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

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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 Patient Information, or the Surgeon's Guide, Physician's Package Insert and Important Information Booklet. For more information, visit www.cochlear.com/warnings or contact Cochlear on +1 866 210 9217.

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

Preparation prior to 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.

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

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 or 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 and MR technologist** – Sets up the MR scan using the correct MR parameters and counsels the implant recipient during the MRI examination.

Determine eligibility for MRI

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 8.

  Also consider:

  – 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.

- Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination. See ***Performing MRI safely*** on page 20.

- 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 28.

- 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 are not followed, the potential risks can include:

  – Movement or damage to the device.

  – Weakening of the implant magnet.

  – Uncomfortable sensation for the patient.

  – Skin or 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.
- 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 20.
- 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, an MRI Kit must be obtained beforehand for use during the MR scan, except for CI600 Series implants. See *Obtaining an MRI Kit* on page 33.

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 or 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.

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.

CI600 Series implants

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.

CI500, CI24RE, CI24R, CI24M and CI22M Series implants

For recipients (other than CI600 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. If only a single MRI is required the magnet recess can remain empty. See ***Implant magnet conditions for MRI*** on page 20.

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 without the need for bandaging or use of the MRI Kit.

NOTE

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

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

The non-magnetic cassette, non-magnetic plug, replacement magnet cassette and replacement magnet are supplied separately in sterile packs. All are single-use items.

Preparation for conducting the MRI examination

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.

Confirm the following prior to scanning:

- The implant model has been identified. See *Identifying features* on page 15.
  - For additional information on bilateral recipients, see *Bilateral recipients* on page 12.
- 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 12.
- The implant magnet has been surgically removed if the referring physician has prescribed that the MR scan be performed with the implant magnet removed.
- If the implant magnet is retained for an MR scan at 1.5 T, an MRI Kit is available and ready for use. The MRI Kit is not applicable for CI600 Series implants.
  - See *Table 6: Implant magnet conditions for MRI* on page 20 and *Using the MRI Kit* on page 33 for full details on performing an MRI examination safely.

- Remove the sound processor before entering the MRI room. The sound processor is MR Unsafe.
- Position the patient to minimise discomfort. See ***Patient positioning*** on page 13.
- Discuss the sensations the recipient may experience during the MR Scan. See ***Patient comfort*** on page 13.
- Comply with the ***Scan conditions and SAR limits*** on page 21.

Bilateral recipients

⚠ CAUTION

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.

Performing an MR Scan on other body locations

When an implant recipient requires an MR scan 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 14 and ***Performing MRI safely*** on page 20.

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

When scanning with the implant magnet in place, 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. For implants where use of the MRI Kit is required, 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.

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*** below and ***X-ray guidelines*** along with ***Identifying features*** on the following pages.

X-ray information for identification of Cochlear Nucleus implants

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

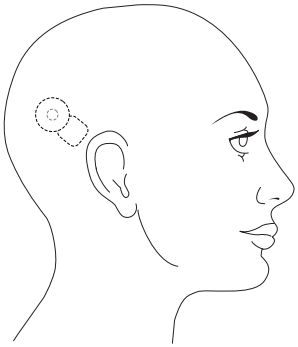


Figure 1: Location behind the ear for Cochlear Nucleus implants

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.

Identifying features

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/CI632P 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.

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.

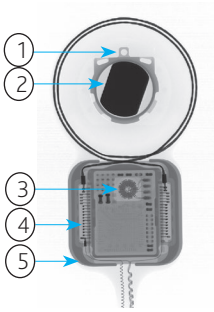
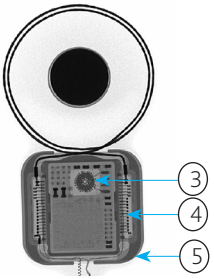
CI600 Series implant X-ray	CI500 Series implant X-ray	Unique identifier
		1. Three holes adjacent to magnet 2. Magnet shape 3. Round shape at coil exit end of electronic assembly layout 4. Series of wire connectors that are visible on both sides of the electronic assembly 5. Square implant body shape

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

Cochlear Nucleus CI24RE Series, CI24R Series, CI24M Series and CI22M Series implants

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

- CI24RE Series – CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- CI24R Series – CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series – CI24M, CI 11+11+2M and ABI24M
- CI22M 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.

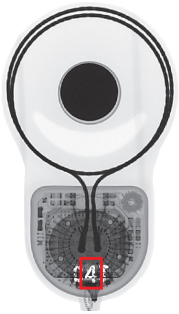
Implant model	Location of second (middle) radiopaque character set	Radiopaque characters
CI422		13
CI24REH (Hybrid L24)		6
CI24RE (CA)		5
CI24RE (CS)		7
CI24RE (ST)		4

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 identified 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 identified 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: CI22M Series implants identified by radiopaque characters

Performing MRI safely

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. See *Using the MRI Kit* on page 33 for instructions on how to apply the MRI Kit prior to the MR scan.

Implant type	MRI field strength (T)	Remove implant magnet Yes/No	MRI Kit required Yes/No
CI600 Series implants			
CI612, CI622, CI624 CI632/CI632P	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
CI 11+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

Scan conditions and SAR limits

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 active scan time of 60 minutes.

WARNING

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

A patient with one or two of these devices can be safely scanned in an MR system meeting conditions on the following pages.

Consider the following prior to scanning:

- Transmit/receive head coils and whole body coils may be safely used within the recommended SAR limits. Refer to the MRI safety information and recommended SAR limit tables in the following pages.
- 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.
- It is safe to use local cylindrical RF receive only coils with cochlear implants during MRI scanning, provided SAR limits for the transmit coil have not been exceeded.
- Local planar (flat linearly polarised) receive only RF coils should be kept more than 10 cm away from the cochlear implant.

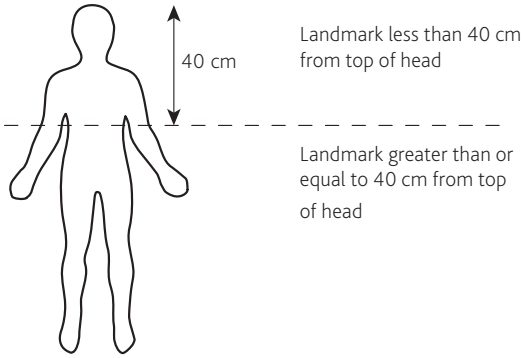


Figure 2: Landmark locations

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)	Maximum allowable spatial gradient field (T/m)	Head average SAR limit (W/kg) Using transmit /receive head coil	Whole body average SAR limit (W/kg) Landmark location		Max Temp. Rise °C
				<40 cm from top of head	≥40cm from top of head	
CI612	1.5	20	<2	<1	<2	4.8
CI622						5.1
CI624						5.1
CI632/ CI632P						5.5
CI612	3	20	<1	<0.5	<1	4.9
CI622				<0.4		5.2
CI624				<0.4		5.2
CI632/ CI632P				<0.4		5.7

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

CI500 Series implants

Implant type	MRI field strength (T)	Maximum allowable spatial gradient field (T/m)	Head average SAR limit (W/kg) Using transmit /receive head coil	Whole body average SAR limit (W/kg) Landmark location		Max Temp. Rise °C
				<40 cm from top of head	≥40cm from top of head	
CI512	1.5	20	<2	<1	<2	4.8
CI522						5.1
CI532						5.5
ABI541						2.0
CI512	3	20	<1	<0.5	<1	4.9
CI522				<0.4		5.2
CI532				<0.4		5.7
ABI541				<0.5		3.2

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

CI24RE Series implants

Implant type	MRI field strength (T)	Maximum allowable spatial gradient field (T/m)	Head average SAR limit (W/kg) Using transmit /receive head coil	Whole body average SAR limit (W/kg) Landmark location		Max Temp. Rise °C
				<40 cm from top of head	≥40cm from top of head	
CI422	1.5	20	<2	<1	<2	5.1
CI24REH (Hybrid L24)						4.5
CI24RE (CA)						4.5
CI24RE (ST)						4.5
CI422	3	20	<1	<0.5	<1	2.8
CI24REH (Hybrid L24)						4.3
CI24RE (CA)						4.3
CI24RE (ST)						4.3

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

CI24R and CI24M Series implants

Implant type	MRI field strength (T)	Maximum allowable spatial gradient field (T/m)	Head average SAR limit (W/kg) Using transmit /receive head coil	Whole body average SAR limit (W/kg) Landmark location		Max Temp. Rise °C
				<40 cm from top of head	≥40cm from top of head	
CI24R (CA)	1.5	20	<2	<1	<2	5.7
CI24R (CS)						5.7
CI24R (ST)						5.7
CI24M						5.1
ABI24M						2.4
CI 11+11+2M	1.5	20	<1	<0.5	<1	4.1
CI24R (CA)	3	20	<1	<0.5	<1	4.6
CI24R (CS)						4.6
CI24R (ST)						4.6
CI24M						5.7
ABI24M						2.5
CI 11+11+2M	3	MRI is contraindicated				

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

CI22M Series implants

<table>
<tr><th rowspan="2">Implant type</th><th rowspan="2">MRI field strength (T)</th><th rowspan="2">Maximum allowable spatial gradient field (T/m)</th><th rowspan="2">Head average SAR limit (W/kg)
Using transmit /receive head coil</th><th colspan="2">Whole body average SAR limit (W/kg)
Landmark location</th><th rowspan="2">Max Temp. Rise
°C</th></tr>
<tr><th><40 cm from top of head</th><th>≥40cm from top of head</th></tr>
<tr><td rowspan="2">CI22M with removable magnet</td><td>1.5</td><td>20</td><td><2</td><td><1</td><td><2</td><td>1.1</td></tr>
<tr><td>3</td><td colspan="5">MRI is contraindicated</td></tr>
<tr><td rowspan="2">CI22M without removable magnet</td><td>1.5</td><td colspan="5" rowspan="2">MRI is contraindicated</td></tr>
<tr><td>3</td></tr>
</table>

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

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 image artefact results[1] on the next page are based on worst-case spin echo scenarios. The images show maximum artefact extension from the centre of the implant and are representative of the axial results across all implants. The optimisation of scan parameters can be used to minimise the extent of the artefact. Tables detailing individual artefact sizes per implant model are on the following pages.

1 Image artefact testing was undertaken according to ASTM F2119 (Standard Test Method for Evaluation of MR Image Artefacts from Passive Implants) with worst case spin echo results provided.

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.

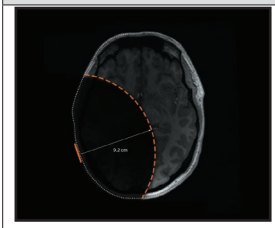
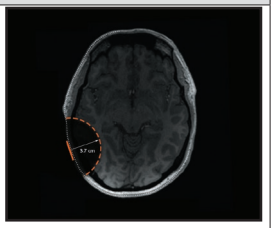
Implant magnet in place	Implant magnet removed
	
9.2 cm (3.6 in)	3.7 cm (1.5 in)

Table 12: Maximum artefact extension at 1.5T across all implant types

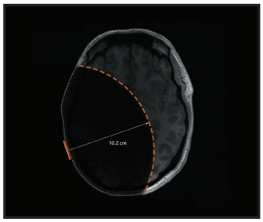
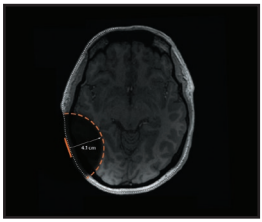
Implant magnet in place (CI600 Series only)	Implant magnet removed
	
10.2 cm (4.0 in)	4.1 cm (1.6 in)

Table 13: Maximum artefact extension at 3 T across all implant types

	MRI field strength (T)	Maximum artefact radius [cm/in]	
		Implant magnet in place	Implant with non-magnetic cassette
		Axial	Axial
CI600 Series implants			
CI612, CI622, CI624 CI632/CI632P	1.5	9.2 / 3.6	4.8 / 1.9
	3	10.2 / 4.0	5.6 / 2.2

Table 14: Artefact dimensions for CI600 implants

	MRI field strength (T)	Maximum artefact radius [cm/in]	
		Implant magnet in place	Implant magnet removed
		Axial	Axial
CI500 Series implants			
CI512, CI522, CI532, ABI541	1.5	5.7 / 2.2	3.7 / 1.5
	3	N/A*	4.1 / 1.6
CI24RE Series implants			
CI422, CI24REH CI24RE (CA), CI24RE (ST)	1.5	5.5 / 2.2	3.2 / 1.3
	3	N/A*	3.4 / 1.3
CI24R Series implants			
CI24R (CA), CI24R (CS), CI24R (ST)	1.5	5.5 / 2.2	3.2 / 1.3
	3	N/A*	3.4 / 1.3
CI24M Series implants			
CI24M, ABI24M	1.5	5.5 / 2.2	3.7 / 1.5
	3	N/A*	4.1 / 1.6
CI 11+11+2M	1.5	5.5 / 2.2	3.7 / 1.5
	3	MRI is contraindicated	
CI22M Series implants			
CI22M with removable magnet	1.5	5.5 / 2.2	6 / 2.4
	3	MRI is contraindicated	
CI22M without removable magnet	1.5	MRI is contraindicated	
	3		

Table 15: Artefact dimensions for CI500, CI24RE, CI24R, CI24M and CI22M Series implants

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

Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)

Intended use

The Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) is intended to be used on Cochlear Nucleus implant recipients to prevent implant magnet dislodgement during MR scans at 1.5 T.

The MRI Kit is for single-use only.

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) and CI24R (ST)
- CI24M Series – CI24M, CI 11+11+2M and ABI24M
- CI22M Series – CI22M (with removable magnet)

See *Table 6: Implant magnet conditions for MRI* on page 20 and *Bilateral recipients* on page 12 for full details on performing an MRI examination safely.

Warning

Although unlikely with the use of the MRI Kit, it is possible for the magnet to move during MRI and dislodge from the implant magnet pocket. In this case, surgical intervention to reposition or replace the magnet would be required.

MRI Kit contraindications

The MRI Kit is contraindicated for use with:

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

See the elasticised compression bandage labelling for related contraindications when using this product.

Obtaining an MRI Kit

Contact Cochlear by telephone on +1 866 296 8189 or by email at canada@cochlear.com to order an MRI Kit.

MRI Kit contents

Item	Description
Flat plastic splints	To be placed against the skin over the implant magnet site. For bilateral recipients, use one splint for each implant.
Elasticised compression bandage	For securing the splint against the implant magnet site.
Surgical tape	For securing the bandage and splint in place.

Using the MRI Kit

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

1. Preparation

1. Prior to entering the MRI room and before removing the sound processor, draw an outline of the BTE sound processor coil or OTE all-in-one unit on the patient's head - see ***Figure 3*** and ***Figure 4.*** Once the sound processor has been removed, mark the centre position of the outline; this is the implant magnet location. If necessary, shave the patient's head at the implant magnet location so this marking is more visible and easier to locate during the splinting process. This marking is essential to ensure that the splint is placed in the correct location. Repeat this step for bilateral recipients.

Note

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

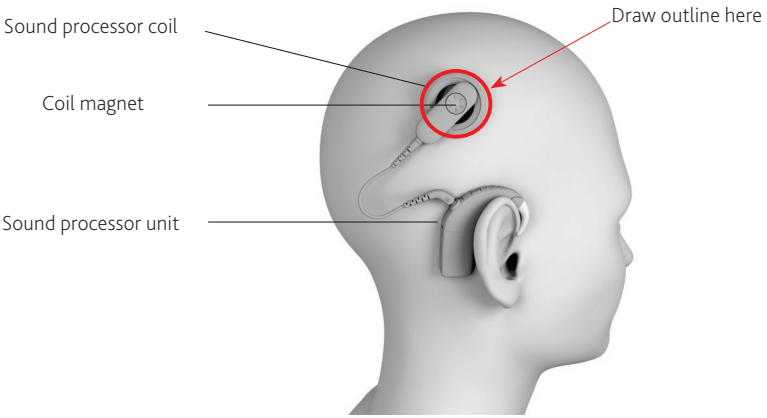


Figure 3: Location of the BTE (behind the ear) sound processor unit, sound processor coil and coil magnet

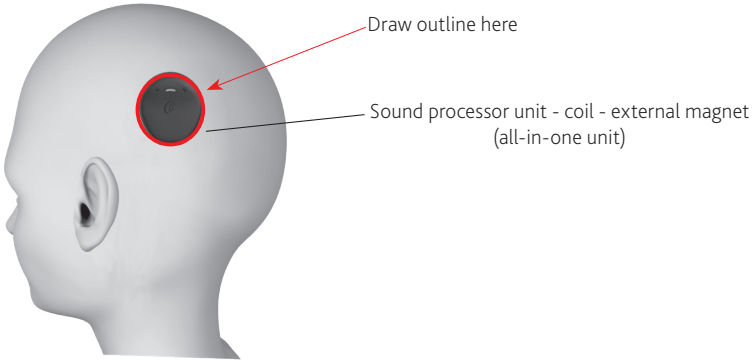


Figure 4: Location of the OTE (off the ear) sound processor unit, coil and external magnet

2. In the event that the location of the implant magnet has not been marked, it can be located by:
   - Using ferromagnetic material, such as a paper clip - the material will be attracted to the implant magnet.

     Warning

     The ferromagnetic material must be removed before entering the MRI room.
   - Touch - gently feel around the implant site to locate the position of the implant coil. The implant is comprised of two components; the round implant coil and the implant body. See *Figure 5* below. The implant magnet will be at the centre of the implant coil.

2. Bandaging

1. Use a splint from the MRI Kit and centre it over the implant magnet site (as marked) against the skin. For bilateral recipients, use one splint for each implant. Ensure each splint is held in place over the implant magnet. See *Figure 5* below for the implant magnet location. You may need the assistance of another person to hold each splint in place while you bandage. Otherwise, use the supplied tape to maintain the splint position prior to bandaging.

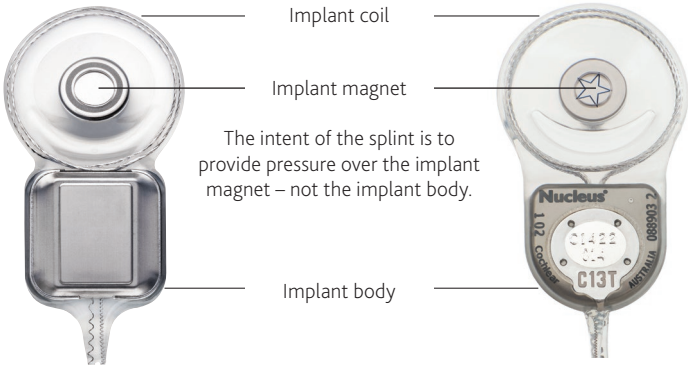


Figure 5: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants

2. Use the elasticised compression bandage from the MRI Kit and ensure the centre line of the bandage is over each implant magnet site and the splint is fully covered. See *Figure 6* below.

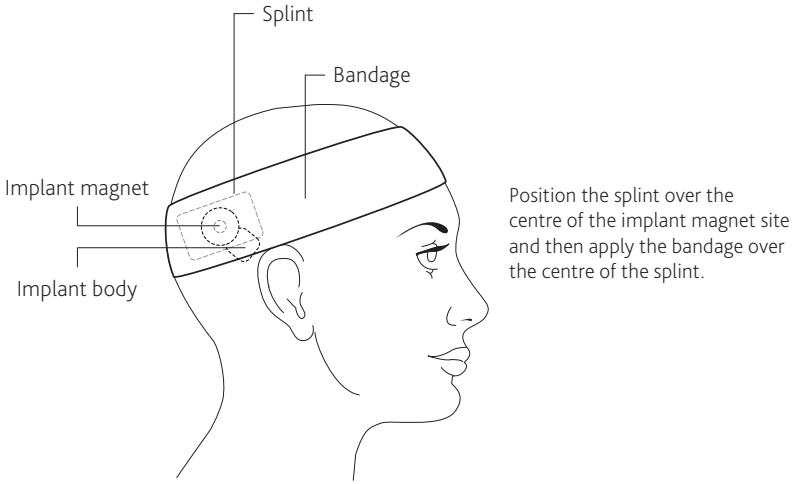


Figure 6: Fitting the MRI Kit splint and compression bandage

3. Use a minimum of two bandage layers at full stretch (no elasticity remaining in the bandage). When the bandage is at its maximum tightness, the small rectangular tension markers will stretch to become square in shape. See ***Figure 7*** below.

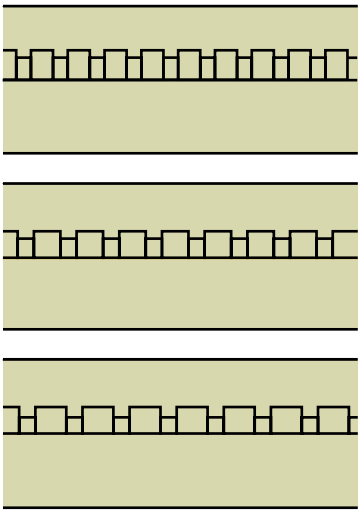


Figure 7: Comparison of compression bandage tightness

4. Use the surgical tape from the MRI Kit to secure the bandage by wrapping two surgical tape layers around the head, over the bandage centre line. Ensure the tape ends overlap.
5. Conduct the MR scan.
6. Once the MR scan is complete, follow the instructions in *Considerations after an MRI examination* on page 38.

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:

- the placement of the sound processor is correct
- there is no discomfort
- sound is perceived as normal.

If there is discomfort or 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.

With the implant magnet removed

See *Considerations for implant magnet removal* on page 9.

Disposal

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

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
	Catalogue number
	Authorised representative in the European Community
	Keep dry
	Do not use if package is damaged
	Recyclable packaging
Rx Only	By prescription
	MR Conditional

Notes

Hear now. And always

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