

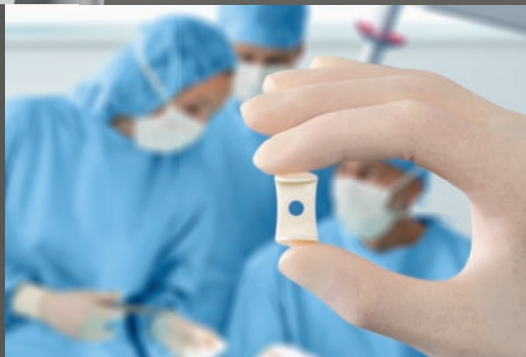
Addendum to

# Surgical Manual

Including  
the MIPS procedure



Choose Sound.  
Choose Ponto



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MEDICAL

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# Introducing the Ponto Bone Anchored Hearing System

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

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<sup>1-6</sup> 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 Ø4 mm / Ø5 mm
- MIPS Surgery Kit, 4 mm, containing:
  - Cannula
  - Cannula guide drill with spacer
  - Cannula widening drill, 4 mm
  - Soft healing cap
  - Insertion indicator

Non-disposable instruments:

- Sound processor indicator
- Double-ended dissector
- Abutment inserter
- Counter torque wrench
- Ruler

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

### 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, 3mm

## Disposable instruments



Cannula



Cannula guide drill with spacer



Cannula widening drill, 4 mm



Soft healing cap



Insertion indicator

## Non-disposable instruments



Sound processor indicator



Double-ended dissector



Abutment inserter



Counter torque wrench



Ruler

# Minimally Invasive Ponto Surgery (MIPS)

## Choosing abutment length

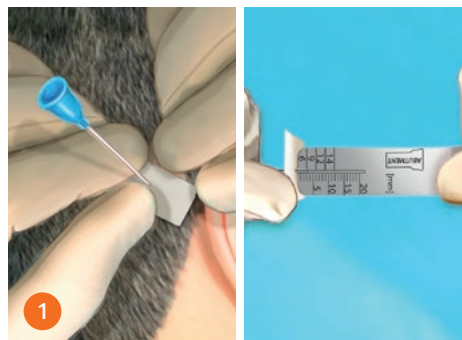
- The skin thickness can be measured before or during surgery to identify the appropriate abutment length. (Fig. 1)
  - Before surgery: measure skin thickness in normal state (without local anesthesia) with a thin needle and be aware of possible compression of the skin.
  - During surgery: measure in 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

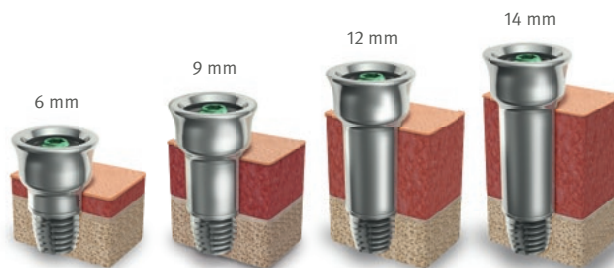
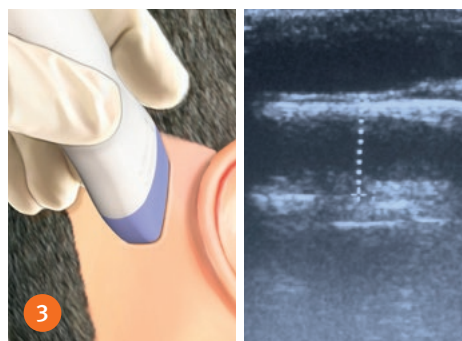
- *Lever effect*  
When placing a longer abutment consider bone thickness and bone quality as the risk of bone fracture increases with abutment length due to the increased lever effect.

## Tips

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



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



The 6, 9, 12, and 14 mm abutment lengths are adapted to different skin thicknesses.

## Step 1: Preparing the site

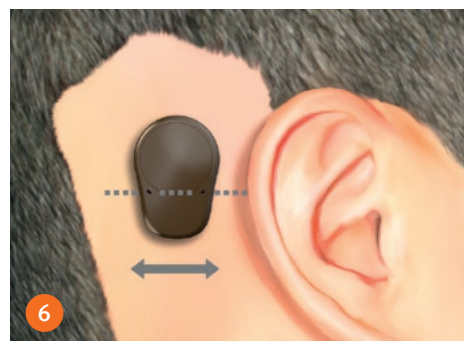
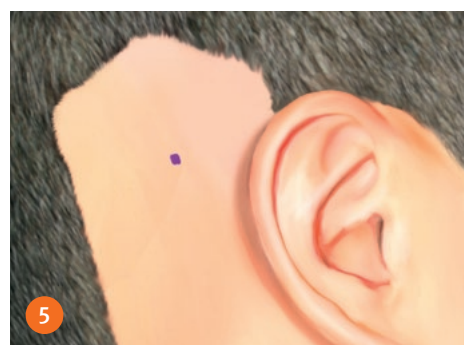
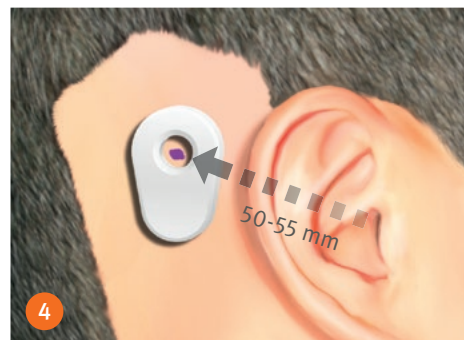
- Use the sound processor indicator to locate the implant site. This is generally 50-55 mm from the center of the ear canal with the top of the indicator placed on a horizontal line from the top of the pinna.
- Shave the area.
- Place the indicator in the right position and mark the exact implant site 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.





## Step 2: Punching and inserting the cannula

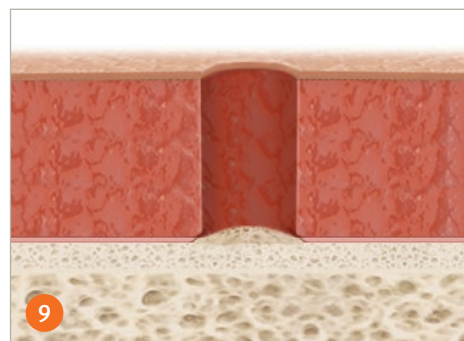
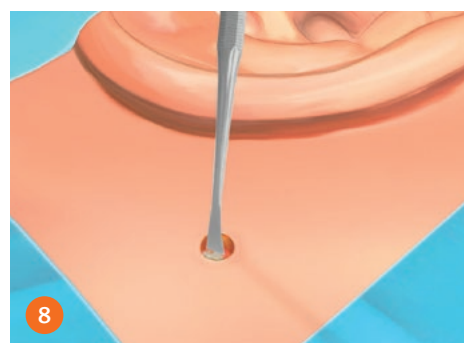
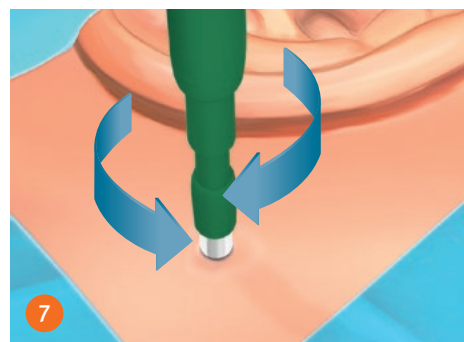
- Use a Ø4 mm / Ø5 mm biopsy punch to make an incision hole in the skin. (Fig. 7)
- Rotate the biopsy punch to incise the periosteum.
- Remove the periosteum at and around the implant site using the double-ended dissector. (Fig. 8-9)
- Insert the cannula in the surgical site. (Fig. 10)

### 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 the following:



- No soft tissue between the cannula and the bone
- Top surface of the cannula parallel to the skin
- Cannula firmly pressed against the bone throughout the procedure



- Fill the cannula with saline prior to drilling
- Continuously apply generous cooling
- Flush the cannula immediately after drilling



- Insert the drill to bone level before starting the drill
- Use the drill tip to find any previously drilled hole
- Use only one down and up drill motion to avoid overheating the bone
- After the single drill motion, immediately flush the cannula to exchange the heated fluid and bone chips with fresh cooling fluid



### 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 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 according to (fig. 13)
- Do not start drilling until the drill is properly inserted in the cannula.
- Ensure that generous irrigation is applied during drilling. (Fig. 14)
- Stop drilling when the stop collar has reached the top of the cannula.
- The bottom of the hole should be checked carefully for bone using the double-ended dissector or another blunt instrument. (Fig. 15)
  - 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. 16)

#### Caution

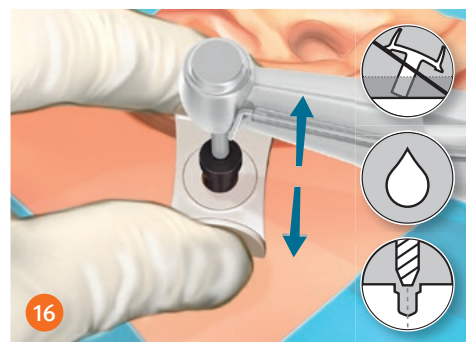
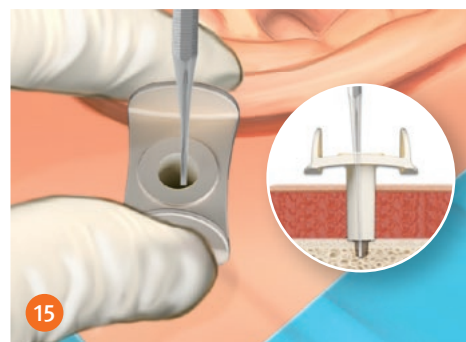
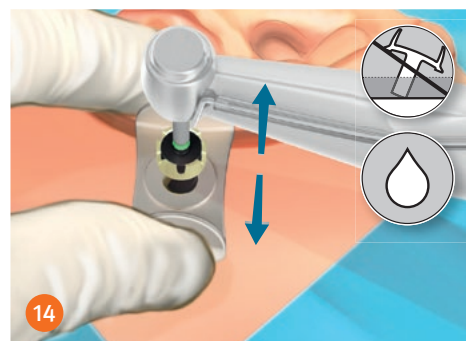
- *Always use the cannula drills together with the cannula*  
The cannula guide drill and widening drills must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

#### 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. 15).

#### 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. 17)
- Select the appropriate cannula widening drill (3 mm or 4 mm) as determined during initial drilling. (Fig. 18)
- 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. 19)
- 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. 20)
- Leave the cannula in place until the implant is ready to be installed.



#### Caution

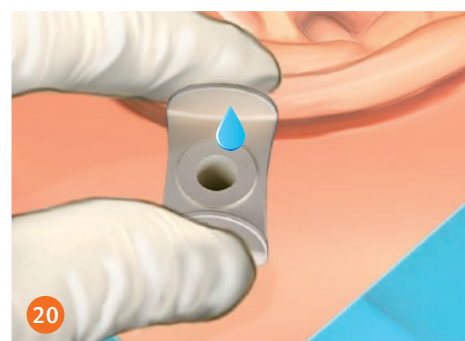
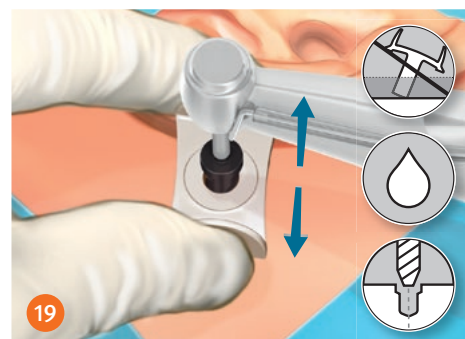
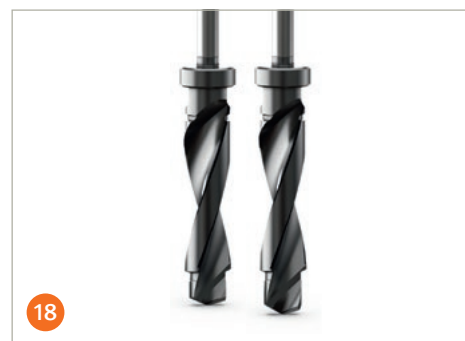
- *Always use the cannula drills together with the cannula*  
The cannula guide drill and widening drills must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

#### 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.

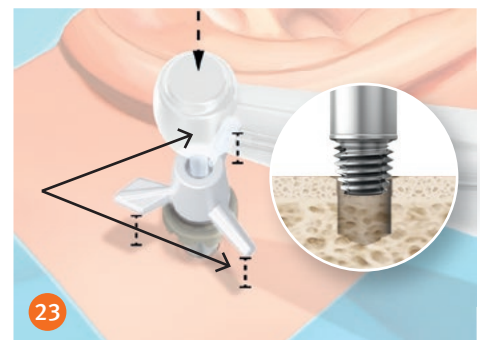


## Step 5: Implant installation

- 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. 21)
- 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. 22)
- Remove the cannula from the surgical site.
- Place the implant axially aligned to the hole and start inserting the implant. (Fig. 23)
- When the implant engages the bone, count the number of turns: 4.5 turns for a 4 mm implant and 3.5 turns for a 3 mm implant. This ensures full installment of the implant. *If the implant engages 3.5 turns or less for the 4 mm implant and 2.5 turns or less for the 3 mm implant, consider backing it out and re-inserting*
- 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. 24)

### 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. 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 it straight up without bending. (Fig. 24) 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

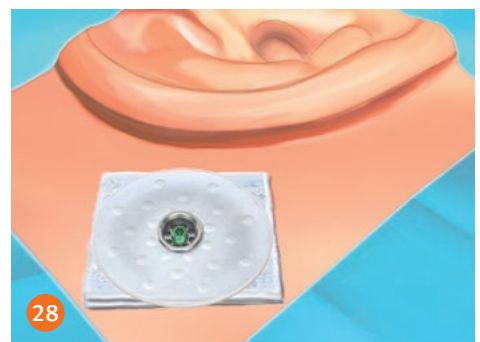
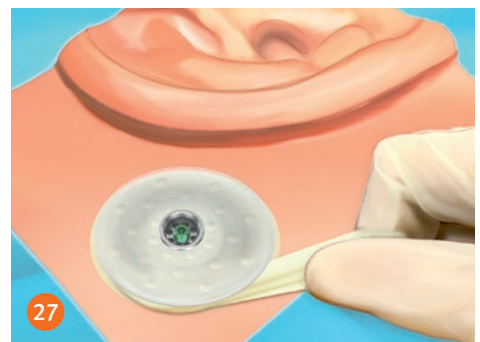
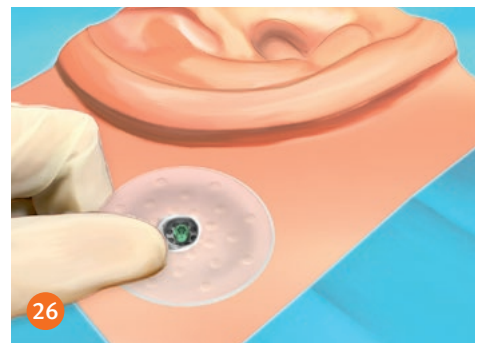
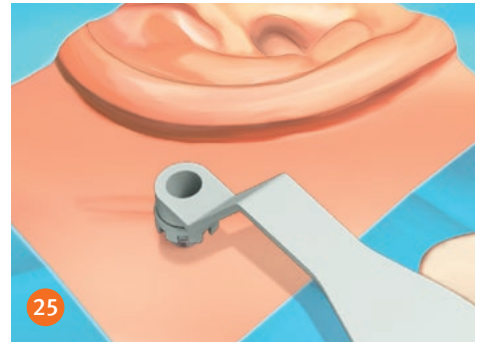
- Apply the dressing and connect the healing cap. Depending on the dressing type used, the healing cap is either placed before or after the dressing is applied. (Fig. 26-27)  
The healing cap holds the dressing in place and minimizes the risk of hematoma.
- Place a mastoid pressure bandage over the dressing 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. 28)
- *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.





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## Because sound matters

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

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



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