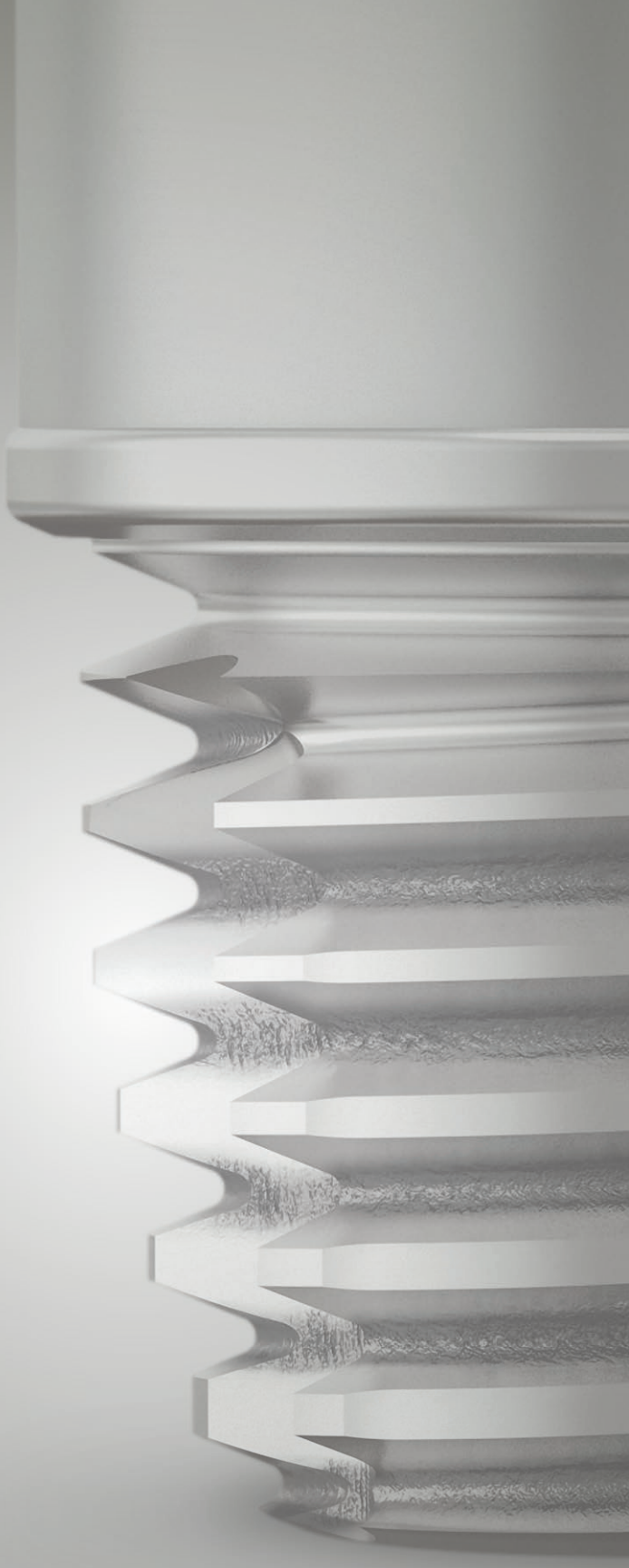
# Ponto Surgical Manual

## Linear incision procedure



Choose Sound.
Choose Ponto

oticon MEDICAL

# Contents

# Introduction

The Ponto Bone Anchored Hearing System is a solution suitable 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 provides guidance to healthcare professionals (surgeons and operating theatre nurses/staff) on overall planning, preparation, follow-up and aftercare aspects; and 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 Ponto 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. Furthermore, the Ponto Surgical Manual offers information on intra-operative and post-operative complications and cautions relevant to bone anchored hearing. A Summary of Safety and Clinical Performance for the Ponto System is 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 which 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 Addenda provide the surgeon with safe procedures for installation and aftercare. The installation of the implant is 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 where needed.*

Note: The surgeon is ENT surgeon, ENT physician, Otolaryngologist, Otologist or equivalent.
The operating theatre nurse is typically specialized as operating nurse.

*Illustrations and images in this manual are not to scale and are not intended to display actual markings.*

Terminology used in this instruction:
– Note: 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.

*https://ec.europa.eu/tools/eudamed
Entering key: Basic UDI-DI 57121491000488

# 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 a 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 peri-operative 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.

**Note**

- *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.

*Soft tissue thickness*

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

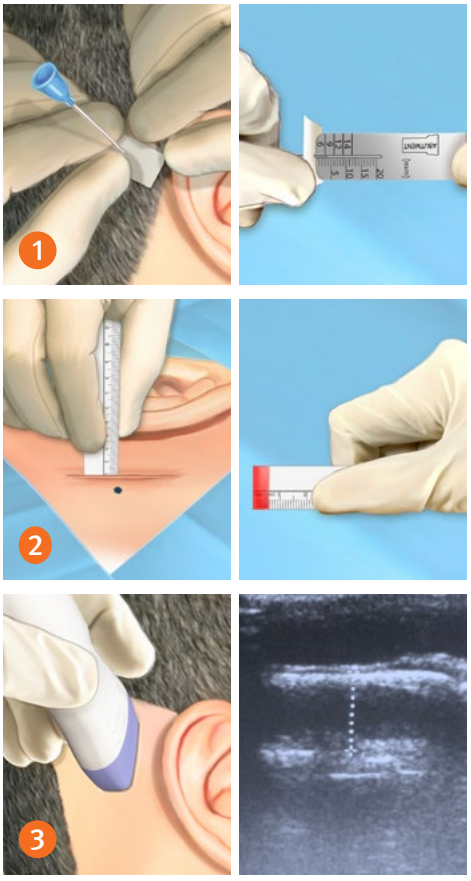
There are several methods to measure the soft tissue thickness:

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

## Osseointegration

Osseointegration is the process where 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.



## 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 implant with pre-mounted abutment, dressing and healing cap | |
| **Surgical follow-up** | **Time after surgery** |
| Remove healing cap and dressing and check implant site. If healed, remove sutures and instruct patient or their family/caregivers on cleaning and aftercare. If not healed refit healing cap and replace dressing | 7-10 days |
| If not healed, 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 surrounding skin area | Down to 2 weeks, based on individual patient evaluation.<br><br>*In the US, 3 months, based on individual patient evaluation.* |
| Fit the sound processor (see Ponto 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.<br>Schedule subsequent follow-up semi-annually or annually | |

## Two-stage surgery

| Surgical procedure, first stage | |
|---|---|
| Place implant (without pre-mounted abutment) and cover screw | |
| **Surgical follow-up** | **Time after surgery** |
| Remove sutures | 7-10 days |
| Osseointegration period | 3-6 months, based on individual patient evaluation |
| **Surgical procedure, second stage** | |
| Remove cover screw, prepare the soft tissue and connect abutment. Place healing cap and dressing | |
| **Surgical follow-up** | **Time after second-stage surgery** |
| Remove healing cap and dressing and check implant site. If healed, remove sutures and instruct patient or their family/ caregivers on cleaning and aftercare. If not healed refit healing cap and and replace dressing | 7-10 days |
| If not healed, 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 surrounding skin area | Approx 10 days, based on individual patient evaluation |
| Fit the sound processor (see Ponto 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.<br>Schedule 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 pre-operatively 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 Ponto Candidacy Guide for more information on pre-operative 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 should be 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 secured 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.

The Ponto System implantable components are manufactured from medical grade titanium. The material that will be in long-term contact with body tissue and/or bone is 100% titanium grade 4 in accordance with to ASTM F67 (Standard Specification for Unalloyed Titanium, for Surgical Implant Applications).

## 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

*The shank is compatible to ISO 1797, type 1.

Recommendation on drilling equipment fulfilling standard IEC 60601 (Electrical equipment for medical use) for safety and efficacy. The equipment shall allow a drill speed of 1500-2000 rpm and implant installation at low speed with torque setting between 10-50 Ncm.

Guide drill

Countersink drill



Soft healing cap

## Non-disposable instruments

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

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

*The ‘Handle with screwdriver’ consists of two parts (handle and screwdriver bit) which are assembled before use.

**The shank is compatible to ISO 1797, type 1.

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.

**Note**

- *Back-up components*
  The single-stage surgical procedure should always be planned so that back-up 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.

- *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 effectivity risks, do not re-sterilize or reuse these single use products.

- *Implant components*
  Keep the implant in the blister pack until it is verified that the bone quality and depth are appropriate to support the implant. The blister pack acts as the sterile barrier; the ampoule is only a container for the sterile product.

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

- *Damaged packaging and expiry date*
  If sterile packaging is punctured or damaged, the components shall be considered as non-sterile and not to be used. If the expiry date is passed, the component should not be used.

- *Infection control routines*
  Non-disposable instruments shall be processed according to local infection control guidelines. See Cleaning and sterilization instructions of non-disposable instruments as provided with the instrument.

  Single-use/Disposable instruments shall not be reprocessed due to contamination and effectivity risks and shall be discarded after each patient.

- *Disposal*
  Disposal of contaminated devices shall be handled according to local regulations and general hospital routines for medical waste.

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

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

## Paediatric 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 described in the Ponto Surgical Manual Addenda, provide the surgeon with safe alternatives.

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 where needed.

# Linear incision technique

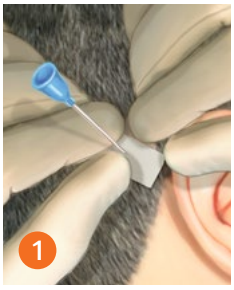
## Choosing abutment length

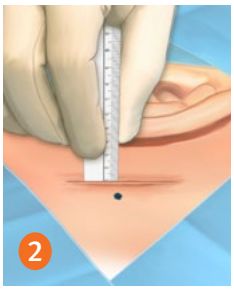
- The soft tissue should be assessed to identify the appropriate abutment length.
  - Assess soft tissue thickness in normal state (without local anaesthesia) with a thin needle and a ruler. (Fig.1)
  - When using the needle be aware of possible compression of the soft tissue.
  - During surgery: measure in the incision line – using a sterile paper ruler; compensate for injections. (Fig.2)
- Select abutment length according to Fig. 3, or as indicated on the Oticon Medical ruler.
- Decide on partial soft tissue reduction if the soft tissue is thicker than what suits the longest abutment.

**Note**

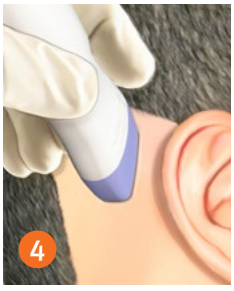
- *Lever effect*
  When placing a longer abutment consider bone thickness and bone quality as the risk of bone fracture increases effect.

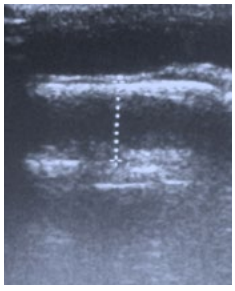
- *Ultrasound*
  Assessment of soft tissue thickness before the procedure can also be done with ultrasound. Avoid compressing the soft tissue during measurement. (Fig.4)



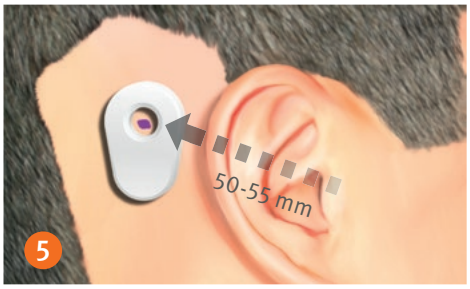

| Natural skin thickness | Abutment length |
|---|---|
| 0.5-3 mm | 6 mm |
| 3-6 mm | 9 mm |
| 6-9 mm | 12 mm |
| 3 9-12 mm | 14 mm |

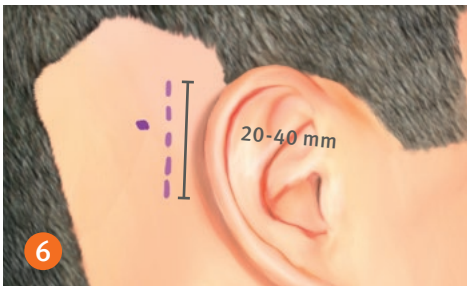


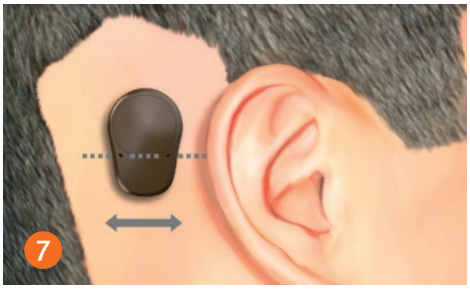



## Step 1: Preparing the site

- Use the sound processor indicator to locate the implant site. This is generally 50-55 mm from the centre 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 implant site on the skin and periosteum through the hole of the sound processor indicator, using a marker. (Fig.5)
- Mark an incision line anterior of the implant site. (Fig.6)
- Inject a local anesthetic with a vasoconstrictor. This should be done even when the surgery is performed under general anesthesia.




**Note**

- *Implant positioning*
  The implant position shall allow for appropriate placement of the sound processor. The sound processor must not touch the pinna or patient's glasses as this may cause feedback and discomfort. Neither should the sound processor be placed too far back, on the head, as this can compromise both the position of the microphones and the esthetics. The microphones of the processor should point in both anterior and posterior directions. (Fig.7)

  When determining the implant position, consider any future reconstructive outer ear surgery or outer ear prostheses.

- *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

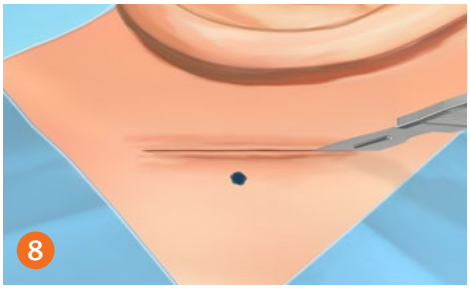
- Make the incision down to the periosteum. (Fig. 8 )
- Open up the incision using a self-retaining retractor. (Fig. 9)
- Incise the periosteum.
- Remove the periosteum around the implant site using a periosteal elevator. (Fig. 10)

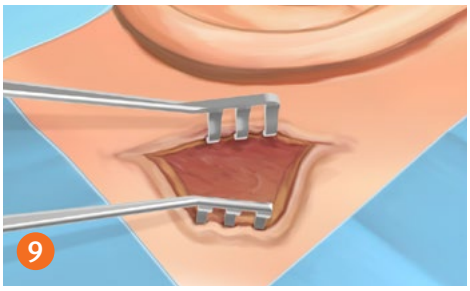
**Note**

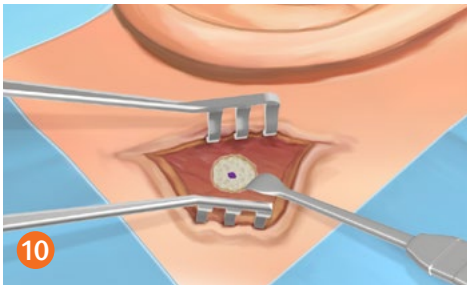
- *Periosteum*
  If it is difficult to move the periosteum aside, it might be helpful to incise the periosteum using a cruciate incision.

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

- *Electro-coagulation*
  If electro-coagulation 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

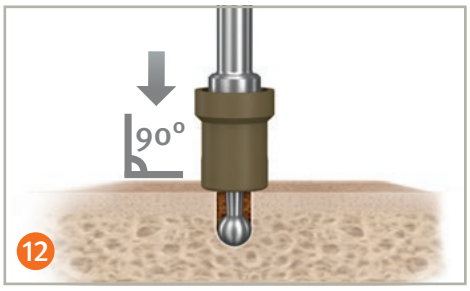
Initial drilling is performed to gauge the bone thickness and guide choice of implant length.

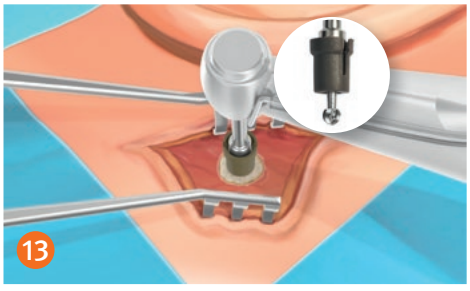
- Set the drill speed to 1500-2000 rpm. (Fig. 11)
- Place the drill perpendicular to the bone, check the angle from several directions. (Fig. 12 )
- Start drilling with the spacer in place applying generous cooling with saline solution irrigation directed towards the tip of the drill. (Fig. 13)
- Move 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 )

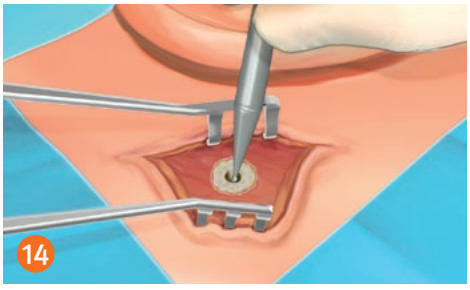
**Note**

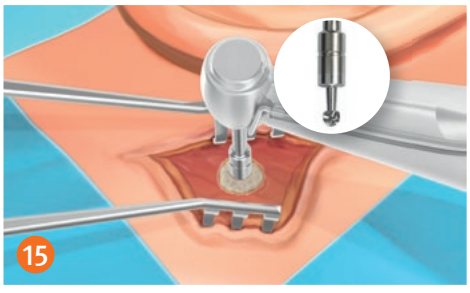
- *Drilling*
  It is important that all drilling is carried out perpendicular to the bone surface. To help the operator maintain the perpendicular direction, the drills are designed with a long shaft. The long shaft provides a sight line for the operator.

- *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.

- Maintain 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.

**Note**

- *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.

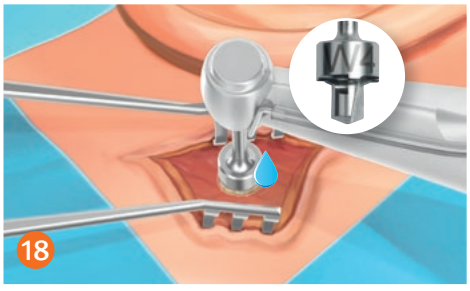
  The drills are designed with a longer shaft to help the operator maintain the perpendicular direction. The long shaft provides a sight line for the operator. Make sure not to over-widen the hole with circular movements, which may reduce the initial stability of the implant.

- *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.

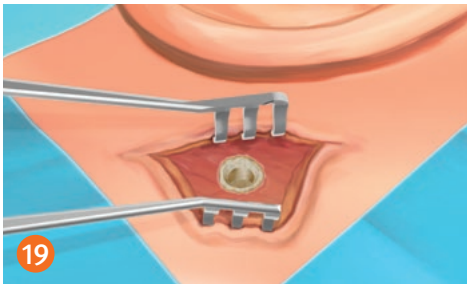
- *Recess*
  The widening of the hole is sufficient when the stop collar of the countersink has reached the bone surface. The contour of the bone surface may further influence the visibility of the recess. (Fig. 20)

16

17



18


19

20

## Step 5: Implant installation

- Set the drill unit to low speed with automatic torque control. (Fig. 21)
  - 40-50 Ncm in compact bone
  - 10-20 Ncm in compromised or soft bone.
- 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 hand piece. (Fig. 22)
- Place the implant axially aligned to the hole and start inserting the implant. (Fig. 23)
- Wait for the drill unit to stop when the preset torque is reached.
- Release the hand piece from the abutment by holding the hand piece close to the abutment and lift straight up. (Fig. 24)

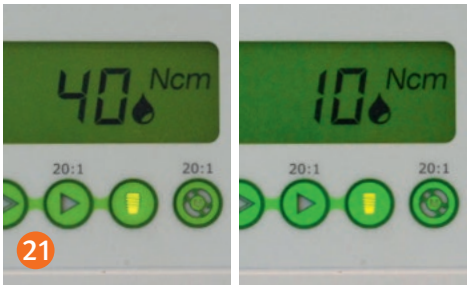
**Note**

- *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.

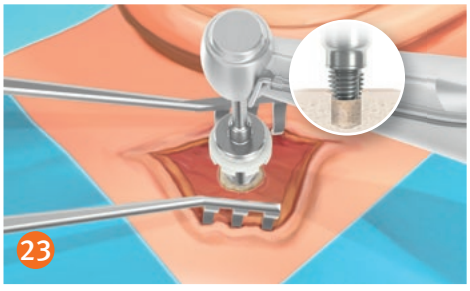
- *Manual insertion*
  If the implant is not fully inserted using the drill unit, the counter torque wrench may be used, with great care, to insert the implant manually until the flange reaches the bone surface. Use the finger tips to gently push the counter torque wrench clockwise. (Fig. 25)

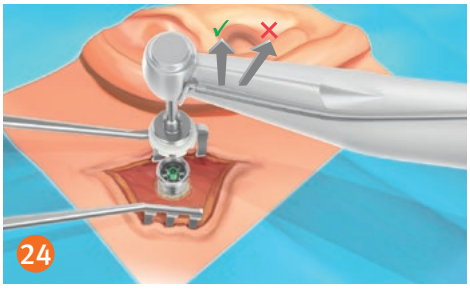
- *Releasing instrument from abutment*
  When releasing the abutment inserter or the counter torque wrench from the abutment, hold close to the tip of the instrument to avoid creating a lever arm effect and lift straight up, without bending. Bending the instrument will lock it to the abutment and possibly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

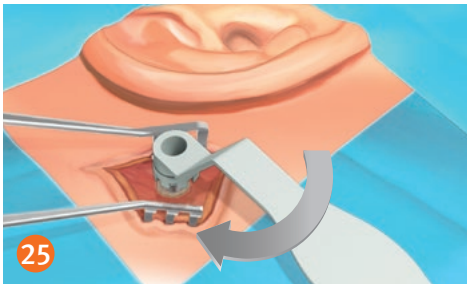
- *Soft tissue reduction*
  In case of soft tissue reduction, remove subcutaneous tissue as needed. Dissect the subcutaneous tissue with a scalpel and/or with scissors and forceps.







## Step 6: Punching and suturing

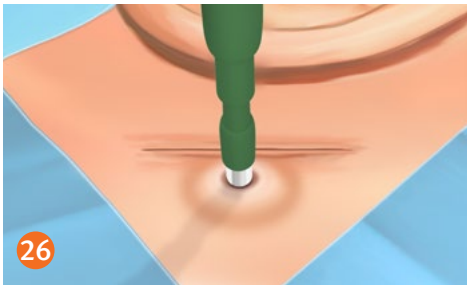
- Punch a hole exactly over the abutment using a biopsy punch (Ø4 mm – Ø5 mm). (Fig. 26)
- Gently ease the skin over the abutment.
- Close the incision. (Fig. 27)

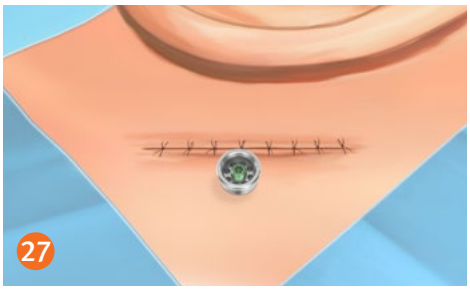
**Note**

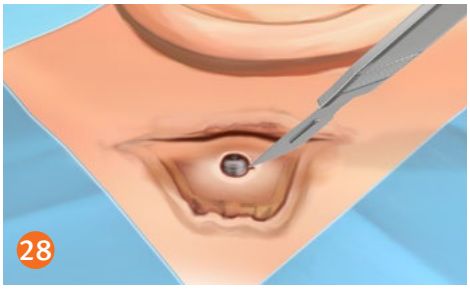
- *Punching*
  The punching of the hole can alternatively be done after skin closure.

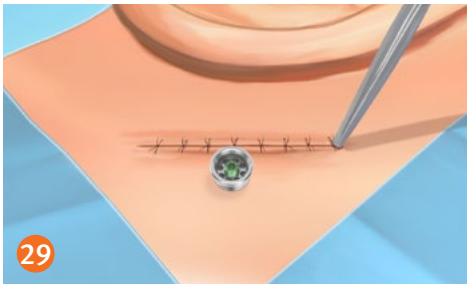
- *Ease the skin over the abutment*
  If the hole needs to be a little enlarged to ease the skin down over the abutment, make a minor incision centered on the side of the punched hole.Avoid making the hole larger than needed to just ease the abutment through. (Fig. 28)

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



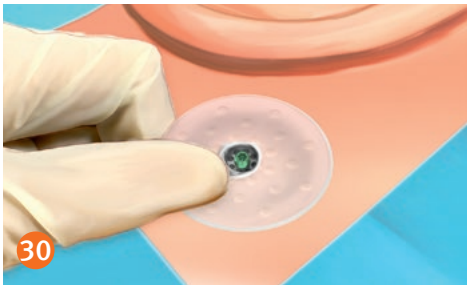



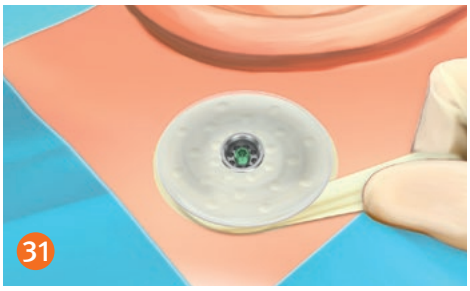



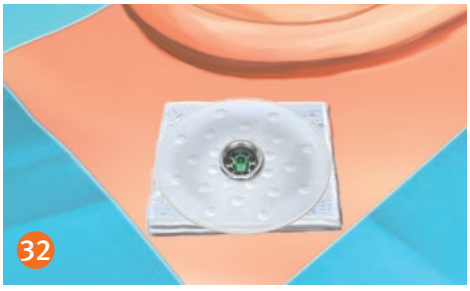
## Step 7: Attaching the healing cap and dressing

The healing cap is intended to be attached to the abutment during the soft tissue healing period after bone anchored implant installation to hold the dressing in place and act as protective mechanical barrier.

- Apply the dressing and connect the healing cap. Depending on the dressing type used, the healing cap is either placed before or after the dressing is applied. (Fig. 30-32)
- *Examples of suitable dressings*
  - Ribbon gauze wrapped around the abutment;
  - A tailor- made foam dressing.
  - Layers of silicone mesh dressing, making sure to provide sufficient pressure.
- The healing cap holds the dressing in place and minimizes the risk of haematoma.
- Place a mastoid pressure bandage outside the dressing and healing cap.




**Note**

- *Dressing*
  The amount of dressing should be appropriate for the space between the healing cap and the skin.

- *Ointment*
  Topical antibiotic ointment is usually used together with the dressing.

- *Swollen soft tissue*
  If the soft tissue is swollen and the space between the skin and the healing cap is too small for a suitable dressing, the swelling can be reduced by gently putting pressure on the soft tissue around the abutment using the fingers.

# 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

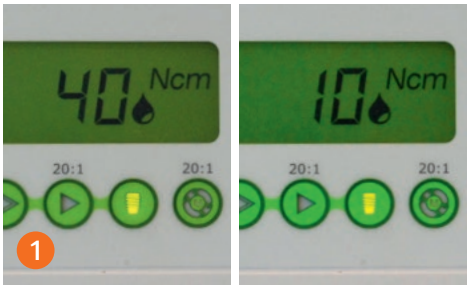
- Set the drill unit to low speed with automatic torque control. (Fig. 1)
  - 10-20 Ncm in compromised or soft bone.
  - 40-50 Ncm in compact bone.
- Place the ampule in the holder and unscrew the ampule lid.
- Pick up the implant with the square fit connection. (Fig. 2)
- Place the implant axially aligned to the hole and start inserting the implant. (Fig. 3)
- Wait for the drill unit to stop when the preset torque is reached.
- Release the hand piece from the implant adapter by holding the hand piece close to the adapter and lift 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 adaptor.
- Place a second (sleeper) implant, if this is planned. A sleeper implant is placed approximately 10 mm from the center of the primary implant.

**Note**

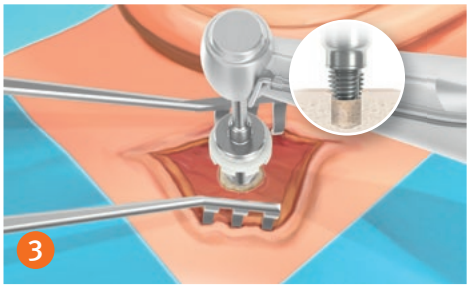
- *Torque*
  When the flange of the implant has reached the bone surface it will stop automatically. If the flange does not reach the bone surface, the torque setting may be increased.

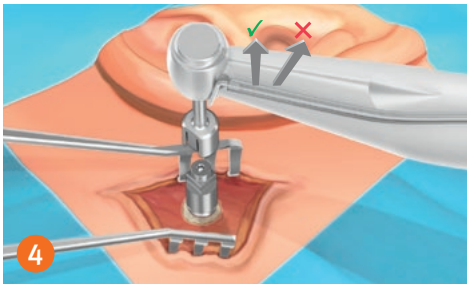
- *Manual insertion*
  If the implant is not fully inserted using the drill unit, the counter torque wrench may be used, with great care, to insert the implant manually until the flange reaches the bone surface. Use the square wrench key on the open end of the counter torque wrench. Use the finger tips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

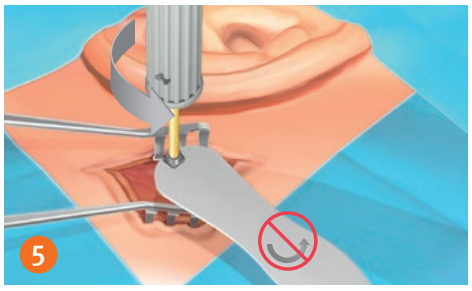
- *Releasing the instrument*
  When releasing the square fit connection, hold close to the tip of the instrument to avoid creating a lever arm effect and lift straight up, without bending. Bending the instrument will lock the square fit connection to the implant adapter and possibly damage the instrument 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)

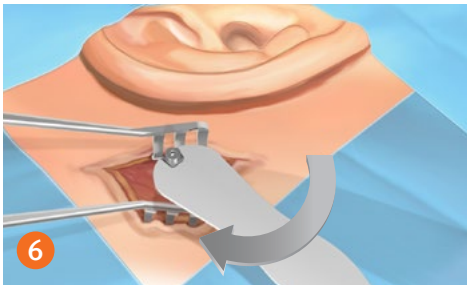
**Note**

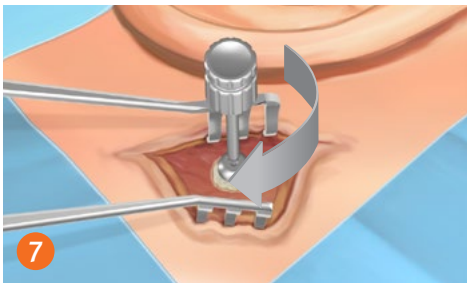
- *Cover screw*
  Do not over-tighten the cover screw as this may loosen the implant when loosening the cover screw in the second stage of the procedure.

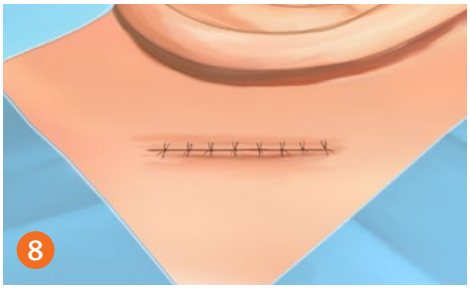
  A sleeper implant should also be covered with a cover screw.

## 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

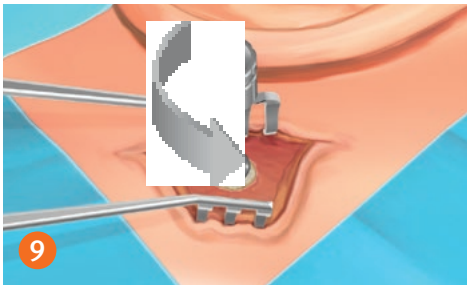
- Use the old scar and/or palpation of the implant to locate the implant site.
- Shave the area.
- Mark the implant site on the skin.
- Mark the incision.
- Measure the skin thickness and decide on an appropriate abutment length according to guidelines; see page 18.
- Inject a local anesthetic, even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

### Step 2: Incision

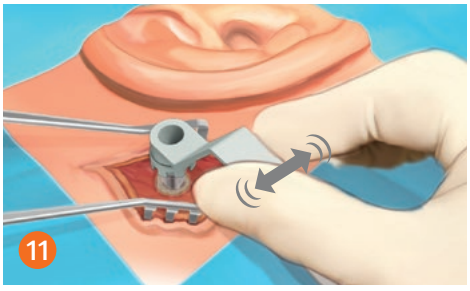
- Make the incision down to the periosteum.

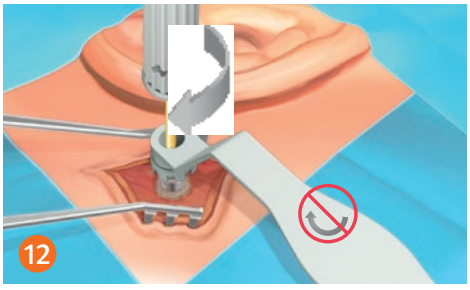
### Step 3: Removal of the cover screw and connection of the abutment

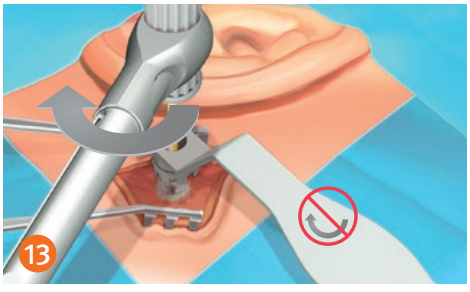
- Incise the periosteum over the cover screw.
- Remove the cover screw from the implant using the hexagon screwdriver and discard the cover screw. (Fig. 9)
- Pick up the abutment from the ampule using the counter torque wrench. (Fig. 10)
- Place the abutment correctly onto the hexagon on the implant. This is done by slowly and carefully turning the abutment with the counter torque wrench holding it by the finger tips, 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 screw driver 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)







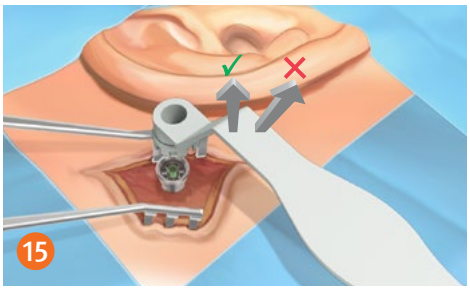
**Note**

- *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 with a torque of 25 Ncm to the implant. Do not overtighten.

- *Releasing instrument from abutment*
  When releasing the abutment inserter or the counter torque wrench from the abutment, hold close to the tip of the instrument to avoid creating a lever arm effect and lift straight up, without bending. Bending the instrument will lock it to the abutment and possibly 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 instruction on page 24-25.

# Aftercare and follow-up

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

Ponto Implant Patient Information and Ponto Implant Card shall be provided to the patient in conjunction to the installation of the implanted component.

There are no indications to suggest an expected end-of-life for the implant components. However, patients should always be informed to contact the clinic in case of suspected complications.

The Ponto System consists of small parts which, if detached and swallowed, may represent a risk of choking and/or damage to the gastrointestinal tract. Inform patients to keep small parts and accessories out of reach of children.

# Post-operative

## 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.

**Note**

- *Using softband after implantation*
  A test band, head band or softband must not be placed on top of an abutment, implant or sleeper implant.
- *Exposure to high temperatures*
  Avoid exposing the implant/abutment area to high temperatures (e.g. sauna, hot air drying) in the post-surgical period, until the area is fully healed.

## Cleaning of the abutment site

- Clean the skin thoroughly with mild soap and warm water, to remove debris every few days. For hair washing, use a mild shampoo; debris becomes softer and is more easily removed.
- Use a non-alcoholic wet wipe to clean the area around the abutment during the first period before the skin is fully healed.
- Use a moist cotton swab to clean around the outside and towards the inside of the abutment once healing has progressed sufficiently. If the patient is bilaterally implanted, separate cotton swabs should be used for each abutment.
- Note the importance of cleaning both inside and all around the skin-penetrating abutment. This is important to prevent debris build-up.

## Check-up

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

## Abutment adjustment, replacement or removal

The implant is installed for long-term use, and is normally not to be removed, unless medical conditions require explantation. The abutment is a replaceable connection and can, if needed, be adjusted, replaced or removed.

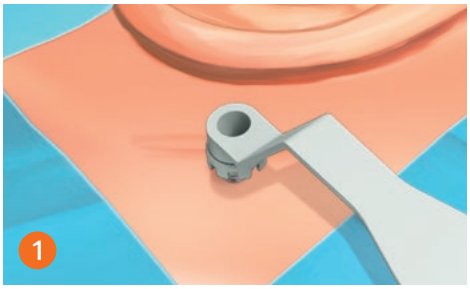
### Tightening of the abutment connection screw

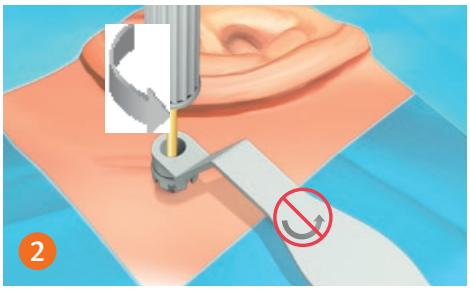
Movement of the abutment may lead to skin infection as well as poor sound quality. The abutment connection screw should be tightened to 25 Ncm with the help of the torque wrench or if available, a drill unit with torque function. The counter torque wrench should be held in a steady position to prevent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

### Replacement of the abutment

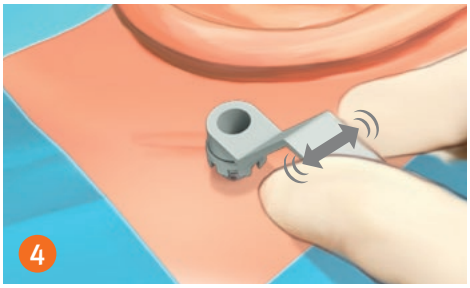
In some cases, skin overgrowth or scar tissue makes it necessary to exchange abutment to a longer one in order to prevent the sound processor from touching the skin.

- 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 finger tips, 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 screw driver 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)

## Removal of abutment

If the patient wishes to discontinue the treatment (i.e. stop using the sound processor), the abutment is removed and a cover screw is placed. The skin is closed whilst the implant is safely kept in place.

A cover screw needs to be attached to the implant 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, in case the patient wants to continue with the treatment in the future.

Follow the first four steps in 'Replacement of the abutment' on previous page and then attach a cover screw (see instructions 'Placing a cover screw' on page 29).

If there is a need/desire to remove the osseointegrated implant the implant would have to be drilled out by the surgeon.

**Note**

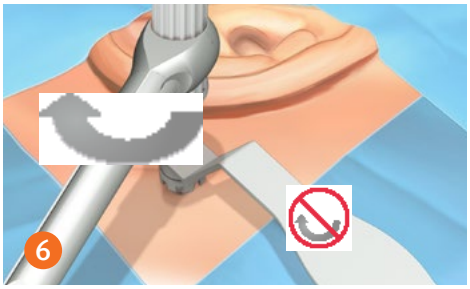
- *Lever effect*
  Consider bone thickness and bone quality when placing a longer abutment as the lever effect increases with the abutment length.

- *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.

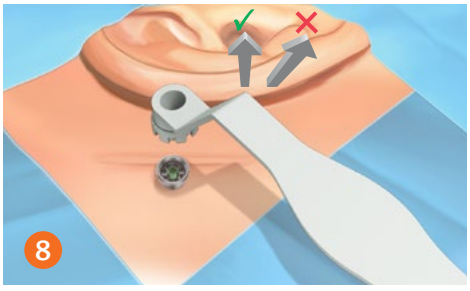
  When securing the connection screw, always use the counter torque wrench and torque wrench or drill unit with torque control. The abutment is fitted with a torque of 25 Ncm to the implant. Do not over-tighten.

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

- *Disposal*
  Disposal of contaminated devices shall be handled according to general hospital routines for medical waste according to local regulations.







# Complications

Success rates for bone anchored hearing surgery are very high but unexpected situations may occur. Importantly, prior to surgery, the patient must be informed of all potential complications related to safety and effectiveness. The chapter below includes a list of potential intra-operative and post-operative 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.

## Surgical events

### Implant becomes stuck during insertion

If the implant gets stuck during the insertion, back out the implant by setting the drill unit to low speed and put it in reverse. Make sure that the alignment is correct and re-insert the implant. If 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.

## Intra-operative complications

### Perforation of the sigmoid sinus or CSF leak

Although rare, a 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.

### Intracranial complications

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

## Post-operative 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 become loose there is normally bone available for surgical placement of a new implant close to the old site. Report all implant losses to Oticon Medical.

### Intracranial complications

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

### 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.

### 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.

### 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.

## 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 re-growth of subcutaneous tissue it may be necessary to perform partial or full subcutaneous tissue reduction surgery. In exceptional cases, an inflammatory reaction may occur and result in complete overgrowth of the abutment by soft tissue.

## Post-operative numbness-paresthesia

Post-operative 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 become loose. 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.

## Bone overgrowth

Bone 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.

# Precautions

MR Conditional

## MRI Safety Information for Ponto Implant System

If the patient needs to undergo MRI (Magnetic Resonance Imaging) the soundprocessor must be disconnected. The implant and abutment can remain in place.[9, 10]

Patients who have other MR Conditional devices can be scanned as long all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met.

Non-clinical testing has demonstrated that the Ponto Implant System is MR Conditional. A patient with this device can be safely scanned in a 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)
- RF excitation with a circularly polarised (CP) RF field
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤2 W/kg or maximum head averaged SAR of 3.2 W/kg in the normal operating mode.
- MR scanner type cylindrical
- B0 field orientation horizontal
- Whole body transmit coil

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Under the scan conditions defined above, the Ponto Implant System is expected to produce a maximum temperature rise of 2.3 ºC after 15 min  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 15 mm from the Ponto Implant System when imaged with a gradient echo pulse sequence and a 1.5 Tesla MRI system.

The Ponto implant and abutment are MR Conditional.
The sound processor is MR 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.

## 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.

## 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.

## Exposure to high temperatures

The implant and abutments are made from titanium and exposure to high temperatures (e.g. sauna, hot air hair drying) may cause heating of the implant/abutment area.

## Explanation of symbols

| | |
|---|---|
| REF | Catalogue number |
| LOT | Batch code/Lot number |
| MD | Medical device |
| UDI | Unique Device Identifier |
| UDI-DI | UDI – Device Identifier |
|  | Manufacturer |
|  | Date of manufacture |
|  | Use by date |
|  | Do not re-use |
|  | 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 |
|  | MR Conditional |
| Rx only | Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed medical practitioner |
| CE 0123 | The device complies with all required EU regulations and directives. The four digit number indicates the identification of the Notified Body |
| CE | The device complies with all required EU regulations and directives |

# 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**<br>Ponto 5<br>Ponto 4 | **Compatible products from Cochlear BAS**<br>Baha® abutments (90305, 90410)<br>Baha® implants with abutment (90434, 90480) |
| | **Incompatible products from Cochlear BAS**<br>Baha® BA300 Series abutments<br>Baha® BA210 Series abutments<br>Baha® BA400 Series abutments |
| **Ponto Implant System**<br><br>Ponto Implants with pre-mounted abutments<br>Ponto Abutments | **Compatible sound processors from Cochlear BAS**<br>Baha® 5 SuperPower (96004, 96003, 96002, 96001)<br>Baha® 6 Max (P1668389, PP1668390, P1668391, P1668392, P1668393, P1668394) |

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 that is being used.

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

# References


1. *Davids T, Gordon KA, Clutton D, Papsin BC. Bone-anchored hearing aids in infants and children younger than 5 years. Archives of Otolaryngology-Head and Neck Surgery; 2007 Jan; 133 (1): 51-5.*

2. *Tjellström A, Håkansson B, Granström G. Bone-anchored hearing aids: current status in adults and children. Otolaryngologic Clinics of North America; 2001 Apr; 34(2): 337-64.*

3. *Papsin BC, Sirimanna TK, Albert DM, Bailey CM. Surgical experience with bone-anchored hearing aids in children. Laryngoscope; 1997 Jun; 107(6): 801-6.*

4. *Dun CA, Faber HT, de Wolf MJ, Mylanus EA, Cremers CW, Hol MK. Assessment of more than 1,000 implanted percutaneous bone conduction devices: skin reactions and implant survival. Otology & Neurotology; 2012 Feb; 33(2): 192-8.*

5. *Hultcrantz, M. Outcome of the bone-anchored hearing aid procedure without skin thinning: a prospective clinical trial. Otology & Neurotology; 2011 Sep; 32(7): 1134-9.*

6. *Lanis A, Hultcrantz M. Percutaneous Osseointegrated Implant Surgery Without Skin Thinning in Children: A Retrospective Case Review. Otology & Neurotology; 2013 Jun; 34(4): 715-22.*

7. *Hawley K, Haberkamp TJ. Osseointegrated hearing implant surgery: outcomes using a minimal soft tissue removal technique. Otolaryngol Head Neck Surg.; 2013 Apr; 148(4): 653-7.*

8. *Husseman J, Szudek J, Monksfield P, Power D, O'Leary S, Briggs R. Simplified bone-anchored hearing aid insertion using a linear incision without soft tissue reduction. J Laryngol Otol.; 2013 Jul; 127 Suppl 2: S33-8.*

9. *Fritsch MH, Naumann IC, Mosier, KM. BAHA devices and magnetic resonance imaging scanners. Otology & Neurotology; 2008 Dec; 29(8): 1095-9.*

10. *Arndt S, Kromeier J, Berlis A, Maier W, Laszig R. Aschendorff, A. Imaging procedures after bone-anchored hearing aid implantation. Laryngoscope; 2007 Oct; 117(10): 1815-8.*

Oticon Medical AB
Datavägen 37B
SE-436 32 Askim
Sweden
Tel: +46 31 748 61 00

CE 0123

266971en - version A / 2023.03

oticon MEDICAL | Because sound matters

www.oticonmedical.com