Cochlear®

Cochlear™ Osia®

Magnetic Resonance Imaging (MRI) Guidelines

Canada

EN

FOR PROFESSIONALS

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

How to navigate this guide

All professionals:

- Review the content in ***About this guide*** on page 4.
- Review the content in ***Preparation prior to an MRI examination*** on page 5.

Referring physicians:

- To refer a Cochlear™ Osia® implant recipient for an MRI scan, follow the process in ***Determine eligibility for MRI*** on page 6.

Radiologists or MR technologists:

- To perform the MRI scan, follow the process in ***Perform the MRI scan*** on page 19.

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.com/mri or contact your regional Cochlear office. Contact numbers are available on the back cover of these guidelines.

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. 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 and/or device malfunction.

Cooperation between specialists

Preparing for and conducting an MRI examination for implant recipients requires cooperation between medical professionals.

Medical professional	Role
Cochlear Osia implant device specialist	• Knows the implant type. • Knows where to find the correct MR parameters for the implant type.
Referring physician	• Knows the location of the MRI scan and diagnostic information required. • Decides if 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 6. • Confers with the radiologist or MR technologist on artefact size and likely diagnostic value of the scan.
Cochlear Osia implant physician	• If requested by the referring physician, the implant physician surgically removes the implant magnet or magnet cassette and may temporarily replace it with a non-magnetic plug or a non-magnetic cassette. • After the MRI scan, the implant physician implants a new sterile replacement magnet or replacement magnet cassette.
Healthcare professional	• Prepares the patient for MRI scans by applying the MRI Kit (if required).
Radiologist or MR technologist	• Sets up the MRI scan using the correct MR parameters and patient positioning. • Counsels the implant recipient during the MRI examination.

Table 1: Medical professionals and corresponding roles

Determine eligibility for MRI

If you are a physician referring a Cochlear Osia implant recipient for an MRI scan, follow the process below.

1. Identify	Instuction details
The recipient's Cochlear Osia implant model.	Refer to ***Identifying the Cochlear Osia implants*** on page 8. Bilateral recipients may have two different models. Refer to ***Bilateral recipients*** on page 21.
If the recipient has any other implants, active or abandoned.	If another implant is present, verify MRI compatibility before referring the recipient for an MRI examination. **Note:** 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.
2. Determine	**Instruction details**
If the implant magnet can remain in place, or if surgical removal is required.	Refer to ***Implant magnet and magnet cassette conditions for MRI*** on page 10.
If an MRI Kit is required.	For OSI200, 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. Contact the nearest Cochlear office or official distributor to order an MRI Kit. OSI300 does not require an MRI Kit at 1.5 T or 3 T, even with the magnet in place. Refer to ***Implant magnet and magnet cassette conditions for MRI*** on page 10.
If the device artefact will obscure the area of interest.	The Cochlear Osia implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Confer with the radiologist or MR technologist on artefact size and likely diagnostic value of the MRI scan. Refer to the relevant artefact dimension tables in the section ***Image interference and artefacts*** on page 11. If the required diagnostic information is in the area of the implant, the implant magnet or magnet cassette may need to be surgically removed to minimise the artefact. Refer to ***Considerations for implant magnet removal*** on page 17.

3. Confirm understanding	Instruction details
Understand the conditions for an MRI scan and ensure that there is a clear indication for the MRI examination.	Review the implant magnet, MRI kit and artefact information determined in the previous steps and consider whether it is appropriate for the MRI scan to proceed. **Note:** 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 and inform the patient of the risks associated with MRI scans.	Refer to ***Risks associated with MRI and Cochlear Osia implants*** on page 16. If it was determined that the implant magnet or magnet cassette should be surgically removed, or that an MRI Kit will be used, inform the patient. If required, refer the patient to an appropriate physician to arrange for the implant magnet to be surgically removed before the MRI scan. Additionally, refer to ***Patient counselling*** on page 21.

Table 2: Determine eligibility for an 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 model can be identified without surgical intervention. Refer to ***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 ***Fig.1***–***Fig.6*** to assist with identifying Cochlear Osia implants when using an X-ray.

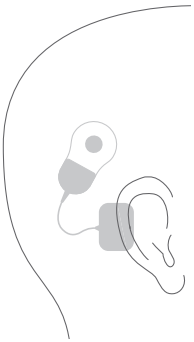


Fig.1: Approximate location of the OSI100 Implant

*Fig.2: OSI100 Implant**

* *The identifying features of the OSI100 implant are provided for reference; however, this model is not approved for sale in Canada. If an OSI100 recipient requires an MRI, please reach out to Cochlear Ltd for further information.*

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

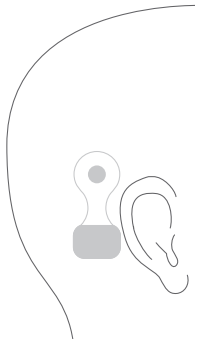


Fig.3: Approximate location of the OSI200 Implant

Fig.4: OSI200 Implant

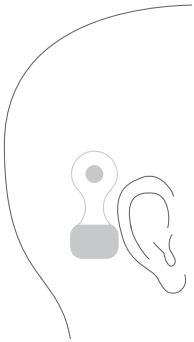


Fig.5: Approximate location of the OSI300 Implant

Fig.6: OSI300 Implant

Implant magnet and magnet cassette conditions for MRI

For OSI200 Implants, the implant magnet must be surgically removed for 3 T scans. Bandaging with an MRI Kit is required if the implant magnet is present for 1.5 T scans on the OSI200 implant. If the device artefact will obscure the area of interest, the referring physician may prescribe implant magnet removal. If the implant magnet has been removed, an MRI Kit is not required.

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. If the device artefact will obscure the area of interest, the referring physician may prescribe implant magnet cassette removal.

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

Implant type	MRI field strength (T)	Mandatory 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 3: Implant magnet and magnet cassette conditions for MRI.

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 before the MRI scan. Refer to ***Considerations for implant magnet removal*** on page 17.

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 optimisation 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 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:

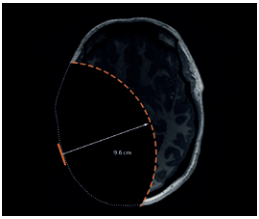
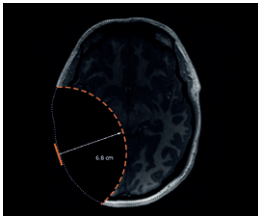
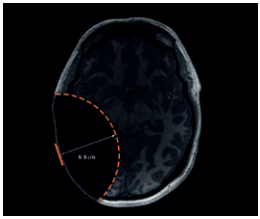
With implant magnet in place	With non-magnetic plug	Implant magnet removed
		
9.6 cm (3.7 in)	6.8 cm (2.7 in)	6.3 cm (2.5 in)

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.

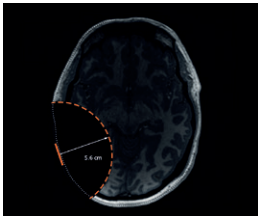
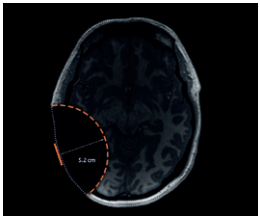
With non-magnetic plug	Implant magnet removed
	
5.6 cm (2.2 in)	5.2 cm (2.0 in)

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.

OSI300 Implant 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:

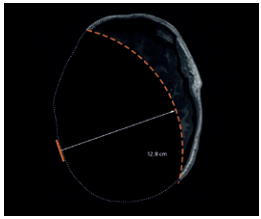
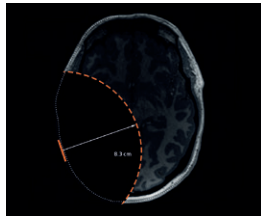
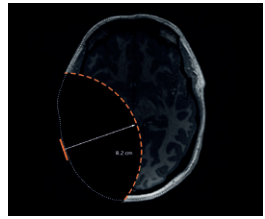
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
12.8 cm (5.0 in)	8.3 cm (3.3 in)	8.2 cm (3.2 in)

Table 6: Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.

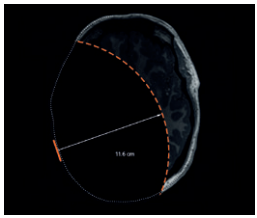
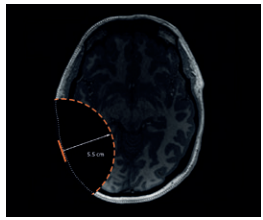
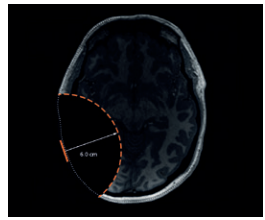
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
11.6 cm (4.6 in)	5.5 cm (2.2 in)	6.0 cm (2.4 in)

Table 7: 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 optimisation of scan parameters can be used to minimise the extent of the artefact.

For bilateral recipients, the image artefacts as shown on ***page 15*** 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 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:

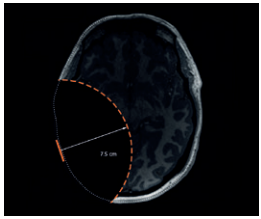
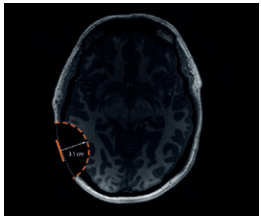
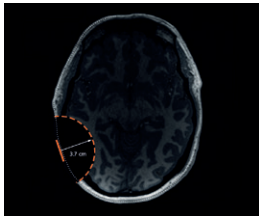
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
7.5 cm (3.0 in)	3.1 cm (1.2 in)	3.7 cm (1.5 in)

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

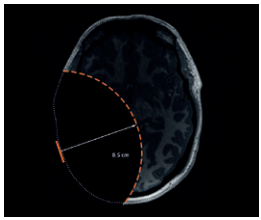
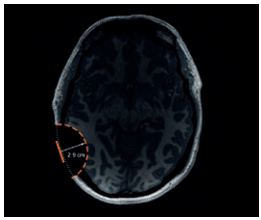
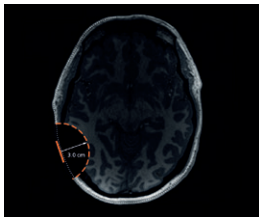
With implant magnet cassette in place	With non-magnetic cassette	Implant magnet cassette removed
		
8.5 cm (3.3 in)	2.9 cm (1.1 in)	3.0 cm (1.2 in)

Table 9: Maximum image artefact from centre at 3 T (MARS sequence)

Parameter	1.5 T MARS Parameters	3 T MARS Parameters
Scanning sequence	Spin echo	Spin echo
Slice selection	Axial	Axial
Slice thickness	5 mm	5 mm
Repetition time	2375 ms	4000 ms
Echo time	17 ms	50 ms
Bandwidth	81,664 Hz	199,936 Hz
Flip angle	90°	90°

Table 10: MARS scan parameters

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.

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 MRI 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 MRI RF conditions 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.

If the MRI examination, implant magnet or magnet cassette removal and replacement will be completed on the same day, the magnet recess can remain empty.

If MRI examinations are needed over a period of time with the implant magnet or magnet cassette removed, it must be replaced in a sterile surgical environment with either a non-magnetic plug or non-magnetic cassette, depending on the implant model.

In the magnet's absence, the non-magnetic plug or non-magnetic cassette prevents fibrous tissue growing into the implant recess. Such growth would make replacement difficult.

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.

Warning

To minimise the risk of infection or fibrous tissue growing into the implant recess, do not leave the magnet pocket empty for MRI examinations taking place over several days. When removing a magnet cassette or implant magnet, replace with a non-magnetic cassette or non-magnetic plug.

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, remove the non-magnetic cassette or non-magnetic plug and replace with a new replacement magnet cassette or sterile replacement magnet.

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

Considerations for implant magnet in place

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

Usability of MRI Kit

The MRI Kit is intended for use with the OSI200 Implant with magnet in place at 1.5 T.

⚠ 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 and splints.

⚠ 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.

Perform the MRI scan

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.

Patient management and MRI scan steps

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

For medical professionals performing the MRI scan, follow the process below.

1. Confirm prior to scanning	Instruction details
The implant model has been identified.	Refer to ***Identifying the Cochlear Osia implants*** on page 8. Bilateral recipients may have two different models. Refer to ***Bilateral recipients*** on page 21.
If the recipient has any other implants, active or abandoned.	If another implanted device is present, verify MRI compatibility before conducting an MRI examination. **Note:** 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.
Patient positioning requirements are compatible with the MRI scan type, and achievable for the patient.	Refer to ***Patient positioning*** on page 21.
If the implant magnet is in place, or has been surgically removed for the MRI scan.	Refer to ***Implant magnet and magnet cassette conditions for MRI*** on page 10. **Note:** • Implant magnet removal is required for some implant models and MRI field strengths. • Additionally, the referring physician may have prescribed implant magnet removal for the MRI scan, for example, to minimise artefact in the area of interest.

1. Confirm prior to scanning	Instruction details
If required, an MRI Kit has been obtained prior to the MRI scan.	Refer to ***Implant magnet and magnet cassette conditions for MRI*** on page 10. Review section ***Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)*** on page 23 prior to the MRI scan. Contact the nearest Cochlear office or official distributor to order an MRI Kit.
The expected artefact has been considered, and there is still diagnostic value in performing the MRI scan.	Refer to ***Image interference and artefacts*** on page 11.
2. Counsel the patient prior to scanning	**Instruction details**
If an MRI Kit will be used, explain to the patient how they will be wrapped.	Refer to ***Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)*** on page 23.
Discuss the sensations the recipient may experience during the MRI scan.	Refer to ***Patient comfort*** on page 22.
Explain to the patient how they will be positioned for the MRI scan.	Refer to ***Patient positioning*** on page 21.
3. Perform the MRI scan	**Instruction details**
Before entering the MRI scan room, remove the sound processor and related accessories, and apply the MRI Kit if it is required. The sound processor is MR Unsafe.	**Note:** Once the sound processor has been removed, the patient may no longer be able to hear. If an MRI Kit is required, apply it immediately prior to entering the MRI scan room to minimise discomfort. Refer to ***Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)*** on page 23.
Position the patient to minimise discomfort.	Refer to ***Patient positioning*** on page 21.
Comply with the MRI machine conditions for the relevant implant models.	Refer to ***MRI machine conditions*** on page 28. Bilateral recipients may have two different implant models. Use the MRI safety information of the patient's implant model with the most restrictive MRI exposure requirements.

4. After the MRI scan	Instruction details
Immediately after the MRI scan, check the patient status.	Refer to ***Considerations after an MRI examination*** on page 29.

Table 11: Patient management and MRI scan steps

Bilateral recipients

Use the MRI safety information of the patient's implant model with the most restrictive MRI exposure requirements.

⚠ **Caution**

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

Patient counselling

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 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 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.

Patient comfort

Explain to the patient that they may perceive sounds during the MRI scan.

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 21.

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.

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

Intended use

The MRI Kit is intended to be used on Cochlear Osia implant recipients to prevent implant magnet dislodgement during MRI scans at 1.5 T. If the implant magnet has been removed, an MRI Kit is not required.

The MRI Kit is for single-use only.

Indications for use

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

- CI500 Series – CI512, CI522, CI532, CI532P, ABI541
- CI24RE Series – CI422, CI24REH, CI24RE (CA), CI24RE (ST)
- CI24R Series – CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series – CI24M, CI 11+11+2M, ABI24M
- CI22M Series – CI22M with removable magnet

⚠ Warning

Although unlikely with the use of the MRI Kit, it is possible for the implant magnet to move during an MRI scan and dislodge from the implant magnet pocket. In this case, surgical intervention to reposition or replace the implant magnet would be required.

Contraindications

The MRI Kit is contraindicated for use with:

- CI22M implants without removable magnet
- MRI scans other than 1.5 T.

Refer to the elasticised compression bandage labelling for related contraindications when using this product.

Obtaining an MRI Kit

Contact the nearest Cochlear office or official distributor to order an MRI Kit – contact numbers are available on the back cover of this document.

MRI Kit contents

The following items are provided in your MRI Kit:

Item	Description
Flat plastic splints x 2	To be placed against the skin over the implant magnet site. For bilateral recipients, use one splint for each applicable implant. Refer to ***Indications for use*** on page 23.
Elasticised compression bandage x 1	To provide compression on each splint at the implant magnet site.
Surgical tape x 1	To secure the bandage and splint in place.

Table 12: Content of MRI Kit

Using the MRI Kit

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

1. Preparation

1. Prior to entering the MRI room and before removing the sound processor, ensure you have the contents of the MRI Kit available and within easy reach.
2. Use a marker to draw an outline of the sound processor on the patient's head. Refer to ***Fig.7*** on page 25.
3. Remove the sound processor.

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

4. Once the sound processor has been removed from the head, use a marker to draw the centre position of the outline; this is the implant magnet location.
   - If necessary, shave the patient's head at the implant magnet location so this marking is more visible and easier to locate during the splinting process.

   Note:
   This marking is essential to ensure that the splint is placed in the correct location.

5. Repeat steps 2, 3 and 4 on the other implant site for bilateral recipients if required. Refer to ***Indications for use*** on page 23.

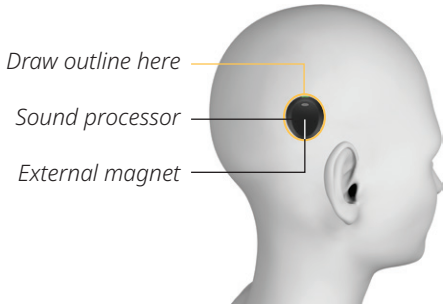


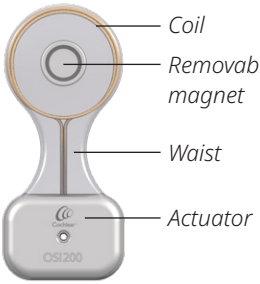
Fig.7: Location of the sound processor with external magnet

6. If the location of the implant has not been marked, it can be located by:

   - using ferromagnetic material, such as a paper clip – the material will be attracted to the implant magnet

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

   - touch – gently feel around the implant site to locate the position of the implant coil. The implant is comprised of the round implant coil, the waist and the actuator. The implant magnet will be at the centre of the implant coil. Refer to ***Fig.8*** on page 25.



Skin side

Fig.8: OSI200 Implant (P1170466)

2. Bandaging

1. Use a splint from the MRI Kit and centre it over the implant magnet site as marked on the skin. For bilateral recipients, use one splint for each applicable implant. Ensure each splint is positioned over the centre of the implant magnet site. Refer to ***Fig.8*** on page 25 for the implant magnet location.
   You may need the assistance of another person to hold the splint in place while you bandage. Otherwise, use the supplied tape to maintain the splint position prior to bandaging.

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

2. Apply the elasticised compression bandage. Ensure the centre line of the bandage is over each implant magnet site and the splints are fully covered. Refer to ***Fig.9*** on page 26.
3. Use a minimum of two bandage layers at full stretch (no elasticity remaining in the bandage).
   When the bandage is at its maximum tightness, the small rectangular tension markers will stretch to become square in shape. Refer to ***Fig.10*** on page 27.
4. Use the surgical tape from the MRI Kit to secure the bandage by wrapping two surgical tape layers around the head, over the bandage center line. Ensure the tape ends overlap.
5. Conduct the MRI scan. Follow the instructions in ***Perform the MRI scan*** on page 19.
6. Once the MRI scan is complete, follow the instructions in ***Considerations after an MRI examination*** on page 29.

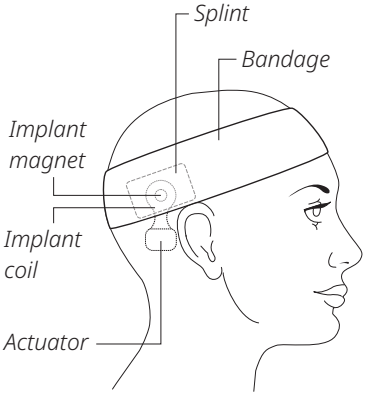


Fig.9: Fitting the MRI Kit splint and compression bandage.Position the splint over the implant magnet site and then apply the bandage over the centre of the splint and the centre of the implant magnet site.

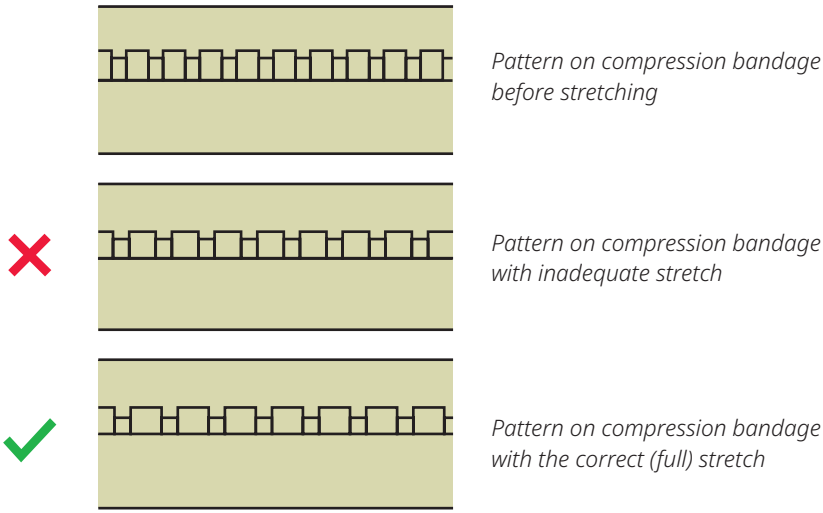


Fig.10: Comparison of compression bandage tightness

MRI machine conditions

The following table details MRI machine conditions for Osia Cochlear implants.

Scan conditions for Osia Implants

Parameter	Condition
Device name	OSI200 Implant and OSI300 Implant
Static magnetic field strength (B_0)	1.5 T and 3 T
Type of nuclei	Hydrogen
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 must be performed in quadrature mode or circular polarization (CP) mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.
RF transmitting coil conditions	• Any RF transmitting coil can be used. • Scan in Normal Operating Mode. There are no additional SAR restrictions for the Osia implants.
RF receiving coil conditions	No restrictions on RF receiving coils.
Operating mode	Normal operating mode
Scan duration	Scan for up to 60 minutes per appointment.
Scan regions	Any landmark is acceptable

Table 13: Scan conditions for the Osia Implants.

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. Refer to ***Cochlear Nucleus® Implant Bandage and Splint Kit for MRI (MRI Kit)*** on page 23 for full instructions and warnings.

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

Refer to ***Considerations for implant magnet removal*** on page 17.

Trademark legal notice

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