using Baha surgical components and instruments. It offers guidance needed for performing the procedure, but, as with any technical guide, the surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.
Baha

Registration

Register your patient's Baha implant today and allow your patients to stay connected with Cochlear.

Why is important to register patients?

• **Activates** the recipient’s service **warranty**.
• Will allow recipients to receive **updates about new Cochlear products**, exclusive promotions, notice of upcoming events and **receive service and repair support**.
• Gives recipients the opportunity to **activate a Cochlear Family membership**.

Please fill out the Registration Card and send it by mail. It is included in your patient's Baha system order, in the box that is sent directly to the OR for surgery.

**Also you can register your patients online at:** [https://secure.mycochlear.com](https://secure.mycochlear.com)

If you don’t have an account you can request access on the link above, click on the access form and fill out the form.
• Osscora Drill Components
• Osscora Handpiece Assembly
• Osscora Drill Quick Guide
• Osscora Drill Errors
Osscora

**Drill Components**

All Osscora surgical sets are delivered with the following components:

- Control unit 115 Volts
- Foot control S-N1
- Motor with 3.5 m cable, includes motor protective cover
- Osscora contra-angle handpiece
- Medical grade power supply
- Irrigation tubing set (6 pcs) and stand

**OSSCORA ACCESSORIES**

The following Sterilization Cassette can be ordered as an accessory to the Osscora surgical set:

- **91102** Sterilization Cassette (Houses the Handpiece, Motor with Cable & Motor Protective Cover)

**OSSCORA SPARE PARTS**

Note: The following articles can be ordered as spare parts for the Osscora surgical set:

- **04032600** Motor Protective Cover
- **91050** Osscora Handpiece 20:1
- **91054** Osscora Motor with Cable 3.5 m

**INSTRUMENT ORGANIZER**

The Baha instrument organizer includes the Surgical tray.

- **90139** Surgical Organizer (Titanium Tray)
- **90146** Baha Instrument Cassette

*Included when purchase a new drill.*
Osscora

Handpiece Assembly

Contra-angle handpiece

- The handpiece consists of 5 pieces. To ensure proper assembly follow the steps below.
- Orient all the pieces so you can read the numbers and align them in a row.

**STEP ONE**

Insert the Middle gear into Contra-angle head until it engages ("clicks"). Rotate Middle gear to ensure it is engaged to the head. (Once both pieces are engaged the Chuck head must turn also. Figure A)

**STEP TWO**

Insert the Knee into the Contra-angle head until it engages. (4 positions are possible, but the image shown below is the preferred connection).

**STEP THREE**

Put the Shaft into the Knee.
- Make sure the tiny metal peg on the Shaft fits into the notch of the Knee.

**STEP FOUR**

Align pins on Knee with slots on Sheath. Press the Sheath firmly against the Knee.

**STEP FIVE**

Twist clockwise until it engages.

**STEP SIX**

Connect handpiece to the motor.

**NOTE:**

For Cleaning and sterilization of the Osscora Handpiece and motor with cable, see the Osscora Cleaning and Sterilization Quick Guide.
OSSCORA FOOT CONTROL

- Pump ON/OFF
- Change programs 1-3
- Change motor direction Forward/Reverse rotation (Factory Setting=Variable)
- Start Motor VARIABLE or ON/OFF

OSSCORA SURGICAL SET QUICK GUIDE

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>PROGRAM</th>
<th>DISPLAY</th>
<th>COOLING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermatome*</td>
<td>1</td>
<td>2000 rpm</td>
<td>No</td>
</tr>
<tr>
<td>Drilling**</td>
<td>2</td>
<td>2000 rpm</td>
<td>YES</td>
</tr>
<tr>
<td>Implant Installation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Hard Bone</td>
<td></td>
<td></td>
<td>YES, after two turns</td>
</tr>
<tr>
<td>- Soft Bone</td>
<td></td>
<td></td>
<td>YES, after two turns</td>
</tr>
<tr>
<td>Reverse</td>
<td></td>
<td></td>
<td>YES</td>
</tr>
</tbody>
</table>

OSSCORA SETTINGS

<table>
<thead>
<tr>
<th>SPEED</th>
<th>TORQUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>The speed is adjusted by using the + and - buttons when using program 1 and 2</td>
<td>The torque is adjusted by using the + and - buttons when using the program.</td>
</tr>
</tbody>
</table>

CAUTION:

The clinical situation must be taken into consideration when choosing the settings.

* Dermatome procedure is no longer recommended in any of Baha surgeries.
** Program 1 and 2 are similar.
# Drill Error Messages

<table>
<thead>
<tr>
<th>OSSCORA ERROR MESSAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERROR NO.</td>
</tr>
<tr>
<td>00</td>
</tr>
<tr>
<td>01</td>
</tr>
<tr>
<td>07</td>
</tr>
<tr>
<td>09</td>
</tr>
<tr>
<td>19</td>
</tr>
<tr>
<td>99</td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

## RESET FACTORY SETTINGS:

| Factory setting | Always starts with program 1 (P1) | Switch off the control unit, Keep P1 pressed and simultaneously switch on the control unit. Keep P1 pressed as long as “DE FAU” appears on the display. |

If one of the error messages described above cannot be rectified by switching off the Osscora surgical set and then switching it on again, the equipment must be checked by a service agent. For contact details, please contact your local Cochlear office or your local Cochlear representative.

If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.
Baha Connect System

- Surgical Instruments and Components
- FAST Surgery Guide
- Two stage Surgery Guide
- Dressing guidelines & Patient Aftercare instructions
Baha Connect

Surgical Instruments and Components

**REUSABLE INSTRUMENTS**

- **90944** Raspatorium
- **90943** Dissector
- **90469** Screwdriver Unigrip 95mm
- **HIA 009-0** Counter Torque Wrench
- **92143** Multi Wrench & ISO Adapter

- **90474** Abutment Inserter
- **90381** Machine Screwdriver Unigrip 25mm
- **92142** Implant Inserter
- **91116** Drill Indicator for WS-75 and Osscora
- **91095** Indicator for Baha

**DISPOSABLE INSTRUMENTS - ONE TIME USE ONLY**

- **93363** Conical Guide Drill 3+4mm
- **92140** Widening Drill 3mm with Countersink
- **92141** Widening Drill 4mm with Countersink
- **Y00022** Biopsy Punch Ø 5mm

- **95084** Healing cap with plug Ø 30mm
- **FUD021** Allevyn Non-Adhesive Wound Care Dressing
- **P806653** Indicator for Baha 5 SuperPower (Will be included on the system order)

Images are not to scale.

*ISO Adapter can be ordered separately.*
Baha Connect

FAST Surgery Guide

**ADDITIONAL ITEMS NEEDED**

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/ patient preparation solution
- Saline (for irrigation)
- Sterile drapes in various sizes
- Basic ear instrument set
- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Antimicrobial ointment for dressing
- Self-retaining retractor

*Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.*
**STEP ONE**

**PREPARE THE SITE**

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.

**A1**  
- Use the indicator for Baha and preferred marker to mark the location of the planned implant site, generally 50–55 mm from the ear canal and with the indicator in line with the top of the pinna.

**A2**  
- *If the surgery is for the Baha 5 SuperPower:*  
  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.

**B**  
- Marker will be needed to mark the incision, generally 20-30 mm long, following the direction of the hair line. Also, the implant site will be marked 10 mm posterior to the incision line. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.

**C**  
- Measurement of the tissue thickness is before local anesthesia is injected.  
  - May use a thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler to measure the thickness of the skin.  
  
  **NOTE:** Ensure not to depress the tissue when measuring.

- 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.

**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. Do not open the abutment at this point.

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</tr>
<tr>
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<td>14 with soft tissue thinning</td>
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</table>
STEP TWO

MAKE THE INCISION

• Use a scalpel to make an incision down to the periosteum.

• To open up the incision to expose the periosteum use a self-retaining retractor. (Any other retractor may also be used.)

• To 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 a raspatorium.

NOTE: The use of cauterization, particularly monopolar, should be minimized where possible.

STEP THREE

DRILL WITH THE GUIDE DRILL

Drilling must be done at a perpendicular angle to the bone surface. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement. Ensure there is abundant irrigation during all drilling procedures.

• Insert the guide drill on the handpiece to start drilling with the guide drill and 3 mm spacer (already on the drill bit).

• Set the drill unit to the high-speed setting, 2000 rpm (program 2 for the Osscora surgical set).

NOTE: Program 1 and 2 are similar.

• Surgeon may use the dissector to check the bottom of the site repeatedly for bone.

• If there is adequate bone thickness, the white spacer on the guide drill can be removed and continue drilling to a depth of 4 mm.

NOTE: The DermaLock Abutment is delivered pre-mounted on 4 mm implants. A 3 mm implant can be considered for FAST surgery when there is sufficient bone quality and thickness. In that case the abutment should be manually attached after having placed the implant.
**STEP FOUR**

**DRILL WITH THE WIDENING DRILL**

- Keep the drill unit on the high-speed setting, 2000 rpm (program 2 for the Osscora surgical set).
- Change the guide drill for the widening drill on the handpiece. (Press the button at the top of the head of the handpiece to remove the guide drill.)
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill.
- Continue to use abundant irrigation during all drilling procedures.

**STEP FIVE**

**PLACE THE IMPLANT AND ABUTMENT**

- Inside of the sterile product box of the abutment and implant there is a peel-open pack with a plastic ampoule. (This is only a container for the sterile product.) Inside the plastic ampoule, a titanium casing holds the product. The product should not be touched but rather picked up with the relevant instrument.
- Over the titanium tray, open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the tray.
- The implant must not come in contact with anything other than the ampoule and abutment inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.
- Change the widening drill on the handpiece for the abutment inserter.
- Set the drill to the torque setting (program Implant Installation for the Osscora surgical set).
- Set the torque limit to suit the quality of the bone. 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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<tr>
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**STEP FIVE CONT.**

**PLACE THE IMPLANT AND ABUTMENT**

- To pick up the implant and abutment use the abutment inserter.

  **NOTE:** The implant can be inserted manually with the multi wrench with ISO adapter and the abutment inserter. Rotate the whole multi wrench shaft clockwise ("IN" facing upwards) until the implant is fully seated. The multi wrench is not intended to be used as a torque wrench for implant placement as the torque limit is 25 Ncm.

- Implant is placed 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.

- The Osscora surgical set stops automatically and beeps when the preset torque is reached.

**STEP SIX**

**CLOSE AND SUTURE**

- Biopsy punch Ø 5 mm is use to punch a hole in the skin next to the incision, exactly over 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 stabilize both the skin and the underlying tissue during the healing.
**STEP SEVEN**

**ATTACH THE HEALING CAP**

- Use a biopsy punch Ø 5 mm to punch a hole in the middle of the Allevyn wound care dressing.
- Apply a thin, low or non-adherent dressing and attach the healing cap with plug.

**NOTE:** Allevyn wound care dressing (provided on the surgical kit) it is recommended to change the dressing and healing cap if needed or up to 7 days of application.

- Remove the dressing, sutures and healing cap 10-14 days postop. 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.
**ADDITIONAL ITEMS NEEDED**

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/patient preparation solution
- Saline (for irrigation)
- Sterile drapes in various sizes
- Basic ear instrument set
- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Dressing and bandage
- Antimicrobial ointment for dressing
- Self-retaining retractor

*Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.*
## STEP ONE

**PREPARE THE SITE**

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.

- **A1** Use the indicator for Baha and preferred marker to mark the location of the planned implant site, generally 50–55 mm from the ear canal and with the indicator in line with the top of the pinna.

- **A2** If the surgery is for the Baha 5 SuperPower: 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.

- **B** Marker will be needed to mark the incision, generally 20-30 mm long, following the direction of the hair line. Also, the implant site will be marked 10 mm posterior to the incision line. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.

## STEP TWO

**MAKE THE INCISION**

- **C** Use a scalpel to make an incision down to the periosteum.

- **D** To open up the incision to expose the periosteum use a self-retaining retractor. (Any other retractor may also be used.)

- To 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 a raspatorium.

**NOTE:** The use of cautery, particularly monopolar, should be minimized where possible.
### STEP THREE

**DRILL WITH THE GUIDE DRILL**

Drilling must be done at a perpendicular angle to the bone surface. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement. **Ensure there is abundant irrigation during all drilling procedures.**

**E**  • Insert the guide drill on the handpiece to start drilling with the guide drill and 3 mm spacer (already on the drill bit).

**F**  • Set the drill unit to the high-speed setting, 2000 rpm (program 2 for the Osscora surgical set).

**NOTE:** Program 1 and 2 are similar.

**G**  • Surgeon may use the dissector to check the bottom of the site repeatedly for bone.

  • If there is adequate bone thickness, remove the white spacer on the guide drill to continue drilling to a depth of 4 mm.

**NOTE:** The DermaLock Abutment is delivered pre-mounted on 4 mm implants. A 3 mm implant can be considered for FAST surgery when there is sufficient bone quality and thickness. In that case the abutment should be manually attached after having placed the implant.

### STEP FOUR

**DRILL WITH THE WIDENING DRILL**

**H**  • Keep the drill unit on the high-speed setting, 2000 rpm (program 2 for the Osscora surgical set).

  • Change the guide drill for the widening drill on the handpiece. (Press the button at the top of the head of the handpiece to remove the guide drill.)

  • Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill.

  • Continue to use abundant irrigation during all drilling procedures.
STEP FIVE

PLACE THE IMPLANT

1. Inside of the sterile product box of the implant there is a peel-open pack with a plastic ampoule. (This is only a container for the sterile product.) Inside the plastic ampoule, a titanium casing holds the product. The product should not be touched but rather picked up with the relevant instrument.

2. Over the titanium tray, open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the tray.

3. The implant must not come in contact with anything other than the ampoule and abutment inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.

4. Change the widening drill on the handpiece for the implant inserter.

5. Set the drill to the torque setting (program Implant Installation for the Osscora surgical set).

6. Set the torque limit to suit the quality of the bone. If unsure about the bone quality, start the torque low and increase if needed.

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</table>

7. Pick up the implant using the implant inserter.

   NOTE: The implant can be inserted manually with the multi wrench with ISO adapter and the abutment inserter. Rotate the whole multi wrench shaft clockwise ("IN" facing upwards) until the implant is fully seated. The multi wrench is not intended to be used as a torque wrench for implant placement as the torque limit is 25 Ncm.

8. Implant is placed without irrigation until the first threads of the implant are well within the bone.

9. Once the implant is in the bone, continue with irrigation. If unsure about the bone quality, start the torque low and increase if needed.
### STEP FIVE CONT. PLACE THE IMPLANT

**K**
- Place the implant without irrigation until the first threads of the implant are well within the bone (two rotations). Irrigation at this time would result in cooling solution being compressed into the marrow spaces in the bone by the implant.
- Once the implant is in the bone, continue implant placement with irrigation.

**NOTE:** The implant must not come in contact with anything other than the ampoule and implant inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.

- The Osscora surgical set stops automatically and beeps when the preset torque is reached.
- If the implant enters the hole incorrectly, put the drill in reverse to unscrew the implant.
- Then find the correct angle and re-insert the implant. **This should only be attempted once.**

- If the drill stops prematurely – before the flange of the implant is seated in the countersunk bone – reverse one thread and increase the torque by 5 Ncm on the control panel of the drill system.

**L**
- For patients with bone <3 mm, countersinking risks diminishing the bone available for osseointegration. Instead the implant can be placed flush with the calvarial surface even if it slightly abuts or depresses the dura mater (A). Alternatively, make an incomplete insertion can be made and leave the implant protruding with bone chips, collected from the widening drill, placed under the flange (B).

**NOTE:** The implant can be inserted manually with the multi wrench and the implant inserter. Rotate the whole multi wrench shaft clockwise (“IN” facing upwards) until the implant is fully seated. The multi wrench is not intended to be used as a torque wrench for implant placement as the torque limit is 25 Ncm.
STEP FIVE CONT.

PLACE THE IMPLANT

Placing a sleeper implant

• Since there is a slightly higher rate of implant loss in children, placing a sleeper implant is recommended in order to reduce the time between the potential loss of an implant and hearing being restored.

• Leave at least 10 mm between the centers of the two implants. However, the thickness of the cortical bone must be considered.

STEP SIX

PLACE THE COVER SCREW

• Inserting a cover screw protects the internal threads of the implant from tissue and bone overgrowth during the healing phase.

• To place and hand tighten the cover screw use the Unigrip screwdriver.

• Use resorbable sutures over the implant to suture down the periosteum.

• Use preferred sutures for the incision.

• Apply a suitable dressing.
Baha Connect

Two stage Surgery Guide - Stage 2

**ADDITIONAL ITEMS NEEDED**

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/patient preparation solution
- Saline (for irrigation)
- Sterile drapes in various sizes

- Basic ear instrument set
- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Antimicrobial ointment for dressing

*Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.*
STEP ONE

MAKE THE INCISION

A • Locate the implant position.
• Measurement of the tissue thickness is before local anesthesia is injected.
• May use a thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler to measure the thickness of the skin.

NOTE: Ensure not to depress the tissue when measuring.

• 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.

B • 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.
Do not open the abutment at this point.

C • Use a scalpel to make an incision down to the periosteum in the same incision line as in Stage 1.

D • To open up the incision to expose the periosteum use a self-retaining retractor. (Any other retractor may also be used.)
• To 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 a raspatorium.

NOTE: The use of cautery, particularly monopolar, should be minimized where possible.

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**STEP TWO**  
**REMOVE THE COVER SCREW**

- Use Unigrip screwdriver to remove the cover screw.

**STEP THREE**  
**CONNECT THE ABUTMENT**

- To pick up the abutment use the counter torque wrench and place it into the implant.

- Ensure the tri-lobe connection is locked together and then gently pre-tighten the abutment screw with the Unigrip screwdriver.

- To finalize the tightening of the abutment screw:
  - Set the drill to the torque setting (program Implant Installation for the Osscora surgical set) and set the torque limit to 25 Ncm.
  - Put the machine Unigrip screwdriver on the handpiece and use the counter torque wrench to hold the abutment while tightening.

**NOTE:** For manual tightening, tighten the abutment screw to 25 Ncm using the multi wrench (“IN” facing upwards), with the machine Unigrip screwdriver.

**NOTE:** The counter torque wrench should always be used to avoid rotational forces on the implant.
<table>
<thead>
<tr>
<th>STEP FOUR</th>
<th>CLOSE AND SUTURE</th>
</tr>
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<tbody>
<tr>
<td>J</td>
<td>• Use a biopsy punch Ø 5 mm to punch a hole in the skin next to the incision, exactly over the abutment.</td>
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<td>• Ensure that the skin edges around the abutment do not create an unwanted pocket around the abutment.</td>
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<td>• Use a biopsy punch Ø 5 mm to punch a hole in the middle of the Allevyn wound care dressing.</td>
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<td>• Apply a thin, low or non-adherent dressing and attach the healing cap with plug.</td>
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**NOTE:** Allevyn wound care dressing (provided on the surgical kit) it is recommended to change the dressing and healing cap if needed or up to 7 days of application.

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.
# Aftercare Dressing Guidelines

## 1 Day Post-op

1. Remove the mastoid dressing.
2. Leave the dressing and healing cap in situ.
3. Ensure that the patient does not allow any water to come in contact with the site before complete healing of the wound.

## 7 Days Post-op

1. If using Allevyn Non-Adhesive wound care dressing (provided on the surgical kit) it is recommended to change the dressing if needed or up to 7 days of application. (Healing cap should also be changed.)

## 10-14 Days Post-op

1. Remove and discard the healing cap.
2. Carefully remove the dressing.
3. Remove the sutures (if applicable).
4. Gently clean the wound with normal saline and gauze.
5. Gently remove any dried blood or debris.
6. Assess the wound site and treat accordingly.
7. If healed, no further dressing is required.
8. Provide the patient with aftercare instructions and emphasize the importance of daily cleaning. For the first few weeks, a skin-friendly shampoo should be used.

## 17-21 Days Post-op

1. If necessary, repeat relevant steps as in the previous visit.
2. If the wound site has not healed consult a wound care specialist.

**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 during the healing phase and at all times.

Avoid using ribbon gauze or take special care to avoid excessive packing and not generate downward pressure on the soft tissue.

## Patient Aftercare Instructions

- Good hygiene is critical to maintaining normal usage of the Baha sound processors. Patients who are unable to clean the skin around the abutment need help from their family or caregivers. The cleaning should be light, independent on the method selected.

- Start daily cleaning with an alcohol-free wet wipe after dressing removal. Be careful not to interfere with the tissue integration during the healing phase.

- After the initial healing phase (up to 12 weeks), continue to clean once a day with an alcohol-free wet wipe. Mild soap and warm water may also be used.

- After the wound has healed, half yearly or yearly checkups at the outpatient clinic are recommended.

- For detailed cleaning instructions, please refer to patient user manuals or Baha Support App.

- In case of infection, the patient’s cleaning routine should be assessed.

**NOTE:** Independent of the method selected, the cleaning should be light.

When healed, a small part of the coating may protrude above the skin. The coating is sensitive to low pH-solutions (such as certain soaps) and will in acidic environment partly dissolve into its ionic components. These ions are found abundantly in the human body (e.g. blood and bone) and none are considered harmful. Underneath the coating is blasted titanium.

---

## Important:

Remember to provide your patient the:
- **BUN156 - Baha Post-Surgical Care Guide** (in the box that is sent directly to the OR for surgery).
- **MRI Card** (inside of the DocuPack that is in the box that is sent directly to the OR for surgery).
Baha Attract System

- Surgical Instruments and Components
- One-stage Surgery Guide
- Two-stage Surgery Guide
Baha Attract

Surgical Instruments and Components

**REUSABLE INSTRUMENTS**

- 90944  Raspatorium
- 90943  Dissector
- 90469  Screwdriver Unigrip 95mm
- 92143  Multi Wrench & ISO Adapter
- 95070  Soft Tissue Gauge 6mm
- 95180  Bone Bed Indicator

- 94071  Implant Magnet Template
- 90381  Machine Screwdriver Unigrip 25mm
- 92142  Implant Inserter
- 91116  Drill Indicator for WS-75 and Osscora
- 93571  Indicator for Baha Attract

**DISPOSABLE INSTRUMENTS - ONE TIME USE ONLY**

- 93363  Conical Guide Drill 3+4mm
- 92140  Widening Drill 3mm with Countersink
- 92141  Widening Drill 4mm with Countersink
- P806693  Indicator for Baha 5 SuperPower (Will be included on the system order)

Images are not to scale.
ISO Adapter can be ordered separately.
Baha Attract

One-Stage Surgery Guide

**ADDITIONAL ITEMS NEEDED**

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/ patient preparation solution
- Saline (for irrigation)
- Sterile drapes in various sizes
- Basic ear instrument set
- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Dressing and bandage
- Antimicrobial ointment for dressing

*Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.*
### Prepare the Site

#### Step 1: Prepare the Site

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.

- **A1** Use the indicator for Baha Attract and preferred marker to mark the location of the planned implant site. It is usually 50-70 mm from the ear canal, and the superior edge of the processor should be in line with the top of the pinna.

- **A2** If the surgery is for the Baha 5 SuperPower:
  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.

- **B** Marker will be needed to mark the incision, is a 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** Measurement of the tissue thickness is before local anesthesia is injected.
  - May use a thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler to measure the thickness of the skin in three positions (anterior magnet edge, middle of magnet, posterior magnet edge).
  - If the soft tissue is thicker than 6 mm, soft tissue reduction is required.
  - Inject local anesthesia around the implant site.

**NOTE:** Ensure not to depress the tissue when measuring.
STEP TWO

MAKE THE INCISION

D • 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.

E • To open up the incision to expose the periosteum use a self-retaining retractor.
  • The Implant magnet template will be placed on the periosteum to ensure good positioning of the implant magnet in relation to the incision and the bone.
  • The selected position of the implant will be marked on the periosteum with a pen or the sharp tip on the Implant magnet template.
  • To make a cruciate incision (6 mm square) in the periosteum to expose enough bone for the implant flange and raise the edges with a raspatorium.

STEP THREE

DRILL WITH THE GUIDE DRILL

F Drilling must be done at a perpendicular angle to the bone surface. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement. Ensure there is abundant irrigation during all drilling procedures.
  • Insert the guide drill on the handpiece to start drilling with the guide drill and 3 mm spacer (already on the drill bit).
  • Set the drill unit to the high-speed setting, 2000 rpm (program 2 for the Osscora surgical set).
  NOTE: Program 1 and 2 are the similar.

G • Surgeon may use the dissector to check the bottom of the site repeatedly for bone.
  • If there is adequate bone thickness, the white spacer on the guide drill can be removed and continue drilling to a depth of 4 mm.
STEP FOUR  

**DRILL WITH THE WIDENING DRILL**

- Keep the drill unit on the high-speed setting, 2000 rpm (program 2 for the Osscora surgical set).
- Change the guide drill for the widening drill on the handpiece. (Press the button at the top of the head of the handpiece to remove the guide drill.)
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill.
- Continue to use abundant irrigation during all drilling procedures.

STEP FIVE  

**PLACE THE IMPLANT**

- Inside of the sterile product box of the implant there is a peel-open pack with a plastic ampoule. (This is only a container for the sterile product.) Inside the plastic ampoule, a titanium casing holds the product. The product should not be touched but rather picked up with the relevant instrument.
- Over the titanium tray, open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the tray.
- The implant must not come in contact with anything other than the ampoule and abutment inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.
- Change the widening drill on the handpiece for the implant inserter.
- Set the drill to the torque setting (program Implant Installation for the Osscora surgical set).
- Set the torque limit to suit the quality of the bone. 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>
</tr>
</thead>
<tbody>
<tr>
<td>Compact bone</td>
<td>40-50 Ncm</td>
</tr>
<tr>
<td>Soft Bone</td>
<td>20-30 Ncm</td>
</tr>
</tbody>
</table>

- Pick up the implant and abutment using the abutment inserter.
**STEP FIVE CONT.**

**PLACE THE IMPLANT**

**K1**
- Implant is placed 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.
- The Osscora surgical set stops automatically and beeps when the preset torque is reached.

**K2**
- **NOTE:** The implant can be inserted manually with the multi wrench with ISO adapter and the abutment inserter. Rotate the whole multi wrench shaft clockwise ("IN" facing upwards) until the implant is fully seated. The multi wrench is not intended to be used as a torque wrench for implant placement as the torque limit is 25 Ncm.

**L**
- The bone bed indicator will be placed on the implant and gently hand tighten it to the implant threads by turning the top knob. It needs to be properly tightened. It’s used to ensure it does not touch the bone by rotating it clockwise. This will allow sufficient clearance for the correct mounting of the Implant magnet.

**M**
- If the bone bed indicator touches soft tissue, tissue will need to be removed. If the bone bed indicator touches bone, the surgeon will need to remove excessive bone. First, should open up the periosteum in that area and then bone should be polish using a standard otological high-speed drill. Using the bone bed indicator will check repeatedly that sufficient bone has been removed.
- When sufficient bone has been removed, the periosteum should be put back over the area and, if necessary, sutured in place.
### ATTACH THE IMPLANT MAGNET

**N**  
- Inside of the sterile product box of the implant magnet there is a peel-open pack with a plastic packaging were the implant magnet is.
- To remove the implant magnet from sterile package hold it with both hands and pop it down onto the sterile field.
  
  **NOTE:** Do not pick it out or try to pull it, it is seated tightly and can hover and land on the ground. The implant magnet can be handled and touch sterile field towel/etc.
- Implant magnet will be placed in the conical connection of the implant.
- The arrow on the Implant magnet is orientated towards the top of the patient’s head.
- Implant magnet screw should be gently hand-tighten with the Unigrip screwdriver, while holding the implant magnet with your fingers.

**O**  
- To continue tightening use the Machine screwdriver Unigrip and the Multi wrench with ISO adapter to 25 Ncm, while holding the magnet with your fingers.

**P**  
- To evaluate the thickness of the flap use the Soft tissue gauge. The gauge should always be moved sideways over the entire flap. It should fit loosely in the soft tissue gauge to verify correct tissue thickness.
  
  **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.

**Q**  
- If the skin flap is thicker than 6 mm, surgeon will have to thin the flap carefully, until it fits loosely in the Soft tissue gauge.
STEP SEVEN

CLOSE AND SUTURE

R • The flap will be placed over the Implant magnet and suture. Need 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.

S • Apply a pressure dressing over the wound for 24-48 hours.

**NOTE:** Do not remove the sutures before the incision is sufficiently healed. Do not fit the Sound Processor Magnet before the wound is sufficiently healed.
ADDITIONAL ITEMS NEEDED

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/ patient preparation solution
- Sterile drapes in various sizes
- Basic ear instrument set

- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Dressing and bandage

Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.
## Baha Attract Two Stage Surgery Guide - Stage 1

### STEP ONE
**PREPARE THE SITE**

Follow the procedure described in the one-stage surgery section on page 34, until the incision is marked out. **Measuring the soft tissue thickness is not necessary in this step of the two-stage procedure.**

### STEP TWO
**MAKE THE INCISION**

Follow the procedure described in the one-stage surgery section on page 35.

### STEP THREE
**DRILL WITH THE GUIDE DRILL**

Follow the procedure described in the one-stage surgery section on page 35.

### STEP FOUR
**DRILL WITH THE WIDENING DRILL**

Follow the procedure described in the one-stage surgery section on page 36.

### STEP FIVE
**PLACE THE IMPLANT**

Follow the procedure described in the one-stage surgery section on page 36, until the implant is inserted, and then continue with step 6 below. This means that no bone polishing should be done at this stage.

### STEP SIX
**PLACE THE COVER SCREW**

- Inserting a cover screw protects the internal threads of the implant from tissue and bone overgrowth during the healing phase.
- Place and hand-tighten the cover screw using the screwdriver Unigrip 95 mm.
- Suture down the periosteum with resorbable sutures over the implant.
- Suture the incision.
- Apply a suitable dressing.

---

**ADDITIONAL ITEMS NEEDED**

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/patient preparation solution
- Sterile drapes in various sizes
- Basic ear instrument set
- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Dressing and bandage
Baha Attract

Two Stage Surgery Guide - Stage 2

ADDITIONAL ITEMS NEEDED

- Razor for shaving hair
- Marking pen and ruler
- Needle, clamp/hemostat and methylene blue
- Local anesthetic solution and syringe
- Antiseptic solution/patient preparation solution
- Sterile drapes in various sizes
- Basic ear instrument set
- Scalpel blades
- Suction tubing and tip
- Gauze swabs
- Suture material
- Dressing and bandage

Possible Mayo Stand set-up with Baha surgical instruments and additional instruments.
STEP ONE

MAKE THE INCISION

A • Locate the implant position.
   • Measurement of the tissue thickness is before local anesthesia is injected.
   • May use a thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler to measure the thickness of the skin in three positions (anterior magnet edge, middle of magnet, posterior magnet edge).
   • If the soft tissue is thicker than 6 mm, soft tissue reduction is required.
   NOTE: Ensure not to depress the tissue when measuring.
   • Administer local anesthetic injection around the implant site.

B • Use a scalpel to make an incision down to the periosteum in the same incision line as in stage 1. Retract soft tissue posteriorly/superiorly via blunt dissection. The temporalis is retracted superiorly down to the periosteum.

C • Use a self-retaining retractor to open up the incision to expose the implant and cover screw.

STEP TWO

REMOVE THE COVER SCREW

D • Remove the cover screw using the screwdriver Unigrip 95 mm

ADDITIONAL ITEMS NEEDED
• Razor for shaving hair
• Marking pen and ruler
• Needle, clamp/hemostat and methylene blue
• Local anesthetic solution and syringe
• Antiseptic solution/patient preparation solution
• Sterile drapes in various sizes
• Basic ear instrument set
• Scalpel blades
• Suction tubing and tip
• Gauze swabs
• Suture material
• Dressing and bandage
### ATTACH THE IMPLANT MAGNET

#### STEP THREE

| E | • The bone bed indicator will be placed on the implant and gently hand tighten it to the implant threads by turning the top knob. It needs to be properly tightened. Rotate clockwise to ensure it does not touch bone. This will allow sufficient clearance for the correct mounting of the implant magnet. |
| F | • If the bone bed indicator touches soft tissue, tissue will need to be removed. If the bone bed indicator touches bone, will need to remove excessive bone. First, should open up the perio steum in that area and then bone should be polish using a standard otological high-speed drill. Using the bone bed indicator will check repeatedly that sufficient bone has been removed.  
• When sufficient bone has been removed, put the perio steum back over the area and if needed suture it in place. |
| G | • Inside of the sterile product box of the implant magnet there is a peel-open pack with a plastic packaging were the implant magnet is.  
• To remove the implant magnet from sterile package hold it with both hands and pop it down onto the sterile field.  
**NOTE:** For more details on how to remove the implant magnet follow the steps described in the Awareness section on page 56.  
• Implant magnet will be placed on in the conical connection of the implant.  
• The arrow on the Implant magnet is orientated towards the top of the patient’s head.  
• Implant magnet screw should be gently hand-tighten with the Unigrip screwdriver, while holding the implant magnet with your fingers. |
| H | • To continue tightening use the Machine screwdriver Unigrip and the Multi wrench with ISO adapter to 25 Ncm, while holding the magnet with your fingers. |

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25 Ncm
### STEP THREE CONT.

**ATTACH THE IMPLANT MAGNET**

- **I** To evaluate the thickness of the flap use the Soft tissue gauge. The gauge should always be moved sideways over the entire flap. It should fit loosely in the soft tissue gauge to verify correct tissue thickness.

  **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.

- **J** If the skin flap is thicker than 6 mm, surgeon will have to thin the flap carefully, until it fits loosely in the Soft tissue gauge.

### STEP FOUR

**CLOSE AND SUTURE**

- **K** The flap will be placed over the Implant magnet and suture. Need 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.

- **L** Apply a pressure dressing over the wound for 24-48 hours.

  **NOTE:** Do not remove the sutures before the incision is sufficiently healed. Do not fit the Sound Processor Magnet before the wound is sufficiently healed.
ONE IMPLANT TWO SYSTEMS
• Removing an abutment - Instruments
• Removing or Replacing of an implant magnet
• Adjustment of Abutment
Baha Connect

Removing Abutment - Instruments Needed

**INSTRUMENTS NEEDED TO CHANGE AN ABUTMENT**

90469 Screwdriver Unigrip 95mm

HIA 009-0 Counter Torque Wrench

92143 Multi Wrench & ISO Adapter

90381 Machine Screwdriver Unigrip 25mm

**INSTRUMENTS NEEDED TO TAKE OUT AN ABUTMENT**

90469 Screwdriver Unigrip 95mm

HIA 009-0 Counter Torque Wrench

90381 Machine Screwdriver Unigrip 25mm

**INSTRUMENTS NEEDED TO TIGHTEN AN ABUTMENT**

HIA 009-0 Counter Torque Wrench

92143 Multi Wrench & ISO Adapter

90381 Machine Screwdriver Unigrip 25mm

Images are not to scale.
ISO Adapter can be ordered separately.
# Adjustment of Abutment

## Step One: Tighten the Abutment

In rare instances the abutment may become slightly loose and need adjustment. In case of persistent soft tissue complications the abutment may need to be replaced. The procedure takes a few minutes and local anesthetic is seldom required.

When adjusting abutment, always use the counter torque wrench with the multi wrench to minimize load on the implant.

- Tighten the abutment screw to 25 Ncm using the Multi wrench (the arrow pointing downwards) with machine screwdriver Unigrip 25 mm and the Counter torque wrench.

## Step Two: Replace the Abutment

- Loosen the abutment screw using the Multi wrench (arrow pointing upwards) with the machine screwdriver Unigrip 25 mm and the Counter torque wrench.

- Clean the skin thoroughly. If needed, let the area heal 2–4 weeks. If needed, then punch a new hole with a biopsy punch Ø4 mm.

- Pick up the new abutment with the Counter torque wrench

- Place the abutment on the implant. For the BA210 abutments: be sure to fit the abutment onto the hexagon head of the implant.

- Tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with machine screwdriver Unigrip 25 mm.
# Removing or Replacing the Implant Magnet

## STEP ONE
### MAKE THE INCISION

In rare instances the implant magnet may need to be removed or replaced. This requires a surgical procedure, which is described briefly below.

- Locate the implant magnet position.
- Inject local anesthesia with adrenalin.
- Use a scalpel to make an incision down to the periosteum in the same incision line as used when the patient was implanted.

![Incision](image)

- Open up the incision to expose the implant magnet using a self-retaining retractor. Other retractors may also be used.

**NOTE:** Incision should not be done over the implant magnet, if a new implant magnet will be inserted.

## STEP TWO
### REMOVE THE IMPLANT MAGNET

- Loosen the screw from the implant using the screwdriver Unigrip 95 mm or the Multi wrench with Machine screwdriver Unigrip, while holding the implant magnet with your fingers.
- Remove the implant magnet from the implant.

![Removing magnet](image)
### STEP THREE (A) ATTACH A NEW IMPLANT MAGNET

- If the implant magnet is being replaced now, continue from step 6 on page 38 for attaching the new implant magnet to the implant and closing the incision.

### STEP THREE (B) PLACE THE COVER SCREW AND CLOSE THE INCISION

If the implant magnet will not be replaced at this stage, continue by inserting a cover screw. Inserting a cover screw protects the internal threads of the implant from tissue and bone overgrowth when the implant magnet has been removed.

- Place and hand-tighten the cover screw using the screwdriver Unigrip 95 mm.
- Lay the flap back over the implant and suture the incision. Make sure to suture the deep layer to the periosteum or suture the skin to the periosteum and back to the skin.
- Apply a compressive dressing to avoid a pouch or an abscess forming, this is especially important if the magnet is removed due to an infection.

### STEP THREE (C) PLACE AN ABUTMENT

- If an abutment will be placed, please refer to the Cochlear Baha Connect Two Stage: Stage 2 on page 26 section of this document for more details.
• Baha Implant Compatibility Guide
• How to use the Multi Wrench
• How to use the healing cap
• How to remove the implant magnet
• Complications
• Special considerations
## Baha Implant Compatibility Guide

<table>
<thead>
<tr>
<th>BA300 &amp; BA400 SERIES ABUTMENT</th>
<th>BA200 SERIES ABUTMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>(New Abutment and Implant)</td>
<td>(Older Style Abutment and Implant)</td>
</tr>
</tbody>
</table>

- **Tri-lobe shape connection from abutment to implant**
- **Hexagonal shape connection from abutment to implant**

**Image of the top of the BI300 implant.**

**Image of the top of the 200 series implant.**

---

**Note:**

- The BA300 and BA400 Series abutments are only compatible with BI300 Series implants.
- The BA210 Series abutments are compatible with the previous Baha implants with hexagonal connection. Be sure to fit the abutment onto the hexagon head of the implant.
How to Use

THE MULTI WRENCH

A1 • Tightening of abutment screw to 25 Ncm using the Multi Wrench (“IN” facing upwards) and the machine screwdriver Unigrip 25 mm.
  • Insert the ISO adapter in the multi wrench and then insert the machine Unigrip screwdriver in the ISO adapter.

A2 • To minimize load on the implant, the Multi Wrench should always be used with the counter torque wrench.

A3 • The multi wrench torque limit is 25 Ncm.

B • Manual insertion of implant during surgery with abutment inserter or implant inserter. Rotate the whole Multi Wrench shaft clockwise (“IN” facing upwards).
# The Healing Cap with Plug

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>Place the healing cap first.</td>
</tr>
<tr>
<td>A2</td>
<td>Then insert the plug to ensure that the healing cap sits safely in place.</td>
</tr>
<tr>
<td>B1</td>
<td>When removing the healing cap, always remove the plug first (B2), then tilt the healing cap (B3).</td>
</tr>
</tbody>
</table>

**How to Use**
The Implant Magnet

A1 • To remove the implant magnet from sterile package hold it with both hands (A2).

B1 • Press in the middle where the implant magnet is and pop it down onto the sterile field.

Note: Do not twist package (B2), pick or pull out magnet from the package. It is seated tightly and can hover and land on the ground.

The implant magnet can be handled and touch sterile field towel/etc.
Complications During Surgery

Implant becomes stuck during insertion
This can occur if the implant is not correctly aligned. Set the drill unit to reverse mode and remove the implant. Determine the correct alignment and re-insert the implant. If the same happens again, prepare a new implant site at least 5 mm from the first one.

Implant continues to rotate when seated
This may occur when drilling in compromised and soft bone, and when the torque setting is too high in relation to the quality of the bone. Prepare a new implant site at least 5 mm from the first one and then place the implant using lower torque.

Exposure of dura mater or perforation of the sigmoid sinus
Although rare, a mild CSF or blood leak can occur during guide hole drilling. If this occurs, it is a low-pressure system that can be sealed easily. If there is good bone volume, place the implant to seal the leak. If the bone is too thin, seal the leak with soft tissue or bone wax. Then choose a new implant site at least 5 mm from the original one (as close as possible without intersecting).

Subdural hematoma
This condition, caused by venous bleeding under the dura, is rare and typically slow developing. It is not often identified during surgery but is more likely caused by direct trauma and will develop gradually over time and display general neurological symptoms. Should this occur, a CT scan can be used to verify the diagnosis. Treat this condition according to general practice.
Soft tissue complications

Inflammation and infection around the abutment
Poor or excessive personal hygiene is the most common cause of irritation. It could also be due to a loose abutment or insufficient osseointegration.

If the skin around the abutment becomes inflamed/infected, thoroughly clean the entire implant site with an alcohol-free wet wipe. If appropriate, apply antimicrobial cream and/or a high strength corticosteroid cream. Provide the patient with the appropriate aftercare instructions.

If further treatment is needed, oral antibiotic and/or a steroid injection1 to the site might be considered.

Persistent soft tissue complications

When medical therapy has failed and the patient has a persistent problem, remove the abutment. You may have to excise the soft tissue from the abutment. Clean the skin thoroughly. Perform a culture before providing the appropriate antimicrobial and anti-inflammatory treatment. Place a cover screw and allow the area to heal before placing a new abutment. Ensure that the skin edges do not create an unwanted pocket around the abutment.

There are cases when transitioning from the Baha Connect System to the Baha Attract System may provide patient benefits. Such cases may include persisting skin reactions at the implant site that preclude the use of the abutment system. It may also include cases where patient lifestyle indicates that the Baha Attract System will be a more suitable option. Good outcomes can be achieved if pre-operative assessment and surgery is managed carefully2-4

Skin overgrowth

In some patients (predominantly male teenagers) an inflammatory reaction may occur and result in soft tissue thickening or complete overgrowth of the abutment by soft tissue. Treatment with a longer abutment, topical steroid cream or a steroid injection may be considered1,5

Keloids

In the case of keloids that do not subside over time, an injection with Kenalog might be considered. Another option is to place a silicone disc6 over the keloid and keep pressure on the silicone disc for 7-10 days.

Postoperative numbness - Paresthesia

Postoperative numbness may occur. Usually this will subside after a few months.
Complications

Postoperative Complications – Connect

Bone complications

**Implant loss**
Potential causes for failure of osseointegration include lack of adequate bone quantity/quality, trauma, infection, generalized diseases and surgical complications. If removal of the implant is needed, manually unscrew the implant using the implant inserter and multi wrench (“OUT” facing outwards). If manual removal is not possible, remove the implant by drilling away the bone with the guide drill.

**Bony overgrowth**
The potential for a bony overgrowth around the implant is highest in children implanted at a very young age. Removal of some bone will allow sufficient clearance between the skin and the Baha sound processor.

**Pain**
If the patient experiences pain when touching the abutment, in rare instances when this occurs the risk of implant loss increases significantly. In most cases, the loose implant can be removed and another placed in adjacent bone. In others, the implant must be removed and the defect then carefully curetted and filled with blood coagulates. In most cases adjacent bone is available and suitable for the placement of another implant. If the patient experiences pain even without touching the abutment, removal of the abutment and implant may be considered.7

**Bone infection leading to osteonecrosis**
This is seen almost exclusively in patients with previously irradiated implant sites. It may be avoided by administering hyperbaric oxygen (HBO) before and after surgery and by striving for minimal tissue damage during surgery.8

Special Considerations

**MRI and magnetic fields**
Be certain to caution patients about procedures that could be harmful to the sound processor, such as MRI and any other involving magnetic fields. Always remove the sound processor before an MRI procedure. The implant itself and the abutment are considered MR Conditional and can be safely scanned within defined conditions at 1.5 and 3.0 Tesla. For more information, refer to the MRI information supplied with the product.9,10

**Radiation therapy**
If a patient already has an implant and is scheduled for radiation therapy around the implant area, the abutment should be removed, but the implant could be left in place to allow healing of the site before radiation is performed. A cover screw can be used to cover the implant until the abutment is replaced.

**Sporting activities**
It is important to educate the parents and caregivers about the need for helmets and other safety precautions during sporting activities to minimize traumatic events. Traumatic implant loss can still occur across all age groups.
Soft tissue Complications
Local reaction in the soft tissue surrounding the implant magnet.
If the skin around the implant magnet becomes inflamed it is recommended to treat this according to normal procedures. If the inflammation persists and the skin breaks down, remove the implant magnet, place a cover screw and allow the area to heal. Then consider implanting a new magnet. Though fitting of the Sound Processor and Sound Processor Magnet are typically performed four weeks following surgery, this process should be delayed if there is inflammation of the skin or the incision area is not completely healed.

Bone complications
Implant loss
Potential causes for failure of osseointegration include lack of adequate bone quantity/quality, trauma, infection, generalized diseases and surgical complications.

Pain from the implant
If the patient experiences pain around the implant, this may be due to a loose implant or implant magnet. If it is determined that the pain is due to a loose implant magnet, the implant magnet should be replaced. If it is determined that the pain is due to a loose implant, the loose implant can be removed and another one placed in adjacent bone. In some cases, the implant must be removed and the defect then carefully curetted and filled with blood coagulates. In most cases adjacent bone is available and suitable for the placement of another implant.

MRI Safety Information
Be certain to caution patients about procedures that could be harmful, such as MRI and any other procedures involving magnetic fields. The patient can only safely undergo MRI scanning under very specific conditions. Scanning under other conditions may result in severe patient injury or device malfunction. As long as the Baha Sound Processor and Sound Processor Magnet and Implant Magnet are removed for the MRI procedure, a patient with the osseointegrated titanium implant may be exposed to an MRI examination without any risk.

MRI and magnetic fields information
The Baha sound processor and SP Magnet must be removed before entering a room where an MRI scanner is located.

Non-clinical testing has demonstrated that the BIM400 Implant Magnet, in combination with BI300 Implant, is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions. Scanning under other conditions may result in severe patient injury or device malfunction.
• Static magnetic field of 1.5 Tesla only
• Maximum spatial gradient field of 26600 Gauss/cm (266 T/m)
• Maximum switched gradient slew rate per axis of 200 mT/m/ms
• Maximum switched gradient amplitude per axis of 45 mT/m
• Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)
• Baha sound processor and SP Magnet must be removed before patient enters a room containing an MRI scanner

Additional instructions essential to safe use in the MR environment:
• Under the scan conditions defined above, the BIM400 Implant Magnet is expected to produce a maximum temperature rise of 2.1 °C after 15 minutes of continuous scanning.
• In non-clinical testing, the BIM400 Implant Magnet produced a temperature rise of less than 2.1 °C (extrapolated) at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg (extrapolated) assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla Intera, Philips Medical Systems (Software: 12.6.1.3, 2010-12-02) MR Scanner.
• In non-clinical gradient-induced heating testing the BIM400 Implant Magnet produced a temperature rise (extrapolated) of less than 4.5 °C at a time rate of change of the theoretical maximum worst-case gradient magnetic field dB/dt (extrapolated) of 200 T/s during 30 min. of continuous exposure in a test laboratory system (Pulsed Magnetic Field Generator) equivalent with a gradient system of a 1.5 Tesla MR system.
• In non-clinical testing with the implant magnet in place, the image artefact caused by the device extends approximately 11.5 cm (4.5 in.) from the BIM400 Implant Magnet when imaged with a gradient echo pulse sequence and a 1.5 Tesla MRI system.
### WARNINGS

**DO NOT EXCEED 137.0 °C (278.6 °F)**

| Limitations on reprocessing | Repeated processing has minimal effect on these instruments. End of life is normally determined by wear or damage. |

### INSTRUCTIONS

**Containment & transportation**

Reprocess instruments as soon as possible following use. If reprocessing is delayed, submerge the instruments in a disinfectant solution.

**Preparations for cleaning**

Disassemble the following instruments: • Multi wrench • Bone bed indicator

**Cleaning. Automatic**

- **Equipment:** Automatic standard approved washer-disinfector.
- **Detergent:** Low alkaline detergent as recommended by the manufacturer of the washer-disinfector.
- **Final rinsing phase/disinfection stage:** 85.0-93.0 °C (185.0-199.4 °F) for 1–3 minutes.
- **Water quality:** Processed water or according to the hospital’s established routines.
- **After washer-disinfection ensure that even narrow parts of instruments are completely free from visible soil. If necessary repeat cycle or use manual cleaning.**

**Cleaning. Manual**

- **Equipment:** Interdental brush soaked with detergent solution. Items that can be submerged in water should be cleaned under water, in order to avoid aerolisation spray. If additional cleaning is necessary, put the instrument in a manual ultrasonic bath.
- **Detergent:** All low alkaline detergents commonly used for surgical instruments.
- **Initial pre-rinsing phase:** Rinse in cold water. The temperature should not exceed 35.0 °C (95.0 °F).
- **Final rinsing phase:** Rinse in hot water.
- **Water quality:** Processed water or according to the hospital’s established routines.

**Chemical disinfection**

Before manual cleaning if risk for infection, otherwise after manual cleaning.

**Disinfectants:** All disinfectants commonly used for surgical instruments or alcohol (ethanol: 70%, or isopropanol: 45%) with added surfactants. Soak instruments in the disinfectant solution for at least 10 minutes.

**Drying**

- **Automatic:** Dry instruments in the washer-disinfector. Do not exceed 137.0 °C (278.6 °F).
- **Manual:** Dry each item with a clean lint free towel or let it air dry in controlled conditions.

**Maintenance, inspection and testing**

**All instruments:** Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Where instruments form part of a larger assembly, check assembly with mating components.

**Packaging**

- **Individually:** In heat sealable pouches. Ensure that the pack is large enough to contain the instruments without stressing the seals.
- **In sets:** Package the instrument cassette in a double layer of sterilization wrap.

**Sterilization**

Sterilization parameters must conform to EN 554 or be set by a validation study.

- **Equipment:** Steam sterilizers which fulfil the requirements of EN 285 (large sterilizers) or EN 13060 (small sterilizers). The process intended for use should be validated in accordance with EN 554.
- **Sterilant:** Saturated steam under pressure. Do not exceed 137.0 °C (278.6 °F).
- **Drying:** Check that the instruments are dry before storing.

**Temperature**

- **Minimum holding time:**
  - 134.0 °C (273.2 °F) for 3 minutes
  - 121.0 °C (249.8 °F) for 15 minutes

**Storage**

Store sterilized and packed articles in a controlled environment free from dust, moisture and large temperature changes.

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### Special Considerations

**Radiation therapy**

If a patient already has an implant and is scheduled for radiation therapy around the implant area, the implant magnet should be removed but the implant could be left in place to allow the site to heal before radiation is performed. A cover screw can be used to cover the implant until the implant magnet is replaced.

**Sporting activities**

It is important to inform parents and caregivers about the need for helmets and other safety precautions during sporting activities to minimize traumatic events. Traumatic implant loss can still occur across all age groups.

Reprocess all surgical instruments in accordance with the established local routines at the hospital clinic. Cochlear provides the following recommendations.
As the global leader in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people with moderate to profound hearing loss. We have helped over 450,000 people of all ages live full and active lives by reconnecting them with family, friends and community.

We aim to give our recipients the best lifelong hearing experience and access to innovative future technologies. For our professional partners, we offer the industry’s largest clinical, research and support networks.

That’s why more people choose Cochlear than any other hearing implant company.

As your patient’s partner in hearing for life, Cochlear believes it is important to convey not only the benefits, but also the potential risks associated with a Baha procedure.

Not everyone with hearing loss is a candidate for a Baha System. The Baha System is contraindicated in patients with inadequate bone quality or quantity to provide stability and support for the implant, or in patients who will be unable to maintain and clean the skin around the abutment. In the U.S., use of the implanted fixture is also contraindicated in children under age 9 years.

All surgical procedures include an element of risk, and it is impossible to guarantee success. The device may fail to osseointegrate for a number of reasons, including physiological and surgical issues as well as traumatic impact to the implant site. On rare occasions the skin around the abutment may become inflamed from a mild infection or the skin may grow back towards its original thickness. 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.

References: