



Blending hearing technology with human capacity

Millions of people live with hearing loss around the world, struggling daily to pick up on the sounds around them and communicate with their friends, family and co-workers.¹ Although treatments for hearing loss all have the same goal, their approach and success rates vary.

Reconstructive surgeries to treat the underlying condition can be a good option for people with Chronic Otitis Media (COM), Atresia/Microtia and Otosclerosis. However, with COM for example, clinical evidence shows that while many surgeries are successful, in 30% of cases there remains hearing loss that requires further treatment² and repeat surgeries are common.³

Hearings aids can also be a solution, 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^{4,5} that may negate their effectiveness.

The goal of the Cochlear[™] Osia[®]
System is to effectively treat the hearing loss of patients with conductive hearing loss, mixed hearing loss and single-sided sensorineural deafness (SSD). It is designed to help people live their lives and provide the performance needed to hear in noisy situations where they tell us they struggle most.

The system utilises innovative technologies specifically chosen and designed to work in and with the body.⁶ We call this approach Human Design™, and the result is the new Osia System.

Human Design™



Digital link

A hearing implant reimagined

The Cochlear Osia System is 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. The system builds off our innovation heritage to provide you with a new option to treat patients with conductive hearing loss, mixed hearing loss and SSD.

It's not the sound that's changed, it's how you hear it

The Cochlear Osia System includes an active implant that sits fully under the skin. With this in mind, we innovated and made technology choices specifically suited for this type of application.⁶

The Piezo Power difference

At the heart of the Osia implant lies our Piezo Power™ transducer that uses piezoelectric material to generate vibrations that are sent to the bone.

The piezoelectric effect is the ability of certain materials to generate an electrical charge from mechanical stress, or in reverse, to generate vibrations from an electrical charge. Piezoelectric material is used in many applications, including microphones, watches, ultrasound machines, microscopes and high-end speakers.

The advantages of the Piezo Power transducer include its sensitivity at high frequencies and its suitability for implantation where there is a high demand on power, size and reliability.

'It's active, it's powerful. It's the technology that patients and surgeons have been aspiring to have for a long time.'

Surgeon involved in first experience programs

A digital sound experience

To optimise the transfer of power and deliver on sound quality, the Osia System uses a digital link between implant and sound processor. This connection provides two-way communication that transfers 100% of the signal regardless of the coil-to-coil distance (up to the 10 mm maximum allowed by the system) and without risk for interference*.¹¹

Piezo Power™ technology







More power, more gain. Better hearing

The high output power and gain of the Osia System enables a fitting range of up to 55 dB SNHL to help you treat a broad range of patients. A large dynamic range has been shown in studies to improve patients' ability to understand speech in noise¹², and it also provides capacity should the patient's hearing loss worsen over time.

High power

Thanks to Piezo Power technology and efficiencies in design, the Osia System produces output power on par with percutaneous bone conduction (BC) implant systems with an equivalent fitting range.^{13,14}

'The patients say that the sound is very clear. We see the benefits of gain in their speech comprehension and performance in noisy environments.'

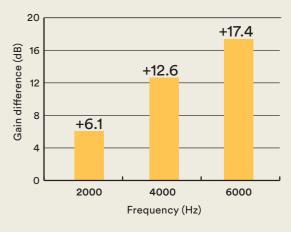
Audiologist involved in first experience programs

High gain

The Osia implant has a monolithic design that ensures a consistent distance between the sound processor's microphones and the transducer to minimise feedback.

Fitting data show that patients using the Osia System* have access to an average 12 dB more available gain at high frequencies, compared with patients using a percutaneous bone conduction implant system with an equivalent fitting range.¹⁵

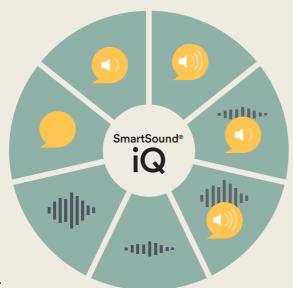
Additional available gain of the Osia System* compared with a percutaneous bone conduction implant system with an equivalent fitting range¹⁵



^{*} Data collected using an investigational system.

Hear what you want to hear, no matter where you are

The Osia System features our SmartSound® iQ signal processing suite. The Scene Classifier scans the soundscape 200 times per second to select the best signal processing strategy for the patient's sound environment. With this information, the signal processing aims to deliver a clear signal, helping the patient fully take in their surroundings.



Enhance speech

Dual microphones automatically adapt directionality patterns, aimed to help the patient localise sound and focus on conversation in a noisy situation.

Features:

- Active Balanced Directionality
- Position Compensation II

Reduce noise

Through signal monitoring, analysis, noise detection and select amplification, our signal processing suite actively works to manage and reduce unwanted noise, including wind noise.

Features:

- Noise Manager II
- Windshield[™] wind noise reduction

Increase comfort

Designed to deliver more comfortable hearing, our Feedback Manager works to analyse and manage any changes to the feedback path, while the Active Gain feature adjusts volume based on the sound environment.

Features:

- Dimensional Feedback Manager
- Active Gain



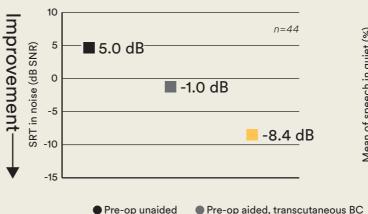


In both quiet and noise, there's a big improvement

The Osia System has been the subject of two multicentre clinical investigations.^{7,16} In the published study, patients demonstrated a significant improvement in hearing in both noise and quiet when using the Osia System* compared to a transcutaneous BC system with equivalent fitting range.⁷ The study also reported that patients demonstrated a clinically significant improvement in health-related quality of life when using the system compared to the unaided and transcutaneous BC system aided situation.⁷

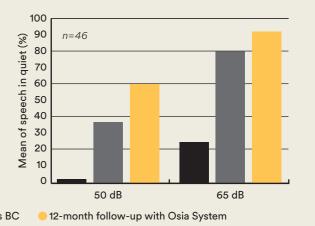
Patients demonstrate an average 7.4 dB improvement in hearing in noise⁷

Speech reception thresholds in noise



Patients demonstrate an average improvement of up to 58% in hearing in quiet⁷

Word recognition scores in quiet



'Using the health utility index, we measured the patients' quality of life and we've seen a significant improvement.'

Surgeon involved in the multicentre clinical investigation

* Data collected using an investigational system.

Designed to implant, made to last

Designed for reliability

The Piezo Power transducer is made of piezoelectric layers that expand and contract to send vibrations through to the cochlea. This is not only great for speech understanding⁷, it has other advantages too. Unlike electromagnetic transducers first designed for external use, the Piezo Power transducer has no movement between parts that can cause wear over time and, without an airgap, there is no risk for collapse.

A straightforward surgical procedure

The Osia OSI200 Implant is designed to allow a straightforward surgical procedure. In a published study, the authors report that the surgery "was straightforward with no major complications".8 The monolithic design helps coil insertion and ensures there is no coil migration. The implant's thin profile and fixation to the BI300 Implant minimises the need for extensive bone removal and risk for dura exposure. A preoperative CT scan is not required.

Suitable for MRI

One of the benefits of Piezo Power technology is its suitability for MRI. With no magnetic material in the transducer, patients with an OSI200 Implant can undergo a MR scan at both 1.5 T and 3 T.* In addition, testing demonstrates that the performance of the transducer remains consistent after MR exposure at 1.5 T and 3 T.¹⁷

Lifetime testing shows

powerful and consistent

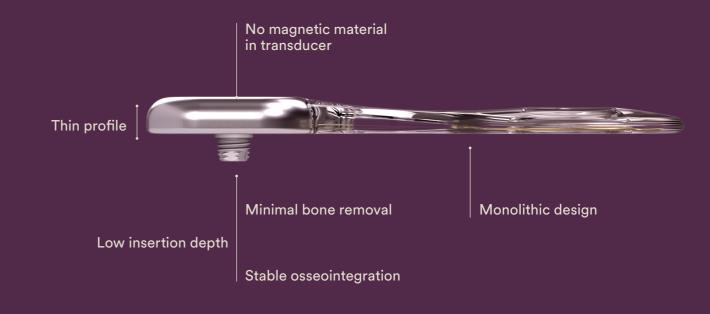
technology provides

output performance.6

that Piezo Power

'The surgery is easy to perform, and the results have been really, really encouraging. It will become a new standard in the market.'

Surgeon involved in first experience programs



10-year warranty



Nothing in, on or around the ear. Just light and comfortable

The slim, off-the-ear sound processor is light and comfortable to wear⁷. As an all-in-one magnet retained unit, your patients can put it in place, adjust their hair and they are ready to go. There are no small pieces to deal with for patients with limited dexterity, and the ear and ear canal are left open and free to reduce the risk for recurring infections and irritation.¹⁸

With every sound processor your patients get five colour options to interchange at will. Blend in or stand out, it's their choice.

Designed to be durable

The Osia 2 Sound Processor was designed and tested with durability in mind. It is dust and moisture resistant and carries an IP57 rating.*

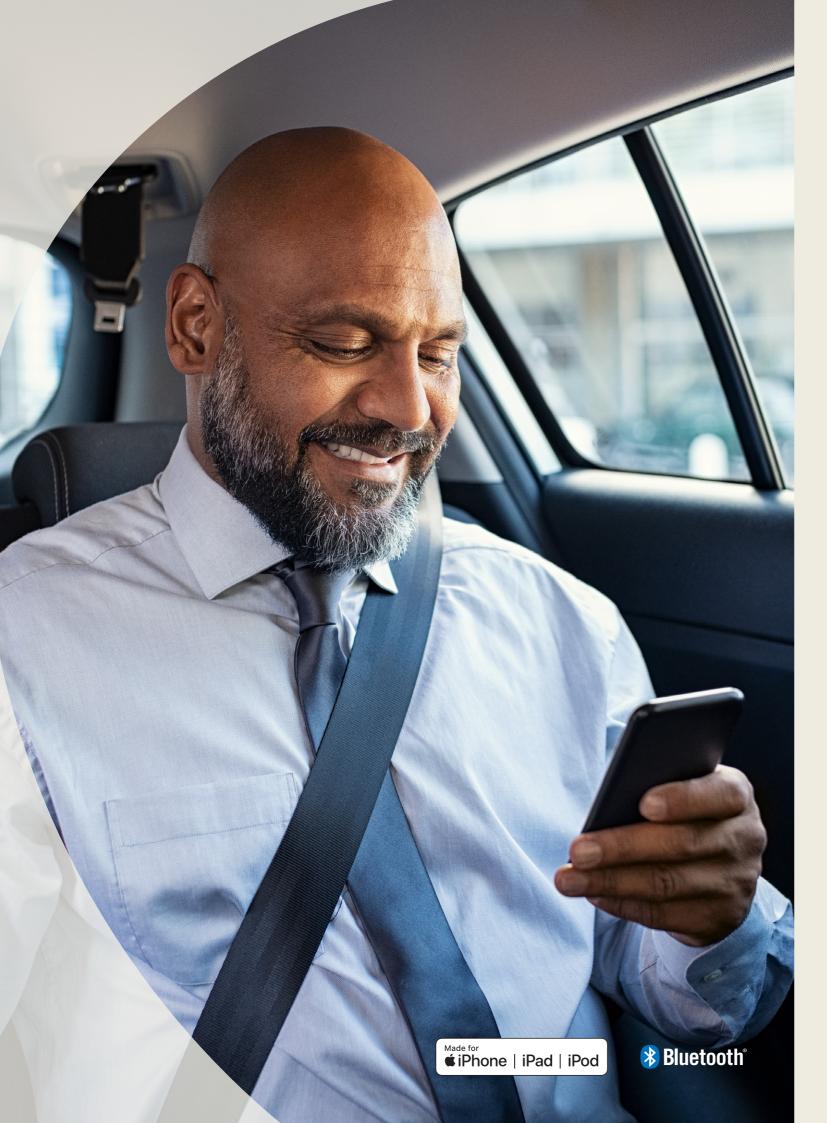


Slim, light and discreet

Weighing only 9.4 g, the Osia 2 Sound Processor is a lightweight device. It sits streamlined against the head with a low 10.4 mm projection.



The Cochlear Osia 2 Sound Processor, with battery compartment excluded, is dust and water resistant to level IP57 of the International Standard IEC60529. Refer to the relevant User Guide for more information.



Streaming, as easy as it should be

For a lot of people, digital mobile devices have become essential tools for work and for connecting with friends and family. With Made for iPhone technology, the Osia System becomes a simple extension of these devices, streaming sound directly to the sound processor from any compatible* Apple device. For Android™ and other smartphones, patients can stream using the Cochlear Wireless Phone Clip.

True Wireless™ technology

The Osia System connects to Cochlear's wide range of True Wireless™ devices. Whether it's in a meeting or the classroom, at home or on the phone, the accessories help patients feel closer to sounds and experiences.

Personalised experience

The Osia Smart App lets your patients control and adjust their sound processor easily and discreetly. From a smartphone or Apple Watch, they'll be able to tune the sound the way they want to hear it and monitor their status and settings.





^{*} The Cochlear Osia 2 Sound Processor is compatible with Apple devices. The Cochlear Osia Smart App is available on App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility.

No need to stand back, just jump in

Hearing better shouldn't get in the way of having fun. The Osia 2 Aqua+ accessory covers the sound processor to let your patients enjoy water activities with friends and family. With an Aqua+ accessory, the Osia 2 Sound Processor is waterproof down to three metres and carries an IP68 rating.*





^{*} The Osia 2 Sound Processor with Aqua+ is water resistant to level IP68 of the International Standard IEC60529 when used with LR44 alkaline or nickel metal hydride disposable batteries. Refer to the relevant User Guide for more information.

Driving progress, inspired by you

For the last 40 years, we have worked with research collaborators, professionals and communities to transform the way people treat and understand hearing loss. That collaboration has led to Cochlear being the pioneer in implantable hearing systems.

We have been innovating and bringing people all over the globe into the world of sound. Most importantly, we don't stop. And we don't do it alone. We are always listening to the people who use our hearing implants to hear every day. And we listen to you, the hearing health professionals who make it all happen.

The new Osia System is a product of this collaboration. It's a result of many years of investment in time, effort and focus on the important things that can truly make a difference in people's lives.



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 600,000 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 collaborate with leading clinical, research and support networks.

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

References

- 1. World Health Organization. Deafness & hearing loss [Internet]. 2020 [cited 21 August 2020]. Available from: https://www.who.int/newsroom/fact-sheets/detail/deafness-and-hearing-loss.
- 2. Lewis AT, Vanaelst B, Hua H, et al. Success rates in restoring hearing loss in patients with chronic otitis media: a systematic review. Submitted to Acta Otorhinolaryngol Ital.
- 3. Berenholz L, Burkey J, Lippy W. Total Ossiculoplasty: Advantages of Two-Point Stabilization Technique. Int J Otolaryngo. 2012;346260: 9.
- 4. Orji FT, O Onyero E, Agbo CE. The clinical implications of ear canal debris in hearing aid users. Pak J Med Sci. 2014;30(3):483-487.
- 5. Karaca CT, Akçay SS, Toros SZ, et al. External auditory canal microbiology and hearing aid use. Am. J. Otolaryngol. 2013;34(4):
- 6. Dotevall M. Osia OSI200 Implant Technical Brief. Cochlear Bone Anchored Solutions AB, Sweden. 2020; D1602089.
- 7. Mylanus EAM, Hua H, Wigren S, et al. Multicenter Clinical Investigation of a New Active Osseointegrated Steady-State Implant System. Otol Neurotol. 2020;41(9):1249-1257.
- 8. Lau K, Scotta G, Wright K, et al. First United Kingdom experience of the novel Osia active transcutaneous piezoelectric bone conduction implant. Eur Arch Otorhinolaryngol. 2020;10.
- 9. Vanaelst B. Literature review and Evaluation: BI300 Implant years and survival rate. Cochlear Bone Anchored Solutions AB, Sweden. 2019; D1322539.

Cochlear Ltd, (ABN 96 002 618 073), 1 University Avenue, Macquarie University, NSW 2109 Australia

ECREP Cochlear Deutschland GmbH & Co. KG, Karl-Wiechert-Allee 76A, 30625 Hannover, Germany

Regional Offices

Cochlear Ltd, (ABN 96 002 618 073), 1 University Avenue, Macquarie University, NSW 2109 Australia Tel: +61 2 9428 6555, Fax: +61 2 9428 6352

Cochlear Americas, 10350 Park Meadows Drive, Lone Tree, CO 80124, USA Tel: +1 303 790 9010, Fax: +1 303 792 9025

- 10. Rigato C, Reinfeldt S, Håkansson B, Fredén Jansson KJ, Renvall E, Eeg-Olofsson M. Effect of transducer attachment on vibration transmission and transcranial attenuation for direct drive bone conduction stimulation. Hear Res. 2019;15;381:107763.
- 11. Sunnerud H. Design Verification Report Osia System. Cochlear Bone Anchored Solutions AB, Sweden. 2019; D1575584.
- 12. Gawliczek T, Wimmer W, Caversaccio M, Kompis M. Influence of maximum power output on speech understanding with bone anchored hearing systems. Acta Otolaryngol. 2020;140(3):225-229.
- 13. Bryman M. Osia 2 System Datasheet. Cochlear Bone Anchored Solutions AB, Sweden. 2019; D1618102.
- 14. Land J. Baha 5 Power Connect Datasheet, Cochlear Bone Anchored Solutions AB, Sweden, 2019; D801286.
- 15. Dotevall M. Technical Report: Available Gain in Osia vs Baha 5 Power. Cochlear Bone Anchored Solutions AB, Sweden. 2019; D1664198.
- 16. ClinicalTrials.gov. [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT04041700. Clinical Performance, Safety and Patient Reported Outcomes of an Active Osseointegrated Steady-State Implant System. Feb 2019. [cited 2020 Oct 6]. Available from: https://clinicaltrials.gov/ct2/show/study/NCT04041700.
- 17. Goh J. OSI200 Implant MRI Safety Verification Report. Cochlear Bone Anchored Solutions AB, Sweden. 2019; D1439962.
- 18. Orji FT, O Onyero E, Agbo CE. The clinical implications of ear canal debris in hearing aid users. Pak J Med Sci. 2014;30(3):483-487.

Cochlear AG, EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland Tel: +41 61 205 8204, Fax: +41 61 205 8205

Cochlear Latinoamerica, S. A., International Business Park Building 3835, Office 403 Panama Pacifico, Panama Tel: +507 830 6220, Fax: +507 830 6218

www.cochlear.com

This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

Views expressed are those of the individual. Consult your health professional to determine if you are a candidate for Cochlear technology. Any testimonial featured is not intended for a New Zealand audience.

This material is not intended for use in the United States and Canada. In the United States and Canada there may be indications and considerations that differ to those presented in this material.

Cochlear, 科利耳, コクレア, 코클리어, Hear now. And always, Osia, SmartSound, the elliptical logo, and marks bearing an ® or ™ symbol, are either trademarks or registered trademarks of Cochlear Bone Anchored Solutions AB or Cochlear Limited (unless otherwise noted).

Google Play and the Google Play logo are trademarks of Google LLC. Android is a trademark of Google LLC.

Apple, the Apple logo, iPhone, iPad and iPod are trademarks of Apple Inc., registered in the U.S. and other countries.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cochlear Limited is under license. © Cochlear Limited 2020. All rights reserved. 2020-11.

D1617700-V3