Sentio Candidacy Guide

Sentio™ System
Feel it to believe it

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Contents

Introducing the Sentio Bone Anchored Hearing System 3

Identifying patients for a bone conduction solution 4
- Conductive or mixed hearing loss 5
- Single-sided deafness (SSD): Unilateral profound sensorineural hearing loss 7
- Other conditions 7

Evaluating bone conduction sound preoperatively 8
- Preoperative trial with a percutaneous solution on a softband or headband 9
- Counselling 11

Moving forward with Sentio 12
- Surgical considerations 12
- Other considerations 13

Intended use 14
- Indications for use 14
- Contraindications 14

References 15

Introducing the Sentio Bone Anchored Hearing System

This guide provides detailed information to the multidisciplinary hearing healthcare team (including surgeons, audiologists and nurses) on how to select patients who will benefit from the Sentio bone anchored hearing system.

The Sentio™ System (a sound processor and an implant) will compensate for hearing loss, i.e., improve the hearing of patients within the indicated use manifested by:

- Improved ability to hear sounds
- Improved speech intelligibility

For a patient with a unilateral hearing loss, the benefit will primarily be experienced for sounds directed to the fitted side/the hearing-impaired side. In general, with bone anchored hearing systems, if the patient has symmetrical bone conduction (BC) hearing loss and is bilaterally fitted, the binaural benefits will, for example, be in the improved ability to localise sounds.

In addition, bone conduction amplification is also expected to provide improved quality of life and reduce the disability caused by a hearing loss for patients within the intended use.

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. A magnet in the external sound processor keeps it retained on the implant area on the patient's head. Once the Sentio 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 indicated for use in patients with conductive or mixed hearing loss or single-sided deafness (SSD) (see page 7).

For successful implantation, individual assessment is needed (see page 12).

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 Ti Implant: 57121491001083
Basic UDI-DI Sentio Sound Processor: 57121491001185

Identifying patients for a bone conduction solution

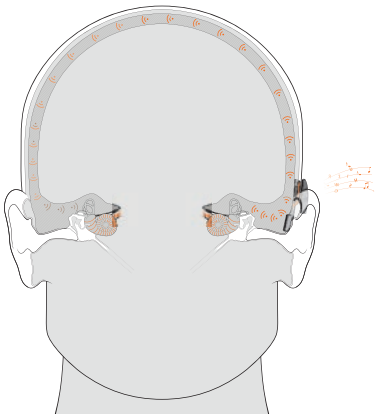
The Sentio System is a beneficial solution for several patient groups. An audiological evaluation is the first step to determining candidacy. Pure tone air and bone conduction testing are the basic measurements used to evaluate candidates for a bone anchored sound processor.

There are three main audiological indications:

- Conductive hearing loss
- Mixed hearing loss
- Single-sided deafness (SSD)

Conductive or mixed hearing loss

Patients with conductive and mixed hearing loss, who can still benefit from the amplification of sound, may be candidates for a bone conduction solution.

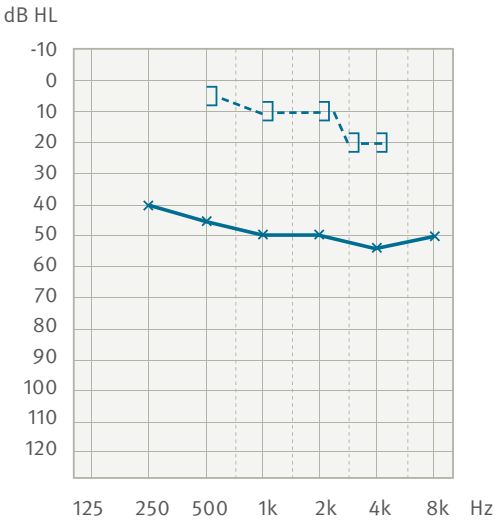


The sound processor transmits sound directly to the cochlea via bone conduction. The sound signal bypasses the conductive element of the hearing loss (the air-to-bone gap), and therefore less amplification is required compared to conventional hearing aids.

Size of air-bone gap
Studies indicate that patients with an air-bone gap of more than 30 dB PTA (the mean threshold of 0.5, 1, 2, and 4 kHz), will benefit significantly from a bone conduction sound processor, compared to an air conduction hearing aid.[1,2,3]

Size of sensorineural element in a mixed hearing loss
The pure tone average bone conduction (BC) threshold for the indicated ear should be better than or equal to 45 dB HL (measured at 0.5, 1, 2 and 3 kHz). This criterion is to ensure that the sound processor can provide sufficient amplification for the sensorineural component for a patient with mixed hearing loss.

Example: Conductive hearing loss



Is Air-Bone Gap larger than 30 dB?
ABG = ((45-5) + (50-10) + (50-10) + (55-20)) / 4
ABG = (40 + 40 + 40 + 35) / 4 = 39 dB
39 dB › 30 dB ✓

Possible causes of conductive and mixed loss:

- Chronic otitis media
- Congenital causes
- Aural atresia and/or Microtia
- External otitis
- Cholesteatoma
- Otosclerosis
- Traumatic injury to middle ear structures
- Other Ossicular disease

The above conditions may occur in isolation, resulting in a conductive hearing loss, or along with a cochlear hearing loss component, resulting in a mixed hearing loss.

Treatment benefits

Advantages compared to conventional air conduction hearing aids:

- The sound signal bypasses the conductive component of the hearing loss. This means that less amplification is needed, which has a positive effect on the sound quality.
- The ear canal remains completely open, which means that the situation for patients with ear infections as well as draining ears can be improved.
- The reduced amplification needed also decreases the risk of feedback.

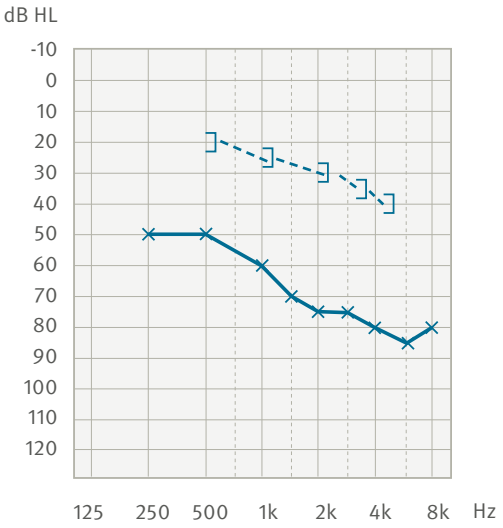
Advantages compared to middle ear surgery:

- The benefits and effectiveness of bone conduction sound processing can be evaluated prior to surgery with a non-surgical solution like a softband or headband by the patient and audiologist.
- The implantation does not expose the patient to any risk of additional hearing impairment.

Advantages compared to other bone conduction hearing solutions:

- No need for continuous care or cleaning of the implant area after healing.
- Low risk of local infection or inflammation after healing.
- Better sound quality than with passive transcutaneous (skin transmission) solutions as there is no attenuation of the sound vibrations passing through the skin.

Example: Mixed hearing loss

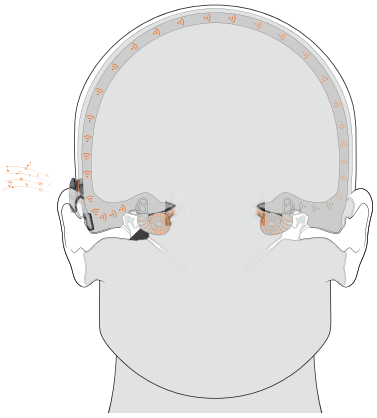


Is the Air-Bone Gap larger than 30 dB?
ABG = ((50-20) + (60-25) + (75-30) + (80-40)) / 4
ABG = (30 + 35 + 45 + 40) / 4 = 38 dB
38 dB › 30 dB ✓

Is the average BC threshold less than or equal to 45 dB HL?
Avg BC = (20 + 25 + 30 + 35) / 4 = 28 dB HL
28 dB HL ≤ 65 dB HL ✓

Single-sided deafness (SSD): Unilateral profound sensorineural hearing loss

Patients who suffer from a profound sensorineural hearing loss in one ear with normal hearing in the opposite ear may be suitable candidates for a bone conduction hearing system. In this application the sound processor acts as a CROS (contralateral routing of signals) device. It is placed on the patient's deaf side to pick up sound which is then transferred via the bone to the functioning cochlea on the opposite side.



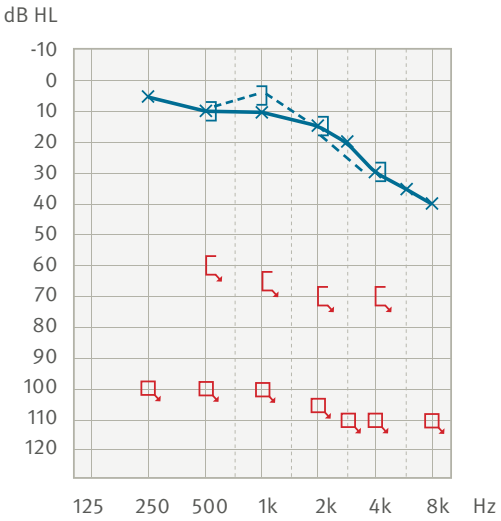
Degree of hearing loss in the good ear
The pure tone average air conduction threshold of the hearing ear should be better than or equal to 20 dB HL AC (measured at 0.5, 1, 2 and 3 kHz).

Also, the use of a bone conduction system can be considered for any patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but for some reason cannot or will not use an AC CROS.

Possible causes of single-sided deafness:

- Acoustic neuroma tumours
- Sudden deafness
- Congenital causes
- Ménière's disease
- Neurological degenerative disease
- Ototoxic drugs
- Surgical interventions

Example: Single-sided deafness (SSD)



Is the average AC threshold in the good ear less than or equal to 20 dB HL?
Avg AC = (10 + 10 + 15 + 20) / 4 = 14 dB HL
14 dB HL ≤ 20 dB HL ✓

Treatment benefits

Single-sided deafness patients may benefit from a bone conduction sound processor in terms of reduced head shadow effect and improved speech intelligibility in noise.[4]

Advantages compared to an AC CROS aid:

- The ear canals remain completely open.
- Only one device is needed, rather than the two units needed for an AC CROS system.

Other conditions

Besides the types of hearing losses discussed above, patients with other medical conditions may also be candidates for the Sentio bone anchored hearing system.

Skin allergies or external otitis
These conditions may be aggravated by the use of an ear mould.

Ear canal stenosis
If the size of the patient's canal, whether congenital or as a result of previous ear surgery, has made an ear mould unsuitable.

Evaluating bone conduction sound preoperatively

Once it has been determined that a patient meets the necessary candidacy criteria, it is important that they are offered an opportunity to experience the difference bone conduction sound can make for them.

An individual trial provides the patient with valuable information about the benefits bone conduction sound can offer them. It is important that the audiologist encourages the patient to use the trial period in the most effective way. Using a percutaneous sound processor like Ponto on a non-surgical solution such as a softband or headband in many different listening situations will allow the patients themselves to assess the benefits and hearing improvements of a bone conduction solution in the best way.

Appropriate patient counselling is also an important step. Throughout the evaluation of bone conduction sound and counselling process, it is vital that the patient care team, including surgeons, audiologists and nurses, cooperate closely in order to achieve an optimal patient outcome from both a surgical and audiological perspective.

Preoperative trial with a percutaneous solution on a softband or headband

Patient candidates should be tested preoperatively with a sound processor on a headband or softband to evaluate the benefit. It is recommended to trial both at the clinic and at home to evaluate the benefits of bone conduction using the Ponto or other percutaneous systems. It is particularly important to afford the SSD patients a trial at home and, preferably for one or two weeks, to ensure that the sound processor offers the expected benefits.

For the best possible testing preoperatively, the sound processor should be fitted according to the patient's individual needs. For patients with symmetrical conductive or mixed hearing loss who are not going to be bilaterally implanted the test will also help determine the optimal implant side.

Please see page 11 for further information.

Choosing test access

To demonstrate the sound processor and to evaluate the benefits for the patients, the Ponto sound processors can be connected to any of the following test accessories:

Test band
The test band is a firm head spring, and is used when testing a sound processor for shorter periods, mainly inside the clinic or hospital.

Headband
The headband has a softer head spring than the test band, and can be used when testing a sound processor during longer periods.

Softband
The softband is a soft headband with a connection plate used when evaluating a sound processor during longer periods. It is also suitable for daily use with paediatric patients prior to surgical candidacy.

The softband is available for either monaural or binaural fitting. The headband and testband only come in unilateral versions.

Bilateral fittings

Bilateral fitting should be considered for candidates with bilateral conductive or mixed hearing losses. If the patient has a symmetrical BC threshold, then fitting bilateral processors can result in improved sound localisation and speech recognition in noise.[5] To obtain bilateral hearing, the difference between the left and right sides' bone conduction 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.

If bone conduction thresholds are quite asymmetric, then a bilateral bone conduction hearing system will likely not confer the advantages associated with binaural hearing, such as localisation and improved speech perception in noise. However, patients may still benefit from reduction of the head shadow effect.[6]

Side selection

For patients with bilateral hearing loss fitted with a single sound processor, the side with the best bone conduction threshold is preferable from an audiological point of view. In cases where it is difficult to determine which side is the best from the audiogram, the trial should include placing a sound processor on each side to help the patient decide which side is the best for placement for the implant and sound processor.

In addition to the audiological factors, practical considerations may influence side selection. Ensure the patient has the manual dexterity to handle the sound processor and place it correctly on the implant site. Practical concerns specific to the patient should be considered when choosing implant side. For example, patients who often drive a car with accompanying a passenger, will typically want the implant on the side facing the passenger.

Trialing a percutaneous solution on a softband preoperatively

The Genie Medical BAHS fitting software has a dedicated fitting mode for a softband/headband which automatically addresses the attenuation of the signal through the skin. Because of attenuation, it may be beneficial to use a SuperPower processor in the preoperative evaluation, even if the patient has no or only a mild sensorineural hearing loss. For paediatric patients, age-appropriate tests should be used when evaluating audibility and speech understanding during in-clinic trials. It is important that the patient's first experience with the bone conduction sound is positive.

Please refer to the Ponto Audiological Manual for information on fittings on a softband as well as information about skull simulator measurements, which are useful to ensure a sound processor works as intended in the preoperative trial.

Note: It is important to inform the patient that the sound performance will be further improved with the implanted solution.

Counselling

When counselling the patient, it is important to understand their diagnostic background, as patients with different types of hearing loss require different types of counselling to successfully manage their expectations. Please refer to pages 7 and 9 for treatment benefits, and consider guiding the patient on how to trial the device in many different listening situations and sound environments to support a good foundation for decision-making.

Note that a patient may be a good candidate for bone conduction sound but may be a poor candidate for a transcutaneous solution for surgically or medically related issues. In these cases, other alternatives such as sound processors on abutment, softband or headband should be considered. Provide the patient with information regarding sound processor features and accessories, as this may influence the device selection.

Parents or caregivers of hearing-impaired children and young adults generally have a great need for counselling. Issues related to the patient's development are central and many parents and caregivers need advice on what they can do to help the child in their social and language development. The treatment should be discussed with the parents from a short as well as long-term perspective. Access to hearing rehabilitation is crucial for the patient's speech, language and educational development.

Realistic patient expectations

It is vital that the patient develops realistic expectations about the use of the Sentio System prior to deciding on implantation. This can be achieved through providing clear information about the treatment and aftercare requirements.

Allow the patient to see the actual size of the implant and sound processor (in combination), understand how and where the implant will be placed in the skull bone and where the Sentio sound processor will be placed after surgery.

Provide an understanding of what the Sentio System may do for that individual patient. In most cases, a bone conduction sound processor leads to significantly improved sound quality, comfort and speech intelligibility. However, in some patients this may not be the case. For patients with chronically draining ears, the main benefit may be reduced infection and a dry ear.

Moving forward with Sentio

Once the patient has had an opportunity to test bone conduction sound and evaluate its benefit for themselves, they should also receive information about the surgical procedure, including complications and precautions.

The patient should understand that the next step in the process of obtaining a bone conduction system is surgery, in which a Sentio implant will be placed under the skin in the temporal and mastoid bone area behind the ear in question. It is helpful to explain that the implant will be connected to the sound processor magnetically with the skin between an internal magnet in the implant and an external magnet in the sound processor.

When the skin is completely healed and no post-surgical swelling remains (2-6 weeks), the sound processor is adjusted to the patient's individual needs by a hearing care professional and can be used.

Surgical considerations

Surgical candidacy is based on several aspects, which are discussed in detail with the physician performing the procedure. Success rates for the implantation of the Sentio Ti Implant and similar devices are high but complications may occur. The major aspects are discussed below.

Typical risks associated with surgery

Patients who meet the indications for implantation should be informed about typical risks associated with surgery (effects from general anaesthesia, bleeding, blood cloth, infections, etc.), which are not specifically related to the product/treatment itself. This also includes temporary numbness and/or pain that could occur around the implant area during the healing period.

Preoperative considerations

The fixation screws engage 2.7 mm in the bone. A preoperative CT scan is typically not necessary for patients with normal anatomy. A preoperative CT scan is recommended for patients where thin bone is expected including:

- Patients who have had 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, for example congenital aural atresia, hemifacial microsomia/Goldenhar syndrome, Treacher Collin like syndromes and Branchio-Oto-Renal (BOR) syndrome.
- Patients under the age of 18.

Patients with severe seborrheic eczema or ongoing middle ear infection must be treated before implantation. Special consideration should be taken before choosing to place an implant if the patients have had previous medical treatments such as radiotherapy at the implant site or other factors (e.g. medical conditions) affecting bone and soft tissue quality.

Other considerations

Daily use

- Participation in contact sports is not advised as a severe impact may damage the implant and sound processor.
- Deep-sea diving below a depth of 20 meters is not advised.

MRI

- The Sentio Ti Implant is MR Conditional. The sound processor is MR Unsafe.
- If the patient needs to undergo MRI (Magnetic Resonance Imaging) the sound processor must be removed. The implant can remain in place.
- A patient with this device can be safely scanned in a MR system meeting the conditions stated in the MRI safety section in the Instructions for Use, available on www.oticonmedical.com/MRI-Sentio.

Active implants

- Patients already implanted with, or to be implanted with, programmable CSF shunts are contraindicated.
- Caution is required before placing active implants. In general, the guidelines recommended by manufacturers of already implanted active implants (e.g implantable defibrillators, pacemakers or neurostimulators) should be followed before placing a Sentio Ti Implant. Note that when the sound processor is mounted on the head, the distance between the Sentio sound processor and the active implant should be more than 15 cm.
- The guidelines recommended by manufacturers of implantable defibrillators and pacemakers regarding the 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 treatments

- Do not use monopolar electrocautery, electroconvulsive therapy (ECT) or transcranial magnetic stimulation (TMS) in the vicinity of the implant since these procedures can damage the tissue or the implant.
- A Sentio Ti Implant must not be exposed to therapeutic levels of ultrasound energy, as the implant can inadvertently concentrate the ultrasound field and cause harm.
- A Sentio Ti Implant must not be exposed to a total dose greater than 80Gy of therapeutic ionising radiation.
- The Sentio Ti Implant may remain in place during X-ray, CT/MR/PET scanning, electrotherapy, surgery, etc.

Intended use

The Sentio System (Sentio implant in combination with Sentio sound processor) is intended for the 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 users
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).

Indications 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 judgement.
- 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.

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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. 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

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