



**Cochlear**<sup>®</sup>  
Hear now. And always

Cochlear™ Osia® System

# Reliability Report

**For more than 40 years, Cochlear has been bringing people all over the globe into the world of sound.**

As the global leader in implantable hearing solutions, Cochlear has provided more than 700,000 implantable devices, helping recipients of all ages, in more than 180 countries, to hear and live full and active lives. Cochlear is also the industry leader in data on short term and long-term reliability, and whether our devices were implanted today or many years ago, we aim to give our recipients the best lifelong hearing experience.

## Osia System reliability data

The Cochlear™ Osia® System works through bone conduction, and is designed as a long-term solution to help people hear. While it is based on more than 40 years of research and innovation in Cochlear's bone conduction technology, the Osia System represents a totally new approach to hearing loss treatment. Introduced in 2019, this type of hearing implant uses a process called digital piezoelectric stimulation to conduct sound vibrations through the bone.

The Cochlear Osia OSI200 Implant has been developed to meet Cochlear's commitment to provide the industry's most reliable implantable hearing solutions.<sup>1</sup> This report provides reliability data on the OSI200 Implant. The implant data in this report is based on the reporting principles outlined in the **European Consensus Statement on Cochlear Implant Failures and Explantations**<sup>2</sup> and the reporting methodology recommended by

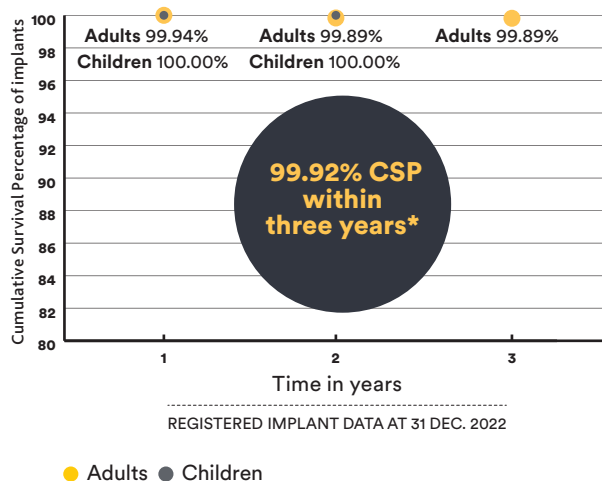
*Osia 2 Sound Processor*



### **International Standard ISO 5841-2<sup>3</sup>.**

The consensus statement is the most relevant statement available for this type of hearing implant, and it outlines how device failures and reliability should be reported, and the seven principles of best practice reporting.

## OSI200 Implant Reliability



Number of registered OSI200 Implants – 31 Dec. 2022


Adults	Children	Combined
4447	1724	6171

**Note:** Individual population for children in 2022 is less than the minimum required for a valid calculation.<sup>3</sup>

\* Based on implant registration data. Reliability refers to Cumulative Survival Percentage as defined in relevant industry-recognised reliability reporting standards, which includes both device and accident-related implant failures.

## References

1. Cochlear Limited. D1602089 V1 2020-12. Osia OSI200 Implant Technical Brief.
2. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005 Nov;26(6):1097-9.
3. International Standard ISO 5841-2. Implants for Surgery — Cardiac Pacemakers — Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads. Geneva (Switzerland): International Organization for Standardization. 2000, 2014.

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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 follow the directions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information. For the Cochlear Osia System in Australia: The Osia System is indicated for patients with conductive, mixed hearing loss and single-sided sensorineural deafness (SSD) aged 10 years and above with up to 55 decibels sensorineural hearing loss. Patients should have sufficient bone quality and quantity to support successful implant placement. Surgery is required to use this product. Any surgical procedure carries risk. This product is not available for purchase by the general public. For information on funding and reimbursement please contact your healthcare professional.

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