

A BONE CONDUCTION HEARING SOLUTION

# Surgery Guide

Cochlear™ Baha® DermaLock™ Surgical Procedure



*Hear now. And always*



Cochlear®

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.

Cochlear accepts no responsibility for any adverse outcomes if 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.

## ●●● Acknowledgements

The protocol detailed in this manual originates from the clinical work carried out by:

Peter Weber, M.D., MBA, Medical Advisor, Cochlear Americas.

# Contents

Introduction	5
Preparations	6
FAST surgery	11
Two-stage surgery	17
Aftercare	24
Complications	26
References	29



**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.*

*FAST surgery is the same as one-stage surgery.*

*This guide is applicable for DermaLock™ Surgical Procedure using BIA400 Implants with Abutments, BI300 Implants and BA400 Abutments.*

*DermaLock Abutments is the same as BA400 Abutments.*

*Traditional Baha surgery with soft tissue removal is carried out using BA210 Abutments, BA300 Abutments or previous generation Baha abutments.*

*For more information, see Baha Surgery guide BI300 Implant system.*





# Introduction

Since 1977, the Cochlear™ Baha® Bone Conduction Implant has proven successful for thousands of patients worldwide. The system – which combines a small titanium implant, an abutment, and a sound processor – has yielded excellent results for certain patient groups, particularly for those individuals with conductive or mixed hearing loss, or single-sided sensorineural deafness.<sup>1</sup>

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.

Since the introduction, the surgical procedure for implantation has been modified by surgical teams worldwide to further improve the results and to shorten the surgery time.

The Cochlear Baha DermaLock Abutment has been designed to allow for a surgical technique with minimally invasive surgery with soft tissue preservation.

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

# Preparations

## ●●● Technique selection

### ●● FAST surgery vs. two-stage surgery

The surgeon will decide to use either the FAST 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. FAST surgery is performed in one stage, and the procedure involves placing an implant with a pre-mounted abutment. Generally, FAST 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).

### ●● Children

For children with bone thickness of 3-4 mm, factors such as patient age, developmental delay and bone quality may warrant the more conservative two-stage procedure. Children with cortical bone thickness > 4 mm could be considered for FAST surgery.

The timing of the second stage of surgery depends on the thickness and quality of the bone encountered at stage one. The poorer the bone quality, the longer the time between stage one and two. As age and bone thickness increase, 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 FAST surgery.

A key consideration for children with hearing loss is the importance of early auditory input to avoid compromising their language development. Since there is a slightly higher rate of implant loss in children,<sup>2,3</sup> placing a sleeper implant is recommended<sup>4</sup> in order to reduce the time between the potential loss of an implant and hearing being restored.

●●●

#### NOTE:

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

Bone thickness	FAST	Two-stage	Sleeper implants
< 3 mm		•	•
3-4 mm	±	•	•
> 4 mm	•		±

### ●● Table 2: Technique selection for children

FAST surgery
Selection criteria
Good bone quality and thickness > 3mm

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

## ●●● Treatment schedule

FAST surgery	
Place implant with abutment.	
Surgical follow-up	Time after surgery
Remove dressing and assess the wound site. If healed, no further dressing is required. Instruct patient or their family/caregivers on cleaning and aftercare. If not healed, place a new dressing and healing cap.	10-14 days
If necessary, repeat relevant steps as in the previous visit.	17-21 days
Fitting the sound processor	Time after surgery
Check and clean abutment.	12 weeks, given that the soft tissue is sufficiently healed
Fit the sound processor.	
Ensure patients' ability to handle sound processor.	
Follow up	
After the sound processor has been fitted, patients will return for audiological assessment. At this time the abutment 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 cover screw and place abutment.	
Surgical follow-up	Time after 2nd stage
Remove dressing and assess the wound site. If healed, no further dressing is required. Instruct patient or their family/caregivers on cleaning and aftercare. If not healed, place a new dressing and healing cap.	10-14 days
If necessary, repeat relevant steps as in the previous visit.	17-21 days
Fitting of the sound processor	Time after 2nd stage
Check and clean abutment.	Sound processor can be attached when wound healing has occurred.
Fit the sound processor.	
Ensure patients' ability to handle sound processor.	
Follow up	
Following the fitting of the sound processor, patients will return for audiological assessment. At this time the abutment and tissue will also be checked. Generally, patients will have annual or biannual check ups.	

## ●●● Selecting the implant site

Even though the surgeon will ultimately select the implant site, 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 site requires attention to the following factors and considerations:

- **Audiological factors.** In patients with a bilateral hearing loss, bilateral fitting is recommended. Studies show that the patient benefits from bilateral fitting in terms of greater stimulation level, better directional hearing and space perception as well as overall better speech understanding in noise.<sup>6</sup> In case of unilateral fitting, place the implant on the side with the best cochlea function (i.e. best bone conduction thresholds). For patients with single-sided sensorineural deafness, place the implant on the deaf side.
- **Physiological factors.** Incorrect implant placement too far from the cochlea can change the audiological outcome.<sup>7</sup> 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 (generally 60-65 mm from ear canal) for children who will undergo autogenous reconstruction.
- **Manual dexterity.** Ensure patients' (or families'/caregivers') ability to utilize controls as well as remove and replace the sound processor.
- **Driving habits.** Patients that regularly drive with a passenger seated next to or behind them usually prefer their implant on the side facing the passenger.
- **Telephone use.** Patients that frequently use the telephone prefer the implant on the side opposite to their "writing" hand.
- **Head gear.** Special consideration is warranted for patients who regularly wear a hat or helmet for work or certain activities (e.g. construction workers and cyclists). Patients that wear a hat or glasses should bring them to the surgical appointment.

## ●●● Preparations for surgery

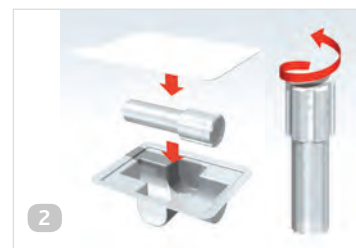
Prepare the patient as for any surgical procedure, i.e. sterilize the incision area. Local or general anaesthesia can be used for adult patients. When children undergo Baha surgery, general anaesthesia is most often used.

### ●●● **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 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 is only a container for the sterile product. Inside the plastic ampoule, a titanium casing holds the product (Fig. 2). The product should not be touched but rather picked up with the relevant instrument.*

*A set of all components should always be available because FAST surgery may change to two-stage surgery or a different implant or abutment size may be required. It is also recommended that one extra of each component is available in case a component is dropped.*





## ●●● DermaLock Abutments

The DermaLock Abutment is coated with a hydroxyapatite layer that is intended to be in contact with the tissue. The coating is applied up to 3 mm below the top surface (2 mm below the top surface on 6 mm abutments).

The abutment is available in five different heights (6 mm, 8 mm, 10 mm, 12 mm and 14 mm, measured from below the implant flange) to accommodate different skin thicknesses. The abutments are delivered pre-mounted on the BI300 implant (4 mm) and as separate articles, as listed below.

See Baha Product Catalogue Modules for all surgical products needed for Baha Connect System.

### ●● FAST surgery (4 mm)



93329  
BIA400

Implant 4 mm w  
Abutment 6 mm



93330  
BIA400

Implant 4 mm w  
Abutment 8 mm



93331  
BIA400

Implant 4 mm w  
Abutment 10 mm



93332  
BIA400

Implant 4 mm w  
Abutment 12 mm



93338  
BIA400

Implant 4 mm w  
Abutment 14 mm

### ●● Two-stage surgery



93333  
BA400

Abutment 6 mm



93334  
BA400

Abutment 8 mm



93335  
BA400

Abutment 10 mm



93336  
BA400

Abutment 12 mm



93337  
BA400

Abutment 14 mm





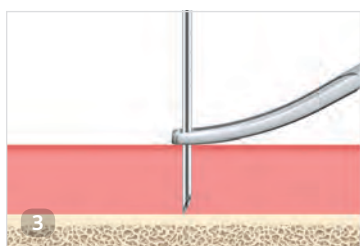
## FAST surgery

Generally, FAST surgery is recommended for patients with good bone quality and thickness. FAST surgery is performed in one stage, and the procedure involves placing an implant with a pre-mounted abutment.

This section provides step-by-step instructions for FAST surgery with no soft tissue reduction, also known as soft tissue preservation surgery.



# FAST Surgery



## ●●● STEP 1 Prepare the site

- Use the indicator for Baha to carefully mark the location of the planned implant site, generally 50–55 mm from the ear canal and with the indicator in line with the top of the pinna. Anatomical landmarks, such as the zygomatic line, are useful guides. Avoid the sound processor touching the pinna (Fig. 1).
- Mark the incision, generally 20–30 mm mm long, posterior to the pinna following the direction of the hairline (Fig. 2). The length of the incision may vary depending on the tissue thickness but should be sufficiently long to ensure visibility of the planned implant site. Mark the implant site 10 mm posterior to the incision line. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.
- Measure the tissue thickness. A thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler may be used (Fig. 3). Inject local anaesthesia. The amount of injection should be limited for minimal distortion of tissue thickness. If surgery is performed under general anaesthesia, 1-2 ml of local anaesthesia is generally sufficient.
- Select the appropriate abutment length based on the measured tissue thickness (table 3). The coating is applied up to 3 mm below the top surface (2 mm below the top surface on 6 mm abutments) (Fig. 4). The coating is intended to be in contact with the tissue. In a few patients, the coating may be slightly visible. This will not impact the outcome.

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

●● Table 3: Suggested abutment selection

●●●

**NOTE:**

*Ensure not to depress the tissue when measuring.*

*If in doubt when choosing between two abutment options, **choose the longer one.***

*If it is not possible to use a 14 mm abutment due to excessive tissue thickness, remove fat tissue to achieve a thickness of approximately 11 mm and 40x60 mm across.*

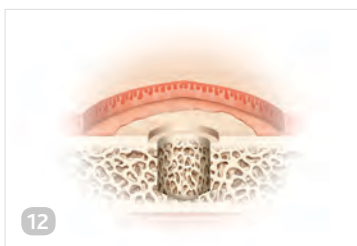
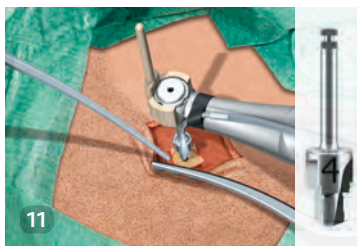
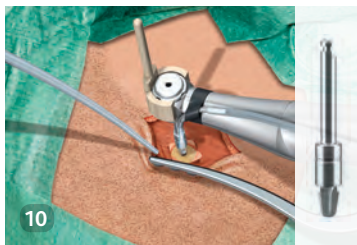
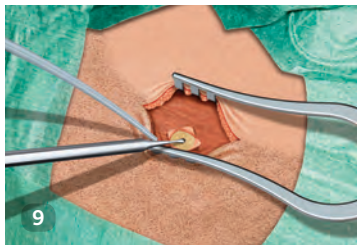
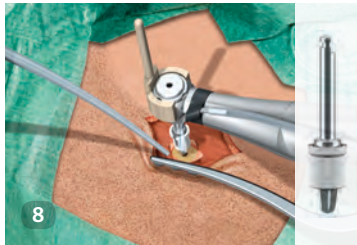
## ●●● STEP 2 Make the incision

- Use a scalpel to make an incision down to the periosteum (Fig. 5).
- Open up the incision to expose the periosteum using a self retaining retractor. Any other retractor may also be used. Make a cruciate incision (6 x 6 mm square) in the periosteum to expose enough bone for the implant flange and raise the edges with a raspatorium (Fig. 6).

●●●

**NOTE:**

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



### ●●● STEP 3 Drill with the guide drill

Be certain to drill at an angle perpendicular to the soft tissue and bone surface. 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 guide drill with 3 mm spacer (Fig. 8).
- 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 hole 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).

●●●

**NOTE:**

*The DermaLock Abutment is delivered pre-mounted on 4 mm implants. A 3 mm implant can be considered for FAST surgery when there is sufficient bone quality and thickness. In that case the abutment should be manually attached after having placed the implant (for more information about how to attach an abutment, see page 23).*

*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.*

### ●●● 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).
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill (Fig. 11).
- 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 hole larger than the actual drill size.
- Use the dissector to remove bone chips frequently from the drill flutes.
- 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.

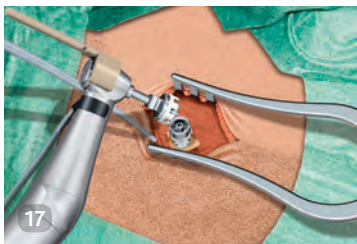
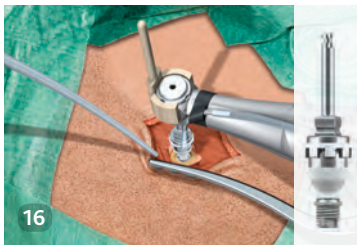
●●●

**NOTE:**

*Do not use the guide drill after the widening drill since the guide drill 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 or you risk losing initial implant stability.*

*In cases with uneven bone, it may not be possible to achieve a complete 360° countersink. It is better to avoid excessive countersinking.*



## ●●● STEP 5 Place the implant and abutment

- 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. If unsure about the bone quality, start the torque low and increase if needed.

Bone quality	Suggested Torque
Compact bone	40–50 Ncm

- 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 and the abutment using the abutment inserter (Fig. 15).
- Place the implant without irrigation until the first threads of the implant are well within the bone (two rotations). Irrigation at this time would result in cooling solution being compressed into the marrow spaces in the bone by the implant (Fig. 16).
- Once the implant is 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 handpiece to remove the abutment inserter from the abutment (Fig. 17).

### ●●● NOTE:

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

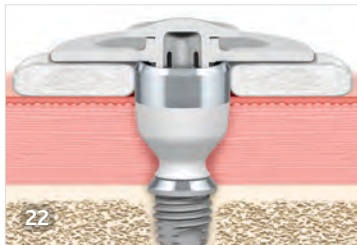
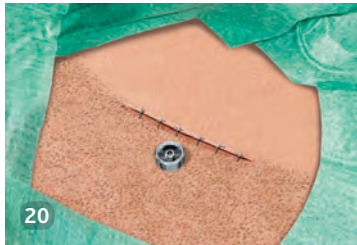
*When placing the implant in hard bone, slight pressure may need to be applied during the initial insertion.*

*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.*

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

*Be very careful not to loosen the implant through a lever arm effect. 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 abutment inserter. Rotate the whole multi wrench shaft clockwise (“IN” facing upwards) until the implant is fully seated (Fig. 18). The multi wrench is not intended to be used as a torque wrench for implant placement as the torque limit is 25 Ncm.*



## ●●● STEP 6 Close and suture

- Use a biopsy punch Ø 5 mm to punch a hole in the skin next to the incision. Take special care to place the punched hole exactly over the abutment. Failing to line up the abutment with the punched hole could create unwanted tension in the soft tissue. Carefully ease the skin over the abutment.
- Ensure that the skin edges do not create an unwanted pocket around the abutment.
- Suture the incision (Fig. 20). The sutures should stabilize both the skin and the underlying tissue during the healing.
- Ensure that the abutment is free of blood and clotted debris above the skin level.



### NOTE:

*Ensure that the hole is located directly over the abutment. Avoid stretching the skin and ensure that the sutures do not pull the skin in an unnatural way. Increased tension in the skin, and the resulting push/pull forces, could lead to discomfort around the abutment. This could also result in the formation of a gap between the abutment and the surrounding tissue. The gap could prevent good tissue integration with the DermaLock Abutment, resulting in a pocket formation around the abutment.*

## ●●● STEP 7 Attach the healing cap

- Apply a thin, low or non-adherent dressing and attach the healing cap with plug.
- Avoid using a thick dressing underneath the healing cap as this may cause unwanted compression of the soft tissue during healing. In order to obtain a good seal between the hydroxyapatite-coating and the full thickness of the surrounding tissue, a stress-free interface without tissue compression should be maintained at all times, especially during the healing phase (Fig. 22).
- The dressing should be kept in place during the healing period to protect the wound (Fig. 21).
- Remove the dressing, sutures and healing cap 10-14 days post-op. If not healed, apply a new dressing and a new healing cap.



### NOTE:

*If a silver dressing is used and if the coating of the abutment is protruding, the coated part of the abutment will be discolored by the silver in the dressing. This is not harmful to the abutment or tissue.*

*Avoid using ribbon gauze or take special care to avoid excessive packing and not generate downward pressure on the soft tissue (Fig. 23)*







## Two-stage surgery

Generally, two-stage surgery is recommended for patients with compromised or soft bone with a bone thickness < 3 mm. For children with bone thickness 3-4 mm, factors such as patient age, developmental delay and bone quality may warrant the more conservative two-stage procedure. The bone quality and thickness may also influence the length of the inter-stage interval and placement of a sleeper implant.

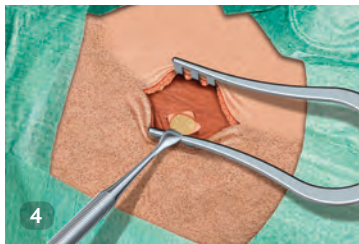
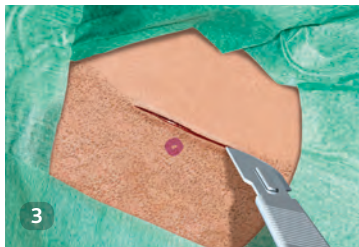
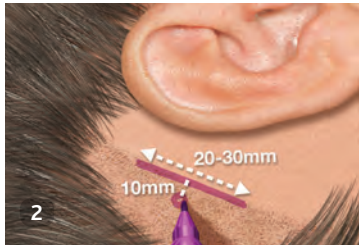
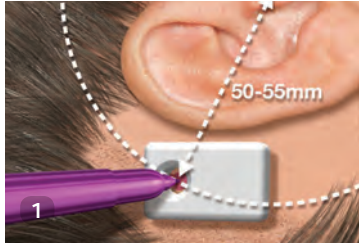
### ●●● When FAST surgery becomes a two-stage procedure

Disconnect the abutment from the implant by using the counter torque wrench and the screwdriver Unigrip. Place a cover screw into the implant at this time.

#### ●●● NOTE:

*This section illustrates two-stage surgery with a straight incision. However, a skin flap may also be used*

# Two-stage surgery: Stage I



## ●●● STEP 1 Prepare the site

- Use the indicator for Baha to carefully mark the location of the planned implant site, generally 50–55 mm from the ear canal and with the indicator in line with the top of the pinna. Anatomical landmarks, such as the zygomatic line are useful guides. Avoid the sound processor touching the pinna (Fig. 1).
- Mark the incision, generally 20–30 mm long, posterior to the pinna following the direction of the hairline (Fig. 2). The length of the incision may vary depending on the tissue thickness but should be sufficiently long to ensure visibility of the planned implant site. Mark the implant site 10 mm posterior to the incision line. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.

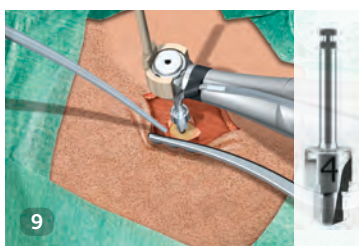
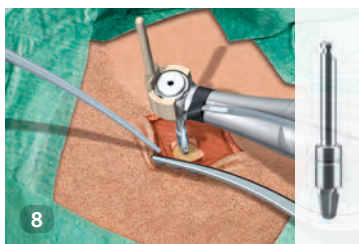
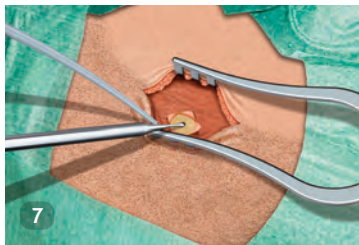
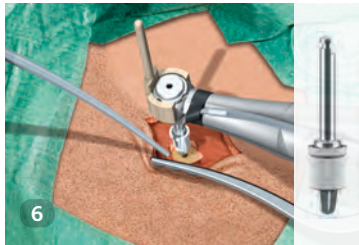
## ●●● STEP 2 Make the incision

- Use a scalpel to make an incision down to the periosteum (Fig. 3).
- Open up the incision to expose the periosteum using a self retaining retractor. Any other retractor may also be used.
- Make a cruciate incision (6 x 6 mm square) in the periosteum to expose enough bone for the implant flange and raise the edges with a raspatorium (Fig. 4).

●●●

### NOTE:

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



### ●●● STEP 3 Drill with the guide drill

Be certain to drill at an angle perpendicular to the soft tissue and bone surface. 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 Oscora surgical set) (Fig. 5).
- Begin drilling with the guide drill with 3 mm spacer (Fig. 6).
- 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 hole repeatedly for bone, both visually and with the dissector (Fig. 7).
- If there is adequate bone thickness, remove the white spacer on the guide drill and continue drilling to a depth of 4 mm (Fig. 8).

●●●

**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.*

### ●●● STEP 4 Drill with the widening drill

- Keep the drill unit on the high-speed setting, 2000 rpm with coolant (program 2 for the Oscora surgical set).
- Use either a 3 or 4 mm widening drill, depending on the depth reached with the guide drill (Fig. 9).
- 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 hole larger than the actual drill size.
- Use the dissector to remove bone chips frequently from the drill flutes.
- When reaching the bone surface, use the widening drill to create a small countersink in the bone (maximum 0.5 mm) (Fig. 10). 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. For patients with bone less than 3 mm, countersinking risks diminishing the bone available for osseointegration.

●●●

**NOTE:**

*Do not use the guide drill after the widening drill since the guide drill 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 or you risk losing initial implant stability.*

*In cases with uneven bone, it may not be possible to achieve a complete 360° countersink. It is better to avoid excessive countersinking.*

*For patients with bone <3 mm, countersinking risks diminishing the bone available for osseointegration.*



## ●●● STEP 5 Place the implant

- Set the drill to the torque setting (program Implant Installation for the Osscora surgical set) (Fig. 11).

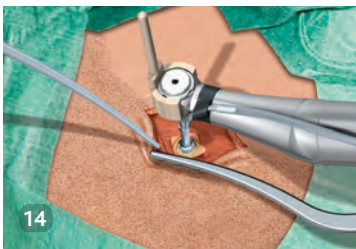
Bone quality	Suggested Torque
Compromised or soft bone	20–30 Ncm



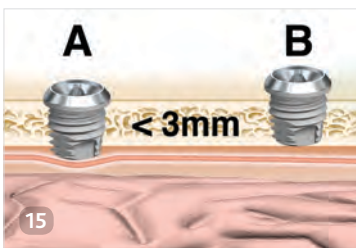
- Set the torque limit to suit the quality of the bone.
- Open the ampoule upright by unscrewing the lid so the bottom section can be placed in the holder on the tray (Fig. 12).



- Pick up the implant using the implant inserter. It is easier to fit the implant inserter in the implant if the drill motor is running. A click will indicate when the implant inserter is correctly positioned (Fig. 13).



- Place the implant without irrigation until the first threads of the implant are well within the bone (two rotations). Irrigation at this time would result in cooling solution being compressed into the marrow spaces in the bone by the implant (Fig. 14).



- Once the implant is 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 handpiece to remove the implant inserter from the implant.

●●●  
**NOTE:**

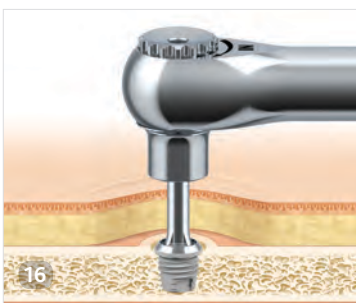
*The implant must not come in contact with anything other than the ampoule and implant inserter before being placed in the bone. The surface must be kept free from contamination for successful osseointegration.*

*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.*

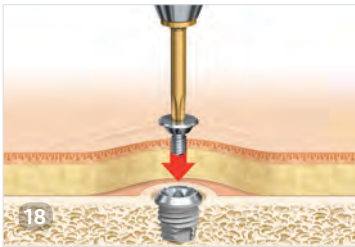
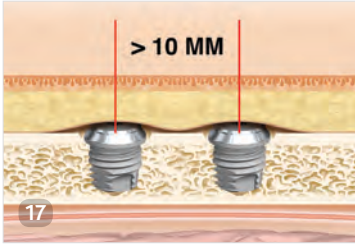
*If the drill stops prematurely – before the flange of the implant is seated in the countersunk bone – reverse one thread and increase the torque by 5 Ncm on the control panel of the drill system.*

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

*For patients with bone < 3 mm, countersinking risks diminishing the bone available for osseointegration. Instead place the implant flush with the calvarial surface even if it slightly abuts or depresses the dura mater (A). Alternatively, make an incomplete insertion and leave the implant protruding with bone chips, collected from the widening drill, placed under the flange (B) (Fig. 15).*



*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. 16). The multi wrench is not intended to be used as a torque wrench for implant placement as the torque limit is 25 Ncm.*



## ●● Placing a sleeper implant

- Since there is a slightly higher rate of implant loss in children,<sup>2,3</sup> placing a sleeper implant is recommended<sup>4</sup> in order to reduce the time between the potential loss of an implant and hearing being restored.
- Leave at least 10 mm between the centers of the two implants (Fig. 17). However, the thickness of the cortical bone must be considered. Insert a cover screw to protect the internal threads of the implant from tissue and bone overgrowth during the healing phase.



### NOTE:

*In cases of bilateral hearing loss, contralateral placement of a sleeper implant may also be considered.*

## ●●● 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 Unigrip screwdriver (Fig. 18).
- 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.
- Measure the tissue thickness. A thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler should be used (Fig. 3). Inject local anaesthesia. The amount of injection should be limited for minimal distortion of tissue thickness. If surgery is performed under general anaesthesia, 1-2 ml of local anaesthesia is generally sufficient.
- Select the appropriate abutment length based on the measured tissue thickness.

●●●

### NOTE:

*Ensure not to depress the tissue when measuring (Fig. 19, 20).*

*If in doubt when choosing between two abutment options, **choose the longer one.***

- The coating is intended to be in contact with the tissue. In some patients, the coating may be slightly visible. This will not impact the outcome.
- The coating is applied up to 3 mm below the top surface (2 mm below the top surface on 6 mm abutments) (Fig. 20).

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

●●●

### NOTE:

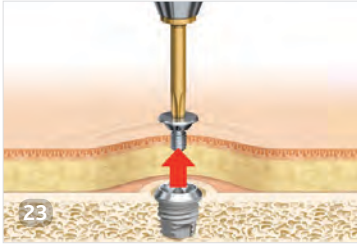
*If it is not possible to use a 14 mm abutment due to excessive soft tissue thickness, remove fat tissue to achieve a thickness of approximately 11 mm and 40x60 mm across.*

- Make an incision in the same incision line as in Stage 1 (Fig. 21).
- Open up the incision to expose the periosteum using a self retaining retractor (Fig. 22). Any other retractor may also be used.

●●●

### NOTE:

*If the implant is felt through the tissue, it may be possible to attach the abutment without incising the tissue. Use a biopsy punch 5 mm to punch a whole in the skin exactly over the implant, remove the cover screw, and attach the abutment.*



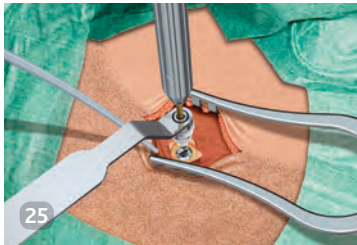
## ●●● STEP 2 Remove the cover screw

- Remove the cover screw using the Unigrip screwdriver (Fig. 23).



## ●●● STEP 3 Connect the abutment

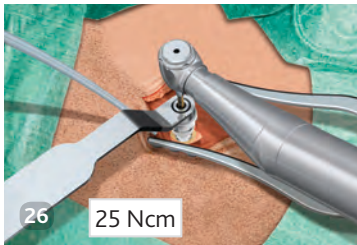
- Pick up the abutment with the counter torque wrench and place it into the implant (Fig. 24).
- Ensure the tri-lobe connection is locked together and then gently pre-tighten the abutment screw with the Unigrip screwdriver (Fig. 25).
- Set the drill to the torque setting (program Implant Installation for the Osscora surgical set) and set the torque limit to 25 Ncm.
- Finalize the tightening of the abutment screw to 25 Ncm with the machine Unigrip screwdriver and the counter torque wrench (Fig. 26).
- For manual tightening, tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards), with the machine Unigrip screwdriver (Fig. 27).

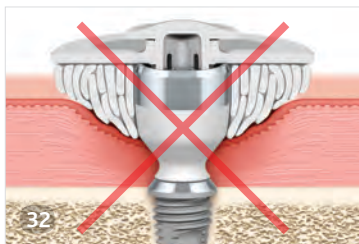
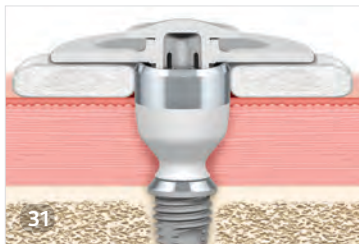
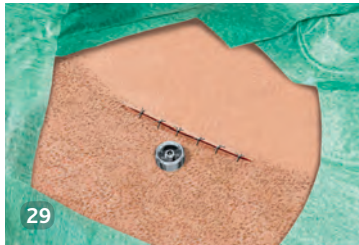


●●●

### NOTE:

*The counter torque wrench should always be used to avoid rotational forces on the implant.*





## ●●● STEP 4 Close and suture

- Use a biopsy punch Ø 5 mm to punch a hole in the skin next to the incision. Take special care to place the punched hole exactly over the abutment. Failing to line up the abutment with the punched hole could create unwanted tension in the soft tissue.
- Ensure that the skin edges do not create an unwanted pocket around the abutment.
- Suture the incision (Fig. 29). The sutures should stabilize both the skin and the underlying tissue during the healing.

●●●

### NOTE:

*Ensure that the hole is located directly over the abutment. Avoid stretching the skin and ensure that the sutures do not pull the skin in an unnatural way. Increased tension in the skin, and the resulting push/ pull forces, could lead to discomfort around the abutment. This could also result in the formation of a gap between the abutment and the surrounding tissue. The gap could prevent good tissue integration with the DermaLock Abutment, resulting in a pocket formation around the abutment.*

- Ensure that the abutment is free of blood and clotted debris above the skin level.
- Apply a thin, low or non-adherent dressing and attach a healing cap with plug.
- Avoid using a thick dressing underneath the healing cap as this may cause unwanted compression of the soft tissue during healing. In order to obtain a good seal between the hydroxyapatite-coating and the full thickness of the surrounding tissue, a stress-free interface without tissue compression should be maintained at all times, especially during the healing phase (Fig. 31).
- The dressing should be kept in place during the healing period to protect the wound (Fig. 30).
- Remove the dressing, sutures and healing cap 10-14 days post-op. If not healed, apply a new dressing and a new healing cap.

●●●

### NOTE:

*If a silver dressing is used and if the coating of the abutment is protruding, the coated part of the abutment will be discolored by the silver in the dressing. This is not harmful to the abutment or tissue.*

*Avoid using ribbon gauze or take special care to avoid excessive packing and not generate downward pressure on the soft tissue (Fig. 32)*



# Aftercare

## ●●● Dressing guidelines

1 day post-op	10-14 days post-op	17-21 days post-op
<ol style="list-style-type: none"> <li>1. Remove the mastoid dressing.</li> <li>2. Leave the dressing and healing cap in situ.</li> <li>3. Ensure that the patient does not allow any water to come in contact with the site before complete healing of the wound.</li> </ol>	<ol style="list-style-type: none"> <li>1. Remove and discard the healing cap.</li> <li>2. Carefully remove the dressing.</li> <li>3. Remove the sutures (if applicable).</li> <li>4. Gently clean the wound with normal saline and gauze.</li> <li>5. Gently remove any dried blood or debris.</li> <li>6. Assess the wound site and treat accordingly.</li> <li>7. If healed, no further dressing is required.</li> <li>8. Provide the patient with aftercare instructions and emphasize the importance of daily cleaning. For the first few weeks, a skin-friendly shampoo should be used.</li> </ol>	<ol style="list-style-type: none"> <li>1. If necessary, repeat relevant steps as in the previous visit.</li> <li>2. If the wound site has not healed consult a wound care specialist.</li> </ol>

●●●

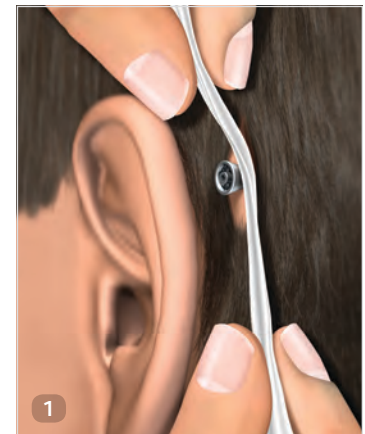
### NOTE:

*Avoid using a thick dressing underneath the healing cap as this may cause unwanted compression of the soft tissue during healing. In order to obtain a good seal between the hydroxyapatite-coating and the full thickness of the surrounding tissue, a stress-free interface without tissue compression should be maintained during the healing phase and at all times.*

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

## ●●● Patient aftercare instructions

- Good hygiene is critical to maintaining normal usage of the Baha sound processors. Patients who are unable to clean the skin around the abutment need help from their family or caregivers. The cleaning should, independent on the method selected, be light.
- Start daily cleaning with an alcohol-free wet wipe after dressing removal. Be careful not to interfere with the tissue integration during the healing phase (Fig 1).
- After the initial healing phase (up to 12 weeks), continue to clean once a day with an alcohol-free wet wipe. Mild soap and warm water may also be used.
- After the wound has healed, half yearly or yearly checkups at the outpatient clinic are recommended.
- For detailed cleaning instructions, please refer to patient user manuals or Baha Support App.
- In case of infection, the patient's cleaning routine should be assessed.



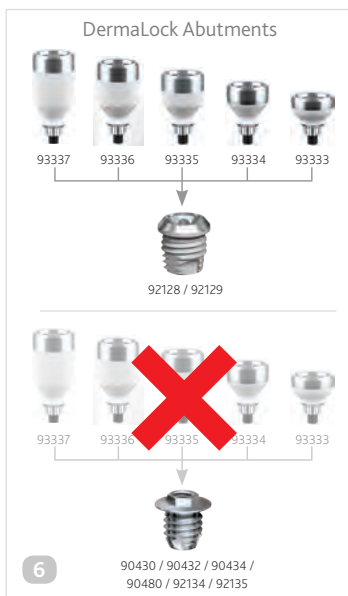
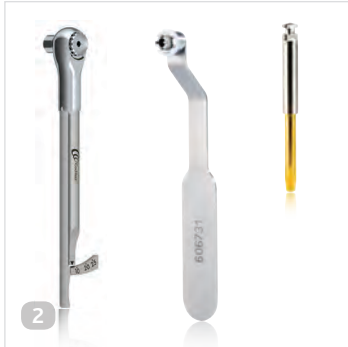
●●●

### NOTE:

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

*The abutment cleaning brush is not recommended for daily cleaning of the DermaLock Abutment. If you use a soft cleaning brush, remember to to always rinse it in mild soap and warm water and let it air dry. Change the brush every three months, or if you have had an infection.*

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



## ●●● Adjusting the abutment

Occasionally the abutment may need to be tightened or replaced. The multi wrench with ISO adapter, the machine Unigrip screwdriver and the counter torque wrench are required (Fig. 2). Insert the ISO adapter in the multi wrench and then insert the machine Unigrip screwdriver in the ISO adapter (Fig. 3).

The counter torque wrench should always be used to avoid rotational forces on the implant.

### ●● Tighten the abutment

- Tighten the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with machine Unigrip screwdriver (Fig. 5).

### ●● Replacing the abutment

- If healing is complete at the time of removal, the patient's tissue will have integrated with the abutment. To help break this integration, gently pull away the tissue from the abutment. In most cases, this is a painless and uneventful procedure that can be performed in an out-patient clinic room without the need for anaesthesia.
- In case of tissue overgrowth, either topical anaesthetic cream or local anaesthesia may be appropriate. If needed, use a biopsy punch  $\varnothing$  5 mm to punch a hole in the skin.
- Loosen the abutment screw using the multi wrench ("OUT" facing upwards) with the machine Unigrip screwdriver. Remove the abutment from the implant. If the abutment is difficult to remove, gently rock the counter torque wrench side to side to loosen the abutment.
- Clean the skin thoroughly. If needed, allow the area to heal before placing a new abutment. A cover screw can be used to cover the implant during healing. If the wound has healed, use a biopsy punch  $\varnothing$  5 mm to create a fresh wound in the skin.
- Pick up the new abutment with the counter torque wrench (Fig. 4) and place it into the implant (Fig. 4).
- Ensure the tri-lobe connection is locked together and then gently pre-tighten the abutment screw with the Unigrip screwdriver.
- Finalize the tightening of the abutment screw to 25 Ncm using the multi wrench ("IN" facing upwards) with machine Unigrip screwdriver (Fig. 5).

●●●

#### NOTE:

*The DermaLock Abutments are only compatible with B1300 Implants (Fig. 6).*

*For patients with 200 series and older implants, 5.5 mm and 8.5 mm replacement abutments are available. Contact your local Cochlear office for details.*

# Complications

The success rate for Baha® surgery is very high. However, unexpected situations, both intra-operatively and postoperatively, may occur. 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.

The regulation of medical devices requires the manufacturer to report adverse events to the appropriate authority. Should such an incident occur, notify your local Cochlear office or its official distributor as soon as possible.

## ●●● Complications during surgery

### ●● Implant becomes stuck during insertion

This can occur if the implant alignment is incorrect. Set the drill unit to reverse mode. Then unscrew the implant. Find 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 site.

### ●● Implant continues to rotate when seated

This may occur when drilling in compromised and soft bone, and when the torque is set too high in relation to the quality of the bone. Prepare a new implant site at least 5 mm from the first site and then place the implant with a 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 bone wax. Any remaining open holes should also be sealed and if appropriate, prophylactic antibiotic treatment is recommended. Then choose a new implant site at least 5 mm from the original site (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 or MRI can be used to verify the diagnosis. Treat this condition according to general practice.

## ●●● Postoperative soft tissue complications

### ●● Inflammation and infection around the abutment

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

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

If further treatment is needed, oral antibiotic and/or a steroid injection<sup>11</sup> to the site might be considered.

### ●● Persistent soft tissue complications

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

There are cases when transitioning from the Baha Connect System to the Baha Attract System may provide patient benefits. Such cases may include persisting skin reactions at the implant site that preclude the use of the abutment system. It may also include cases where patient lifestyle indicates that the Baha Attract System will be a more suitable option. Good outcomes can be achieved if pre-operative assessment and surgery is managed carefully.<sup>7-9</sup>

### ●● Skin overgrowth

In some patients (predominantly male teenagers) an inflammatory reaction may occur and result in soft tissue thickening or complete overgrowth of the abutment by soft tissue. Treatment with a longer abutment, topical steroid cream or a steroid injection may be considered.<sup>10, 11</sup>

### ●● Keloids

In the case of keloids that do not subside over time, an injection with Kenalog might be considered. Another option is to place a silicone disc<sup>12</sup> over the keloid and keep pressure on the silicone disc for 7-10 days.

### ●● Postoperative numbness - Paresthesia

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

## ●●● 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. If removal of the implant is needed, manually unscrew the implant using the implant inserter and multi wrench ("OUT" facing outwards). If manual removal is not possible, remove the implant by drilling away the bone with the guide drill.

### ●● Bony overgrowth

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

### ●● Pain

If the patient experiences pain when touching the abutment, the risk of implant loss increases significantly. In most cases, the loose implant can be removed and another placed in adjacent bone. In others, the implant must be removed and the defect then carefully curetted and filled with blood coagulates. In most cases adjacent bone is available and suitable for the placement of another implant. If the patient experiences pain even without touching the abutment, removal of the abutment and implant may be considered.<sup>13</sup>

### ●● Bone infection leading to osteonecrosis

This is seen almost exclusively in patients with previously irradiated implant sites. It may be avoided by administering hyperbaric oxygen (HBO) before and after surgery and by striving for minimal tissue damage during surgery.<sup>14</sup>

## ●●● Special Considerations

### ●● MRI and magnetic fields

Be certain to caution patients about procedures that could be harmful to the sound processor, such as MRI and any other involving magnetic fields. Always remove the sound processor before an MRI procedure. The implant itself and the abutment are considered MR Conditional and can be safely scanned within defined conditions at 1.5 and 3.0 Tesla. For more information, refer to the MRI information supplied with the product.<sup>15,16</sup>

### ●● Radiation therapy

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

### ●● Sporting activities

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

# 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; 195:2-12.
2. de Wolf MJ, Hol MK, Huygen PL, Mylanus EA, Cremers CW. Nijmegen results with application of a bone-anchored hearing aid in children:simplified surgical technique. *Ann Otol Rhinol Laryngol.* 2008;117(11):805-14.
3. McDermott AL, Williams J, Kuo M, Reid A, Proops D. The Birmingham pediatric bone-anchored hearing aid program: a 15 year experience. *Otol Neurotol.* 2009; 30(2):178-83.
4. Durvasula VS, Patel H, Mahendran S, Gray RF. Bone anchored hearing aids: a second fixture reduces auditory deprivation in Cambridge. *Eur Arch Otorhinolaryngol.* 2007; 264(9):991-4.
5. Priwin C, Stenfelt S, Granström G, Tjellström A, Håkansson B. Bilateral bone-anchored hearing aids (BAHAs): an audiometric evaluation. *Laryngoscope* 2004;114(1):77-84.
6. 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; 47(12):761-9.
7. Wigren S, Weber P. Clinical guidance and considerations for successful outcomes with the Cochlear Baha Attract System. Cochlear Bone Anchored Solutions AB, E83356, 2015.
8. Wigren S. Considerations for transitioning from Baha Connect System to Baha Attract System. Cochlear Bone Anchored Solutions AB, E83345, 2014
9. Cristobal R. Cochlear Baha Connect to Baha Attract System Transition Surgery. Cochlear Bone Anchored Solutions AB E83358, 2014
10. Falcone MT, Kaylie DM, Labadie RF, Haynes DS. Bone-anchored hearing aid abutment skin overgrowth reduction with clobetasol. *Otolaryngol Head Neck Surg.* 2008;139(6):829-32.
11. Ghossaini SN, Spitzer JB. Local steroid injections in the management of skin growth over the abutment in Baha patients. *Otolaryngol Head Neck Surg.* 2009;141(4):530-2.
12. Wiseman S, Tapia G, Schaaf N, Sullivan M, Loree T. Utilization of a plastic "washer" to prevent auricular prosthesis abutment overgrowth: report of a case and description of a technique. *Int J Oral Maxillofac Implants.* 2001;16(6):880-82.
13. Granström G, Tjellström A, Brånemark PI. Osseointegrated implants in irradiated bone: a case controlled study using adjunctive hyperbaric oxygen therapy. *J Oral Maxillofac Surg.* 1999; 57(5):493-9.
14. Fritsch MH, Naumann IC, Mosier, KM. BAHA devices and magnetic resonance imaging scanners. *Otol Neurotol.* 2008;29(8):1095-9.
15. Arndt S, Kromeier J, Berlis A, Maier W, Laszig R, Aschendorff A. Imaging procedures after bone-anchored hearing aid implantation. *Laryngoscope.* 2007;117(10):1815-8.
16. Siau D, Nik H, Hobson JC, Roper AJ, Rothera MP, Green KM. Bone-anchored hearing aids and chronic pain: a long-term complication and a cause for elective implant removal. *J Laryngol Otol.* 2012;126(5):445-9.

Products in this manual are protected by the following patents: US 5 735 790, US 5 935 170, EP 0715839, EP 0715838, US 07074222, WO 02/09622, US 7409070, EB 01633284, US 27009853, WO 04105650 , US 2010249784 (A1) and corresponding patents in other countries and pending patent applications. All products can be subject to change without notice. No part of this publication may be replaced, stored in a retrieval system, or transmitted, in any form by means, electronic, mechanical, photocopying, recording or otherwise, without the prior written permission of the publisher.



# Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people with moderate to profound hearing loss. We have helped over 400,000 people of all ages live full and active lives by reconnecting them with family, friends and community.

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

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

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

[www.Cochlear.com/US](http://www.Cochlear.com/US)

Follow us on   

## Cochlear Americas

13059 East Peakview Avenue  
Centennial, CO 80111 USA  
Telephone: 1 303 790 9010  
Support: 1 800 483 3123

## Cochlear Canada Inc.

2500-120 Adelaide Street West  
Toronto, ON M5H 1T1 Canada  
Telephone: 1 416 972 5082  
Fax: 1 416 972 5083

©Cochlear Limited 2015. All rights reserved. Hear now. And always and other trademarks and registered trademarks are the property of Cochlear Limited or Cochlear Bone Anchored Solutions AB. The names of actual companies and products mentioned herein may be the trademarks of their respective owners.



BUN128 ISS4 NOV15

