FOR PROFESSIONALS

Cochlear®
Hear now. And always

Surgery guide

Cochlear™ Baha® DermaLock™ Surgical Procedure

A bone conduction hearing solution

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 when required.

Cochlear accepts no responsibility for 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:

Brian Kaplan, Global Head of Clinical Innovation, Cochlear Americas

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.

FAST surgery is the same as one-stage surgery.

This guide is applicable for the DermaLock™ surgical procedure using BIA400 Implants with Abutments, BI300 Implants and BA400 Abutments. DermaLock Abutments are 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 Cochlear Baha Connect System (300 series) surgery guide.

Introduction

Since 1977, the Cochlear™ Baha® System 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.[1]

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

Baha 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, patients with special needs (e.g. patients with mental or physical disabilities) 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 interstage interval.

When children undergo Baha surgery, general anesthesia is often used. When selecting the surgical technique, the potential to avoid a second anesthetic should be evaluated against the safety profile for 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,[2,3] placing a sleeper implant is recommended[4] 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.

Table 1: Technique selection

Baha FAST surgery	Baha two-stage surgery	
Selection criteria	**Selection criteria**	
Good bone quality and thickness > 3 mm	Compromised or soft bone Irradiated bone Bone thickness < 3 mm	In conjunction with other surgery (e.g. acoustic neuroma removal)

Table 2: Technique selection for children

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

● Recommended

± Sleeper or FAST may still be considered/utilized

Treatment schedule

Baha FAST surgery	
Place implant with abutment.	
Surgical follow-up	**Time after surgery**
Remove healing cap and dressing and gently clean area. If healed, sutures can be removed. Instruct patient or their family/caregivers on cleaning and aftercare.	5–7 days
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 surgery**
Check and clean abutment.	12 weeks, given that the soft tissue is sufficiently healed
Fit the sound processor.	
Ensure patient's 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 checkups.	

Baha 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 second stage**
Remove healing cap and dressing and gently clean area. If an incision has been made and it is healed, sutures can be removed. Instruct patient or family/ caregivers on cleaning and aftercare.	5–7 days
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 second stage**
Check and clean abutment.	Sound processor can be attached at 12 weeks.
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 checkups.	

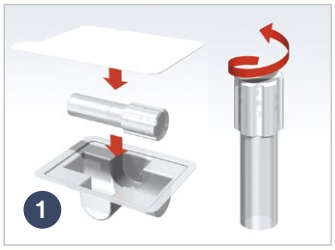
Selecting the implant site

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.** For patients with mixed and conductive hearing loss, place the implant on the side with the best cochlear function (i.e. best bone conduction thresholds). For patients with single-sided sensorineural deafness, place the implant on the deaf side. In patients with a bilateral conductive 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.
- **Physiological factors.** Incorrect implant placement too far from the cochlea can change the audiological outcome.[6] 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.** Educate patient and family/caregiver on usage of sound processor controls and consider their ability to 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/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 anesthesia can be used for adult patients. When children undergo Baha surgery, general anesthesia is most often used.



Note

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

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. 1). 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 the event a component is dropped.

DermaLock abutments

The DermaLock Abutment is coated with a hydroxyapatite (HA) layer that is intended to be in contact with the soft tissue. The coating is applied 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) or as separate articles, as listed below.

See the Baha Product Catalog for all surgical products needed for the Baha Connect System.

FAST surgery

93329
BIA400
Implant 4 mm with Abutment 6 mm

93330
BIA400
Implant 4 mm with Abutment 8 mm

93331
BIA400
Implant 4 mm with Abutment 10 mm

93332
BIA400
Implant 4 mm with Abutment 12 mm

93338
BIA400
Implant 4 mm with 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

Typical set-up for Baha surgery

Sterile products

Note

The set-up below details the typical products needed for the most common types of Baha surgery. See Baha Product catalog for more information.

FAST surgery:

93363
Conical guide drill 3+4 mm

or

92140
Widening drill 3 mm with countersink

92141
Widening drill 4 mm with countersink

P806653
Indicator for Baha 5 SuperPower, Baha Connect System

or

or

or

or

93329
BIA400 Implant 4 mm with Abutment 6 mm

93330
BIA400 Implant 4 mm with Abutment 8 mm

93331
BIA400 Implant 4 mm with Abutment 10 mm

93332
BIA400 Implant 4 mm with Abutment 12 mm

93338
BIA400 Implant 4 mm with Abutment 14 mm

Y00022
Biopsy punch Ø 5 mm

or

95083
Healing cap with plug Ø 20 mm

95084
Healing cap with plug Ø 30 mm

Two-stage surgery:

Stage 1

93363
Conical guide drill 3+4 mm

or

92140
Widening drill 3 mm with countersink

92141
Widening drill 4 mm with countersink

or

92129
BI300 implant 4 mm

92128
BI300 implant 3 mm

92136
Cover screw conical

Stage 2

or

or

or

or

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

Y00022
Biopsy punch Ø 5 mm

or

95083
Healing cap with plug Ø 20 mm

95084
Healing cap with plug Ø 30 mm

P806653
Indicator for Baha 5 SuperPower, Baha Connect System

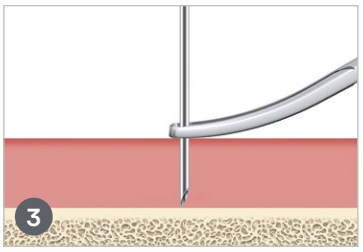
FAST surgery

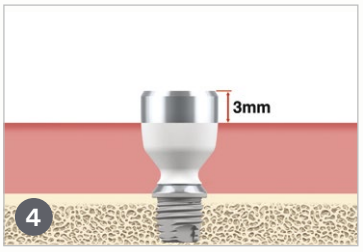
Generally, FAST surgery is recommended for patients with good bone quality and thickness. FAST surgery is performed in one stage, and the procedure involves placing an implant with a pre-mounted abutment.

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

STEP 1 Prepare the site

- Use the Baha Indicator 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). It is recommended to place the incision line 10 mm anterior to the previously marked implant site. 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 bone with the location of the implant site. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.
- Measure the tissue thickness. A thin (27 gauge/0.4 mm) hypodermic needle, a clamp and a ruler may be used (Fig. 3). Inject local anesthesia. The amount of injection should be limited for minimal distortion of tissue thickness. If surgery is performed under general anesthesia, 1–2 ml of local anesthesia is generally sufficient.
- Select the appropriate abutment length based on the measured tissue thickness (table 3). The DermaLock hydroxyapatite (HA) coating is applied 3 mm below the top surface (2 mm below the top surface on 6 mm abutments) (Fig. 4). The HA coating is intended to be in contact with the tissue. In a few patients, the HA coating may be slightly visible. This will not impact the outcome.





Note

Ensure not to depress the tissue when measuring.

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

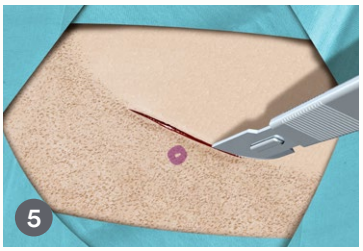
If it is not possible to use a 14 mm abutment due to excessive tissue thickness, remove fat tissue to achieve a thickness of approximately 11 mm and 40 x 60 mm across.

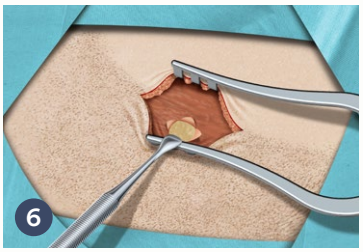
Approximate tissue thickness (mm)	Abutment length (mm)
3 or less	6
4–5	8
6–7	10
8–9	12
10–11	14
12 or more	14 with soft tissue thinning

Table 3: Suggested abutment selection

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 using the broader end of the Raspatorium/Probe, exposing enough bone for the implant flange and countersink (Fig. 6).





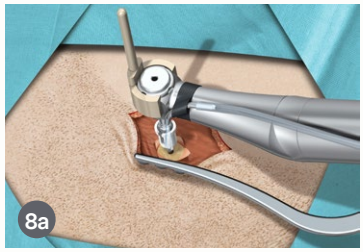
Note

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

STEP 3 Drill with the Conical 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.

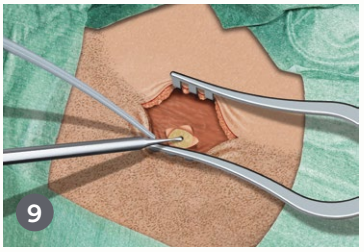
- Set the drill unit to the high-speed setting, 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 7).
- Begin drilling with the Conical guide drill with 3 mm spacer (Fig. 8a, 8b).
- While drilling, move the burr up and down to ensure visual inspection and that coolant reaches the tip 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).

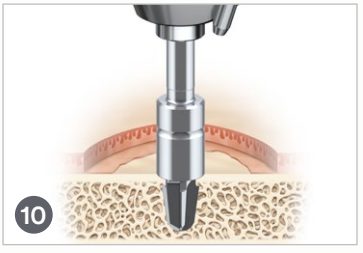


Note

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 32).

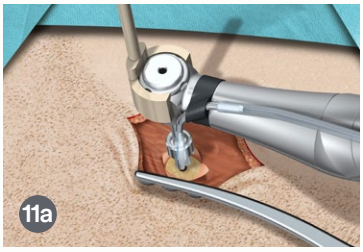
Observe the quality and quantity of the cortical bone and spongiosa air cells during initial penetration. Proceed with care to avoid penetrating the wall of the sigmoid sinus or damaging the dura mater.





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. 11a, 11b).
- 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 the narrow end of the Raspatorium/Probe 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 (approximately 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 Conical guide drill after the Widening drill since the Conical 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 site.

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
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. 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 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. If the same issue occurs again, select a new implant site at least 5 mm from the first site and place it perpendicular to the bone.

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 and continue to implant at this increased torque.

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 needing more than 25 Ncm torque, as that is the torque limit of the wrench.

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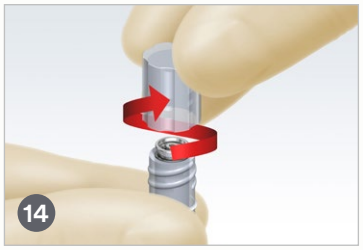
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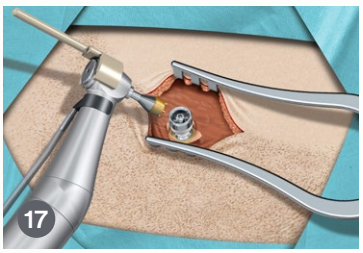
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18

STEP 6 Close and suture

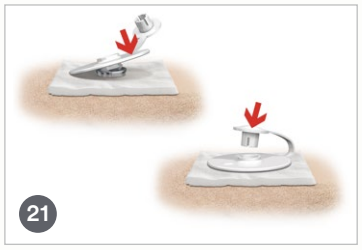
- Use a biopsy punch Ø 5 mm to punch a hole in the skin directly over the abutment (Fig.19). Take special care to place the punched hole exactly over the abutment. Failing to line up the abutment with the punched hole could create unwanted tension in the soft tissue. Carefully ease the skin over the 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.

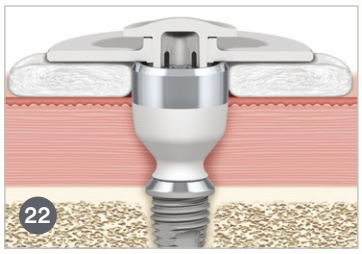
Note

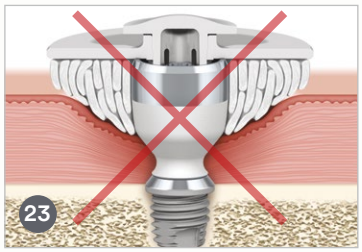
Ensure that the hole is located directly over the abutment. Avoid stretching the skin and ensure that the sutures do not pull the skin in an unnatural way. Increased tension in the skin, and the resulting push/pull forces, could lead to discomfort around the abutment. This could also result in the formation 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 (Fig. 21).
- 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, 23).
- The dressing should be kept in place during the healing period to protect the wound.
- 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).

* If using Allevyn Non-Adhesive wound care dressing (provided in the surgical kit) it is recommended to change the dressing if needed or up to 7 days of application.

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 Unigrip screwdriver. Place a cover screw into the implant at this time.

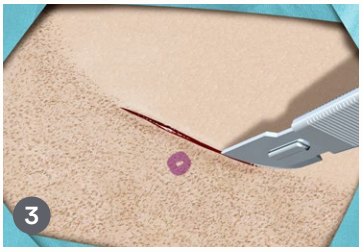
Two-stage surgery: Stage 1

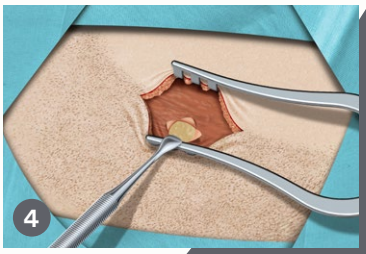
This section illustrates two-stage surgery with a straight incision. However, a skin flap may also be used.

STEP 1 Prepare the site

- Use the Baha Indicator 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). It is recommended to place the incision line 10 mm anterior to the previously marked implant site. 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 bone with the location of the implant site. Some methylene blue may be applied on a needle to mark the bone to facilitate identification of implant site after opening the incision.

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 using the broader end of the Raspatorium/Probe, exposing enough bone for the implant flange and countersink. (Fig. 4).

Note

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

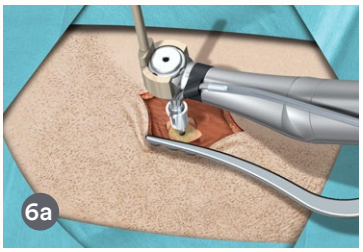
STEP 3 Drill with the Conical guide drill

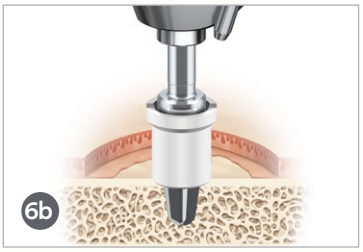
Be certain to drill at an angle perpendicular to the soft tissue and bone surface. The Drill indicator facilitates correct drill orientation and should be used during drilling and implant placement.

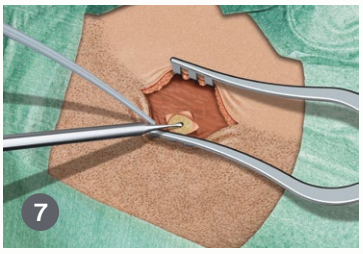
- Set the drill unit to the high-speed setting, 2000 rpm with coolant (program 2 for the Osscora surgical set) (Fig. 5).
- Begin drilling with the Conical guide drill with 3 mm spacer (Fig. 6a, 6b).
- While drilling, move the burr up and down to ensure visual inspection and that coolant reaches the tip 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 the narrow end of the Raspatorium/Probe (Fig. 7).
- If there is adequate bone thickness, remove the white spacer on the Conical guide drill and continue drilling as appropriate to accommodate the required BI300 Implant. (Fig. 8).

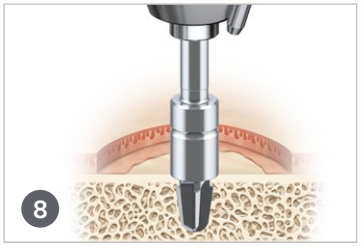
Note

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.



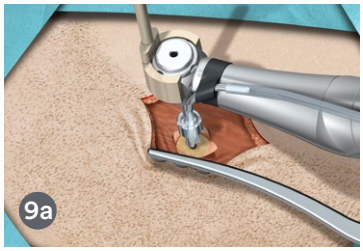


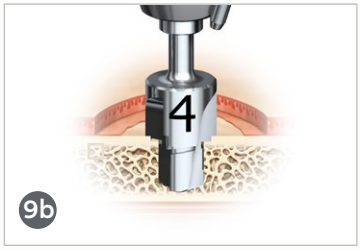




STEP 4 Drill with the Widening drill

- Keep the drill unit on the high-speed setting, 2000 rpm with coolant (program 2 for the Osscora surgical set).
- Use either a 3 or 4 mm Widening drill, depending on the depth reached with the guide drill (Fig. 9a, 9b).
- 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 the narrow end of the Raspatorium/Probe 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 (approximately 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 Conical guide drill after the widening drill since the Conical 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 site.

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
Compact bone	40–50 Ncm
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. (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.

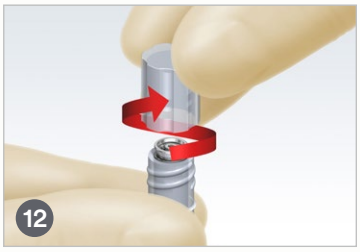
If the implant enters the site incorrectly, put the drill in reverse and unscrew the implant. Then find the correct angle and re-insert the implant. This should only be attempted once.

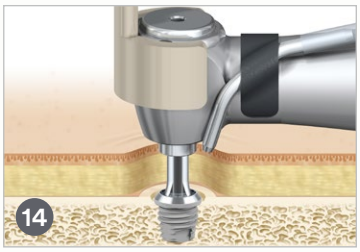
If the drill stops prematurely – before the flange of the implant is seated in the countersunk bone – reverse one thread and increase the torque by 5 Ncm on the control panel of the drill system.

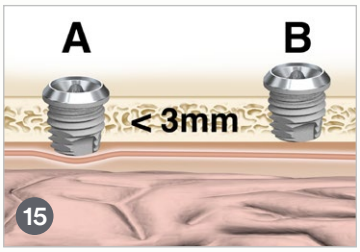
Be very careful not to loosen the implant through a lever arm effect. The risk of this occurring is quite high if implanting a patient with thin or compromised bone.

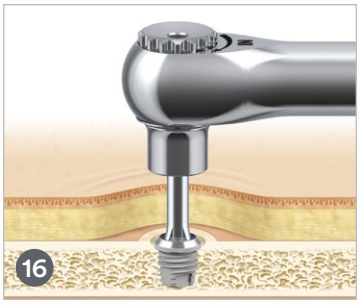
For patients with bone < 3 mm, countersinking risks diminishing the bone available for osseointegration. Instead place the implant flush with the calvarial surface even if it slightly abuts or depresses the dura mater (A). Alternatively, make an incomplete insertion and leave the implant protruding with 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 needing more than 25 Ncm torque, as that is the torque limit of the wrench.

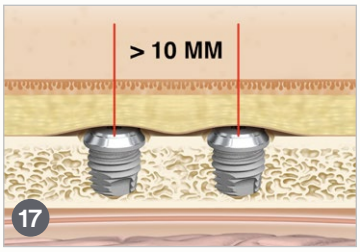








Placing a sleeper implant

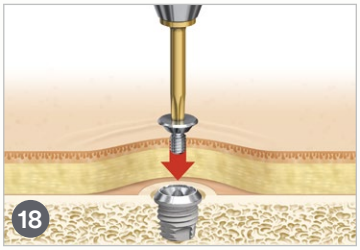


- Since there is a slightly higher rate of implant loss in children,[2,3] placing a sleeper implant is recommended[4] in order to reduce the time between the potential loss of an implant and hearing being restored.
- Leave at least 10 mm between the centers of the two implants (Fig. 17). However, the 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

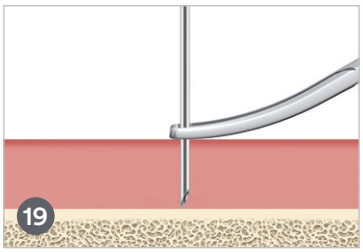


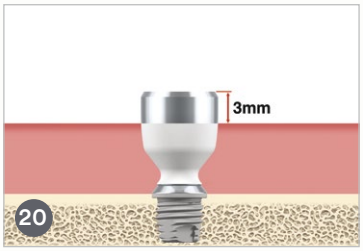
Inserting a cover screw protects the internal threads of the implant from tissue and bone overgrowth during the healing phase.

- 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. 19). Inject local anesthesia. The amount of injection should be limited for minimal distortion of tissue thickness. If surgery is performed under general anesthesia, 1–2 ml of local anesthesia is generally sufficient.
- Select the appropriate abutment length based on the measured tissue thickness.

Note

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

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

- The DermaLock hydroxyapatite (HA) 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 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 40 x 60 mm across.

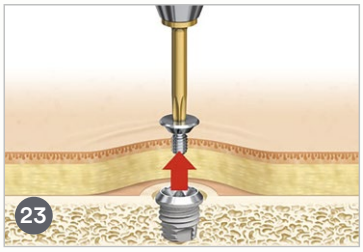
- Follow the incision utilized during the first stage (Fig. 21).

Or

- If the implant is felt through the soft tissue it may be possible to attach the abutment without incising the skin. Use a biopsy punch Ø 5 mm to punch a hole in the skin exactly over the implant (Fig. 22).

STEP 2 Remove the cover screw

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

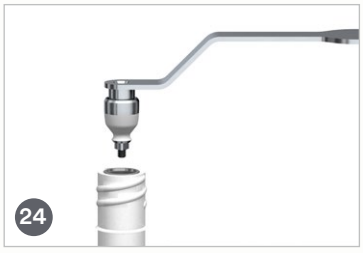


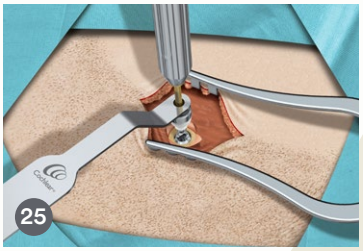
STEP 3 Connect the abutment

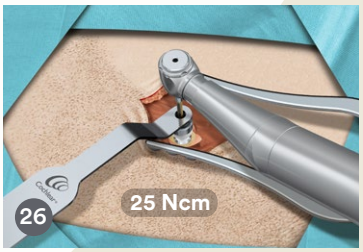
- Pick up the abutment with the counter torque wrench and place it into the implant (Fig. 24).
- Ensure the tri-lobe connection is locked together and then gently pre-tighten the abutment screw with the Unigrip screwdriver (Fig. 25).
- Set the drill to the torque setting (program Implant Installation 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).

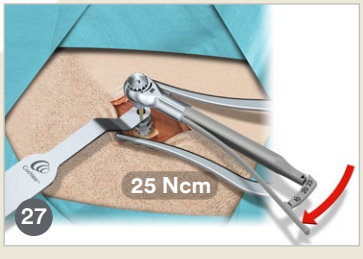
Or

- For manual tightening, tighten the abutment screw to 25 Ncm using the Multi wrench with ISO adapter (“IN” facing upwards) with the Machine Unigrip screwdriver 25 mm (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 directly over the abutment. 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

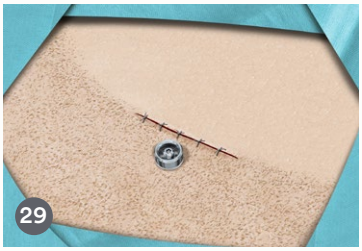
Ensure that the hole is located directly over the abutment. Avoid stretching the skin and ensure that the sutures do not pull the skin in an unnatural way. Increased tension in the skin, and the resulting push/pull forces, could lead to discomfort around the abutment. This could also result in the formation 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.

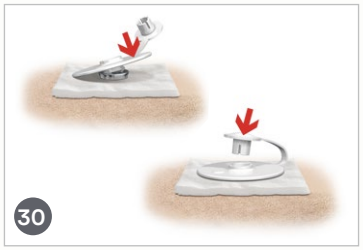
- Ensure that the abutment is free of blood and clotted debris above the skin level.
- Apply a thin, low or non-adherent dressing and attach a healing cap with plug. (Fig. 30).
- Avoid using a thick dressing underneath the healing cap as this may cause unwanted compression of the soft tissue during healing. 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, 32).
- The dressing should be kept in place during the healing period to protect the wound.
- Remove the dressing*, sutures and healing cap 10–14 days post-op. If not healed, apply a new dressing and a new healing cap.

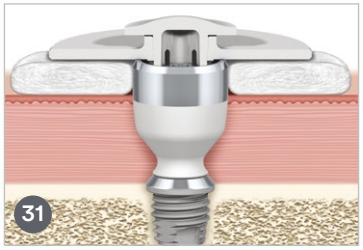
Note

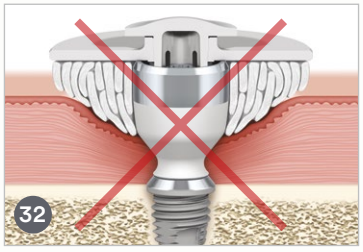
If a silver dressing is used and if the coating of the abutment is protruding, the coated part of the abutment will be discolored by the silver in the dressing. This is not harmful to the abutment or tissue.

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









* If using Allevyn Non-Adhesive wound care dressing (provided in the surgical kit) it is recommended to change the dressing if needed or up to 7 days of application.

Aftercare

Dressing guidelines

1 day post-op	10–14 days post-op	17–21 days post-op
1. Remove the mastoid dressing. 2. Leave the dressing and healing cap in situ. 3. Ensure that the patient does not allow any water to come in contact with the site before complete healing of the wound.	1. Remove and discard the healing cap. 2. Carefully remove the dressing. 3. Remove the sutures (if applicable). 4. Gently clean the wound with normal saline and gauze. 5. Gently remove any dried blood or debris. 6. Assess the wound site and treat accordingly. 7. If healed, no further dressing is required. 8. Provide the patient with aftercare instructions and emphasize the importance of daily cleaning. For the first few weeks, a skin-friendly shampoo should be used.	1. If necessary, repeat relevant steps as in the previous visit. 2. If the wound site has not healed consult a wound care specialist.

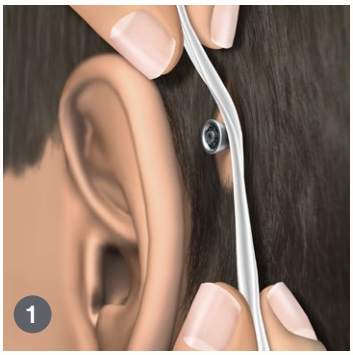
Note

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

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

Patient aftercare instructions

- Good hygiene is critical to maintaining normal usage of the Baha sound processors. Patients who are unable to clean the skin around the abutment need help from their family or caregivers. The cleaning should, 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.
- In case of infection, the patient's cleaning routine should be assessed.



Note

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

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

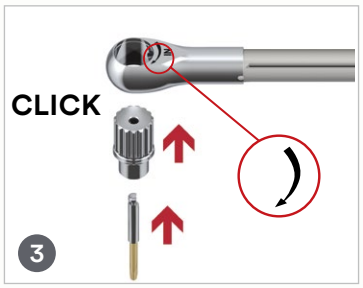
Adjusting the abutment

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.

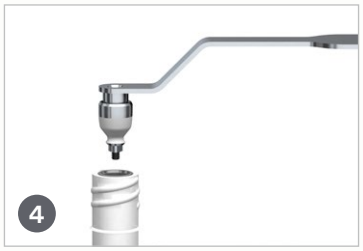
Tighten the abutment

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



Replacing the abutment

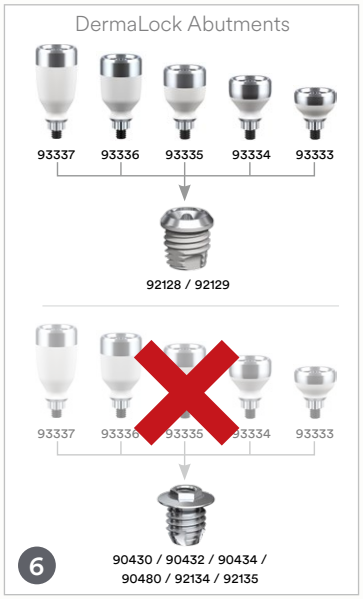
- There may be an HA/tissue bond when removing the abutment and the abutment may not release freely.
- In case of tissue overgrowth, either topical anesthetic cream or local anesthesia may be appropriate. If needed, use a biopsy punch Ø 5 mm to punch a hole in the skin.
- Loosen the abutment screw using the multi wrench (“OUT” facing upwards) with the machine Unigrip screwdriver. Remove the abutment from the implant. If the abutment is difficult to remove, a clamp or hemostat may be used to pull straight up on 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 Ø 5 mm to create a fresh wound in the skin.
- Pick up the new abutment with the counter torque wrench 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 BI300 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 System 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 back out the implant from the bone.

Find the correct alignment and re-insert the implant. If the same issue occurs 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 and perforation of the sigmoid sinus

Although rare, a mild CSF or blood leak can occur when using the conical guide drill. 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

Treat this rare 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[8] 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 Osia 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 Osia System will be a more suitable option.

Skin overgrowth

If the skin grows over the abutment, change to a longer abutment or perform skin reduction surgery. In some patients (predominantly male teenagers) an inflammatory reaction may occur and result in complete overgrowth of the abutment by soft tissue. Treatment with topical steroid cream or an injection of steroid may be considered.[7, 8]

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[9] 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 or high speed drill.

Bony overgrowth

The potential for a bony overgrowth around the implant is highest in children implanted at a very young age. In the event of bony overgrowth during the second step of a two-stage procedure, removal of some bone around the implant may be necessary to attach the abutment.

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.[10]

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.[11]

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.[12,13]

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 patients 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.

Reusable instruments

The set-up below details the typical instruments needed for the most common types of Baha surgery. See the Baha Product catalog for more information.

P1582203
Baha Indicator

91116
Drill indicator for WS-75 and Osscora

P1593725
Raspatorium / Probe

P1582229
Abutment inserter

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

P1582231
Counter torque wrench

Notes

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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.

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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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