Cochlear™ Nucleus® Implants Magnetic Resonance Imaging (MRI) Guidelines

Europe / Middle East / Africa

Hear now. And always

Cochlear®

About this guide

This guide applies to Cochlear™ Nucleus® implants. It is intended for:

- specialised health care professionals who prepare and perform MR scans
- physicians who refer a Cochlear Nucleus implant recipient for an MR scan
- Cochlear Nucleus implant recipients and/or their carers.

This guide provides information about the safe application of an MR scan on Cochlear Nucleus implant recipients.

MR scans performed under different conditions than those presented in this guide may result in severe patient injury or device malfunction.

Due to the risks associated with using MRI with an implanted medical device, it is important to read, understand, and comply with these instructions to prevent potential harm to the patient and/or device malfunction.

This guide should be read in conjunction with the relevant documents that accompany a Cochlear Nucleus implant, such as the Physician's Guide and Important Information Booklet. For more information, visit www.cochlear.com/warnings.

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

MRI safety information

In order to determine if a patient may receive an MR scan, you must first identify the patient's Cochlear Nucleus implant model.

After you have identified the implant model, see ***MRI safety information for Cochlear Nucleus implants on page 12*** to locate the MRI safety information for that specific implant model.

All external components of the Cochlear implant system (e.g. sound processors, remote assistants and related accessories) are MR Unsafe. The patient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

Bilateral recipients

If one or more of the implants is a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

If a bilateral recipient has implant models (other than the CI22M cochlear implant without a removable magnet), read the MRI safety information for each implant model relevant to the recipient. Use the MRI safety information of the recipient's implant model with the most restrictive MRI exposure requirements.

Identifying the Cochlear Nucleus implant

The implant model can be found on the patient's Cochlear patient identification card.

If the patient does not have their patient identification card with them, the implant type and model can be identified without surgical intervention. See ***X-ray information for identification of Cochlear Nucleus implants on page 6*** and ***Implant model identification on page 7***.

X-ray information for identification of Cochlear Nucleus implants

Cochlear Nucleus implants are made of metal and implanted under the skin behind the ear.

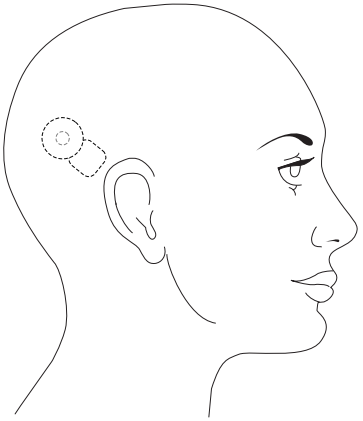


Figure 1: Location behind the ear for Cochlear Nucleus implants

X-ray guidelines

Lateral X-ray at 70 kV/ 3 mAs provides sufficient contrast to identify the implant.

A modified Stenver's view is not recommended for implant identification as implants may appear oblique.

Imaging should include an unobstructed view of antenna coils and implant bodies.

Bilateral recipients may have different implant models on either side of the head. A lateral skull X-ray with a 15 degree cranial tube angle will offset the implants in the image, enabling identifying features to be distinguished.

Implant model identification

Identifying features on Cochlear Nucleus implant X-ray images are explained in the following pages. Other implant models may have other identifying features.

Cochlear Nucleus CI600 Series and CI500 Series implants

Cochlear Nucleus CI600 Series implants - CI612, CI622, CI624 and CI632 and CI500 Series implants – CI512, CI522, CI532 and ABI541 – do not have radiopaque characters.

Using an X-ray, CI500 Series and CI600 Series implants can be identified by the implant shape and electronic assembly layout. If further implant details are required, contact your Cochlear representative who will provide instructions on how to determine the following:

- Manufacturer
- Model
- Year of manufacture.

*Not all products are available in all countries.
Please contact your local Cochlear representative for product information.

The electronic assembly layout is identical for Cochlear CI600 and CI500 Series implants. The unique identifier for CI600 Series implants is the magnet shape and the three holes next to the magnet, as illustrated in the table below.

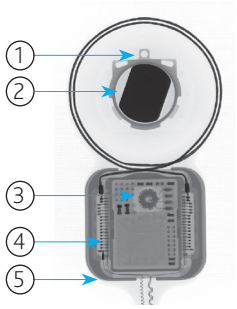
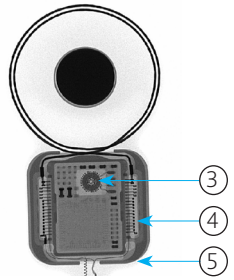
CI600 Series implant X-ray	CI500 Series implant X-ray	Unique identifier
		1. Three holes adjacent to magnet 2. Magnet shape 3. Round shape at coil exit end of electronic assembly layout 4. Series of wire connectors that are visible on both sides of the electronic assembly 5. Square implant body shape

Table 1: CI600 & CI500 Series implant identified by their shape and electronic assembly

Cochlear Nucleus CI24RE Series, CI24R Series, CI24M Series and CI22 Series implants

Cochlear Nucleus implants that can be identified by the radiopaque characters printed on them are:

- CI24RE Series: CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- CI24R Series: CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series: CI24M, CI11+11+2M and ABI24M
- CI22 Series: CI22M.

There are three sets of radiopaque characters printed on each implant.

1. The first character identifies the manufacturer – 'C' indicates Cochlear Ltd.
2. The second (middle) character identifies the implant model.
3. The third character indicates the year of manufacture. To determine the year of manufacture of your implant, contact your Cochlear representative.

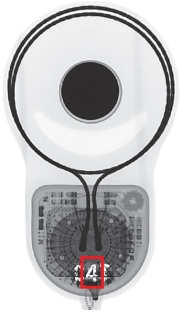
Implant model	Location of second (middle) radiopaque character set	Radiopaque characters
CI422		13
CI24REH		6
CI24RE (CA)		5
CI24RE (CS)		7
CI24RE (ST)		4

Table 2: CI24RE Series implants identified by radiopaque characters

Implant model	Location of second (middle) radiopaque character set	Radiopaque characters
CI24R (CA)		2
CI24R (CS)		C
CI24R (ST)		H

Table 3: CI24R Series implants identifed by radiopaque characters

Implant model	Location of second (middle) radiopaque character set	Radiopaque characters
CI24M		T
CI 11+11+2M		P
ABI24M		G

Table 4: CI24M Series implants identifed by radiopaque characters

Implant model	Location of second (middle) radiopaque character set	Radiopaque characters
CI22M with removable magnet		L or J
CI22M without removable magnet		Z

Table 5: CI22 Series implants identifed by radiopaque characters

MRI safety information for Cochlear Nucleus implants

Non-clinical testing has demonstrated that Cochlear Nucleus implants are MR Conditional.

The MRI safety information provided in these guidelines only applies to 1.5 T and 3 T MRI horizontal scanners (closed bore or wide bore) with a circularly polarised (CP) RF field for a maximum scan time of 60 minutes.

A patient with one or two of these devices can be safely scanned in an MR system meeting conditions on the following pages. All scans shall be performed according to the specified SAR limits for the relevant implant.

Consider the following prior to scanning:

- Determine if the magnet should be removed, or use the MRI Kit. See *Implant magnet conditions for MRI on page 13*.
- Remove the sound processor before entering the MRI room. The sound processor is MR Unsafe.
- It is safe to use local cylindrical RF receive only coils with cochlear implants during MRI scanning.
- Local planar (flat linearly polarised) receive only RF coils should be kept more than 10 cm away from the cochlear implant.
- Local cylindrical transmit/receive coils may be safely used, without SAR restriction, provided that the distance between the entire implant and the end of the local RF coil is at least equal to the radius of the local RF coil.
- Transmit/receive head coils may be safely used. Refer to the MRI safety information and recommended SAR level tables in *Indications for using MRI safely on page 14*.
- Maximum allowable MRI scan time is 60 minutes of continuous scanning, with the SAR limitations provided in this guide. See *Indications for using MRI safely on page 14*.

Implant magnet conditions for MRI

For some implant models and MRI field strengths, bandaging with an MRI kit is required, or the implant magnet needs to be surgically removed. Refer to the table below for information on each Nucleus implant model.

Implant type	MRI field strength (T)	Remove implant magnet Yes/No	MRI Kit required Yes/No
CI600 Series implants			
CI612, CI622, CI624, CI632	1.5	No	No
	3		
CI500 Series implants			
CI512, CI522, CI532, ABI541	1.5	No	Yes
	3	Yes	No
CI24RE Series implants			
CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (ST)	1.5	No	Yes
	3	Yes	No
CI24R & CI24M Series implants			
CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M	1.5	No	Yes
	3	Yes	No
CI11+11+2M	1.5	No	Yes
	3	MRI is contraindicated	
CI22M Series implants			
CI22M with removable magnet	1.5	No	Yes
	3	MRI is contraindicated	
CI22M without removable magnet	1.5	MRI is contraindicated	
	3		

Table 6: Implant magnet conditions for MRI

Indications for using MRI safely

WARNING

MR scans at 3 T must be performed in quadrature mode for the radio frequency (RF) transmit coil. Using a multi-channel mode may result in localised heating above safe levels.

CI600 Series implants

CI600 Series implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Implant type	MRI field strength (T)	Max. spatial gradient field (T/m)	Head average SAR (W/kg) Using transmit /receive head coil	Whole body average SAR (W/kg) Landmark location	
				<40 cm from top of head	≥ 40cm from top of head
CI600 Series implants					
CI612	1.5	20	<2	<1	<2
CI622					
CI624					
CI632					
CI612	3	20	<1	<0.5	<1
CI622				<0.4	
CI624				<0.4	
CI632				<0.4	

Table 7: MRI safety information and recommended SAR levels CI600 Series implants

CI500 Series implants

Implant type	MRI field strength (T)	Max. spatial gradient field (T/m)	Head average SAR (W/kg) Using transmit /receive head coil	Whole body average SAR (W/kg) Landmark location	
				<40 cm from top of head	≥ 40cm from top of head
CI512	1.5	20	<2	<1	<2
CI522					
CI532					
ABI541					
CI512	3	20	<1	<0.5	<1
CI522				<0.4	
CI532				<0.4	
ABI541				<0.5	

Table 8: MRI safety information and recommended SAR levels for CI500 Series implants

CI24RE Series implants

Implant type	MRI field strength (T)	Max. spatial gradient field (T/m)	Head average SAR (W/kg) Using transmit /receive head coil	Whole body average SAR (W/kg) Landmark location	
				<40 cm from top of head	≥ 40cm from top of head
CI422	1.5	20	<2	<1	<2
CI24REH					
CI24RE (CA)					
CI24RE (ST)					
CI422	3	20	<1	<0.5	<1
CI24REH					
CI24RE (CA)					
CI24RE (ST)					

Table 9: MRI safety information and recommended SAR levels for CI24RE Series implants

CI24R and CI24M Series implants

Implant type	MRI field strength (T)	Max. spatial gradient field (T/m)	Head average SAR (W/kg) Using transmit /receive head coil	Whole body average SAR (W/kg) Landmark location	
				<40 cm from top of head	≥ 40cm from top of head
CI24R (CA)	1.5	20	<2	<1	<2
CI24R (CS)					
CI24R (ST)					
CI24M					
ABI24M					
CI11+11+2M	1.5	20	<1	<0.5	<1
CI24R (CA)	3	20	<1	<0.5	<1
CI24R (CS)					
CI24R (ST)					
CI24M					
ABI24M					
CI11+11+2M	3	MRI is contraindicated			

Table 10: MRI safety information and recommended SAR levels for CI24R and CI24M Series implants

CI22 Series implants

Implant type	MRI field strength (T)	Max. spatial gradient field (T/m)	Head average SAR (W/kg) Using transmit /receive head coil	Whole body average SAR (W/kg) Landmark location	
				<40 cm from top of head	≥ 40cm from top of head
CI22M with removable magnet	1.5	20	<2	<1	<2
	3	MRI is contraindicated			
CI22M without removable magnet	1.5	MRI is contraindicated			
	3				

Table 11: MRI safety information and recommended SAR levels for CI22M Series implants

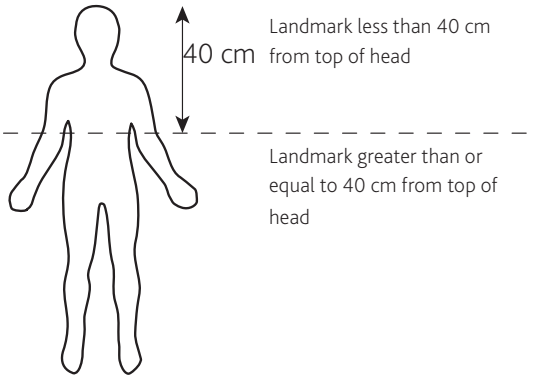


Figure 2: Landmark locations

Image interference and artefacts

The Cochlear Nucleus implant will create shadowing on the MR image near the implant, resulting in a loss of diagnostic information.

If inspecting near the implant, consider removing the implant magnet as MR image quality may be compromised with it in place.

If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MR scan.

The following image artefact results are based on maximum artefact extension from the centre of the implant when scanned at 1.5 T and 3 T in non-clinical testing, using a common Metal Artefact Reduction Sequence (MARS).

The further optimisation of scan parameters can be used to minimise the extent of the artefact.

The image artefact extends from the centre of the implant. The MARS parameters detailed in the table below were used to produce the artefact sizes detailed in the following pages.

Sequence:	MARS Turbo spin-echo	
	1.5 T	3. T
Echo Time (TE) [msec]	17	50
Repetition Time (TR) [msec]	2375	4000
Flip angle [°]	90	90
Bandwidth per Pixel [Hz/pixel]	319	781
Bandwidth [kHz]	82	200

Table 12: MARS parameter settings

The following artefact images are representative of the axial results across all implants. Individual artefact sizes per implant model are detailed in the following tables.

For bilateral implant recipients, the image artefacts as shown below are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.

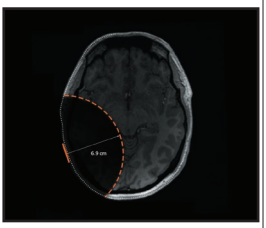
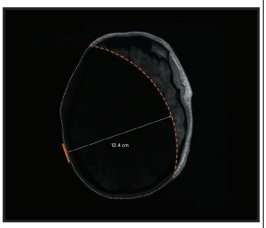
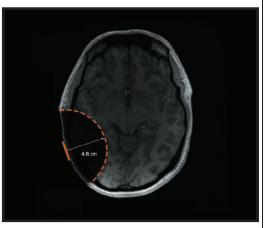
Implant with magnet in place (CI600 Series only)	Implant magnet + magnetic splint	Implant magnet removed
		
6.9 cm (2.7 in.)	12.4 cm (4.9 in.)	4.8 cm (1.9 in.)

Table 13: Maximum artefact extension at 1.5T across all implant types

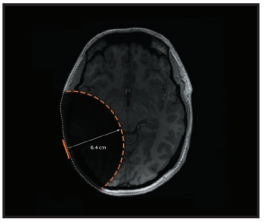
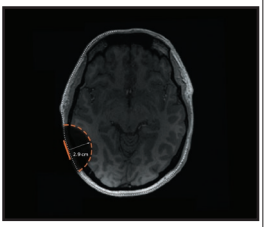
Implant with magnet in place (CI600 Series only)	Implant magnet removed
	
6.4 cm (2.5 in.)	2.9 cm (1.1 in.)

Table 14: Maximum artefact extension at 3 T across all implant types

	MRI field strength (T)	Maximum artefact radius (with MARS sequence) [cm]	
		With implant magnet in place	Without implant magnet
		Axial	Axial
CI600 Series implants			
CI612, CI622, CI624, CI632	1.5	6.9	2.9
	3	6.4	2.9

Table 15: Artefact dimensions for CI600 implants

	MRI field strength (T)	Maximum artefact radius (with MARS sequence) [cm]	
		With implant magnet + magnetic splint	Without implant magnet
		Axial	Axial
CI500 Series implants			
CI512, CI522, CI532, ABI541	1.5	12.4	2.9
	3	N/A*	2.9
CI24RE Series implants			
CI422, CI24REH CI24RE (CA), CI24RE (ST)	1.5	11.3	2.6
	3	N/A*	2.5
CI24R Series implants			
CI24R (CA), CI24R (CS), CI24R (ST)	1.5	11.3	2.6
	3	N/A*	2.5
CI24M Series implants			
CI24M, ABI24M	1.5	11.3	2.8
	3	N/A*	2.5
CI11+11+2M	1.5	11.3	2.8
	3	MRI is contraindicated	
CI22 Series implants			
CI22M with removable magnet	1.5	11.3	4.8
	3	MRI is contraindicated	
CI22M without removable magnet	1.5	MRI is contraindicated	
	3		

Table 16: Artefact dimensions for CI500, CI24RE, CI24R, CI24M and CI22M Series implants

* Surgically remove the implant magnet before MR scans at 3 T.

Preparation prior to an MRI examination

Cooperation between specialists

Preparing for and conducting an MRI examination for implant recipients requires cooperation between a specialist for the device and/or Cochlear Nucleus implant physician, referring physician and radiologist / MR technologist.

- **Cochlear Nucleus implant device specialist** – Knows the implant type and where to find the correct MR parameters for the implant.
- **Referring physician** – Knows the location of the MR scan and diagnostic information required, and makes a decision on whether the implant magnet needs to be removed for the MRI examination.
- **Cochlear Nucleus implant physician** – If requested by the referring physician, surgically removes the implant magnet and replaces with a non-magnetic plug or non-magnetic cassette. After the MR scan, the implant physician replaces it with a new sterile replacement implant magnet.
- **Radiologist / MR technologist** – Sets up the MR scan using the correct MR parameters and counsels the implant recipient during the MRI examination.

Considerations for implant magnet removal

If the implant magnet needs to be removed prior to an MRI examination, close coordination is required between the specialists to perform the implant magnet removal, MR scan, and subsequent implant magnet replacement.

For CI600 Series implant recipients, if single or multiple MRI examinations on the head are needed with the magnet removed, the implant magnet must be replaced (in a sterile surgical environment) with a non-magnetic cassette.

WARNING

To prevent infection, do not leave the magnet pocket empty for CI600 implants. When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

For CI24RE, CI24R, CI24M, CI22 and CI500 Series implant recipients requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic plug. In the magnet's absence, the non-magnetic plug prevents fibrous tissue growing into the implant recess. Such growth would make implant magnet replacement difficult.

CAUTION

Non-magnetic plugs for CI500 Series implants are a different size to non-magnetic plugs for CI24RE Series implants. Ensure the correct plug is used.

With the non-magnetic cassette or non-magnetic plug in place, MR scans can be safely done at both 1.5 T and 3 T without the need for bandaging or use of the Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit).

NOTE

While the magnet is removed, the recipient must wear a retainer disc to hold their sound processor coil in place. Retainer discs are available from Cochlear.

When there is no further need for MRI examinations, the non-magnetic cassette / non-magnetic plug is removed and replaced by a new sterile replacement implant magnet.

The non-magnetic cassette / non-magnetic plug and replacement implant magnet cassette and implant magnet are supplied separately in sterile packs. Both are single-use items.

Considerations for conducting an MRI examination

These guidelines are specific to Cochlear Nucleus implants and supplement other MRI examination considerations specified by the MRI machine manufacturer or protocols at the MRI facility.

Prerequisites

The following additional conditions must be met:

- The implant model has been identified. See *Implant model identification on page 7*.
- The artefact has been considered, and there is still diagnostic value in performing the MRI scan. See *Image interference and artefacts on page 19*.
- The implant magnet has been surgically removed if the referring physician has prescribed that the MR scan be performed with the implant magnet removed. See *Preparation prior to an MRI examination on page 23*.
- The Cochlear MRI (MRI Kit) is required for MR scans at 1.5 T with the implant magnet in place for CI500 Series, CI24RE Series, CI24R Series, CI24M Series and CI22 Series implants. See *Using the MRI Kit on page 30* for instructions on how to apply the MRI Kit prior to the MR scan.

Patient positioning

For safety, the patient should be in a supine position (lying flat on back, face upward) prior to entering the MRI bore.

Align the patient's head with the bore axis of the MRI machine. Advise the patient to lie as still as possible and to not move their head during the MR scan.

⚠ CAUTION

Ensure that the patient does not move more than 15 degrees (15°) from the centreline (Z-axis) of the bore during the MR scan.

Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain.

Patient comfort

Explain to the patient that they may sense the implant magnet moving. The MRI kit will reduce the likelihood of the implant magnet moving. However, they may still sense resistance to movement as pressure on the skin. The sensation will be similar to pressing down firmly on the skin with the thumb.

If the patient experiences pain, consult the patient's physician to determine if the implant magnet should be removed or if a local anaesthetic may be applied to reduce discomfort.

⚠ CAUTION

If administering local anaesthetic, take care not to perforate the implant silicone.

In addition, explain to the patient that they may perceive sounds during the MR scan.

Perform the MR scan

The MR scan must be performed using the MRI safety information identified for the patient's implant model. See *Identifying the Cochlear Nucleus implant on page 5* and *Implant magnet conditions for MRI on page 13*.

Performing an MR Scan on other body locations

When an implant recipient requires an MRI on a location of their body away from the implant site, you must still follow the MRI safety information for the recipient's implant model. See *Identifying the Cochlear Nucleus implant on page 5* and *Implant magnet conditions for MRI on page 13*.

Cochlear™ MRI Kit

Intended use

The Cochlear MRI Kit is intended to be used on Cochlear Nucleus implant recipients to prevent implant magnet dislodgement during MR scans at 1.5 T as described in *Table 6: Implant magnet conditions for MRI on page 13*.

The MRI Kit is intended for use with the following Cochlear Nucleus implants for both unilateral and bilateral recipients:

- CI500 Series: CI512, CI522, CI532 and ABI541
- CI24RE Series: CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- CI24R Series: CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series: CI24M, CI11+11+2M and ABI24M
- CI22 Series: CI22M (with removable magnet).

Contraindications

The Cochlear MRI Kit is contraindicated for use with:

- CI22 Series: CI22M implants with non-removable magnet
- MR scans other than 1.5 T.

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 Splints x 2	Magnetic splints – to be placed against the skin over the implant magnet site/s. For bilateral patients use one splint for each implant.
Bandage x 1	Compression bandage – for securing the splint/s against the implant magnet site.
Instructions	Instructions detailing bandaging procedure.

Using the MRI Kit

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

For more information, including video instructions for using the MRI Kit prior to an MRI, visit www.cochlear.com/MRI or contact your nearest Cochlear office.

WARNING

To minimise possible pain and discomfort, apply the splint/s and bandage immediately prior to entering the MRI room.

Remove the splint/s and bandage immediately after the MRI procedure and the recipient is outside of the MRI room.

If the splint/s become loose inside the MRI room, this could lead to damage of the MRI equipment and / or injury to the MRI staff or recipient.

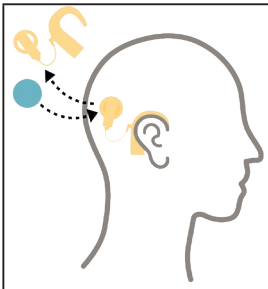
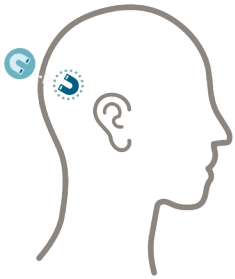
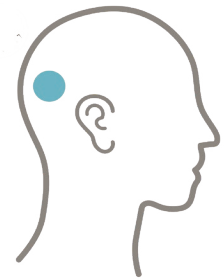
1. Preparation (Steps 1-2)

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.

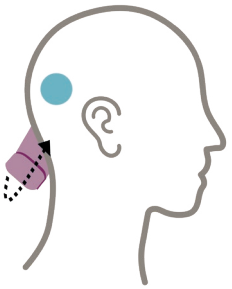
NOTE

Once the sound processor coil 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 coil 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 coil. 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)

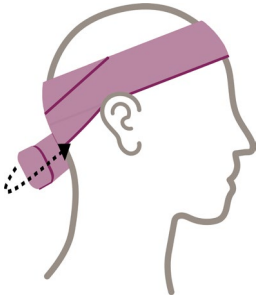


1. Clear all hair away from the forehead.

   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/s do not move, but not too tight to cause pain.
- Check that the splint/s have 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/s are covered on each wrap.

   Check that the splint/s have not moved out of place.

	3. Continue bandaging until the entire bandage has been used. Do not cut the bandage. 4. Once the bandaging is complete, carefully press your hands around the entire bandage to ensure the layers of the bandage have adhered and is secure. 5. Conduct the MR scan. 6. Once the MR scan is complete, follow the instructions in *Considerations after an MRI examination* on page 34.

WARNING

Do not conduct the MR scan if the splint/s do 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

With the implant magnet in place

Remove the MRI Kit bandage and splint.

After the patient leaves the MRI room, ask the patient to place the sound processor on their head and turn it on. Confirm that the placement of the sound processor coil is correct and that there is no discomfort and sound is perceived as normal.

If there is discomfort or a change in sound perception, or problems with the placement of the sound processor coil, ask the patient to seek assistance from their implant clinician as soon as possible.

With the implant magnet removed

See *Considerations for implant magnet removal on page 24*.

Considerations for referring physicians

If you are a physician referring a Cochlear Nucleus implant recipient for an MR scan, it is essential that you consider the following:

- Understand and inform the patient of the risks associated with MRI. See *Risks associated with MRI and Cochlear Nucleus implants on page 37*.
- Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination. See *Implant magnet conditions for MRI on page 13* and *Indications for using MRI safely on page 14*.
- Identify if the patient has any other medical device implants, active or abandoned. If another implanted device is present, verify MRI compatibility before conducting an MRI examination. If MRI safety information for the implanted devices is not followed, the potential risks include movement or damage to the device, weakening of the implant magnet and uncomfortable sensation or skin/tissue trauma for the patient. Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning, and there is no increased heating risk to the Cochlear implant.
- The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. Refer to the relevant artefact dimension tables in *Image interference and artefacts on page 19*.
- For MR scans at 1.5 T or 3 T, identify if the implant magnet needs to be removed. See *Implant magnet conditions for MRI on page 13*.
- For MR scans on a body location away from the implant site, MRI safety information for the recipient's implant model must be followed. See *Performing an MR Scan on other body locations on page 28*.

CI600 Series Implant coil plate with magnet cassette in pocket

CI500 Series removable implant magnet inside implant magnet pocket

Figure 3: CI600 and CI500 Series implant with removable magnet

Consider the following:

- If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.
- Timing of the implant surgery and MRI exposure.
- Age and general health of the implant recipient and time to recover from the implant magnet surgery or potential trauma.
- Existing or potential for tissue scarring in the location of the implant magnet.

- If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MR scan.
- If the implant magnet is retained for an MR scan at 1.5 T, a Cochlear MRI Kit must be obtained beforehand for use during the MR scan, except for CI600 Series implants. See *Obtaining an MRI Kit on page 29*.

Risks associated with MRI and Cochlear Nucleus implants

The potential risks of performing MRI examinations on patients with Cochlear Nucleus implants include:

- Device movement

  Scanning outside of the parameters contained in these guidelines may lead to the implant magnet or device moving out of position during an MRI examination causing skin/tissue trauma.

- Damage to the device

  MRI exposure beyond the values contained in these guidelines may cause damage to the device.

- Weakening of implant magnet
  - Scanning at static magnetic field strengths at values other than those contained in these guidelines may lead to a weakening of the implant magnet.
  - Incorrect patient positioning prior to the MR scan or head movement during the scan may result in implant magnet demagnetisation.

- Uncomfortable sensation

  MRI exposure beyond the values contained in these guidelines may result in the patient perceiving sound or noise and / or pain.

- Implant heating

  Use the recommended SAR values contained in these guidelines to ensure the implant does not heat beyond safe levels.

- Image artefact

  The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information.

  If inspecting near the implant, removal of the implant magnet should be considered as MR image quality may be compromised with it in place.

Labelling symbols

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

	Consult instructions for use
	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
	Keep dry
	Do not re-use
	Do not use if package is damaged
	Recyclable packaging
Rx Only	By prescription
	MR Conditional
CE 0123	CE registration mark with notified body number

Certification and applied standards

The Cochlear MRI Kit fulfils the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as per the conformity assessment procedure in Annex 2. The year in which authorisation to affix the CE mark was granted was 2019.

CE 0123

Disposal

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

Hear now. And always

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 Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove, NSW 2066, 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
Cochlear Americas 10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010 Fax: +1 303 792 9025
Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 416 972 5082 Fax: +1 416 972 5083
Cochlear AG EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205
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
Cochlear Benelux NV Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70
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
Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62
Cochlear Nordic AB Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60
Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Çubuklu Mah. Boğaziçi Cad., Boğaziçi Plaza No: 6/1, Kavacık, TR-34805 Beykoz-Istanbul, Turkey
Tel: +90 216 538 5900 Fax: +90 216 538 5919
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
Cochlear Korea Ltd 1st floor, Cheongwon Building 33, Teheran-ro 8 gil, Gangnam-gu, Seoul, Korea
Tel: +82 2 533 4450 Fax: +82 2 533 8408
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
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
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
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
Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403, Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218
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

www.cochlear.com

D1536014 V4 2020-09

Cochlear®