ADDENDUM TO

Surgical Manual

including
Skin flap technique
and Linear incision with
tissue reduction

Ponto™
– The Bone Anchored Hearing System

oticon MEDICAL
Contents

Introduction ............................................................................................................. 3

Single-stage surgical procedure ........................................................................ 4
  Skin flap technique ......................................................................................... 6
  Linear incision technique with tissue reduction ............................................. 16

References ........................................................................................................... 24
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 booklet is an Addendum to the Surgical Manual, and includes detailed description of two alternative single-stage surgical techniques. The Surgical Manual offers guidance including planning, preparation, two-stage surgery technique and follow-up aspects; and it sets forth detailed recommended procedures for using bone anchored surgical components and instruments.

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

Note: This Addendum and the Surgical Manual describe 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.
The Addendum does not offer complete guidance, it only describes the detailed steps for surgical techniques, please refer to the Surgical Manual for complete guidance.
Single-stage surgical procedures

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.
In this Addendum two surgical techniques, differing in terms of incision and soft tissue handling, are described:

- The skin flap technique where a hair-free skin flap is created manually or with the dermatome.¹
- The linear incision technique with tissue reduction.²-⁵

The surgical techniques described in this Addendum and the Surgical Manual 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.
Skin flap technique

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, about 3 cm around the planned implant site.
- 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. 1)
- Mark the incision line for the skin flap with the implant site positioned in the center of the marked area. (Fig. 2)
- Mark an area for subcutaneous tissue reduction. (Fig. 3)
- Inject a local anesthetic, pressing on the tissue to even the surface of the skin flap. (Fig. 4)

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. 5)

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.

- **Skin flap orientation**
  A superiorly-based skin flap is preferred since this offers better blood supply and healing.\(^\text{14}\)
Step 2: Incision
The skin flap technique includes making a skin flap at the location of the desired implant site.

This can be done in several ways, outlined here as:
Step 2A: Creating the skin flap manually, or
Step 2B: Creating the skin flap with the dermatome.

Step 2A: Creating the skin flap manually and making the incision of the periosteum
- Start by making an initial incision straight down the marked line into the dermal layer. (Fig. 6)
- Separate the skin flap carefully from the subcutaneous tissue, and remove all hair follicles. Create a skin flap of around 1.0 mm thickness. Take great care not to perforate the skin flap. (Fig. 7)
- Protect the skin flap with moist gauze during the continued surgery until it is time to suture it back to the periosteum. (Fig. 8)
- Make an incision in the subcutaneous tissue along the edges of the flap area down to the periosteum.
- Separate and remove all subcutaneous tissue within the flap area from the periosteum up to the base of the skin flap. Use a scalpel and/or scissors and forceps. (Fig. 9)
- Punch a hole in the periosteum at the planned implant position, using a biopsy punch (Ø4 mm – Ø5 mm). (Fig. 10)
- Instead of a punch, the periosteum can be incised using a cruciate incision with a scalpel.
- Make four small incisions in a radial direction outwards from the hole. (Fig. 11)
- Push the periosteum further aside from the planned implant position.

Step 2B: Creating the skin flap with the dermatome and making incision of the periosteum
- Apply a small amount of lubricant (i.e. paraffin) to facilitate the use of the dermatome.
- Start making a skin flap using the dermatome. The flap should be 1.0 mm thick and approximately 25 mm wide. Consult the dermatome instructions for setting the flap thickness. (Fig. 12)
- Stop cutting with the dermatome when the desired flap length is reached and carefully pull it back along the same route. (Fig. 13)
- Protect the skin flap with moist gauze during the continued surgery until it is time to suture it back to the periosteum. (Fig. 14)
- Make an incision in the subcutaneous tissue along the edges of the dermatome area down to the periosteum. (Fig. 14)
- Separate and remove all subcutaneous tissue from the periosteum in the flap area by using a scalpel and/or scissors and forceps. (Fig. 15)
- Punch a hole in the periosteum at the planned implant position, using a biopsy punch (Ø4 mm – Ø5 mm). (Fig. 10)
Instead of a punch, the periosteum can be incised using a cruciate incision with a scalpel.

- Make four small incisions in a radial direction outwards from the hole. (Fig. 11)
- Push the periosteum further aside from the planned implant position.

**Important**

- **Healing**
  Leave as much of the periosteum as possible around the implant site to support the healing of the skin flap.

- **Dermatome**
  Avoid too much lubricant as it can make the dermatome slide. Consult the dermatome instructions for use prior to the surgery.

- **Mobile tissue**
  It is important to remove all fascia tissue on the surface of the periosteum, as this tissue can cause mobility in the flap and cause healing problems.

- **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.
Step 3: Initial drilling with guide drill
- Set the drill speed to 1500-2000 rpm. (Fig. 16).
- Place the drill perpendicular to the bone, check the angle from several directions. (Fig. 17)
- Start drilling with the spacer in place applying generous cooling with saline solution irrigation directed towards the tip of the drill. (Fig. 18)
- Move the drill carefully up and down to ensure cooling.
- Check the bottom of the hole repeatedly for bone using a blunt instrument. (Fig. 19)
  - 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. 20)

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 drill 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. 21).
- Widen the hole for the implant using the appropriate countersink as determined during initial drilling (3 or 4 mm). (Fig. 22.) 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. 23)
- Stop drilling with the countersink when the stop has reached the bone. (Fig. 24)
- 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. Check 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. 25)
Step 5: Tissue reduction of the subcutaneous tissue

- Perform soft tissue resection in the area under the flap by generously undermining the soft tissue around the flap. Do this in all directions within an area of about 25-30 mm radius from the implant site, creating a gradual slope down towards the implant site. (Fig. 26, 27, 28).
Step 6: 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. 29)
- 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. 30)
- Place the implant axially aligned to the hole and start inserting the implant. Start irrigation once the first thread has entered the bone. (Fig. 31)
- 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. 32)

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. 33)

- **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. 32)
**Step 7: Punching and suturing**

- Lay back the skin flap and stretch it out with skin hooks over the periosteum. (Fig. 34)
- Punch a hole exactly over the abutment using a biopsy punch (Ø4 mm – Ø5 mm). (Fig. 35)
- Gently ease the skin over the abutment. (Fig. 36)
- Suture the skin flap. (Fig. 37)
Step 8: 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. 38) 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. 39)
  - Layers of silicone mesh dressing, making sure to provide sufficient pressure.
Linear incision technique with tissue reduction

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. 1)
- Mark an incision line anterior of the implant site. (Fig. 2)
- Mark the tissue reduction area in an elliptical form. (Fig. 3)
- 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. 4)

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.

**Tips**
- **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. 5)
- Open up the incision using a self-retaining retractor. (Fig. 6)
- Incise the periosteum.
- Remove the periosteum around the implant site using a periosteal elevator. (Fig. 7)

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, especially in irradiated patients, in order to reduce tissue trauma.
Step 3: Initial drilling with guide drill

- Set the drill speed to 1500-2000 rpm. (Fig. 8)
- Place the drill perpendicular to the bone, check the angle from several directions. (Fig. 9)
- Start drilling with the spacer in place applying generous cooling with saline solution irrigation directed towards the tip of the drill. (Fig. 10)
- Move the drill carefully up and down to ensure cooling.
- Check the bottom of the hole repeatedly for bone using a blunt instrument. (Fig. 11)
  - 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. 12)

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. 13)
- Widen the hole for the implant using the appropriate countersink as determined during initial drilling (3 or 4 mm). (Fig. 14) 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. 15)
- Stop drilling with the countersink when the stop has reached the bone. (Fig. 16)
- 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. Check 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. 17)
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. 18)
- 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. 19)
- Place the implant axially aligned to the hole and start inserting the implant. Start irrigation once the first thread has entered the bone. (Fig. 20)
- 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. 21)

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. 22)

- 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. 21)
Step 6: Reducing soft tissue
- Remove subcutaneous tissue in an area of approximately 40 x 60 mm. Dissect the subcutaneous tissue with a scalpel (blade 10, 11 or 15) and/or with scissors and forceps. (Fig. 23)
- Use skin hooks for presenting the subcutaneous tissue.
- Slide the scalpel, and use the fingertip from the outside to gauge whether the desired degree of soft tissue thinning is achieved in all directions around the implant site. (Fig. 24, 25)
Step 7: 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 8: 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)
  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. 31)
  - Layers of silicone mesh dressing, making sure to provide sufficient pressure.


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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