EN-US English

# Cochlear™ Osia®

## Magnetic Resonance Imaging (MRI) Guidelines

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# About this document

This guide applies to the Cochlear™ Osia® OSI200 Implant. It is intended for:

- Specialised health care professionals who prepare and perform MR scans
- Physicians who refer a Cochlear Osia implant recipient for an MR scan
- Cochlear Osia implant recipients and/or their carers.

This guide provides information about the safe application of an MR scan on Cochlear Osia OSI200 Implant recipients.

MR scans performed under different conditions than those presented in this guide may result in severe patient injury or device malfunction.

Due to the risks associated with using MRI with an implanted medical device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or device malfunction.

This guide should be read in conjunction with the relevant documents that accompany a Cochlear Osia OSI200 Implant, such as the *Physician's Guide* and *Important information for Osia implant recipients*.
For more information, contact Cochlear by calling your regional Cochlear office – contact numbers are available on the back cover of this guide or visit www.cochlear.com/warnings.

## 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.


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# MRI safety information

In order to determine if a patient may receive an MR scan, you must first identify the patient's implant model.

After you have identified the implant model, locate the MRI safety information for that specific implant model.


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 system before entering a room where an MRI scanner is located.

## Identifying the Cochlear Osia implant

The implant model can be found on the patient's Cochlear patient identification card.

If the patient does not have their patient identification card with them, the implant type and model can be identified without surgical intervention using X-ray or the Cochlear Osia fitting software.

## X-ray information

Cochlear Osia OSI200 Implants are made of metal and implanted under the skin behind the ear. Using an X-ray, the implant can be identified by its shape and the shape of the actuator unit.

Use the Fig. 1 and the Fig. 2 to assist with identifying the differences between Cochlear Osia implant models when using an X-ray.

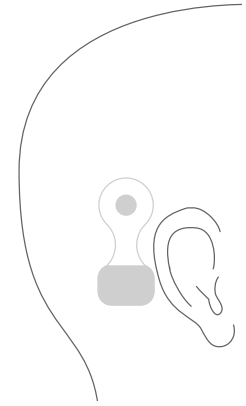

**Fig. 1** Approximate location of the OSI200 Implant


Skin side Bone side

**Fig. 2** OSI200 Implant (P1170466)


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# MRI safety information for Osia OSI200 Implant with BI300 Implant


Non-clinical testing has demonstrated that the Osia OSI200 Implant, in combination with the BI300 Implant, are MRI Conditional. Patients can be scanned at 1.5 T and 3 T only if the magnet has been removed. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

## 1.5 T scans

- Surgically remove the implant magnet before MR scans at 1.5 T. See OSI200 Implant Physician's Guide for additional information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of 3.2 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

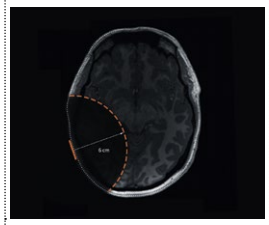
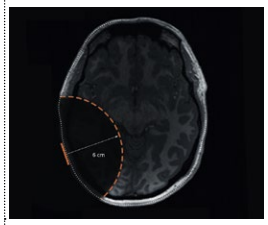
| Non-Magnetic Plug | No Magnet |
|---|---|
|  |  |
| 6 cm (2.4 in) | 6 cm (2.3 in) |

**Table 1** Maximum image artefact from centre at 1.5 T (gradient echo sequence).

## 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T. See *OSI200 Implant Physician's Guide* for additional information.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of 3.2 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg.

Scans must be performed in circular polarization mode.

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

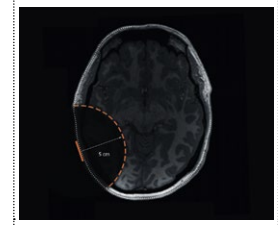
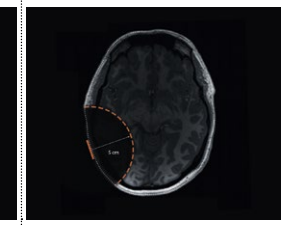
| Non-Magnetic Plug | No Magnet |
|---|---|
|  |  |
| 5 cm (2 in) | 5 cm (2 in) |

**Table 2** Maximum image artefact from centre at 3 T (gradient echo sequence).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# Preparation prior to an MRI examination

## Cooperation between specialists

Preparing for and conducting an MRI examination for implant recipients requires cooperation between a specialist for the device and/or Osia implant physician, referring physician and radiologist/MR technologist.

### Cochlear Osia implant device specialist

Knows the implant type and where to find the correct MR parameters for the implant.

### Referring physician

Knows the location of the MR scan and diagnostic information required.

### Cochlear Osia implant physician

Surgically removes the implant magnet and replaces it with a new sterile replacement implant magnet.

### Radiologist/MR technologist

Sets up the MR scan using the correct MR parameters and counsels the implant recipient during the MRI examination.

## Considerations for implant magnet removal

Close coordination is required between the specialists to perform the implant magnet removal, MR scan, and subsequent implant magnet replacement. For details on implant magnet removal, please refer to the *OSI200 Implant Physician's Guide* supplied with the system.

For implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the non-magnetic plug prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

While the implant magnet is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the non-magnetic plug is removed and replaced by a new sterile replacement implant magnet.

The sterile non-magnetic plug and sterile replacement magnet are supplied separately in sterile packs. Both are single-use items.


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# Considerations for conducting an MRI examination

These guidelines are specific to Cochlear Osia implants and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility.

## Prerequisites

The following additional conditions must be met:

- The implant model has been identified.
- The implant magnet has been surgically removed when the referring physician has prescribed that the MR scan be performed with the implant magnet removed.

### Patient positioning

The patient should be positioned prior to entering the MRI machine. The patient should be placed in the supine position (lying flat on back, face upward), with their head aligned with the bore axis of the MRI machine.

The patient should be advised to lie as still as possible and to not move their head during the MR scan.

**⚠ CAUTION**

- Ensure that the patient does not move more than 15 degrees (15°) from the centreline (Z-axis) of the bore during the MR scan.
- Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain.

**⚠ CAUTION**

Explain to the patient that they may perceive sounds during the MR scan. The sound levels are not hazardous.

### Perform the MR scan

The MR scan must be performed using the MRI safety information identified for the patient's implant model.

### Performing an MR Scan on other body locations

When an implant recipient requires an MRI on a location of their body away from the implant site, you must still follow the MRI safety information for the recipient's implant model. See Implant model identification and related *MRI safety information* on page 6.

# Considerations for referring physicians

If you are a physician referring a Cochlear Osia implant recipient for an MR scan, it is essential that you consider the following:

- Understand and inform the patient of the risks associated with MRI. See ***Risks associated with MRI and Cochlear Osia implants*** on page 17.
- Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination.
- Identify if the patient has any other medical device implants, active or abandoned. If another implant is present, verify MRI compatibility before conducting an MRI procedure. If MRI guidelines for specific devices are not followed potential risks include: movement or damage to the device, weakening of the implant magnet and uncomfortable sensation or skin/tissue trauma for the patient.
- The Cochlear Osia implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.
- *See MRI safety information for Osia OSI200 Implant with BI300 Implant* on page 6.

### Consider the following:

- Timing of the implant surgery and MRI exposure.
- Age and general health of the implant recipient and time to recover from the implant magnet surgery or potential trauma.
- Existing or potential for tissue scarring in the location of the implant magnet.
- When the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MR scan.


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# Risks associated with MRI and Cochlear Osia implants

The potential risks of performing MRI examinations on patients with Cochlear Osia implants include:

### Damage to the device

MRI exposure beyond the values contained in these guidelines may cause damage to the device.

### Uncomfortable sensation

MRI exposure beyond the values contained in these guidelines may result in the patient perceiving sound or noise and/or pain.

### Implant heating

Use the recommended SAR values contained in these guidelines to ensure the implant does not heat beyond safe levels.

### Image artefact

The Cochlear Osia implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.

## Labelling symbols

The following symbols may appear on the product, the components and/or the packaging.

| | | | |
|---|---|---|---|
|  | Refer to instruction manual |  | Keep dry |
|  | Specific warnings or precautions associated with the device, which are not otherwise found on the label |  | Do not re-use |
|  | Manufacturer |  | Do not use if package is damaged |
|  | Date of manufacture | Rx Only | By prescription |
|  | Catalogue number |  | MR Conditional |
|  | Authorised representative in the European Community |  | MR Unsafe |


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