FOR PROFESSIONALS

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Cochlear™ Osia® MRI Safety Checklist

This form guides you through the critical aspects of performing an MR scan safely for patients with a Cochlear™ Osia® Implant. Before using this form, review the Osia Magnetic Resonance Imaging (MRI) Guidelines, available on the website: **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.

☐ **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: .....

☐ **2** Determine if implant magnet removal is required, or if the Cochlear 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 Sequence (MARS) is recommended for optimal results.
- Implant magnet removal may be avoided at certain field strengths with use of the Cochlear 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 coil to be used:

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

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☐ **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 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.

- For patients where an implant magnet is in place, explain to the patient that they may sense the implant magnet moving. The 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 MRI Kit, if identified as 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 also 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, 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.
- Correctly patient positioning prior to the MR scan will 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.
- 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	• Local cylindrical RF receive only coils can be placed anywhere, with respect to the implant. • Comply with the Whole Body Average SAR limit for the relevant implant type, field. strength and landmark location (see Table 2).
Transmit/receive head coil	• Comply with the head SAR limit for the relevant implant model and field strength (see Table 2).
Other local transmit/receive coils (e.g. knee)	• Ensure distance between coil and implant is greater than the coil radius. • 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.

Table 1: Specific conditions for RF transmit coil

Implant type	MRI field strength (T)	Remove implant magnet Yes/No	Cochlear 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			

Table 2: MRI safety information and recommended SAR limits

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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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