Surgical Manual
including Linear incision with tissue preservation

Ponto™
– The Bone Anchored Hearing System
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Introduction

The Ponto Bone Anchored Hearing System is a solution for many patients with mixed/conductive hearing loss or single-sided deafness. It 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; and it sets forth detailed recommended procedures for using bone anchored surgical components and instruments. The tissue preservation surgical technique is described in this manual, while other safe surgical technique alternatives such as the skin flap and linear incision technique with tissue reduction are described in the Surgical Manual Addendum. Please refer to the Candidacy Guide for information about which patients are candidates for a bone anchored hearing system.

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 necessary 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 the standard 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.
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, as well as the skin preparation, are carried out in the same procedure. The sound processor is then generally fitted 3 months after surgery.

Single-stage surgery is recommended for:
- Adult patients with normal bone quality and thickness (>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 depth 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 and Canada, the placement of a bone anchored implant is contra-indicated 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. In these cases a modified surgical technique with for example, a polytetrafluoroethylene (PTFE) membrane can be used. If a PTFE membrane is used it must be removed in the second stage surgery. 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.\textsuperscript{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)
- 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 for osseointegration before loading the implant must be judged by the surgeon based on assessment of the bone depth and quality during the first stage of the surgical procedure. Generally 3 months osseointegration is recommended for patients with normal bone thickness and normal adult bone quality. 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 values 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.

<table>
<thead>
<tr>
<th>Single-stage surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical procedure</strong></td>
</tr>
<tr>
<td>Place implant with pre-mounted abutment, dressing and healing cap</td>
</tr>
<tr>
<td><strong>Surgical follow-up</strong></td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>If not healed after 7-10 days, repeat instructions above</td>
</tr>
<tr>
<td><strong>Fitting of the sound processor</strong></td>
</tr>
<tr>
<td>Check that the implant is firmly integrated. Check that the abutment is well connected to the implant. Check surrounding skin area</td>
</tr>
<tr>
<td>Fit the sound processor (see Audiological Manual)</td>
</tr>
<tr>
<td><strong>Routine follow-up</strong></td>
</tr>
<tr>
<td>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 subsequent follow-up semi-annually or annually</td>
</tr>
</tbody>
</table>
**Two-stage surgery**

**Surgical procedure, first stage**

Place implant (without pre-mounted abutment) and cover screw

<table>
<thead>
<tr>
<th>Surgical follow-up</th>
<th>Time after surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove sutures</td>
<td>7-10 days</td>
</tr>
<tr>
<td>Osseointegration period</td>
<td>3-6 months, based on individual patient evaluation</td>
</tr>
</tbody>
</table>

**Surgical procedure, second stage**

Remove cover screw, prepare the soft tissue and connect abutment. Place healing cap and dressing

<table>
<thead>
<tr>
<th>Surgical follow-up</th>
<th>Time after second-stage surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 refill healing cap and replace dressing</td>
<td>7-10 days</td>
</tr>
<tr>
<td>If not healed after 7-10 days, repeat instructions above</td>
<td>14 days</td>
</tr>
</tbody>
</table>

**Fitting of the sound processor**

Check that the abutment is well connected to the implant. Check surrounding skin area

<table>
<thead>
<tr>
<th>Time after second-stage surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approx 10 days, based on individual patient evaluation</td>
</tr>
</tbody>
</table>

**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 subsequent follow-up semi-annually or annually
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 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.

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 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.

Disposable components and instruments for single-stage surgery:
- Implant with abutment
- Guide drill
- Countersink drill
- Healing cap
Disposable components and instruments for two-stage surgery,
First stage:
• Implant (with pre-mounted implant adapter)
• Guide drill
• Countersink drill
• Cover screw hexagon
Second stage:
• Abutment
• Healing cap

For detailed instructions on required components and instruments, please consult the Surgical Set-Up Guide for the Ponto System (can be ordered from your Oticon Medical representative or found at www.oticonmedical.com).

Cleaning and sterilization of non-disposable instruments

• Limitations on reprocessing
  Repeated reprocessing has a minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Instructions

• Containment and transportation
  It is recommended that instruments are reprocessed as soon as reasonable practical following use.

• Preparations for cleaning
  The ‘screwdriver, machine, 35 mm’ should be removed from the screwdriver handle prior to cleaning. For the torque wrench, follow the manufacturer’s instruction for use supplied with the instrument.

• Automated cleaning
  The non-disposable instruments can be cleaned in a washer-disinfector using a low alkaline detergent recommended by the washer-disinfector manufacturer. For the torque wrench, follow the manufacturer’s instruction for use supplied with the instrument.

• Manual cleaning
  The non-disposable instruments are cleaned using water and a mild detergent to remove blood and other contaminants. If additional cleaning is necessary an ultrasonic bath can be used.

• Disinfection
  Isopropyl alcohol should be used in accordance with label instructions.

• Drying
  When performing manual cleaning let each instrument air dry in controlled conditions.
• **Inspection**
  Visually inspect all instruments for damage, wear and complete removal of visible soiling.

• **Packaging**
  Standard wrapping materials in accordance with EN 868 / ISO 11607 should be used.

• **Sterilization**
  Vacuum autoclave in saturated steam at 132°C / 270°F for minimum holding time 4 minutes or at 134°C/273.2°F minimum holding time 3 minutes. Minimum drying time 20 minutes.
  The sterilization parameters should conform to ISO 17665-1 or be set by a validation study. Do not exceed 137°C/278.6°F and ensure that the autoclave’s maximum load is not exceeded.

• **Storage**
  Sterilized and packed instruments should be stored in a controlled environment protected from dust, moisture and large temperature fluctuations.

**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**

• **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.
  Consider the risk of dropping products.

• **Single-use components**
  The implant components including the guide drill and countersinks are for single use only and not intended for re-sterilization.

• **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.
• **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.

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

• **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.

• **Infection control routines**
  Non-disposable surgical instruments shall be processed according to local infection control guidelines. See Cleaning and sterilization of non-disposable instruments above. Disposable instruments shall be discarded after each patient.
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, a polytetrafluoroethylene (PTFE) membrane or bone chips may be used to create additional bone for implant anchorage. See also page 6.

- **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. 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

Two other surgical techniques, differing in terms of incision and soft tissue handling, are described in the Surgical Manual Addendum:

- The skin flap technique where a hair-free skin flap is created manually or with the dermatome.9
- The linear incision technique with tissue reduction.10–13

These three 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 with tissue preservation

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)

<table>
<thead>
<tr>
<th>Natural skin thickness</th>
<th>Abutment length</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5-3 mm</td>
<td>6 mm</td>
</tr>
<tr>
<td>3-6 mm</td>
<td>9 mm</td>
</tr>
<tr>
<td>6-9 mm</td>
<td>12 mm</td>
</tr>
</tbody>
</table>
Single-stage surgery

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 of 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 patient’s glasses as this may cause feedback and discomfort. On the other hand, the sound processor should not be placed too far back, since both the position of the microphones and the esthetics may then be compromised. The microphones of the processor should point to 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 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

- 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, 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)
**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 ampoule in the holder and unscrew the ampoule 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. 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 hand piece from the abutment by holding the hand piece close to the abutment and lift 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 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)
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**
  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
- Apply dressing and connect the healing cap. Depending on the dressing type used, the healing cap is placed 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

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 or more months between the two stages.

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 be fitted after the soft tissue has healed from the second surgery.

For more information on when to select two-stage procedure, see the chapter: Selecting single or two-stage surgery.
First-stage
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.

Important
- **Extra caution**
  Patients suitable for a two-stage procedure may require extra caution.

- **Electro-coagulation**
  If electro-coagulation is used at any time during the procedure it should be used with care, especially in irradiated patients, in order to reduce tissue trauma.

- **Do not use dermatome**
  Do not use the dermatome during the second stage of a two-stage surgical procedure.

**Step 1: Preparing the site**
Linear incision technique with tissue preservation, see instructions on page 19.
Skin flap technique, see instructions on page 6 of the Addendum.
Linear incision technique with tissue reduction, see instructions on page 16 of the Addendum.

**Step 2: Incision**
Linear incision technique with tissue preservation, see instructions on page 20.
Skin flap technique, see Step 2A of the instructions on page 7 of the Addendum.
Linear incision technique with tissue reduction, see instructions on page 17 of the Addendum.

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

**Step 4: Drilling with the countersink**
See instructions in Step 4 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 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.

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 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)

Important
- 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.

Important
- Skin flap technique: if a planned single-stage procedure becomes a two-stage procedure.
  If initial skin reduction has already been performed, such as when a planned single-stage procedure becomes a two-stage procedure, appropriate pressure must be applied to the skin flap during healing. A 40 mm pad may be placed over the flap for 1 week. A number of sutures across the gauze and into the surrounding tissue may be used to create pressure.
Second-stage
During the second stage, tissue reduction may or may not be performed depending on chosen technique and the first-stage. The cover screw is removed and the abutment is connected 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:
  - For the skin flap technique: mark the incision for the skin flap with the implant site positioned in the center of the marked area.
  - For the linear incision techniques: mark the incision anterior of the implant site, from the previous surgery.
- In case of surgery with tissue preservation:
  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 and eventual soft tissue reduction
- Make the incision down to the periosteum.
- For eventual soft tissue reduction:
  - Skin flap technique, see instructions for soft tissue reduction on page 11 of the Addendum.
  - Linear incision technique with tissue reduction, see instructions on page 21 of the Addendum.

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)
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 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. 15)

Step 4: Punching, suturing and attaching the healing cap and dressing
Linear incision technique with tissue preservation, see instructions on page 24 and 25. 
Skin flap technique, see instructions on page 13 and 14 of the Addendum.
Linear incision technique with tissue reduction, see instructions on page 22 and 23 of the Addendum.
Aftercare and follow-up

Post-operative

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.

The Ponto Care Kit can be used to facilitate cleaning of the abutment and the implant site and to establish a good daily aftercare routine. The Ponto Care Guide also has useful information on this topic.
Aftercare

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.

Important
- Using 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 becomes softer and is 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 swap 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 to prevent debris build-up.

Important
- Replace 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.
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 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 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)
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 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)
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 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.
Intra-operative complications

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.

Perforation of the sigmoid sinus and exposure of dura mater
Although rare, a mild blood or CFS 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.

Damage to the skin graft
Irreversible damage to the skin during the skin flap technique may require use of a hairless skin graft. A graft from the retroauricular fold may be a suitable option. This technique may also be used if the skin around the preferred implant site is uneven due to scar tissue from previous surgery.

Epidural hematoma
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.

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. Please refer to the sound processor Instructions for Use and the Ponto Care Guide.

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 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.

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 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.
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.

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.

MRI 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.\textsuperscript{15, 16}

Non-clinical testing has demonstrated the Ponto Implant System is MR Conditional. It can be scanned safely under the following conditions:
• Static magnetic field of 3 Tesla or less.
• Maximum spatial gradient magnetic field of 720 Gauss/cm.
• Maximum whole body averaged specific absorption rate of 4 W/kg for 15 minutes of scanning in the first level controlled mode.

In non-clinical testing, the Ponto Implant System produced a temperature rise of less than 2.2\textdegree C at a maximum whole body average specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MRI scanning in a (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI scanner.

• 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 for the presence of this implant. The maximum artifact size extends approximately 10 mm relative to the size and shape of the implant.
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<th>Symbol</th>
<th>Description</th>
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<td>Consult instructions for use</td>
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# Compatibility guide

## Products that can be used with the Ponto System

<table>
<thead>
<tr>
<th>Ponto System components</th>
<th>Products with ref. no manufactured by Cochlear Bone Anchored Solutions AB</th>
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<tbody>
<tr>
<td>Ponto Plus sound processors</td>
<td>Compatible products from Cochlear BAS</td>
</tr>
<tr>
<td>Ponto Plus Power sound processors</td>
<td>Baha® abutments (90305, 90410)</td>
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<tr>
<td>Ponto and Ponto Pro sound processors</td>
<td>Baha® implants with abutment (90434, 90480)</td>
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<tr>
<td>Ponto Pro Power sound processors</td>
<td>Baha® audio adapter* (90065)</td>
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<td></td>
<td>Baha® telecoil unit* (80185)</td>
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<table>
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<tr>
<th>Incompatible products from Cochlear BAS</th>
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<tbody>
<tr>
<td>Baha® BA300 Series abutments</td>
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<tr>
<td>Baha® BA210 Series abutments</td>
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<td>Baha® BA400 Series abutments</td>
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<tr>
<th>Ponto Implant System</th>
<th>Compatible sound processors from Cochlear BAS</th>
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<tr>
<td>Ponto implants with pre-mounted abutments</td>
<td>Baha® sound processors with snap coupling:</td>
</tr>
<tr>
<td>Ponto abutments</td>
<td>Baha® Classic 300 snap (HCB-410-0, HCB-411-0, HCB-412-0).</td>
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<tr>
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<td>Baha® Compact (90140, 90141, 90142).</td>
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<td>Baha® Divino (90500, 90510, 90501, 90511, 90502, 90512, 90503, 90513).</td>
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<td>Baha® Intenso (90730, 90731, 90732, 90733).</td>
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<td>Baha® Cordelle (HCB 400-0, HCB 401-0, HCB 402-0).</td>
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<td>Baha® BP100 (91300, 91301, 91302, 91303, 91304, 91305).</td>
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<td>Baha® 3 Power BP110 (92840, 92841, 92842, 92843, 92844, 92845).</td>
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<td>Baha® 4 (93630, 93631, 93632, 93633, 93634).</td>
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*This does not apply for Ponto Plus and Ponto Plus Power*

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 is determined by the sound processor that is being used.
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Email: yh.lai@hongkin.com.hk
About Oticon Medical

Oticon Medical combines more than a century of experience in audiology and sound processing with decades of pioneering experience in hearing implant technology. As a business within the William Demant Group, Oticon Medical enjoys valuable resources including the power to invest in the further development of hearing implant systems and unique access to knowledge, resources and technology of leading hearing solution manufacturer Oticon.

Oticon Medical’s “People First” philosophy is a direct heritage from Oticon. Every product Oticon Medical creates – from sound processors and surgical components to fitting, counseling and support tools – is designed with user needs in mind. With a strong focus on creating lifelong patient outcomes, Oticon Medical’s starting point will always be the patient’s everyday challenges and how to overcome them. Oticon Medical aims to empower all users of hearing implant systems to realize their full potential and live life to the fullest.

www.oticonmedical.com