EN-US English

Cochlear®

Cochlear™ Osia®

Magnetic Resonance Imaging (MRI) Guidelines

FOR PROFESSIONALS

About this guide

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

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

This guide provides information about the safe application of an MRI scan on Cochlear Osia implant recipients.
MRI 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 implant, such as the ***Physician's Guide*** and ***Important information for Osia System recipients***.
For more information, visit www.cochlear.us/mri or contact your regional Cochlear office. Contact numbers are available on the back cover of these guidelines.

Symbols used in this guide

	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

Preparation prior to an MRI examination

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

Non-clinical testing has demonstrated that the Cochlear Osia implants, in combination with the BI300 Implant, are MR Conditional. A patient with a Cochlear Osia implant can be safely scanned under the conditions described in this document. Failure to follow these conditions may result in injury to the patient.

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 or 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 MRI scan and diagnostic information required, and makes a decision on whether the implant magnet or magnet cassette needs to be removed for the MRI examination. Confers with the Osia implant physician regarding the considerations listed in ***"Determine eligibility for MRI"*** on ***page 5***.

Cochlear Osia implant physician

If requested by the referring physician, surgically removes the implant magnet or magnet cassette and replaces with a non-magnetic plug or a non-magnetic cassette. After the MRI scan, the implant physician replaces it with a new sterile replacement magnet or magnet cassette.

Radiologist or MR technologist

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

Determine eligibility for MRI

If you are a physician referring a Cochlear Osia implant recipient for an MRI 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 7***.
  Also consider:
  - Timing of the implant surgery and MRI exposure, to allow healing of the tissue surrounding the implant.
  - Age and general health of the implant recipient and time to recover from the implant magnet or magnet cassette surgery or potential trauma.
  - Existing or potential for tissue scarring in the location of the implant magnet or magnet cassette.

- Understand the conditions for an MRI scan and ensure that there is a clear indication for the MRI examination. See ***"Performing MRI safely"*** on ***page 16***.
- The Cochlear Osia implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant artefact dimension tables in the section ***"Image interference and artefacts"*** on ***page 23***.
- 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 examination. If MRI safety information for the implanted devices are not followed potential risks include:
  - movement or damage to the device
  - weakening of the implant magnet or magnet cassette
  - uncomfortable sensation for the patient
  - skin or tissue trauma for the patient

- Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning, and there is no increased heating risk to the Cochlear Osia implants.
- For MRI scans at 1.5 T or 3 T, identify if the implant magnet or magnet cassette needs to be removed. See ***"Implant magnet and magnet cassette conditions for MRI"*** on ***page 16.***
- If the implant magnet or magnet cassette needs to be removed, refer the patient to an appropriate physician to arrange for the magnet or magnet cassette to be removed before the MRI scan.
- If the implant magnet is retained for an MRI scan at 1.5 T, an MRI Kit must be obtained beforehand for use during the MRI scan, except for the OSI300 Implant. Contact the nearest Cochlear office or official distributor to order an MRI Kit.

Risks associated with MRI and Cochlear Osia implants

The potential risks of performing MRI examinations on patients with Cochlear Osia implants if the MRI safety information is not followed include:

Device movement

Scanning outside of the parameters contained in these guidelines may lead to the implant magnet or device moving out of position during an MRI examination causing skin or tissue trauma.

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 implants 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 or magnet cassette should be considered as MR image quality may be compromised with it in place.

Considerations for implant magnet removal

See ***"Implant magnet and magnet cassette conditions for MRI"*** on ***page 16***.

Clinicians and recipients should weigh the benefits and risks of completing an MRI scan at 1.5 T and choose one course of action:

1. Keep the magnet in place and use an MRI Kit (except for OSI300 Implants).
2. Remove the implant magnet and replace it via surgical procedures.
3. Do not perform the MRI scan.

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, MRI scan, and subsequent implant magnet replacement.

For details on implant magnet removal, please refer to the ***OSI200 Implant Physician's Guide*** or the ***OSI300 Implant Physician's Guide*** supplied with the system.

Note

While the magnet or magnet cassette is removed, the recipient may wear a Cochlear Disk Retainer to hold their sound processor in place. Disk retainers are available from Cochlear.

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

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

OSI300 Implant

For OSI300 Implant recipients, if single or multiple MRI examinations on the head are needed with the magnet cassette removed, the magnet cassette must be replaced (in a sterile surgical environment) with a non-magnetic cassette. In the magnet's absence, the non-magnetic cassette prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

⚠ Warning

To prevent infection, do not leave the magnet pocket empty (for OSI300 Implants). When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

OSI200 Implant and OSI100 Implant

For recipients (other than OSI300 Implant recipients) , if single or multiple MRI examinations on the head are needed with the magnet removed, 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.

⚠ Warning

To prevent infection, do not leave the magnet pocket empty. When removing the magnet, replace the magnet with a non-magnetic plug.

⚠ Caution

Non-magnetic plugs for OSI200 Implants are a different size to non-magnetic plugs for OSI100 Implants. Ensure the correct plug is used.

With the non-magnetic cassette or non-magnetic plug in place, MRI scans can be done both at 1.5 T and 3 T without the need for bandaging or use of an MRI Kit.

Considerations for implant magnet in place

The information below is being provided to ensure an appropriate treatment decision can be made.

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 MRI scan or head movement during the scan may result in implant magnet demagnetisation.

Usability of Cochlear Osia MRI Kit

The Cochlear Osia MRI Kit is intended for use with the OSI200 Implant and the OSI100 Implant with magnet in place at 1.5 T.
Cochlear conducted usability testing on the Cochlear Osia MRI Kit with chinstrap, including associated accompanying documentation. Test results showed that the MRI Kit and accompanying documentation protects users from committing potentially harmful use errors that could lead to patient harm or suboptimal therapy.

⚠ Warning

To minimise possible pain and discomfort, apply the items contained in the MRI Kit immediately prior to entering the MRI room.
Ensure the recipient has left the MRI room, and the MRI procedure is complete, before removing the bandage, splints, and chinstrap.
If a splint becomes loose inside the MRI room, this could lead to MRI equipment damage, and/or could cause injury to the MRI staff or recipient.

⚠ Warning

Do not conduct the MRI scan if the splint does not stay in place.
Misalignment between the splint and implant magnet may result in the dislodgement of the implant magnet and could cause pain or result in explantation.

Preparation for conducting the MRI examination

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 Cochlear Osia System before entering a room where an MRI scanner is located.

Confirm the following prior to scanning:

- The implant model has been identified. See ***"Identifying the Cochlear Osia implants"*** on ***page 14***.
- For additional information for bilateral recipients, see ***"Bilateral recipients"*** on ***page 12***.
- For MRI scans on a body location away from the implant site, MRI safety information for the recipient's implant model must still be followed. See ***"Performing an MRI scan on other body locations"*** on ***page 12***.
- If the referring physician has prescribed that the MRI scan be performed without the implant magnet or magnet cassette, confirm that the implant magnet or magnet cassette has been surgically removed.
- If the implant magnet is retained for an MRI scan at 1.5 T, an MRI Kit must be obtained beforehand for use during the MRI scan, except for OSI300 Implants. Contact the nearest Cochlear office or official distributor to order an MRI Kit.
- See ***"Implant magnet and magnet cassette conditions for MRI"*** on ***page 16*** for details on performing an MRI examination safely. For all implants other than OSI300, please also refer to the section *Using the MRI Kit* of the *Cochlear Osia MRI Kit User Guide* provided with the MRI Kit.
- Discuss the sensations the recipient may experience during the MRI scan. See ***"Patient comfort"*** on ***page 12***.
- Explain to the patient how they will be positioned for the MRI scan. See ***"Patient positioning"*** on ***page 13***.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.

Note

Once the sound processor has been removed, the patient may no longer be able to hear.

- Position the patient to minimise discomfort. See ***"Patient positioning"*** on ***page 13***.
- Comply with the ***"Scan conditions and SAR limits"*** on ***page 16***.

Bilateral recipients

⚠ **Caution**

If one of the implants is a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

If a bilateral recipient has a cochlear implant model (other than the CI22M cochlear implant without a removable magnet), read the MRI safety information for each implant model relevant to the recipient. Use the MRI safety information of the recipient's implant model with the most restrictive MRI exposure requirements.

Performing an MRI 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 ***"Identifying the Cochlear Osia implants"*** on ***page 14*** and related ***"Performing MRI safely"*** on ***page 16***.

Patient comfort

For patients where an implant magnet or magnet cassette is in place, explain that they might feel the implant magnet moving slightly and might sense resistance to movement as pressure on the skin. To minimise risk of discomfort, follow the instructions in the section ***"Patient positioning"*** on ***page 13***.

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.

⚠ **Warning**

To minimise possible pain and discomfort, apply the items contained in the MRI Kit immediately prior to entering the MRI room.

If the patient experiences pain, consult the patient's physician to determine if the implant magnet or magnet cassette should be removed or if a local anaesthetic may be applied to reduce discomfort.

⚠ **Caution**

If administering local anaesthetic, take care not to perforate the implant silicone.

In addition, explain to the patient that they may perceive sounds during the MRI scan.

Patient positioning

For safety and comfort, 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. Advise the patient to lie as still as possible and to not move their head during the MRI scan.

Best practise for minimising risk of discomfort:

- Where possible, the patient should enter the scanner feet-first.
- If a detachable MRI table is available, position the patient on the table outside the MRI room. Make sure the patient is comfortable and immobilized in their scanning position before wheeling into the room.
- If scanning head-first, avoid any head movement (pitching or rolling) near the bore entry and within the bore.
    - Place head pillows or supports as far away from the bore entry as practical.
    - Position the patient and immobilize before moving the table into the bore.

⚠ **Caution**

When scanning with the implant magnet or magnet cassette in place, ensure that the patient does not move more than 15 degrees (15°) from the centreline (Z-axis) of the bore during the MRI scan.

Failure to position the patient correctly prior to the MRI scan may result in increased torque on the implant and cause pain, or may cause demagnetisation of the implant magnet.

Identifying the Cochlear Osia implants

The implant model can be found on the patient's Cochlear patient implant card. If the patient does not have their patient implant card with them, the implant type and model can be identified without surgical intervention. See ***"X-ray guidelines"*** and ***"X-ray information for identification of Cochlear Osia implants"*** below.

X-ray guidelines

Lateral X-ray at 70 kV/ 3 mAs provides sufficient contrast to identify the implant.
A modified Stenver's view is not recommended for implant identification as implants may appear oblique. Imaging should include an unobstructed view of antenna coils and implant bodies.
Bilateral recipients may have different implant models on either side of the head. A lateral skull X-ray with a 15 degree cranial tube angle will offset the implants in the image, enabling identifying features to be distinguished.

X-ray information for identification of Cochlear Osia implants

Cochlear Osia implants are made of metal and are implanted under the skin behind the ear.
Use the ***Fig.1***–***Fig.6*** to assist with identifying Cochlear Osia implants when using an X-ray.

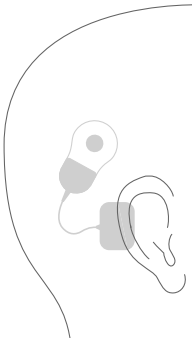


Fig.1: Approximate location of the OSI100 Implant

Fig.2: OSI100 Implant

OSI300 Implants can be distinguished from OSI200 Implants by the three holes adjacent to the magnet. See ***Fig.4*** and ***Fig.6***.

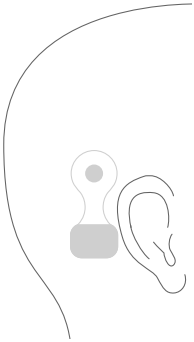


Fig.3: Approximate location of the OSI200 Implant

Fig.4: OSI200 Implant

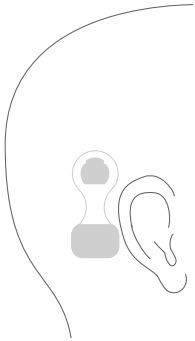


Fig.5: Approximate location of the OSI300 Implant

Fig.6: OSI300 Implant

Performing MRI safely

Implant magnet and magnet cassette conditions for MRI

For some implant models and MRI field strengths, bandaging with an MRI Kit is required, or the implant magnet or magnet cassette needs to be surgically removed.

Head bandaging is not required for OSI300 Implants, even with a magnet cassette in place, at 1.5 T or 3 T. Unnecessary use of a head bandage or splint with OSI300 Implants will apply undue pressure and may increase patient discomfort.

Refer to the table below for information on each Osia implant model.

Implant type	MRI field strength (T)	Required to remove magnet or magnet cassette Yes/No	MRI Kit required Yes/No
Osia OSI100 Implant	1.5	No	Yes
	3	Yes	No
Osia OSI200 Implant	1.5	No	Yes
	3	Yes	No
Osia OSI300 Implant	1.5	No	No
	3	No	No

Table 1: Implant magnet and magnet cassette conditions for MRI.

Scan conditions and SAR limits

A patient with one or two of these implants can be safely scanned in an MR system meeting scan conditions and SAR limits on the following pages.

Bilateral recipients may have two different implant models. For additional information, see ***"Bilateral recipients"*** on ***page 12***.

Failure to follow these conditions, and other restrictions in this guide, may result in injury.

Scan conditions and SAR limits for the OSI100 Implant

Parameter	Condition
Device name	OSI100 Implant
Static magnetic field strength (B_0)	1.5 T and 3 T
Device configuration	• **1.5 T** Use an MRI Kit for MRI scans at 1.5 T with the implant magnet in place. See ***"Table 1: Implant magnet and magnet cassette conditions for MRI."*** on ***page 16***. • **3 T** Surgically remove the implant magnet before MRI scans at 3 T. See ***"Table 1: Implant magnet and magnet cassette conditions for MRI."*** on ***page 16***. See also the OSI100 Implant Physician's Guide for additional information on the surgical procedure. • See ***"Patient positioning"*** on ***page 13*** for orientation information.
Patient preparation	• Counsel the patient prior to scanning: - Discuss the sensations the recipient may experience during the MRI scan. See ***"Patient comfort"*** on ***page 12***. - Explain to the patient how they will be positioned for the MRI scan. See ***"Patient positioning"*** on ***page 13***. • Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe. **Note** Once the sound processor has been removed, the patient may no longer be able to hear. • Position the patient to minimise discomfort. See ***"Patient positioning"*** on ***page 13***.
Type of nuclei	Hydrogen

Parameter	Condition
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate	200 T/m/s per axis for 1.5 T and 3 T
RF excitation	Circularly Polarized (CP) for 1.5 T and 3 T ⚠ **Warning** MRI scans at 3 T must be performed in quadrature mode or circular polarization mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
RF transmit coil types	Integrated whole body transmit coil, transmit/receive head coils, and other local cylindrical transmit/receive coils.
RF receive coil types	Integrated whole body coil, and any local cylindrical RF receive coils
Operating mode	Normal operating mode
RF conditions	• When using the integrated whole body transmit coil: Whole-body Averaged (WBA) Specific Absorption Rate (SAR) of ≤ 2 W/kg. • When using a transmit/receive head coil: Head-averaged Specific Absorption Rate (SAR) of ≤ 3.2 W/kg.
Scan duration	Scan for up to 60 minutes
Scan regions	Any landmark is acceptable
Image artefact	The implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant artefact dimension tables in the section ***"Image interference and artefacts"*** on ***page 23***.
Patient care after an MRI examination	See ***"Considerations after an MRI examination"*** on ***page 32***.

Table 2: Scan conditions and SAR limits for the OSI100 Implant.

Scan conditions and SAR limits for the OSI200 Implant

Parameter	Condition
Device name	OSI200 Implant
Static magnetic field strength (B_0)	1.5 T and 3 T
Device configuration	• **1.5 T** Use an MRI Kit for MRI scans at 1.5 T with the implant magnet in place. See ***"Table 1: Implant magnet and magnet cassette conditions for MRI."*** on ***page 16***. • **3 T** Surgically remove the implant magnet before MRI scans at 3 T. See ***"Table 1: Implant magnet and magnet cassette conditions for MRI."*** on ***page 16***. See also the OSI200 Implant Physician's Guide for additional information on the surgical procedure. • See ***"Patient positioning"*** on ***page 13*** for orientation information.
Patient preparation	• Counsel the patient prior to scanning: - Discuss the sensations the recipient may experience during the MRI scan. See ***"Patient comfort"*** on ***page 12***. - Explain to the patient how they will be positioned for the MRI scan. See ***"Patient positioning"*** on ***page 13***. • Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe. **Note** Once the sound processor has been removed, the patient may no longer be able to hear. • Position the patient to minimise discomfort. See ***"Patient positioning"*** on ***page 13***.
Type of nuclei	Hydrogen

Parameter	Condition
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate	200 T/m/s per axis for 1.5 T and 3 T
RF excitation	Circularly Polarized (CP) for 1.5 T and 3 T ⚠ **Warning** MRI scans at 3 T must be performed in quadrature mode or circular polarization mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
RF transmit coil types	Integrated whole body transmit coil, transmit/receive head coils, and other local cylindrical transmit/receive coils.
RF receive coil types	Integrated whole body coil, and any local cylindrical RF receive coils
Operating mode	Normal operating mode
RF conditions	• When using the integrated whole body transmit coil: Whole-body Averaged (WBA) Specific Absorption Rate (SAR) of ≤ 2 W/kg. • When using a transmit/receive head coil: Head-averaged Specific Absorption Rate (SAR) of ≤ 3.2 W/kg.
Scan duration	Scan for up to 60 minutes
Scan regions	Any landmark is acceptable
Image artefact	The implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant artefact dimension tables in the section ***"Image interference and artefacts"*** on ***page 23***.
Patient care after an MRI examination	See ***"Considerations after an MRI examination"*** on ***page 32***.

Table 3: Scan conditions and SAR limits for the OSI200 Implant.

Scan conditions and SAR limits for the OSI300 Implant

Parameter	Condition
Device name	OSI300 Implant
Static magnetic field strength (B_0)	1.5 T and 3 T
Device configuration	• Head bandaging is not required for OSI300 Implants, even with a magnet cassette in place, at 1.5 T or 3 T. See ***"Table 1: Implant magnet and magnet cassette conditions for MRI."*** on ***page 16***. • See ***"Patient positioning"*** on ***page 13*** for orientation information.
Patient preparation	• Counsel the patient prior to scanning: - Discuss the sensations the recipient may experience during the MRI scan. See ***"Patient comfort"*** on ***page 12***. - Explain to the patient how they will be positioned for the MRI scan. See ***"Patient positioning"*** on ***page 13***. • Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe. **Note** Once the sound processor has been removed, the patient may no longer be able to hear. • Position the patient to minimise discomfort. See ***"Patient positioning"*** on ***page 13***.
Type of nuclei	Hydrogen
MRI scanner type	Cylindrical (closed bore or wide bore)
B_0 field orientation	Horizontal

Parameter	Condition
Maximum verified spatial field gradient	20 T/m (2000 gauss/cm) for 1.5 T and 3 T
Maximum verified gradient slew rate	200 T/m/s per axis for 1.5 T and 3 T
RF excitation	Circularly Polarized (CP) for 1.5 T and 3 T ⚠ **Warning** MRI scans at 3 T must be performed in quadrature mode or circular polarization mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
RF transmit coil types	Integrated whole body transmit coil, transmit/receive head coils, and other local cylindrical transmit/receive coils.
RF receive coil types	Integrated whole body coil, and any local cylindrical RF receive coils
Operating mode	Normal operating mode
RF conditions	• When using the integrated whole body transmit coil: Whole-body Averaged (WBA) Specific Absorption Rate (SAR) of ≤ 2 W/kg. • When using a transmit/receive head coil: Head-averaged Specific Absorption Rate (SAR) of ≤ 3.2 W/kg.
Scan duration	Scan for up to 60 minutes
Scan regions	Any landmark is acceptable
Image artefact	The implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant artefact dimension tables in the section ***"Image interference and artefacts"*** on ***page 23***.
Patient care after an MRI examination	See ***"Considerations after an MRI examination"*** on ***page 32***.

Table 4: Scan conditions and SAR limits for the OSI300 Implant.

Image interference and artefacts

The Cochlear Osia implants will create shadowing on the MR image near the implant, resulting in a loss of diagnostic information.
If inspecting near the implant, consider removing the implant magnet or magnet cassette as MR image quality may be compromised with it in place. The image artefact extends from the centre of the implant.
If the implant magnet or magnet cassette needs to be removed, refer the patient to an appropriate physician to arrange for the magnet or magnet cassette to be removed before the MRI scan.

Gradient echo sequence

Note

The image artefact results are based on worst-case scenarios showing maximum artefact extension from the centre of the implant when scanned using a gradient echo sequence.

The further optimization of scan parameters can be used to minimise the extent of the artefact.

For bilateral recipients, the image artefacts as shown below are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

OSI100 Implant and 1.5 T scans with gradient echo sequence

In non-clinical testing, the image artefact caused by the OSI100 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

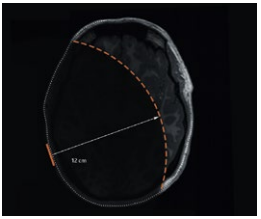
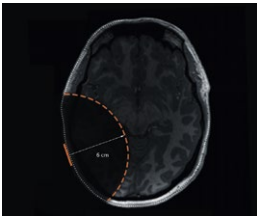
With implant magnet	Implant magnet removed
	
11.8 cm (4.6 in)	6.2 cm (2.4 in)

Table 5: Maximum image artefact for OSI100 Implants at 1.5 T scans (gradient echo sequence).

Note

The image artefact with implant magnet + magnetic splint may extend further in the axial, coronal or sagittal plane.

OSI100 Implant and 3 T scans with gradient echo sequence

In non-clinical testing, the image artefact caused by the OSI100 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

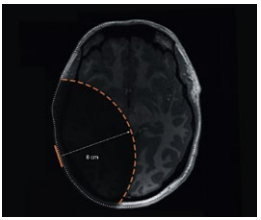
Implant magnet removed

7.9 cm (3.1 in)

Table 6: Maximum image artefact for OSI100 Implants at 3 T scans (gradient echo sequence).

OSI200 Implant and 1.5 T scans with gradient echo sequence

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:

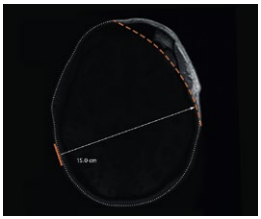
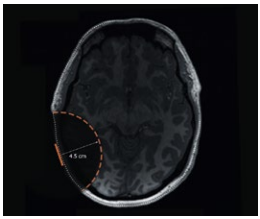
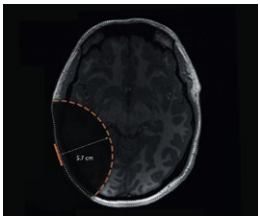
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
15.0 cm (5.9 in)	4.5 cm (1.8 in)	5.7 cm (2.2 in)

Table 7: Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

OSI200 Implant and 3 T scans with gradient echo sequence

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:

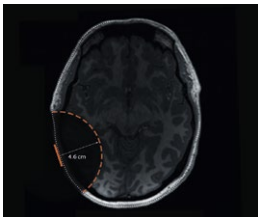
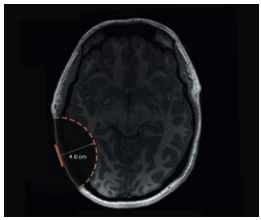
With non-magnetic plug	Implant magnet removed
	
4.6 cm (1.8 in)	4.0 cm (1.6 in)

Table 8: Maximum image artefact from centre at 3 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

OSI300 Implant and 1.5 T scans with gradient echo sequence

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

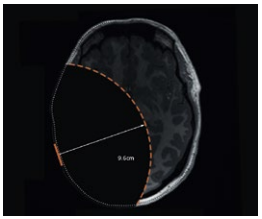
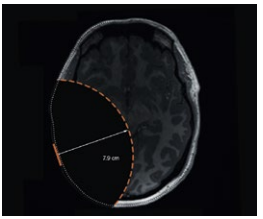
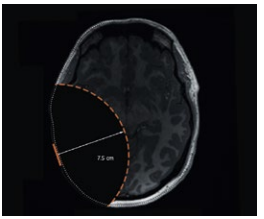
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
9.6 cm (3.8 in)	7.9 cm (3.1 in)	7.5 cm (2.9 in)

Table 9: Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

OSI300 Implant and 3 T scans with gradient echo sequence

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

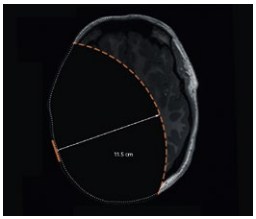
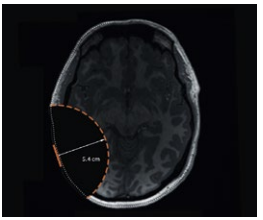
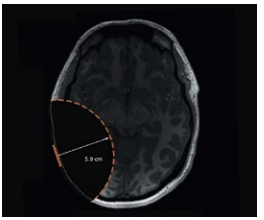
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
11.5 cm (4.5 in)	5.4 cm (2.1 in)	5.9 cm (2.3 in)

Table 10: Maximum image artefact from centre at 3 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

Metal Artefact Reduction Sequence (MARS)

Note

The image artefact results show maximum artefact extension from the centre of the implant when scanned using a Metal Artefact Reduction Sequence (MARS).

The further optimization of scan parameters can be used to minimise the extent of the artefact.

For bilateral recipients, the image artefacts as shown below are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

OSI200 Implant and 1.5 T scans with MARS sequence

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

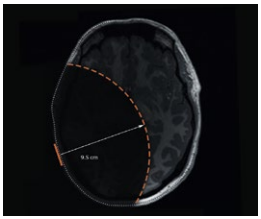
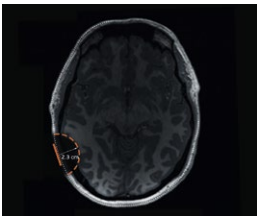
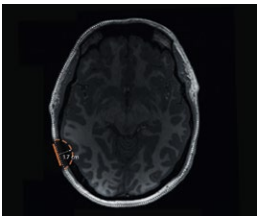
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
9.5 cm (3.7 in)	2.3 cm (0.9 in)	1.7 cm (0.7 in)

Table 11: Maximum image artefact from centre at 1.5 T (MARS sequence).

Parameter	MARS
Scanning sequence	Spin echo
Slice selection	Axial
Slice thickness	3 mm
Repetition time	4056 ms
Echo time	80 ms
Echo train length	15
Pixel bandwidth	435 Hz/pixel
Acquisition matrix	499x451
Flip angle	90°

Table 12: Scan parameters for scanning in a 1.5 T scanner

OSI200 Implant and 3 T scans with MARS sequence

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

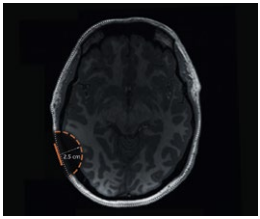
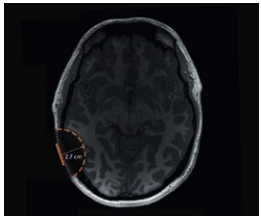
With non-magnetic plug	Implant magnet removed
	
2.5 cm (1.0 in)	2.7 cm (1.1 in)

Table 13: Maximum image artefact from centre at 3 T (MARS sequence).

Parameter	MARS
Scanning sequence	Spin echo
Slice selection	Axial
Slice thickness	3 mm
Repetition time	4809 ms
Echo time	80 ms
Echo train length	12
Pixel bandwidth	1029 Hz/pixel
Acquisition matrix	300x268
Flip angle	90°

Table 14: Scan parameters for scanning in a 3 T scanner

OSI300 Implant and 1.5 T scans with MARS sequence

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a MARS sequence scan in the axial plane is:

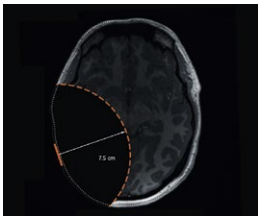
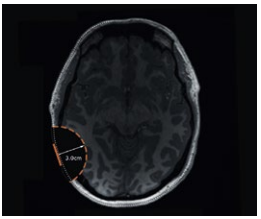
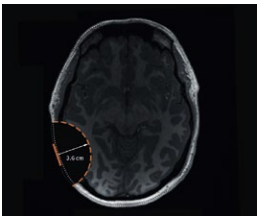
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
7.5 cm (2.9 in)	3.0 cm (1.2 in)	3.6 cm (1.4 in)

Table 15: Maximum image artefact from centre at 1.5 T (MARS sequence).

Parameter	MARS
Scanning sequence	Spin echo
Slice selection	Axial
Slice thickness	5 mm
Repetition time	2375 ms
Echo time	17 ms
Bandwidth	81,664 Hz
Flip angle	90°

Table 16: Scan parameters for scanning in a 1.5 T scanner

OSI300 Implant and 3 T scans with MARS sequence

In non-clinical testing, the maximum image artefact caused by the OSI300 Implant when imaged with a MARS sequence scan in the axial plane is:

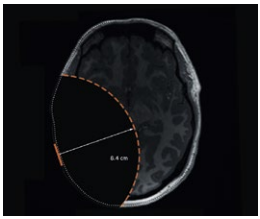
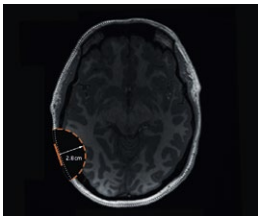
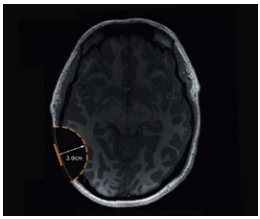
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
8.4 cm (3.3 in)	2.8 cm (1.1 in)	3.0 cm (1.1 in)

Table 17: Maximum image artefact from centre at 3 T (MARS sequence).

Parameter	MARS
Scanning sequence	Spin echo
Slice selection	Axial
Slice thickness	5 mm
Repetition time	4000 ms
Echo time	50 ms
Bandwidth	199,936 Hz
Flip angle	90°

Table 18: Scan parameters for scanning in a 3 T scanner

Considerations after an MRI examination

With the implant magnet in place

After the patient leaves the MRI room, remove the MRI Kit contents from the patient's head, as required. Ask the patient to place the sound processor on their head and turn it on.

Confirm:

- Placement of the sound processor is correct
- There is no discomfort
- Sound is perceived as normal

If there is discomfort or a change in sound perception, or problems with the placement of the sound processor, ask the patient to seek assistance from their implant clinician as soon as possible.

See ***"Considerations for implant magnet in place"*** on ***page 10***.

With the implant magnet removed

See ***"Considerations for implant magnet removal"*** on ***page 8***.

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