FOR PROFESSIONALS

Cochlear®
Hear now. And always

Cochlear™ Osia® System

Reliability report

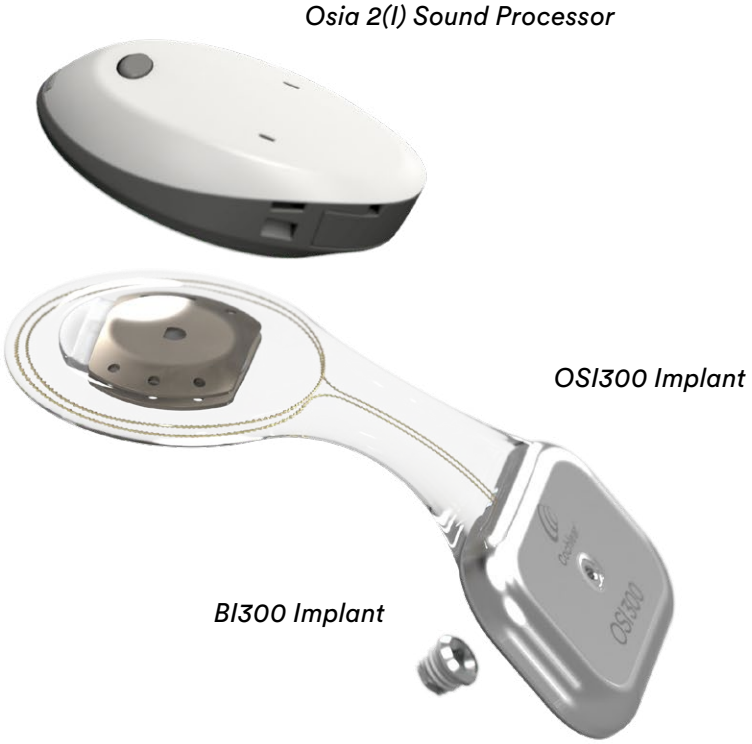
Volume 5 | December 2024

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 750,000 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 reporting 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.

About this report

The Cochlear™ Osia® System, which works through bone conduction, is designed as a long-term solution to help people hear. While it is based on more than 40 years of research and innovation, the Osia System represents a reimagined approach to hearing. This type of hearing implant uses an implanted piezoelectric transducer, instead of a traditional electromagnetic transducer, to conduct sound vibrations through the bone. The Osia System was first introduced in 2019 and continues to be a hallmark of Cochlear's innovation in bone conduction hearing.



Cochlear Osia implants have been designed with Cochlear's commitment to provide the industry's most reliable implantable hearing solutions in mind. This report provides reliability data on the OSI300 Implant, OSI200 Implant and Osia 2/2(I) Sound Processor.

The implant data in this report is based on the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations[1] and the reporting methodology recommended by International Standard ISO 5841-2[2]. The sound processor data in this report is based on the reporting principles and methodology recommended by ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.[3] These reporting methodologies are the most relevant standards available for this type of hearing implant system, and they outline how device failures and reliability should be reported.

Implant reliability

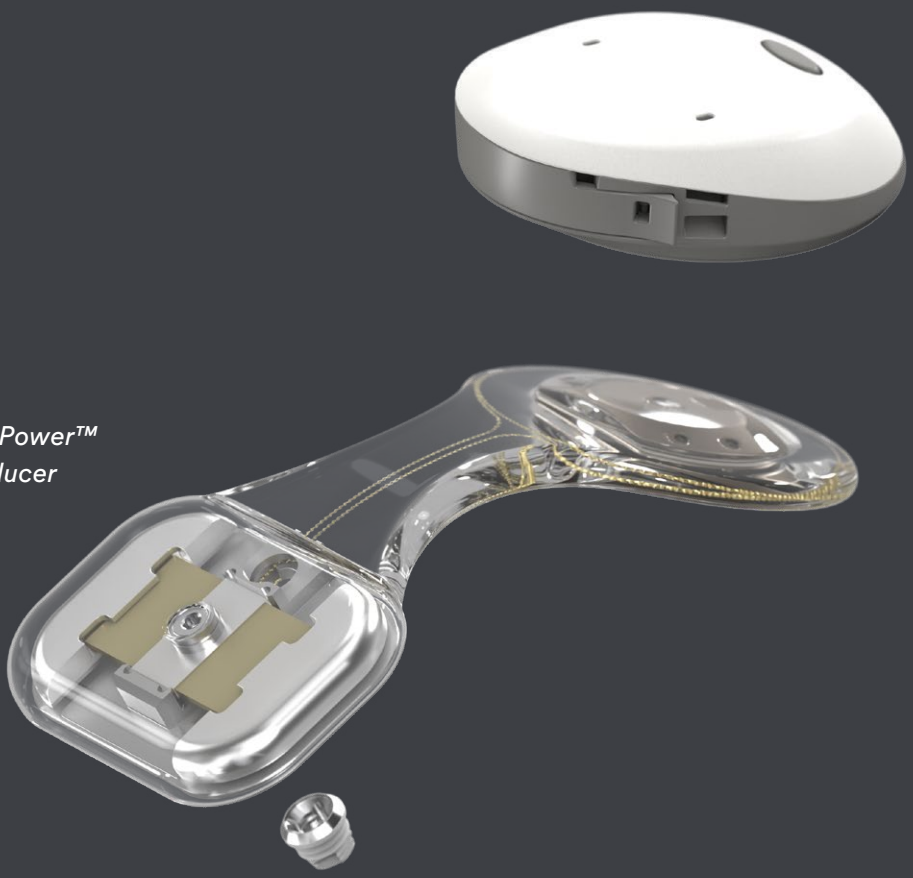
Why implant reliability matters

Longevity is an important factor when choosing an active implant, especially if you are choosing for a child. High implant reliability can mean greater recipient satisfaction and less risk of additional surgery.

What is Cumulative Survival Percentage (CSP)?

CSP is the metric used in this report to measure implant reliability. CSP provides information regarding the reliability of each make and model of implant over time.

CSP tells you the cumulative percentage of functioning implants over a given time period. For example, a CSP of 99% after five years means the chance of obtaining continued benefit from the implant, as described for its intended use, is 99% after five years. Put another way, the implant is 99% reliable within five years.



Piezo Power™ transducer

Calculation of CSP

In this report, CSP includes both device and accident-related issues. The reliability calculations used in this report are in accordance with the International Standard ISO 5841-2.[2], They are probability calculations, which use a modified actuarial analysis estimator. This data estimates the probability of survival within a period of time and is represented as CSP.

About the results

Results for adults and children are shown separately with 95% confidence intervals (ǂ) as stipulated by the European Consensus Statement.[1] “Combined data” shows the cumulative survival percentage of both adult and children populations combined.

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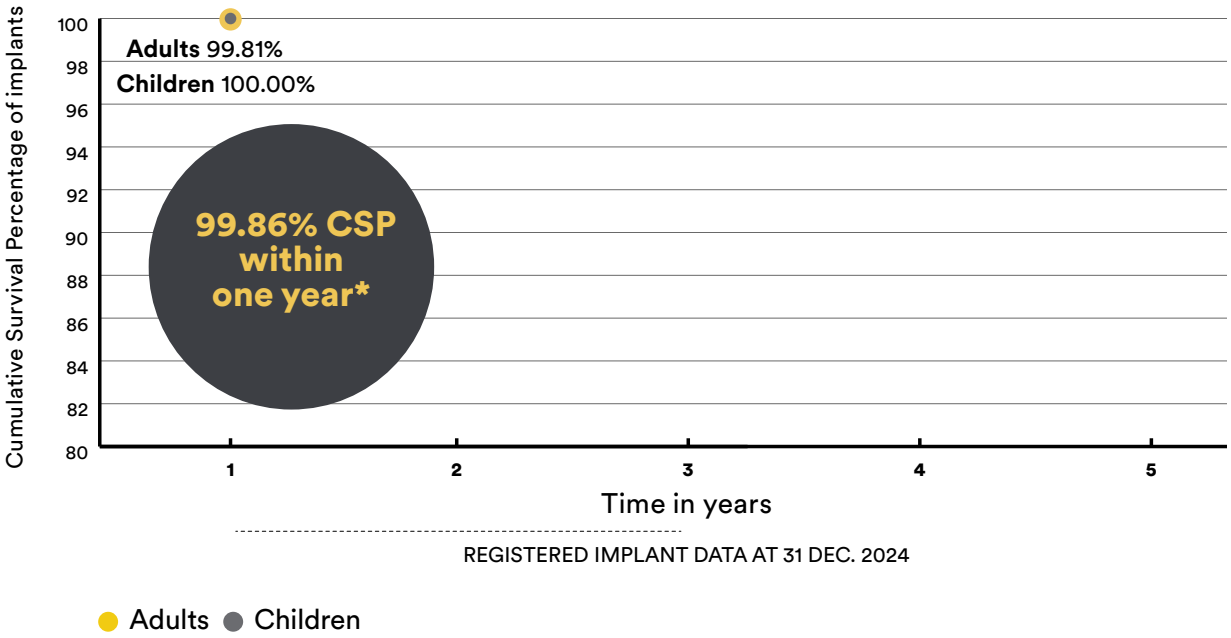
OSI300 Implant reliability data

Number of registered OSI300 Implants – 31 Dec. 2024

Adults	Children	Combined
2765	1070	3835

OSI300 Implant Reliability



* 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.

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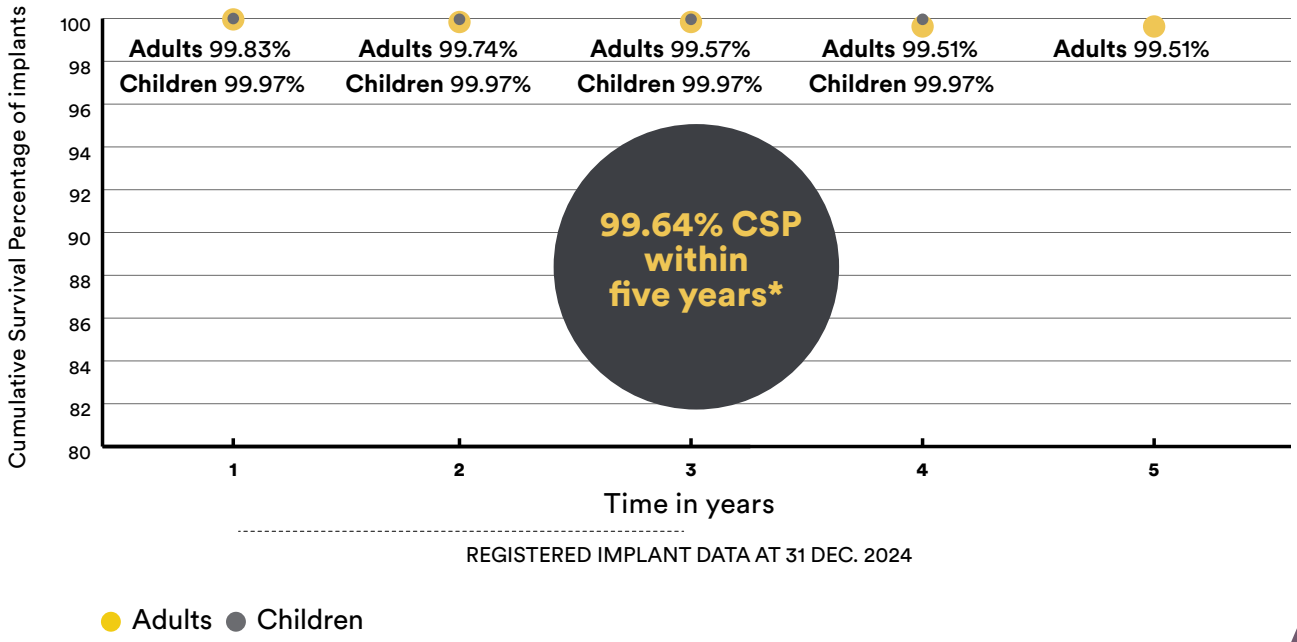
OSI200 Implant reliability data

Number of registered OSI200 Implants – 31 Dec. 2024

Adults	Children	Combined
8379	3260	11639

OSI200 Implant Reliability



* 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.

Note: Individual population for children in Year 5 is less than the minimum required for a valid calculation.[2]

Sound processor reliability

Why sound processor reliability matters

The reliability of a hearing implant system depends not only on the implant, but also on the sound processor. Sound processors, an externally worn device, are typically used for a number of years, so high reliability enables ongoing access to a consistent hearing experience.

What is Failed Component Return Rate (FCRR)?

Failed Component Return Rate (FCRR) is the metric used in this report to measure sound processor reliability. This report shows FCRR data over the previous 24 months.

Cochlear tests sound processors that have been returned to determine if they are working and, if not, why they failed. The FCRR is a percentage which represents the total number of failed processors received within a month compared to the total number of the same processor sold by the end of that month.

For example, if 20 faulty sound processors are returned in a month and 10,000 of the same sound processors have been sold as at the end of the month, the FCRR is 0.2%.

About the results

- **Mechanical failure:** A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use
- **Electrical failure:** A functional failure of the electronics or the electronic assembly
- **Moisture damage failure:** A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.
- **Other/unknown failure:** Failures that don't fit in the stated categories (e.g. firmware failures)
- **Fault-free data:** A returned device that is found to be fully functional is classified as fault-free. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discolouration), corrosion, and/or moisture damage that did not result in a functional failure.

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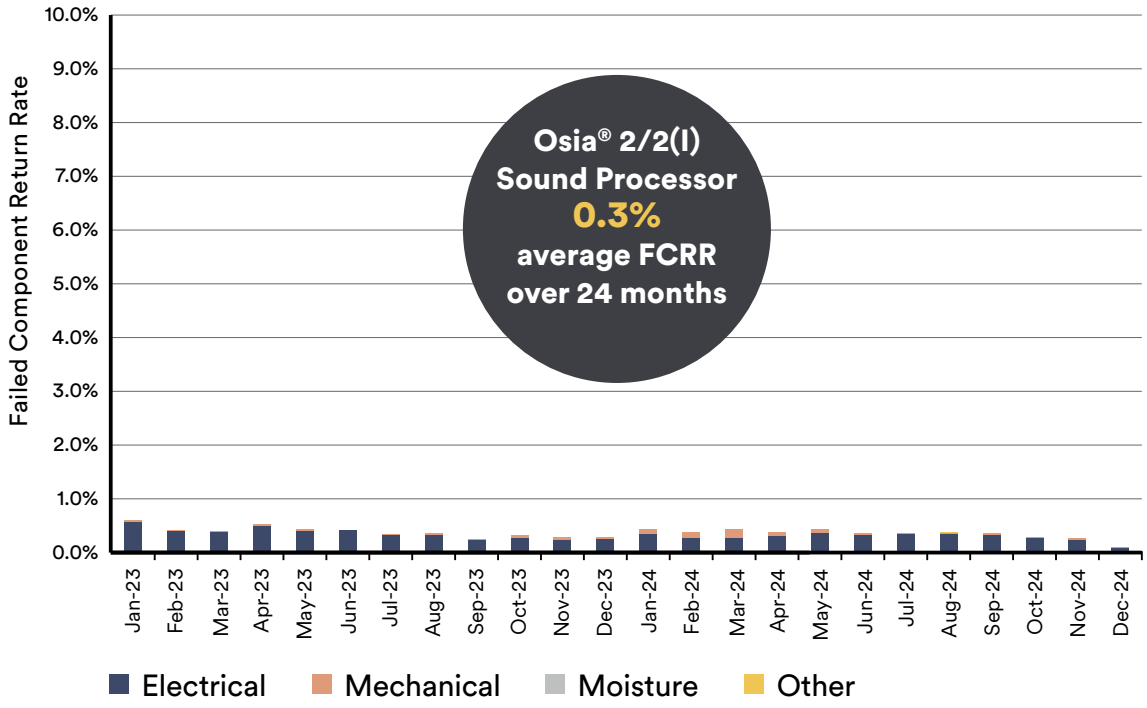
Osia 2/2(I) Sound Processor reliability data



Osia 2/2(I) Sound Processor – Failed Component Return Rate

	Electrical	Mechanical	Moisture	Other	Fault Free
Jan-23	0.5%	0.0%	0.0%	0.0%	0.2%
Feb-23	0.3%	0.0%	0.0%	0.0%	0.2%
Mar-23	0.3%	0.0%	0.0%	0.0%	0.3%
Apr-23	0.4%	0.0%	0.0%	0.0%	0.3%
May-23	0.3%	0.0%	0.0%	0.0%	0.2%
Jun-23	0.3%	0.0%	0.0%	0.0%	0.4%
Jul-23	0.2%	0.0%	0.0%	0.0%	0.3%
Aug-23	0.2%	0.0%	0.0%	0.0%	0.5%
Sep-23	0.2%	0.0%	0.0%	0.0%	0.3%
Oct-23	0.2%	0.0%	0.0%	0.0%	0.2%
Nov-23	0.2%	0.0%	0.0%	0.0%	0.2%
Dec-23	0.2%	0.0%	0.0%	0.0%	0.2%

	Electrical	Mechanical	Moisture	Other	Fault Free
Jan-24	0.3%	0.1%	0.0%	0.0%	0.2%
Feb-24	0.2%	0.1%	0.0%	0.0%	0.2%
Mar-24	0.2%	0.1%	0.0%	0.0%	0.2%
Apr-24	0.2%	0.1%	0.0%	0.0%	0.2%
May-24	0.3%	0.1%	0.0%	0.0%	0.2%
Jun-24	0.2%	0.0%	0.0%	0.0%	0.2%
Jul-24	0.3%	0.0%	0.0%	0.0%	0.2%
Aug-24	0.3%	0.0%	0.0%	0.0%	0.2%
Sep-24	0.2%	0.0%	0.0%	0.0%	0.2%
Oct-24	0.2%	0.0%	0.0%	0.0%	0.2%
Nov-24	0.2%	0.0%	0.0%	0.0%	0.2%
Dec-24	0.0%	0.0%	0.0%	0.0%	0.1%

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 750,000 devices and helped 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 next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

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

References

1. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005 Nov;26(6):1097-9.
2. 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.
3. ANSI/AAMI CI86. Cochlear implant systems: Requirements for safety, functional verification, (2017). Arlington, VA: American National Standards Institute

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D1841762-V6 2025-04