EN-CA 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.

Contents

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.

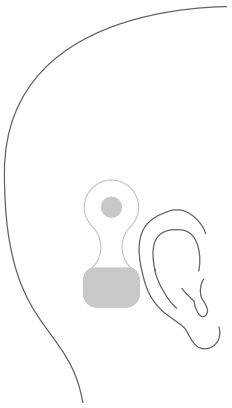


Fig. 1 Approximate location of the OSI200 Implant

Skin side Bone side

Fig. 2 OSI200 Implant (P1170466)

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 with the magnet in place or removed. Patients can be scanned at 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

- Remove the sound processor before entering the MRI scan room. The sound processor is MR unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus® Implant Bandage and Splint Kit* for MRI (MRI Kit) on page 12.
- Static magnetic field of 1.5 T.
- 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:

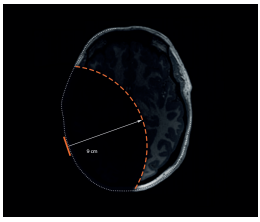
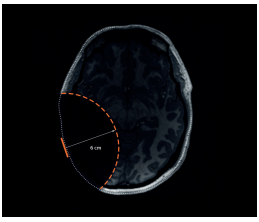
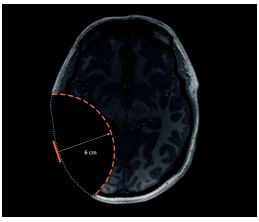
Magnet	Non-Magnetic Plug	No Magnet
		
9 cm (3.7 in)	6 cm (2.4 in)	6 cm (2.3 in)

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:

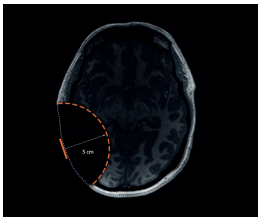
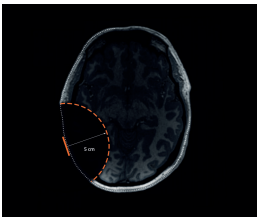
Non-Magnetic Plug	No Magnet
	
5 cm (2 in)	5 cm (2 in)

Table 2 Maximum image artefact from centre at 3 T (gradient echo sequence).

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, and makes a decision on whether the implant magnet needs to be removed for the MRI examination.

Cochlear Osia implant physician

Surgically removes the implant magnet and replaces it with a new sterile replacement implant magnet, if the referring physician has requested the implant magnet be removed.

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

If the implant magnet needs to be removed prior to an MRI examination, 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.

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 if the referring physician has prescribed that the MR scan be performed with the implant magnet removed.
- The Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) is required for MR scans at 1.5 T with the implant magnet in place. See *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 12 for instructions on how to apply the MRI Kit prior to the MR scan.

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.

Patient comfort

Explain to the patient that 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.

If the patient experiences pain, verify the correct appliance of the MRI kit and/or consult the patient's physician to determine if the implant magnet should be removed or any other precautions.

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.

Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)

Intended use

The MRI Kit is intended to be used on Cochlear Osia implant recipients to prevent implant magnet dislodgement during MR scans at 1.5 T.

The MRI Kit is intended for use with Cochlear Osia implants and the following Cochlear Nucleus implants:

- CI500 Series – CI512, CI522, CI532 and ABI541
- CI24RE Series – CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)

Contraindications

There are no contraindications for the MRI Kit.

Obtaining an MRI Kit

Contact the nearest Cochlear office or official distributor to order an MRI Kit.

The MRI Kit contains:

Item	Description
Flat-plastic splints	To be placed against the skin over the implant magnet site.
Elasticised compression bandage	For securing the splint against the implant magnet site.
Surgical tape	For securing the bandage and splint in place.

Fig. 3 Content of MRI Kit

Using the MRI Kit

Follow this procedure to use the MRI Kit. When used as instructed, the supplied splint and bandage should reduce the likelihood of magnet movement when in or near the MRI scanner.

1. Preparation

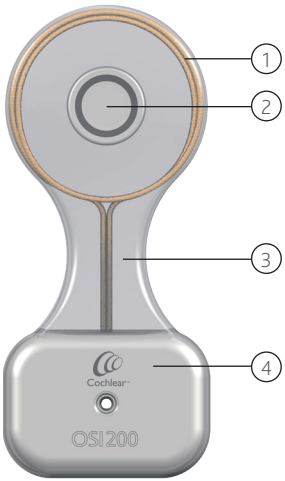
1. Prior to entering the MRI room and before removing the sound processor, mark on the patient's head an outline of the sound processor. Once the sound processor has been removed from the head, mark on the patient's head the centre position of the sound processor magnet. If necessary, shave the patient's head at the sound processor magnet location so this marking is more visible and easier to locate during the splinting process. This marking is essential to ensure that the splint is placed in the correct location.
2. In the event that the location of the implant has not been marked, it can be located by:
   - Using ferromagnetic material, such as a paper clip – the material will be attracted to the implant magnet

     WARNING

     The ferromagnetic material must be removed before entering the MRI room.

   - Touch - gently feel around the implant site to locate the position of the implant coil. The implant is comprised of the round implant coil, the waist and the actuator (Fig 4).

The implant magnet will be at the centre of the implant coil. For further explanation of the prevailing implant see X-ray information for Cochlear Osia implants section.



1 Coil
2 Removable magnet
3 Waist
4 Actuator

Fig. 4 OSI200 Implant (P1170466)

NOTE

The intent of the splint is to provide pressure over the implant magnet – not the actuator.

2. Bandaging

1. Use a splint from the MRI Kit and centre it over the implant magnet site (as marked) against the skin. Ensure the splint is held in place over the implant magnet. You may need the assistance of another person to hold the splint in place while you bandage. Otherwise, use the supplied tape to maintain the splint position prior to bandaging.

2. Use the elasticised compression bandage from the MRI Kit and ensure the centre line of the bandage is over the implant magnet site and the splint is fully covered. *See Figure 5.*

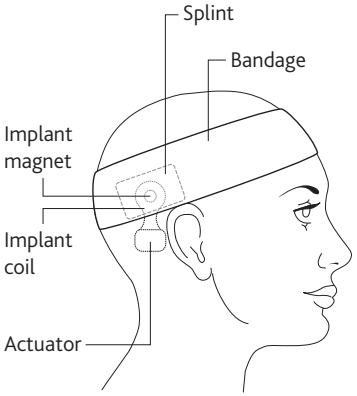


Fig. 5 Fitting the MRI Kit splint and compression bandage.
Position the splint over the implant magnet site and then apply the bandage over the centre of the splint and the centre of the implant magnet site.

3. Use a minimum of two bandage layers at full stretch (no elasticity remaining in the bandage). When the bandage is at its maximum tightness, the small rectangular tension markers will stretch to become square in shape. *See Figure 6.*
4. Use the surgical tape from the MRI Kit to secure the bandage by wrapping two surgical tape layers around the head, over the bandage centre line. Ensure the tape ends overlap.
5. Conduct the MR scan.

6. Once the MR scan is complete, follow the instructions in *Considerations after an MRI examination* on page 17.

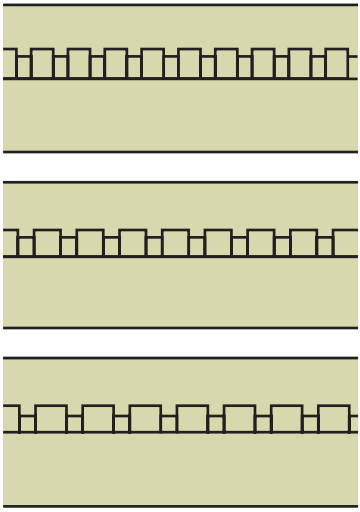


Fig. 6 Comparison of compression bandage tightness

Considerations after an MRI examination

With the implant magnet in place

Remove the MRI Kit bandage and splint.

After the patient leaves the MRI room, ask the patient to place the sound processor on their head and turn it on. Confirm that the placement of the sound processor is correct and that there is no discomfort and sound is perceived as normal. If there is discomfort or a change in sound perception, or problems with the placement of the sound processor coil, ask the patient to seek assistance from their clinician as soon as possible.

With the implant magnet removed

See ***Considerations for implant magnet removal*** on page 9.

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:

- If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.
- 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.
- If 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.
- If the implant magnet is retained for an MR scan at 1.5 T, a Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) must be obtained beforehand for use during the MR scan. See *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 11.

Risks associated with MRI and Cochlear Osia implants

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

Device movement

The implant magnet or device may move out of position during an MRI examination due to vibration, force or torque causing skin/tissue trauma.

Damage to the device

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

Weakening of implant magnet

Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to a weakening of the implant magnet.

Incorrect patient positioning prior to the MR scan or head movement during the scan may result in implant demagnetisation.

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.

If inspecting near the implant, removal of the implant magnet should be considered as MR image quality may be compromised with it in place.

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
	CE registration mark with notified body number		

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This content is meant for professional use. If you are a consumer, please seek advice from your medical practitioner or health professional about treatments for hearing loss. They will be able to advise you on a suitable solution for your hearing loss condition. All products should be used only as directed by your medical practitioner or health professional. Not all products are available in all countries. Please contact your local Cochlear representative.

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