Candidacy Guide

Ponto™
– The Bone Anchored Hearing System

oticon MEDICAL

Contents

Introduction

This manual provides detailed information to the multidisciplinary hearing health care team on how to select patients who will benefit from the Ponto bone anchored hearing system. The Ponto System is a beneficial hearing solution designed to give patients improved hearing through direct bone conduction. It is indicated for use in several patient groups, including those with conductive or mixed hearing loss or single-sided deafness (SSD).

The Ponto System transmits sound to the cochlea independently of the function of the ear canal and middle ear. For individuals with conductive or mixed hearing loss, any conductive element of the hearing impairment is overcome. For individuals with SSD, the Ponto System works to transmit sound received on the impaired side directly to the working cochlea in the better ear.

The Ponto sound processors may be used on a head band or soft band by patients where the placement of a bone anchored implant is not suitable, or in the period before the surgery is performed.

When surgery is elected, an implant is inserted into the skull bone behind the ear via 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.

The Ponto sound processors convert sound into vibrations that are transmitted via the abutment and implant through the skull bone directly to the cochlea. For patients using the device prior to or instead of implant surgery, the vibrations are transmitted via the connector plate on a soft band or head band.

A range of Ponto sound processors are available, including regular, Power and SuperPower devices, both with and without wireless capabilities.*

**SuperPower is only available with wireless capabilities.*

Identifying patients for a bone anchored solution

The Ponto 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.

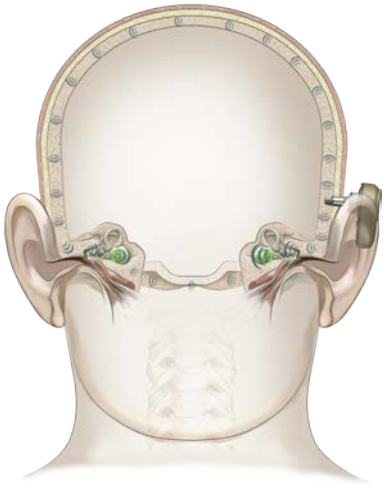
There are three main audiological indications:

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

There are also other medical indications that may identify an individual as a Ponto candidate, which are covered in this section on page 9.

Conductive or mixed hearing loss

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



The sound processor sends 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.

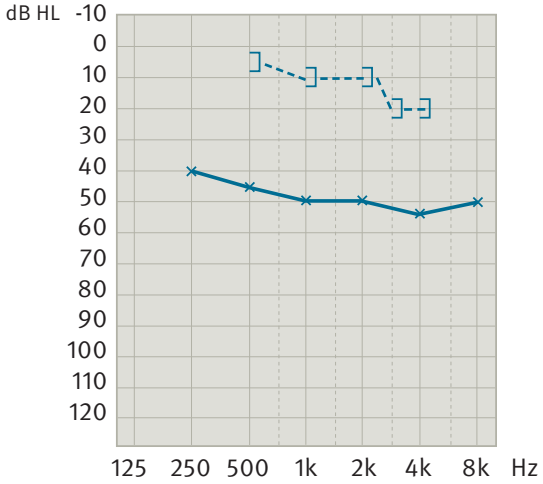
Size of air-bone gap

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 anchored 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 65 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 in a patient with mixed hearing loss. The most powerful Ponto sound processors can compensate for a sensorineural element of up to and including 65 dB HL.

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 ✓

Average BC threshold is always less than 65 dB HL in conductive hearing loss

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 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.

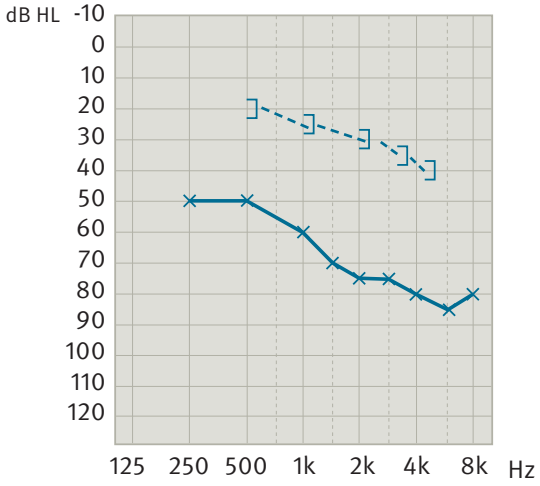
Advantages compared to middle ear surgery:

- The bone anchored sound processor can be evaluated by the patient and audiologist before surgery.
- The implantation involves a surgical procedure that is simple, reversible and does not expose the patient to any risk of additional hearing impairment.

Advantages compared to conventional bone conductors:

- Patient comfort is improved as there is no constant pressure against the skull.
- Sound quality is better as there is no attenuation of the signal passing through the skin.
- An implanted sound processor is more discreet.

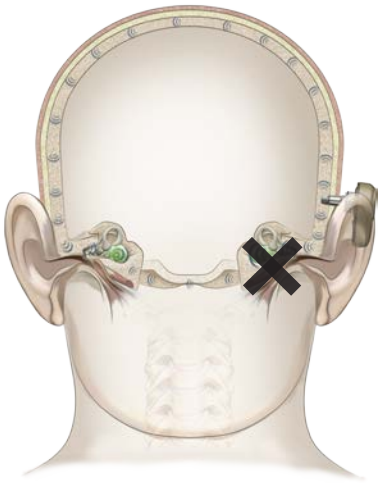
Example: Mixed hearing loss



Is 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 average BC threshold less than or equal to 65 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

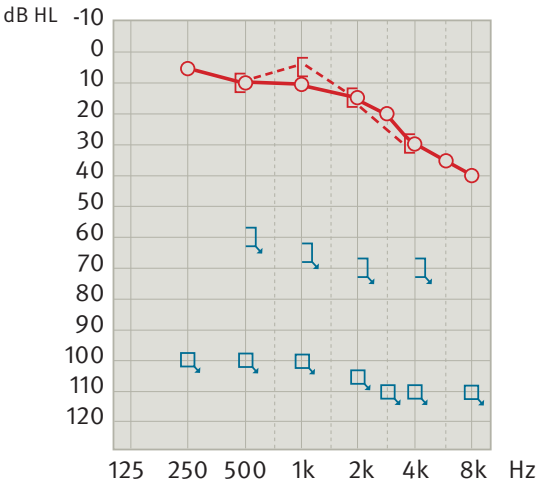


Patients who suffer from a profound sensorineural hearing loss in one ear with normal hearing in the opposite ear may be suitable candidates for a bone anchored hearing system. In this application the sound processor acts as a CROS (contralateral routing of signals) device. It is placed on the patient's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

Example: Single-sided deafness (SSD)



Is 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 ✓

Possible causes of single-sided deafness:

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

Treatment benefits

Single-sided deafness patients may benefit from a bone anchored 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.
- No cables are needed for transmitting sound to the hearing cochlea.
- Only one device is needed, rather than the two units needed for an AC CROS system.

Other indications

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

Skin allergies or external otitis

These conditions may be aggravated by the use of an ear mould, while using Ponto maintains an open ear.

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.


Morten Steen
Salling Olesen

Evaluating Ponto

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 Ponto can make for them.

An individual trial provides the patient with valuable information about the benefits Ponto can offer them. It is important that the audiologist encourages the patient to use the trial period in the most effective way. Using Ponto in as many different listening situations as possible will allow the patient to best evaluate improvement.

Appropriate patient counseling is also an important step towards success with Ponto. Throughout the evaluation 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.

Pre-operative trial

Patient candidates should be tested pre-operatively with the sound processor on a head band or soft band to evaluate the benefit. If possible, additional time at home should be afforded to the patient to evaluate the benefits of using the Ponto system.

For an SSD patient, it is recommended that the patient wears the sound processor on a soft band or head band in daily situations for at least a week, to ensure that the sound processor offers the expected benefits.

It is also recommended to fit the sound processor according to the patient's individual hearing loss for the pre-operative trial. Please see page 14 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 the sound processor for shorter periods, mainly inside the clinic or hospital.

Head band

The head band has a softer head spring than the test band, and can be used when testing the sound processor during longer periods. It is also appropriate for daily use by patients who are unsuitable for implantation but who can gain from using the sound processor as a traditional bone conductor.

Soft band

The soft band is a soft head band with a connection plate used when evaluating the sound processor during longer periods. It is also suitable for daily use with paediatric patients prior to surgical candidacy, or for individuals who are unsuitable for implantation. The soft band is available for either monaural or binaural fitting.

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 4 kHz), or less than 15 dB at individual frequencies.

If bone conduction thresholds are quite asymmetric, then a bilateral bone anchored hearing system will likely not confer 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]

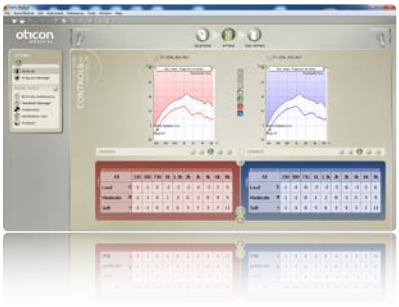
The soft band is available in two versions, for either monaural or binaural fitting.

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 the processor on each side to help the patient decide which side is the best for placement of the 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 connect/disconnect it from the abutment, as well as clean around the abutment. Patients who frequently talk on the phone might prefer to have their 'writing' hand free, and the implant on the opposite side of their writing hand. Patients who often drive a car with a passenger will typically want the implant on the side facing the passenger.

Testing the Ponto processor



The Genie Medical fitting software has a dedicated fitting mode for soft band/head band that automatically compensates for the attenuation of the signal through the skin. Because of attenuation, it may be beneficial to use a power processor in the pre-operative evaluation, even when the patient has only a mild cochlear hearing loss.

It is recommended that each patient be fitted individually using Genie Medical.

- Enter the patient's AC and BC hearing thresholds in the database.
- Connect the processor to Genie Medical.
- Select "Soft band" for demonstration purposes with all patients.
- Select "Single sided deafness" when applicable for SSD patients.
- Place the band on the candidate's head, placing the connection plate against the selected mastoid.
- Attach the sound processor to the band.
- To avoid feedback, make sure the processor doesn't touch the ear or skin.
- Run the Feedback Manager.
- If time allows, a BC in-situ measurement can be completed. This is an especially helpful aspect of programming for patients who will continue the trial outside of the clinic.

Note: It is important to inform the patient that the sound performance will be further improved once the sound processor is connected to the abutment, with no skin in between.

Please refer to the Audiological Manual for additional fitting information, as well as information about skull simulator measurements, which are useful for ensuring the sound processor works as intended in the pre-operative trial.

For additional information about trial set-up for children, please see page 20.

Sound processor and accessories selection

Provide the patient with information regarding sound processor features and accessories, as this may influence device selection.

A range of Ponto sound processors are available, including regular, Power and SuperPower devices, both with and without wireless capabilities.*

- The regular devices accommodate mixed hearing losses up to and including 45 dB HL BC
- The Power devices accommodate mixed hearing losses up to and including 55 dB HL BC
- The SuperPower device accommodates mixed hearing losses up to and including 65 dB HL BC

All sound processors can be individually fitted using Genie Medical software. Specific information about processors and related products can be found in the Product Information sheet. A complete overview of sound processors and accessories is available in the Product Catalogue.

**SuperPower is only available with wireless capabilities.*

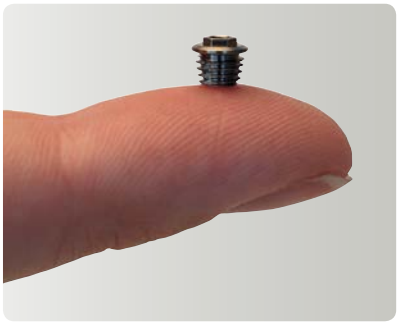
Counselling

When counseling the patient, it is important to understand their diagnostic background, as patients with different types of hearing loss require different styles of counselling to successfully manage their expectations. Please refer to pages 7 and 9 for treatment benefits, and consider the use of supplemental questionnaires to assist the patient in documenting their evaluation of Ponto.

Note that a patient may be a good candidate for a Ponto processor, but may be a poor surgical candidate for other reasons, necessitating the use of the processor on a soft band or head band.

Realistic patient expectations

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



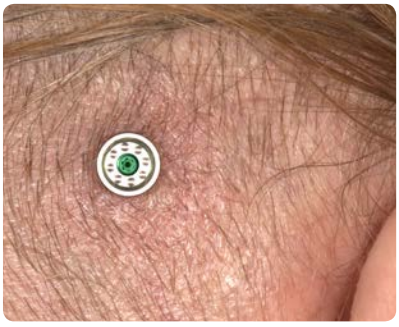
Allow the patient to see the actual size of the implant and abutment, understanding that only the small implant will be placed in the skull bone.

Express the importance of maintaining sufficient hygiene around the abutment and what the patient will be required to do to ensure this (for specific support, see the Patient Care Guide).

Provide an understanding of what the Ponto System may do for that individual patient. In most cases, a bone anchored sound processor leads to significantly improved sound quality, comfort, and speech intelligibility. In some patients, however, 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 Ponto

Once the patient has had an opportunity to try a Ponto processor 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 anchored system is a minor surgery, in which a small titanium implant will be placed behind the chosen ear. It is helpful to explain that the implant will be connected to an abutment, and it is the abutment that will protrude through the skin.

After the surgery, the patient will have a dressing placed over the abutment, which will be removed within 7-10 days after the surgery, and removed completely within two weeks. A period of osseointegration, where the implant becomes fixed in the bone, will be required before the processor can be fitted onto the abutment.

Surgical candidacy is based on several aspects, which are best discussed in detail with the physician performing the procedure. For more detailed information about healing time please refer to the Surgical Manual.

Cautions and contraindications for implantation

It is important to understand that there are patients who are not suited for or who are too young to receive an implant.

- Poor hygiene significantly increases the risk of adverse skin reactions. It is vital to be able to maintain proper hygiene around the abutment. Factors that affect this ability should be considered, as well as the possibilities of obtaining help to maintain sufficient hygiene, if necessary. In children the responsibility falls on the parents or caregiver. Inability to maintain, or lack of help with maintaining sufficient hygiene around the abutment, is a contraindication for use.

- Patients with insufficient bone depth and bone quality have an increased risk of implant failure and potential need for revision surgery. Disease, history of irradiation or other factors that may affect the bone quality should always be considered in the individual surgical planning and assessment of the patient, before choosing to place an implant.

- Children must have sufficient bone volume and bone quality before implant placement. Studies indicate that the child should have a skull bone at least 2.5 mm thick.[7, 8, 9] In the US, Canada, and Singapore, the placement of a bone anchored implant is contraindicated in children below the age of five.

- Any skin status or condition resulting in an expected reduced healing capacity or increased risk of skin reactions should always be considered.

Details on surgical considerations and possible complications may be found in the Surgical Manual.

Paediatrics

It is important to fit children as early as possible to provide the best opportunity for language development. Ponto sound processors can be used on a soft band until the child is able to receive an implant.

The audiological criteria for fitting children with a Ponto processor are the same as outlined in Audiological indications, pages 6-9.

Pre-operative trial

For children who are too young to have an implant, as well as for other patients who are not suited for implantation, the sound processor can be used long-term on a soft band or head band.

For paediatric patients, age-appropriate tests should be used when evaluating audibility and speech understanding during in-clinic trials.

For further information about programming the sound processor, please refer to the Audiological Manual.

It is important that the child's first experience with the soft band is positive.

- Turn on the sound processor, attach to the test rod, and listen to the device to ensure it is functioning.
- Put the soft band on the child's head, loosely at first, with the connection disc against the mastoid or some other bony part of the skull. Make sure that the whole disc is in contact with the skin. Avoid placing the disc against the temporal bone as this may be uncomfortable for the child.
- Tighten the soft band so that an effective sound transmission can be achieved, but loose enough so as not to cause any discomfort. You should be able to put a finger between the soft band and the child's skull.
- Attach the sound processor to the connection plate on the soft band.
- Ask the parent or caregiver to talk to the child. It is important that the first sound experience is positive. Observe how the child reacts to the sound.
- Use a safety line to avoid losing the sound processor during out-of-clinic trials.

Implantation in children

Using a Ponto sound processor on a soft band is a pre-operative hearing solution. The benefit provided will increase when the processor is connected to an implant. A child can be considered for the implant once their bone volume and quality is sufficient, which can vary from child to child. Please see page 17 of this manual for more detailed information.

Counselling

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

Test rod

A connection rod that can be pressed against the head is included with every processor. Parents and caregivers may find it useful to attach the processor to the test rod to check its function prior to placing it on the child. The hand must not touch the sound processor when holding the test rod.

References

References

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2. *De Wolf MJ, Hendrix S, Cremers CW Snik AF. Better performance with bone anchored hearing aid than acoustic devices in patients with severe air-bone gap. The Laryngoscope 2011;121:613-16.*

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4. *Wazen JJ, Spitzer JB, Ghossaini SN, Fayad JN, Niparko JK, et al. Transcranial contralateral cochlear stimulation in unilateral deafness.Otolaryngology-Head & Neck Surgery 2003;129(3):248-54.*

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6. *Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: A systematic review. Otolaryngology- Head & Neck Surgery 2012;147(3):412-22.*

7. *Tjellström A, Håkansson B, Granström G, Bone-anchored hearing aids: current status in adults and children. Otolaryngologic Clinics of North America 2001 Apr;34(2):337-64.*

8. *Davids T, Gordon KA, Clutton D, Papsin BC. Bone-anchored hearing aids in infants and children younger than 5 years. Archives of Otolaryngology-Head & Neck Surgery, 2007 Jan;133(1):51-5.*

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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** **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).

**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.

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 a member of one of the world's largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advances in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we 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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