Addendum to

Surgical Manual

Including the MONO procedure

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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.

The long-term success of tissue preservation techniques[1–2, 5–7] and the success of MIPS[3–4] procedure has inspired Oticon Medical to develop the MONO procedure as an alternative minimally invasive procedure for adult patients.

This instruction is an Addendum to the Surgical Manual and includes a detailed description of Ponto implant installation using the MONO procedure. The Surgical Manual provides guidance on overall planning, preparation, follow-up and aftercare aspects relating to the Ponto bone anchored hearing system. Furthermore, the Surgical Manual offers information on intra-operative and post-operative complications and cautions relevant to bone anchored hearing.

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

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

This Addendum does not offer complete guidance for the Ponto bone anchored hearing system implantation, it only describes the detailed steps for the MONO procedure. For complete guidance, please refer to the Surgical Manual.

Terminology used in this instruction:
– Note: Important information and/or advice
– Precaution / Caution: Indicates need for action to be taken in advance to prevent or reduce the impact of possible harm or device failure.

Planning and preparation for the MONO procedure

Selecting the MONO procedure

The MONO procedure is a single-stage Ponto Implant installation technique. For selection aspects relating to single-stage or two-stage procedure, please refer to the Surgical Manual.

The type of single stage technique should be selected individually, taking the anatomy, age, patient circumstances, bone quality and bone thickness into account.

Use of the MONO procedure is indicated for the following subpopulation of patients indicated for the Ponto bone anchored hearing system:

- Adult patients (18 years and above) with normal anatomy and expected bone thickness of at least 5 mm, where no complications during surgery are expected.
- Patients, as per above, with a soft tissue thickness of 12 mm or less.

Use of the MONO procedure is contraindicated for children and patients with expected bone thickness below 5 mm.

Note

Possible reasons for expecting thin bone may include previous surgery in the area of the implant site, and/or congenital craniofacial or auricular anomalies where a hypoplasia of the mastoidal anatomy might be present, e.g. congenital aural atresia, hemifacial microsomia/Goldenhar syndrome, Treachers Collins like syndromes and Branchio-Oto-Renal (BOR) syndrome. For these patients, an alternative procedure for implant installation is recommended, see Surgical Manual. Alternatively, a pre-operative CT scan could be performed to evaluate bone thickness.

Please refer to the Candidacy Guide for information about which patients are candidates for a bone anchored hearing system.

⚠ Caution

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

Note

- *Conversion from MONO procedure to linear incision*
  During a MONO procedure, a decision to change to a linear incision technique can be made at any time. The MONO drill can still be used, but the drill must always be used with the cannula to prevent drilling deeper than intended.

- *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 procedure.

Disposable components and instruments for the MONO procedure:

- Ponto implant (Ø4.5 mm), 4 mm with pre-mounted abutment
- Biopsy punch Ø4 mm or Ø 5 mm
- MONO Surgery Kit, containing:
  - Cannula
  - MONO drill
  - 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.

Note

- *Back-up components*
  Multiple abutment lengths should be available for different soft tissue thicknesses. Consider if there is a need for surgical back-up components for other techniques.

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

- *Single-use/disposable components*
  The implant components (implant with pre-mounted abutment) and the MONO Surgery Kit are for single use only. Due to contamination and effectivity risks, do not re-sterilize or reuse these single use items.

Disposable instruments

Cannula

MONO drill

Soft healing cap

Insertion indicator

Non-disposable instruments

Sound processor indicator

Double-ended dissector

Abutment inserter

Counter torque wrench

Ruler

The MONO procedure

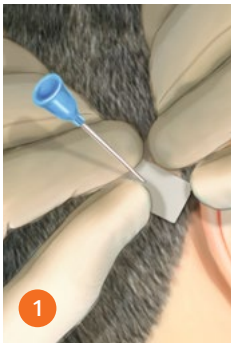
Choosing abutment length

- The soft tissue should be assessed to identify the appropriate abutment length.
- Assess soft tissue thickness in normal state (without local anaesthesia) with a thin needle and a ruler. (Fig. 1)
- When using the needle be aware of possible compression of the soft tissue.
- Select abutment length according to Fig. 2, or as indicated on the Oticon Medical ruler.
- If the soft tissue is thicker than 12 mm, convert to a linear incision technique with partial soft tissue reduction. See the Surgical Manual for detailed instructions.

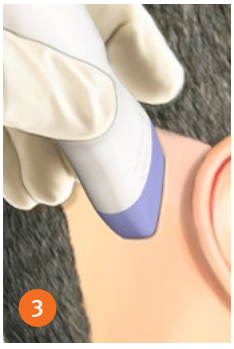
Note

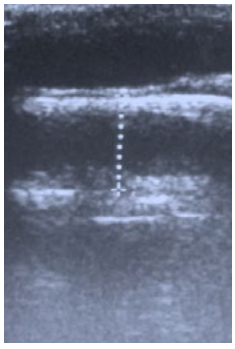
- *Lever effect*
  When placing a longer abutment consider bone thickness and bone quality as the risk of bone fracture increases with abutment length due to the increased lever effect.

- *Ultrasound*
  Assessment of soft tissue thickness before the procedure can also be done with ultrasound. Avoid compressing the soft tissue during measurement. (Fig. 3)



Natural soft tissue thickness	Abutment length
0.5-3 mm	6 mm
3-6 mm	9 mm
6-9 mm	12 mm
2 9-12 mm	14 mm





Step 1: Preparing the site

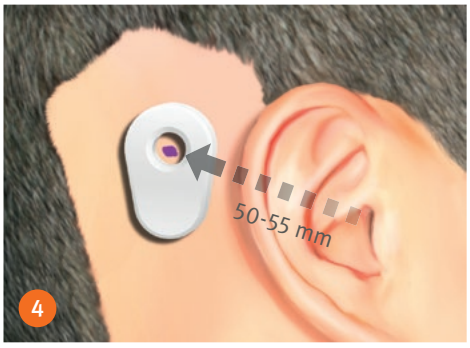
- Use the sound processor indicator to locate the implant site. This is generally 50-55 mm from the centre of the ear canal with the top of the indicator placed on a horizontal line from the top of the pinna.
- Shave the area.
- Place the indicator in the correct position and mark the implant site on the skin using a marker through the hole of the sound processor indicator. (Fig. 4-5)
- Inject a local anaesthetic with a vasoconstrictor. This should be done even when the procedure is performed under general anaesthesia.

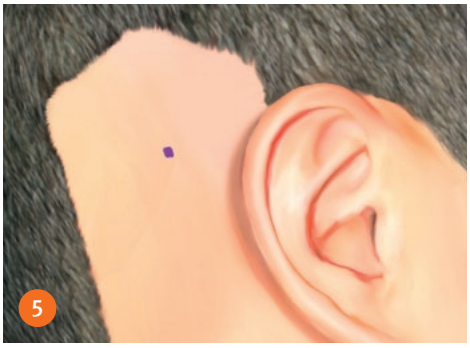
Note

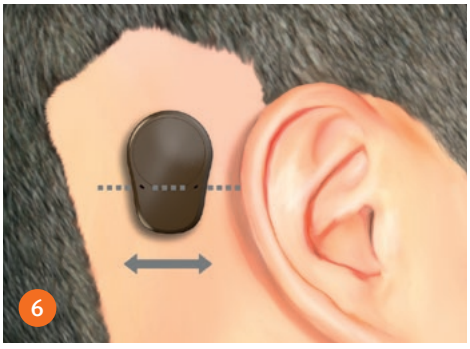
- *Implant positioning*
  The sound processor must not touch the pinna or the patient's glasses as this may cause feedback and discomfort. Neither should the sound processor be placed too far back on the head, as this can compromise both the position of the microphones and the aesthetics. The microphones 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

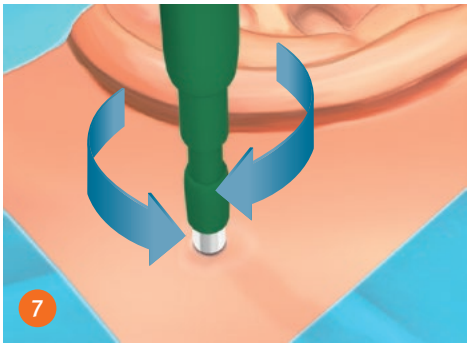
- Use a Ø4 mm or Ø5 mm biopsy punch to make a circular incision in the soft tissue. (Fig. 7)
- Rotate the biopsy punch to incise the periosteum.
- Remove the periosteum at and around the implant site using the double-ended dissector. (Fig. 8-9)
- Insert the cannula. (Fig. 10)
- After inserting the cannula, let go of the cannula so it can find its natural position in the soft tissue. Ensure the soft tissue is not tensed.
- Once the natural position is found, hold the cannula against the bone.

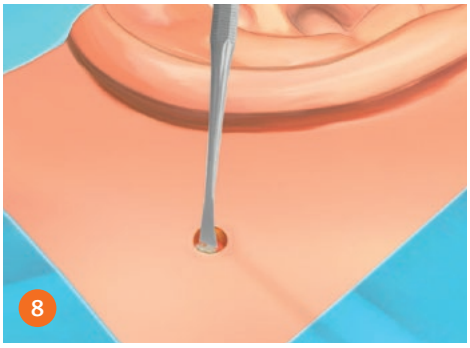
Note

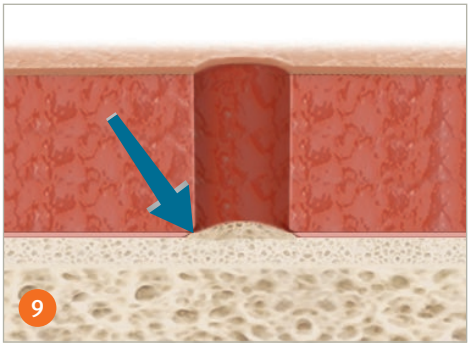
- *Removal of periosteum*
  Ensure that the bone is exposed at the entire site, and that all periosteum and soft tissue are removed from the bone surface before inserting the cannula. This is important to allow the correct placement of the cannula and to ensure correct drill depth in the proceeding steps.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

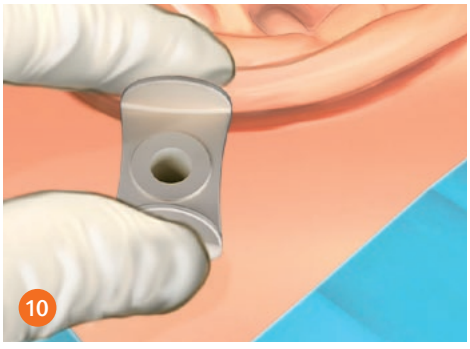
- *Cannula position*
  Maintain the cannula firmly pressed against the bone throughout the procedure, to reduce the soft tissue tension around the cannula, and later around the inserted abutment.

- *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 used to establish a port of entry through the soft tissue (after incision with the biopsy punch); it protects the soft tissue during drilling and ensures correct drill depth by providing a hard stop for the MONO drill. It is not a fixed position marker.

When drilling with the cannula, 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 cooling fluid before introducing the MONO drill
- Continuously apply generous cooling during drilling
- Flush the cannula excessively immediately after drilling

- Position the drill at bone level before starting to drill
- Use a single downward and upward drilling motion to avoid overheating the bone

Caution

- *Always use the MONO drill together with the cannula*
  The MONO drill 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*
  Generous irrigation of the drill and bone is important in order to prevent heat-induced bone tissue trauma, which may impede osseointegration. Excessive or lengthy drilling will also generate unnecessary heat.

- *Conversion from the MONO procedure to linear incision*
  During a MONO procedure, a decision to change to a linear incision technique can be made at any time. The MONO drill can still be used, but the drill must always be used with the cannula to prevent drilling deeper than intended.

Step 3: Drilling

The MONO drill is intended to create the osteotomy in the skull bone in a one-step drilling procedure. The MONO drill is used together with the cannula, which protects the soft tissue during drilling and ensures correct drill depth by providing a hard stop with the drill.

- Set 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.
- Insert the drill in the cannula and position the drill at bone level before starting to drill.
- Ensure that generous irrigation is applied during the entire drilling.
- Use a single downward and upward drilling motion. Keep the drilling procedure below 4 seconds to avoid overheating the bone. (Fig 13)
- Stop drilling when the stop collar of the MONO drill reaches the top of the cannula.
- Immediately remove the drill and insert the tip of the irrigation syringe.
- Flush the cannula to exchange the heated fluid and bone chips with fresh cooling fluid. (Fig. 14)
- With the cannula still in place, carefully check for bone at the bottom of the hole, using the double ended dissector. (Fig 15)
- Leave the cannula in place until the implant is ready to be installed.

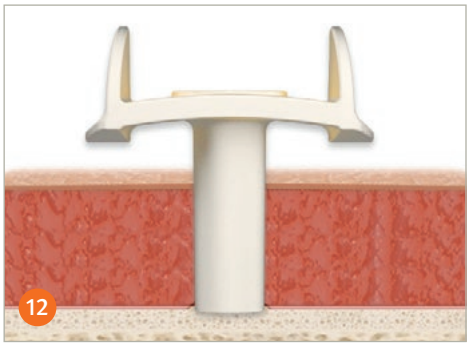
Caution

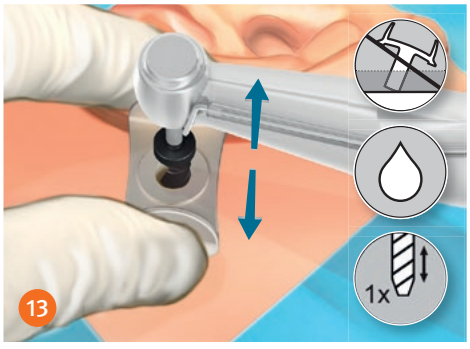
- *Always use the MONO drill together with the cannula*
  The MONO drill must always be used together with the cannula. The cannula provides the stop that prevents drilling deeper than intended.

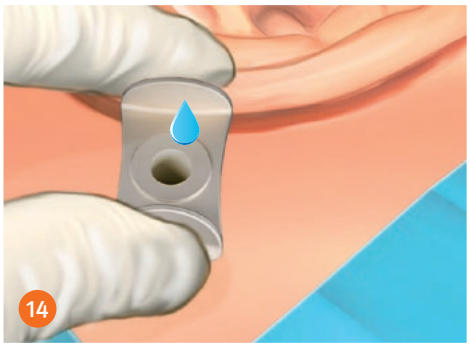
Note

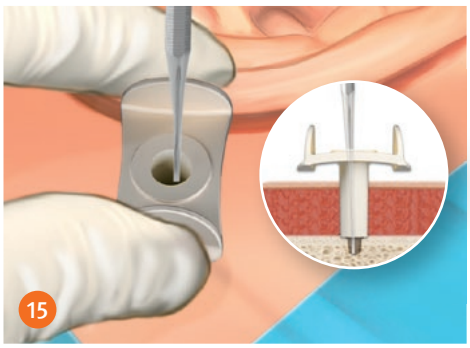
- *One motion drilling*
  Excessive or lengthy drilling will generate unnecessary heat. When the stop collar of the MONO drill has reached the top of the cannula, the hole has the required depth.

- *Preparing for implant installation*
  The cannula and drilled hole must be flushed to remove remaining bone fragments as debris may affect implant insertion. Leaving the cannula in place after drilling prevents skin retraction and thus facilitates implant installation.



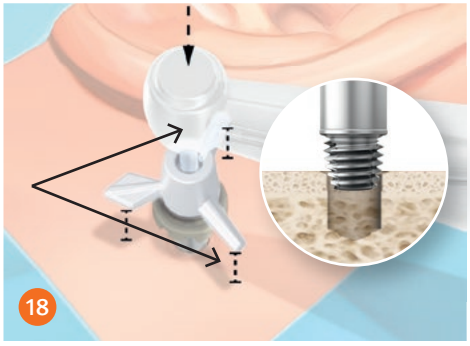


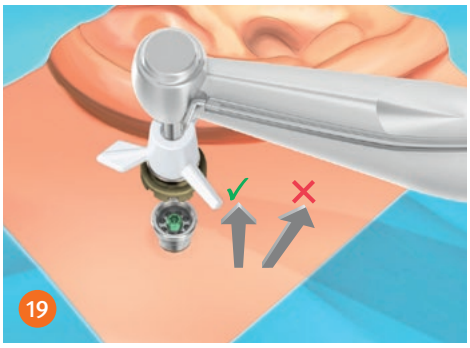


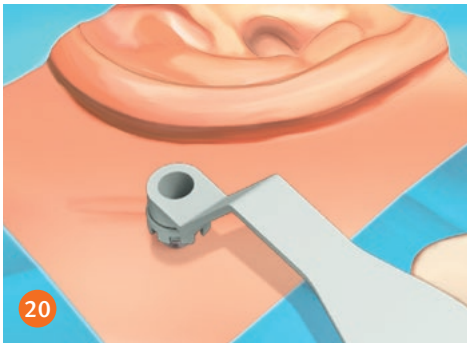


Step 4: Implant installation

- Set the drill unit to low speed with automatic torque control. (Fig. 16)
  - 40-50 Ncm in compact bone.
  - 10-20 Ncm in compromised or soft bone.
- Attach the insertion indicator on the abutment inserter.
- Open the ampoule packaging holding the implant with pre-mounted abutment.
- Pick up the implant with the pre-mounted abutment using the abutment inserter mounted to the hand piece. (Fig. 17)
- Remove the cannula from the site.
- Place the implant axially aligned to the hole and start inserting the implant. Let the implant engage with the bone without forcing it. (Fig. 18)
  - Start counting the number of turns as visualized by the insertion indicator.
- Wait for the drill unit to stop when the pre-set torque is reached.
  - 5 turns are an indication that the implant is fully inserted. If the implant engages 4 turns or less, consider reversing the drill and re-inserting, or carefully manually tighten, the implant until it reaches 4.5 to 5 turns.
- Release the abutment inserter from the abutment by holding the hand piece close to the abutment and lift straight up. (Fig. 19)







Note

- *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 is intended for use during implant insertion as a guide to visualise correct placement/ insertion of the implant.
  - Keeping the arms of the insertion indicator parallel to the skin while installing the implant aligns the implant with the drilled hole.
  - The insertion indicator can also be used as a guide when counting the number of turns before the pre-set 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 the drill unit 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. Use the fingertips to gently push the counter torque wrench clockwise. (Fig. 20)

- *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. Bending the instrument will cause it to lock to the abutment and could damage the instrument or, at worst case, cause implant loss. (Fig. 19)

Step 5: Attaching the healing cap and dressing

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

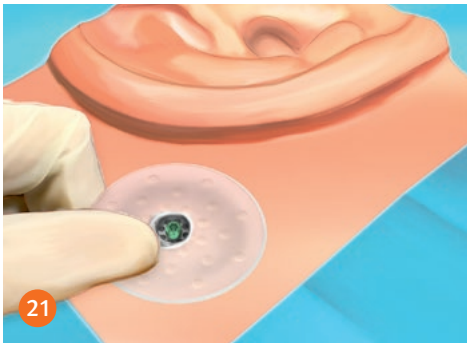
- Apply the dressing and connect the healing cap. Depending on the dressing type used, the healing cap is either placed before or after the dressing is applied. (Fig. 21-23)
  Examples of suitable dressings
  - Ribbon gauze wrapped around the abutment
  - A tailor-made foam dressing
  - Layers of silicone mesh dressing
- 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.

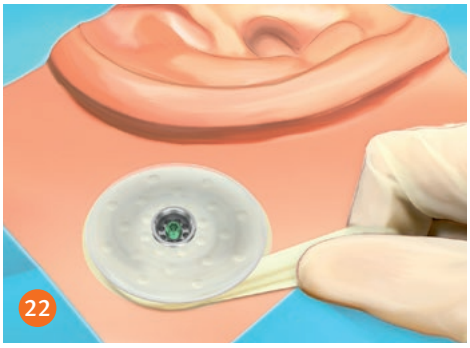
Note

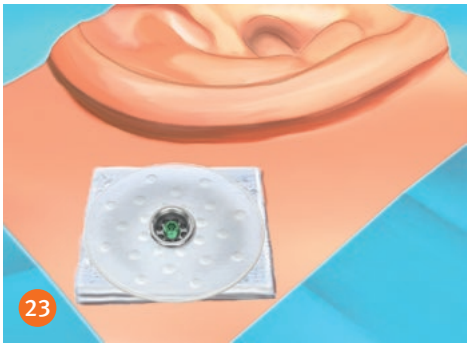
- *Dressing*
  The amount of dressing should be appropriate for the space between the healing cap and the skin.

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

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







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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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