

MRI for Cochlear™ Nucleus® implant recipients

Radiographer's instructions


CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M, CI 11+11+2M and CI22M implants

Europe / Middle East / Africa

These instructions apply only in Europe, the Middle East and Africa. If you are in another region, refer to the MRI safety information available at www.cochlear.com/warnings or from your local Cochlear™ representative.

These instructions are a summary of the MRI safety information for Cochlear Nucleus® CI24R (CA), CI24R (CS), CI24R (ST), CI24M, ABI24M, CI 11+11+2M and CI22M implants.

For MRI safety information for other Cochlear Nucleus implants, see the *MRI Guidelines* available at www.cochlear.com/warnings or by calling your local Cochlear representative.


 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.

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 using Cochlear fitting software, or if necessary, an X-ray.

X-ray information for the identification of Cochlear Nucleus implants is shown below.

 **Note:** Not all implants are available in all regions.




Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters
CI24R (CA)		2
CI24R (CS)		C
CI24R (ST)		H
CI24M		T
ABI24M		P
CI 11+11+2M		G
CI22M without removable magnet		L or J
CI22M with removable magnet		Z

Table 1: Cochlear Nucleus implant identification

Hear now. And always

Indications for using MRI safely

MRI machines provide specific absorption rate (SAR) level monitoring for head or whole body levels according to specific landmarks.

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

Implant type	MRI safety information	MRI field strength (T)	Maximum spatial gradient field (T/m)	Maximum head SAR (W/kg)	Whole body average SAR (W/kg)
ABI24M, CI24R (CA), CI24R (CS), CI24R (ST), CI24M	Splint and bandage the implant site for MR scans with the implant magnet in place. The magnet can also be surgically removed for MR scans.	1.5	20	1	1
	Surgically remove the implant magnet before MR scans. Tissue damage may occur if the magnet is in place during MRI.	3	20	1	0.5
CI22M with removable magnet	Surgically remove the implant magnet before MR scans. Tissue damage may occur if the magnet is in place during MRI.	1.5	20	1	1
	MRI is contraindicated				
CI22M without removable magnet	MRI is contraindicated				
CI11+11+2	MRI is contraindicated				

Table 2: MRI safety information and recommended SAR levels for maximum 60 minutes MRI scan time

Contraindications

MRI is contraindicated for:

- CI22M implants without removable magnet at any field strength
- CI22M implants with removable magnet at 3 T
- CI 11+11+2M implants.

Risks associated with MRI and Cochlear Nucleus implants

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

- Device movement

The implant magnet or device may move out of position during an MRI examination due to vibration, force or torque 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.

- 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 interference and artefacts

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

With the magnet in place when scanned at 1.5 T, image shadowing may extend as far as 11.9 cm (~4.7 in.) from the implant. See *Figure 1*.

With the magnet removed when scanned at 3 T, image shadowing may extend as far as 4.7 cm (~1.8 in.) from the implant. See *Figure 2*.

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.

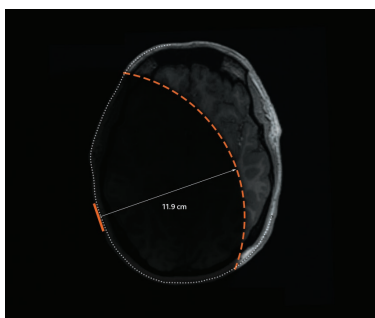


Figure 1: Sample MR image with the implant magnet in place.
Significant amount of shadowing and artefact present

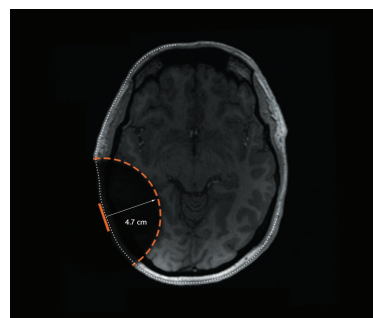


Figure 2: Sample MR image with the implant magnet removed.
Shadowing and artefact significantly less than *Figure 1*.

Splinting and bandaging

The magnet can only be left in place for some implants at certain field strengths – see Table 2 on page 2.

Warning: Although unlikely with the recommended bandaging, it is possible for the magnet to move during MRI and dislodge from the implant magnet pocket. This would require surgical intervention to reposition or replace the magnet.

The following requirements and procedure are intended for use with Cochlear Nucleus implants.

Requirements

You will require the following items:

- Flat-plastic splint to place between the implant magnet site and the bandage. Similar to a credit card or ID card without a magnetic strip or SIM chip. Alternatively use a paper splint, made by taking an A4, 80 gsm sheet of copy paper and folding five times along the longer edge.
- Elasticised compression bandage with a maximum width of 10 cm (4 in.), for securing the splint against the implant magnet site. Generic bandages are suitable. No special bandage is required.
- Surgical tape, for securing the bandage and splint.

Procedure

Follow this splinting and bandaging procedure. When used as instructed, the likelihood of magnet movement when in or near the MRI scanner should be reduced.

1. Prior to entering the MRI room and before removing the sound processor, mark on the patient's head an outline of the sound processor coil. See **Figure 3** below to identify the sound processor coil. Once the coil has been removed from the head, mark on the patient's head the centre position of the coil magnet. Clear away as much hair as possible. If necessary, shave the patient's head at the coil 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.

Note

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

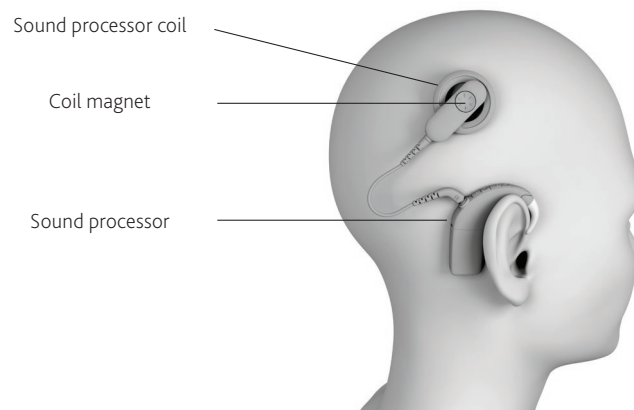


Figure 3: Location of the sound processor, sound processor coil and coil magnet

2. In the event that the location of the implant 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 4* below. The implant magnet will be at the centre of the implant coil.

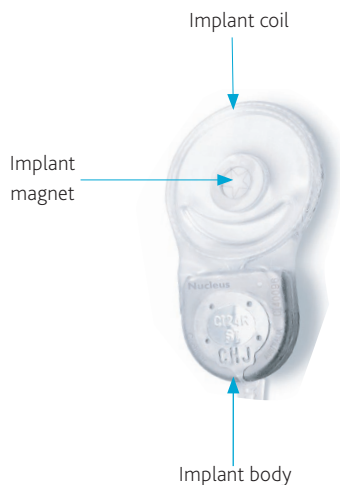


Figure 4: Location of the implant magnet on CI24R implant

3. Use a splint and centre it over the implant magnet site (as marked) against the skin. Ensure the 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 the splint in place while you bandage. Otherwise, use the supplied tape to maintain the splint position prior to bandaging.

4. Use the elasticised compression bandage and ensure the centre of the bandage is over the implant magnet site and the splint is fully covered. See **Figure 5** below.

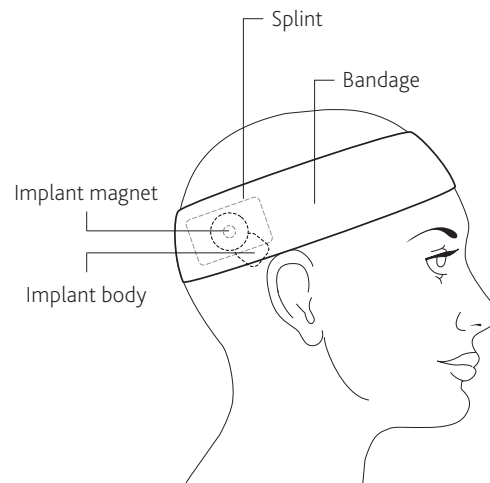


Figure 5: Fitting the splint and compression bandage

Use a minimum of two layers at or near full stretch to apply firm pressure to the implant site. 'Full stretch' = no elasticity remaining in bandage.

5. Use the surgical tape to secure the bandage by wrapping two surgical tape layers around the head, over the bandage centre line. Ensure the tape ends overlap.
6. Conduct the MR scan.

Patient comfort

Explain to the patient that the compression bandage 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 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.

Hear now. And always

Symbols



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.



MR Unsafe

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The statements made in this guide are believed to be true and correct as of the date of publication. However, specifications are subject to change without notice.

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