

Cochlear Osia 2 Hearing System User Manual

Home » Cochlear » Cochlear Osia 2 Hearing System User Manual

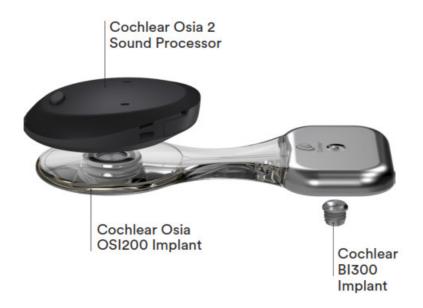


FOR PROFESSIONALS
Radiographer's instructions for MRI
Cochlear ™Osia®2 System

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 radiographers' instructions for MRI do not replace the MRI Guidelines. For warnings and precautions refer to the MRI Guidelines prior to conducting an 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.



Contents [hide

- 1 Performing MRI safely
- 2 Cochlear Osia MRI Kit
- 3 Preparation (Steps 1 -
- 2)
- 4 Bandaging (Steps 1 6)
- 5 T scans
- 6 Hear now. And always
- 7 Documents / Resources
- **8 Related Posts**

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.

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.
- The 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 artifact caused by the OSI200 Implant when imaged with a gradient echo pulse sequence scan in the axial plane (Table 1).

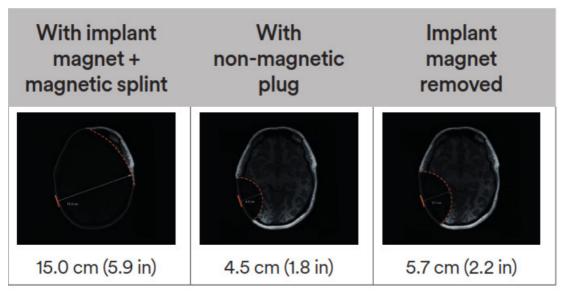


Table 1: Maximum image artifact from the center at 1.5 T (gradient echo sequence). The image artifact may extend further in the coronal or sagittal plane.2 In non-clinical testing, the maximum image artifact caused by the OSI200 Implant when imaged with the SEMAC-VAT metal artifact reduction sequence scan in the axial plane (Table 2).

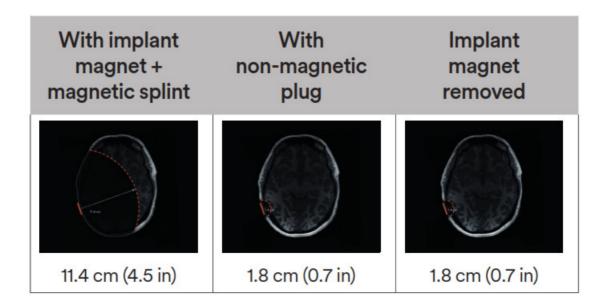


Table 2: Maximum image artifact from the center at 1.5 T (SEMAC-VAT). The image artifact may extend further in the coronal or sagittal plane. 2

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 minimize possible pain and discomfort, apply the splint and bandage immediately prior to 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 to 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:

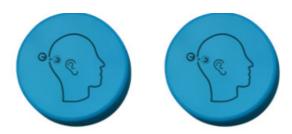


Fig. 1: Magnetic splints – to be placed against the skin over the implant magnet site. For bilateral patients use one splint for each implant.



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

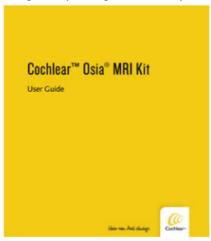


Fig. 3: User guide showing how to apply splints and bandage

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.



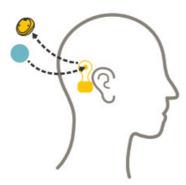
Once the sound processor has been removed, the recipient will no longer be able to hear.

To ensure the 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.

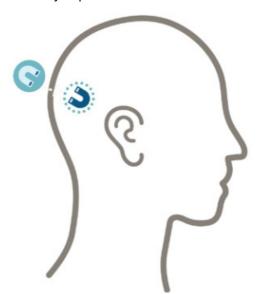
1. Remove the sound processor and replace the sound processor with a magnetic splint from the MRI Kit. See Step 2.

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 in the place where you removed the sound processor.

Repeat this step if the recipient is bilaterally implanted.

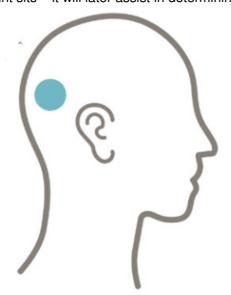




NOTE

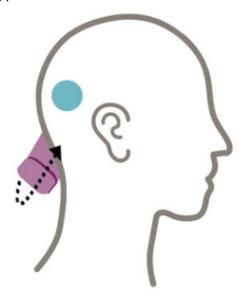
The splint should stay in place without any need to hold.

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



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 role as the bandage is applied on the head. Ensure the splints have been fully covered and have not moved from their starting position.





NOTE

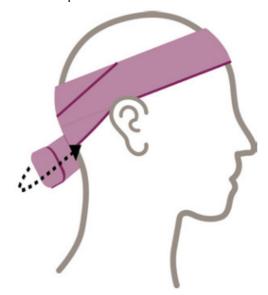
The bandage should be wrapped firmly to ensure the splint does not move, but not too tight to cause pain. Check that the splint has not moved before continuing to bandage.

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 from slipping off).

Ensure that the splint is covered on each wrap.

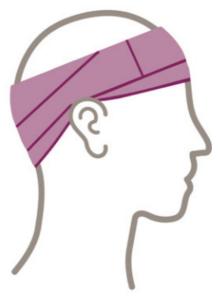
Check that the splint has not moved out of place.



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.

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.
- The 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 artifact caused by the OSI200 Implant when imaged with a gradient echo pulse sequence scan in the axial plane (Table 3).

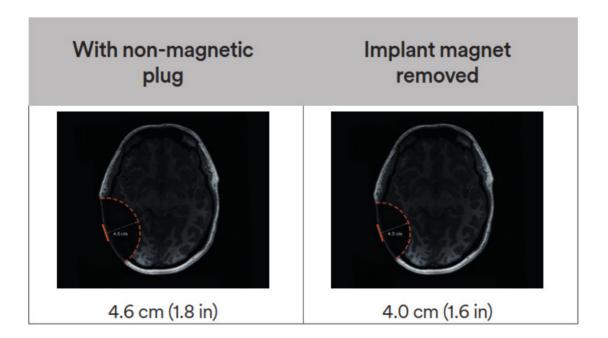


Table 3: Maximum image artifact from the center at 3 T (gradient echo sequence). The image artifact may extend further in the coronal or sagittal plane. 2

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

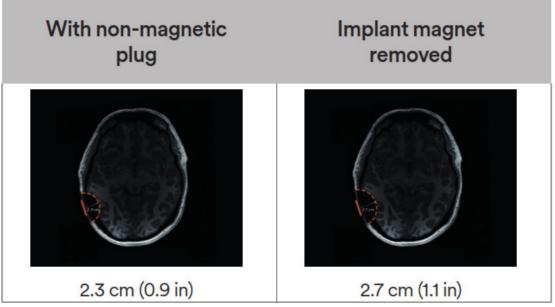


Table 4: Maximum image artifact from the center at 3 T (SEMAC VAT). The image artifact may extend further in the coronal or sagittal plane.2

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; 1670327.

Cochlear Ltd, (ABN 96 002 618 073), 1 University Avenue, Macquarie University, NSW 2109

Australia

Tel: +61 2 9428 6555, Fax: +61 2 9428 6352

EC|REP Cochlear Deutschland GmbH & Co. KG, Karl-Wiechert-Allee 76A, 30625 Hannover, Germany

Tel: +49 511 542 770, Fax: +49 511 542 7770

Regional Offices

Cochlear Ltd, (ABN 96 002 618 073), 1 University Avenue,

Macquarie University, NSW 2109 Australia Tel: +61 2 9428 6555, Fax: +61 2 9428 6352

Cochlear Americas, 10350 Park Meadows Drive, Lone Tree, CO 80124, USA

Tel: +1 303 790 9010, Fax: +1 303 792 9025

Local Offices

Cochlear Europe Ltd, 6 Dashwood Lang Road, Bourne Business Park,

Addlestone, Surrey, KT15 2HJ, United Kingdom Tel: +44 1932 26 3400, Fax: +44 1932 26 3426

www.cochlear.com

The content of this guideline is intended as a guide for information purposes only and does not replace or remove clinical judgment or the professional care and duty necessary for each specific recipient case. The information has been prepared with reference to the best information available at the time of preparation. However, no assurance is given that the information is entirely complete or accurate in every respect. Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise. 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.

Cochlear, , Hear now. And always, Osia, SmartSound, the elliptical logo, and marks bearing an ® or ™ symbol, are either trademarks or registered trademarks of Cochlear Bone Anchored Solutions AB or Cochlear Limited (unless otherwise noted).

© Cochlear Limited 2021. All rights reserved. 2021-02.

D1809687-V1

Documents / Resources



Cochlear Osia 2 Hearing System [pdf] User Manual Osia 2, Hearing System, Osia 2 Hearing System

Manuals+, home privacy