

Cochlear® Baha® 4 Attract System Surgical Procedure

Surgery Guide





* The Cochlear Baha Attract System consists of:
Cochlear Baha BI300 Implant, Cochlear Baha BIM400
Implant Magnet, Cochlear Baha Sound Processor
Magnet, Cochlear Baha Sound Processor.

The techniques shown in this guide are provided
for your consideration only, and do not constitute
direct medical advice from Cochlear. This guide is
not a substitute for actual medical education and
hands-on training.

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. The protocol detailed in this manual has been developed in co-operation with Pete Weber, M.D., MBA, Chief Medical Officer, Cochlear Ltd.

Cochlear accepts no responsibility for any adverse outcomes if the surgical components and instruments described here are used with products not recommended by Cochlear. Close cooperation in an interdisciplinary team is essential for a successful outcome. Hands-on surgical workshops are available from Cochlear. Contact your local Cochlear office for details.

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Note:

Images in this guide are not to scale.

Not all products are available in all markets. Product availability is subject to regulatory approval in the respective markets.

This guide is applicable for BIM400 Implant magnet and BI300 Implants. These products are used for the Baha Attract System surgical procedure.



Introduction



Since 1977, the Cochlear™ Baha® Bone Conduction Implant System has proven successful for thousands of patients worldwide.

The Baha System has yielded excellent results for certain patient groups, particularly for those individuals with conductive or mixed hearing loss, or single-sided sensorineural deafness.¹

The Cochlear Baha Attract System is a magnetic bone conduction implant system. The system includes an osseointegrated BI300 Implant and a BIM400 Implant magnet that are implanted beneath the skin. The Baha Sound Processor and Sound Processor Magnet are worn on the head.

The long-term predictability and success of Baha Implants result from the creation of an active bond between the titanium implant and the surrounding bone tissue — a process known as osseointegration.

The use of a precise implantation technique is vital to successful, long-term osseointegration.

When selecting a surgical approach, the techniques in this guide provide the recommended alternatives.





Preparations

Selecting Surgical Technique

One-Stage Surgery vs. Two-Stage Surgery

The surgeon will decide to use either the one-stage or two-stage procedure. This decision is based on several factors including the thickness and quality of the cortical bone as well as the patient's age. Generally, One-Stage Surgery is recommended for patients with good bone quality and thickness greater than 3 mm. Two-Stage Surgery is generally recommended for patients with compromised or soft bone, irradiated bone, bone thickness less than 3 mm, special-needs patients (e.g., mentally or physically compromised) or in conjunction with other surgery (e.g., acoustic neuroma removal), see Table 1.

One-Stage Surgery	Two-Stage Surgery
Selection criteria	Selection criteria
Good bone quality and thickness > 3 mm	Compromised or soft bone Irradiated bone Bone thickness < 3 mm In conjunction with other surgery (e.g. Acoustic Neuroma removal)

Table 1: Technique selection

Children

The timing of the second stage of surgery depends on the thickness and quality of the bone encountered in stage one. The poorer the bone quality, the longer the time between stages one and two. As age and bone thickness increase, the inter-stage interval may decrease. Children with a cortical bone thickness of < 3 mm can require more than the usual 3–6 month inter-stage interval.

When children undergo Baha surgery, general anesthesia is often used. When selecting the surgical technique, the potential to avoid a second anesthetic should be evaluated against the safety profile for One-Stage Surgery.

Note:

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

Note:

The optimal soft tissue thickness, to suit the range of Sound Processor Magnets available, is between 3–6 mm. For tissue thickness above 6 mm the Sound Processor Magnets may fall off and for tissue thickness below 3 mm the Sound Processor Magnets may be too strong, which may cause discomfort and skin problems.

Treatment Schedule



One-Stage Surgery	
Place the implant and implant magnet.	
Surgical follow-up	Time after surgery
Remove the dressing and assess the wound site. If healed, no further dressing is required. If not healed, place a new dressing.	5–7 days
If necessary, repeat the relevant steps as in the previous visit. Remove sutures if incision is sufficiently healed.	10–14 days
Fitting the sound processor	Time after surgery
Check and clean skin.	4 weeks, assuming that the soft tissue is sufficiently healed.
Fit the selected Sound Processor Magnet and sound processor.	
Ensure the patient knows how to handle the Sound Processor Magnet, Baha SoftWear™ Pad* and sound processor.	
Follow up	
After the sound processor has been fitted, patients will return for an audiological assessment. At this time the skin and tissue will also be checked. Generally, patients will have annual or biannual check-ups.	

Two-Stage Surgery	
First stage	
Place implant and cover screw.	
Surgical follow-up	Time after surgery
Remove sutures, if healed.	1 week
Osseointegration period.	3–6 months
Second stage	
Remove the cover screw and place the implant magnet.	
Surgical follow-up	Time after 2nd stage
Remove the dressing and assess the wound site. If healed, no further dressing is required. If not healed, place a new dressing.	5–7 days
If necessary, repeat the relevant steps as in the previous visit. Remove sutures if incision is sufficiently healed.	10–14 days
Fitting of the sound processor	Time after 2nd surgery
Check and clean skin.	4 weeks, assuming that the soft tissue is sufficiently healed.
Fit the selected Sound Processor Magnet and sound processor.	
Ensure the patient knows how to handle the Sound Processor Magnet, Baha SoftWear Pad* and sound processor.	
Follow up	
After the sound processor has been fitted, patients will return for an audiological assessment. At this time, the skin and tissue will also be checked. Generally, patients will have annual or biannual check-ups.	

* Sound Processor Magnet soft pad



Selecting the Implant Site

Even though the surgeon will ultimately select the implant placement, successful treatment relies on an interdisciplinary approach that includes consultation with other clinicians involved in the case, as well as the patient and/or the patient's family/caregiver. Choosing the appropriate implant placement requires attention to the following factors and considerations:

- **Audiological factors:** In patients with bilateral hearing loss, bilateral fitting is recommended. Studies show that the patient benefits from bilateral fitting in terms of a greater stimulation level, better directional hearing and space perception as well as generally better speech understanding in noise.² For unilateral fittings, place the implant on the side with the best cochlea function (i.e., best bone conduction thresholds). For patients with single-sided deafness, place the implant on the deaf side.
- **Physiological factors:** Incorrect implant placement, too far from the cochlea, can change the audiological outcome.³ Estimate the site location in cases of complete aural atresia or place the Baha in the parietal cortex rather than the thicker mastoid bone in children with craniofacial abnormalities. Move the site posteriorly for children who will undergo autogenous reconstruction.
- **Manual dexterity:** Ensure the patient's (or family's/caregiver's) ability to use controls as well as to remove and replace the Sound Processor Magnet, SoftWear Pads and sound processor.
- **Driving habits:** Patients who regularly drive with a passenger seated next to or behind them usually prefer their implant on the side facing the passenger.
- **Telephone use:** Patients who frequently use the telephone usually prefer the implant on the side opposite to their "writing" hand.
- **Head gear:** Special consideration is warranted for patients who regularly wear glasses, or a hat or helmet for work or certain activities (e.g., construction workers and cyclists).

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Preparations for Surgery

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:

All single-use products are delivered sterile (sterilized using irradiation) Do not use products with damaged packaging or after the expiry date Due to contamination and effectivity risks, do not re-sterilize or reuse these single-use products (Fig. 1).

The peel-open pack inside the sterile product box acts as the sterile barrier. The plastic ampoule (when applicable) is only a container for the sterile product. Inside the plastic ampoule (Fig. 2), a titanium casing holds the product. The implant should not be touched but rather picked up from the plastic ampoule with the implant inserter.

A set of all components should always be available because a different implant size may be required. It is also recommended that one extra of each component be available in case a component is dropped.

Sterile Products



All sterile products are for single use only.

Implant Magnet

Note:

The BIM400 Implant Magnet is compatible with the BI300 Implants.

The BIM400 Implant Magnet screw should be tightened to 25 Ncm.



Implants

Note:

The cover screw conical is used for Two-Stage procedures or sleeper implants and is only compatible with the BI300 Implants.



Drills

Note:

The guide drill has a removable spacer for drilling to different depths.

If available, 92139 Guide drill 3+4 mm, can also be used for Baha Attract System surgery.



Reusable Instruments

Note:

These instruments are specific for Baha Attract System surgery. For additional instruments that are needed for the Baha Attract System surgical procedure, please refer to the Baha Attract System Product catalogue insert.







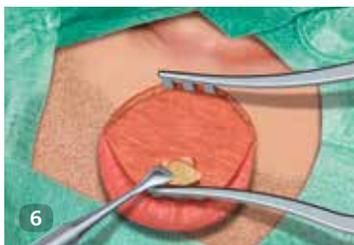
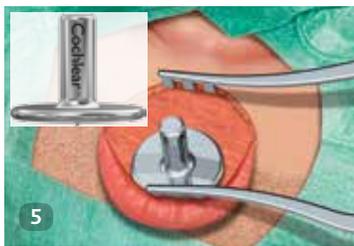
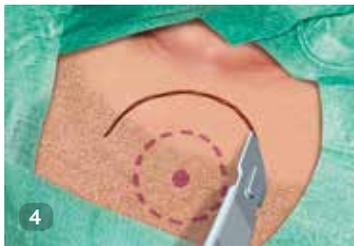
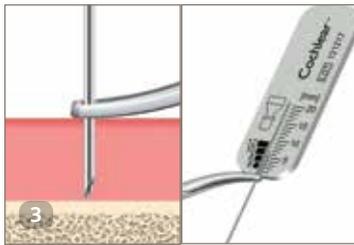
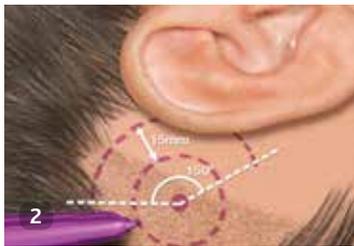
One-Stage Surgery

Generally, One-Stage Surgery is recommended for patients with good bone quality and thickness. One-Stage Surgery involves placing an implant and an implant magnet in the same procedure.

This section provides our recommended step-by-step method for One-Stage Surgery with the BI300 Implant and BIM400 Implant Magnet.



One-Stage Surgery



STEP 1 Prepare the Site

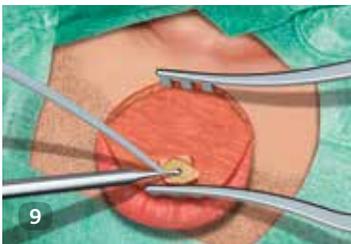
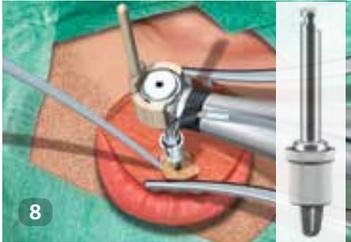
- Identify the implant site with the Indicator for Baha Attract. It is usually 50-70 mm from the ear canal, and the superior edge of the processor should be in line with the top of the pinna (Fig. 1). Ensure the sound processor and Sound Processor Magnet do not touch the pinna.
- Mark the C-shaped incision anterior of the position of the magnet, at least 15 mm from the edge of the magnet (Fig. 2). The length of the incision can be extended for easier access.
- Before local anesthesia is injected, measure the tissue thickness in several positions around the planned implant site. A thin hypodermic needle, a clamp and a ruler should be used (Fig. 3). Ensure not to depress the tissue when measuring. If the soft tissue is thicker than 6 mm, soft tissue reduction is required.
- Administer local anesthetic injection around the implant site.

Note:

The optimal soft tissue thickness, to suit the range of Sound Processor Magnets available, is between 3–6 mm. For tissue thickness above 6 mm the Sound Processor Magnets may fall off and for tissue thickness below 3 mm the Sound Processor Magnets may be too strong, which may cause discomfort and skin problems.

STEP 2 Make the Incision

- Use a scalpel to make an incision down to the periosteum (Fig. 4). Retract soft tissue posteriorly/superiorly via blunt dissection. The temporalis is retracted superiorly down to the periosteum.
- Open up the incision using a self retaining retractor. Place the implant magnet template on the periosteum to ensure good positioning of the implant magnet in relation to the incision and the bone (Fig. 5). Try to find a relatively flat bone surface for the implant and Implant Magnet. Mark the selected position of the implant on the periosteum with a pen or with the sharp tip on the implant magnet template.
- Make a cruciate incision (6 mm square) in the periosteum to expose enough bone for the implant flange. Raise the edges with the raspatorium (Fig. 6).



STEP 3 Drill with the Guide Drill

Be certain to drill at an angle perpendicular to the bone surface. Perpendicular drilling will help minimize the need for bone polishing later in the procedure. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement.

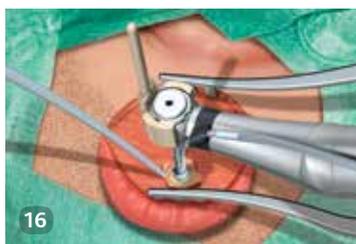
- Set the drill unit to the high-speed setting: 2000 rpm with coolant (Fig. 7).
- Begin drilling with the guide drill with a 3 mm spacer (Fig. 8). Use abundant irrigation during all drilling procedures.
- While drilling, move the burr up and down to ensure visual inspection and that coolant reaches the tip of the drill. Cooling is critical to preserve osteocytes, which are crucial for the osseointegration process.
- Check the bottom of the site repeatedly for bone, both visually and with the dissector (Fig. 9).
- If there is adequate bone thickness, remove the white spacer on the guide drill and continue drilling to a depth of 4 mm (Fig. 10).
- If the bone is found to be thinner than 3mm, a Two-Stage Surgery is recommended. Please see the instructions for a Two-Stage Surgery on pg 16.

Note:

Observe the quality and quantity of the cortical bone and spongiosa air cells during initial penetration. Proceed with care to avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.

Make sure that any sleeper implant is placed outside the area of the implant magnet because a sleeper implant may negatively affect the attachment between the activated implant and implant magnet.

If available, Guide drill 3+4 mm Ø2.3 mm, can also be used for Baha Attract System surgery. In that case, move the burr up and down and slightly enlarge the hole to facilitate visual inspection and ensure coolant reaches the tip of the drill.



STEP 4 Drill with the Widening Drill

- Keep the drill unit on the high-speed setting: 2000 rpm with coolant.
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill (Fig. 11).
- Use the dissector to remove bone chips from the drill flutes if necessary.
- When reaching the bone surface, use the widening drill to create a small countersink in the bone (maximum 0.5 mm) (Fig. 12). The widening drill has been designed to allow early recognition of when countersinking is complete. However, take care not to press too hard, especially in soft bone, to avoid excessive countersinking.

Note:

Do not use the guide drill after the widening drill since the guide drill's stop diameter is smaller than the site.

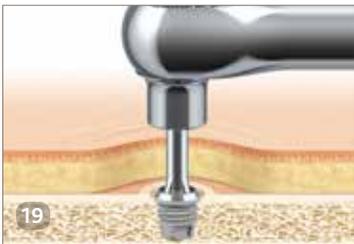
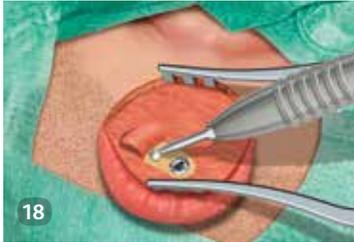
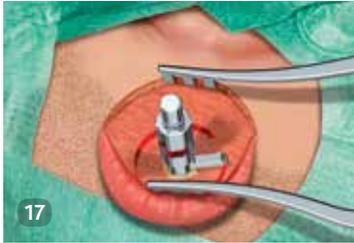
The blunt tip of the widening drill minimizes the risk of damage to tissue at the bottom of the hole.

Be very careful not to over-widen the section that will contain the implant threads to avoid risk of losing initial implant stability.

STEP 5 Place the Implant

- Set the drill to the torque setting (program Implant Installation for the Osscora surgical set). (Fig. 13).
- Set the torque limit to suit the quality of the bone.
- Open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the tray (Fig. 14).
- Pick up the implant using the Implant inserter (Fig. 15).
- Place the implant without coolant 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 (Fig. 16).
- Once in the bone, continue implant placement with irrigation.
- The Osscora surgical set stops automatically and beeps when the preset torque is reached.
- Carefully lift up the hand-piece to remove the Implant inserter from the implant.

Bone quality	Suggested Torque
Compact bone	40–50 Ncm
Compromised or soft bone	20–30 Ncm



- 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 to ensure it does not touch the bone (Fig. 17). This will allow sufficient clearance for the correct mounting of the Implant magnet.
- If the bone bed indicator touches bone, remove excessive bone. First, open up the periosteum in that area and polish the bone using a standard otological high-speed drill (Fig. 18). 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 needed suture it in place.

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.

When placing the implant in hard bone, slight pressure may need to be applied during the initial insertion.

If the drill stops prematurely — before the implant is seated in the bone — reverse one thread and increase the torque by 5 Ncm on the drill system's control panel.

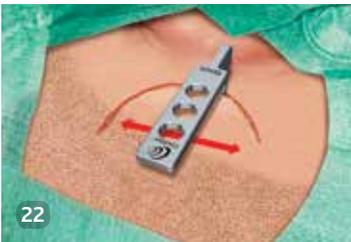
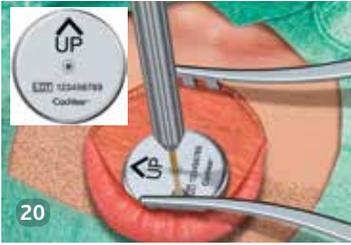
If the implant enters the hole incorrectly, put the drill in reverse and unscrew the implant. Then find the correct angle and re-insert the implant. This should only be attempted once.

Make sure to fit the bone bed indicator properly to the implant to avoid damaging the threads of the implant.

While polishing the bone, remove the bone bed indicator so it doesn't wobble around and is damaged by the high-speed drill bit.

Be very careful not to loosen the implant through leverage. The risk of this occurring is quite high if implanting a patient with thin or compromised bone.

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 (Fig. 19). The Multi wrench is not intended to be used as a torque wrench for implant placement because its torque limit is 25 Ncm.



STEP 6 Attach the Implant Magnet

- Pick up the implant magnet and place it in the conical connection of the implant. Make sure the arrow and the word "UP" on the implant magnet is oriented towards the top of the patient's head, ie pointing in the superior direction (Fig. 20). Hand-tighten the screw with the Unigrip screwdriver, while holding the implant magnet with your fingers (Fig. 20).
- 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 (Fig. 21). Evaluate the thickness of the flap over the magnet using the Soft tissue gauge (Fig. 22). The skin flap should not be thicker than 6 mm and should fit loosely in the Soft tissue gauge.
- If the skin flap is thicker than 6 mm, carefully thin the flap down to 6 mm (Fig. 23), i.e., until it fits loosely in the soft tissue gauge. Try to achieve a uniform skin thickness over the whole flap area.

Note:

When placing the implant magnet on the implant, make sure the internal screw is protruding over the magnet surface before tightening the screw with the screwdriver. This will prevent damage to the implant threads and ensure a good connection between the implant magnet and implant.

Make sure that any sleeper implant is placed outside the area of the implant magnet because a sleeper implant may negatively affect the attachment between the activated implant and implant magnet.

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



STEP 7 Close and Suture

- Place the flap over the implant magnet and suture (Fig 24). Make 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 (Fig 25).

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.



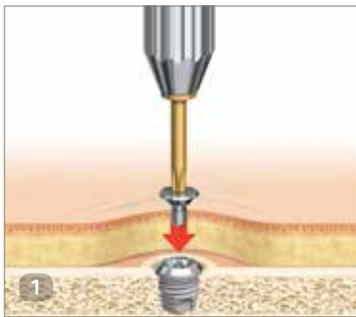
Two-Stage Surgery

Generally, Two-Stage Surgery is recommended for patients with compromised or soft bone with a bone thickness < 3 mm. The bone quality and thickness may also influence the length of the inter-stage interval and placement.

When One-Stage Surgery Becomes a Two-Stage Procedure

After having placed the implant, place a cover screw into the implant at this time.

Two-Stage Surgery: Stage I



STEP 1 Prepare the Site

- Follow the procedure described in the One-Stage Surgery section on pg 10, until the incision is marked out. Measuring the soft tissue thickness is not necessary in this stage of the Two-Stage procedure.

STEP 2 Make the Incision

- Follow the procedure described in the One-Stage Surgery section on pg 10.

STEP 3 Drill with the Guide Drill

- Follow the procedure described in the One-Stage Surgery section on pg 11.

STEP 4 Drill with the Widening Drill

- Follow the procedure described in the One-Stage Surgery section on pg 12.

STEP 5 Place the Implant

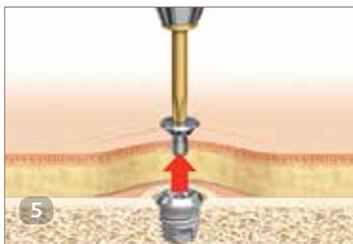
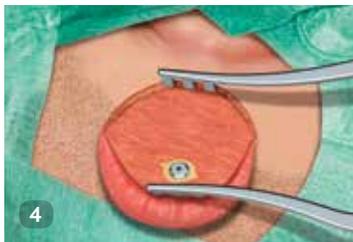
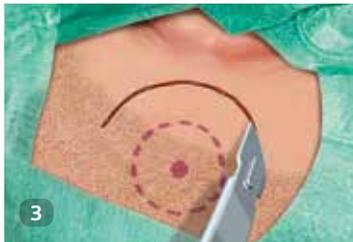
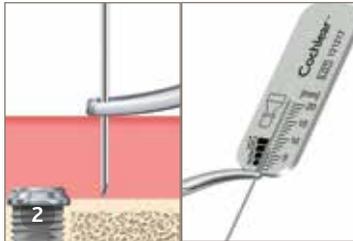
- Follow the procedure described in the One-Stage Surgery section on pg 12, until the implant is inserted, and then continue with step 6 below. This means that no bone polishing should be done at this stage.

STEP 6 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 (Fig. 1).
- Suture down the periosteum with resorbable sutures over the implant.
- Suture the incision.
- Apply a suitable dressing.

Two-Stage Surgery: Stage 2

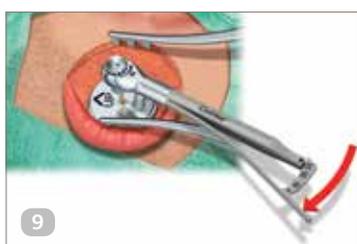
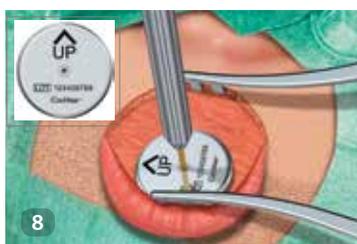
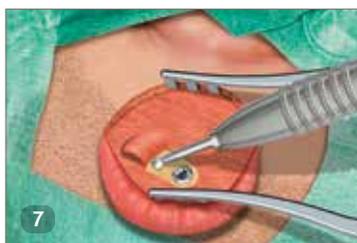


STEP 1 Make the Incision

- Locate the implant position.
- Before local anesthesia is injected, measure the tissue thickness in several positions around the planned implant site. A thin hypodermic needle, a clamp and a ruler should be used (Fig. 2).
- Administer local anesthetic injection.
- Use a scalpel to make an incision down to the periosteum in the same incision line as in stage 1 (Fig. 3). Retract soft tissue posteriorly/superiorly via blunt dissection. The temporalis is retracted superiorly down to the periosteum.
- Open up the incision to expose the implant and cover screw using a self-retaining retractor (Fig. 4).

STEP 2 Remove the Cover Screw

- Remove the cover screw using the screwdriver Unigrip 95 mm (Fig. 5).



STEP 3 Attach the Implant Magnet

- 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 to ensure it does not touch the bone (Fig. 6). This will allow sufficient clearance for the correct mounting of the Implant magnet.
- If the bone bed indicator touches bone, remove excessive bone. First, open up the periosteum in that area and polish the bone using a standard otological high-speed drill (Fig. 7). 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 needed suture it in place.
- Pick up the implant magnet and place it in the conical connection of the implant. Make sure the arrow and the word "UP" on the implant magnet is oriented towards the top of the patient's head, ie pointing in the superior direction (Fig. 8). Hand-tighten the screw with the Unigrip screwdriver, while holding the implant magnet with your fingers (Fig. 8).
- 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 (Fig. 9).
- Evaluate the thickness of the flap over the magnet using the Soft tissue gauge (Fig. 10). The skin flap should not be thicker than 6 mm and should fit loosely in the Soft tissue gauge.
- If the skin flap is thicker than 6 mm, carefully thin the flap down to 6 mm (Fig. 11), i.e., until it fits loosely in the soft tissue gauge. Try to achieve a uniform skin thickness over the whole flap area.

Note:

When placing the implant magnet on the implant, make sure the internal screw is protruding over the magnet surface before tightening the screw with the screwdriver. This will prevent damage to the implant threads and ensure a good connection between the implant magnet and implant.

Make sure to fit the bone bed indicator properly to the implant to avoid damaging the threads of the implant.

While polishing the bone, remove the bone bed indicator so it doesn't wobble around and is damaged by the high-speed drill bit.

When 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.



STEP 4 Close and Suture

- Place the flap over the implant magnet and suture (Fig 12). Make 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 (Fig 13).

Note:

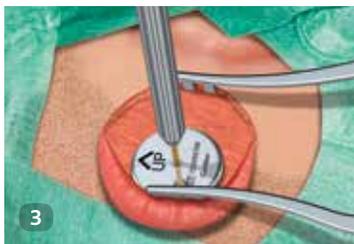
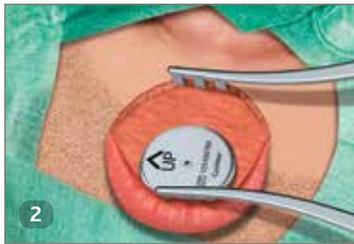
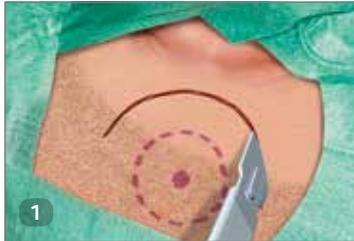
Do not remove the sutures before the incision is sufficiently healed.

Do not fit the Sound Processor Magnet before the wound is sufficiently healed.



Removing or Replacing the Implant Magnet

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



STEP 1 Make the Incision

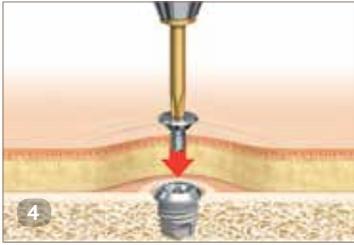
- Locate the implant magnet position.
- Administer local anesthetic injection.
- Use a scalpel to make an incision down to the periosteum in the same incision line as used when the patient was implanted (Fig. 1).
- Open up the incision to expose the implant magnet using a self-retaining retractor (Fig. 2) Other retractors may also be used.

Note:

Do not make an incision over the implant magnet, if a new implant magnet will be inserted.

STEP 2 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 (Fig. 3).
- Remove the implant magnet from the implant.



STEP 3a Attach a New Implant Magnet

- If the implant magnet is being replaced now, continue from STEP 6 on pg 14 for attaching the new implant magnet to the implant and closing the incision.

..... OR



STEP 3b 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 (Fig. 4).
- 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.

Note:

If the patient is going to have an implant magnet reinserted at a later stage, refer to Two-Stage Surgery: Stage 2 on pg 18. Always use a new implant magnet; the implant magnet cannot be re-sterilized. The Implant magnet is only compatible with B1300 Implants (Fig 5).

..... OR

STEP 3c Place a DermaLock™ Abutment

If an abutment will be placed, please refer to the Cochlear™ Baha® DermaLock Surgery Guide for more details.



Complications

Below is a list of potential complications and recommendations for handling them. Importantly, the patient must be informed of all possible complications related to safety and effectiveness prior to surgery.

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 unscrew 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.

Postoperative 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.

Postoperative 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 Safety Information

The Baha Sound Processor and Sound Processor 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 Sound Processor 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 4.5°C after 30 minutes of continuous scanning.
- In non-clinical testing with the implant magnet in place, the image artifact 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.

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.

Cleaning and Sterilization Guidelines



Please refer to the Cochlear Baha Surgical Tools Reprocessing Guidelines for complete instructions.

References

1. Snik AF, Mylanus EA, Proops DW, Wolfaardt JF, Hodgetts WE, Somers T, Niparko JK, Wazen JJ, Sterkers O, Cremers CW, Tjellström A. Consensus statements on the BAHA system: where do we stand at present? *Ann Otol Rhinol Laryngol Suppl.* 2005 Dec;195:2-12.
2. Priwin C, Stenfelt S, Granström G, Tjellström A, Håkansson B. Bilateral Bone-Anchored Hearing Aids (BAHAs): an audiometric evaluation. *The Laryngoscope* 2004;114(1):77-84.
3. Eeg-Olofsson M, Stenfelt S, Tjellström A, Granström G. Transmission of bone conducted sound in the human skull measured by cochlear vibrations. *Int J Audiol.* 2008 Dec;47(12):761-9.

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

Hear now. And always

As the leading global expert in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. For thirty years, Cochlear has pioneered this technology, helping more than a quarter of a million people reconnect to their families and friends.

Along with the industry's largest investment in research and development, we continue to partner with leading international researchers and hearing professionals, ensuring that we are at the forefront of hearing science.

For our customers, that means access to our latest technologies throughout their lives, and the ongoing support they need.

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. Baha 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 5 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

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BUN226 ISS2 JAN14



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