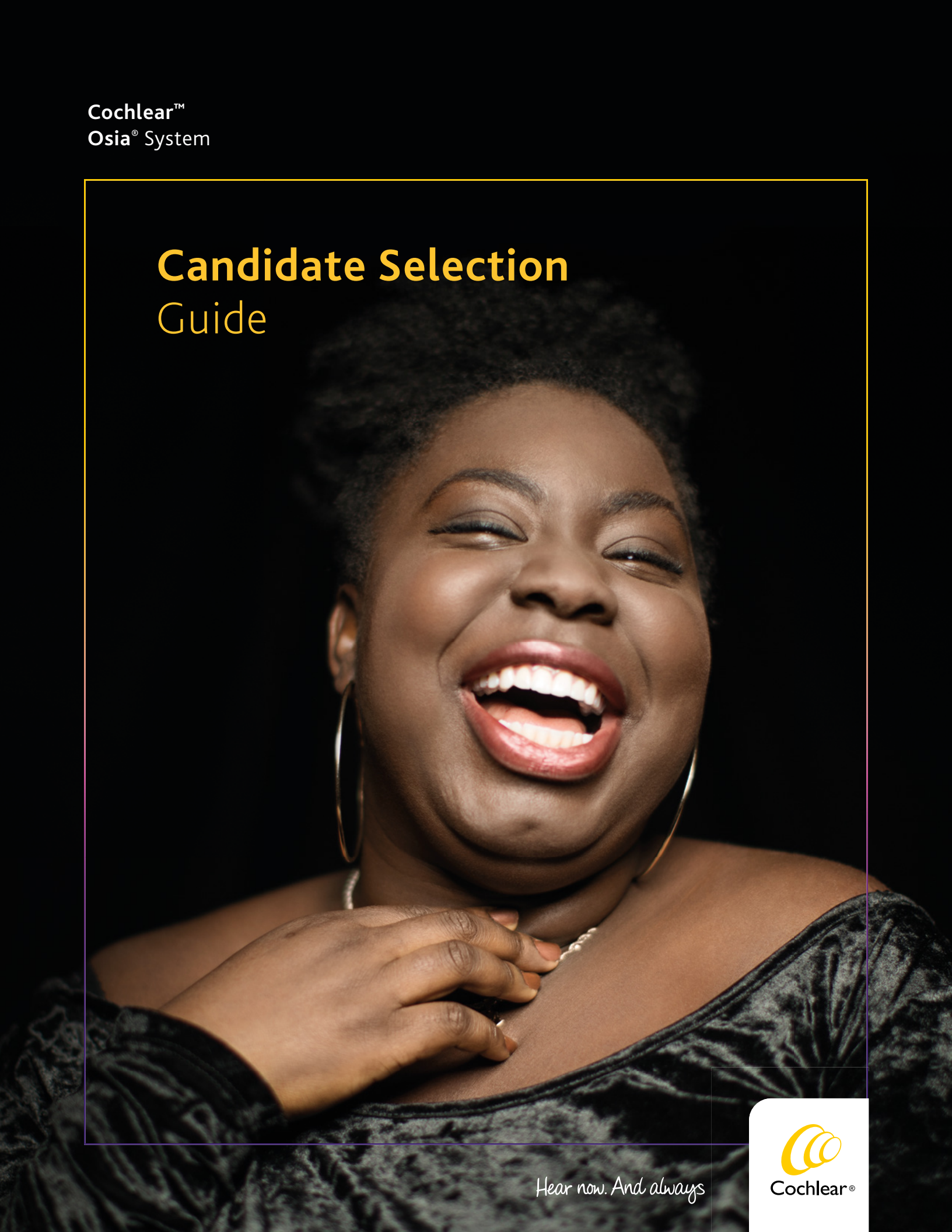
Cochlear™
Osia® System

Candidate Selection Guide



Hear now. And always

Cochlear®

Contents

Introduction 3

Ear Anatomy and Physiology 4

How the Osia® System works 4

Audiological Indications 6

Conductive hearing loss 6
Mixed hearing loss 6
Single-sided deafness (SSD) 8

Medical Indications 10

Acoustic neuroma. 10
Chronic otitis externa. 10
Chronic suppurative otitis media (COM) 10
Otosclerosis. 11
Previous ear surgery 11
Skin allergies 12
Sudden sensorineural hearing loss. 12
Syndromic hearing losses 12

Evaluating Patients. 14

Conductive/mixed hearing loss 14
SSD 14
Demonstrating bone conducted amplification 14
Evaluation of young patients 15

Counseling Patients 16

Counseling pathway. 16
Patients with a syndromic hearing loss. 18
Pediatric patients 18
Additional counseling and support 18

How-to Guide 20

Demonstration using the test rod 20
Evaluation using the Baha® Softband 20
Evaluation using the Baha® SoundArc 21

Introduction

Hearing loss is one of the world's most common disabilities, with millions of people struggling every day to hear and communicate.[1] Untreated, hearing loss is a key risk factor for isolation and overall health.[2-4] In some cases, reduced hearing sensitivity may cause limited access to education or make it increasingly difficult to perform in the workplace.[5,6]

Air conduction (AC) hearing aids can be a solution for conductive hearing loss, mixed hearing loss and single-sided deafness (SSD), but some people don't want to, or can't wear them. In addition, wearing hearing aids can cause side effects or complications such as increasing the risk for ear infections[7] that may negate their effectiveness. For many of these patients, bone conduction (BC) stimulation may be a better solution.

The goal of the Cochlear™ Osia® System is to effectively treat the hearing loss of patients with conductive hearing loss, mixed hearing loss and SSD and it's like no other hearing implant system. It's the world's first osseointegrated steady-state implant (OSI) that uses digital piezoelectric stimulation to bypass damaged areas of the natural hearing system and send sound directly to the cochlea.

When appropriate, an Osia System should be considered as a first step in rehabilitation of hearing impairment. Systems that use bone conduction have been shown to have several benefits when compared with AC hearing aids or middle ear reconstructive surgery. They can relieve the frustration related to hearing aid wear, increase user motivation and receptivity to habilitation, and provide the necessary amplification to overcome the patient's hearing loss.[8]

This guide introduces the physiology of BC hearing and the Osia System. It will teach you how to identify, evaluate and counsel candidates for an Osia System.

Ear Anatomy and Physiology

In an ear without conductive barriers, sound waves collected by the pinna travel unimpeded through the ear canal, the middle ear and on to the cochlea.

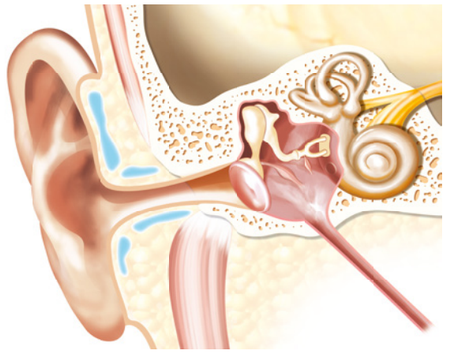


Fig. 1: Healthy ear

If there are deformities or other barriers in the outer or middle ear, sound waves need to overcome these obstructions to be perceived. With this type of hearing loss, ears may feel plugged and speech may sound muffled, especially if there is a lot of background noise.

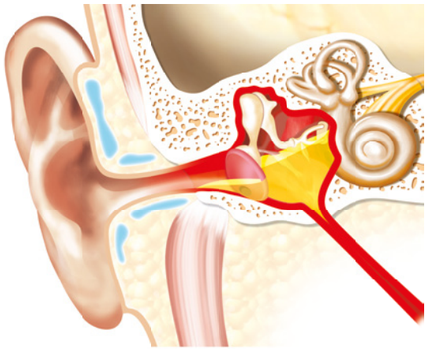


Fig. 2: Middle ear with obstructive fluid

Routing sound through an individual's bone, rather than trying to push it through the ear canal and middle ear, stimulates the cochlea and bypasses any barriers in the air conduction pathway.

How the Osia System works

The Osia System uses digital piezoelectric stimulation to bypass barriers in the outer and middle ear. For individuals with single-sided deafness (SSD), the system transfers the sound from the deaf side to the hearing ear.

There are three core components to the system: a sound processor, an active implant and a small titanium implant that bonds to the bone in a process known as osseointegration.

1. The sound processor captures sound in the air and digitally analyzes the signal.
2. The processed signal and power are sent through a digital link to the active implant.
3. The Piezo Power™ transducer vibrates, sending vibrations through the implant to the bone.
4. The vibrations travel to the inner ear where they are converted into electrical impulses and sent to the brain to be interpreted as sound.

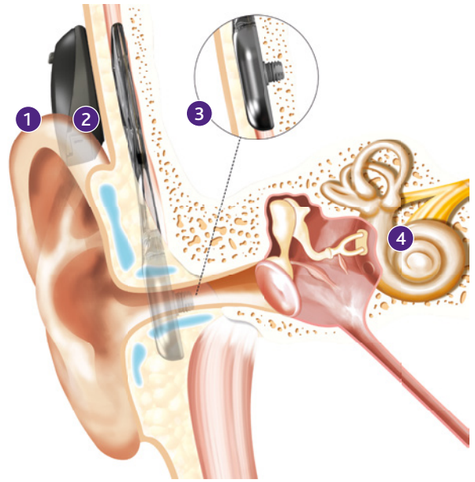


Fig. 3: Ear with an Osia System

Counseling considerations: When working to motivate patients, giving them basic knowledge of their own condition and possible solutions can make rehabilitation more successful.[9]

Audiological Indications

Audiological evaluation is the basis for determining Osia System candidacy. Candidates for the Osia System fall into three main categories: conductive hearing loss, mixed hearing loss, and SSD. To ensure success, candidates should be counseled on the advantages of the Osia System, the necessary follow-up and rehabilitation.

Conductive hearing loss

The audiometric air-bone gap (ABG) is a strong indicator of candidacy for an Osia System. The greater the ABG, the greater the benefit of a bone conduction implant as compared to an AC hearing aid.[10]

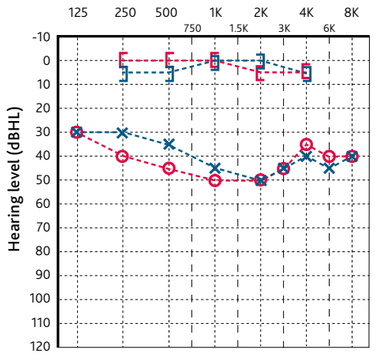


Fig. 4: Audiogram indicates a pure conductive hearing loss with AC thresholds of 45 dB PTA4 and BC thresholds of 3 dB PTA4 bilaterally. A patient with symmetrical, conductive hearing loss is a very good audiological candidate for a bilateral Osia System.

Chronic conductive hearing loss can be caused by:

- Chronic Otitis Media (COM)
- Eustachian tube dysfunction
- Otosclerosis
- A benign tumor or cholesteatoma, causing damage to the middle ear
- Microtia
- Atresia

Selection criteria for conductive hearing loss

Clinical data indicates that patients with an air-bone gap of more than 30 dB (PTA4) will experience significant advantages from a bone conduction system as compared to using an AC hearing aid.[10]

Mixed hearing loss

A mixed hearing loss is a combination of conductive and sensorineural hearing loss (SNHL). Mixed hearing loss can be difficult to fit with AC hearing aids because of the 1:1 compensation needed to overcome the conductive hearing loss, plus around 50% compensation for the sensorineural hearing loss. As the Osia System bypasses the air conduction pathway, gain is provided to the sensorineural component only, thereby reducing the overall gain required for individuals with mixed hearing loss.

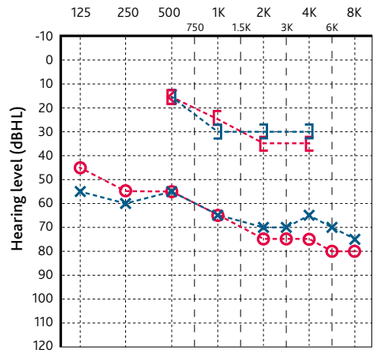


Fig. 5: Audiogram indicates a symmetrical mixed hearing loss, with AC threshold of 68 dB PTA4 and BC threshold of 28 dB PTA4 on the right side, and AC thresholds of 64 dB PTA4 and BC threshold of 27 dB PTA4 on the left side. A patient with symmetrical, mixed hearing loss (up to 55 dB SNHL) is a very good audiological candidate for a bilateral Osia System.

Selection criteria for mixed hearing loss

Just like in conductive hearing loss the air-bone gap is a good indication of candidacy as long as the SNHL is not outside the 55 dB fitting range.

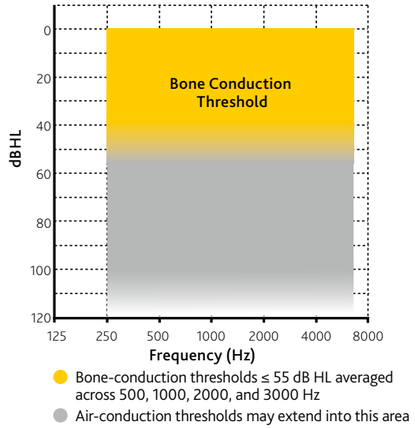


Fig. 6: Osia System fitting range

Indications for bilateral fitting

To achieve binaural hearing, BC thresholds should be symmetrical, within a 10 dB difference on average (PTA4), or up to 15 dB difference at individual frequencies. AC thresholds are not considered.

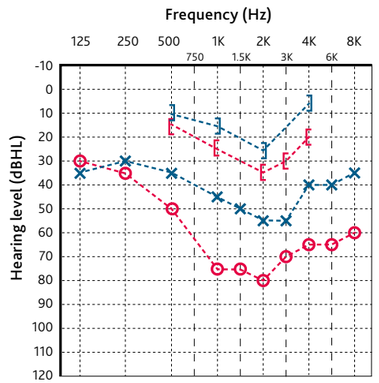


Fig. 7: Audiogram shows a bilateral mixed conductive hearing loss with AC threshold right side of 68 dB PTA4 BC thresholds 24 dB PTA4 and left AC threshold of 44 dB PTA4 and BC threshold of 14 dB PTA4, indicating BC asymmetry of no more than 10 dB PTA4. A patient with this type of asymmetrical mixed hearing loss is a very good audiological candidate for an Osia System.

Single-sided deafness (SSD)

For patients with SSD, the sound processor is placed on the affected side and transfers the sounds to the normal hearing cochlea, overcoming the head shadow effect. Providing speech from the affected side to the normal hearing cochlea gives improved speech understanding and 360° sound awareness.[11,12]

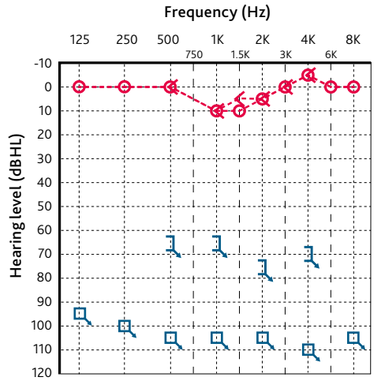


Fig. 8: Audiogram indicates normal hearing in the right ear, and a profound sensorineural hearing loss in the left ear indicating SSD. A patient with SSD (with BC thresholds in the opposite ear no poorer than 20 dB SNHL) is a very good audiological candidate for an Osia System.

SSD can be caused by:

- Genetic factors
- Sudden sensorineural hearing loss
- Acoustic neuroma
- Noise exposure
- Head injury or trauma
- Virus, infection or disease
- Ototoxic medications
- Autoimmune inner ear disease

Selection criteria for SSD

To benefit from the Osia System, hearing in the opposite ear should be normal, with thresholds no poorer than 20 dB SNHL.

It is important to ensure that patients have a realistic expectation regarding the benefits of the Osia System and that they are highly motivated.

Counseling considerations: Some patients may continue for years without appropriate hearing rehabilitation or considering alternatives to AC hearing aids. Considering hearing history and using questionnaires in addition to their audiogram can suggest that alternative solutions, such as an Osia System, may provide better outcomes for the individual.

Medical Indications

Acoustic neuroma

Acoustic neuroma, also known as vestibular schwannoma, is a non-cancerous growth that develops on the acoustic or vestibular nerve and may cause problems with hearing, balance and sound localization. If surgical removal of the tumor is required, the hearing nerve may be damaged or even destroyed preventing normal hearing. Studies on BC systems in individuals with SSD after acoustic neuroma removal indicate improved speech understanding and demonstrate high levels of patient satisfaction.[13,14]

Chronic otitis externa

Chronic otitis externa is a diffuse infection of the outer ear and/or ear canal, sometimes causing difficulties with swelling and pain. Wearing an AC hearing aid has been shown to exacerbate the problem because bacteria on the ear mold or dome is re-introduced with each insertion.[7] With an Osia System, the ear canal is unobstructed, allowing the ear to respond to treatment and avoiding new infections.[15]

Chronic suppurative otitis media (COM)

Acute otitis media affects around 75% of children*, but spontaneously resolves in the vast majority (80%) of cases.[16,17] Antibiotics are used in persistent cases, but these are not always effective and in these cases the disease may progress to Chronic Otitis Media (COM).[18] COM may cause irreversible changes to the structure of the middle ear, including bony pathological changes and changes in the tissue structure.[19] The disease can lead to ossicular stiffening, fusion or even destruction causing a hearing loss.[20] Surgical interventions may be attempted to remove the infection and restore normal hearing, but a persistent conductive or mixed hearing loss frequently remain.[20] The Osia System may provide a good solution to address the hearing loss earlier in the treatment process for these patients having to place anything in or on the ear, which may exacerbate infections.[7]

Much like in cases of otitis externa, AC hearing aid use may exacerbate COM because the ear canal is occluded and the ear mold or dome in use may contain bacteria.[7] Using an Osia System allows the ear canal to remain open and dry, reducing the number of recurring medical visits for treatment of COM.[15]

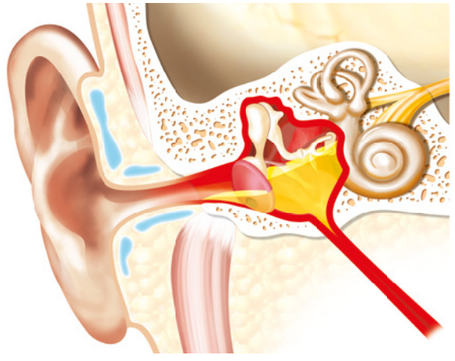


Fig. 9: Image shows COM in an ear. There is a perforation in the eardrum causing the inflammatory fluid to leak out into the ear canal. The inner ear is normally not affected by the inflammation.

* In the United States the Osia 2 System is contraindicated in children below the age of 12.

Ear canal stenosis

A stenotic ear is an abnormally narrow canal leading from the outer ear to the middle ear, making the use of AC hearing aids with ear molds or domes difficult or impossible. In these cases, an Osia System may be recommended to bypass the non-functioning ear canal for improved hearing performance.

Microtia and atresia

A common cause of conductive or mixed hearing loss in children is atresia, where there is an absence or closure of the external auditory canal. Children with bilateral atresia are known to be at risk for speech and language delays and poor educational outcome.[21] Children with unilateral atresia also show reduced educational outcomes and require additional support in school.[21] Early amplification through a non-surgical BC system helps children gain better access to hearing to avoid delayed speech development, both in bilateral and unilateral cases.[21] An individual's decision to implant the Osia System at a later date can be made in conjunction with the physician and hearing professional.

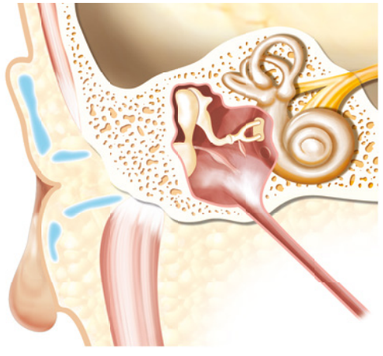


Fig. 10: Image shows atresia in an ear. The inner ear is normally not affected by the malformation, giving the patient very good hearing opportunities with an Osia System.

Otosclerosis

Otosclerosis is a form of bone overgrowth in the middle ear restricting the movement of the ossicles. This may lead to conductive hearing losses. In cases where stapedectomy/stapedotomy is contraindicated or has not been successful, an Osia System can provide a good solution.[22]

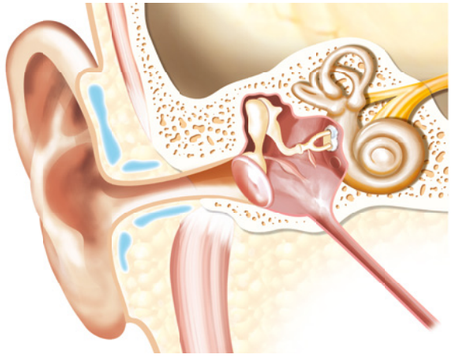


Fig. 11: Image shows an ear in the early stages of Otosclerosis, with overgrowth of bone on the stapes plate.

Previous ear surgery

Patients who have undergone a failed tympanoplasty or ossiculoplasty with poor hearing outcomes may be excellent candidates for an Osia System as it will provide reliable hearing outcomes in patients with conductive hearing losses.

Patients with a canal wall down procedure, may find it difficult to wear an ear mold without feedback problems. The Osia System is a viable alternative since an ear mold is not required. Hence, it also removes the reoccurring need to take an ear mold impression, which risks impression material impaction.

Skin allergies

Allergies in the outer ear or ear canal may be aggravated by the placement of an AC hearing aid.[23] In contrast, an Osia System maintains an open ear canal.

Sudden sensorineural hearing loss

In patients with profound unilateral sudden hearing loss, an Osia System may improve speech understanding.[22] Studies on patients with other bone conduction systems have demonstrated high levels of patient satisfaction.[13,22]

Syndromic hearing losses

Individuals with syndromes such as Down, Goldenhar and Treacher Collins often have a higher prevalence of conductive hearing loss and may experience benefit from an Osia System.[24,25] Use of implantable hearing systems might require special considerations and counseling. Please see the chapter *"Counseling Patients" (starting on page 16)* for more information.

Counseling considerations: While treatment of the underlying medical issues are critical, the failure to address hearing loss and its impact on the individual comes at a cost to the patient and society as a whole.[26] The patient should be informed early in the process about the possibility to treat their hearing loss with an Osia System.

Evaluating Patients

Candidacy evaluation for an Osia System must be based on audiological testing. However, it's also important to let the candidate listen to how bone conducted amplification works when considering an Osia Implant.

Conductive/mixed hearing loss

Audiological evaluation

Use the patient's air-bone gap as a guide to predict the expected benefits from an Osia System. You may read more about the audiological indications in the chapter "*Audiological Indications" (starting on page 6)*.

Basis for audiological evaluation

It is recommended to perform AC and BC pure tone audiometry at 500, 1000, 2000, and 3000 Hz. Together with speech perception testing as appropriate, you will get a good basis for your evaluation.

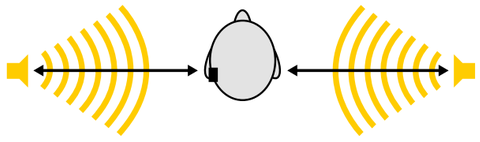
Bilateral fitting

Bilateral fittings improve speech understanding, sound localization and overall patient satisfaction.[27] Optimal bilateral benefits are achieved when the bone conduction thresholds are symmetrical, with an average difference of less than 10 dB (PTA4) or less than 15 dB at individual frequencies.

SSD

Audiological evaluation

For SSD, the main benefits of the Osia System will be a reduction in the head shadow effect and improved hearing in noisy situations. In SSD cases, motivation might increase if patients are able to compare their aided and unaided hearing to assess potential benefit. A setup for such an evaluation is illustrated below.



Demonstrating bone conducted amplification

Using a Baha® 5 Power Sound Processor on a test rod, Baha SoundArc or Softband, the patient can experience bone conduction and begin to understand the possible benefits of an Osia System.

For a more realistic experience, allow the patient to test a sound processor in different sound environments, for example by taking a walk around the hospital/clinic or during a home trial. A description on how to fit the sound processor on a Softband or a SoundArc may be found in the chapter *"How-to Guide" (starting on page 20)*.

Evaluation of young patients

Hearing is very important for the development of speech understanding, providing the ability to receive and process information. To enable early habilitation and reduce the risk of further delaying speech and language development it is important to get started with bone conduction amplification early when indications exist.

The Osia System can provide significant benefit for children and young adults that meet the audiological criteria.

Early amplification is important

Early access to sound amplification is crucial for a child's speech, language and educational development. Yoshinaga-Itano et al. (1998) reports that children who begin hearing habilitation before the age of six months perform significantly better in language tests at the age of three to four years than children who begin hearing habilitation at a later age. The study concluded that delay in intervention may lead to a permanent language deficit.[28] As a first step we recommend fitting infants with the Baha Softband. For older children who are still too young or not medically ready for implantation, fitting with the Baha SoundArc may be more appropriate. This can immediately improve the child's hearing and is a very good introduction to the benefits of the Osia System, both for the child and their parents or caregivers. A decision on implantation can be discussed at a later stage. Patients should have sufficient bone quality and quantity to support successful implant placement and the surgeon should fully evaluate the child prior to any decision, following the Osia Surgical Guidelines.

Recommended time for implantation*

Implantation is appropriate when the child has developed sufficient bone thickness and bone quality, which can vary from child to child. For children where such conditions are not met, it is recommended to use the Baha System on a Softband/SoundArc until the appropriate bone and skin thickness is developed and the child can be considered for an Osia System. Instructions on how to fit a Baha on a Softband/SoundArc can be found in the *"How-to Guide" (starting on page 20)*.

Additional considerations

Clinical research suggests that children with binaural conductive hearing loss should be fitted bilaterally, preferably before the age of six months.[27] If bilateral fitting is contraindicated, fit the side with the best bone conduction thresholds.

Counseling considerations: Sharing a patient's test result with them may give them more confidence, increase their awareness about their own situation and provide a better base to make conscious decisions on how to proceed in their hearing journey.

* In the United States the Osia 2 System is contraindicated in children below the age of 12.

Counseling Patients

Your patients are the experts in their own personal hearing situation. Discussing their wishes, their thoughts and how they understand their hearing will help you obtain greater insight into their expectations from an implantable system. Doing so will help them make the right choice and lead to an increase in patient satisfaction.

Counseling pathway

Through information and discussion, help the patient to explore both the audiological and medical benefits of the Osia System related to their particular situation. Be sure to provide your patient with knowledge about their medical and audiological indications, the Osia System, the path to implantation and post-surgical considerations. Using Cochlear provided counseling tools you can explain how the implant can provide a more efficient hearing pathway in comparison to other hearing systems such as AC hearing aids. Discuss the Wireless Accessories, Apps and Made for iPhone* options and how these may be an effective complement when using the Osia System. Together with the patient you can use demonstration equipment, the Cochlear website and brochures to explore the Osia System and guide the patient through the process of candidacy evaluation as well as life as an Osia System recipient.

Expectations

Ensure the patient and/or caregiver have realistic expectations of hearing rehabilitation. Pre-operative testing can be beneficial in cases where the patient is uncertain how to proceed. An in-clinic test or a longer trial using a Baha 5 Power Sound Processor on a test rod or Baha Softband/SoundArc might give the patient more confidence in making an informed choice.

A well-informed patient will use their knowledge and experience in their decision making and improve their treatment outcomes.[29]

Post-operative care

With the Osia System the post-operative care is limited to changing the dressing, if needed, while the surgical site is healing.

* For compatibility information visit www.Cochlear.com/Compatibility.

COCHLEAR™ OSIA® SYSTEM

MRI

The Osia 2 System OSI200 Implant is MR Conditional with the implant magnet removed at 1.5T and 3.0T. For more information, please refer to the Osia System MRI guidelines.

Aesthetic and practical solution

The Osia System provides a discreet solution which demands no after care once the surgical site has healed. It is compatible with wireless accessories to provide connectivity and enhance hearing in more challenging listening situations. Specially designed accessories are available for the sound processor that allow the user to live an active lifestyle with the system.

Cost, reimbursement and funding

Reimbursement of the cost of the Osia System is an important topic and this should be discussed during the pre-operative counseling. Terms and conditions for reimbursement and funding vary. For information about the terms and conditions applicable in your area, please consult your local Cochlear representative.

Patients with SSD

SSD patients may have specific expectations due to their type of hearing loss, it is particularly important to ensure that the expectations are realistic. The audiologist or physician can help individuals understand their perceived difficulties and, more importantly, increase their motivation for better hearing. After fitting, the Osia System will lift the head shadow effect improving hearing sounds coming to the deaf side as well as improved hearing in noise,[22] however; restoration of directional hearing should not be expected as all sounds will be processed by the remaining functioning cochlea.

Patients with a syndromic hearing loss

A personal counseling plan which takes into account the type of syndrome, the severity of the condition and the individual's general abilities is recommended. For some patients with syndromes, parents or caregivers will play an active role in the maintenance and handling of the system and will need to be involved early in the counseling process.

Pediatric patients*

Although the pediatric candidate is the main priority, counseling should target the entire family. Parents may have concerns regarding the developmental impact of hearing loss and should be provided with counseling and guidance about how to help their child achieve the best possible results, especially in speech and language development. They will want to know why an Osia System is the best solution for their child. A home trial period using a Baha 5 Power Sound Processor on a Softband is recommended and parents should be counseled to use a home trial log to follow the child's behavior and development during the trial.

Additional counseling and support

Often, a meeting with a current Osia System user, preferably of a similar age, hearing loss/syndrome or life situation, can give additional support to patients who still have concerns or questions about what to expect.

Counseling pathway

Hearing Education	Treatment	Product	After Surgery
• How hearing works • Type of hearing loss • Effects of hearing loss • Benefits from the Osia System • Hearing expectation • Trial with Softband or SoundArc	• Surgical procedure • Risks involved • Reversible procedure • No risk of losing hearing • Satisfaction rate • Clinical evidence • Wound care	• Product features and benefits • How it looks on the patient • Wireless options • Service • Costs involved	• Fitting • Rehabilitation • Care of implant site • Lifestyle considerations • MRI considerations • Accessories

Counseling considerations: Once a patient has been counseled on the Osia System, they should be well informed about the following:

- The need for a referral to a surgeon for further evaluation and to determine candidacy.
- The risks of surgery and how the surgery is reversible.
- The implant location, cosmetics, and sound processor placement.
- The four weeks post-operative fitting guideline, to allow the site to heal.
- The fitting expectations and basic sound processor use.

More detailed information about the surgical procedure should be provided by the surgeon.

* In the United States the Osia 2 System is contraindicated in children below the age of 12.

How-to Guide

Demonstration using the Test Rod

The Test Rod is a simple device for quick demonstrations. Attach the Baha 5 Power Sound Processor on the Test Rod using the out of box settings, insert the battery and turn it on. Test that the sound processor works by first putting the Test Rod to own mastoid, blocking your ear canals and introducing sound. Not touching the actual sound processor, let the patient press the Test Rod to the forehead and listen.

Fig. 12: Demonstrating bone conducted amplification

Evaluation using the Baha Softband

A comfortable and effective solution to be used for patient evaluation:

1. Attach a Baha SoftWear™ Pad to the Connector disc of the Softband. Allow five minutes for the pad to achieve the ideal shape.
2. Put the Softband around the patient's head, quite loosely at first. It may be helpful to let the patient get familiar with the Softband before putting in on their head.
3. Place the Connector disc against the mastoid or another bony location on the skull. Avoid placing it on the temple, as this may be uncomfortable. Make sure the entire pad is in contact with the skull.
4. Tighten the Softband until it is close-fitting, enough to ensure effective sound transmission, while also loose enough so as not to cause discomfort. Make sure you can fit one finger between the head and the Softband—this will ensure it is not too tight.
5. Using the Baha Fitting Software you now program the sound processor to fit the patient's hearing loss. Optimize the sound processor fitting by selecting suitable parameters in the BC Select screen. Whenever possible, conduct BC Direct and make sure you conduct a Feedback Analyzer measurement once the Softband has been positioned correctly.
6. Be sure to talk to the patient to help the patient familiarize themselves with the hearing experience.

NOTE:
Once the Softband is tight enough to transmit sound effectively, additional tightening will only marginally increase the sound and so is not advised.

Evaluation using the Baha SoundArc

A comfortable, effective and stylish device for children, too young or not ready for an implant. An excellent option for patient evaluation.

1. Before fitting, slide the Connector disc on to the back end of the soft tip. Attach a Baha SoftWear Pad to the connector disc of the SoundArc. Allow five minutes for the SoftWear Pad to achieve the ideal shape.
2. Place the SoundArc just above the ears and following the contour of the head. Fit the SoundArc with any accessories (glasses, hats or other headworn accessory) in place, so that they can be removed without affecting the position of the SoundArc.
3. Ensure that the entire area of the Connector disc sits flush against the skin on the head above and behind the ear; it should not wobble. You may have to adjust the shape of the SoundArc to achieve this. It may be necessary to move or part the hair to ensure that the Connector disc is in contact with the skin. The Connector disc should not be placed too close to the ear as this may increase the risk of feedback.
4. Program the sound processor to the patient's hearing loss using the Baha Fitting Software. Optimize the sound processor fitting by selecting suitable parameters in the BC Select screen. Whenever possible, conduct BC Direct and Feedback Analyzer measurements once the SoundArc has been positioned correctly.

The entire soft tip should rest slightly in front of the ear and feel comfortable on both sides. Be sure to talk to the patient to help the patient become familiar with the hearing experience.

NOTE:
Always check that the sound processor is working by testing it on your own head prior to attaching the accessory to the patient's head.

COCHLEAR™ OSIA® SYSTEM

References

1. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet (London, England). 2017;390(10100):1211-1259.
2. Mick P, Kawachi I, Lin FR. The association between hearing loss and social isolation in older adults. Otolaryngol Head Neck Surg. 2014;150(3):378-384.
3. Theunissen SC, Rieffe C, Kouwenberg M, Soede W, Briaire JJ, Frijns JH. Depression in hearing-impaired children. International journal of pediatric otorhinolaryngology. 2011;75(10):1313-1317.
4. Wei J, Hu Y, Zhang L, et al. Hearing Impairment, Mild Cognitive Impairment, and Dementia: A Meta-Analysis of Cohort Studies. Dementia and Geriatric Cognitive Disorders Extra. 2017;7(3):440-452.
5. Khairi Md Daud M, Noor RM, Rahman NA, Sidek DS, Mohamad A. The effect of mild hearing loss on academic performance in primary school children. International journal of pediatric otorhinolaryngology. 2010;74(1):67-70.
6. Punch R. Employment and Adults Who Are Deaf or Hard of Hearing: Current Status and Experiences of Barriers, Accommodations, and Stress in the Workplace. Am Ann Deaf. 2016;161(3):384-397.
7. Orji FT, E OO, Agbo CE. The clinical implications of ear canal debris in hearing aid users. Pak J Med Sci. 2014;30(3):483-487.
8. Banga R, Lawrence R, Reid A, McDermott AL. Bone-anchored hearing aids versus conventional hearing aids. Advances in oto-rhino-laryngology. 2011;71:132-139.
9. Hawkins DB. Effectiveness of counseling-based adult group aural rehabilitation programs: a systematic review of the evidence. Journal of the American Academy of Audiology. 2005;16(7):485-493.
10. 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(3):613-616.
11. Kim G, Ju HM, Lee SH, Kim HS, Kwon JA, Seo YJ. Efficacy of Bone-Anchored Hearing Aids in Single-Sided Deafness: A Systematic Review. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology. 2017;38(4):473-483.
12. Gawliczek T, Wimmer W, Munzinger F, Caversaccio M, Kompis M. Speech Understanding and Sound Localization with a New Nonimplantable Wearing Option for Baha. BioMed Research International. 2018;2018:8.
13. Andersen HT, Schroder SA, Bonding P. Unilateral deafness after acoustic neuroma surgery: subjective hearing handicap and the effect of the bone-anchored hearing aid. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology. 2006;27(6):809-814.
14. Schroder SA, Ravn T, Bonding P. BAHA in single-sided deafness: patient compliance and subjective benefit. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology. 2010;31(3):404-408.
15. Macnamara M, Phillips D, Proops DW. The bone anchored hearing aid (BAHA) in chronic suppurative otitis media (CSOM). The Journal of laryngology and otology Supplement. 1996;21:38-40.
16. Klein JO. Otitis media. Clin Infect Dis. 1994;19(5):823-833.
17. Worrall G. Acute otitis media. Can Fam Physician. 2007;53(12):2147-2148.
18. Rosenfeld RM, Vertrees JE, Carr J, et al. Clinical efficacy of antimicrobial drugs for acute otitis media: metaanalysis of 5400 children from thirty-three randomized trials. J Pediatr. 1994;124(3):355-367.
19. Bhutta MF, Thornton RB, Kirkham L-AS, Kerschner JE, Cheeseman MT. Understanding the aetiology and resolution of chronic otitis media from animal and human studies. Dis Model Mech. 2017;10(11):1289-1300.
20. Horvath T, Lukacs D, Horvath B, Ferenci T, Liktor B. Does The Type of Ossicular Chain Lesion Affect Outcomes in Chronic Suppurative Otitis Media Without Cholesteatoma? The journal of international advanced otology. 2019;15(1):28-33.
21. Lo JFW, Tsang WSS, Yu JYK, Ho OYM, Ku PKM, Tong MCF. Contemporary hearing rehabilitation options in patients with aural atresia. BioMed research international. 2014;2014:761579-761579.
22. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US); 2017March 22. Identifier NCT03086135. Clinical Performance of a New Implant System for Bone Conduction Hearing; 2019 January 31 [cited 2019 July 1]; [4 screens]. Available from: https://clinicaltrials.gov/ct2/show/NCT03086135.
23. Di Berardino F, Pigatto PD, Ambrosetti U, Cesarani A. Allergic contact dermatitis to hearing aids: literature and case reports. Contact Dermatitis. 2009;60(5):291-293.
24. McDermott AL, Williams J, Kuo MJ, Reid AP, Proops DW. The role of bone anchored hearing aids in children with Down syndrome. International journal of pediatric otorhinolaryngology. 2008;72(6):751-757.
25. Lo JFW, Tsang WSS, Yu JYK, Ho OYM, Ku PKM, Tong MCF. Contemporary Hearing Rehabilitation Options in Patients with Aural Atresia. BioMed Research International. 2014;2014:8.
26. Olusanya BO, Neumann KJ, Saunders JE. The global burden of disabling hearing impairment: a call to action. Bulletin of the World Health Organization. 2014;92(5):367-373.
27. Janssen RM, Hong P, Chadha NK. Bilateral bone-anchored hearing aids for bilateral permanent conductive hearing loss: a systematic review. Otolaryngol Head Neck Surg. 2012;147(3):412-422.
28. Yoshinaga-Itano C, Sedey AL, Coulter DK, Mehl AL. Language of early- and later-identified children with hearing loss. Pediatrics. 1998;102(5):1161-1171.
29. Meibos A, Muñoz K, Schultz J, et al. Counseling users of hearing technology: a comprehensive literature review. International journal of audiology. 2017;56(12):903-908.

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 550,000 implantable devices, helping people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to innovative future technologies. We have the industry's best clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

www.Cochlear.com/US Follow us on

Cochlear Americas
13059 East Peakview Avenue
Centennial, CO 80111 USA
Telephone: 1 303 790 9010
Support: 1 800 483 3123

New Address Effective April 1, 2020
10350 Park Meadows Drive
Lone Tree, CO 80124 USA
Telephone: 1 303 790 9010
Support: 1 800 483 3123

Cochlear Canada Inc.
2500-120 Adelaide Street West
Toronto, ON M5H 1T1 Canada
Support: 1 800 483 3123

OSI007 ISS1 DEC19

Cochlear®