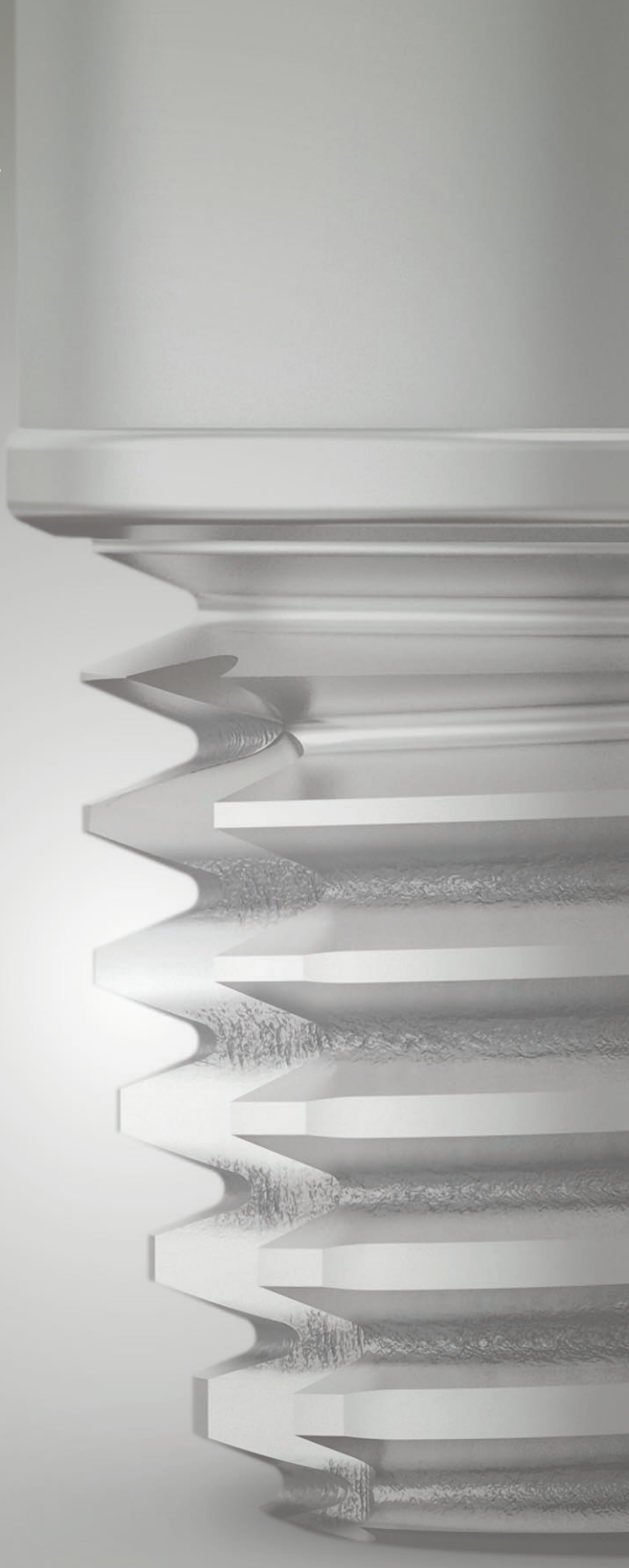
Ponto Surgical Manual

Linear incision procedure



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Introduction

The Ponto Bone Anchored Hearing System is a solution for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single-sided deafness. The system consists of a small titanium implant placed in the temporal bone, a percutaneous abutment and a sound processor.

This manual offers guidance including planning, preparation and follow-up aspects; it sets forth detailed recommended procedures for using Ponto bone-anchored surgical components and instruments. The linear incision technique is described in this manual, while other safe surgical technique alternatives are described in Surgical Manual Addenda. Please refer to the Ponto Candidacy Guide for information about which patients are candidates for a bone-anchored hearing system, and for clinical benefits with the system. Summary of Safety and Clinical Performance (SSCP) for the Ponto System is made available*.

After implant placement, the titanium implant will become integrated with the bone through a process known as osseointegration. Once the sound processor is fitted, it will convert incoming sound into vibrations that are transmitted through the bone directly to the cochlea, bypassing the outer and middle ear.

A successful surgical outcome requires a stable implant and a healthy skin penetration area. Thorough planning and a carefully performed surgery are key factors to achieve this. Before placing a Ponto Implant, it is vital that all members of the surgical team have obtained appropriate information and/or training in the surgical procedure and related aspects. It is strongly recommended that a close interdisciplinary collaboration is maintained between surgical and audiological teams throughout the evaluation, treatment and follow-up phases. In case of malformations, the reconstructive surgeon may also have valuable input for the best site selection and timing of the surgery.

Please contact your local Oticon Medical representative for any information or support.

Note: This manual and the Surgical Manual Addendum describe recommended surgical procedures. All patients must be given individual assessment and the procedure should be adapted to individual factors where necessary.

Illustrations and images in this manual are not to scale.

Terminology used in these instructions:
– Important/tips: Important information and/or advice
– Precaution/caution: Indicates need for action to be taken in advance to prevent or reduce the impact of possible harm or device failure.

*www.oticonmedical.com/SSCP

Planning

At the planning stage, the individual treatment is planned based on a number of patient-related factors. The choice of either a single- or two-stage surgical procedure, as well as the expected time that will be required to allow for osseointegration before loading the implant, are the main factors influencing the individual treatment schedule and how to prepare the surgery.

Selecting single- or two-stage surgery

Pre- and perioperative assessment of the quality and thickness of the patient's temporal bone is necessary for planning whether the surgery should be performed in one or two stages. If the surgeon determines that the implantation is appropriate for a patient with a thin bone (‹3 mm) or poor bone quality, a surgical procedure in two stages with a prolonged osseointegration period (3 to 6 months or more) is recommended.

Single-stage surgery

Single-stage surgery is applied to most patients. In a single-stage surgical procedure, the implant and abutment placement are carried out in the same procedure. See treatment schedule on page 8.

Single-stage surgery is recommended for:

- Adult patients with normal bone quality and thickness above 3 mm, where no complications during surgery are expected.
- Children with normal bone quality and a bone thickness above 4 mm (typically 12 years or older) provided that age, development status and other known factors have been considered and found suitable for single-stage surgery.

Two-stage surgery

Patients with expected soft/poor bone quality or thin bone are indicated for a two-stage surgical procedure, with a prolonged osseointegration period of 3 to 6 months or more between the two stages. The implant is placed and a cover screw connected to it in the first stage. After 3 to 6 months the second stage is performed, including removing the cover screw, connection of the abutment and skin preparation.

The exact time required for osseointegration is based on the surgeon's assessment of the bone depth and quality during the first stage of the surgical procedure. The sound processor can then be fitted after the soft tissue has healed from the second surgery.

Two-stage surgery is recommended for/when:

- Adult patients with an expected bone thickness below 3 mm or expected poor bone quality. (Reasons for expecting poor bone quality or thin bone may for example include disease or history of irradiation.)
- Children with a bone thickness below 4 mm, or where age development status or other factors make single-stage surgery unsuitable.
- An implant is placed in association with the removal of an acoustic neuroma.
- Contact with the dura mater or the wall of the sigmoid sinus is expected, or if there is any risk of complications.

Important

- *Children below the age of five*
  In the US, Canada and Singapore, the placement of a bone-anchored implant is contraindicated in children below the age of five.

- *Bone depth below 3 mm*
  The two-stage surgical procedure may be applied for patients with a bone depth of less than 3 mm. The individual assessment of each patient candidate must be carefully carried out and the surgical procedure performed with great care.

- *Conversion from single-stage surgery to two-stage surgery*
  If, during a planned single-stage procedure, it appears that the bone is of poor quality, a decision to convert to a two-stage procedure can be made.

- *Patients not suited for a bone-anchored implant*
  Patients who are not suited for or who are too young to receive a bone-anchored implant may instead use the sound processor connected to a head band or soft band.

Prediction and verification of bone status and soft tissue thickness

Bone status

Possible reasons for expecting poor bone quality or thin bone may include disease, previous surgery in the area of the implant site, or history of irradiation. Children must have sufficient bone volume and bone quality before implant placement. Studies indicate that the child should have a skull bone at least 2.5 mm thick.[1, 2, 3]

The quality and thickness of the bone is further assessed during the drilling phase of the surgery in order to verify the choice of surgical procedure and/or to determine the time needed for osseointegration before loading the implant.

Skin thickness

Patients have different skin thicknesses, and the evaluation of skin thickness is important to support the planning of the surgical approach and determine which abutment length is appropriate. Both skin thickness in the area after surgery, and expected skin thickening, should be taken into consideration.

There are several methods to measure the skin thickness:

- Needle – before incision (Fig. 1)
- Paper ruler – inspection after incision (Fig. 2)
- Ultrasound – before incision (Fig. 3)

Osseointegration

Osseointegration is the process in which the implant and bone integrate to form a firm anchorage for the sound processor.

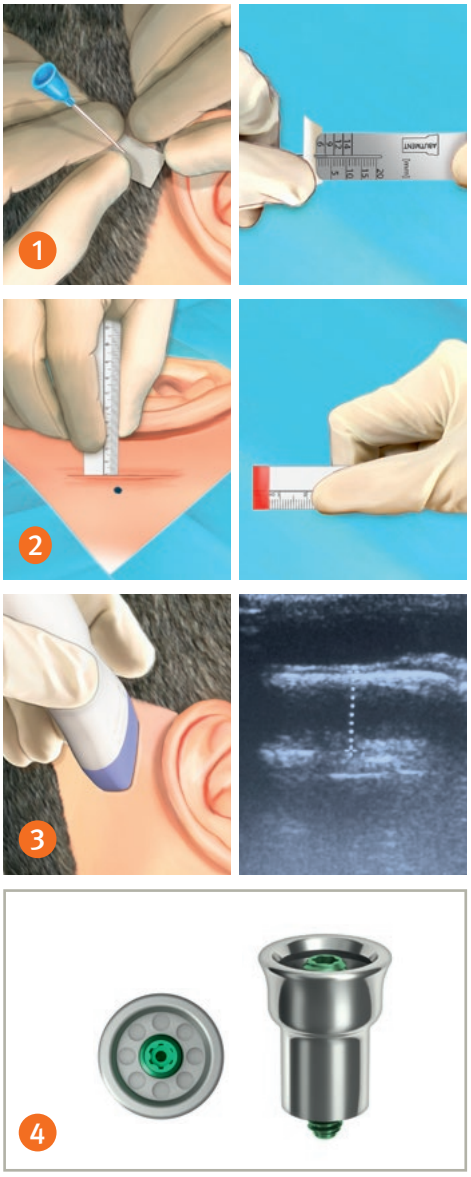
How much time to leave before loading the implant must be judged by the surgeon based on assessment of the bone depth and quality during the surgical procedure, see treatment schedule on page 8–9. In children, the time allowed for osseointegration is often longer (3–6 months) than the time for adults. Whenever a two-stage surgical procedure is performed due to soft or thin bone, a prolonged osseointegration period of 3 to 6 months or more is recommended.

Measuring implant stability

Implant stability can be measured after implantation at any stage of the treatment, to follow up on the integration of the implant in the bone. The measurement is carried out using the Osstell® ISQ and the Osstell® Mentor stability meters. The green connection screw indicates compatibility with the Osstell® equipment (Fig. 4).

While an increasing implant stability quotient (ISQ) value during follow-up examinations is an indication that the implant is successfully integrating, a low and decreasing ISQ value may provide an early indication of implant failure.

For more information on ISQ visit www.osstell.com



Treatment schedule

The below are recommended times. The exact time should be based on the surgeon's assessment of the patient's bone depth, bone quality and healing progress.

Single-stage surgery

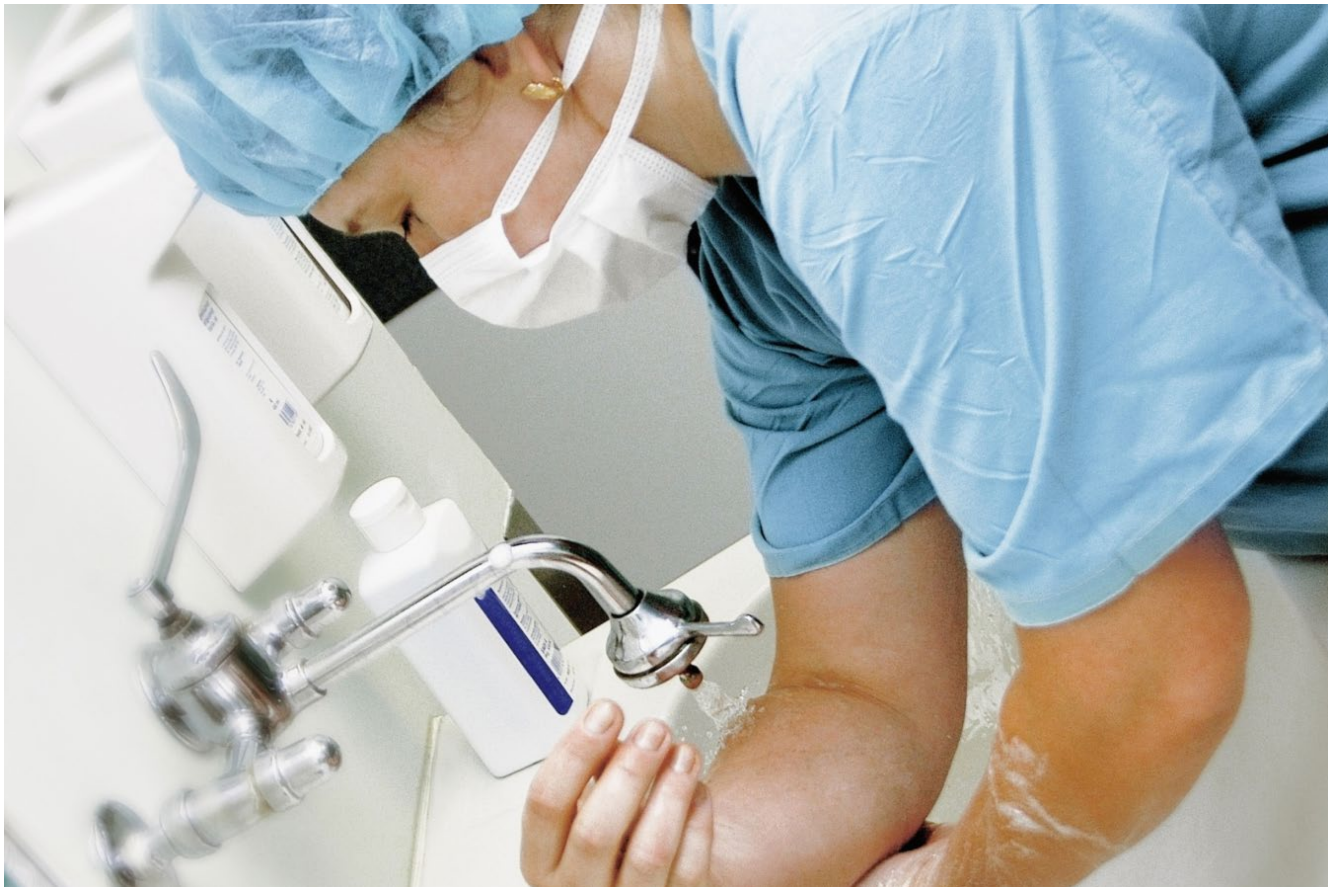
Surgical procedure	
Place the implant with pre-mounted abutment, dressing and healing cap	
Surgical follow-up	**Time after surgery**
Remove the healing cap and dressing and check the implant site. If healed, remove the sutures and instruct the patient or their family/caregivers on cleaning and aftercare. If not healed, refit the healing cap and replace the dressing	7–10 days
If not healed after 7–10 days, repeat instructions above	14 days
Fitting of the sound processor	
Check that the implant is firmly integrated. Check that the abutment is well connected to the implant. Check the surrounding skin area	Down to 2 weeks, based on individual patient evaluation. *In the US, 3 months, based on individual patient evaluation.*
Fit the sound processor (see Audiological Manual)	
Routine follow-up	
Evaluate the fitting of the sound processor, as well as the condition of the skin penetration area and the abutment within 2 months after the initial fitting. Schedule a subsequent follow-up semi-annually or annually	

Two-stage surgery

Surgical procedure, first stage	
Place the implant (without pre-mounted abutment) and cover screw	
Surgical follow-up	**Time after surgery**
Remove the sutures	7–10 days
Osseointegration period	3–6 months, based on individual patient evaluation
Surgical procedure, second stage	
Remove the cover screw, prepare the soft tissue, and connect the abutment. Place the healing cap and dressing	
Surgical follow-up	**Time after second-stage surgery**
Remove the healing cap and dressing and check the implant site. If healed, remove the sutures and instruct the patient or their family/caregivers on cleaning and aftercare. If not healed, refit the healing cap and replace the dressing	7–10 days
If not healed after 7–10 days, repeat instructions above	14 days
Fitting of the sound processor	**Time after second-stage surgery**
Check that the abutment is well connected to the implant. Check the surrounding skin area	Approx. 10 days, based on individual patient evaluation
Fit the sound processor (see Audiological Manual)	
Routine follow-up	
Evaluate the fitting of the sound processor, as well as the condition of the skin penetration area and the abutment within 2 months after the initial fitting. Schedule a subsequent follow-up semi-annually or annually	

Preparations

The preparation procedure involves selecting the implant site as well as preparing the operating room and the patient for surgery.



Selecting implant site

It is always recommended that the patient test the sound processor preoperatively to evaluate the benefit. The test will also help determine the optimal implant side for the patients with conductive or mixed hearing losses who are not going to be bilaterally implanted.

Audiological factors will most often determine the implant side. However, aspects such as manual dexterity, telephone use and driving habits should also be considered for patients receiving only one implant for treatment of bilateral conductive or mixed hearing losses. These should be discussed with the patient and/or their family/caregiver. See Candidacy Guide for more information on preoperative testing and side selection.

A number of aspects should be considered and discussed in order to choose the optimal site and position of the implant:

- *Reconstruction of outer ear: ensure there is room for an outer ear prosthesis or reconstructive outer ear surgery in cases of atresia.*
- *Head gear and glasses: identify if patient frequently wears a hat, helmet, wig or glasses, and take that into consideration.*
- *Cosmetic aspects: wherever feasible, consider cosmetic aspects such as hair growth.*
- *The sound processor contains a magnet. Caution must be taken with programmable CSF shunts. Follow the guidelines for required minimum distance recommended by the shunt manufacturer.*

Preparation for surgery

Operating room preparations

The operating room is prepared as for any otologic procedure. Make sure all components and instruments are available, functional and sterile. All components and instruments should be handled as any sterile products using gloves or suitable instruments.

Keep the implant in the blister pack until it is ensured that the bone quality and depth are appropriate to handle the implant. The blister pack acts as the sterile barrier; the ampule is only a container for the sterile product.

Ponto Implant components

	Single-stage	Two-stage	
		First stage	Second stage
Implant with pre-mounted abutment			
Implant			
Abutment			
Cover screw hexagon			

Note: Selection of implant and abutment model is based on individual patient assessment.

Disposable instruments and accessories for linear incision

- Guide drill, 3–4 mm
- Wide countersink, 3 mm
- Wide countersink, 4 mm
- Soft healing cap/Healing cap

Recommendation for drilling equipment fulfilling standard IEC 60601 (Electrical equipment for medical use) for safety and efficacy.

Guide drill

Countersink drill

Soft healing cap

Non-disposable instruments

- Counter torque wrench
- Torque wrench
- Handle with screwdriver
- Abutment inserter, machine
- Screwdriver, machine, 35 mm
- Square fit connection, machine
- Screwdriver hexagon
- Sound processor indicator
- Double-ended dissector
- Ruler

For detailed instructions on reprocessing non-disposable instruments, please consult the instructions provided by the manufacturer of the device.

Sound processor indicator

Abutment inserter

Counter torque wrench

Torque wrench

Handle with screwdriver

Screwdriver, machine, 35 mm

Square fit connection, machine

Screwdriver hexagon

Double-ended dissector

Ruler

Patient preparation

In the operating room, the patient is prepared as for conventional ear surgery. The patient is positioned in a way that gives optimal access to the skull bone on the implant side. The incision area is shaved and disinfected according to hospital practice. An adhesive surgical draping is recommended.

In adults, either local or general anesthesia may be used, while general anesthesia is recommended for children.

Important

- *Backup components*
  The single-stage surgical procedure should always be planned to ensure that backup components and instruments necessary for placing a 3 mm implant, or performing the surgery in two stages, are available. Multiple abutment lengths should also be available to match the skin thickness. Consider the need for replacing dropped products.

- *Single-use components/disposable*
  The implant components (implant, abutment, cover screw) including healing cap, the guide drill and countersinks are for single use only. Due to contamination and efficacy risks, do not resterilize or reuse these single-use products.

- *Damaged packaging and expiration date*
  If sterile packaging is punctured or damaged, the components must be considered non-sterile and are not to be used. If the expiration date has passed, the component should not be used.

- *Infection control routines*
  Non-disposable instruments must be processed according to local infection control guidelines. See cleaning and sterilization instructions for non-disposable instruments provided with the instrument.

  Single-use/disposable instruments must not be reprocessed due to contamination and efficacy risks and must be discarded after each patient.

- *Unpacked dropped components*
  Dropped non-disposable instruments must not be used until they have passed the proper infection control routines. Dropped disposable components must be discarded.

- *Protect cutting properties*
  To protect the cutting properties and osseointegration surface, the implant must be stored in the ampule until insertion.

- *Avoid contamination*
  After being picked up, the implant should not come in contact with anything. This is to avoid contamination that could jeopardize successful osseointegration. Use correct instruments when picking up the components.

Pediatric considerations

A number of special considerations should be applied for children.

- *Anesthesia*
  General anesthesia is recommended for children.

- *Drilling*
  Due to thin and soft bone, drilling during surgery must be performed with great care. Drilling with the countersink should be carried out very carefully to take advantage of all the bone needed for a good anchoring of the implant.

- *Creating additional bone*
  In children, bone chips may be used to create additional bone for implant anchorage.

- *Sleeper implant*
  The risk of trauma to the implant is greater in children, especially young children (age < 12 years), due to physical activity as well as soft and/or thin bone.[4] Children are often very dependent on their sound processor for development of social and language skills. It is therefore recommended that an extra sleeper implant with a cover screw is “banked” approximately 10 mm from the center of the primary implant. In case of implant loss, the child can then be fitted with the sound processor again directly after a new abutment has been connected to the sleeper implant and the soft tissue has healed.

- *X-ray*
  X-ray examination is recommended as part of the surgical planning.

Single-stage surgical procedure

Over the years, the surgical procedure for bone-anchored hearing system implantation has been modified by surgical teams all over the world to further improve the outcome.

This section outlines the linear incision technique with tissue preservation, where no, or only partial, tissue reduction is conducted.[5–8]

Other surgical techniques, differing in terms of incision and soft tissue handling, are described in the Surgical Manual Addenda.

These surgical techniques provide the surgeon with safe alternatives. The surgical technique instructions are described step by step, but as with any technical guide, the surgeon must assess all patients individually, and the procedure should be adapted to the individual situation as needed.

Linear incision technique

Choosing abutment length

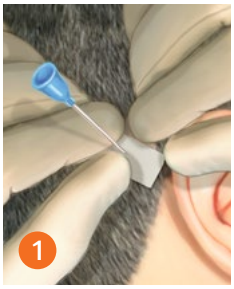
- The skin thickness can be measured before or during surgery to identify the appropriate abutment length.
  - Before surgery: measure skin thickness in normal state (without local anesthesia) with a thin needle; be aware of possible compression of the skin. (Fig. 1)
  - During surgery: measure in the incision line – using a sterile paper ruler; compensate for injections. (Fig. 2)
- Select abutment length. (Fig. 3)
- Decide on partial soft tissue reduction if the skin is thicker than what suits the longest abutment.

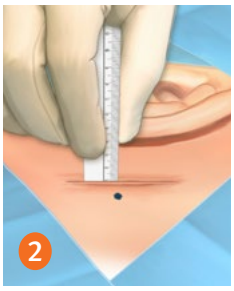
Important

- *Lever effect*
  Consider bone thickness and bone quality when placing a longer abutment, as the lever effect increases with the abutment length.

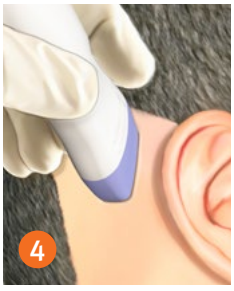
Tips

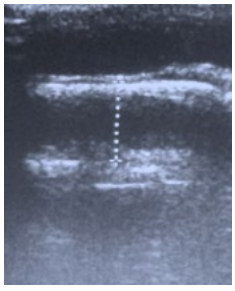
- *Ultrasound*
  Measuring skin thickness before surgery can also be done with ultrasound; avoid compressing the skin during measurement. (Fig. 4)





Natural skin thickness	Abutment length
0.5–3 mm	6 mm
3–6 mm	9 mm
6–9 mm	12 mm
3 9–12 mm	14 mm





Step 1: Preparing the site

- Use the sound processor indicator to locate the implant site, generally 50–55 mm from the center of the ear canal with the top of the indicator placed on a horizontal line from the top of the pinna.
- Shave the area.
- Place the indicator in the right position and mark the exact implant site on the skin and periosteum through the hole of the sound processor indicator. (Fig. 5)
- Mark an incision line anterior to the implant site. (Fig. 6)
- Inject a local anesthetic with a vasoconstrictor, even when the surgery is performed under general anesthesia.

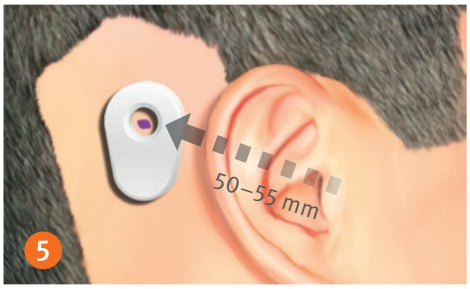
Important

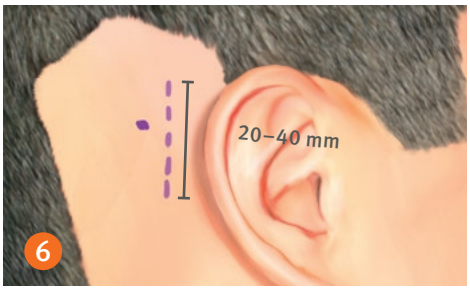
- *Implant positioning*
  The sound processor must not touch the pinna or the patient's glasses, as this may cause feedback and discomfort. On the other hand, the sound processor should not be placed too far back, as both the position of the microphones and the aesthetics may then be compromised. The microphones of the processor should point in both anterior and posterior directions. (Fig. 7)

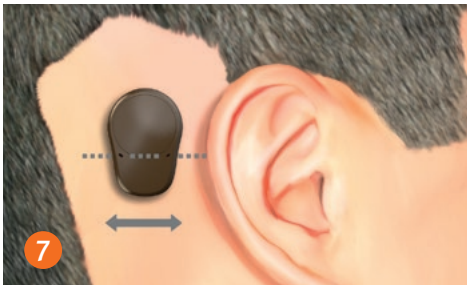
  Possible future reconstructive outer ear surgery or outer ear prostheses should be considered when determining the implant position. Anatomical landmarks should be identified, especially for patients with congenital malformation.

- *Shaving*
  Follow the hospital's guidelines for hair removal to minimize the risk of infections.

- *Implant in incision line*
  As a variation, the implant can also be placed in the incision line.







Step 2: Incision

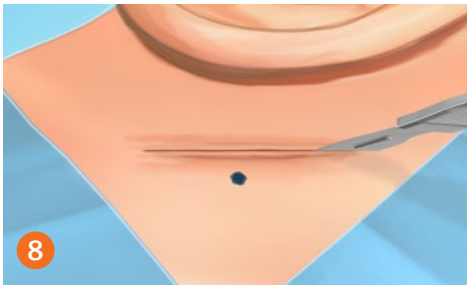
- Make the incision down to the periosteum. (Fig. 8)
- Open up the incision using a self-retaining retractor. (Fig. 9)
- Incise the periosteum.
- Remove the periosteum around the implant site using a periosteal elevator. (Fig. 10)

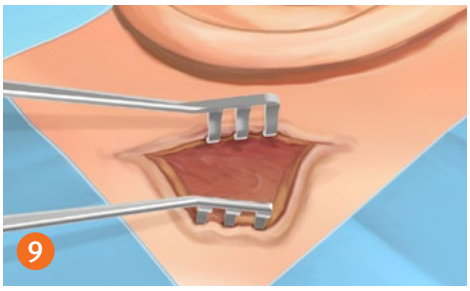
Tips

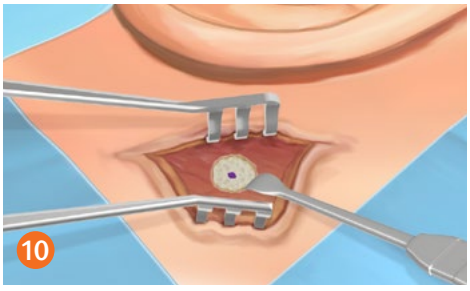
- *Periosteum*
  If it is difficult to move the periosteum aside, it might be helpful to incise the periosteum using a cruciate incision.

- *Retractor position*
  Place the retractor in such a way that it does not impede the necessary movement of the drill.

- *Electrocoagulation*
  If electrocoagulation is used at any time during the procedure, it should be used with care in order to reduce tissue trauma.







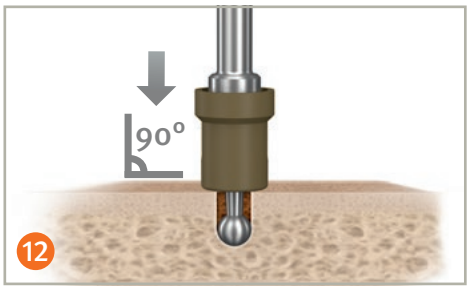
Step 3: Initial drilling with guide drill

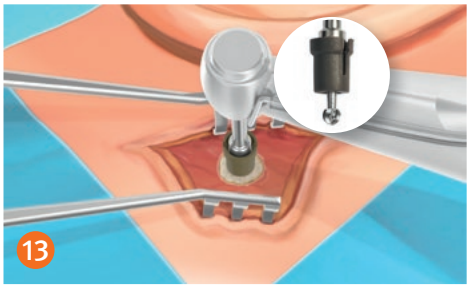
- Set the drill speed to 1500–2000 rpm. (Fig. 11)
- Place the drill perpendicular to the bone; check the angle from several directions. (Fig. 12)
- Start drilling with the spacer in place, applying generous cooling with saline solution irrigation directed towards the tip of the drill. (Fig. 13)
- Move the drill carefully up and down to ensure cooling.
- Check the bottom of the hole repeatedly for bone using a blunt instrument. (Fig. 14)
  - If there is no bone at the bottom of the hole after drilling with the spacer, consider using a 3 mm implant.
  - If the bone thickness is sufficient, remove the spacer and drill to prepare for a 4 mm implant. (Fig. 15)

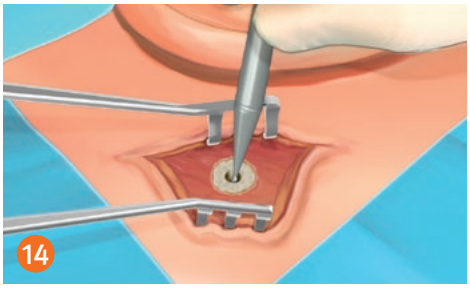
Important

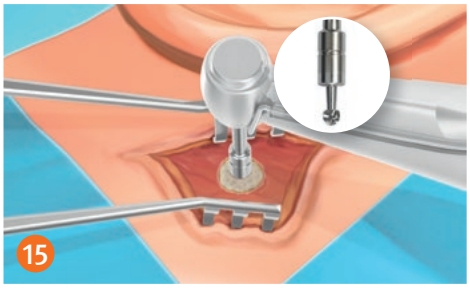
- *Drilling*
  It is important that all drilling is carried out perpendicular to the bone surface. To help the operator maintain the perpendicular direction, the drills are designed with a long shaft. The long shaft provides a sight line for the operator.

- *Cooling*
  Generous irrigation of the drill and bone is very important during the entire drilling procedure in order to prevent heat-induced bone tissue trauma, which may impede osseointegration.









Step 4: Drilling with the countersink

The countersink is used to widen the hole and prepare the bone for the implant. The drilling procedure is of decisive importance for successful osseointegration and treatment.

- Keep the preset drill speed at 1500–2000 rpm. (Fig. 16)
- Widen the hole for the implant using the appropriate countersink as determined during initial drilling (3 or 4 mm). (Fig. 17) Make sure to apply generous irrigation during the entire drilling procedure.
- To check the countersink site and clear the flutes, the countersink is repeatedly and carefully removed throughout drilling. This is done carefully so as to not over-widen the hole. (Fig. 18)
- Stop drilling with the countersink when the stop has reached the bone. (Fig. 19)
- After widening the hole, check to ensure there is bone at the bottom of the hole.

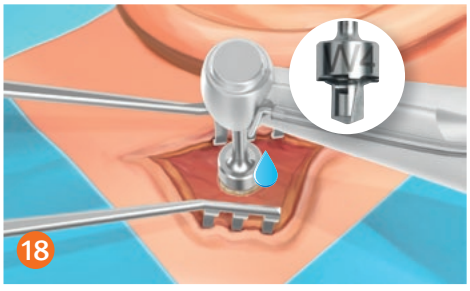
Important

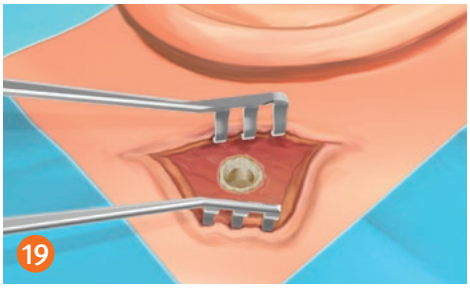
- *Drilling*
  It is important that all drilling is carried out perpendicular to the bone surface. This is more important than creating an intact or distinct recess. Inspect this from several directions.

  The drills are designed with a longer shaft to help the operator maintain the perpendicular direction. The long shaft provides a sight line for the operator. Make sure not to over-widen the hole with circular movements, as this may reduce the initial stability of the implant.

- *Cooling*
  Generous irrigation of the drill and bone is very important during the entire drilling procedure in order to prevent heat-induced bone tissue trauma, which may impede osseointegration.

- *Recess*
  The widening of the hole is sufficient when the stop collar of the countersink has reached the bone surface. The contour of the bone surface may further influence the visibility of the recess. (Fig. 20)





Step 5: Implant installation

- Set the drill unit to low speed with automatic torque control
  - 40–50 Ncm in compact bone.
  - 10–20 Ncm in compromised or soft bone. (Fig. 21)
- Place the ampule in the holder and unscrew the ampule lid.
- Pick up the implant with the pre-mounted abutment using the abutment inserter mounted to the handpiece. (Fig. 22)
- Place the implant axially aligned to the hole and start inserting the implant. Start irrigation once the first thread has entered the bone. (Fig. 23)
- Wait for the drill unit to stop when the preset torque is reached.
- Release the handpiece from the abutment by holding the handpiece close to the abutment and lifting straight up. (Fig. 24)

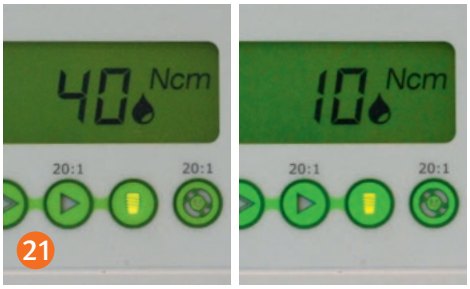
Important

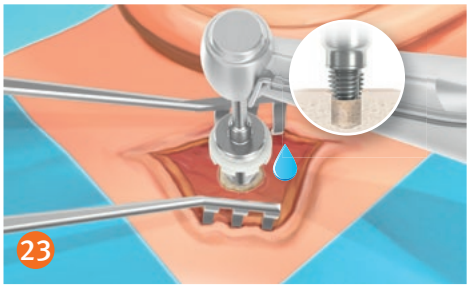
- *Torque*
  When the flange of the implant has reached the bone surface, it will stop automatically. If the flange does not reach the bone surface, the torque setting may be increased. It may be difficult to restart the torque phase, even with an increased torque, if the initial torque turns out to be too low to fully insert the implant. Therefore, it is recommended to start insertion at 50 Ncm for confirmed hard adult bone.

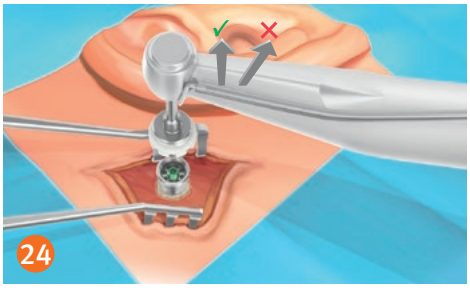
- *Manual insertion*
  If the implant is not fully inserted using the drill unit, the counter torque wrench may be used, with great care, to insert the implant manually until the flange reaches the bone surface. (Fig. 25)

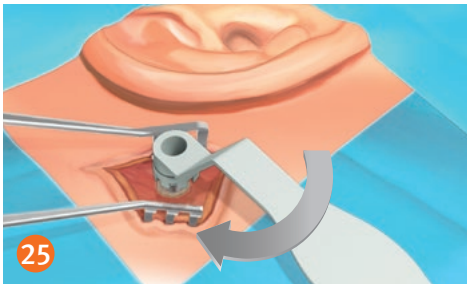
- *Releasing the instrument from the abutment*
  When releasing the abutment inserter or the counter torque wrench from the abutment, hold the instrument close to the tip to avoid creating a lever arm effect, and lift it straight up without bending. Bending the instrument will cause it to lock to the abutment and could damage the instrument or, in the worst case, cause implant loss. (Fig. 24)

- *Soft tissue reduction*
  In case of soft tissue reduction, remove subcutaneous tissue as needed. Dissect the subcutaneous tissue with a scalpel and/or with scissors and forceps.









Step 6: Punching and suturing

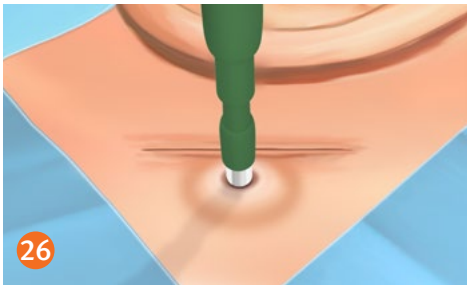
- Punch a hole exactly over the abutment using a biopsy punch (Ø4 mm – Ø5 mm). (Fig. 26)
- Gently ease the skin over the abutment.
- Close the incision. (Fig. 27)

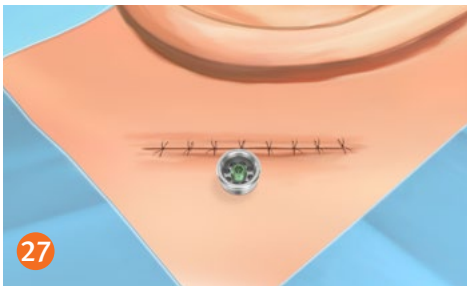
Tips

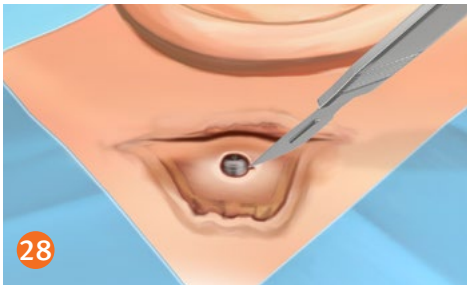
- *Punching*
  Punching the hole can alternatively be done after closing the skin.

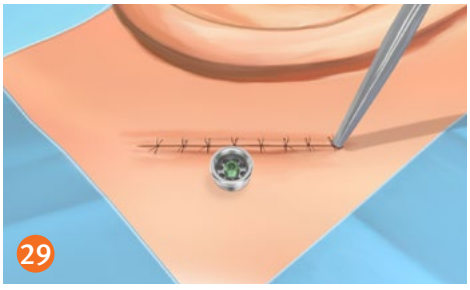
- *Ease the skin over the abutment*
  If the hole needs to be slightly enlarged to ease the skin down over the abutment, make a minor incision centered on the side of the punched hole. Avoid making the hole larger than needed to just ease the abutment through. (Fig. 28)

- *Closing the incision*
  Suction can be used to generate a vacuum in the wound during closure of the skin. (Fig. 29)



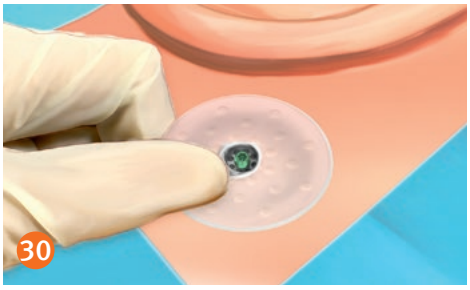


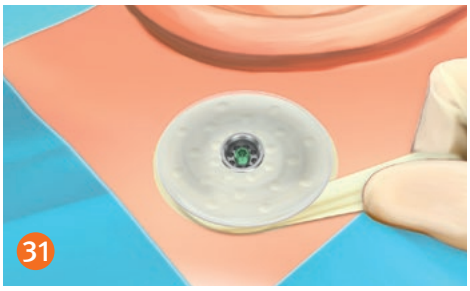


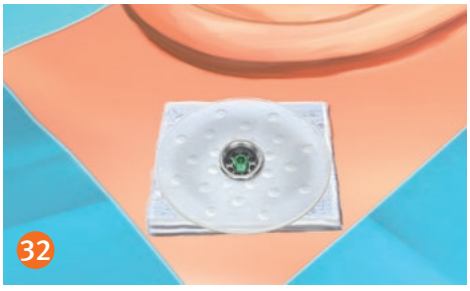


Step 7: Attaching the healing cap and dressing

- Apply the dressing and connect the healing cap. Depending on the dressing type used, the healing cap is placed either before or after the dressing is applied. (Fig. 30, 31) The healing cap holds the dressing in place and minimizes the risk of hematoma.
- Place a mastoid pressure bandage outside the dressing and healing cap.







Important

- *Ointment*
  Usually, topical antibiotic ointment is used.

- *Dressing*
  It is important that the pressure from the dressing is not too high, as this can stop the blood supply and delay healing of the wound or cause necrosis.

Tips

- *Examples of suitable dressings*
  - Ribbon gauze wrapped around the abutment;
  - A tailor-made foam dressing (Fig. 32);
  - Layers of silicone mesh dressing, making sure to provide sufficient pressure.

Two-stage surgical procedure

The implant is placed and a cover screw is connected to it in the first-stage surgical procedure. After an appropriate time for osseointegration, the second-stage procedure is performed, including connection of the abutment and skin preparation.

The instructions on the two-stage procedure only provide details for those steps with significant differences from the single-stage procedure.

First-stage

Step 1: Preparing the site
See instructions on page 19.

Step 2: Incision
See instructions on page 20.

Step 3: Initial drilling with guide drill
See instructions on page 21.

Step 4: Drilling with the countersink
See instructions on page 22.

Step 5: Implant installation

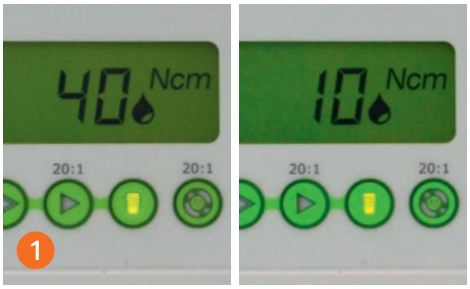
- Set the drill unit to low speed with automatic torque control.
  - 10–20 Ncm in compromised or soft bone.
  - 40–50 Ncm in compact bone. (Fig. 1)
- Place the ampule in the holder and unscrew the ampule lid.
- Pick up the implant with the square fit connection. (Fig. 2)
- Place the implant axially aligned to the hole and start inserting the implant. Start irrigation once the first thread has entered the bone. (Fig. 3)
- Wait for the drill unit to stop when the preset torque is reached.
- Release the handpiece from the implant adapter by holding the handpiece close to the adapter and lifting straight up. (Fig. 4)
- Remove the implant adapter by unscrewing the connection screw with the screwdriver, while using the open end of the counter torque wrench as a counter torque. (Fig. 5) Discard the connection screw and the adapter.
- Place a second (sleeper) implant, if this is planned. A sleeper implant is placed approximately 10 mm from the center of the primary implant.

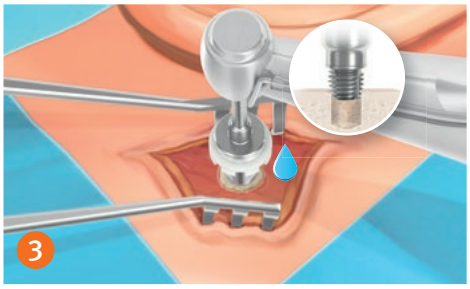
Important

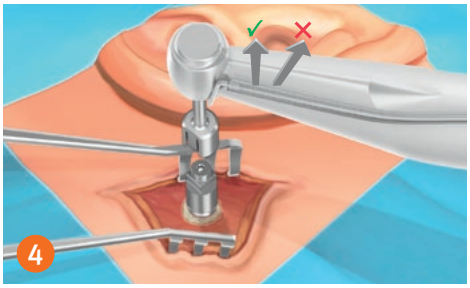
- *Torque*
  When the flange of the implant has reached the bone surface, it will stop automatically. If the flange does not reach the bone surface, the torque setting may be increased.

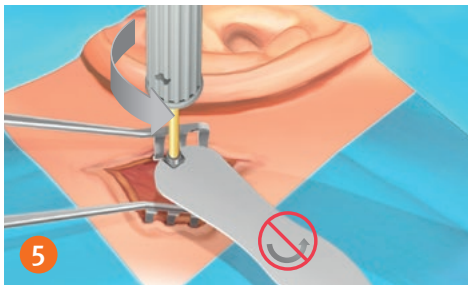
- *Manual insertion*
  If the implant is not fully inserted using the drill unit, the counter torque wrench may be used, with great care, to insert the implant manually until the flange reaches the bone surface. Use the square wrench key on the open end of the counter torque wrench. (Fig. 6)

- *Releasing the instrument*
  When releasing the square fit connection, hold the instrument close to the tip to avoid creating a lever arm effect, and lift straight up without bending. Bending the instrument will cause the square fit connection to lock to the implant adapter and could damage the instrument or, in the worst case, cause implant loss. (Fig. 4)









Step 6: Placing the cover screw

The placement of a cover screw is important to prevent bone from growing over the implant flange, into the abutment interface of the implant, and potentially into the internal threads of the implant.

- Remove the cover screw ampule lid and place the cover screw ampule in the ampule holder.
- Pick up the cover screw using the screwdriver hexagon.
- Screw the cover screw onto the implant. (Fig. 7)

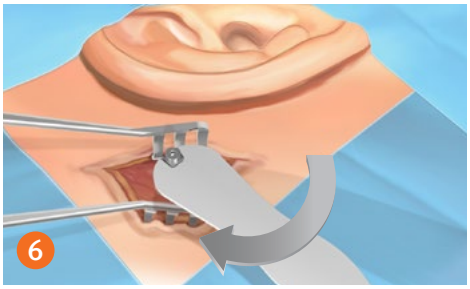
Important

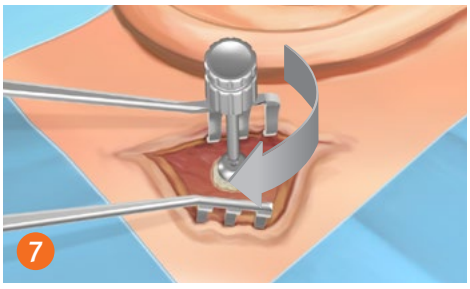
- *Cover screw*
  Do not overtighten the cover screw, as this may loosen the implant when loosening the cover screw in the second stage of the procedure.

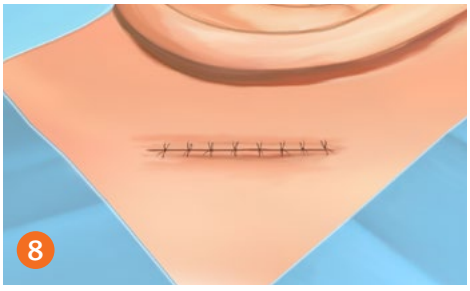
  A sleeper implant should also be covered with a cover screw.

Step 7: Closing the incision and dressing

- Close the incision. (Fig. 8)
- Apply a mastoid dressing. It is left in place for 1–2 days and is then replaced by a small bandage, at which point most patients can resume normal activity.







Second-stage

After an appropriate time for osseointegration, the second stage of the procedure is performed, including removal of the cover screw and connection of the abutment to the implant.

Step 1: Prepare the site

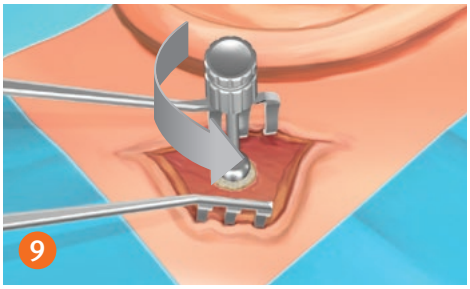
- Use the old scar and/or palpation of the implant to locate the implant site.
- Shave the area.
- Mark the implant site on the skin.
- Mark the incision.
- Measure the skin thickness and decide on an appropriate abutment length according to guidelines, see page 18.
- Inject a local anesthetic, even when the surgery is done under general anesthesia.

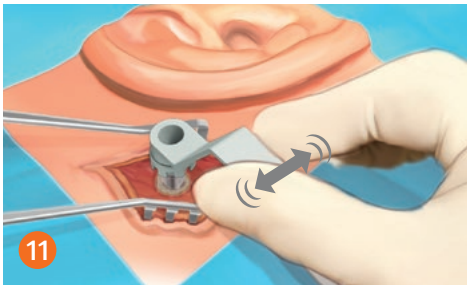
Step 2: Incision

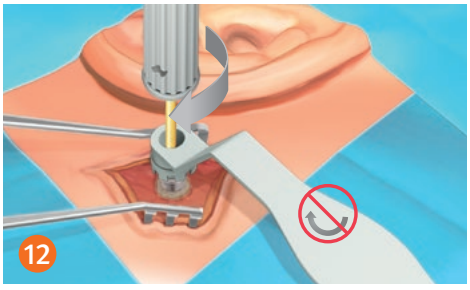
- Make the incision down to the periosteum.

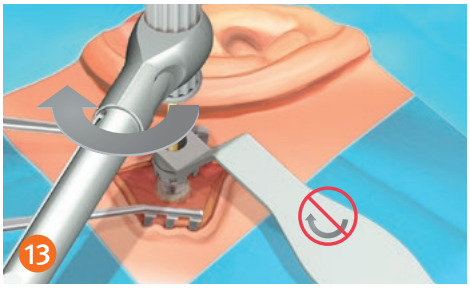
Step 3: Removal of the cover screw and connection of the abutment

- Incise the periosteum over the cover screw.
- Remove the cover screw from the implant using the hexagon screwdriver and discard the cover screw. (Fig. 9)
- Pick up the abutment from the ampule using the counter torque wrench. (Fig. 10)
- Place the abutment correctly onto the hexagon on the implant.
- This is done by slowly and carefully turning the abutment with the counter torque wrench, holding it by the fingertips, until the abutment hexagon is fitted on the implant hexagon. (Fig. 11)
  The abutment should stop turning when the hexagons match.
  Make sure that no tissue is pinched between the implant and abutment.
- Hold the counter torque wrench in a steady position. Turn the connection screw to a stop position without tightening, using the screwdriver through the hole of the counter torque wrench. (Fig. 12)
- Attach the torque wrench to the screwdriver handle and tighten the connection screw with a torque of 25 Ncm. (Fig. 13, 14) Alternatively, the drill unit with the screwdriver machine can be used; the torque controller should be set to low speed with a torque of 25 Ncm.
- Disconnect the counter torque wrench. (Fig. 15)









Important

- *Avoid increased load on the implant*
  Always use the counter torque wrench when releasing or securing the abutment connection screw and hold it in a steady position. This helps in preventing the screwdriver torque from loading the implant, possibly damaging the integrity of the bone and compromising proper osseointegration.

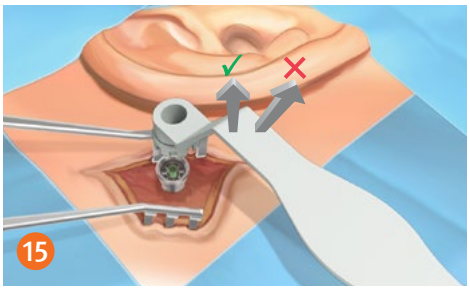
  The abutment connection screw is fitted to the implant with a torque of 25 Ncm. Do not overtighten.

- *Releasing the instrument from the abutment*
  When releasing the abutment inserter or the counter torque wrench from the abutment, hold the instrument close to the tip to avoid creating a lever arm effect, and lift it straight up without bending. Bending the instrument will cause it to lock to the abutment and could damage the instrument or, in the worst case, cause implant loss. (Fig. 15)

- *Soft tissue reduction*
  In case of soft tissue reduction, remove subcutaneous tissue as needed. Dissect the subcutaneous tissue with a scalpel and/or with scissors and forceps.

Step 4: Punching, suturing and attaching the healing cap and dressing

See instructions on page 24–25.



Aftercare and follow-up

It is very important to instruct the patient to maintain a good daily cleaning routine, using soap and water, in order to avoid debris buildup in the area of the implant site/abutment. Insufficient cleaning could initiate infections, which could result in implant extrusion even after several years.

Patient implant information and implant card must be provided as available to the patient in conjunction with the installation of the implanted component.

Postoperative

Removal of dressings

The mastoid pressure bandage may be removed the day after surgery. The dressing and stitches may be removed after 7–10 days, when the soft tissue has healed. Removal of the dressing may be facilitated if the dressing is wet. The healing cap and dressing are carefully removed, and the wound is gently cleaned using saline and gauze. The wound site is examined and treated if needed. At this stage, the patient should be informed about how to take care of the abutment and surrounding skin to maintain proper hygiene and avoid problems with skin irritation and infection. If the patient is unable to maintain hygiene himself, his caregiver should be instructed.

If the skin has not yet fully healed, a new visit for removing the healing cap and dressing should be planned approximately one week later.

If the skin around the abutment site is infected, check that the abutment is well attached and immobile. Prescribe an antibiotic ointment to apply around the abutment and check one week later. If the infection persists, check cleaning routines and instruct again.

Important

- *Using a soft band after implantation*
  A test band, head band or soft band must not be placed on top of an abutment, implant or sleeper implant.

Cleaning of the abutment site

- Clean the skin thoroughly to remove debris every few days. Use shampoo for hair washing; debris softens and is thus more easily removed.
- Use a non-alcoholic baby wipe to clean the area around the abutment during the first period before the skin is fully healed.
- Use an extra-soft cleaning brush or a cotton swab to clean around the outside and towards the inside of the abutment once healing has progressed sufficiently. Antibacterial soap is recommended.
- Note the importance of cleaning both inside and all around the skin-penetrating abutment. This is important for the prevention of debris buildup.

Important

- *Replace the brush*
  If a cleaning brush is used, replace it about once every 3 months. Bilaterally implanted patients should have two brushes, one dedicated for each side.

Checkup

After the fitting of the sound processor, the patient should be scheduled for 1–2 visits/year. During the scheduled visits:

- Inspect the skin surrounding the abutment to check if this skin is infected, elevated or irritated.
- Check that the abutment is well attached to the implant.
- Check for debris and hygiene. Give instructions on cleaning and hygiene if needed.
- Instruct the patient to immediately contact the clinic in the event of any problems.

Abutment adjustment and replacement

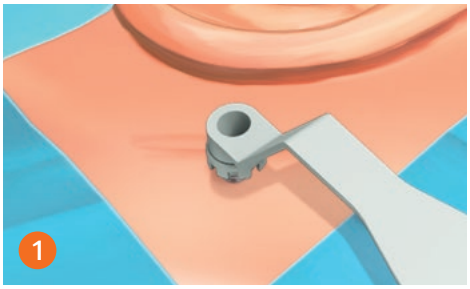
Tightening of the abutment connection screw

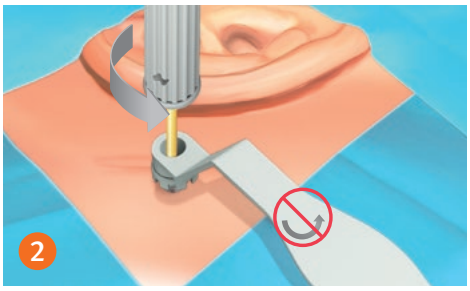
Movement of the abutment may lead to skin infection as well as poor sound quality. The abutment connection screw should be tightened to 25 Ncm with the help of the torque wrench or, if available, a drill unit with torque function. The counter torque wrench should be held in a steady position to prevent the screwdriver torque from loading the implant.

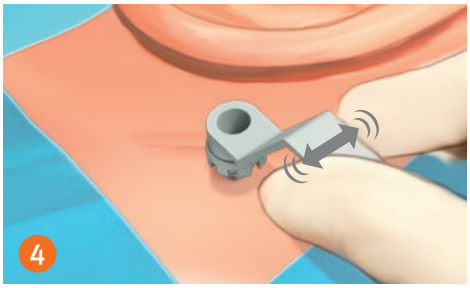
Replacement of the abutment

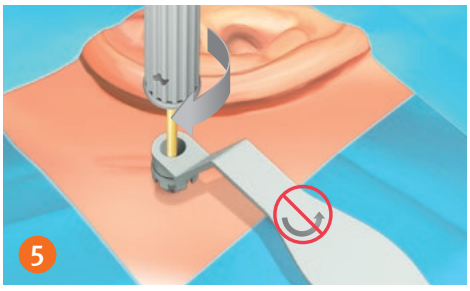
In some cases, skin overgrowth or scar tissue makes it necessary to exchange the abutment for a longer one in order to prevent the sound processor from touching the skin.

- Clean the area around the abutment. Wipe hairs away from the abutment so that they are not in the way.
- Connect the counter torque wrench to the abutment on the patient and hold it in a steady position. (Fig. 1)
- Release the abutment from the implant using the handle with screwdriver and unscrew the connection screw. (Fig. 2) Remove the screw and abutment.
- Disconnect the abutment from the counter torque wrench and discard it.
- Pick up the new abutment from the ampule using the counter torque wrench. (Fig. 3)
- Place the abutment correctly onto the hexagon on the implant.
  This is done by slowly and carefully turning the abutment with the counter torque wrench, holding it by the fingertips, until the abutment hexagon is fitted on the implant hexagon. (Fig. 4)
  The abutment should stop turning when the hexagons match.
  Make sure that no tissue is pinched between the implant and abutment.
- Hold the counter torque wrench in a steady position. Turn the connection screw to a stop position without tightening, using the screwdriver through the hole of the counter torque wrench. (Fig. 5)









- Attach the torque wrench to the screwdriver handle and tighten the connection screw with a torque of 25 Ncm. (Fig. 6, 7) Alternatively, the drill unit with the screwdriver machine can be used; the torque controller should be set to low speed with a torque of 25 Ncm.
- Disconnect the counter torque wrench. (Fig. 8)

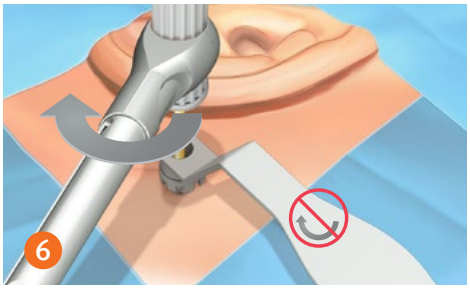
Important

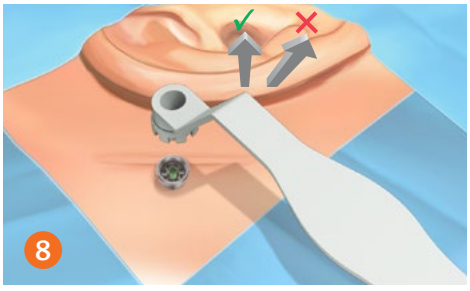
- *Lever effect*
  Consider bone thickness and bone quality when placing a longer abutment, as the lever effect increases with the abutment length.

- *Avoid increased load on the implant*
  Always use the counter torque wrench when releasing or securing the abutment connection screw and hold it in a steady position. Holding the counter torque wrench in a steady position prevents the screwdriver torque from loading the implant and possibly damaging the integrity of the bone, compromising proper osseointegration.

  When securing the connection screw, always use the counter torque wrench and torque wrench or drill unit with torque control. The abutment is fitted to the implant with a torque of 25 Ncm. Do not overtighten.

- *Releasing the instrument from the abutment*
  When releasing the abutment inserter or the counter torque wrench from the abutment, hold the instrument close to the tip to avoid creating a lever arm effect, and lift it straight up without bending. Bending the instrument will cause it to lock to the abutment and could damage the instrument or, in the worst case, cause implant loss. (Fig. 8)





Complications

Success rates for bone-anchored hearing surgery are very high, but unexpected situations may occur. It is important to inform the patient, prior to surgery, of all complications related to safety and effectiveness. The chapter below includes a list of potential intraoperative and postoperative complications and instructions on how to handle them. Medical device regulations require the manufacturer to report serious incidents to the appropriate authority. Should such an incident occur, notify your local distributor as soon as possible.

Intraoperative complications

Implant becomes stuck during insertion

If the implant gets stuck during the insertion, take the implant back out by setting the drill unit to low speed and putting it in reverse. Make sure that the alignment is correct and reinsert the implant. In the case of confirmed hard compact bone, start with 50 Ncm.

If the flange of the implant does not fully reach the bone surface using the drill unit, the final insertion can be carried out manually by carefully using the counter torque wrench.

If it is not possible to reach the flange due to improper alignment of the implant, then select a new implant site nearby.

Implant continues to rotate when the flange is down

When the torque setting is too high in relation to the quality of the bone, the implant may continue to rotate. This most often happens when dealing with soft or compromised bone. If this should occur, prepare a new implant site at least 5 mm from the first site and place the implant with a lower torque setting. If the second or third attempt also leads to a rotating implant, switch over to a two-stage procedure, place a cover screw and leave the implant for osseointegration.

Implant mobility

If the implant is mobile after insertion, find a new implant site at least 5 mm from the first implant site.

Perforation of the sigmoid sinus and exposure of dura mater

Although rare, a mild blood or CSF leak can occur during drilling. In very rare cases, a rupture of the sigmoid sinus can lead to heavy bleeding. Seal the leak according to regular clinical practice and choose a new implant site as close as possible without the two sites intersecting.

Epidural hematoma

Epidural hematoma is caused by blood buildup between the dura and the skull. It is a very rare complication. Intracranial complications should be monitored and treated according to regular clinical practice.

Postoperative complications

Implant loss

Failure of osseointegration has a variety of potential causes, including lack of adequate bone quality and/or quantity, lack of irrigation during surgery, surgical complications, infection, generalized diseases and trauma to the implant. Should the implant loosen, there is normally bone available for surgical placement of a new implant close to the old site. Report all implant losses to Oticon Medical.

Inflammation and infection around the abutment

Poor hygiene is the most common reason for skin problems around the abutment, but skin problems could also be related to movement of skin around the abutment, an abutment being too short, a loose abutment connection screw or insufficient implant stability. If the skin around the abutment becomes inflamed, thoroughly clean the implant site and apply antibiotic ointment if appropriate. Instruct the patient on how to maintain adequate hygiene and provide the patient with the appropriate aftercare instructions.

If the skin problems persist, remove the abutment and clean the skin thoroughly. Consider changing to a longer abutment. Perform a culture before providing the appropriate oral antibiotic. Allow the area to heal for 1–2 weeks and then place a new abutment.

Skin overgrowth

If the skin around the abutment grows up along the abutment, the abutment should be changed to a longer one. When the patient has very thick skin, or where there is persistent regrowth of subcutaneous tissue, it may be necessary to perform partial or full subcutaneous tissue reduction surgery. In exceptional cases, an inflammatory reaction may occur, resulting in complete overgrowth of the abutment by soft tissue.

Skin flap necrosis

Partial or, rarely, sub-total flap necrosis has been seen in the first weeks after surgery when using a surgical technique with tissue reduction. In most cases, an extended healing period is enough to overcome the problems. If appropriate, apply a mild antibiotic ointment or, as an alternative, a systemic antibiotic treatment. A skin graft is seldom required.

Intracranial complications

Trauma to the implant site can, in rare cases, result in intracranial complications such as perforated dura mater and bleeding, possibly resulting in epidural or subdural hematoma. Typically, the conditions will result in general neurological symptoms. Intracranial complications should be monitored and treated according to regular clinical practice.

Postoperative numbness – paresthesia
Postoperative numbness may occur after tissue reduction. Most often this will disappear within a few months, but it may be permanent. If a significant amount of subcutaneous tissue has been removed, the risk of permanent numbness increases.

Pain
If the patient experiences pain when touching the abutment, the abutment should be checked to see if it has come loose, as this could cause painful pinching. After a two-stage procedure or abutment change, pain can be caused by tissue that has become pinched between the implant and abutment.

Pain when touching the abutment can also be a sign that the implant has loosened. In rare cases, the patient can experience pain without touching the abutment. In most of these cases, the pain will subside when the implant is removed and a new implant is placed in the adjacent bone.

Bony overgrowth
Bony overgrowth around the implant can be removed at the time of soft tissue revision surgery to allow for an appropriate skin thickness. The potential occurrence of this complication increases for children implanted at a very young age.

Keloids
Keloids are an excessive amount of scar tissue around the implant site. Treat this condition according to general practice. To avoid repeated surgery, choose a longer abutment.

Bone infection, potentially causing osseonecrosis
This can occur primarily if the implant is installed in irradiated implant sites. It can be avoided by administering hyperbaric oxygen (HBO) before and after surgery and by striving for minimal tissue damage during surgery.

Precautions

Sporting activities
It is important to educate the patient on precautions to minimize trauma to the implant. The use of a helmet is important and some contact sports should be avoided.

Radiation therapy
If the patient needs to undergo radiation therapy in the head, the abutment should be disconnected from the implant and the site should be allowed to heal before being subjected to radiation.

MR Conditional

MRI Safety Information for Ponto Implant System
If the patient needs to undergo MRI (Magnetic Resonance Imaging), the sound processor must be disconnected. The implant and abutment can remain in place.[15, 16]

Non-clinical testing has demonstrated that the Ponto Implant System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg in the first level-controlled mode.

Under the scan conditions defined above, the Ponto Implant System is expected to produce a maximum temperature rise of 3.2ºC after 15 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters to compensate for the presence of this implant.

In non-clinical testing, the image artifact caused by the device extends approximately 10 mm from the Ponto Implant System when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

The Ponto Implant and abutment are MRI Conditional.
The sound processor is MRI Unsafe.

Longer abutments
It is important to consider bone thickness and bone quality when placing a longer abutment as the risk of bone fracture increases with the abutment length due to increased lever effect. Especially young children are potentially susceptible to trauma when selecting longer abutments.

List of symbols

REF	Catalog number
LOT	Batch code/lot number
MD	Medical device
UDI	Unique Device Identification
UDI-DI	Unique Device Identification – Device Identifier
	Manufacturer
	Date of manufacture
	Use-by date
	Do not reuse
	Do not resterilize
STERILE R	Sterilized using irradiation
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Caution
	MRI Conditional
RX only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed medical practitioner
CE 0413	CE mark with notified body identification number
CE	CE mark

Compatibility guide

Products that can be used with the Ponto System

Ponto System components	Products with ref. no. manufactured by Cochlear Bone Anchored Solutions AB
Ponto Sound Processor Family Ponto 5 Ponto 4 Ponto 3	**Compatible products from Cochlear BAS** Baha® abutments (90305, 90410) Baha® implants with abutment (90434, 90480)
	Incompatible products from Cochlear BAS Baha® BA300 Series abutments Baha® BA210 Series abutments Baha® BA400 Series abutments
Ponto Implant System Ponto Implants with pre-mounted abutments Ponto Abutments	**Compatible sound processors from Cochlear BAS** Baha® 5 (95201, 95202, 95203, 95204, 95205) Baha® 5 Power (95470, 95471, 95472, 95473, 95474, 95475) Baha® 5 SuperPower (96004, 96003, 96002, 96001)

Oticon Medical Ponto series sound processors and abutments used together with the above-listed sound processors and abutments from Cochlear Bone Anchored Solutions AB secure similar sound transmission, connection force and disconnection force. The sound quality and experience are determined by the sound processor being used.

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

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Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the power of sound to people at every stage of life. As part of the Demant group, a global leader in hearing health care with more than 16,500 people in over 30 countries and users benefitting from our products and solutions in more than 130 countries, we have access to one of the world's strongest research and development teams and the latest technological advances and insights into hearing care.

Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology. We work collaboratively with patients, physicians and hearing care professionals to ensure that every solution we create is designed with user needs in mind. We have a strong passion to provide innovative solutions and support that enhance quality of life and help people live full lives – now and in the future.
Because we know how much sound matters.

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