Sentio Audiological Guide

Sentio™ System
Feel it to believe it

oticon
MEDICAL

Contents

Introducing the Sentio Bone Anchored Hearing System

This guide provides detailed information for audiologists working with patients who have received a Sentio Ti Implant and will be fitted with a Sentio sound processor. The Sentio System is designed to give patients improved hearing and speech intelligibility through direct bone conduction.

The Sentio Ti Implant is surgically placed in the temporal and mastoid bone area and consists of a transducer and a receiver coil with a magnet. The external sound processor is retained on the patient's head with a magnet. Once the sound processor is fitted it will transmit incoming sound signals to the Sentio Ti Implant, where they are converted into vibrations which pass through the bone directly to the cochlea, bypassing the outer and middle ear.

The Sentio System is a beneficial solution for several patient groups, including those with conductive or mixed hearing loss or single-sided deafness (SSD) from the age of 12, see page 12 for more details. If candidacy has yet to be determined, please refer to the Sentio Candidacy Guide for further information and instruction.

Children younger than 12 and other patients who are not suitable for implantation with the Sentio System can still be candidates for bone conduction systems, either through a percutaneous solution or to use a sound processor for longer periods of time on a headband or softband. When the Sentio System is chosen, an implant is placed under the skin in the temporal and mastoid bone area. For successful implantation, further individual assessment is needed to consider anatomical aspects which could impact placement of the implant. For detailed information on preoperative considerations, please refer to the Sentio Ti Implant Kit Instructions for Use and Sentio Candidacy Guide.

The Sentio sound processor is programmed with the Genie Medical BAHS fitting software which enables the hearing care professional to measure the patient's hearing threshold via the sound processor to achieve an initial setting of the device. Also, the hearing care professional can adjust the frequency response and adjust various signal processing parameters of the sound processor in accordance with a patient's individual hearing requirements. A guide to the fitting process is included in this guide.

Illustrations and images in this guide are not to scale and are not intended to display actual markings.

Summary of Safety and Clinical Performance (SSCP) report for the Sentio System is publicly available in the EUDAMED database:
https://ec.europa.eu/tools/eudamed
Entering keys:
Basic UDI-DI Sentio Sound Processor: 57121491001185

Fitting

The Sentio sound processor can be used when the soft tissue has completely healed from surgery. Following healing time, the hearing care professional will be responsible for fitting the sound processor and educating the patient in the care and use of the Sentio System. Sound processors should be used only as directed and adjusted by the hearing care professional. The fitting procedure includes several aspects related to the physical fit and programming of the device.

The Sentio sound processor comes in six different colours designed to blend with many hair colours.

Checking the implant site

The Sentio sound processor can be fitted when the soft tissue has completely healed from surgery (2-6 weeks). The skin area around the implant site should be checked to ensure that it is healed, shows no signs of redness or swelling, and is ready for sound processor fitting.

Selecting the correct magnet strength

The magnets in the Sentio sound processor and the Sentio implant ensure correct placement and attachment of the sound processor to the head. The sound processor should attach comfortably and securely to the head. The magnet can be changed to adjust the retention strength to find the right balance between comfort and retention. If the magnetic force is too weak there is a risk that the sound processor will fall off too easily. If the magnetic force is too strong, there is a risk of discomfort or skin irritation and in worst case break down of skin and underlying tissue (skin necrosis).

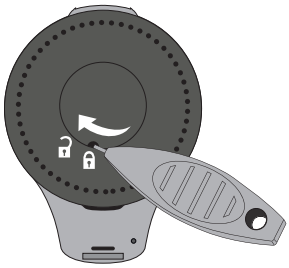
The most prominent variables impacting the magnet force are the thickness and quality of the skin and underlying tissue, and in some cases hair thickness. Every patient is unique and finding the right magnet strength is achieved through experience. Young adults and people of diminished mental capacity should have their implant site monitored regularly by caregivers.

Magnet fitting procedure

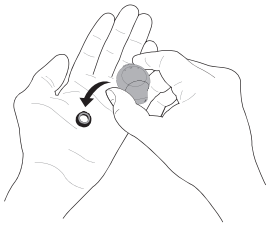
Each magnet is built into a container, which also forms the lid of the magnet holder at the back of the sound processor. The magnet system includes six magnets of steadily increasing strength, with magnet #1 being the weakest and #6 the strongest. The sound processor comes with a default magnet #3, which fits most patients and serves as a starting point for the magnet fitting procedure.

1. Gently attach and detach the Sentio sound processor with the default magnet #3 to get a sense of the retention force.
2. Allow the patient to also attach and detach the Sentio sound processor to obtain a subjective sense of the retention force.
3. Evaluate if the magnet strength in the sound processor seems suitable for everyday life activity. It should stay in place during a shake of the head or normal paced walk, but may fall off during more vigorous activities like intense jumping. The sound processor should fit comfortably and securely in place with the right balance between comfort and retention.
4. If judged relevant, change to a weaker or stronger magnet, and re-evaluate.
5. Re-evaluate again before the patient leaves the clinic; If wearing the sound processor causes numbness, redness, discomfort, or pain, or if the sound processor seems to fall off too easily, the magnet strength must be reconsidered.

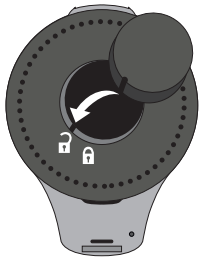
1. Open
Insert the pin tool into the dent. Move clockwise towards the open padlock.



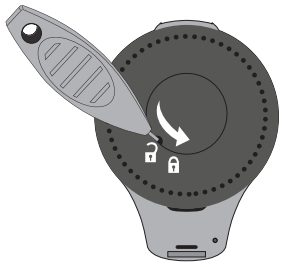
2. Remove
Gently drop the magnet into the hand.



3. Insert
Align the dent of the new magnet with the open padlock.



4. Lock
Insert the pin tool into the dent. Move counter clockwise towards the locked padlock.

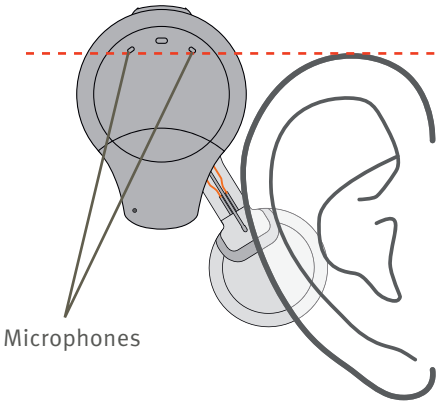


The magnet system includes six magnets of steadily increasing strength, with magnet #1 being the weakest and #6 the strongest.

Placement and positioning of the sound processor

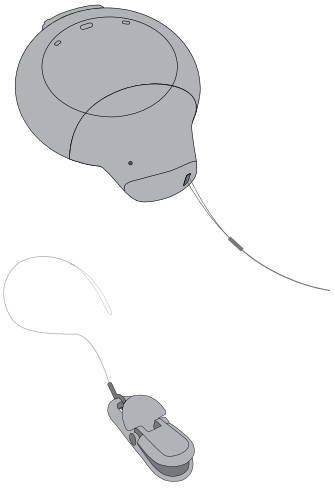
The magnets in the Sentio sound processor and the Sentio implant ensure correct placement of the sound processor above the implant.

For optimal performance from the directional microphone system, the sound processor should be positioned with the microphone inlets in the horizontal position.



Retention in particularly active situations

Inform the patient that the sound processor should sit comfortably and securely in place during daily use and that it is recommended to use the safety line in particularly active situations such as sports activity, gardening, etc. In addition to particularly active situations, it is also recommended to use the safety line when the patient is getting used to wearing the device.



Programming guidelines

Genie Medical BAHS fitting software is NOAH compatible and can also run in stand-alone mode with its own database.The sound processor can be programmed wirelessly using the Noahlink Wireless or by cable using a standard programming device such as HI-Pro 2 or ExpressLink. Information on all sound processor features and functionalities can be found in the Product Information sheet, and the Instructions for Use.

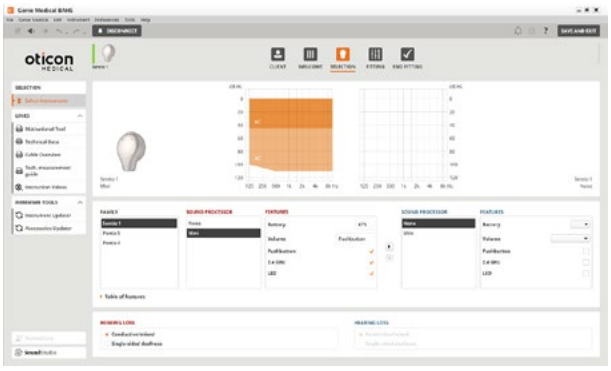
To the right is a guide to the recommended programming flow.

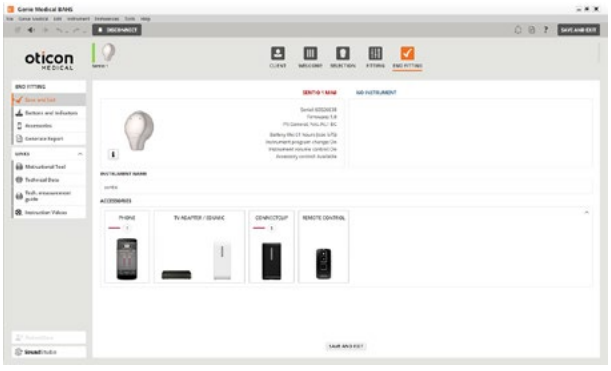
Select / Connect instrument

- Select type of Hearing Loss
- Conductive / mixed – if the sound processor is fitted to a patient with conductive or mixed hearing loss.
- Single-sided deafness (SSD) – if the sound processor is fitted to stimulate the cochlea on the opposite side.
- Attach the sound processor to the patient's implant.
- Measure the individual feedback limit in the Feedback Analyser.
- Conduct BC In-situ Audiometry
- Evaluate the settings and, if necessary, adjust the settings.

End Fitting step

- Click Save and Exit.





Connectivity devices

No specific programming is needed in Genie Medical BAHS to allow the Sentio sound processor to receive signals from, for example, ConnectClip, EduMic or TV Adapter.

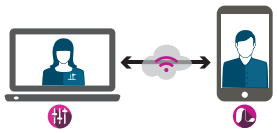
The sound processor and the wireless connectivity devices just need to be paired following the instructions for the wireless accessory.

The sound from the wireless connectivity devices can be fine-tuned in the tool Accessories in the End Fitting step of Genie Medical BAHS.

Re-evaluate the need for accessories

It is recommended to provide the patient with information regarding sound processor accessories, as their needs may change over time.

RemoteCare



RemoteCare lets you conduct a follow-up fitting session with a patient located elsewhere. The fitting takes place in Genie Medical BAHS and the patient wearing the sound processors is connected via the Oticon app.

Before using RemoteCare

Before you can conduct your first RemoteCare session, you must contact Oticon Medical to be set up as a user, and you must ensure that you and the patient meet the technical requirements for using RemoteCare.

Getting ready for a RemoteCare session

Make sure that the patient does the following before the remote session begins:

- Plugs the device (e.g. smartphone) into a power supply or ensures that the device is fully charged, and that Bluetooth is turned on.
- Ensures that the sound processor(s) have new batteries.
- Pairs the sound processor(s) with the device. For Apple® devices, the patient must pair the sound processor(s) with the device before the app for RemoteCare can be used. For Android™ devices, the patient can pair the sound processor(s) in the Oticon app.
- Is online and logged in with the email account used to create the RemoteCare account.

How to log in to RemoteCare

1. Select your client in the Client step if you are using the Genie Medical BAHS stand-alone or from the patient browser in NOAH.
2. Click RemoteCare in the task pane. A window opens outside Genie Medical BAHS where you can enter your login information. The RemoteCare window will then open.
3. Select the desired camera and microphone source from the drop-down lists.
4. Enter your patient's email to establish the remote session. The window displays the client's status.
5. If your patient has already logged in and is waiting in the virtual waiting room, you can start the remote fitting session.

In case of connection problems, see Troubleshooting RemoteCare in the Genie Medical BAHS help files.

How to conduct a session in RemoteCare

1. Click Start a visit. Connect the sound processor(s) by clicking Connect in the toolbar.
2. In Genie Medical BAHS, you can now modify the fitting as you would in an in-office fitting session.
3. Ensure that Genie Medical BAHS is connected to the sound processor(s) and click Upload to apply the new setting. Be sure to upload after each change to the sound processor(s), so your patient can evaluate the change. In the communication window, there are icons and status indicators that let you communicate with your patient and view the status of the sound processor(s).

How to end a session in RemoteCare

1. Tell your client that you will be ending the session. Ensure that you have saved all changes.
2. When you are finished, click Disconnect to disconnect the sound processors from RemoteCare. The sound processor(s) will restart.
3. In the End Fitting step, click Save and Exit (NOAH) or Save and go to Client step (stand-alone) to save and end the session.

	Refresh video.
	Turn the camera on or off.
	Turn the microphone on or off.
	Show or hide the chat panel.
	If the icon appears next to the chat icon, you have unread chat messages.
	Upload settings to the sound processors. The upload icon becomes active when you have new settings to upload. When there are no new settings to upload, the icon is greyed out.

Patient instruction and information

Practise operating the sound processor

- Demonstrate the correct position of microphones.
- Show how to attach and detach the sound processor to the implant area.
- Practise operating the sound processor, such as push button, battery insertion and how to use the safety line
- Demonstrate how to properly store the sound processor when not in use.
- Demonstrate how to clean the sound processor according to the guidelines in the Instructions for Use.

Sentio Listener

The Sentio Listener can be used to listen to the output of the sound processor without having an implant oneself.
The Sentio Listener is used to check the basic functionality of the Sentio sound processor.
Through the listener, the hearing care professional or caregiver may ensure that the sound processor microphones are detecting sounds and that the coil is transmitting signal.

The Sentio Listener is not a validation or verification tool. The listening experience through a Sentio Listener and headphones is not representative of the listening experience of the user listening through the Sentio implant and Sentio sound processor.

The Sentio Listener should therefore not form the basis of fitting or fine tuning adjustments or assessment of sound quality.

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.

Skin care and retention

Inform the patient, that if wearing the sound processor causes numbness, redness or discomfort, or if the sound processor seems to fall off frequently, he or she should return to the clinic to have the magnet exchanged. In case of significant skin irritation, blistering or signs of skin breakdown, use of the device should be suspended until the wound site can be assessed.

For young adults and people of diminished mental capacity, the parents or caregivers are responsible for skin care and retention comfort.

Note: *No magnet other than the Sentio sound processor shall be placed over the implant site. This may damage the implant and/or the skin.*

Maintenance, 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. Please refer to the sound processor Instructions for Use for recommendations for handling, cleaning and precautions.

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 the sections about Sound processor maintenance, Important Information, Warnings and precautions.

Follow-up evaluation

To get the maximum benefit from the Sentio System, it is recommended that the patient attends follow-up sessions after the initial sound processor fitting.

Follow-up frequency

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

The frequency of follow-up appointments will depend upon the clinic's specific protocol and the patient's needs. Medical device regulations require the manufacturer to report serious incidents to the appropriate authority. Should such an incident occur, notify your local distributor or the manufacturer as soon as possible.

Retention and skin evaluation

Evaluation of retention, comfort and skin and must be done at every visit.
The most prominent variables impacting the retention force are the thickness and quality of skin and underlying tissue, and in some cases hair thickness. In addition, skin can compress over time, which in some cases can give rise to a need for a weaker magnet. Pay extra attention if the patients' health status has changed with changed in terms of weight or skin condition.

Note: *The sound processor's magnet can be degraded after exposure to strong magnetic fields.*

Step-by-step retention evaluation

- Ask for the patient's subjective evaluation of retention and if the sound processor sometimes fall off.
- Ask if the patient ever experiences discomfort, numbness, tickling, soreness or pain during or after wearing the sound processor.
- Make a visual inspection of the area under the sound processor looking for signs of skin being affected in any way. Look especially for paleness or redness, or for the skin being either swollen or excessively compressed compared to the surrounding area.
- With a finger, gently press on the skin at the sound processor site to reveal any tenderness or pain.

Solution guide

- If the sound processor falls off frequently during everyday activities, consider changing to a stronger magnet. Re-evaluate the magnet selection.
- If the sound processor only falls off during particularly active situations, recommend using the safety line. Re-evaluate the magnet selection.
- If the skin is affected by the retention pressure, change to a weaker magnet, and re-evaluate. It can be relevant to recommend temporary relief for symptoms to subside.
- In case of significant skin irritation, blistering or signs of skin breakdown, use of the device should be suspended until the wound site has healed.
- Remind the patient (or caregiver) that if wearing the sound processor causes numbness, redness or discomfort in any way, or if the sound processor seems to fall off frequently, he or she should return to the clinic to have the magnet exchanged.

Subjective measurements

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

Objective functionality 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 both the clinician and the patient about the patient's progress.

Aided sound field threshold measurements
Aided threshold measurement may be conducted, but one must be aware that this test is affected by several variables, such as loudspeaker set-up, test signal, sound processor settings, 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.

Paediatrics and Special Needs consideration

When fitting children under the age of 18, Genie Medical BAHS prescribes paediatrics settings. Please review these and how they are appropriately adjusted for the patient.

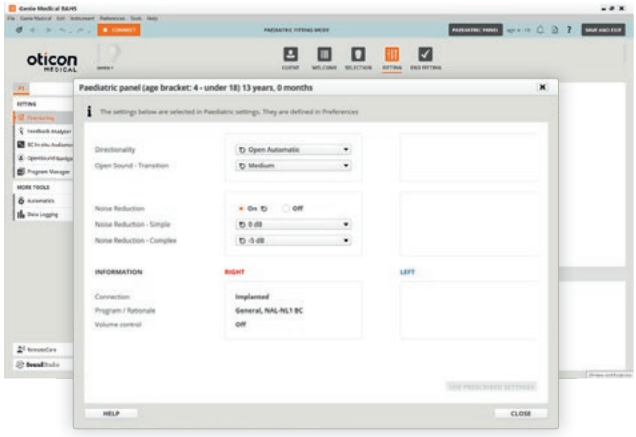
Fitting

There are special considerations, and subsequent selections to be made in the Genie Medical fitting software when working with paediatric cases. Refer to the adult programming guidelines on page 7 of this guide, and consider the following:

Obtaining BC thresholds
We recommend using BC In-situ tool for all Sentio fittings, also for children.

If no BC values are entered, then Genie Medical prescribes gain for a BC hearing threshold of 0 dB HL.

Tamper-resistant options
When fitting young adults or patients with diminished mental capacity, it is important that the tamper-resistant mechanism is activated which will prevent access to the battery. Other practical considerations include deactivating default controls, such as the mute functionality and the volume control. In the End Fitting step, select the Control task, and uncheck the boxes to disable these functions.



Safety line
A safety line is included with the sound processor. Even if the sound processor is removed from the implant site it will remain attached to the clothing or the hair to prevent loss of the device.

Accessory use
Like conventional hearing instruments, the Sentio System works with EduMic and Connectivity devices. These options should be considered for paediatric fittings, especially for school-aged children and young adults who could benefit from additional assistance in the classroom.

Considerations when using the Sentio System

Success rates for treatments with Sentio System and similar systems are high but complications may occur. The major aspects are listed below.

Daily use

- A hearing device will not restore normal hearing and will not prevent or improve a hearing impairment. A hearing device is only part of hearing rehabilitation and may need to be supplemented by auditory training and lip reading.
- In case the sound processor is dropped, make sure the shell is not cracked or any parts of the sound processor have broken.
- The sound processor has achieved IP57 classification, referring to being water resistant, not waterproof. Always disconnect the sound processor before showering or bathing/swimming.
- The user should be aware of the possibility that the sound processor may stop working without notice. Keep this in mind in situations where the user is dependent on warning sounds (e.g. when you are in traffic).
- Participation in contact sports is not advised as a severe impact may damage the implant and sound processor.

Active implants

- Patients already implanted with, or to be implanted with, programmable CSF shunts are contraindicated.
- Caution must be taken with active implants.
- In general, the guidelines recommended by manufacturers of implantable defibrillators and pacemakers regarding use of mobile phones and magnets should be followed.
- If the patient has an active brain implant, the manufacturer should be contacted for information about the risk of disturbance.

Other medical treatment

The sound processor should be removed before X-ray, CT/MR/PET scanning electrotherapy, surgery etc. as it may be damaged when exposed to strong fields.

Choking hazard

The sound processor contains small parts that may be a choking hazard for small children. Batteries can also be harmful if swallowed. Always keep batteries out of reach of small children or people of diminished mental capacity. If a sound processor is accidentally swallowed, seek medical attention at the nearest emergency department.

Battery

Never attempt to recharge air/zinc batteries and never dispose of batteries by burning them. There is a risk that the batteries will explode. Use only high-quality batteries. Batteries of low quality may leak and cause bodily harm.

Heat and chemicals

The sound processor must never be exposed to extreme heat, for example left inside a parked car in the sun. The sound processor must not be dried in microwave ovens or other ovens.

Disposal

Never dispose of the sound processor, by burning them. There is a risk that they will explode and cause serious injury. Dispose of the sound processor according to local regulation for electronic equipment.

Interference with other electronic devices

Although unlikely, nearby electronic devices may be affected by the sound processor. Similarly, the sound processor may be affected by nearby electronic devices which may cause odd sounds in the sound processor. In that case, move the sound processor away from the affected electronic device.

Intended use

The Sentio System (Sentio implant in combination with Sentio sound processor) is intended 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 intended purpose of the Sentio sound processor is to pick up sound, process it and transmit the processed signal through the intact skin to the Sentio implant.

The intended purpose of the Sentio implant is to be surgically placed in the temporal and mastoid bone area. It is intended to retain the sound processor, receive signals from the sound processor, transform signals into vibrations and transmit the vibrations via the skull bone to the inner ear.

Intended user
Intended users of the Sentio System are: patient (user of the implant and sound processor), caregivers (providing care for the patient), hearing care professionals (fitting the sound processor), surgeons and operating room nurses (during surgery).

Indication for Use
The Sentio Ti Implant, in combination with Sentio 1 Mini, is indicated for the following patients:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of the sound. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear should be better than or equal to 45 dB HL.
- Patients having a symmetrically conductive or mixed hearing loss are candidates for a bilateral fitting. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2 and 3 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).
- Patients who are indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.
- Prior to receiving the device, it is recommended that an individual has experience with appropriately fitted air conduction or bone conduction hearing aids.
- Patients 12 years of age or older.

Contraindications
- Known chronic or non-revisable vestibular or balance disorder.
- Known abnormally progressive hearing loss.
- Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment.
- Skin or scalp conditions that may preclude attachment of the sound processor or that may interfere with the use of the sound processor.
- Patients already implanted with, or to be implanted with, programmable CSF shunts.

Follow-up evaluation

Depending on the age of the patient and/or mental capacity, the number and frequency of follow-up appointments will vary.
Subjective evaluations will more often involve input from the patient's family.

- Inform the patient's parent or caregiver about practicalities of use and provide additional counselling or instruction if needed.
- Use survey tools (a range of questionnaires are available in Genie Medical BAHS) to track the patient progress over time.

Compatibility guide

Products that can be used with the Sentio System

Sentio System components	Sentio sound processors
Sentio sound processor family Sentio 1 Mini	**Fitting software** Genie Medical 2024.2 or later
Sentio Implant System Sentio Ti Implant	**Compatibility with other articles** ConnectClip TV Adapter 3.0 Remote Control 3.0 Oticon app EduMic Sentio Listener

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 power of sound to people at every stage of life. For more than a decade, we have made bone anchored hearing systems more accessible by simplifying the treatment for physicians, audiologists, and patients alike.

We believe that patients and hearing care professionals should be able to choose the best possible solution at any time along the patient journey. We call it “Freedom of Choice” and it has always been paramount to Oticon Medical. This is the reason why our solutions are designed to be compatible whenever possible. As a result, an implant from Oticon Medical stands as a true testament to our unwavering lifelong support.

We work collaboratively with professionals to ensure that every solution we create is designed with our users’ needs in mind. We have a strong passion to provide innovative solutions and support that enhance quality of life and help people live life to the fullest – now and in the future.

Because we know how much sound matters.

Manufacturer
Oticon Medical AB
Datavägen 37B
SE-436 32 Askim
Sweden
Tel: +46 31 748 61 00

CE 0123

27512en – Version B / 2024.07

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