EN-GB English

Cochlear™ Osia® OSI200 Implant

Magnetic Resonance Imaging (MRI) Guidelines

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About this guide

This guide applies to 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/mri

If you are a consumer, please seek advice from your medical practitioner or health professional prior to an MR scan.

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 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 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 under the conditions described in section *"Performing MRI safely"* on *page 12 to 14*. 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/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

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

Radiologist/MR technologist

Sets up the MR 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 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 6*.
  Also consider:
  - 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.
- Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination. See *"Performing MRI safely"* on *page 12*.
- 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 *"Image interference and artefacts"* on *page 16*.
- 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 and uncomfortable sensation or skin/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 MR scans at 1.5 T or 3 T, identify if the implant magnet needs to be removed. See *"Implant magnet conditions for MRI"* on *page 12*.
- 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 Osia MRI Kit must be obtained beforehand for use during the MR scan. See *"Obtaining an MRI Kit"* on *page 25*.

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Risks associated with MRI and Cochlear Osia implants

The potential risks of performing MRI examinations on patients with Cochlear Osia implants 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/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 magnet 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.

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.

WARNING

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

For recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. See *"Implant magnet conditions for MRI"* on *page 12*.

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.

With the non-magnetic plug in place, MR scans can be safely done without the need for bandaging or use of the Cochlear Osia MRI Kit.

NOTE

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.

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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 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 implant"* on ***page 10***.
- For additional information for bilateral recipients, see ***"Bilateral recipients"*** on ***page 8***.
- For MR scans on a body location away from the implant site, MRI safety information for the recipient's implant model must be followed. See ***"Performing an MR scan on other body locations"*** on ***page 9***.
- The implant magnet has been surgically removed when the referring physician has prescribed that the MR scan be performed with the implant magnet removed.
- If the implant magnet is retained for an MR scan at 1.5 T, a Cochlear Osia MRI Kit is available and ready for use. See ***"Using the MRI Kit"*** on ***page 25***.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Position the patient to minimise discomfort. See ***"Patient positioning"*** on ***page 9***.
- Discuss the sensations the recipient may experience during the MR Scan. See ***"Patient comfort"*** on ***page 9***.
- Comply with the ***"Scan conditions and SAR limits"*** on ***page 12***.

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 implant models (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 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 ***"Identifying the Cochlear Osia implant"*** on ***page 10*** and related ***"Performing MRI safely"*** on ***page 12***.

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

When scanning with the implant magnet in place, 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 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.

If the patient experiences pain, consult the patient's physician to determine if the implant magnet 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 MR scan. The sound levels are not hazardous.

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 Cochlear Osia OSI200 Implants when using an X-ray.

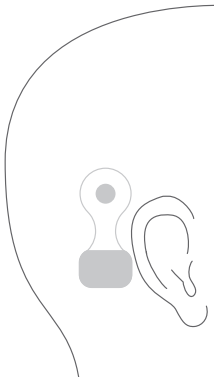

Fig. 1 Approximate location of the OSI200 Implant

Skin side Bone side

Fig. 2 OSI200 Implant (P1170466)

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.

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Performing MRI safely

Implant magnet conditions for MRI

For some implant models and MRI field strengths, bandaging with an MRI kit is required, or the implant magnet needs to be surgically removed. Refer to the table below for information on the OSI200 Implant. See *"Using the MRI Kit"* on *page 25* for instructions on how to apply the MRI Kit prior to the MR scan.

Implant type	MRI field strength (T)	Remove implant magnet Yes/No	MRI Kit required Yes/No
Osia OSI200 Implant	1.5	No	Yes
	3	Yes	No

Table 1 Implant magnet conditions for MRI.

Scan conditions and SAR limits

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners closed bore or wide bore with a circularly polarised (CP) RF field for a maximum active scan time of 60 minutes.

WARNING

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.

A patient with one or two of these devices can be safely scanned in an MR system meeting conditions on the following pages.

Consider the following prior to scanning:

- Transmit/receive head coils and whole body coils may be safely used within the recommended SAR limits. Refer to the MRI safety information and recommended SAR limit tables in the following pages.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- It is safe to use local cylindrical RF receive only coils with implants during MRI scanning, provided SAR limits for the transmit coil have not been exceeded.
- Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm away from the implant.

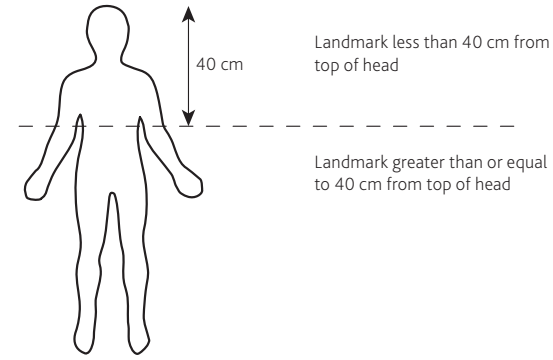

Fig. 3 Landmark locations

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OSI200 Implant and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the Cochlear Osia MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *"Using the MRI Kit"* on *page 25.*
- 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:

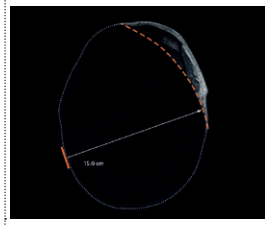
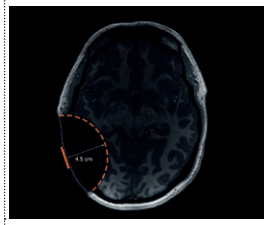
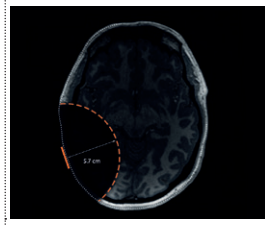
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
15.0 cm (5.9 in)	4.5 cm (1.8 in)	5.7 cm (2.2 in)

Table 2 Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

NOTE

The image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

For bilateral OSI200 Implant recipients, the image artefacts as shown above 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 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:

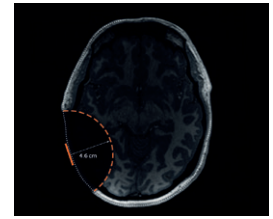
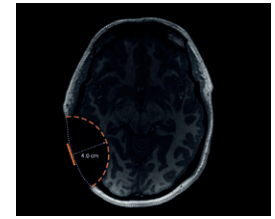
With non-magnetic plug	Implant magnet removed
	
4.6 cm (1.8 in)	4.0 cm (1.6 in)

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

Image interference and artefacts

The Cochlear Osia OSI200 Implant 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 as MR image quality may be compromised with it in place.

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.

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

The image artefact extends from the centre of the implant. The Metal Artefact Reduction Sequence (MARS) parameters detailed in the tables below were used to produce the artefact sizes detailed in the following pages.

Parameter	Gradient echo	SEMAC-VAT	MARS	Optimized MARS
Scanning sequence	Gradient echo	Spin echo	Spin echo	Spin echo
Slice selection	Axial	Axial	Axial	Axial
Slice thickness	4 mm	3.5 mm	3 mm	3 mm
Repetition time	100 ms	3810 ms	4056 ms	3190 ms
Echo time	15 ms	80 ms	80 ms	80 ms
Echo train length	1	22	15	15
Pixel bandwidth	35 Hz/pixel	436 Hz/pixel	435 Hz/pixel	859 Hz/pixel
Acquisition matrix	256x256	343x310	499x451	499x442
Flip angle	30°	90°	90°	90°
SAR	0.02 W/kg	1.67 W/kg	1.20 W/kg	1.90 W/kg
dB/dt	6.86 T/s	71.64 T/s	88.40 T/s	93.38 T/s
B1rms	0.39 µT	3.43 µT	2.91 µT	3.66 µT
Duration	544 s (9min04s)	720 s (12 min)	709 s (11min49s)	344 s (5min44s)

Table 4 Scan parameters for scanning in a 1.5 T scanner

The following image artefact results are based on maximum artefact extension from the centre of the implant when scanned at 1.5 T using different Metal Artefact Reduction Sequence (MARS) sequences.

For bilateral implant 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.

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OSI200 Implant and 1.5 T scans with SEMAC-VAT sequence

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

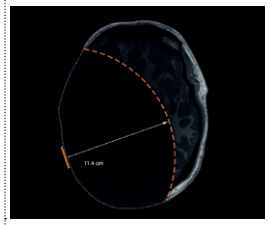
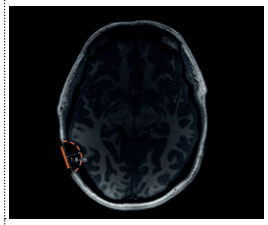
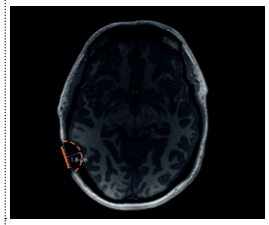
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
11.4 cm (4.5 in)	1.8 cm (0.7 in)	1.8 cm (0.7 in)

Table 5 Maximum image artefact from centre at 1.5 T (SEMAC-VAT sequence).

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant with a SEMAC-VAT sequence scan in the **coronal plane** is:

With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
7.5 cm (3.0 in)	2.0 cm (0.8 in)	2.0 cm (0.8 in)

Table 6 Maximum image artefact from centre at 1.5 T (SEMAC-VAT sequence).

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant with a SEMAC-VAT sequence scan in the **sagittal plane** is:

With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
9.0 cm (3.5 in)	2.8 cm (1.1 in)	2.5 cm (1.0 in)

Table 7 Maximum image artefact from centre at 1.5 T (SEMAC-VAT sequence).

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:

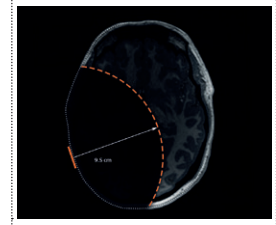
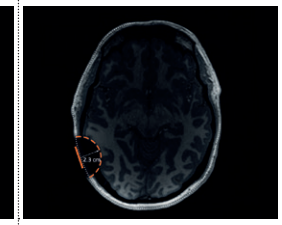
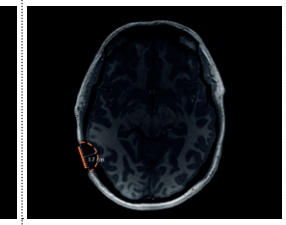
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
9.5 cm (3.7 in)	2.3 cm (0.9 in)	1.7 cm (0.7 in)

Table 8 Maximum image artefact from centre at 1.5 T (MARS sequence).

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

With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
6.6 cm (2.6 in)	2.3 cm (0.9 in)	1.9 cm (0.7 in)

Table 9 Maximum image artefact from centre at 1.5 T (MARS sequence).

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

With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
7.1 cm (2.8 in)	3.0 cm (1.2 in)	2.8 cm (1.1 in)

Table 10 Maximum image artefact from centre at 1.5 T (MARS sequence).

OSI200 Implant and 1.5 T scans with Optimized MARS sequence

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

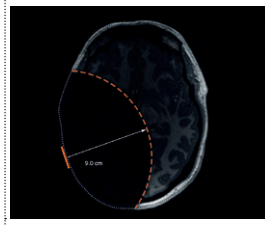
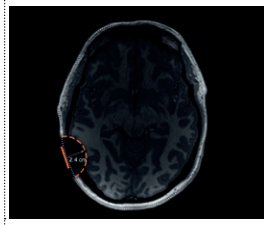
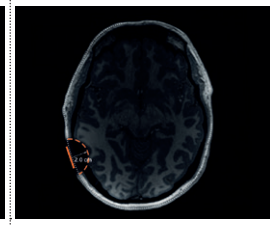
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
9.0 cm (3.5 in)	2.4 cm (0.9 in)	2.0 cm (0.8 in)

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

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant with an Optimized MARS sequence scan in the **coronal plane** is:

With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
8.2 cm (3.2 in)	1.9 cm (0.8 in)	1.7 cm (0.7 in)

Table 12 Maximum image artefact from centre at 1.5 T (Optimized MARS sequence).

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant with an Optimized MARS sequence scan in the **sagittal plane** is:

With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
6.8 cm (2.7 in)	2.4 cm (0.9 in)	3.2 cm (1.3 in)

Table 13 Maximum image artefact from centre at 1.5 T (Optimized MARS sequence).

Parameter	Gradient echo	SEMAC-VAT	MARS
Scanning sequence	Gradient echo	Spin echo	Spin echo
Slice selection	Axial	Axial	Axial
Slice thickness	4 mm	3.5 mm	3 mm
Repetition time	100 ms	3197 ms	4809 ms
Echo time	9 ms	80 ms	80 ms
Echo train length	1	14	12
Pixel bandwidth	217 Hz/pixel	1244 Hz/pixel	1029 Hz/pixel
Acquisition matrix	256x256	307x277	300x268
Flip angle	80°	90°	90°
SAR	0.89 W/kg	1.88 W/kg	0.98 W/kg
dB/dt	16.20 T/s	58.31 T/s	53.21 T/s
B1rms	1.33 µT	1.93 µT	1.40 µT
Duration	182 s (3min02s)	409 s (6min49s)	289 s (4min49s)

Table 14 Scan parameters for scanning in a 3 T scanner

The following image artefact results are based on maximum artefact extension from the centre of the implant when scanned at 3 T using different Metal Artefact Reduction Sequence (MARS) sequences.

For bilateral implant 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 3 T scans with SEMAC-VAT sequence

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

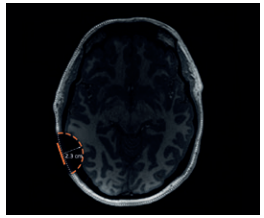
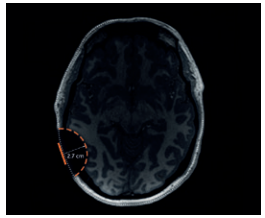
With non-magnetic plug	Implant magnet removed
	
2.3 cm (0.9 in)	2.7 cm (1.1 in)

Table 15 Maximum image artefact from centre at 3 T (SEMAC-VAT sequence).

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant with an SEMAC-VAT sequence scan in the **coronal plane** is:

With non-magnetic plug	Implant magnet removed
2.4 cm (0.9 in)	2.4 cm (0.9 in)

Table 16 Maximum image artefact from centre at 3 T (SEMAC-VAT sequence).

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant with an SEMAC-VAT sequence scan in the **sagittal plane** is:

With non-magnetic plug	Implant magnet removed
3.3 cm (1.3 in)	3.1 cm (1.2 in)

Table 17 Maximum image artefact from centre at 3 T (SEMAC-VAT sequence).

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:

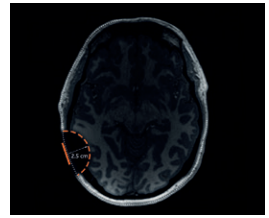
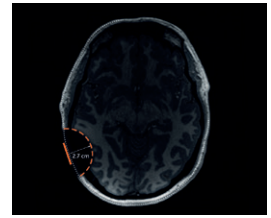
With non-magnetic plug	Implant magnet removed
	
2.5 cm (1.0 in)	2.7 cm (1.1 in)

Table 18 Maximum image artefact from centre at 3 T (MARS sequence).

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

With non-magnetic plug	Implant magnet removed
2.9 cm (1.1 in)	2.6 cm (1.0 in)

Table 19 Maximum image artefact from centre at 3 T (MARS sequence).

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

With non-magnetic plug	Implant magnet removed
3.3 cm (1.3 in)	3.7 cm (1.5 in)

Table 20 Maximum image artefact from centre at 3 T (MARS sequence).

Cochlear™ Osia® MRI Kit

Intended purpose

Intended to prevent the dislodgement of implanted magnets in a hearing implant during a Magnetic Resonance Imaging (MRI) procedure.

Indications

The Cochlear Osia MRI Kit is indicated for Cochlear Osia Implant recipients who require an MRI scan at 1.5 T and have been assessed by medical professionals as suitable for an MRI scan.

The MRI Kit is intended for use with the following Cochlear Osia implants for both unilateral and bilateral recipients:

- Osia OSI200 Implant

Contraindications

The Cochlear Osia MRI Kit is contraindicated for use with:

- MR scans other than 1.5 T

Intended Users

The MRI Kit is intended for use by specialised healthcare professionals who prepare and perform MR scans.

Clinical Benefits

Benefits include enabling a MR scan at 1.5 T without the need to surgically remove the magnet.

Serious incidents

Serious incidents are rare, any serious incident in relation to your device should be reported to your Cochlear representative and to the medical device authority in your country, if available.

Obtaining an MRI Kit

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

MRI Kit contents

The following items are provided in your MRI Kit:

Item	Description
Round Splints x 2	Magnetic splint – to be placed against the skin over the implant magnet site. For bilateral patients use one splint for each implant.
Bandage x 1	Compression bandage – for securing the splint against the implant magnet site.
Instructions	User guide showing how to apply splint and bandage

Using the MRI Kit

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

For more information, including instructions for using the MRI Kit prior to an MRI, visit www.cochlear.com/mri or contact your nearest Cochlear office.

WARNING

To minimise possible pain and discomfort, apply the splint/s and bandage immediately prior to the entering the MRI room.

Remove the splint/s and bandage immediately after the MRI procedure and the recipient is outside of the MRI room.

If the splint/s become loose inside the MRI room, this could lead to damage of the MRI equipment and / or injury to the MRI staff or recipient.

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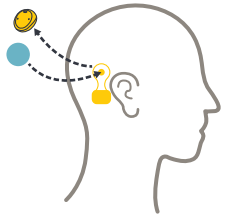
1. Preparation (Steps 1 - 2)

Prior to entering the MRI room and before removing the sound processor, ensure you have the contents of the MRI Kit available and within easy reach.

NOTE

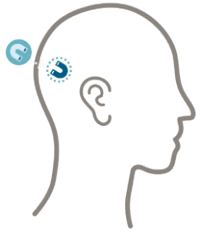
Once the sound processor has been removed, the recipient will no longer be able to hear.

To ensure greatest magnet attraction, clear away as much hair as possible from the implant site. For recipients with long hair, it may be necessary to tie the hair up.



1. Remove the sound processor and replace the sound processor with a magnetic splint from the MRI Kit. See *Step 2*.

   Repeat this step if the recipient is bilaterally implanted.



2. As you move the splint towards the implant you will feel a magnetic attraction.

   Ensure the magnetic splint sits exactly on the place where you removed the sound processor.

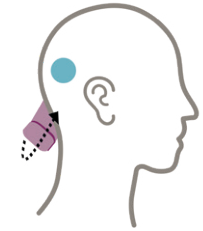
   Repeat this step if the recipient is bilaterally implanted.

NOTE

The splint should stay in place without any need to hold.

Make a visual note of where the splint sits - it will later assist in determining if the splint has moved.

2. Bandaging (Steps 1 - 6)



1. Clear all hair away from the forehead.

Starting at the base of the skull, begin bandaging around the head. Maintain the tension required to unwrap the bandage from its roll as the bandage is applied on the head. Ensure the splints have been fully covered and have not moved from their starting position.

NOTE

The bandage should be wrapped firmly to ensure the splint do not move, but not too tight to cause pain.
Check that the splint has not moved before continuing to bandage.
Do not wrap any higher than the forehead.

2. Continue bandaging using the base of the skull as an anchoring point (this will prevent the bandage slipping off). Ensure that the splint is covered on each wrap.

   Check that the splint has not moved out of place.

3. Continue bandaging until the entire bandage has been used.

   Do not cut the bandage.

4. Once the bandaging is complete, carefully press your hands around the entire bandage to ensure the layers of the bandage have adhered and are secure.

5. Refer to *"Preparation for conducting the MRI examination"* on *page 8*.

6. Once the MR scan is complete, follow the instructions in *"Considerations after an MRI examination"* on *page 28*.

WARNING

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

Considerations after an MRI examination

With the implant magnet in place

After the patient leaves the MRI room, remove the MRI kit bandage and splint. 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, ask the patient to seek assistance from their implant clinician as soon as possible.

With the implant magnet removed

See *"Considerations for implant magnet removal"* on *page 7*.

Disposal

The Cochlear Osia MRI Kit can be disposed of as normal hospital or household waste, or in accordance with local regulations.

The MRI Kit is for single-use only.

Labelling symbols

The following symbols may appear on the product, the components and/or the packaging.

	Specific warnings or precautions associated with the device, which are not otherwise found on the label		Keep dry
	Manufacturer		Do not re-use
	Date of manufacture		Do not use if package is damaged
REF	Catalogue number	Rx Only	By prescription
EC REP	Authorised representative in the European Community	MR	MR Conditional
CE	CE registration mark	MR	MR unsafe
	Consult instructions for use	MD	Medical Device
UDI	Unique device identifier		Use by date
	Recyclable packaging		

Notes

Notes

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Hear now. And always

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