FOR PROFESSIONALS

Cochlear™ Baha® 3

Support Guide for Surgery

A BONE CONDUCTION HEARING SOLUTION

Hear now. And always

Cochlear™

SYMBOLS USED IN BAHA MATERIAL:

LOT Batch code	Manufacturer	STERILE R Sterilized using irradiation	Do not use if package is damaged
Use by	Do not reuse	CE-mark	MR Safe
Caution, consult accompanying documents		**RX ONLY** Caution: Federal law *(USA)* restricts this device to sale by or on the order of a licensed medical practitione	

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

Contents

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

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. Different set-ups for 3 mm implant are also available. When appropriate, a 9 mm abutment may be used. See Baha Product Catalog for information.

Baha FAST surgery *(4 mm)* with Dermatome technique

92127 BIA300 implant 4 mm w with abutment 6 mm

92148 Single use instrument kit with Baha blade 4 mm FAST

90940 Biopsy punch Ø 4 mm

Baha two-stage surgery *(4 mm)*

STAGE 1

92139 Guide drill 3+4 mm Ø 2.3 mm

92141 Widening drill 4 mm with countersink

92129 BI300 implant 4 mm

92136 Cover screw conical

STAGE 2

90329 Baha blade *(optional)*

90940 Biopsy punch Ø 4 mm

92130 BA300 abutment 6 mm

92138 Healing cap with plug Ø 30 mm

Reusable instruments

92147 Baha instrument set
The instruments can also be ordered individually.

91095 Indicator for Baha

90944 Raspatorium

91116 Drill indicator for WS-75 and Osscora

90943 Dissector

90474 Abutment inserter

90381 Machine screwdriver Unigrip 25 mm

92142 Implant inserter *

90469 Screwdriver Unigrip 95 mm

92143 Multi Wrench with ISO adapter *

HIA 009-0 Counter torque wrench

92146 Baha instrument organizer

NOTE:

- Baha instrument organizer includes **92145** Component tray.

* Available upon FDA clearance.

Osscora surgical set

All the Osscora surgical sets are delivered with the following articles:

- Motor with 3.5 m cable incl. motor protective cover, locking pins *(2 pcs)* and clips *(10 pcs)*
- Osscora contra-angle handpiece incl. spray clips *(2 pcs)* and nozzle cleaner
- Irrigation tubing set *(6 pcs)*
- Foot control S-N1
- Irrigation stand
- Country appropriate mains cables

1 Irrigation on/off
2 Program selection
3 Forward/reverse
4 Operation

1 Dermatome *(high-speed, 2000 rpm)*
2 Drilling *(high-speed, 2000 rpm)*
3 Implant placement *(low-speed, 15 rpm)*

Accessories

NOTE:

- The Osscora surgical set is designed for use with the Baha® Dermatome for Osscora only.

91109 Baha Dermatome Osscora

91102 Sterilization cassette

How to use the healing cap with plug

A Place the healing cap first and then insert the plug to ensure that the healing cap sits safely in place.

B When removing the healing cap, always remove the plug first, then tilt the healing cap.

How to assemble the Dermatome

A Remove the spray clip. Then insert the driver pin into the handpiece.

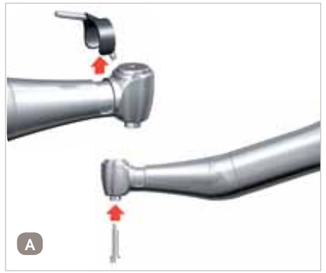
B Slide the blade into the Dermatome with the single groove facing upwards.

C Center the blade when inserting the handpiece into the Dermatome. The driver pin should connect into the groove in the blade.

D Lift the securing screw over the handpiece and tighten firmly. Check the function by running it with the high-speed setting *(2000 rpm)*. The blade should osscilate.

⚠ **CAUTION:** Do not turn over the Dermatome/handpiece until the screw is tightened. The blade may fall out.

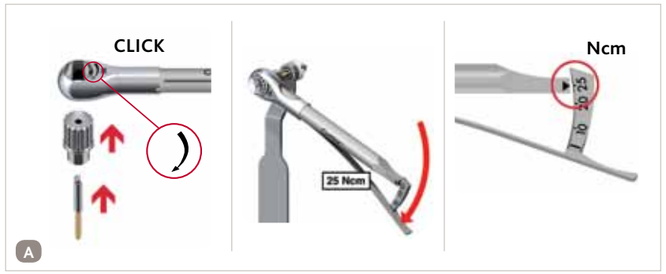
The images above show the Baha Dermatome for Osscora. The instructions are largely the same as for Baha Dermatome *(WS-75)*. For full instructions, see the relevant Dermatome Instructions for Use.



How to use the Multi Wrench

A Tightening of abutment screw to 25 Ncm using the Multi Wrench *("IN" facing upwards)* and the machine screwdriver Unigrip 25 mm. To minimize load on the implant, the Multi Wrench should always be used with the counter torque wrench.

B Manual insertion of implant during surgery with abutment inserter or implant inserter. Rotate the whole Multi Wrench shaft clockwise *("IN" facing upwards)*.



FAST Surgery Quick Guide

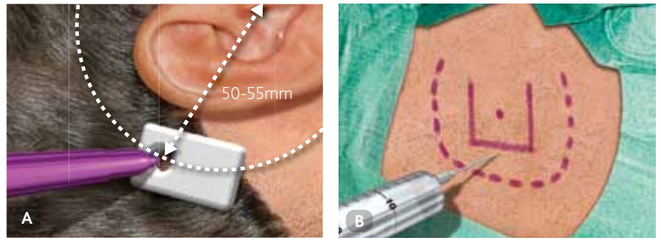
Dermatome Technique

For detailed instructions please see the Cochlear™ Baha® BI300 Implant System Surgery Guide.

STEP 1 Prepare the site

A
- Identify the implant site with the indicator for Baha, generally 50-55 mm from the ear canal and in line with the top of the pinna.
- Shave the implant area.

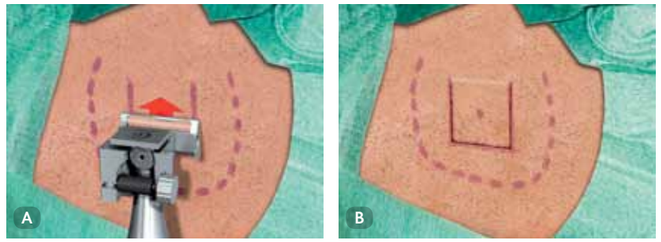
B
- Mark the area for the skin flap *(24 mm square)*.
- Mark the area for subcutaneous tissue reduction *(50-60 mm square)*.
- Make a flat surface for the Dermatome by infiltrating the local anaesthesia down to the periosteum.



STEP 2 Create the skin flap

A
- Cut the flap *(2000 rpm)*.
- Use the Dermatome in the posterior to anterior direction.
- Firm, even pressure should be applied and the correct angle maintained during cutting.

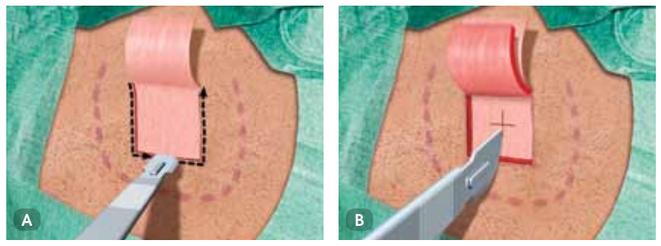
B
- Stop the drill motor and pull the Dermatome back carefully.



STEP 3 Initial soft tissue reduction

A
- Reduce subcutaneous tissue down to the periosteum.
- Keep the skin flap moist.

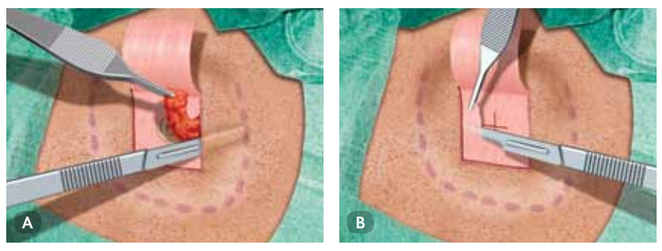
B
- Make a cruciate incision *(6 mm square)* in the periosteum to expose enough bone for the implant flange and raise the edges with the raspatorium.



STEP 4 Reduce subcutaneous tissue

A
- Remove all subcutaneous tissue down to the periosteum from the entire 50-60 mm square area marked out earlier, holding the blade parallel to skin.

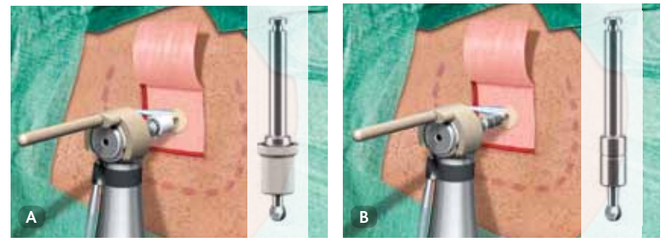
B
- Trim the periosteum down to the innermost layer.
- Suture the flap down to the periosteum at the



STEP 5 Drill with the guide drill

A
- Begin drilling with the guide drill and 3 mm spacer *(2000 rpm)*.
- Move the burr up, down and slightly enlarge the hole to ensure visual inspection and coolant reaches the tip of the drill.
- Check the bottom of the hole repeatedly for bone.
- Use the drill indicator and abundant irrigation during all drilling procedures.

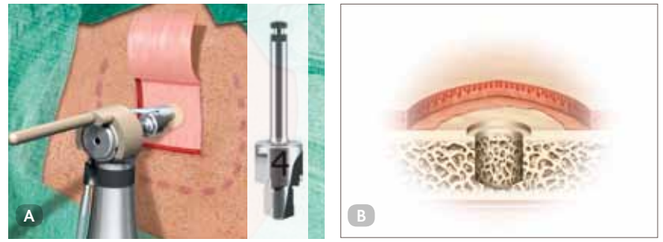
B
- If there is adequate bone thickness, remove the spacer and continue drilling to 4 mm.



STEP 6 Drill with the widening drill

A
- Widen the hole with relevant widening drill *(2000 rpm)*.
- Move the widening drill up and down during drilling to ensure that coolant reaches tip of the drill.

B
- The widening drill is designed with a hard stop to reduce the risk of over countersinking.

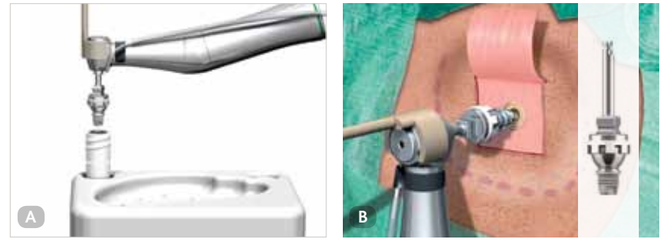


STEP 7 Place the implant

A
- Pick up the implant using the abutment inserter.

B
- Place the implant without irrigation until the first threads of the implant are well within the bone.

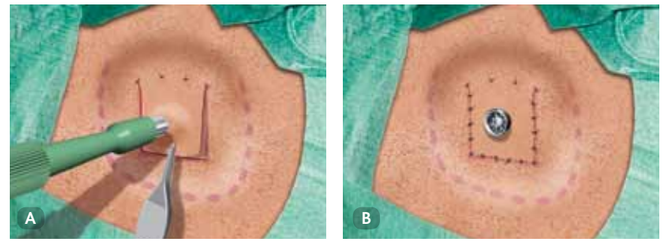
BONE QUALITY	SUGGESTED TORQUE
Compact bone	40–50 Ncm
Compromised or soft bone	20–30 Ncm



STEP 8 Close and suture

A
- Stretch the skin flap over the implant area.
- Punch a hole exactly over the abutment with the biopsy punch Ø4 mm.
- Ease the skin flap down over the abutment.

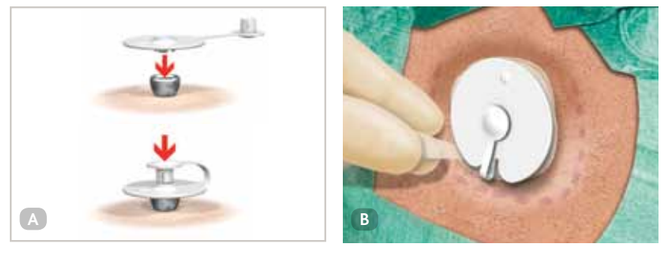
B
- Suture the perimeter of the flap area down to the periosteum.
- Suture the flap in place.



STEP 9 Attach the healing cap

A
- Place the healing cap first and then insert the plug to ensure that the healing cap sits safely in place.

B
- Place the healing cap either before or after the dressing. Place a mastoid dressing.



FAST Surgery Quick Guide

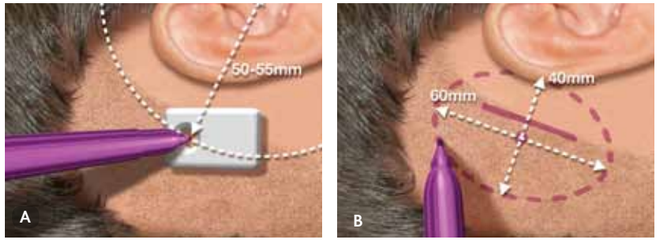
Linear Incision Technique

For detailed instructions please see the Cochlear™ Baha® BI300 Implant System Surgery Guide.

STEP 1 Prepare the site

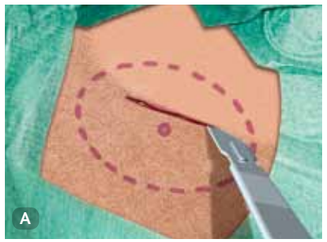
A
- Identify the implant site with the indicator for Baha, generally 50–55 mm from the ear canal, and in line with the top of the pinna.

B
- Mark the 30–35 mm long linear incision, following the direction of the hair line.
- Mark the elliptical area for subcutaneous tissue reduction *(approx. 40x60 mm)*. The implant position will be located in the center of this area.



STEP 2 Make the incision

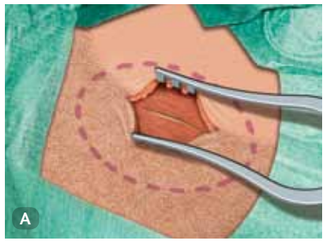
A
- Use a scalpel to make a straight incision down through the periosteum. The marking of the bone will provide a good orientation for implant placement later in the procedure.



STEP 3 Remove the periosteum

A
- Open up the incision using a self-retaining retractor.

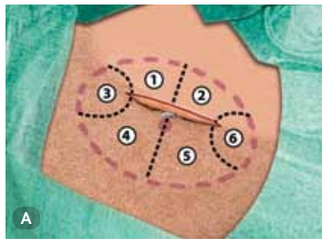
B
- Remove approximately 10 mm of periosteum around the planned implant site using the raspatorium.

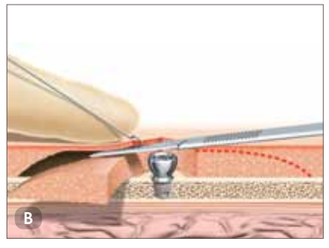


STEP 4 Reduce subcutaneous tissue

A
- Remove subcutaneous tissue extensively approximately 40x60 mm. Follow the sequence as shown.

B
- Use two skin hooks to create a tent like area to allow the blade to slide down the incision using the finger to keep pressure and guide the blade.
- Use the blade or a pair of scissors to cut away the soft tissue all around the incision.

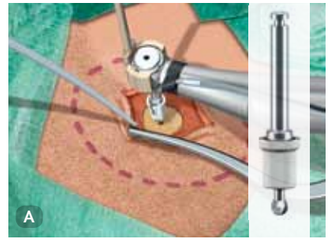


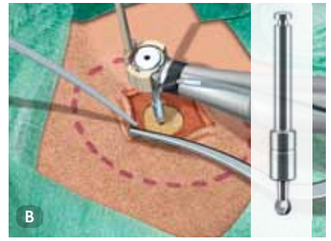


STEP 5 Drill with the guide drill

A
- Begin drilling with the guide drill and 3 mm spacer *(2000 rpm)*.
- Move the burr up and down and slightly enlarge the hole to ensure visual inspection and coolant reaching the tip of the drill.
- Check the bottom of the hole repeatedly for bone.
- Use the drill indicator and abundant irrigation during all drilling procedures.

B
- If there is adequate bone thickness, remove the plastic spacer and continue drilling to 4 mm.

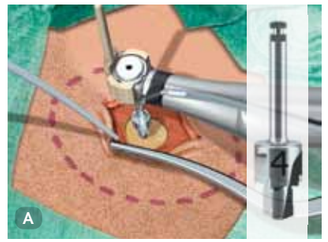




STEP 6 Drill with the widening drill

A
- Widen the hole with the relevant widening drill *(2000 rpm)*.
- Move the widening drill up and down during drilling to ensure that coolant reaches the tip of the drill.

B
- The widening drill is designed with a hard stop to reduce the risk of over countersinking.

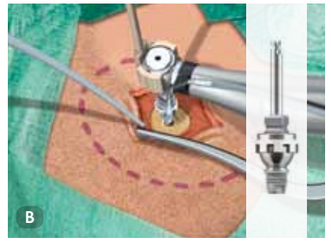


STEP 7 Place the implant

A
- Pick up the implant using the abutment inserter.

B
- Place the implant without irrigation until the first threads of the implant are well within the bone.

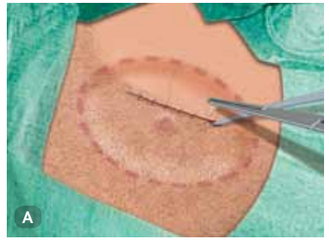
BONE QUALITY	SUGGESTED TORQUE
Compact bone	40–50 Ncm
Compromised or soft bone	20–30 Ncm

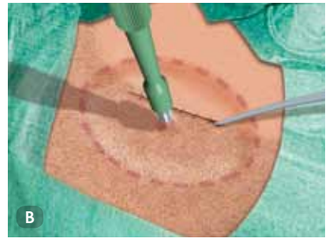


STEP 8 Close and suture

A
- Close the incision. A suction tip can be placed in the small opening in the incision to pull the skin down tightly to the bone and the periosteum.

B
- Punch a hole in the skin exactly over the abutment with the biopsy punch Ø4 mm.
- Carefully ease the skin down over the abutment.





STEP 9 Attach the healing cap

A
- Place the healing cap first and then insert the plug to ensure that the healing cap sits safely in place.

B
- Place the healing cap either before or after the dressing. Place a mastoid dressing.

Two-Stage Surgery Quick Guide

For detailed instructions please see the Cochlear™ Baha® BI300 Implant System Surgery Guide.

FIRST STAGE

STEP 1 Prepare the site

A
- Identify the implant site with the indicator for Baha, generally 50-55 mm from the ear canal and in line with the top of the pinna.
- Shave the implant area.
- Mark the area for the skit flap or incision.

B
- Mark the implant site down to the bone with a needle and dye.
- Create an incision using a manual technique.

C
- Raise the flap.
- Make a cruciate incision in the periosteum exposing the bone *(6 mm square)*.
- Raise the edges of the periosteum with the raspatorium.

STEP 2 Drill with the guide drill

A
- Begin drilling with the guide drill and 3 mm spacer *(2000 rpm)*.
- Move the burr up, down and slightly enlarge the hole to ensure visual inspection and coolant reaches the tip of the drill.
- Check the bottom of the hole repeatedly for bone.
- Use the drill indicator and abundant irrigation during all drilling procedures.

B
- If there is adequate bone thickness, remove the spacer and continue drilling to 4 mm.

STEP 3 Drill with the widening drill

A
- Widen the hole with the relevant widening drill *(2000 rpm)*.
- Move the widening drill up and down during drilling to ensure that coolant reaches the tip of the drill.

B
- The widening drill is designed with a hard stop to reduce the risk of over countersinking.

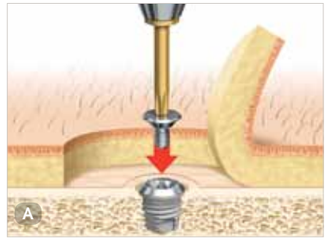
STEP 4 Place the implant

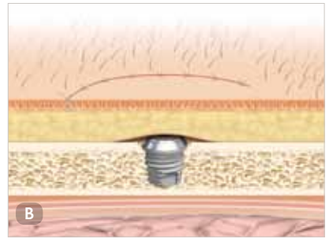
A
- Pick up the implant with the implant inserter.

B
- Place the implant without irrigation until the first threads of the implant are well within the bone.

BONE QUALITY	SUGGESTED TORQUE
Compact bone	40–50 Ncm
Compromised or soft bone	20–30 Ncm

STEP 5 Place the cover screw





A
- Place the cover screw using the screwdriver Unigrip 95 mm.

B
- Lay the flap down and suture.
- Apply a dressing of choice.

SECOND STAGE

STEP 1 Reduce the subcutaneous tissue

A
- Locate the cover screw and raise the flap using either the Dermatome or a manual technique.
- Remove all subcutaneous tissue down to the periosteum from a 50-60 mm square area, holding the blade parallel to the skin.

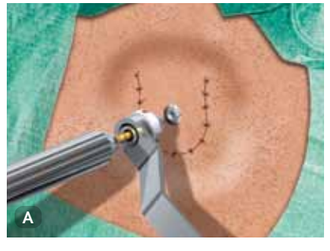
B
- Trim the periosteum down to the innermost layer.
- Suture the flap down to the periosteum at the base of the skin flap.

STEP 2 Remove the cover screw

A
- Punch a hole exactly over the cover screw with the biopsy punch Ø4 mm.
- Remove the cover screw using the screwdriver Unigrip 95 mm.

B
- Reposition the skin flap over the implant area.
- Suture the flap in place.

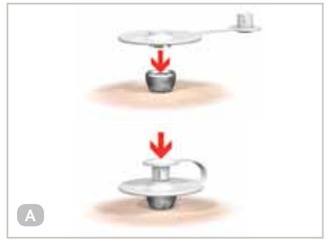
STEP 3 Connect the abutment



A
- Pick up the abutment with the counter torque wrench and place the abutment on the implant.
- Pre-tighten the abutment screw with the screwdriver Unigrip 95 mm and the counter torque wrench.

B
- Finalize the tightening of the abutment screw to 25 Ncm with the machine screwdriver Unigrip 25 mm ***(low speed setting)*** and the counter torque wrench.

STEP 4 Attach the healing cap



A
- Place the healing cap first and then insert the plug to ensure that the healing cap sits safely in place.

B
- Place the healing cap either before or after the dressing. Place a mastoid dressing.

Dressing guidelines

1 DAY POST-OP	5-7 DAYS POST-OP	10–14 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 wound for 5–7 days after surgery.	1. Instruct the patient, if they are able, to wash their hair and wet the dressing prior to their clinic visit as this can make dressing removal easier. 2. Remove the healing cap. 3. Carefully remove the dressing. 4. Remove the sutures *(if applicable)*. 5. Gently clean the wound with normal saline and gauze. 6. Gently remove any dried blood or debris. 7. Assess the wound site and treat accordingly. 8. If healed, no further dressing is required. 9. Provide the patient with aftercare instructions and emphasize the importance of daily cleaning.	10. If necessary, repeat steps 1–9 above. 11. If the wound site has not healed, consult a wound care specialist.

Complications during surgery

Even if success rates for Baha® surgery are very high, unexpected situations intra-operatively and post-operatively may occur. Below is a list of potential complications and recommendations for handling them. Importantly, the patient must be informed of all complications related to safety and effectiveness prior to surgery.

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

Exposure of the dura mater and perforation of the sigmoid sinus

If the patient has good bone volume, place the implant to seal the CSF or blood leak. If the bone is thin, choose a new implant site after sealing the leak with soft tissue or bone wax.

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, select a new implant site nearby.

Implant continues to rotate when the flange is down

This happens most often when dealing with 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 lower torque.

Damaged flap cannot be put back in place

Take a hairless skin flap from, for example, the retro auricular fold. Place a split thickness skin flap directly onto the thinned periosteum.

Subdural haematoma

Treat this rare condition according to general practice.

Notes

Hear now. And always

This is the Cochlear™ promise to you. As the global leader in hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. With our hearing solutions, Cochlear has reconnected over 200,000 cochlear implant and Baha® recipients to their families, friends and communities in more than 100 countries.

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

For patients receiving any Cochlear hearing system, our commitment is that for the rest of your life we will be here to support you.

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

Not everyone with hearing loss is a candidate for a Baha. Baha is contraindicated in patients with inadequate bone quality or quantity to provide stability and support for the implant, or in patients who will be unable to maintain and clean the skin around the abutment. In the U.S., use of the implanted fixture is also contraindicated in children under age 5 years.

All surgical procedures include an element of risk, and it is impossible to guarantee success. The device may fail to osseointegrate for a number of reasons, including physiological and surgical issues as well as traumatic impact to the implant site. On rare occasions the skin around the abutment may become inflamed from a mild infection or the skin may grow back towards its original thickness. For complete information regarding the risks and benefits of a Baha procedure, please refer to the instructions for use for the Baha implant available at **www.CochlearAmericas.com/Bahaindications**

www.CochlearAmericas.com

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