Cochlear®

Cochlear™ Osia®

Magnetic Resonance Imaging (MRI) Guidelines

EN

FOR PROFESSIONALS

About this guide

This guide applies to the Cochlear™ Osia® OSI200 Implant and OSI300 Implant.
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.com/mri or contact your regional Cochlear office. Contact numbers are available on the back cover of these guidelines.

Symbols used in this guide



Warning
Risk of serious injury or death to person.



Caution
Risk of minor harm to person, or risk of damage to equipment.



Note
Important information or advice.

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Preparation prior to an MRI examination

These guidelines are specific to the Cochlear Osia OSI200 Implant and OSI300 Implant and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility. Recipients should consult with their implant physician prior to an MRI examination.



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 MRI 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. Refer to the process detailed in ***"Preparation for conducting the MRI examination"*** on ***page 10*** and ***"Considerations after an MRI examination"*** on ***page 26***.

Determine eligibility for MRI

In order to determine if a patient may receive an MRI scan, you must first identify the patient's Cochlear Osia implant model. See ***"Identifying the Cochlear Osia implants"*** on ***page 13***. After you have identified the implant model, see ***"Performing MRI safely"*** on ***page 15*** to locate the MRI safety information for that specific implant model.

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***.
- 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 15***.
  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.

- 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 ***"Image interference and artefacts"*** section and the ***"Performing MRI safely"*** section.

  - If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed. If required, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MRI scan. See ***"Considerations for implant magnet removal"*** on ***page 8***.

- 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.

  - 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 15.***

    - 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, a Cochlear Osia 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 a Cochlear Osia MRI Kit.

Risks associated with MRI and Cochlear Osia implants

If MRI safety information for the implanted devices is not followed, the potential risks 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.

Weakening of implant magnet (demagnetisation)

Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to implant magnet demagnetisation.
Incorrect patient positioning prior to the MRI scan or head movement during the scan may result in implant magnet demagnetisation.
The implant magnet has been designed and verified to state of the art standards. Demagnetisation is highly unlikely when the patient is positioned following the instructions in these guidelines.

Uncomfortable sensation

MRI exposure beyond the values contained in these guidelines may result in the patient perceiving sound or noise and/or pain.
When an MRI Kit is required, minimise the duration of time that the MRI Kit is applied to reduce possible pain and discomfort. Apply the MRI Kit immediately prior to entering the MRI room.

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

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.

See ***"Implant magnet and magnet cassette conditions for MRI"*** on ***page 15***.

OSI300 Implant

If the MRI examination, implant magnet cassette removal and replacement will be completed on the same day, the magnet cassette recess can remain empty. For OSI300 Implant recipients, if MRI examinations are needed over a period time 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 minimise the risk of infection, do not leave the magnet pocket empty (for OSI300 Implants) for MRI examinations taking place over several days. When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

OSI200 Implant

If the MRI examination, implant magnet removal and replacement will be completed on the same day, the magnet recess can remain empty. For OSI200 Implant recipients, if MRI examinations are needed over a period of time with the implant magnet removed, the implant magnet is 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 minimise the risk of infection do not leave the magnet pocket empty for MRI examinations taking place over several days. When removing the magnet, replace the magnet with a non-magnetic plug.

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 the Cochlear Osia MRI Kit.

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.

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.
A patient with one or two Cochlear Osia implants can be safely scanned in an MR system meeting conditions contained within these guidelines.

Confirm the following prior to scanning:

- The implant model has been identified. See ***"Identifying the Cochlear Osia implants"*** on ***page 13***.
- For additional information for bilateral recipients, see ***"Bilateral recipients"*** on ***page 11***.
- The artefact has been considered, and there is still diagnostic value in performing the MRI scan. See ***"Image interference and artefacts"*** on ***page 21*** and ***"MRI machine conditions and SAR limits"*** on ***page 15.***
- For MRI 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 MRI scan on other body locations"*** on ***page 11***.
- 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. See ***"Preparation prior to an MRI examination"*** on ***page 4***.
- The Cochlear Osia MRI Kit is required for MRI scans at 1.5 T with the implant magnet in place for OSI200 Implants. Refer to the ***Cochlear Osia MRI Kit User Guide*** provided with the MRI Kit for instructions on how to apply the MRI Kit prior to the MRI scan, and see ***"Table 1: Implant magnet and magnet cassette conditions for MRI."*** on ***page 15***.
- If required, an MRI Kit must be obtained beforehand for use during the MRI scan. Contact the nearest Cochlear office or official distributor to order a Cochlear Osia MRI Kit.
- 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.

- 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 scan. See ***"Patient positioning"*** on ***page 11***.
- 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 11***.
- Comply with the ***"MRI machine conditions and SAR limits"*** on ***page 15***.

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 13***, ***"Patient positioning"*** on ***page 11*** and related ***"Performing MRI safely"*** on ***page 15***.

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 immobilised in their scanning position before wheeling into the MRI 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 immobilise 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.

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.

For devices which require a Cochlear Osia MRI Kit, 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.

⚠ **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.

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 information for identification of Cochlear Osia implants"*** and ***"X-ray guidelines"*** below.

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.4*** to assist with identifying Cochlear Osia implants when using an X-ray.

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.

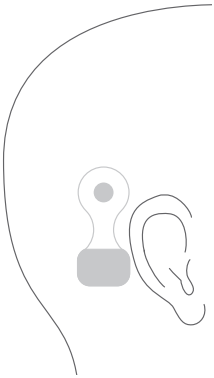


Fig.1: Approximate location of the OSI200 Implant



Fig.2: OSI200 Implant

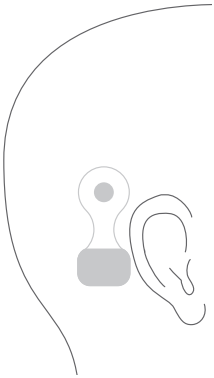


Fig.3: Approximate location of the OSI300 Implant



Fig.4: OSI300 Implant

Performing MRI safely

Implant magnet and magnet cassette conditions for MRI

For some implant models and MRI field strengths, bandaging with a Cochlear Osia MRI kit is required, or the implant magnet needs to be surgically removed. Additionally, if the device artefact will obscure the area of interest, the referring physician may prescribe implant magnet or magnet cassette removal. 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 OSI200 Implant	1.5	No	Yes (if implant magnet is present)
	3	Yes	No
Osia OSI300 Implant	1.5	No	No
	3	No	No

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

MRI machine 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

MRI scans must be performed in quadrature mode or circular polarisation (CP) mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.

All scans shall be performed according to the specified SAR limits for the relevant implant.

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 in this section.
- 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.

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 MRI scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- Maximum gradient slew rate of 200 T/m/s per axis.
- 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:

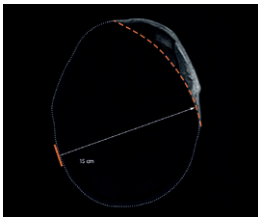
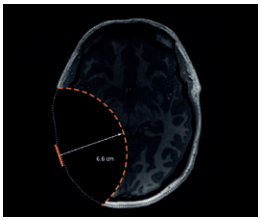
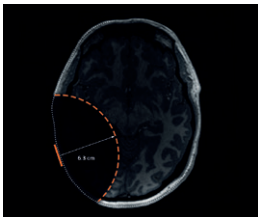
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
15 cm (5.9 in)	6.8 cm (2.7 in)	6.3 cm (2.5 in)

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 further 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 MRI 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).
- Maximum gradient slew rate of 200 T/m/s per axis.
- 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 polarisation 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:

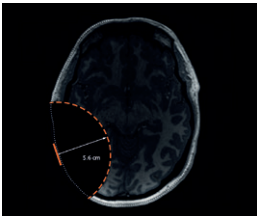
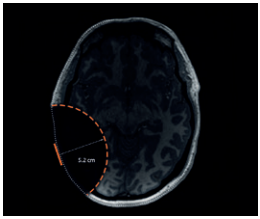
With non-magnetic plug	Implant magnet removed
	
5.6 cm (2.2 in)	5.2 cm (2.0 in)

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.

Note

The image artefact results are based on worst-case scenarios showing maximum artefact extension. The further 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.

OSI300 Implant and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- Maximum gradient slew rate of 200 T/m/s per axis.
- 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 OSI300 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

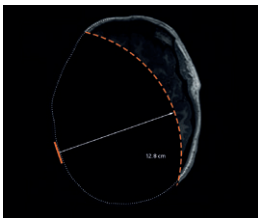
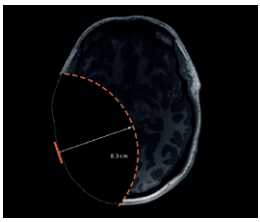
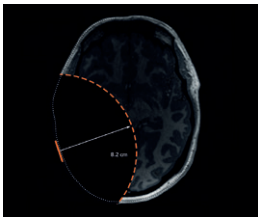
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
12.8 cm (5.0 in)	8.3 cm (3.3 in)	8.2 cm (3.2 in)

Table 4: 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 further optimisation of scan parameters can be used to minimise the extent of the artefact.

For bilateral OSI300 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.

OSI300 Implant and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- Maximum gradient slew rate of 200 T/m/s per axis.
- 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 OSI300 Implant when imaged with a gradient echo pulse sequence scan in the axial plane is as follows:

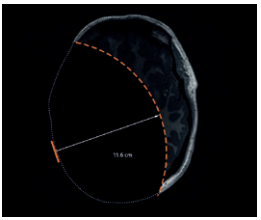
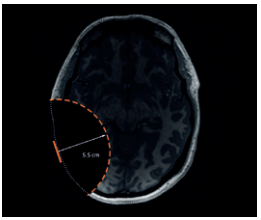
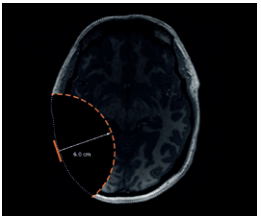
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
11.6 cm (4.6 in)	5.5 cm (2.2 in)	6.0 cm (2.4 in)

Table 5: Maximum image artefact from centre at 3 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 further optimisation of scan parameters can be used to minimise the extent of the artefact.

For bilateral OSI300 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.

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.
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.
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	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°
dB/dt	88.40 T/s
Duration	709 s (11min49s)

Table 6: 1.5 T scan parameters for OSI200

Note

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

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 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:

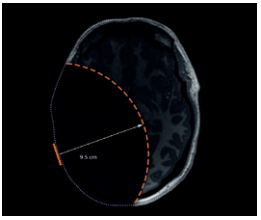
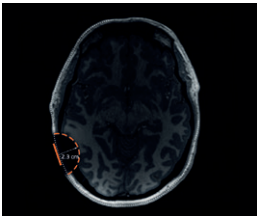
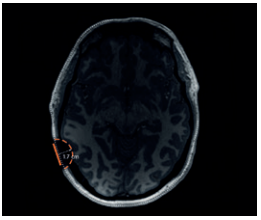
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
9.5 cm (3.7 in)	2.3 cm (0.9 in)	1.7 cm (0.7 in)

Table 7: 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	4809 ms
Echo time	80 ms
Echo train length	12
Pixel bandwidth	1029 Hz/pixel
Acquisition matrix	300x268
Flip angle	90°
dB/dt	53.21 T/s
Duration	289 s (4min49s)

Table 8: 3 T scan parameters for OSI200

Note

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

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 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:

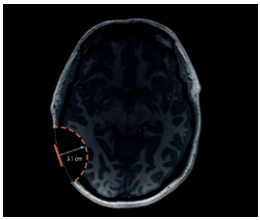
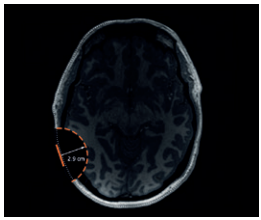
With non-magnetic plug	Implant magnet removed
	
3.1 cm (1.2 in)	2.9 cm (1.1 in)

Table 9: 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	2375 ms
Echo time	17 ms
Bandwidth	81,664 Hz
Flip angle	90°

Table 10: 1.5 T scan parameters for OSI300

Note

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

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.

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:

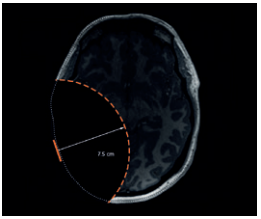
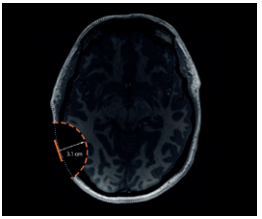
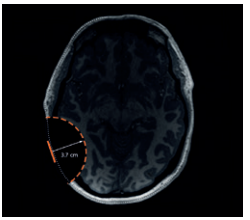
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
7.5 cm (3.0 in)	3.1 cm (1.2 in)	3.7 cm (1.5 in)

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

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

Table 12: 3 T scan parameters for OSI300

Note

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

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.

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:

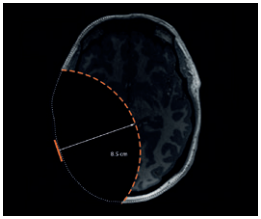
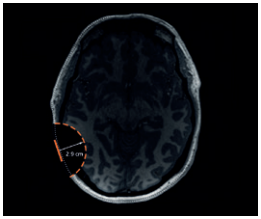
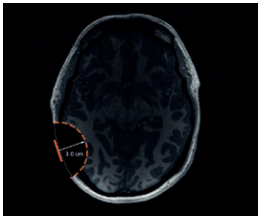
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
8.5 cm (3.3 in)	2.9 cm (1.1 in)	3.0 cm (1.2 in)

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

Considerations after an MRI examination

With the implant magnet in place

After the patient leaves the MRI room, immediately remove the MRI Kit contents, if used, from the patient's head. 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.

With the implant magnet removed

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

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