

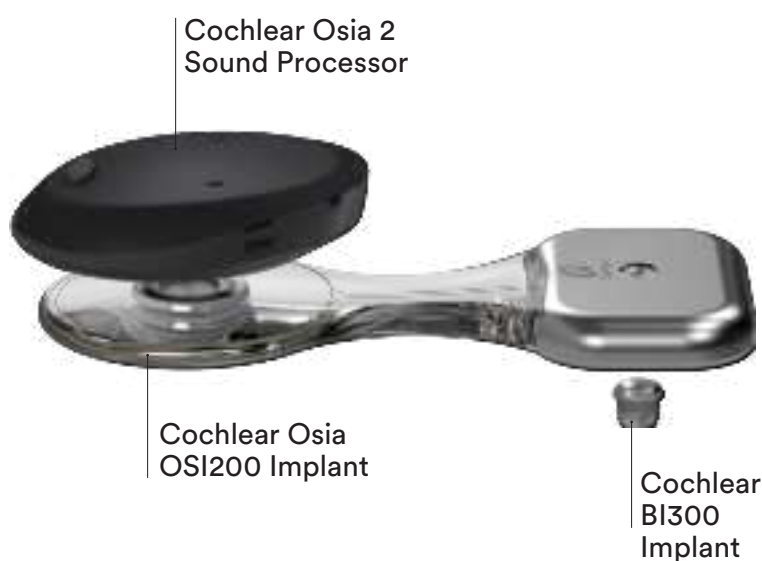
Radiographer's instructions for MRI

Cochlear[™] Osia[®] 2 System

The Cochlear[™] Osia[®] 2 System is an active osseointegrated steady-state implant (OSI) hearing solution that uses digital piezoelectric stimulation to send sound through the bone to the inner ear.

These radiographer's instructions for MRI do not replace the MRI Guidelines. For warnings and precautions refer to the MRI Guidelines prior to conducting a MR scan. Please read this information carefully. Full MRI safety information is available:

- in the Cochlear Osia Magnetic Resonance Imaging (MRI) Guidelines (supplied with the implant)
- by visiting www.cochlear.com/mri
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.



Performing MRI safely

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.

Non-clinical testing has demonstrated that the Osia OSI200 Implant, in combination with the BI300 Implant, are MRI Conditional.¹ 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 following conditions:

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 page 4.
- 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 (Table 1).


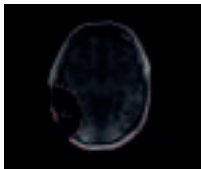
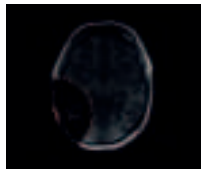
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
15.0 cm (5.9 in)	4.5 cm (1.8 in)	5.7 cm (2.2 in)

Table 1: Maximum image artefact from centre at 1.5 T (gradient echo sequence). The image artefact may extend further in the coronal or sagittal plane.²

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant when imaged with the SEMAC-VAT metal artefact reduction sequence scan in the axial plane (Table 2).

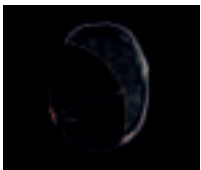
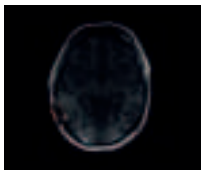
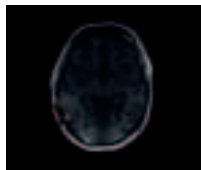
With implant magnet + magnetic splint	With non-magnetic plug	Implant magnet removed
		
11.4 cm (4.5 in)	1.8 cm (0.7 in)	1.8 cm (0.7 in)

Table 2: Maximum image artefact from centre at 1.5 T (SEMAC-VAT). The image artefact may extend further in the coronal or sagittal plane.²

Cochlear Osia MRI Kit

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.

WARNING

To minimise possible pain and discomfort, apply the splint and bandage immediately prior to the entering the MRI room. Remove the splint and bandage immediately after the MRI procedure and the recipient is outside of the MRI room. If the splint becomes loose inside the MRI room, this could lead to damage of the MRI equipment and / or injury to the MRI staff or recipient. 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 dislodgement of the implant magnet and could cause pain.

Obtaining an MRI Kit

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

The MRI Kit contains:



Fig. 1: Magnetic splints – to be placed against the skin over the implant magnet site. For bilateral patients use one splint for each implant.




Fig. 2: Compression bandage – for securing the splint against the implant magnet site.



Fig. 3: User guide showing how to apply splints and bandage

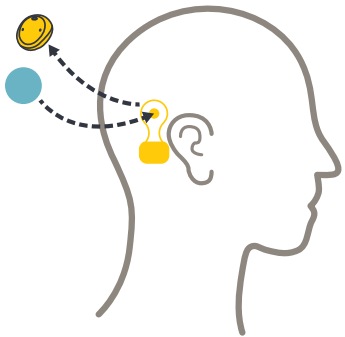
1. Preparation (Steps 1 - 2)

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 does 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.** 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.
4. Refer to *Preparation for conducting the MRI examination* on the **Cochlear Osia Magnetic Resonance Imaging (MRI) Guidelines**. Conduct the MR scan.
5. Once the MR scan is complete, follow the instructions in *Considerations after an MRI examination*.

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 (Table 3).

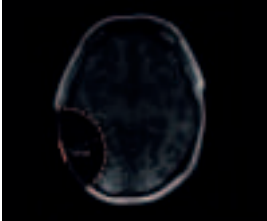
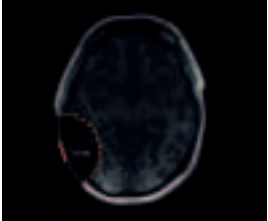
With non-magnetic plug	Implant magnet removed
	
4.6 cm (1.8 in)	4.0 cm (1.6 in)

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.²

In non-clinical testing, the maximum image artefact caused by the OSI200 Implant when imaged with the SEMAC-VAT metal artefact reduction sequence scan in the axial plane (Table 4).

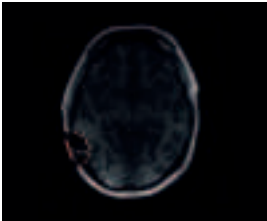
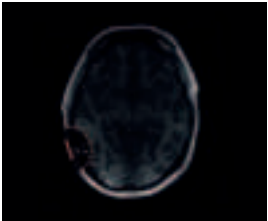
With non-magnetic plug	Implant magnet removed
	
2.3 cm (0.9 in)	2.7 cm (1.1 in)

Table 4: Maximum image artefact from centre at 3 T (SEMAC VAT).
The image artefact may extend further in the coronal or sagittal plane.²

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 600,000 implantable devices, helping people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to innovative future technologies. We collaborate with leading clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

References

1. Nyenhuis J. Measurement and Analysis of OSI 200 Bone Conduction Implant (MRI Testing External Report). Bemcalc, Inc; 2019; D1626921.
2. Fierens G. OSI200 Artefact Reduction in 1.5T and 3T MRI. Cochlear Bone Anchored Solutions AB, Sweden. 2020; D1670327.

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This material is not intended for use in the United States. In the United States there may be indications and considerations that differ to those presented in this material.

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