



Cochlear™ Nucleus® MRI Kit

User Guide

For Professionals

About this guide

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

For more information, including instructions for how to use the Cochlear Nucleus 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.

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Intended purpose

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

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

Indications

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

- CI500 Series: CI512, CI522, CI532, ABI541
- CI24RE Series: CI422, CI24REH (Hybrid L24), 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



Caution:

Cochlear Nucleus cochlear 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 Nucleus Implants MRI Guidelines*.

Contraindications

The Cochlear Nucleus 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. In particular, the Cochlear Nucleus MRI Kit is contraindicated for the following Cochlear Nucleus implant:

- CI22M without removable magnet

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

Intended users

The Cochlear Nucleus 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 Nucleus 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 Nucleus 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">• Size Large• Size Small
Bandage x 1	Compression bandage – to provide compression on each splint at the implant magnet site.

The *Cochlear Nucleus MRI Kit User Guide* is supplied along with the Cochlear Nucleus 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 magnet 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 Nucleus MRI Kit available and within easy reach.



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

The sound processor type could be either:

- BTE (behind-the-ear) sound processor
- *or*
- OTE (off the ear) sound processor

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)



BTE sound processor

1. Before removing the sound processor, divide hair into two sections; one section above and one section below the BTE sound processor coil **or** the OTE 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.



OTE sound processor



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 BTE **or** OTE 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)



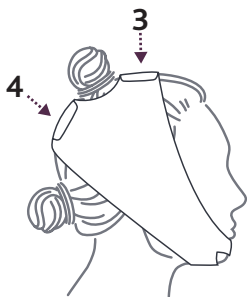
1. Select the appropriate chinstrap size for the recipient's head to secure each splint to the implant magnet site.
2. Place the centre of the chinstrap on the recipient's chin, with the tip of the chin secured into the slit of the chinstrap fabric.



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



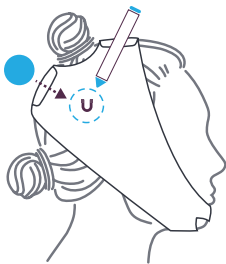
Warning: If the chinstrap is too loose to secure the splints, the MRI Kit should not be used.



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 BTE sound processor coil or OTE 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.

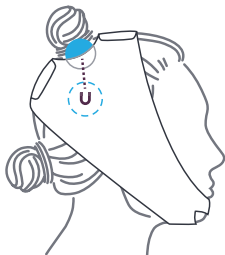
6. Use a marker to draw the outline of the splint on the chinstrap fabric.



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.

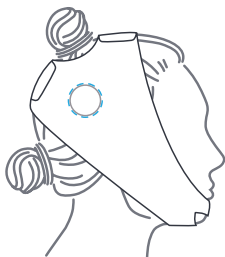


7. Insert the round magnetic splint underneath the chinstrap and directly onto the recipient's head.



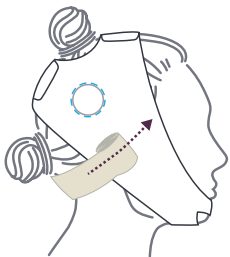
Note: Ensure the splint is placed precisely under the outline marking on the chinstrap fabric.

Repeat this step if the recipient is bilaterally implanted.



Caution: The chinstrap must completely cover the implant magnet site.

5. Bandaging (5 steps)



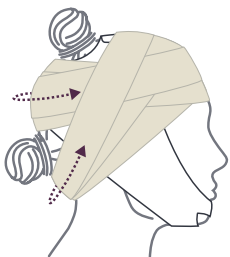
1. Clear all hair away from the forehead.
2. Starting at the base of the skull, begin bandaging around the head.

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

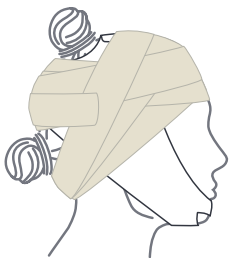


Note:

- 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.
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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)



1. Consult the *Preparation for conducting the MRI examination* section in the *Cochlear Nucleus Implants 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.
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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 Nucleus MRI Kit can be disposed of as normal hospital or household waste, or in accordance with local regulations.

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

Labelling symbols

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

Symbol	Description
	Refer to instruction manual
	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
	Authorised representative in Switzerland

	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

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントウア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, SoundBand, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

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