FOR PROFESSIONALS

Cochlear®
Hear now. And always

Surgery Guide

Cochlear™ Baha® Attract System Surgical Procedure

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

Cochlear accepts no responsibility for 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.

Content

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.


Cochlear

Introduction

Since 1977, the Cochlear™ Baha® 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 implanted beneath the skin. A Baha sound processor and a 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: Technique selection.

One-stage surgery
Selection criteria
Good bone quality and thickness > 3 mm

Two-stage surgery
Selection criteria
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 may be 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 anaesthesia is often used. When selecting the surgical technique, the potential to avoid a second anaesthetic 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 5.

The optimal soft tissue thickness for sound processor retention is between 3–6 mm. Tissue thickness above 6 mm will result in inadequate retention of the sound processor and tissue thickness below 3 mm cause discomfort and skin problems due to overly strong magnet strength. The impact of hair thickness and texture on retention must also be considered.

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 SP 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 SP 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, or 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:** Educate patient and family/caregiver on usage of sound processor controls and consider their ability to manage the sound processor, sound processor magnet and Baha Softwear pads.
- **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 prefer the implant on the side opposite to their "writing" hand.
- **Head gear/Glasses:** Special consideration is warranted for patients who regularly wear glasses, or a hat/helmet for work or daily activities (e.g., construction workers and cyclists). Patients that wear a hat or glasses should bring them to the surgical appointment.

Preparations for surgery

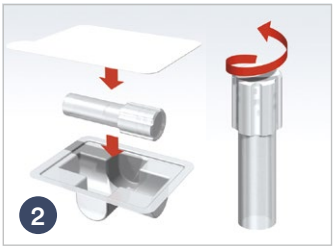
Prepare the patient as for any surgical procedure, i.e., sterilize the incision area. Local or general anaesthesia can be used for adult patients. When children undergo Baha surgery, general anaesthesia is most often used.

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 effectiveness risks, do not re-sterilize or reuse 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 be available as a different implant size may be required. It is also recommended that one extra of each component be available in the event a component is dropped.



Sterile products

All sterile products are for single use only.

Implant Magnet

93550
BIM400
Implant Magnet

Note

The BIM400 Implant Magnet is compatible with the BI300 Implants.

Implants

92128
BI300 Implant
3 mm

92129
BI300 Implant
4 mm

92136
Cover screw
conical

Note

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

Drills

93363
Conical guide
drill 3 + 4 mm

92140
Widening drill
3 mm with
countersink

92141
Widening drill
4 mm with
countersink

Note

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

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 using the Baha Indicator. 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 to 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 anaesthesia is injected, measure the soft tissue thickness in three positions (anterior magnet edge, middle of magnet, posterior magnet edge). A thin hypodermic needle, a clamp and a ruler should be used (Fig. 3). Ensure not to depress the tissue when measuring. If the soft tissue is thicker than 6 mm, soft tissue reduction will be needed later in the procedure.
- Administer local anesthetic injection around the implant site.

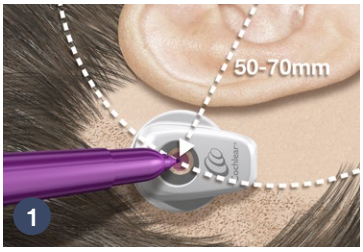
Note

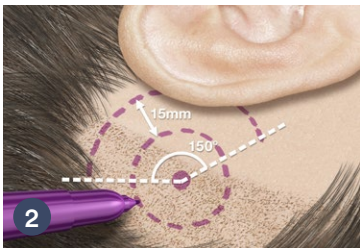
The optimal soft tissue thickness, to suit the range of sound processor magnet available is between 3–6 mm. For tissue thickness above 6 mm the sound processor magnet may fall off and for tissue thickness below 3 mm the sound processor magnet may be too strong, which may cause discomfort and skin problems.

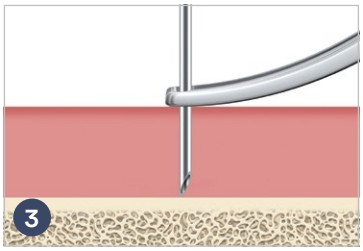
If the patient wears glasses, head gear or an auricular prosthesis, take this into account when choosing the position.

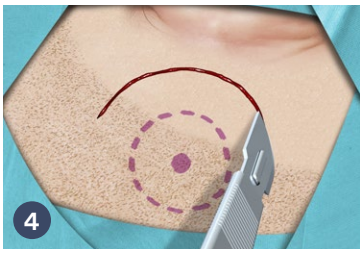
STEP 2 Make the incision

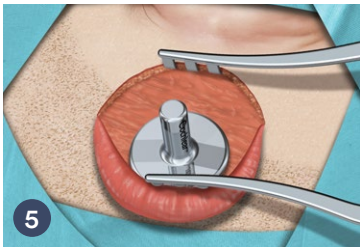
- Use a scalpel to make an incision down to the periosteum (Fig. 4). The length of the incision may be extended for easier access. Retract soft tissue posteriorly/superiorly via blunt dissection. The temporalis is retracted superiorly down to the periosteum.
- Open up the incision using a self retaining 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 and countersink. Raise the edges using the broader end of the Raspatorium/ Probe (Fig. 6).

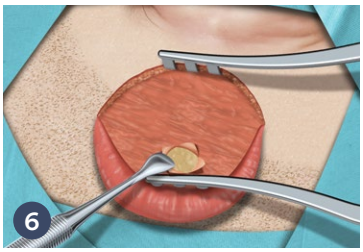












STEP 3 Drill with the Conical guide drill

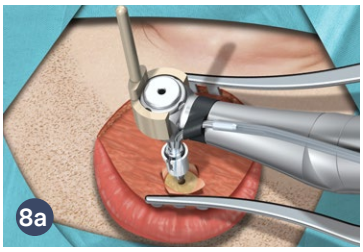
Be certain to drill at an angle perpendicular to the bone surface. Perpendicular drilling will help minimize the need for bone polishing later in the procedure. The drill indicator facilitates correct drill orientation and should be used during drilling and implant placement.

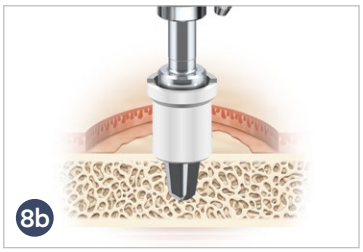
- Set the drill unit to the high-speed setting: 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 7).
- Begin drilling with the Conical guide drill with a 3-mm spacer (Fig. 8a, 8b). Use abundant irrigation during all drilling procedures.
- While drilling, move the burr up and down 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 narrow end of the Raspatorium/Probe (Fig. 9).
- If there is adequate bone thickness, remove the white spacer on the guide drill and continue drilling as appropriate to accommodate the required BI300 Implant (Fig. 10).

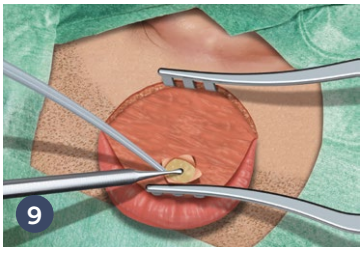
Note

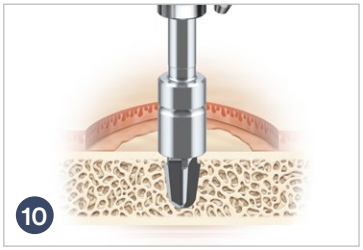
Observe the quality and quantity of the cortical bone and spongiosa air cells during initial penetration. Proceed with care to avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.

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.



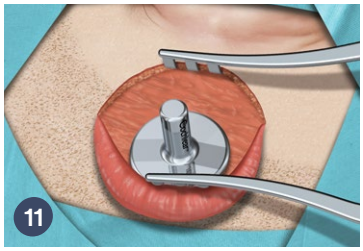


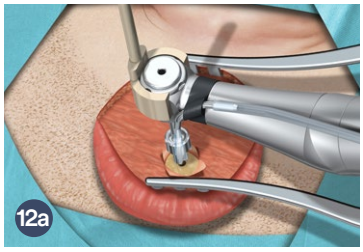




STEP 4 Drill with the Widening drill

- Keep the drill unit on the high-speed setting: 2000 rpm with coolant (program 2 for the Osscora surgical set).
- Be certain to drill at an angle perpendicular to the bone surface. Placing the tip of the implant magnet template in the site created by the guide drill, will give a good indication of the correct drill orientation before drilling with the Widening drill (Fig. 11).
- Use either a 3 or 4 mm Widening drill, depending on the depth reached with the Conical guide drill (Fig. 12a, 12b).
- Move the Widening drill up and down during drilling to ensure that coolant reaches the tip of the drill. Only use up and down movements, do not make the site larger than the actual drill size.
- Use the narrow end of the Raspatorium/Probe frequently to remove bone chips from the drill flutes.
- When reaching the bone surface, use the widening drill to create a small countersink in the bone (approximately 0.5 mm) (Fig. 13). 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 Conical 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 site.

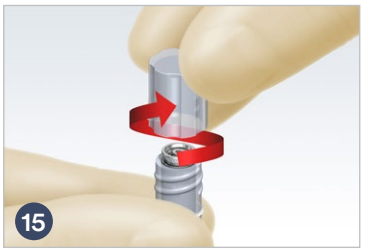
Be very careful not to over-widen the section that will contain the implant threads or you risk losing initial implant stability.

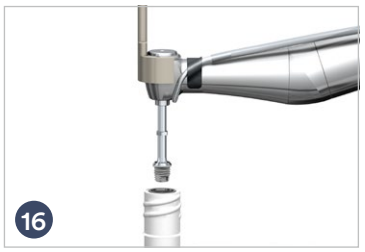
STEP 5 Place the implant

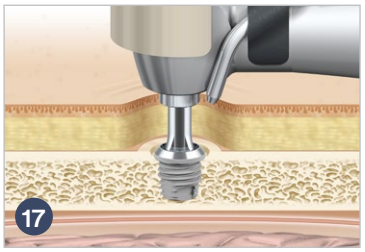
- Be certain to insert the implant at an angle perpendicular to the bone surface.
- Set the drill to the torque setting (program Implant Installation for the Osscora surgical set). (Fig. 14).
- Set the torque limit to suit the quality of the bone.

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

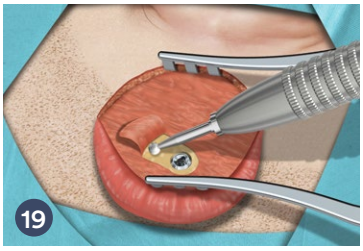
- Open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the tray (Fig. 15).
- Pick up the implant using the Implant inserter (Fig. 16).
- Place the implant without coolant until the first threads of the implant are well within the bone (two rotations). Irrigation at this time would result in cooling solution being compressed into the marrow spaces in the bone by the implant (Fig. 17).
- Once in the bone, continue implant placement with irrigation.
- The Osscora surgical set stops automatically and beeps when the preset torque is reached.

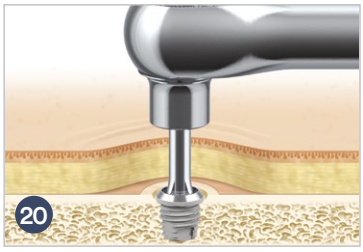






- Carefully lift up the hand-piece to remove the Implant inserter from the implant. Place the bone bed indicator on the implant and gently hand tighten it to the implant threads by turning the top knob. Make sure that it is properly tightened (Fig. 18a). Rotate it to ensure it does not touch the bone (Fig. 18b). This will allow sufficient clearance for the correct mounting of the Implant magnet. Turning the bone bed indicator counter clockwise may lead to that it loosens slightly from the implant.
- If the bone bed indicator only touches soft tissue, remove the tissue. 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. 19). 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 and continue to implant at this increased torque.

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

When attaching the bone bed indicator to the implant, take care to avoid damaging the implant threads.

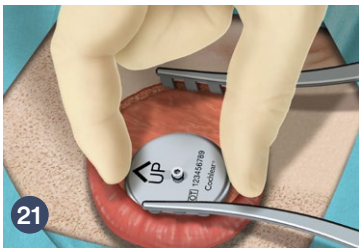
While polishing the bone, remove the bone bed indicator so it doesn't wobble around and is damaged by the high-speed drill bit.

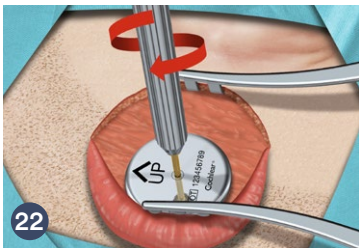
Be very careful not to loosen the implant through leverage. The risk of this occurring is quite high if implanting a patient with thin or compromised bone.

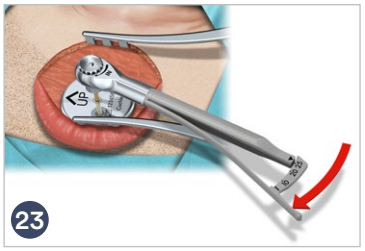
The implant can be inserted manually with the Multi wrench and the implant inserter. Rotate the whole Multi wrench shaft clockwise ("IN" facing upwards) until the implant is fully seated (Fig. 20). The multi wrench is not intended to be used as a torque wrench for implant placement needing more than 25 Ncm.

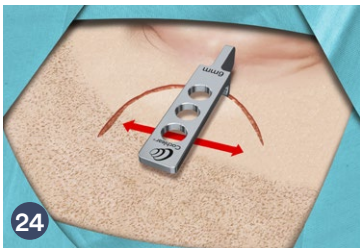
STEP 6 Attach the implant magnet

- Pick up the implant magnet and place it in the conical connection of the implant. Make sure the internal screw is protruding over the magnet surface before tightening the screw with the screwdriver (Fig. 21). This will ensure a proper connection.
- Make sure the arrow and the word “UP” on the implant magnet is oriented towards the top of the patient’s head, i.e. pointing in the superior direction (Fig. 21).
- Gently hand-tighten the screw with the Unigrip screwdriver, while holding the implant magnet with your fingers (Fig. 22).
- 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. 23).
- Evaluate the thickness of the flap using the soft tissue gauge. Always move the gauge sideways over the whole flap area in case of irregularities. (Fig. 24). Do not compress the flap, it should fit loosely in the soft tissue gauge to ensure correct thickness. 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, i.e., until it fits loosely in the soft tissue gauge. Try to achieve a uniform skin thickness over the whole flap area.







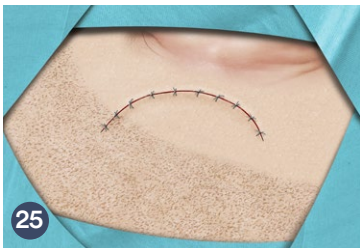


Note

When local anaesthesia 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. 25). 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. 26).



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 1

STEP 1 Prepare the site

Follow the procedure described in the one-stage surgery section on page 12, 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 page 12.

STEP 3 Drill with the Conical guide drill

Follow the procedure described in the one-stage surgery section on page 13.

STEP 4 Drill with the Widening drill

Follow the procedure described in the one-stage surgery section on page 14.

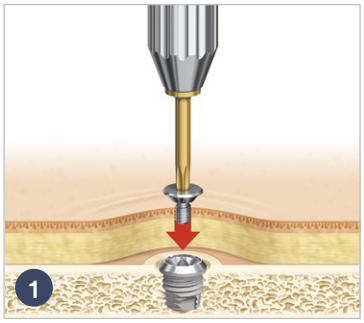
STEP 5 Place the implant

Follow the procedure described in the one-stage surgery section on page 15, 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.

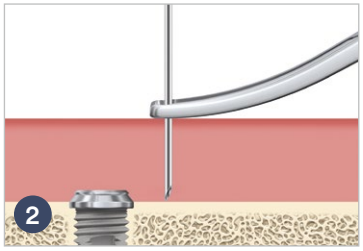
- Place and hand-tighten the cover screw using the screwdriver Unigrip 95 mm (Fig. 1).
- Suture down the periosteum with resorbable sutures over the implant.
- Suture the incision.
- Apply a suitable dressing.

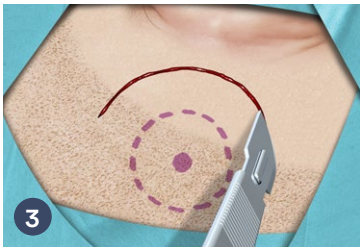


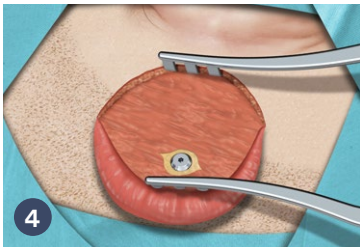
Two-stage surgery: Stage 2

STEP 1 Make the incision

- Locate the implant position.
- Before local anaesthesia is injected, measure the soft tissue thickness in three positions (anterior magnet edge, middle of magnet, posterior magnet edge). Ensure not to depress the tissue when measuring (Fig. 2). If the soft tissue is thicker than 6 mm, soft tissue reduction will be a must later in the procedure.
- 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).

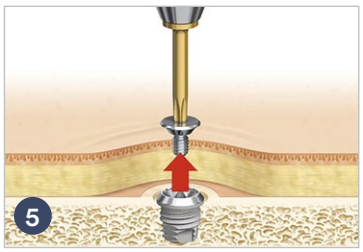






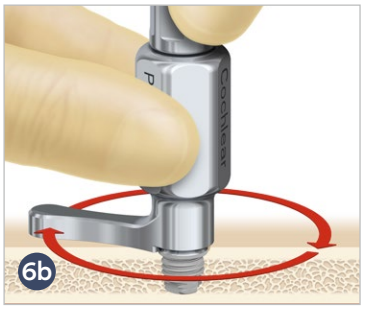
STEP 2 Remove the cover screw

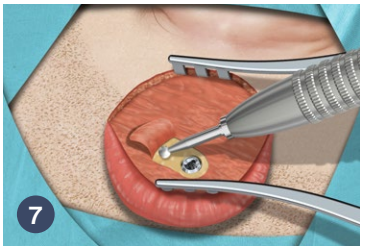
Remove the cover screw using the screwdriver Unigrip 95 mm (Fig. 5).

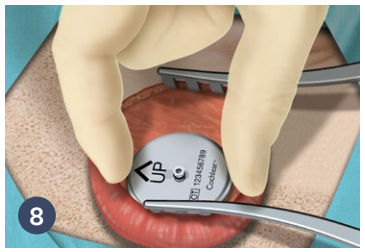


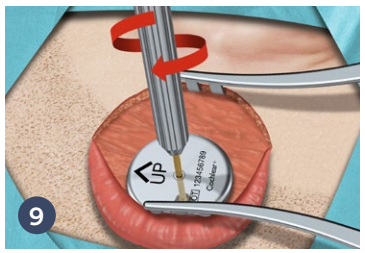
STEP 3 Attach the implant magnet

- 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 (Fig. 6a). Rotate it to ensure it does not touch the bone (Fig. 6b). This will allow sufficient clearance for the correct mounting of the Implant magnet. Turning the bone bed indicator counter clockwise may lead to that it loosens slightly from the implant.
- If the bone bed indicator only touches soft tissue, remove the tissue. 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 internal screw is protruding over the magnet surface before tightening the screw with the screwdriver (Fig. 8). This will ensure a proper connection.
- Make sure the arrow and the word “UP” on the implant magnet is oriented towards the top of the patient’s head, i.e. pointing in the superior direction (Fig. 9).
- Gently hand-tighten the screw with the Unigrip screwdriver, while holding the implant magnet with your fingers (Fig. 9).

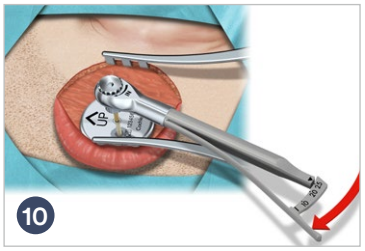


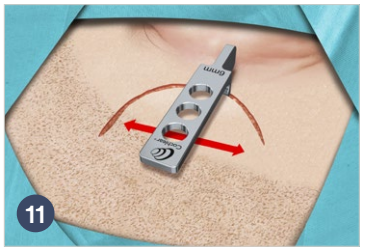






- Continue to tighten to 25 Ncm with the Machine screwdriver Unigrip and the Multi wrench with ISO adapter, while holding the magnet with your fingers (Fig. 10).
- Evaluate the thickness of the flap over the magnet using the Soft tissue gauge (Fig. 11). The skin flap should not be thicker than 6 mm and 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, i.e., until it fits loosely in the soft tissue gauge.





Note

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

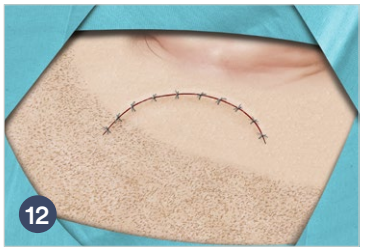
While polishing the bone, remove the bone bed indicator so it doesn't wobble around and is damaged by the high-speed drill bit.

When local anaesthesia 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).



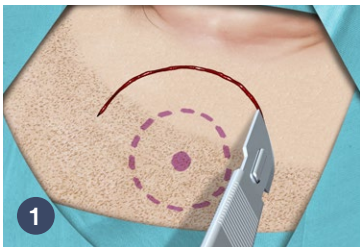
Note

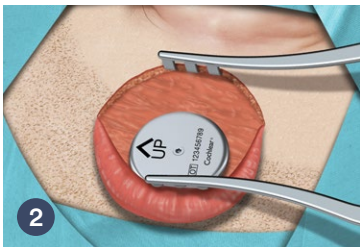
Do not remove the sutures before the incision is sufficiently healed.

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.





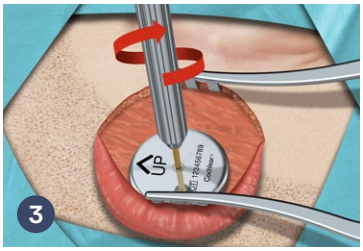
STEP 1 Make the incision

- Locate the implant magnet position.
- Inject local anaesthesia 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 (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

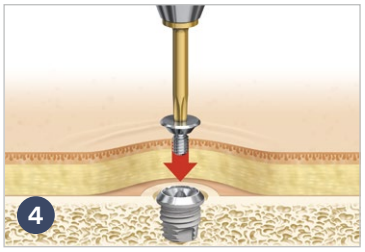
Do not make an incision over the implant magnet, if a new implant magnet will be inserted.

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 page 16 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 two on page 19. Always use a new implant magnet; the implant magnet cannot be re-sterilized. The implant magnet is only compatible with BI300 Implants (Fig 5).

OR

STEP 3c Place an 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 back out 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. Once the CSF leak is managed and controlled through medical principals, a BI300 Implant can be placed successfully in the existing site at the surgeon's discretion. The surgeon also has the option of locating another site for the BI300 Implant if they so choose.

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. The resulting artifacts are minor.

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. It 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 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 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.

Aftercare

Dressing guidelines

1 day post-op	5–7 days post-op	10–14 days post-op
1. If applicable, remove the mastoid dressing. 2. Leave the dressing in-situ. 3. Ensure that the patient does not allow any water to come in contact with the wound for 5–7 days after surgery.	1. Carefully remove the dressing. 2. Remove the sutures (if applicable). 3. Gently clean the wound with normal saline and gauze. 4. Gently remove any dried blood or debris. 5. Assess the wound site and treat accordingly. 6. If healed, no further dressing is required.	1. If necessary, repeat steps described in 5–7 days post op guidelines. 2. If the wound site has not healed, consult a wound care specialist.

Reusable instruments

The set-up below details the typical instruments needed for the Baha Attract surgical procedure. See the Baha Product Catalog for more information.

P1582203
Baha Indicator

91116
Drill indicator for WS-75 and Osscora

P1593725
Raspatorium / Probe

90381
Machine screwdriver Unigrip 25 mm

P1582230
Implant inserter

P1340904
Instrument case

Note

The Instrument Case includes a component tray/ampule holder.

90469
Screwdriver Unigrip 95 mm

C9866
Multi wrench with ISO adapter

Reusable Instruments

P1582203
Baha Indicator

94071
Implant Magnet template

P1578046
Bone bed indicator

95070
Soft tissue gauge 6 mm

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 catalog insert.

Notes

Notes

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 700,000 devices and helped people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

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

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.

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

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

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

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

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