

# Cochlear<sup>™</sup> Osia<sup>®</sup>

## MRI Safety Checklist

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

Ensure the implant site has healed before an MRI 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 MRI scan.

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

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

**2** Determine if implant magnet removal is required, or if a Cochlear Osia MRI Kit is necessary.

- 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 necessary to reduce the artefact. Refer to the **MRI Guidelines** for artefact sizes. Metal Artefact Reduction Sequences (MARS) are recommended for optimal results.
- Implant magnet removal may be avoided at certain field strengths with use of a Cochlear Osia MRI Kit. The intent of an 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 an 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:**

MRI Kit is required for scan   /   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 transmit 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.**



**Note:** If bilaterally implanted, a patient may have two different hearing implant types. Comply with the lowest SAR limit and the lowest allowable spatial gradient of the two devices.

- Lowest SAR limit for recipient's implant types and scan conditions:

.....

- Lowest maximum spatial gradient for recipient's implant types:

.....

5 Counsel the patient on sensations and risks.

- For patients where an implant magnet is in place, explain that they might feel the implant magnet moving slightly and might sense resistance to movement as pressure on the skin.
- For devices which require an MRI Kit, the MRI Kit will reduce the likelihood of the implant magnet moving. 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 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 MRI Kit if determined it is required in step 2.

- Ensure you have the contents of the MRI Kit available and within easy reach.
- Full instructions are supplied with MRI Kits, or are listed in the **MRI Guidelines**.
- Apply the MRI Kit contents 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 with 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 MRI scan.
- Correctly position the patient prior to the MRI scan to minimise discomfort and reduce the risk of implant magnet demagnetisation.

## Scan conditions and SAR limits

- The MRI safety information in the tables below only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field.
- MRI 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>• 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 and field strength (see <b>Table 2</b>).</li> </ul>
Transmit/receive head coil	<ul style="list-style-type: none"> <li>• Comply with the head SAR limit for the relevant implant model and field strength (see <b>Table 2</b>).</li> </ul>
Other local transmit/receive coils (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	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 OSI100 Implant	1.5	No	Yes	20	<3.2	<2
	3	Yes	No			
Osia OSI200 Implant	1.5	No	Yes	20	<3.2	<2
	3	Yes	No			
Osia OSI300 Implant	1.5	No	No	20	<3.2	<2
	3	No	No			


**Table 2: MRI safety information and recommended SAR limits**


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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 700,000 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.


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- advise recipients of their choice and ensure informed consent is obtained prior to delivering care
- provide care within scope of practice, meet all legislative requirements and maintain standards of professional conduct
- apply standard precautions, and additional precautions as necessary, when delivering care
- document all care in accordance with mandatory and local requirements.

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