ADDENDUM TO
Surgical Manual
Including
Minimally Invasive Ponto Surgery (MIPS)

Ponto™
– The Bone Anchored Hearing System
Introduction

The Ponto Bone Anchored Hearing System is a solution suitable 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.

Over the years, surgical teams all over the world have modified the surgical procedure for implanting the bone anchored hearing system in order to further improve the outcome. The long-term success of tissue preservation techniques has inspired Oticon Medical to develop the Minimally Invasive Ponto Surgery (MIPS) as an alternative single-stage surgical technique.

This booklet is an Addendum to the Surgical Manual, and includes a detailed description of Minimally invasive Ponto surgery. The Surgical Manual offers guidance on 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.

If you require any further information or support, please contact your local Oticon Medical representative.

Note: The Surgical Manual and Addendums provide the surgeon with safe surgical procedures. 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.

The Addendum does not offer complete guidance, it only describes the detailed steps for MIPS. For complete guidance, please refer to the Surgical Manual. Illustrations and images in this manual are not to scale.
Planning and preparation for MIPS

Selecting the MIPS procedure
Minimally invasive Ponto surgery (MIPS) is a single-stage surgery. Deciding whether surgery should be performed in one or two stages requires pre- and peri-operative assessment of the quality and thickness of the patient’s temporal bone. If the surgeon determines that implantation is appropriate for a patient with thin bone (<3 mm) or poor bone quality, a two-stage surgical procedure with a prolonged osseointegration period is recommended. This procedure is described in detail in the Surgical Manual.

MIPS is recommended for:
- Adult patients with normal bone quality and bone 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.
- Patients, as per above, with a skin thickness of 12 mm or less.

For patients not suited for Minimally invasive Ponto surgery, please refer to the Surgical Manual.

Caution
- Always use the cannula drills together with the cannula.
The cannula guide drill and widening drills must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

Important
- Conversion from MIPS to linear incision
During a planned MIPS procedure, a decision to change to a linear incision technique with or without tissue preservation can be made at any time. The cannula drills can still be used, but the drills must always be used with the cannula to prevent drilling deeper than intended.

- Conversion from MIPS to two-stage surgery
If during a planned MIPS procedure it appears that the bone is of poor quality, a decision to convert to a two-stage procedure can be made. In this case, follow the instructions for the second stage as described in the Surgical Manual.

- Intra-operative complication handling
In case of intra-operative complications, always consider converting to a linear incision for increased accessibility and visibility. For a detailed description of potential complications, please refer to the Surgical Manual.

Preparation
The operating room should be prepared in the same way as for any bone anchored hearing implant surgery.

Disposable components and instruments for the MIPS procedure:
- Wide Ponto implant (Ø4.5 mm), 4 mm with pre-mounted abutment
- Biopsy punch Ø5 mm
- MIPS Surgery Kit, 4 mm, containing:
  - Cannula
  - Cannula guide drill with spacer
  - Cannula widening drill, 4 mm
  - Soft healing cap

Non-disposable instruments:
- Sound processor indicator
- Double-ended dissector
- Abutment inserter
- Counter torque wrench
- Ruler
- Insertion indicator

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

See the Surgical Manual for information on cleaning and sterilization of non-disposable instruments.

Important
- Back-up components
  When planning the MIPS procedure, back-up components and instruments should always be available. In some cases, it may be necessary to place a 3 mm long implant, or to perform the surgery in two stages. Multiple abutment lengths should also be available for different skin thicknesses.
  - Wide Ponto implant (Ø4.5 mm), 3 mm with pre-mounted abutment
  - MIPS Back-Up Kit, 3 mm, containing:
    - Cannula
    - Cannula widening drill, 3 mm

Disposable instruments
- Cannula
- Cannula guide drill with spacer
- Cannula widening drill, 4 mm
- Soft healing cap

Non-disposable instruments
- Sound processor indicator
- Double-ended dissector
- Abutment inserter
- Counter torque wrench
- Ruler
- Insertion indicator

For a detailed description of potential complications, please refer to the Surgical Manual.
Minimally Invasive Ponto Surgery (MIPS)

Choosing abutment length
- The skin thickness can be measured before or during surgery to identify the appropriate abutment length. (Fig. 1)
- Before surgery: measure skin thickness in normal state (without local anesthesia) with a thin needle and be aware of possible compression of the skin.
- During surgery: measure in the surgical site using sterile instruments and compensate for injections.
- Select abutment length according to Fig. 2, or read the length directly on the Oticon Medical ruler.
- If the skin is thicker than 12 mm, convert to a linear incision technique with partial soft tissue reduction. See the Surgical Manual for detailed instructions.

Important
- Lever effect
  When placing a longer abutment consider bone thickness and bone quality as the risk of bone fracture increases with abutment length due to the increased lever effect.

Tips
- Ultrasound
  Measuring skin thickness before surgery can also be done with ultrasound. Avoid compressing the skin during measurement. (Fig. 3)

Step 1: Preparing the site
- Use the sound processor indicator to locate the implant site. This is 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 through the hole of the sound processor indicator. (Fig. 4-5)
- Inject a local anesthetic with a vasoconstrictor. This should be done even when the surgery is performed under general anesthesia.

Important
- Implant positioning
  The sound processor must not touch the pinna or the patient’s glasses as this may cause feedback and discomfort. 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. 6)

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 infection.

<table>
<thead>
<tr>
<th>Natural skin thickness</th>
<th>Abutment length</th>
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<tbody>
<tr>
<td>0.5-3 mm</td>
<td>6 mm</td>
</tr>
<tr>
<td>3-6 mm</td>
<td>9 mm</td>
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<tr>
<td>6-9 mm</td>
<td>12 mm</td>
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<tr>
<td>9-12 mm</td>
<td>14 mm</td>
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The 6, 9, 12, and 14 mm abutment lengths are adapted to different skin thicknesses.
Step 2: Punching and inserting the cannula
- Use a Ø5 mm biopsy punch to make an incision hole in the skin. (Fig. 7)
- Rotate the biopsy punch to incise the periosteum.
- Remove the periosteum at and around the implant site using the double-ended dissector. (Fig. 8-9)
- Insert the cannula in the surgical site. (Fig. 10)

Important
- Removal of periosteum
  Make sure that the bone is exposed at the entire surgical site, and that all periosteum and soft tissue are removed before inserting the cannula. This is important to allow the correct placement of the cannula and to ensure correct drill depth in the proceeding steps. (Fig. 9)

- Cannula position
  When punching and inserting the cannula, avoid creating tension in the skin, as this will lead to tension around the abutment.

Tips
- 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.

Instructions for drilling with the cannula
The cannula is primarily a stop collar and acts as soft tissue protection during drilling. It is not a fixed position marker.

In each drill step:
- Ensure that there is no soft tissue between the cannula and the bone
- Maintain the top surface of the cannula parallel to the skin
- Hold the cannula firmly pressed to the bone when drilling
- Fill the cannula with saline solution prior to drilling to facilitate cooling
- Continuously apply generous cooling along the drill during drilling
- Insert the drill fully in the cannula, all the way to the bone level, before starting the drill
- For the second and third drill step, use the drill tip to tactually identify the previously drilled hole before starting the drill

Caution
- Always use the cannula drills together with the cannula
  The cannula guide drill and widening drills must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

Important
- Cannula position
  It is important that all drilling is carried out with the cannula positioned in contact with the bone, and with the top surface of the cannula parallel to the skin. This ensures a correct drill depth and drill angle.

- Cooling
  During the entire drilling procedure, generous irrigation of the drill and bone is important in order to prevent heat-induced bone tissue trauma, which may impede osseointegration. Although cannula drills are specifically designed for low friction drills, the cannula must still be filled with saline solution prior to each drill step, and the drills continuously cooled during drilling. Stop drilling as soon as the stop collar of the drill reaches the top of the cannula. Excessive or lengthy drilling will generate unnecessary heat.

- Drilling and alignment
  The cannula can move with the skin, so always confirm that drilling is performed at the intended site. The cannula drills are designed to give tactile feedback on the correct drill position by clearly falling into any previously drilled hole. Do not start the drill until the correct position is found.

- Conversion from MIPS to linear incision
  A decision to change to a linear incision technique can be made at any time. The cannula drills can still be used, but the drills must always be used with the cannula to prevent drilling deeper than intended.
Step 3: Initial drilling with cannula 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)
- Position the cannula with the top surface parallel to the skin. (Fig. 12)
- Fill the cannula with saline solution to facilitate cooling.
- Confirm that the cannula guide drill is used with the spacer in place.
- Do not start drilling until the drill is properly inserted in the cannula.
- Ensure that generous irrigation is applied during drilling. (Fig. 13)
- Stop drilling when the stop collar has reached the top of the cannula.
- If there is no bone at the bottom of the hole after drilling with the spacer, consider using a 3 mm implant.
- If bone thickness is sufficient, remove the spacer to prepare for a 4 mm implant.
- Refill the cannula with saline solution.
- Insert the drill in the cannula and tactually identify the drilled hole.
- Start drilling once the drill tip is positioned inside the drilled hole. (Fig. 15)

Caution
- Always use the cannula drills together with the cannula
  The cannula guide drill and widening drills must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

Important
- Drilling
  Avoid circular movements which can over-widen the hole and reduce the initial stability of the implant.
- Dissector
  Make sure an appropriate dissector or other blunt instrument is used so the tip can reach the bottom of the drilled hole. (Fig. 14).

Tips
- If the cannula has moved, use the tip of the drill or dissector to find the drill hole.

Step 4: Drilling with the cannula widening drill
The cannula widening drill is used to widen the hole and prepare the bone for the implant. The drilling procedure is critical for successful osseointegration and treatment.

- Maintain the preset drill speed of 1500-2000 rpm. (Fig. 16)
- Select the appropriate cannula widening drill (3 mm or 4 mm) as determined during initial drilling. (Fig. 17)
- Fill the cannula with saline solution.
- Insert the drill in the cannula and tactually identify the drilled hole.
- Start drilling once the drill is positioned inside the drilled hole.
- Ensure that generous irrigation is applied during the entire drilling. (Fig. 18)
- Stop drilling when the stop collar has reached the top of the cannula.
- After widening the hole, carefully check for bone at the bottom of the hole.
- Flush the cannula with saline to remove any bone fragments. (Fig. 19)
- Leave the cannula in place until the implant is ready to be installed.

Caution
- Always use the cannula drills together with the cannula
  The cannula guide drill and widening drills must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

Important
- Drilling
  Avoid circular movements which can over-widen the hole and reduce the initial stability of the implant.
- Recess
  When the stop collar of the widening drill has reached the cannula, the hole and the recess have the required depth.
- Preparing for implant installation
  The cannula and drilled hole must be flushed to remove any remaining bone fragments as any debris may affect implant insertion. Leaving the cannula in place after drilling prevents skin retraction and thus eases implant installation.

Tips
- If the cannula has moved, use the tip of the drill or dissector to find the drill hole.
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. 20)
- Attach the insertion indicator on the abutment inserter.
- 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. 21)
- Remove the cannula from the surgical site.
- Place the implant axially aligned to the hole and start inserting the implant. (Fig. 22)
- Count the number of turns the implant engages in the bone.
- Wait for the drill unit to stop when the preset torque is reached.
- Release the abutment inserter from the abutment by holding the hand piece close to the abutment and lift straight up. (Fig. 23)

Important

- Insertion indicator
  It is of great importance that the implant is inserted in line with the drilled hole, and that it is fully inserted. The insertion indicator can help guide implant installation in two ways:
  - Keeping the arms of the indicator parallel with the skin while installing the implant aligns the implant with the drilled hole.
  - The insertion indicator can also be used to count the number of turns before the preset torque is reached. If the number of turns is lower than expected, ensure that the implant was installed in line with the hole. Increase the torque setting of the drill machine, or manually insert the implant.

- Torque
  When the flange of the implant has reached the bone surface it will stop automatically. For confirmed hard adult bone, it is recommended that insertion starts at 50 Ncm.

- Manual insertion
  The counter torque wrench can be used to feel if the implant has been fully inserted. If this is not the case, the counter torque wrench can, with great care, be used to fully insert the implant manually. (Fig. 24)

- 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 it straight up without bending. (Fig. 23) Bending the instrument will cause it to lock to the abutment and could damage the instrument or, in the worst case, cause implant loss.

Step 6: Attaching the healing cap and dressing

- 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. 25-26)
  The healing cap holds the dressing in place and minimizes the risk of hematoma.
- Place a mastoid pressure bandage over the dressing and healing cap.

Important

- Ointment
  Topical antibiotic ointment is usually used.

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

Tips

- Examples of suitable dressings:
  - Ribbon gauze wrapped around the abutment
  - A tailor-made foam dressing
  - Layers of silicone mesh dressing (Fig. 27)

- Swollen skin
  If the skin 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 skin around the abutment using the fingers.
References


Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world’s largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advancements in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with user needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.

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