



# **Cochlear™ Osia® MRI Kit**

## **User Guide**



# About this guide

This guide must be read in conjunction with the *Cochlear™ Osia® Magnetic Resonance Imaging (MRI) Guidelines*.

For more information, including instructions for how to use the Cochlear Osia MRI Kit prior to an MRI examination, visit: [www.cochlear.com/MRI](http://www.cochlear.com/MRI) or contact your nearest Cochlear office.

## Symbols used in this guide

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### Note

Important information or advice.

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### Caution (no harm)

Special care to be taken to ensure safety and effectiveness.  
Could cause damage to equipment.

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### Warning (harmful)

Potential safety hazards and serious adverse reactions.  
Could cause harm to person.

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# Intended purpose

The Cochlear Osia MRI Kit is intended to prevent the dislodgement of the magnet in a Cochlear Osia implant during an MRI procedure.

The Cochlear Osia MRI Kit is for single-use only.

# Indications

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

The Cochlear Osia MRI Kit is indicated for a recipient with the following compatible Cochlear Osia implants:

- Osia OSI100 implant
- Osia OSI200 implant

 **Caution**

The Cochlear Osia implants will create shadowing on the MR image near the implant, resulting in a loss of diagnostic information. Refer to the Image interference and artefacts section of the *Cochlear Osia MRI Guidelines*.

## Contraindications

The Cochlear Osia MRI Kit is contraindicated for use with MRI scans other than 1.5 T and for recipients with any implant except those identified in the indications.

For information on identifying Cochlear Osia implants without surgical intervention, refer to the *Cochlear Osia MRI Guidelines*.

## **Intended users**

The Cochlear Osia MRI Kit is intended for use by specialised healthcare professionals who prepare recipients for MRI scans. The healthcare professional applying the MRI Kit is ear, nose and throat (ENT) physicians.

## **Intended patient population**

The Cochlear Osia MRI Kit is intended to be used on an individual requiring an MRI scan at 1.5 T and who is implanted with a compatible Cochlear Osia implant. There are no restrictions for the intended patient population in terms of age, weight, health or other condition.

## **Clinical benefits**

Benefits include enabling an MRI scan at 1.5 T without the need to surgically remove the implant magnet.

## **Serious incidents**

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



# Obtaining an MRI Kit

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

## MRI Kit contents

The following items are provided in your MRI Kit:

Item	Description
Round Splint x 2	Round magnetic splints – to be placed on the skin over each implant magnet site. For bilateral patients, use one splint for each implant.
Chinstrap x 2	<ul style="list-style-type: none"><li>• Size Large</li><li>• Size Small</li></ul>
Bandage x 1	Compression bandage – to provide compression on each splint at the implant magnet site.

The *Cochlear Osia MRI Kit User Guide* is supplied along with the Cochlear Osia MRI Kit for instructions on how to apply the chinstrap, splint and bandage.

# Using the MRI Kit

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

## 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, splints, and chinstrap.
- If a splint becomes loose inside the MRI room, this could lead to MRI equipment damage and/or could cause injury to the MRI staff or recipient.
- The splint contains a magnet, which should be kept away from neurostimulation devices (for example, deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at 2.5 cm (1 in) from the edge of the implant with the splint in place, in any direction is less than 300 gauss.

## 1. Preparation

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



### Note

Once the sound processors have been removed, the recipient may no longer be able to hear.

To ensure greatest magnet attraction, clear away as much hair as possible from the implant magnet site.

- For recipients with long hair, follow “Management for long hair (2 steps)” on page 12 to securely tie the hair into two sections.
- For recipients with shorter hair that cannot be tied up, skip to “Removing the sound processor (1 step)” on page 13.

## 2. Management for long hair (2 steps)

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*sound processor*

1. Before removing the sound processor, divide hair into two sections; one section above and one section below the sound processor.
2. Tie the first section of hair into a loop or bun at the head crown, and tie the second section of hair into a loop or bun at the nape.



### **Note**

For ease of long hair management, the user (for example, the ENT surgeon or physician) may direct the patient or carer to read the instructions and perform the hair management steps themselves. User to ensure the resulting hair sections adhere to these instructions.

### 3. Removing the sound processor (1 step)

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*sound processor*

1. Remove the sound processor.

Remove both sound processors if the recipient is bilaterally implanted.



#### **Note**

The recipient may no longer be able to hear.

## 4. Chinstrap (7 steps)

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1. Select the appropriate chinstrap size for the recipient's head to secure each splint to the implant magnet site.
2. Place the centre of the chinstrap on the recipient's chin, with the tip of the chin secured into the slit of the chinstrap fabric.



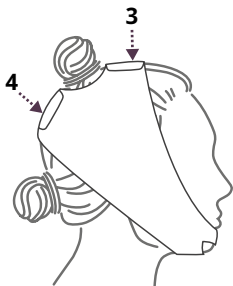
### Note

For recipients with full beards, ensure the tip of the chin is firmly placed in the chinstrap.



### Warning

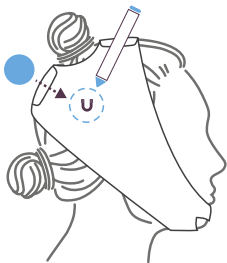
If the chinstrap is too loose to secure the splints, the MRI Kit should not be used.



3. Bring the forward two ends of the chinstrap to the top of the head and attach with the hook and loop fastener.
4. Repeat with the bottom chinstrap ends and attach the hook and loop fastener at the middle back of the head. If hair is tied up, attach the hook and loop fastener in between the two hair sections.

**Note**

Ensure the chinstrap is secured firmly to the recipient's head, but without causing discomfort or pain.



5. Place one round magnetic splint on top of the chinstrap fabric and over the implant magnet site; from where the sound processor was removed.  
As you move the splint towards the implant magnet site you will feel a magnetic attraction. The splint is correctly placed if it holds independently.
6. Use a marker to draw the outline of the splint on the chinstrap fabric.



**Note**

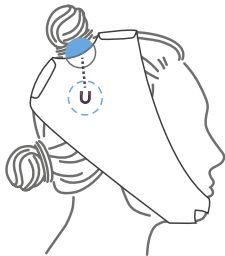
- You should be able to draw the entire splint outline on the chinstrap fabric.
- Adjust the chinstrap placement as needed.

Repeat steps 5 and 6 if the recipient is bilaterally implanted.

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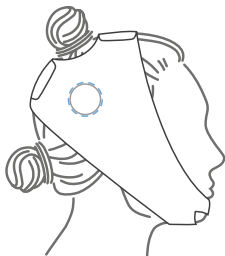
- 
7. Insert the round magnetic splint underneath the chinstrap and directly onto the recipient's head.



**Note**

Ensure the splint is placed precisely under the outline marking on the chinstrap fabric.

Repeat this step if the recipient is bilaterally implanted.



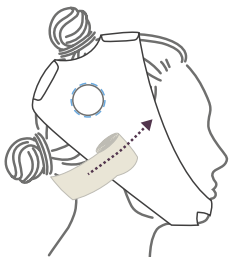
**Caution**

The chinstrap must completely cover the implant magnet site.

## 5. Bandaging (5 steps)

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1. Clear all hair away from the forehead.
2. Starting at the base of the skull, begin bandaging around the head.

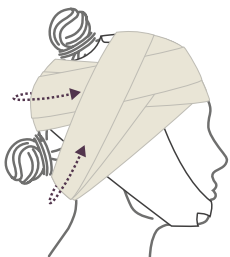


Maintain the tension required to unwrap the bandage from its roll as the bandage is applied on the head.



### Note

- Wrap the bandage firmly, but not so tight that it may cause pain.
- Ensure each splint maintains its position under the marked area while wrapping.



3. Continue bandaging using the base of the skull as an anchoring point. This will prevent the bandage from slipping off.

Alternate bandage wraps between the base of the skull and the middle back of the head.



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



**Do not cut the bandage.**

5. 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.
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## 6. Stop and check

Before conducting the MRI scan, **stop**, and check the following:

- ✓ The patient is comfortable.
- ✓ There is at least one anchoring wrap at the base of the skull.
- ✓ There is at least one wrap around the middle back of the head.
- ✓ Each splint is completely covered by the chinstrap fabric and bandage with no blue visible.
- ✓ The entire bandage has been used.

## 7. MRI scan (3 steps)

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1. Consult the “Preparation for conducting the MRI examination” section in the *Cochlear Osia MRI Guidelines*.
2. Conduct the MRI scan.
3. Once the MRI scan is complete, follow the instructions in “Considerations after an MRI examination” on page 22.



### Warning

Do not conduct the MRI scan until all points listed in “Stop and check” on page 20 are completed.



### 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.

# Considerations after an MRI examination

After the patient leaves the MRI room, remove the MRI Kit bandage, round magnetic splint and chinstrap. 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, 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.

## Disposal

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

The Cochlear Osia MRI Kit is for single-use only.

# Labelling symbols

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



Consult instructions for use



Specific warnings or precautions associated with the device, which are not otherwise found on the label



Manufacturer



Date of manufacture



Catalogue number



Authorised representative in the European Community/  
European Union



Keep dry



Do not re-use



Do not use if package is damaged and consult instructions for use



Recyclable packaging

**Rx Only**

By prescription



MR Conditional



Unique device identifier



Medical Device



Use by date



# Trademark legal notice

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