

Ponto™ –
Bone Anchored Hearing System

Audiological Manual



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MEDICAL

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The Ponto System is designed to give patients improved hearing through direct bone conduction. This manual provides detailed information for audiologists working with patients who have received a bone anchored implant and will be fitted with a Ponto sound processor.

Young children and other patients who are not suitable for implantation can still use a Ponto sound processor for longer periods of time on a head band or Softband. Please refer to the Candidacy Guide for information relevant to fitting on a Softband.

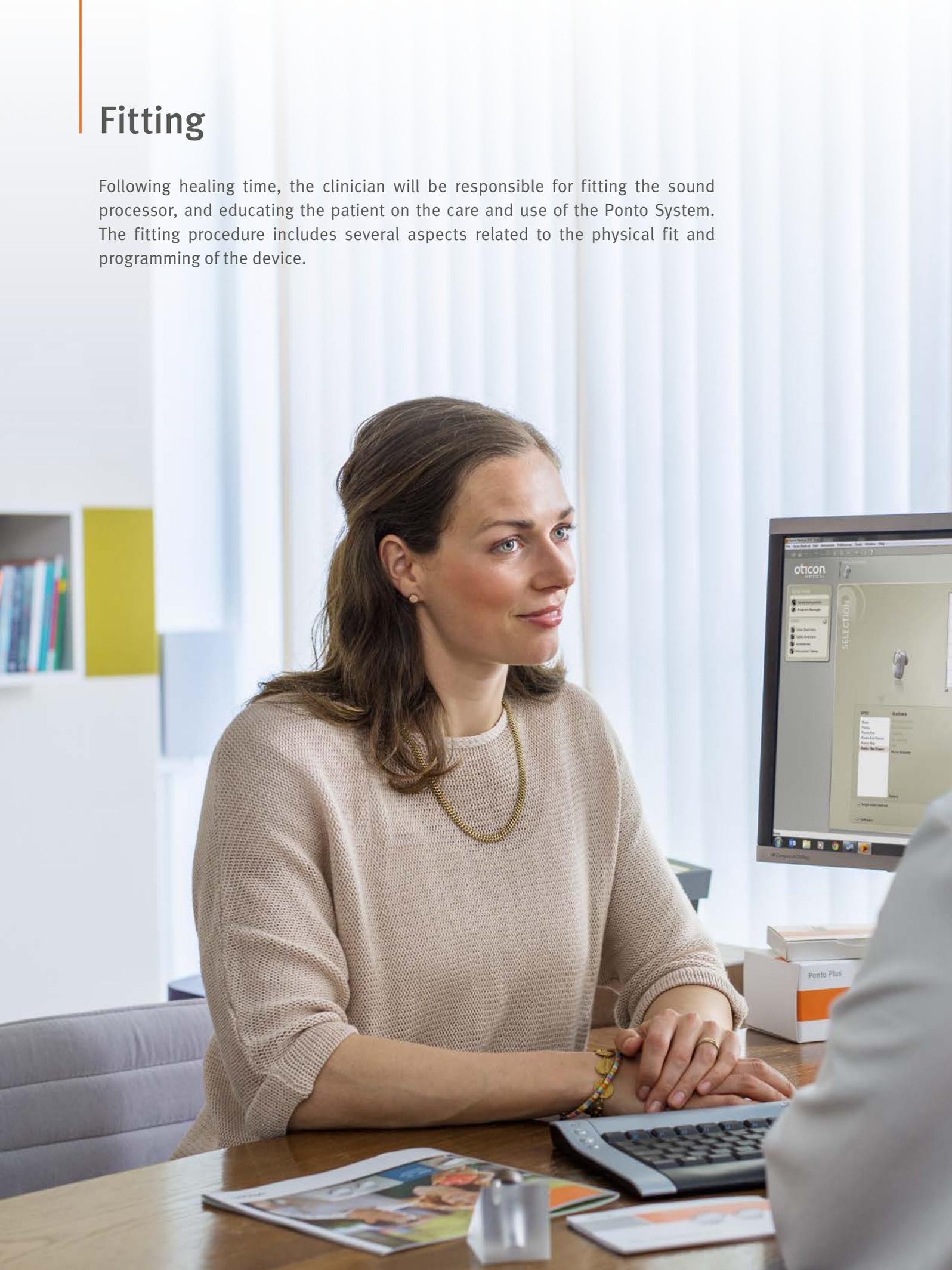
The Ponto System is a beneficial solution for several patient groups, including those with conductive or mixed hearing loss or single-sided deafness (SSD). If candidacy has yet to be determined, please refer to the Candidacy Guide for further information and instruction.

When surgery is elected, an implant is inserted into the skull bone behind the ear in a simple procedure. After a short period of time, during which the bone attaches to the implant through osseointegration, the sound processor can be connected to the abutment. Please refer to the Surgical Manual for further details on the implant process.

A range of Ponto sound processors are available, including regular, Power and SuperPower devices. All Ponto sound processors are programmed individually using Genie Medical software, and a guide to that fitting process is included in this manual.

Fitting

Following healing time, the clinician will be responsible for fitting the sound processor, and educating the patient on the care and use of the Ponto System. The fitting procedure includes several aspects related to the physical fit and programming of the device.



Checking the abutment site

The abutment and surrounding skin area should be checked to ensure the surgical site is healed, healthy, and ready for processor loading.

- Try to gently rotate the abutment to check that it is stable. If the connection is not stable, refer the patient to a trained healthcare professional to have it tightened.
- Inspect the skin surrounding the abutment, and remove any debris around or on the inside of the abutment.
- Inform the patient that in the event of persistent soreness, he or she must contact the clinic. It is easier to treat skin irritations or infections at an early stage.



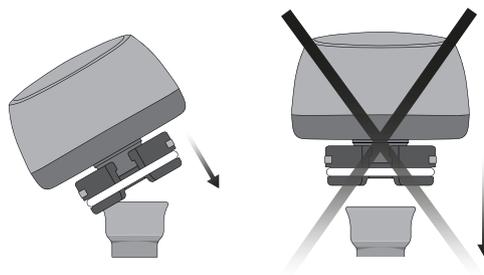
Practise operating the sound processor

- Explain the importance of keeping the coupling clear of hair and debris.
- Practise connecting and disconnecting the sound processor from the abutment.
- Practise operating the sound processor controls.
- Demonstrate sound processor features, such as volume control, push button, battery insertion and how to properly store the sound processor when not in use.

Detailed information on how to operate sound processor controls is included in the Instructions for Use. Additional information on sound processor features is included in the Product Information sheet.

Re-evaluate need for accessories

As described in the Candidacy Guide, again provide the patient with information regarding sound processor accessories, as their needs may change over time. Information on all sound processor features and functionalities can be found in the Product Information sheet, and the Instructions for Use.



Programming guidelines

Genie Medical fitting software is NOAH compatible and can also run in stand-alone mode with its own database.

Programming device

All sound processors can be connected to the PC using a standard programming device such as HI-Pro 2 or ExpressLink. Ponto 4 sound processors can also be programmed wirelessly using the Noahlink Wireless.

Below is a guide to the proper fitting steps.

Selection step

- Select instrument
- **Select type of hearing loss**
 - Conductive / mixed – if the sound processor is fitted to a patient with conductive or mixed hearing loss (default selected).
 - SSD – If the sound processor is fitted to stimulate the cochlear on the opposite side.
- **Select type of connection**
 - Abutment – if the patient is using the sound processor on an implant and abutment (default selected).
 - Softband – if the sound processor is fitted on a Softband or head band.

Fitting step

- Connect the sound processor to the patient's abutment. Mute the sound processor if necessary to avoid feedback.
- Measure the individual feedback limit in the **Feedback Manager/Analyser** tool. If programming cable is used, please ensure that the cable does not pull the device and evoke feedback.
- Conduct **BC In-situ Audiometry**.
- Evaluate the settings and, if necessary, adjust the settings.

End Fitting step

- Click Save, Programme and Exit.

For technical verification of the processor, refer to page 9.

Streaming to the sound processor – no need for programming in Genie Medical

- Ponto 4 sound processors: No specific programming is needed in Genie Medical to get the sound processor to receive signal from e.g. ConnectClip or TV Adapter. The sound processor and the wireless connectivity devices just need to be paired following the instructions included in the wireless accessory.





- Ponto 3 and Ponto Plus sound processors: The Oticon Medical Streamer comes in Open mode and is ready for use out of the box. It can also be paired with a specific sound processor in Genie Medical.

The sound from the wireless connectivity devices and Oticon Medical Streamer can be fine-tuned in the tool Accessories / ConnectLine in the End Fitting step.

More detailed information can be found in the Genie Medical Help Files.

Hygiene and maintenance

The patient should understand their responsibilities in the daily care of their implant and abutment site, care of the sound processor itself, and what to do if they have issues or questions.



Cleaning routines

It is vital to inform the patient about the importance of maintaining good hygiene in the area around the abutment of the bone anchored implant. Caring for the implant site is a simple process that will become part of the patient's daily routine. A mirror may be helpful when cleaning the implant site.

- The skin should be thoroughly cleaned of debris every few days. While washing the hair with shampoo, debris becomes softer and is more easily removed.
- Instruct the patient to maintain a simple daily cleaning routine using soap and warm water.

Service and repair

It is important that the patient handles the sound processor with care and maintains proper hygiene to avoid unnecessary service and repair. Recommendations for handling and precautions are given in the sound processor Instructions for Use.

Go through Instructions for Use

Go through the sound processor Instructions for Use together with the patient to make sure the content is understood. Pay extra attention to Important Patient Information and Warnings, and to the information on maintenance of the sound processors.



Follow-up evaluation

To get the maximum benefit from Ponto, it is recommended that the patient attends follow-up sessions after the initial sound processor fitting. The frequency of these appointments will depend upon the clinic's specific protocol. Information regarding both short-term and long-term care is offered in this section.





Follow-up suggestions

It is recommended that the first follow-up visit takes place within two months of the initial fitting. Subsequent visits once or twice a year will be sufficient to ensure proper maintenance, but some patients may require more frequent appointments.

Subjective measurements

It is recommended to let the patient and/or the patient's family complete a questionnaire that aims to evaluate how much they benefit from and their satisfaction with the sound processor over time.

Objective measurements

Aided word recognition testing in quiet and in noise

It is recommended to measure the patient's word recognition score in quiet and in noise. Speech testing, particularly in the presence of background noise, can provide helpful information to the clinician and the patient about the patient's progress.

Aided sound field threshold measurements

Aided threshold measurement may be conducted, but be aware that this test is affected by a number of variables, such as loudspeaker set-up, test signal, the setting of the sound processor, and the patient's position in the test environment. If warble tones are used as the test signal, the sound processor's feedback cancellation/feedback management needs to be turned off prior to testing.

Technical verification of the sound processor

A Skull Simulator can be used to technically verify the sound processor performance, serving several clinical purposes.

- Checking the performance of sound processors used during a preoperative trial period.
- Measuring the sound processor in user settings for comparison at follow-up meetings.
- Testing the sound processor in technical settings, and comparing it to its product information, to assess a patient complaint of a faulty device.



*Interacoustics Affinity with
SKS 10 Skull Simulator*

Paediatrics

Evaluating and fitting children with a bone anchored sound processor involves some special considerations. Parents of hearing impaired children generally have greater need for counselling. The treatment should be discussed with a parent or caregiver from a short as well as a long term perspective.

The Softband is a valuable tool for evaluation as well as for fitting before the implantation can be performed. It is typical for children to use the Softband for a longer period of time prior to implantation.



Considering implantation

It is recommended that children are fitted with the sound processor on a Softband while they reach the appropriate age for implantation. With the Softband the child can be fitted early to gain access to improved language, speech and educational development.

Before a bone anchored implant can be successfully implanted the bone must be thick enough and sufficiently hard. For detailed information on required bone thickness and special consideration for paediatric patients, see the Oticon Medical Surgical Manual.

Note: In the US, Canada, and Singapore, the placement of a bone anchored implant is contraindicated in children below the age of five.

Care

In many cases, the child patient will not be personally responsible for the care of their processor, Softband, or implant site once they have undergone surgery. It is important that the parent or caregiver of the child is aware of their responsibilities, and the impact of their care on the outcome of their child's hearing health.



Fitting

There are several special considerations, and subsequent selections to be made in the Genie Medical fitting software when working with paediatric cases. Refer to the adult fitting instructions on page 6 of this manual, and consider the following:

Obtaining BC thresholds

Some patients may be too young to provide reliable behavioural testing results. We recommend using the BC In-situ tool as soon as possible; however, estimated BC thresholds can be entered into Genie Medical until the child is old enough to participate. This information may come from Auditory Brainstem Response (ABR) testing, Auditory Steady State Response (ASSR) testing, Behavioural Response Audiometry (BOA), or Visual Reinforcement Audiometry (VRA). If no BC values are entered then Genie Medical prescribes gain for a BC hearing threshold of 0 dB HL.

Placement of the sound processor

Some children will wear their Ponto sound processor in varying locations on the skull. For very young children, it is possible to place the processor on the child's forehead for best access to environmental and speech sounds. If the processor is to be worn in this location, we recommend that the directionality setting be changed to Omni/Surround to ensure maximum benefit. For children wearing the processor on one side specifically, the default microphone setting of Open Automatic/Auto (tri-mode) is recommended.

Childproofing options

When fitting children below the age of 36 months, it is important to secure that the device is fitted with a tamper resistant battery drawer.

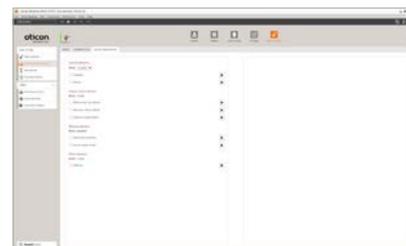
Ponto sound processors either have a built-in tamper resistant battery drawer or an exchangeable battery drawer included in the instrument box. Follow the Instructions for Use and product specific instructions on how to attach and use the tamper resistant battery drawers.

Please check that children and others in need for a tamper resistant option have the correct battery drawer fitted before leaving the clinic.

Other practical considerations of fitting children include deactivating default controls, such as the mute functionality and the volume control. In the End Fitting step, select the Buttons and Beeps task, and uncheck the boxes to disable these functions.

Physical considerations

A safety line is included with the processor, which will connect it to a clip that can be attached to the child's clothing. Even if the child removes the processor from the Softband or abutment, it will remain attached to their clothing to prevent loss of the device.





The processor's battery drawer has a tamper-resistant lock, which will prevent young children from removing the battery on their own.

Follow-up evaluation

Depending on the age of the child, and whether they have an implant or are using the processor on a Softband, the number and frequency follow-up appointments will vary.

Subjective measurements will more often involve input from the child's family.

- Ask the child's parent or caregiver about practicalities of use and provide additional counselling or instruction if needed.
- Use survey tools to track the child's progress over time.

Objective measurements may need to be tailored to the child's age and fitting status.

- It may not be possible to complete aided word recognition tasks, depending on the child's language development level.
- Aided sound field measurements for verification may not be obtainable until the child is older.
- The sound processor can be technically verified using a skull simulator in the same way as described in the adult fitting section, page 9.



Accessory use

Like conventional hearing instruments, the Ponto System has the ability to work with FM systems, a telecoil accessory, direct audio input, and Oticon Medical Streamer and EduMic. These options should be considered for paediatric fittings, especially for school-aged children who could benefit from additional assistance in the classroom.

Cosmetically, the Ponto sound processors feature a colour palette which is designed to blend with many hair colours. For patients who wish to personalise their processor, both stickers and skins are available. The Softband is also available in several colours. Detailed information on all products is available in the Product catalogue.



Compatibility Guide

Products that can be used with the Ponto System

Ponto System components	Products with ref. no. manufactured by Cochlear Bone Anchored Solutions AB
Ponto* Ponto Pro* Ponto Pro Power Ponto Plus Ponto Plus Power Ponto 3 Ponto 3 Power Ponto 3 SuperPower Ponto 4 sound processors	Compatible products from Cochlear BAS Baha® abutments (90305, 90410). Baha® implants with abutment (90434, 90480). Baha® audio adapter** (90065). Baha® telecoil unit** (90185). Incompatible products from Cochlear BAS Baha® BA300 Series abutments Baha® BA210 Series abutments Baha® BA400 Series abutments
Ponto Implant System Ponto Implants with pre-mounted abutments Ponto Abutments	Compatible sound processors from Cochlear BAS Baha® sound processors with snap coupling: Baha® Classic 300 snap (HCB-410-0, HCB-411-0, HCB-412-0). Baha® Compact (90140, 90141, 90142). Baha® Divino (90500, 90510, 90501, 90511, 90502, 90512, 90503, 90513). Baha® Intenso (90730, 90731, 90732, 90733). Baha® Cordelle (HCB 400-0, HCB 401-0, HCB 402-0). Baha® BP100 (91300, 91301, 91302, 91303, 91304, 91305). Baha® 3 Power BP110 (92840, 92841, 92842, 92843, 92844, 92845). Baha® 4 (93630, 93631, 93632, 93633, 93634). Baha® 5 (95201, 95202, 95203, 95204, 95205). Baha® 5 Power (95470, 95471, 95472, 95473, 95474, 95475). Baha® 5 SuperPower (96004, 96003, 96002, 96001).
Ponto Sound processors Ponto 4 Ponto* Ponto Pro* Ponto Pro Power Ponto Plus Ponto Plus Power Ponto 3 Ponto 3 Power Ponto 3 SuperPower	Genie Medical Fitting Software Genie Medical BAHS 2019.1 and later Genie Medical 2016.1

**Discontinued*

***This does not apply for Ponto Plus, Ponto Plus Power, Ponto 3, Ponto 3 Power and Ponto 3 SuperPower.*

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 are determined by the sound processor that is being used.

Not all products are available in all markets. Product availability is subject to regulatory approval in the respective markets.



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 part of the Demant group, a global leader in hearing healthcare with 14,500 people in over 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 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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