

# Cochlear<sup>™</sup> Osia<sup>®</sup> OSI200 Implant MRI Safety Checklist

This form guides you through the critical aspects of performing an MR scan safely for patients with an Osia OSI200 Implant. Before using this form, review the Cochlear<sup>™</sup> Osia<sup>®</sup> OSI200 Implant Magnetic Resonance Imaging (MRI) Guidelines, available on the website: [www.cochlear.com/mri](http://www.cochlear.com/mri)

Ensure the implant site has healed before an MR scan is performed. The implant physician should be consulted if there are any concerns.

Follow these steps prior to inviting the patient into the MRI room and before performing the MR scan.

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**1** Identify and record the Cochlear Osia implant model using the patient identification card, X-ray or surgical/clinical notes in the spaces provided.

- Implant model number for left ear: .....
- Implant model number for right ear: .....

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**2** Determine if implant magnet removal is required, or if the Cochlear Osia MRI Kit (bandage and splint) is necessary.

- Implant magnet removal may be necessary to reduce the artefact. Refer to the MRI Guidelines for artefact sizes. Metal Artefact Reduction Sequence (MARS) is recommended for optimal results.
- Implant magnet removal may be mandatory at certain field strengths for specific implant types. Refer to **Table 2: MRI safety information and recommended SAR limits**.
- Implant magnet removal may be avoided at certain field strengths with use of the Cochlear Osia MRI Kit. The intent of the Cochlear Osia MRI Kit is to provide pressure over the implant magnet – not the implant body. Refer to **Table 2: MRI safety information and recommended SAR limits**.



**NOTE:** If there is no implant magnet present, then the Cochlear Osia MRI Kit is not required.

**Circle the applicable option:**

Implant magnet will be in place for scan /  
Implant magnet will not be in place for scan

**Circle the applicable option:**

Cochlear Osia MRI Kit is required for scan /  
Cochlear Osia MRI Kit is not required for scan

**3** Record the MR parameters and transmit coil to be used for this scan in the spaces provided.

- MRI field strength: .....
- Maximum spatial gradient the patient will encounter entering the MRI bore: .....

**Circle the applicable coil to be used:**

Whole body coil / Head coil / Other local cylindrical transmit coil

**4** Identify and record the SAR limit and maximum allowable spatial gradient for the implant type and MRI RF transmit coil in the spaces provided. Refer to **Table 1.** and **Table 2.** If bilaterally implanted, a patient may have two different implant types. Comply with the lowest SAR limit and lowest allowable spatial gradient of the two devices.

- Lowest SAR limit for implant types and scan conditions:

.....

- Lowest maximum spatial gradient for implant types:

.....

**5** Counsel the patient on sensations and risks.

- If the implant magnet is present, explain to the patient that they may sense the implant magnet moving. The Cochlear Osia MRI Kit will reduce the likelihood of the implant magnet moving. However, they may still sense resistance to movement as pressure on the skin. The sensation will be similar to pressing down firmly on the skin with the thumb.
- Refer to the MRI Guidelines for a complete list of Warnings and Cautions.

**6** Remove the sound processor and any accessories before entering the MRI scan room.

The sound processor is MR Unsafe.



**NOTE:** The patient may no longer be able to hear instructions with the sound processor removed.

**7** Prior to entering the MRI room, apply the Cochlear Osia MRI Kit, if identified as required in step 2.

- Ensure you have the contents of the Cochlear Osia MRI Kit available and within easy reach.
- Contents include: Two (2) magnetic splints and one (1) self-adherent compression bandage.
- Full instructions are supplied with every Cochlear Osia MRI Kit, and are also listed in the **MRI Guidelines.**
- Apply the splint and bandage to the implant site or sites in accordance with the information in **Table 2.**

**8** Comply with patient positioning requirements.

- For safety, the patient should be in a supine position (lying flat on back, face upward) prior to entering the MRI bore.
- Align the patient's head with the bore axis of the MRI machine (max 15° deviation allowed from the z-axis).
- Advise the patient to lie as still as possible and to not move their head during the MR scan.
- Correct patient positioning prior to the MR scan will minimise discomfort and reduce the risk of implant magnet demagnetisation.

## Scan conditions and SAR limits

- The following MRI safety information only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.
- MR scans at 3 T must be performed in quadrature mode or CP mode for the radio frequency (RF) transmit coil.
- Using a multichannel mode may result in localised heating above safe levels.
- Maximum active scan time of 60 minutes with the SAR limits in **Table 2** below.
- The SAR limit depends on the selection of MRI RF transmit coil. Refer to the Specific conditions for RF transmit coil in **Table 1** below.

RF transmit coil	Specific Conditions
Main scanner body coil	<ul style="list-style-type: none"> <li>• Keep local planar (flat linearly polarised) receive only RF coils more than 10 cm away from implant.</li> <li>• Local cylindrical RF receive only coils can be placed anywhere, with respect to the implant.</li> <li>• Comply with the Whole Body Average SAR limit for the relevant implant type, field strength and landmark location (see Table 2).</li> </ul>
Local transmit/ receive coil - head	<ul style="list-style-type: none"> <li>• Comply with the head SAR limit for the relevant implant model and field strength (see Table 2).</li> </ul>
Local transmit/ receive coil – not head coil (e.g. knee)	<ul style="list-style-type: none"> <li>• Ensure distance between coil and implant is greater than the coil radius.</li> <li>• There are no added SAR restrictions due to the presence of the implant. Limit SAR as you would for a typical patient who does not have an implantable device.</li> </ul>

**Table 1: Specific conditions for RF transmit coil**

Implant type	MRI field strength (T)	Remove implant magnet Yes/No	Cochlear Osia MRI Kit required Yes/No	Maximum allowable spatial gradient field (T/m)	Head average SAR limit (W/kg) Using transmit / receive head coil	Whole body average SAR limit (W/kg) Using transmit body coil
Osia OSI200 Implant	1.5	No	Yes	20	<3.2	<2
	3	Yes	No			

**Table 2: MRI safety information and recommended SAR limits for Osia OSI200 Implant.**

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As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 600,000 implantable devices, helping 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 innovative future technologies. We collaborate with leading clinical, research and support networks.

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

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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.

The content of this checklist is intended as a guide for information purposes only and does not replace or remove clinical judgment or the professional care and duty necessary for each specific recipient case. The information has been prepared with reference to the best information available at the time of preparation. However, no assurance is given that the information is entirely complete or accurate in every respect. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

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