FOR PROFESSIONALS

Cochlear™ Osia® OSI300 Implant

Technical Brief – Reliability

The Cochlear™ Osia® System is an active osseointegrated implant (OSI) that uses a piezoelectric transducer to send sound directly to the cochlea. The active implant sits fully under the skin, and the technologies utilized by the implant were specifically chosen with consideration to the performance, safety and reliability requirements of this type of application[1]. Cochlear is committed to comprehensive and regular reporting for the OSI300 Implant and this report summarizes the results of rigorous testing undertaken on the implant.

As the global leader in implantable hearing solutions, Cochlear has provided more than 750,000 devices and helped people of all ages to hear and connect with life's opportunities. Building on this history of trusted innovation, the Cochlear Osia OSI300 Implant (Fig. 1) has been developed using a combination of pioneering technologies from the Cochlear Nucleus® Implant portfolio, and established technologies such as piezoelectricity, to provide an innovative and reliable active Osseointegrated Steady-State Implant (OSI).

The OSI300 Implant utilizes a piezoelectric transducer to generate mechanical vibrations, which are transferred to the cochlea via the skull bone. The Piezo Power™ transducer is constructed using multiple piezo layers, permitting powerful stimulation in a slim design. The piezoelectric transducer does not contain magnetic materials, which limits interference and artifacts during magnetic resonance imaging (MRI).

Device performance and reliability is paramount and Cochlear publishes regular reliability reports for Nucleus and Osia implants in accordance with international standards and clinical recommendations.[2–4]

Fig. 1: OSI300 Implant – Fully-implantable piezoelectric transducer with 3.0 T accessible magnet.*

* The OSI300 implant is MRI conditional at 1.5 T and 3.0 T with magnet in place. Refer to Osia MRI guidelines for further information.

Mechanical, MRI and lifetime testing

Testing was carried out following international standards to comprehensively assess the performance of the implant (Table 1). **Mechanical testing** consisted of temperature and pressure testing, a vibration test, a shock test, and an impact test, among others. **Age-accelerated testing** of the implant's electro-acoustic performance was carried out to estimate the lifetime of the device, and thorough **MRI testing** was also conducted.

Temperature and pressure

Thermal cycling and pressure testing was carried out using both packaged and unpackaged OSI300 Implants. Testing confirmed that OSI300 Implants remain functional with and without their protective packaging following extreme environmental exposures.

Test	Standard
Temperature Cycling	EN 60068-2-14:2009
Low Temperature in Sales Pack	EN 60068-2-1:2007 EN 60068-2-14:2009
Vibration	EN 60068-2-47:2005 EN 60068-2-64:2008+A1:2019
Shock	EN 60068-2-27:2009
Low and High Pressure in Sterile Pack	EN 45502-1:2015 Cl. 25.1
High Pressure Cycle	EN 45502-2-3:2010 Cl. 25.2 ISO 14708-7:2019 Cl. 25.2
Lifetime	EN 45502-1:2015 Cl. 19.1
Hermeticity	EN 45502-2-3:2010 Cl. 19.6 EN 60068-2-75:2014 ISO 14708-7:2019 Cl. 19.6
Impact	EN 45502-2-3:2010 Part 23.8 EN 60068-2-75:2014 ISO 14708-7:2019 Cl. 22.2
MRI Safety	EN 45502-2-3:2010 Cl. 22.2; ISO 14708-7:2019 Cl. 22.2 IEC 60601-2-33:2022 ISO 10974:2018

Table 1: Type of testing conducted, and associated standards followed.

Vibration

Vibration tests were performed to demonstrate that the implant can withstand environmental stresses reliably and remain functional following extreme vibration stress. Vigorous testing determined that the OSI300 Implant is robust enough to withstand random vibrations generated that mimic the conditions of transport, storage and use.

Shock

Mechanical shock testing was carried out to simulate potential shocks that the implant may be subjected to in cases of transport, rough handling and trauma. Shock testing was carried out on the OSI300 Implant itself and packaged OSI300 Implants. Shock testing determined that the implant remains functional after multiple shocks of 500 g.

Impact

Impact testing for the OSI300 Implant has been performed following the applicable requirements of standards for Cochlear Implants to test the functionality of the implant, its removability and its hermeticity following impact.

The tests have been designed to give assurance that impacts experienced during normal daily living will not compromise the implantable portion of the system. Such impacts may include falls or knocks to the head during walking, running or cycling and which don't require medical attention or first aid.

Lifetime

An age-accelerated test was developed to evaluate implant functionality over a 75 year period. To estimate this, the OSI300 implants were exposed to the maximum output level of the implant actuator under accelerated conditions and assessed in line with the reported lifetime standard (Table 1). Based on the outcomes from the lifetime testing the OSI300 implant comes with a 10 year warranty.

Magnetic resonance imaging

It is crucial to examine the magnetic resonance imaging (MRI) compatibility of the OSI300 Implant to understand how it interacts with the strong magnetic fields required during imaging procedures. Comprehensive MRI testing of the implant was therefore conducted to examine the safety of magnetic resonance imaging for implanted recipients. Specifically, magnetic torque, device heating, induced vibration and image artifact was measured during 1.5 T and 3.0 T MRI scanning environments. Additionally, magnet integrity and device functionality were assessed after multiple MRI exposures.

The implant passed all functionality tests after exposure to intense magnetic gradients and radiofrequency heating.

Digital link

Cochlear has implemented digital communications technology successfully in cochlear implants for many years. The same established technology has been utilized in the OSI300 Implant, which accomplishes data transmission via a digital link.

The link also supplies the implant with power via the battery contained within the external sound processor (SP). Digital technology in the OSI300 Implant also permits two-way communication between the implant and the SP. This integral safety feature ensures that the implant is connected to the correct SP, preventing a mismatch of Implant type and SP, which is particularly important in bilateral and pediatric patients.

It is necessary to test the transmission capabilities of the digital link at various distances to ensure that optimal transmission will occur at all skin thicknesses that the implant is designed for. Forward and backwards link testing was carried out over a range of distances representing worst case performance characteristics to ensure that the digital link was functional across its intended frequencies and usage conditions.

Summary

The OSI300 Implant has been developed using long-standing company expertise to meet Cochlear's commitment to provide the industry's most reliable implantable hearing solutions.* Extensive functional and mechanical testing confirmed that the OSI300 Implant is stable, reliable, and capable of enduring the demands of handling and usage without loss of performance and integrity. Impact testing determined that the device remained functional and hermetic following impact and shock. Vibration and impact testing also confirmed that the implant remained functional when subjected to specified tests. Accelerated age testing has been used to evaluate implant functionality over a 75 year period. Furthermore, the digital link was shown to effectively transmit data with no degradation in signal quality and rigorous MRI testing confirmed that the implant passed all functionality tests following exposure to 1.5 T or 3.0 T magnetic fields. Cochlear is confident in the reliability and performance of the OSI300 Implant and is committed to publishing regular reliability updates.

* Based on implant generations released within a comparable period with 5+ years of CSP data.

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. 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.
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; https://www.iso.org/standard/60541.html [Accessed June 20 2023].
3. European consensus statement on cochlear implant failures and explantations. Otol. Neurotol. 2005;26(6):1097-109.
4. Battmer RD, Backous DD, Balkany TJ, et al. International classification of reliability for implanted cochlear implant receiver stimulators. Otol. Neurotol. 2010;31(8):1190-119.

The OSI300 implant is MRI conditional at 1.5 T and 3 T with magnet in place. Refer to Osia MRI guidelines for further information.

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.

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