



Hear now. And always

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Cochlear™ Osia® System: Frequently Asked Questions

If I currently have another type of implanted bone conduction device, can I upgrade to the Osia 2 Sound Processor with my current implant?

The Osia 2 Sound Processor is only compatible with the Osia System's internal active implant (the OSI200 Implant, positioned on top of the bone). Consult with a Hearing Implant Specialist to determine the best path forward for your individual needs.

What is the difference between the Osia System and the Baha® 5 System?

The Baha 5 System is a bone conduction system that uses an external sound processor featuring a BCDrive™ electromagnetic transducer. This transducer creates vibrations that are sent through to the cochlea via an implanted connection: an abutment in the case of Baha Connect, an implanted and external magnet in the case of Baha Attract. The sound processor can also be connected to a range of non-surgical options, e.g. the Baha Softband or Baha SoundArc. The Baha 5 System features a range of sound processors for different levels of hearing loss. The Baha 5 Sound Processor (for up to 45 dB SNHL), the Baha 5 Power Sound Processor (for up to 55 dB SNHL) and the Baha 5 SuperPower Sound Processor (for up to 65 dB SNHL).*

The Osia System is a completely new hearing implant and unlike the Baha 5 System, it is an active bone conduction solution. The system uses a Piezo Power™ transducer that sits within the OSI200 Implant, which is positioned under the skin to send sound to the cochlea. The OSI200 Implant is positioned on top of the bone and connected to the BI300 Implant, which is osseointegrated into the bone; this gives an important single-point of transmission for sound. The system has a fitting range of 55 dB SNHL.

The commonalities between the Osia System and the Baha 5 Systems are that they use the principles of bone conduction to send sound to the cochlea and they are indicated for patients with conductive hearing loss, mixed hearing loss and single-sided deafness (SSD).

Who is the Osia System for?

The Osia 2 System is indicated for use by individuals aged 12 and older with mixed or conductive hearing loss, or single sided deafness. It has an indicated fitting range of up to 55 dB SNHL.*

How does the Osia System's implant conduct sound, if it sits on top of the bone?

While the Osia System's OSI200 Implant does sit on top of the bone, it has a very low profile of only 4.9mm and there is a single point of transmission for the vibrations that go into the bone to conduct sound. This single point of transmission is through the osseointegrated BI300 Implant that is backed by more than 10 years of published clinical research with a 98.4% cumulative stability rate¹.



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What is piezoelectric stimulation and how does it work?

The “piezoelectric effect” is the ability of certain materials to generate an electrical charge from mechanical stress, such as bending or flexing, or in reverse, to generate vibrations from an electric charge. The Piezo Power transducer in the Osia System uses this type of piezoelectric material; creating vibrations in the transducer that are sent through the osseointegrated B1300 Implant to the bone and then on to the cochlea.

Is the use of the B1300 implant reliable? Will it come loose?

Yes, Cochlear’s B1300 Implant is reliable. The stability and reliability of the Cochlear B1300 Implant is backed by more than 10 years of published clinical research and boasts a 98.4% cumulative stability rate with more than 80,000 patients worldwide using the B1300 Implant today.^{1,2}

Is the Osia System meant to replace Baha Systems?

No, Cochlear’s Baha Systems are still great solutions for patients that can benefit from bone conduction hearing systems. In fact, for some patients a Baha System may potentially be a better solution than an Osia System, depending on varying patient factors. Please, consult with a Hearing Implant Specialist to determine the best path forward for your individual needs.

What are the key benefits of the Osia System?

While there are many important benefits to the Osia System, here are a few of the most important:

- *Unlike electromagnetic transducers, the Piezo Power™ transducer in the Osia System has no movement between parts that can cause wear over time³.*
- *The Piezo Power transducer delivers excellent hearing performance in the noisy situations and the high frequencies important to speech understanding, where people tell us they struggle most⁴*
- *The Osia 2 Sound Processor is slim, smart and robust. It has wireless connectivity, Made for iPhone technology, advanced signal processing, and many other important features designed to make the life of recipients simple and stress-free⁵.*
- *Lifetime testing shows that Piezo Power technology provides powerful and consistent performance over time⁶.*

How much does the Osia System cost?

The Osia System is a first-of-its-kind premium implantable hearing system and is priced at a premium to the Cochlear Baha Attract System. Many insurance carriers cover the cost of the Osia System and the healthcare-related expenses required to implant it. Consult with a Hearing Implant Specialist to determine the best path forward for your individual coverage options based on your individual health insurance.*



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Is the Osia System waterproof?

*Yes, with the use of the Cochlear™ Osia® 2 Aqua+ accessory, which has an IP68 rating, the sound processor is waterproof down to 3 meters underwater for up to 2 hours^{7**}, so there's no reason to stand back, just dive in. The Aqua+ accessory encases the Osia 2 Sound Processor, while still allowing normal functionality.*

Can I get an MRI with the Osia System without any additional procedure?

The Osia OSI200 Implant (positioned on top of the bone), in combination with the BI300 Implant (osseointegrated into the bone), are MR Conditional. Patients can be scanned at both 1.5 Tesla and 3 Tesla with the implant magnet removed through a simple, straightforward procedure. Prior to receiving an MRI, please consult with your clinician about proper precautions.

Where can I get an Osia System?

The Osia System is currently available at many select clinics across the United States with new clinics being added to provide the Osia System each day. Please, contact Cochlear to be put in touch with your local Cochlear Consumer Engagement Manager who will help direct you to an Osia System clinic near you.



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References:

1. Vanaelst B. Literature review and Evaluation: BI300 Implant years and survival rate. Cochlear Bone Anchored Solutions AB, Sweden 2019.
2. Cochlear Bone Anchored Solutions sales data current as of January 2019.
3. Preumont A, Mokrani B. Electromagnetic and Piezoelectric Transducers. Springer, Vienna; 2014:213-248
4. D1478473 Data on file Windchill Document
5. D1618102. Osia 2 System Datasheet. Cochlear Bone Anchored Solutions AB, Sweden. 2019
6. D1439967. Goh J. OSI200 Implant Accelerated Life Test Report. Cochlear Bone Anchored Solutions AB, Sweden 2019
7. D1638233. Edward Bennett, OSIA 2 Aqua+ IP68 Tests Design Verification Report. Cochlear Ltd, Australia 2019

*SNHL means sensorineural hearing level.

**Contact your insurance company or local Hearing Implant Specialist to determine your eligibility for coverage.

***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.