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 or contact your nearest Cochlear office.

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

About this guide ......................................................... 3
  Symbols used in this guide ............................................. 3

Intended purpose .......................................................... 6

Indications ..................................................................... 6

Contraindications ........................................................... 7

Intended users ............................................................... 8

Intended patient population ............................................ 8

Clinical benefits ............................................................ 8

Serious incidents .......................................................... 8
Obtaining an MRI Kit ................................................................. 9
  MRI Kit contents. ................................................................. 9

Using the MRI Kit ................................................................. 10
  1. Preparation. ................................................................. 11
  2. Management for long hair (2 steps) ......................... 12
  3. Removing the sound processor (1 step) ................... 13
  4. Chinstrap (7 steps) ....................................................... 14
  5. Bandaging (5 steps) ...................................................... 18
  6. Stop and check ........................................................... 20
  7. MRI scan (3 steps) ....................................................... 21

Considerations after an MRI examination ..................... 22

Disposal ................................................................. 22

Labelling symbols ............................................................. 23

Trademark legal notice ......................................................... 25
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:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round Splint x 2</td>
<td>Round magnetic splints – to be placed on the skin over each implant magnet site. For bilateral patients, use one splint for each implant.</td>
</tr>
</tbody>
</table>
| Chinstrap x 2     | • Size Large  
                    • Size Small                                                        |
| 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.
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)

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)

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)

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.
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)

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.
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)

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

Cochlear, 科利耳, コクレア, 코클리어, Hear now. And always, Osia, SmartSound, the elliptical logo, and marks bearing an ® or ™ symbol, are either trademarks or registered trademarks of the Cochlear group of companies (unless otherwise noted).

© Cochlear Limited 2023. All rights reserved.
AU 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

DE Cochlear Deutschland GmbH & Co. KG
Mailänder Straße 4 a, 30539 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770

CH Cochlear AG
Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 205 8204 Fax: +41 205 8205

US Cochlear Americas
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010

CA Cochlear Canada Inc
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 483 3123 Fax: +1 416 972 5083

UK Responsible Person: 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

BE Cochlear Benelux NV
Schaliënhoedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70

FR Cochlear France S.A.S.
135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National)
Fax: +33 5 34 63 85 80

IT Cochlear Italia S.r.l.
Via Trattati Comunitari Europei 1957-2007 n.17, 40127 Bologna (BO), Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62

SE Cochlear Nordic AB
Konstruktionvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60

www.cochlear.com

TR Cochlear Tibbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Küçükbaakköy Mah, Defne Sok, Büyükhanli Plaza No:3 Kat:3 Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900 Fax: +90 216 538 5919

HK Cochlear (HK) Limited
Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road, Causeway Bay, Hong Kong
Tel: +852 2530 5773 Fax: +852 2530 5183

KR Cochlear Korea Ltd
2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450 Fax: +82 2 533 8408

CN Cochlear Medical Device (Beijing) Co., Ltd
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900

IN Cochlear Medical Device Company India Pvt. Ltd.
Ground Floor, Platina Building, Plot No C-59, G-Block,
Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111 Fax: +91 22 6112 1100

JP 株式会社日本コクレア(Nihon Cochlear Co Ltd)
〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241 Fax: +81 3 3817 0245

AE Cochlear Middle East FZ-LLC
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor,
Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400 Fax: +971 4 361 8925

PA Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218

NZ Cochlear NZ Limited
Level 4, Takapuna Towers, 19-21 Como St, Takapuna,
Auckland 0622, New Zealand
Tel: + 64 9 914 1983 Fax: 0800 886 036