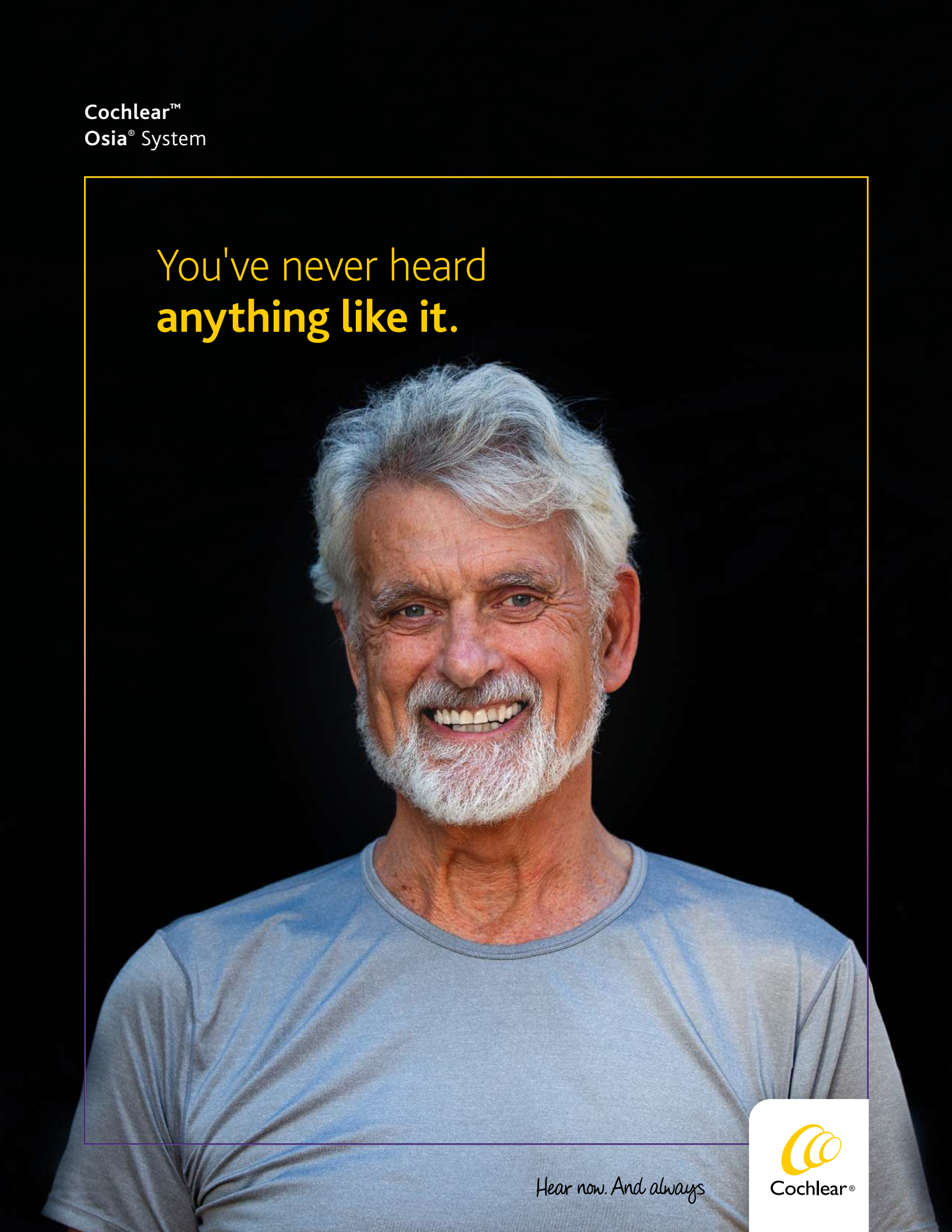
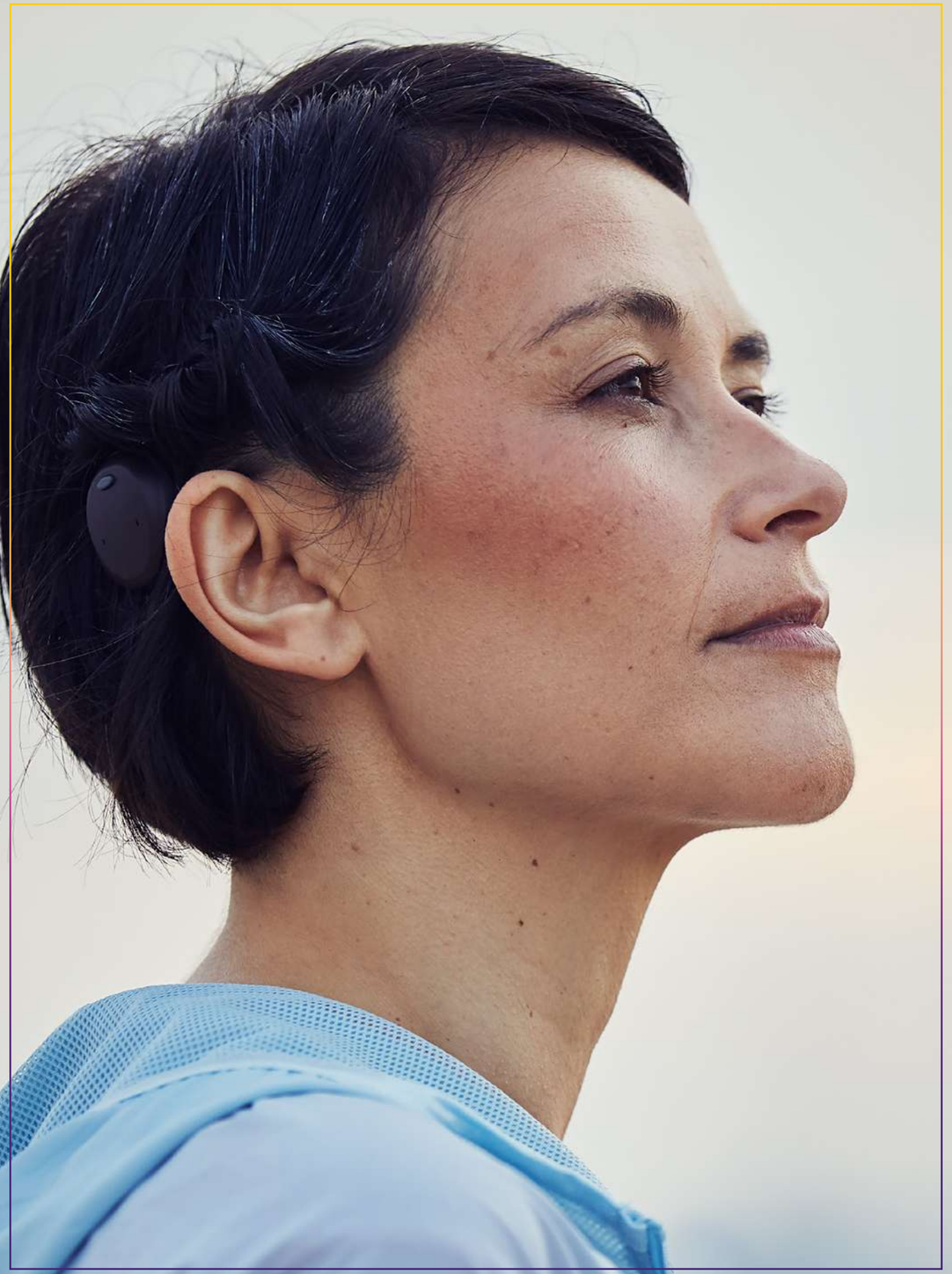
Cochlear™
Osia® System

You've never heard **anything like it.**



Hear now. And always

Cochlear®



Blending hearing technology with human capacity. **Seamlessly.**

Hearing loss is one of the world's most common disabilities, with millions of people struggling every day to hear and communicate.[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 treatment[2] and repeat surgeries are common.[3]

Hearing 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 deafness.* It is designed to help people live their lives without getting in the way, while providing the performance needed to hear in noisy situations where they tell us they struggle most. The system utilizes innovative technologies specifically chosen and designed to work in and with the body. We call this approach Human Design,™ and the result is the **new Osia System—you've never heard anything like it.**

Human Design™

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

Cochlear Osia 2 Sound Processor

- Slim & discreet off-the-ear comfort
- Advanced signal processing & wireless connectivity

Cochlear Osia OSI200 Implant

- High power & gain for performance
- Minimally invasive & straightforward surgery

Cochlear BI300 Implant

Stable osseointegrated foundation for effective sound transmission*

The new Osia® System.
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 new implant and sound processor build off our innovation heritage to deliver on the performance and lifestyle needs of your patients.

Human Design™

* Cochlear BI300 Implant has a demonstrated track record of being stable, safe and reliable in peer-reviewed clinical studies with Cochlear Baha implants.[6,7]

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 and the technology choices we've made are specifically suited for this type of application. Other implants feature traditional bone conduction technology first designed for external use. For the Osia System, we innovated.

The Piezo Power difference

At the heart of the Osia implant lies our Piezo Power™ transducer that uses piezoelectric material to generate vibrations in 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.[8]

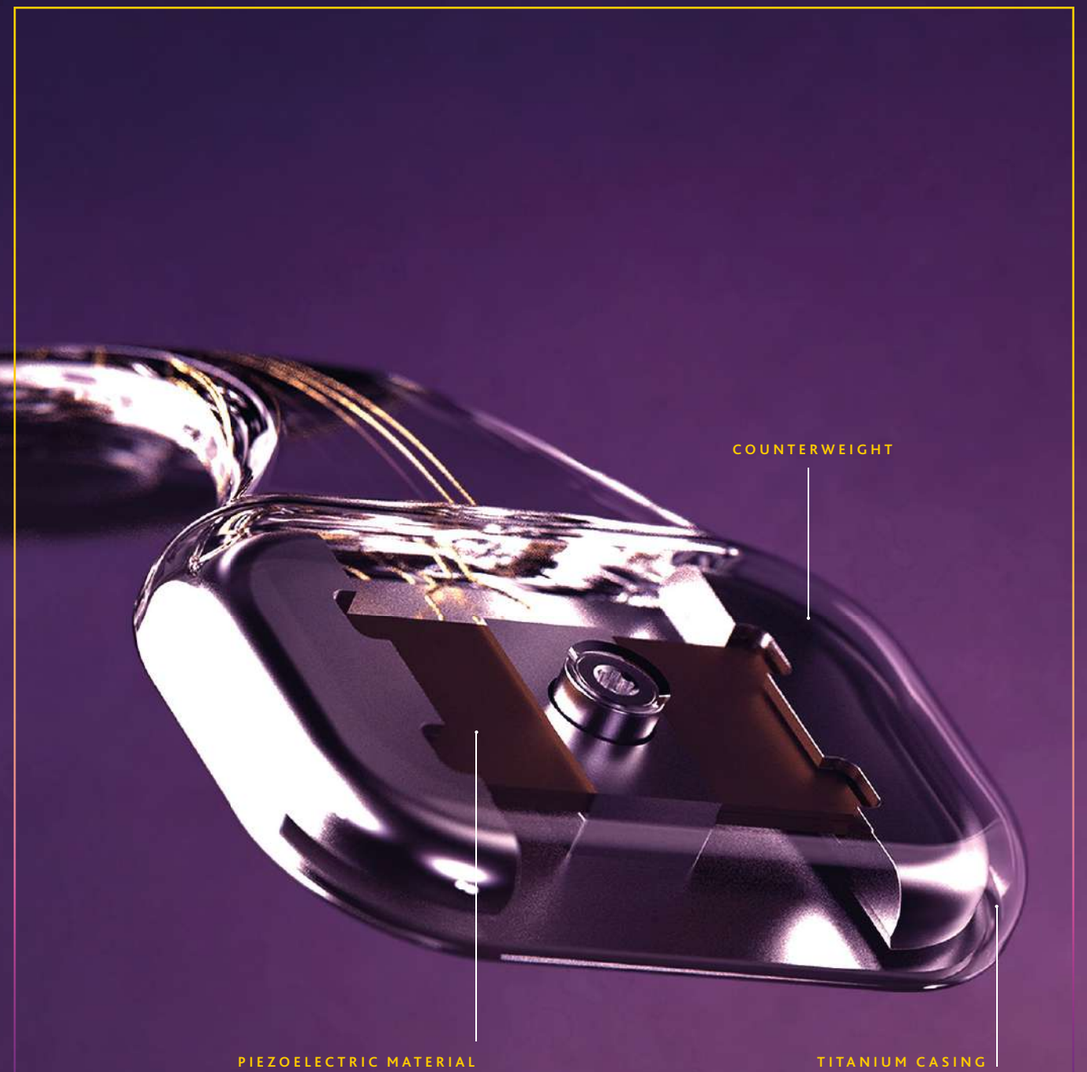
Powerful, thin and reliable[8]

A digital sound experience

To optimize the transfer of power and deliver on sound quality, the Osia System uses a digital link between the implant and sound processor. This connection provides smart two-way communication that **transfers 100% of the signal** regardless of the coil-to-coil distance* and without risk for interference.[9]

"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 Program



Piezo Power™ technology

* Up to the maximum coil-to-coil distance allowed by the system (10 mm).

Designed to implant.
Made to last.

Reliable design

The Piezo Power transducer is made of piezoelectric layers that expand and contract to send vibrations through to the cochlea. This is not only a great choice for speech understanding, 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.[10]

Lifetime testing shows that Piezo Power technology provides powerful and consistent performance over time.[8]

10 year warranty*

Minimally invasive procedure

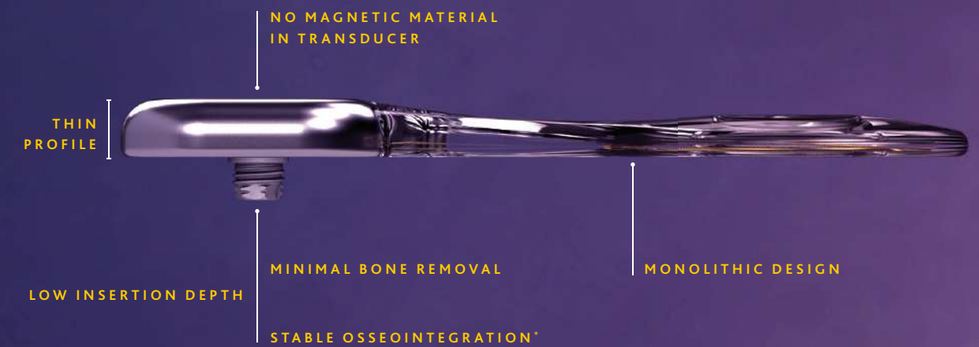
The Osia OSI200 Implant is designed to allow a straightforward surgical procedure. The monolithic design helps to make coil insertion easy and ensure there is no coil migration. Its thin profile and fixation to the BI300 Implant minimizes the need for extensive bone removal and risk for dura exposure. A pre-operative CT scan is not required.

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.

* Terms and conditions may apply.

Minimally invasive surgery



"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 a First Experience Program

* Cochlear BI300 Implant has a demonstrated track record of being stable, safe and reliable in peer-reviewed clinical studies with Cochlear Baha implants.[6,7]

More power. More gain.
Better hearing.

When it comes to hearing, more power can bring greater opportunity. 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. With plenty of headroom, the system has the capacity to allow better hearing on day one and keep patients hearing even as their needs change over time.

55 dB Fitting range

High power

Thanks to Piezo Power technology and efficiencies in design, the Osia System produces output power on par with 55 dB percutaneous bone conduction implant systems.[11]

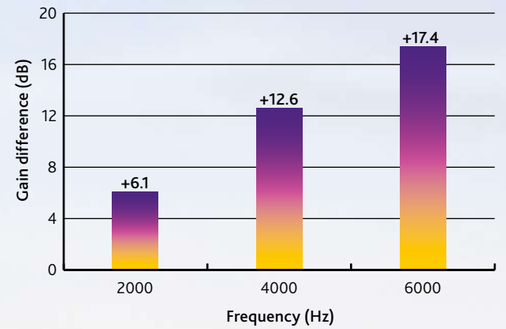
High gain

The system's stable gain architecture, made possible by the implant's monolithic design, ensures a consistent distance between the sound processor's microphones and the transducer. The Osia System delivers an average 12 dB more patient available gain at high frequencies compared with percutaneous bone conduction implant systems.[12,13]

"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 Program

Additional available gain of the Osia System compared with a 55 dB percutaneous BC system.[12,13]



COLOR OPTIONS

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

The slim, off-the-ear sound processor is light and comfortable to wear.[14] As an all-in-one magnet retained unit, your patients can simply place it, 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.[14]

Durable design

The Osia 2 Sound Processor is designed to work where your patients work and play. With an IP57 rating,* it is dust and moisture resistant and has been drop tested at over nine feet.[15]

DUST & MOISTURE RESISTANT

IP57

DROP TESTED AT OVER 9 FEET

Slim design. Only **10.4** mm.

* The Osia 2 Sound Processor is IP57 rated with battery compartment excluded.

Ardium™ Smart inside

Designed to hear what you want to hear.
No matter where you are.

SmartSound® iQ

The Osia System features our most advanced acoustic signal processing and connectivity platform. The Scene Classifier categorizes the patient's acoustic environment to select the best signal processing strategy. Patients can enjoy a natural and dynamic sound experience, helping them hear and communicate in diverse and challenging listening environments.

Osia® SmartSound® iQ

ACTIVE GAIN

Automatically adjusts the amplification levels for the environment

ACTIVE BALANCED DIRECTIONALITY

Balances directional settings for optimal speech and environmental awareness

NOISE MANAGER II

Four step system reduces noise while maintaining speech information

POSITION COMPENSATION II

Compensates for the processor's position in both omni and directional mode

NATURAL SOUND RESOLUTION

Provides high resolution in important speech areas for more exact fittings

DIMENSIONAL FEEDBACK MANAGER

Dual setting feedback cancellation increases available gain and reduces artifacts

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

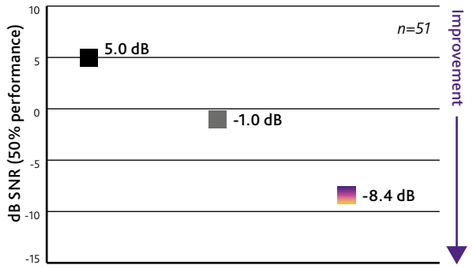
The Osia System has been the subject of a global one year, multi-center clinical investigation looking at the performance and safety of the system. Results show a significant improvement in patients' ability to hear in noise and quiet compared to a transcutaneous BC system. It also yielded a significant improvement in ratings of their overall health-related quality of life compared with the unaided and pre-op aided condition.[13,17]

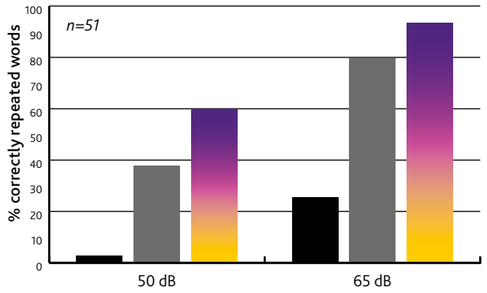
Excellent hearing in noise

Results from the clinical investigation show a significant, average improvement of 7.4 dB in hearing in noise when compared to a 55 dB transcutaneous BC system.[13,17]

Excellent hearing in quiet

Results from the clinical investigation show a significant, average improvement of up to 22 percentage points in hearing in quiet when compared to a 55 dB transcutaneous BC system.[13,17]





Pre-op unaided Pre-op aided, transcutaneous BC 12 month visit using the Osia System

More than **7 dB improvement** in noise[13,17]

Up to **22 percentage points better** in quiet[13,17]

Streaming.
As easy as it should be.

For a lot of people, digital mobile devices have become essential tools 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.

Made for iPhone | iPad | iPod

Bluetooth®

True Wireless™ technology

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

Personalized 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.

* For compatibility information visit www.cochlear.com/compatibility.

* The Cochlear Osia Smart App is available on App Store and Google Play. For compatibility information visit www.cochlear.com/compatibility. The Cochlear Osia Smart App may not be available in all markets and is subject to regulatory approval and product availability.

No need to stand back, **just jump in.**

Hearing better shouldn't get in the way of living life to the fullest. The easy-to-use 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 almost 10 feet.[18]

OSIA 2 AQUA+

IP68

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. The Osia 2 Aqua+ may not be available in all markets and is subject to regulatory approval and product availability.

Committed to a lifetime of innovation. **With you.**

Cochlear is the pioneer in implantable hearing systems. We have been innovating to bring people the gift of sound for over 40 years. Most importantly, we don't stop. And we don't do it alone. We are constantly 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.

"This is a huge addition to our treatment armamentarium. The clinical outcomes have outstripped the expectations."

Surgeon involved in First Experience Program

"The Osia System is an ideal solution for patients with chronic ear and air conduction problems. It will be a widely accepted device among surgeons."

Surgeon involved in First Experience Program

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.

References.

1. https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss
2. Lewis AT, Vanaelst B, et al. Clinical success rates in restoring hearing loss among adult and pediatric patients with chronic otitis media: a systematic review. Unpublished.
3. Berenholz L, Burkey J, Lippy W. Total Ossiculoplasty: Advantages of Two-Point Stabilization Technique. Int J Otolaryngo. 2012;346260: 9.
4. Ahmad N, Etheridge C, Farrington M, Baguley DM. Prospective study of the microbiological flora of hearing aid moulds and the efficacy of current cleaning techniques. J Laryngol Otol. 2007;121(2):110–3.
5. Karaca CT, Akçay SS, Toros SZ, et al. External auditory canal microbiology and hearing aid use. Am. J. Otolaryngol. 2013;34(4): 278-281.
6. Cochlear Bone Anchored Solutions AB, Mölnlycke, Sweden. Long term stability, survival and tolerability of a (novel) Baha® implant system. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). [Cited 2016 Jan 6]. Available from: https://clinicaltrials.gov/ct2/show/NCT02092610. NLM Identifier: NCT02092610.
7. Flynn, M, Cochlear Baha Attract System, Summary of clinical results and benefits, 2014 (E83112).
8. Goh J. OSI200 Implant Accelerated Life Test Report. D1439967. Cochlear Bone Anchored Solutions AB, Sweden 2019.
9. Sunnerud H. D1575584, Design Verification Report Osia System. Cochlear Bone Anchored Solutions AB, Sweden 2019.
10. Preumont A, Mokrani B. Electromagnetic and Piezoelectric Transducers. Springer, Vienna; 2014:213-248.
11. Osia System data sheet; Baha 5 Power Connect data sheet. D1618102; D801286. Cochlear Bone Anchored Solutions AB, Sweden 2019.
12. Dotevall M. Technical Report: Available Gain in Osia vs Baha 5 Power. D1664198. Cochlear Bone Anchored Solutions AB, Sweden 2019.
13. Data collected using an investigational system.
14. Agbo CE. The clinical implications of ear canal debris in hearing aid users. Pak J Med Sci. 2014;30(3):483–487.
15. 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.
16. Kristo S. Excessive handling test report Osia 2 SP. D1611803. Cochlear Bone Anchored Solutions AB, Sweden 2019.
17. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US); 2017 March 22. Identifier NCT03086135. Clinical Performance of a New Implant System for Bone Conduction Hearing; 2019 January 31 [cited 2019 June 20]; [4 screens]. Available from: https://clinicaltrials.gov/ct2/show/NCT03086135.
18. Edward Bennett, OSIA 2 Aqua+ IP68 Tests Design Verification Report. D1638233. Cochlear Ltd, Australia 2019.

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