EN-GB English

Cochlear™ Osia®

Important information for Osia implant recipients

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About this document

This document applies to the Cochlear™ Osia® OSI200 Implant and the Osia 2 Sound Processor. It is intended for Osia implant recipients and their carers.

Read this document carefully!

The information in this document contains important warnings and cautions relating to the device and its use. These warnings and cautions relate to:

- Implant recipient safety
- Device function
- Environmental conditions, and
- Medical treatments.

Before starting medical treatment, discuss the medical treatment warnings in this document with the recipient's physician.

Additional details on device use and care are included in the user guides and product information supplied with the device. Please read these documents carefully – they may contain additional warnings and cautions.

Symbols used in this document

NOTE

Important information or advice.

CAUTION (NO HARM)

Special care to be taken to ensure safety and effectiveness.
Could cause damage to equipment.

WARNING (HARMFUL)

Potential safety hazards and serious adverse reactions.
Could cause harm to person.

Contents

Intended use

Intended purpose

The Cochlear Osia System uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing.

The OSI200 Implant is intended to be used as part of the Cochlear Osia System to convert information from the external Sound Processor into mechanical vibrations.

Indications

The Cochlear Osia System is indicated for patients with the following conditions:

a) Conductive or Mixed hearing loss. Bone conduction thresholds with pure tone average (PTA4; mean of 0.5, 1, 2 and 4 kHz) of ≤ 55 dB HL;
b) Single-sided sensorineural deafness (SSD). Air conduction thresholds with pure tone average (PTA4; mean of 0.5, 1, 2 and 3 kHz) of ≤ 20 dB HL in the good ear.

Contraindications

The Cochlear Osia System is not suitable for individuals with:

- insufficient bone quality and quantity to support successful implant placement.
- a body weight of less than 7kg due to the potential presence of residual ethylene oxide after sterilisation of the device.

Intended patient population

The Osia System is intended for adults and children (no minimum age limit) with conductive or mixed hearing loss (up to 55 dB HL) and single-sided sensorineural deafness (SSD), with a body weight of 7kg* or more and sufficient bone quality and quantity to support successful implant placement.

Prospective OSI200 Implant recipients should be medically suitable to undergo implantation, taking into account their age, medical condition, contraindications and surgical risks. They and their families or caregivers should be well motivated and have appropriate expectations of the potential benefits of the hearing system.

NOTE

*due to the potential presence of residual ethylene oxide after sterilisation of the device.

Intended users

The intended users of the OSI200 Implant in a surgical environment are surgeons and qualified medical professionals (e.g. registered nurses).

Potential complications and adverse effects

Prospective implant recipients should be advised of the following risks:

- General risks associated with surgery and general anaesthesia.
- Osseointegration failure – potential causes for failure of osseointegration include lack of adequate bone quantity/quality, trauma, infection, generalised diseases and surgical complications.
- Other medical complications that may require additional medical treatment, such as:
  - Concurrent Cerebrospinal Fluid (CSF) leakage
  - Subdural injury
  - Subcutaneous haematoma
  - Irritation, inflammation or breakdown of the skin flap; infection; and in some cases, extrusion of the device caused by the presence of a foreign body under the skin

- Failure of device component parts (both external and internal) could result in the perception of an uncomfortably loud sound sensation, intermittent sound, or no sound.
- Partial or full failure of the device could require removal or replacement of the implant.

For implant recipients

Cochlear devices are designed to be safe and effective. However, it is also essential that you take care when using them.

This section contains warnings and cautions for safe and effective use of your device. You should also refer to your user guide for specific warnings and cautions related to the use of external components.

 WARNING

This section includes general warnings to ensure your personal safety.

Small parts hazard

Small parts and accessories could be hazardous if swallowed and could cause choking if ingested or inhaled.

Overheating

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician.

Uncomfortable sound levels

If the sound becomes uncomfortable, remove your external equipment immediately and contact your clinician.

If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left and the processor programmed for your right ear on the right.

Using the wrong processor could also affect the performance of the system.

Head trauma

Impact or injury to your head in the area of the Osia implant could damage the implant and result in its failure.

Impact to external components (e.g. sound processor) while being worn could result in damage to the device or injury.

Pressure

Do not apply continued pressure to the sound processor when in contact with the skin as this may result in pressure sores, e.g. sleeping/lying on sound processor or using tight fitting headwear.

If the magnet in the sound processor is too strong, pressure sores may develop at the implant site. If this happens or if you experience any discomfort in this area, contact your clinician.

Batteries

Batteries could be hazardous if used incorrectly. For information on safe battery use refer to your external component user guides.

Adverse environments

Operation of your Cochlear Osia System could be adversely affected in environments of high magnetic field strength and high electric field strengths, e.g. close to high power commercial radio transmitters.

Seek medical advice before entering any environment that may adversely affect the operation of your implant, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.

⚠ CAUTION

This section includes general cautions to ensure safe and effective use of your Cochlear Osia System, and to avoid causing damage to system components.

General use

Use your Cochlear Osia System only with approved devices and accessories listed in the user guide.

If you experience a significant change in performance, turn off your sound processor and contact your clinician.

Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.

No modification of external equipment is allowed. If your processor is modified or opened by anyone other than Cochlear's qualified service personnel, the product warranty is invalid.

Sound processor

Each sound processor is programmed specifically for each implant.

Your sound processor's sound quality could be intermittently distorted when you are within approximately 1.6 km (~1 mile) of a radio or television transmission tower. The effect is temporary and will not damage your processor.

Theft and metal detection systems

You could experience a distorted sound sensation when passing through or near one of these devices. Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields.

The materials used in your Osia implant may activate metal detection systems. Carry the Cochlear Patient Identification Card with you at all times.

Turn off your sound processor if near or passing through a theft and metal detection system.

Mobile telephones

Some types of digital mobile telephones, e.g. Global System for Mobile communications (GSM) as used in some countries, may interfere with the operation of your external equipment. You could perceive a distorted sound sensation when close, 1-4 m (~3-12 ft), to a digital mobile telephone in use.

Air travel

Some airlines request that passengers turn off portable electrical devices, such as laptop computers and electronic games, during take-off and landing or whenever the seat belt sign is illuminated. Your sound processor is considered to be a medical portable electronic device.

Notify airline personnel that you are using an implant system that allows you to hear. They can then alert you to safety measures, which may include the need to switch your sound processor off.

Transmitting devices such as mobile/cell phones are required to be switched off on aircraft. If you have a remote control (remote assistant) for your sound processor, switch it off before take-off. The remote control (remote assistant) transmits high frequency radio waves when switched on.

To activate flight mode:

1. Turn off your sound processor by opening the battery door.
2. Press the button and close the battery door at the same time.
3. If enabled, audio and visual signals will confirm that flight mode is activated.

To deactivate flight mode:

Turn the sound processor off and then on again (by opening and closing the battery door).

Scuba diving

The maximum diving depths when using an Osia implant is 40 m (~131 ft).

Seek medical advice before participating in a dive to ensure you do not have any conditions that might make diving contraindicated, e.g. middle ear infection.

When wearing a mask, avoid pressure over the implant site.

Do not wear the sound processor under water unless it is inside a waterproof container, such as the Osia 2 Aqua+ accessory and it has waterproof batteries.

Electromagnetic interference with medical devices

Osia sound processors meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the sound processor radiates electromagnetic energy, it is possible that it could interfere with other medical devices such as cardiac pacemakers and implantable defibrillators when used nearby.

It is recommended that you keep your sound processor at least 15 cm (~6 in.) away from devices which could be subject to electromagnetic interference. For added assurance, also consult the recommendations provided by the device manufacturer.

Electrostatic discharge (ESD)

Before engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, remove your processor. In rare cases, a discharge of static electricity can damage the electrical components of the implant system or corrupt the program in the processor.

If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), before the implant system contacts any object or person you should touch something conductive such as a metal door handle.

For parents and carers of implant recipients

 WARNING

This section includes general warnings for parents and carers of implant recipients to ensure recipient safety. Please also read the user guide, which contains specific warnings on external component use, and the information earlier in this document.

Small parts hazard

Keep small parts and accessories out of reach of children.

Small parts and accessories could be hazardous if swallowed and could cause choking if ingested or inhaled.

Strangulation

Parents and carers are advised that unsupervised use of long cables (such as the safety line) may present a risk of strangulation.

Overheating

Parents and carers should touch the processor to check for heat if the recipient is showing signs of discomfort.

Remove the processor immediately if it becomes unusually warm or hot, and seek advice from your clinician.

Uncomfortable sound levels

Carers should routinely check that the system is working at a comfortable volume level. If the sound becomes uncomfortable, remove the external equipment immediately and contact your clinician.

If the recipient has two processors (one for each ear), ensure they always wear the processor programmed for their left ear on the left and the processor programmed for their right ear on the right.

Head trauma

Young children who are developing motor skills are at greater risk of receiving an impact to the head from a hard object, e.g. table or chair.

Impact or injury to the head in the area of the Osia implant could damage the implant and result in its failure.

Impact to external components (e.g. sound processor) while being worn could result in damage to the device or injury.

Pressure

Carers should routinely check the skin over the implant site. Continued pressure to the sound processor when in contact with the skin may result in pressure sores, e.g. sleeping/lying on sound processor or using tight fitting headwear or headband.

If the magnet in the sound processor is too strong, pressure sores may develop at the implant site. If this happens contact your clinician.

For discussion with physicians of implant recipients

Having a Cochlear Osia OSI200 Implant means extra care must be taken when receiving some medical treatments. Before starting medical treatment, the information in this section should be discussed with the recipient's physician.

The sound processor must be removed before starting any of the medical treatments listed in this section.

Medical treatments generating induced currents, heat and vibration

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Before initiating any of the following treatments, deactivate the device.

WARNING

Warnings for specific treatments are provided below.

Diagnostic and therapeutic ultrasound

The implant has been designed to withstand diagnostic ultrasound. It has been tested to the following parameters:

– centre frequency: 3.5 MHz ± 0.175 MHz

– duty cycle: 20 % ± 1 %

– intensity (ISPTA) ≥ A x 1 500 mW/cm²

The sound processor must be removed and turned off during diagnostic ultrasound.

Do not expose the device to therapeutic ultrasound.

Diagnostic and therapeutic ionising radiation

The implant can be exposed to diagnostic ionising radiation (x-rays, CT scans).

The device must be turned off during exposure to ionising radiation.

Do not expose the device to a total dose greater than 70Gy of therapeutic ionizing radiation.

Electrosurgical equipment

Bipolar electrosurgical instruments can be used provided the electrodes are kept more than 1 cm from the device.

The device must be turned off while bipolar electrosurgical instruments are used near the head or neck.

Monopolar electrosurgical instruments must not be used on the head or neck after the device has been implanted.

Therapeutic or medical diathermy

Do not use therapeutic or medical diathermy on the head or neck.

Therapeutic or medical diathermy may be used below the neck.

Neurostimulation

Do not use neurostimulation over the implant.

Defibrillator

Do not place defibrillator electrodes in direct contact with the device.

Electroconvulsive therapy

Do not use electroconvulsive therapy on an implant patient under any circumstances.

Electroconvulsive therapy can cause tissue damage or damage to the implant.

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MRI safety information

The Cochlear Osia OSI200 Implant is MR Conditional.

MRI examinations can be performed safely on a person with this implanted device only under very specific conditions.

MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

- In the Cochlear Osia Magnetic Resonance Imaging (MRI) Guidelines
- By visiting www.cochlear.com/mri
- By calling your nearest Cochlear office – contact numbers are available on the back cover of this guide.

All external components of the Cochlear Osia System (e.g. sound processors, and related accessories) are MR unsafe.

The patient must remove all external components of their Cochlear Osia system before entering a room where an MRI scanner is located.

What is an MRI?

Radiologists/MR technologists are medical specialists experienced in diagnosing disease and injuries using a range of imaging techniques.

One of these imaging techniques is magnetic resonance imaging (MRI).

MRI is a diagnostic tool to obtain images of organs and tissues using a very powerful magnetic field measured in tesla (T). MR scans can range in strength from 0.2 T to 7 T.

Safety concerns for medical device implants and MRI

Due to the powerful magnetic and radio-frequency fields, medical device implants with metallic or ferromagnetic components such as pacemakers, defibrillators, catheters, pumps and Osia implants can create problems for MR scans. The risks include the potential for device repositioning, localised heating, unusual sounds or sensations, pain or injury and distortion of the MR image.

Cochlear Osia implants and MRI compatibility

To ensure MRI compatibility, Cochlear Osia implants contain a removable magnet. The magnet is easy to remove and replace if needed. In the rare case that a recipient needs serial MR scans, a non-magnetic plug is available to prevent fibrous tissue growing in the implant magnet recess.

The Cochlear Osia OSI200 Implant is approved for MR scans under specific conditions at 1.5 T with the magnet in place or removed and at 3 T with the magnet removed.

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Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

The Cochlear Osia OSI200 Implant is intended for use in the electromagnetic environments specified in this document.

Electromagnetic emissions

Emission test	Compliance	Guidance
RF emissions CISPR 11 / EN 55011, Group 1	Class A (programming mode) Class B (stand-alone mode)	The device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
RTCA DO160G: 2010, Section 21, Category M	RTCA DO160G: 2010, Section 21, Category M	
Voltage fluctuations/ flicker emissions IEC 61000-3-3 Harmonic emissions IEC 61000-3-2	Not applicable	

Table 1 Electromagnetic emissions.

Electromagnetic immunity

Immunity	Compliance	Guidance
ESD, IEC 61000-4-2	+/- 8 KV contact, +/-15 KV air discharge	Remove sound processor prior to undertaking activities that may create extreme electrostatic discharge. In rare cases, a discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the processor. If static electricity is present (for example after removing or putting on clothes, or getting out of a vehicle), before the cochlear implant system contacts any object or person, the static electricity should be discharged by touching something conductive such as a metal door handle.
Power frequencies: ISO 14708-3 / EN 45502-2-3: 50Hz and 60Hz	Test level 1200 A/m peak	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment
Radiated RF: IEC 61000-4-3, 80MHz to 2.7GHz	10 V/m	See *Warnings* and *Recommended separation distances* below
Radiated RF: EN 45502-2-3 Section 27.4	As specified in EN 45502-2-3:2010 Section 27.4	None
Magnetic field. EN45502-2-3: Section 27.3	As specified in EN 45502-2-3:2010 Section 27.3	None

Table 2 Electromagnetic immunity.

Recommended separation distances

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in.) to any part of your sound processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Your sound processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled. Keep a distance of at least 30 cm from common devices to reduce the likelihood of electromagnetic interference. Refer to Table 3 for some of the devices that can result in electromagnetic interference.

Frequency band (MHz)	Devices
380-390	Emergency Services - two-way radio
430-470	Walkie Talkie
704-787	Mobile phones on LTE network
800-960	Special two-way radio used by emergency services or in mines. Mobile phones - GSM / LTE /CDMA networks. Push-to-talk services.
1700-1990	Mobiles phones, cordless phones
2400-2570	Bluetooth devices e.g. Bluetooth speakers, Bluetooth headphones etc. Shopping centre barcode readers , RFID readers. 2.4 G Wireless modems/routers
5100-5800	5G Wireless modems/routers

Table 3 List of example devices that can result in electromagnetic interference

WARNING

Use of your sound processor adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, your sound processor and the other equipment should be observed to verify that they are operating normally.

Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on www.cochlear.com or request a copy from Cochlear at the address nearest you.

Certification and applied standards

The Osia OSI200 Implant fulfils the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as per the conformity assessment procedure in Annex 2. The year in which authorisation to affix the CE mark was granted was 2021.

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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 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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