Cochlear™

Nucleus® implants

Magnetic Resonance Imaging (MRI) Guidelines

Asia Pacific

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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 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

Notes

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 *Implant model identification and related MRI safety information* on page 10 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.

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 Cochlear Nucleus implants

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

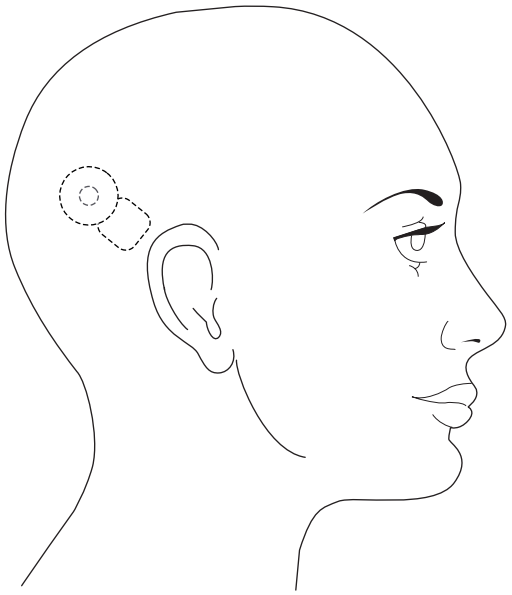


Figure 1: Location behind the ear for Cochlear Nucleus implants

Use the following information to assist with identifying the differences between Cochlear Nucleus implants when using an X-ray.

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)
- Nucleus 24 – CI24R (CA), CI24R (CS), CI24R (ST), CI24M, CI 11+11+2M and ABI24M
- Nucleus 22 – CI22M

There are three sets of radiopaque characters printed on each implant. The second (middle) radiopaque character set identifies the implant model.

Cochlear Nucleus CI500 Series (CI512, CI522 and CI532) implants do not have radiopaque characters. Using an X-ray, CI500 Series implants can be identified by the implant shape and electronic assembly layout. However, the specific model number can be determined only by the patient identification card or Cochlear fitting software.

Implant model identification and related MRI safety information

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI512	 None	None	Page 12
CI522			Page 14
CI532			Page 16
CI422		13	Page 18
CI24REH		6	Page 20
CI24RE (CA)		5	Page 22
CI24RE (CS)		7	Page 22
CI24RE (ST)		4	Page 25
CI24R (CA)		2	Page 27
CI24R (CS)		C	Page 28
CI24R (ST)		H	Page 29

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI24M		T	Page 30
CI 11+11+2M		P	Page 31
ABI24M		G	Page 32
CI22M with removable magnet		L or J	Page 33
CI22M without removable magnet		Z	

Table 1: Cochlear Nucleus implant models identified by second (middle) radiopaque character set and related MRI safety information

MRI safety information for CI512 cochlear implants

Non-clinical testing has demonstrated that CI512 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI512 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

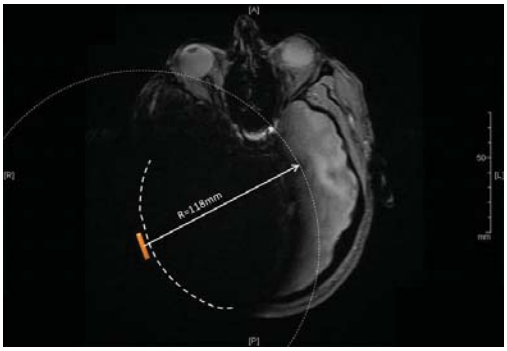
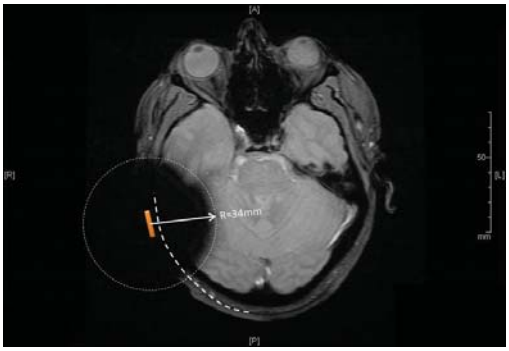
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 2: Largest image artefact for CI512 cochlear implants at 1.5 T scans

CI512 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI512 cochlear implant is expected to produce a maximum temperature rise of less than 3.7 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

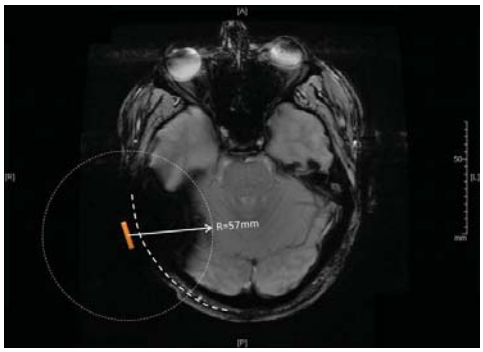
3 T magnet removed

5.7 cm (2.2 in.)

Table 3: Largest image artefact for CI512 cochlear implants at 3 T scans

MRI safety information for CI522 cochlear implants

Non-clinical testing has demonstrated that CI522 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI522 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 3.8 °C a after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI522 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

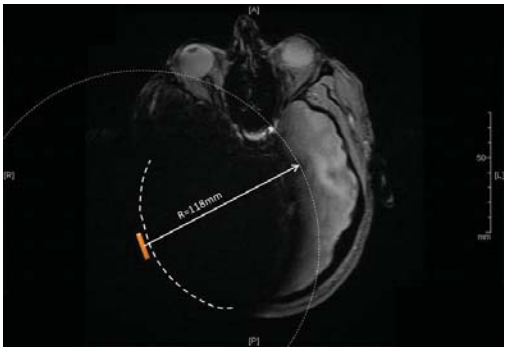
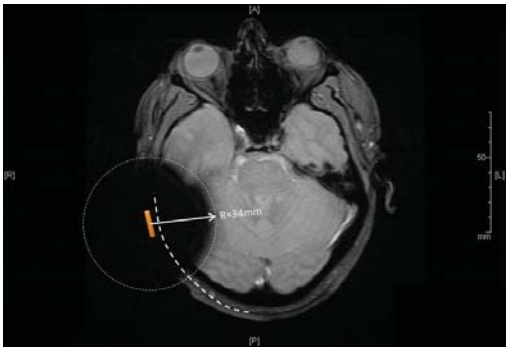
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 4: Largest image artefact for CI522 cochlear implants at 1.5 T scans

CI522 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 4.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI522 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

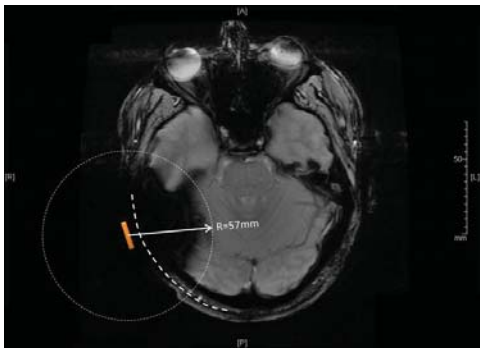
3 T magnet removed

5.7 cm (2.2 in.)

Table 5: Largest image artefact for CI522 cochlear implants at 3 T scans

MRI safety information for CI532 cochlear implants

Non-clinical testing has demonstrated that CI532 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI532 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI532 cochlear implant is expected to produce a maximum temperature rise of less than 4.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

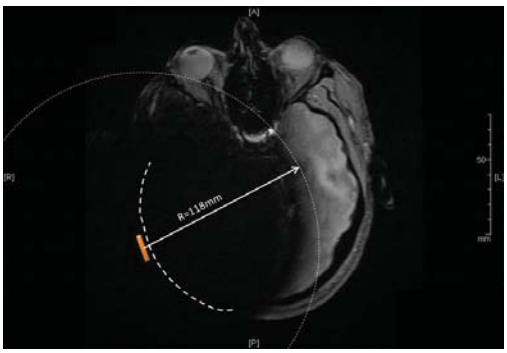
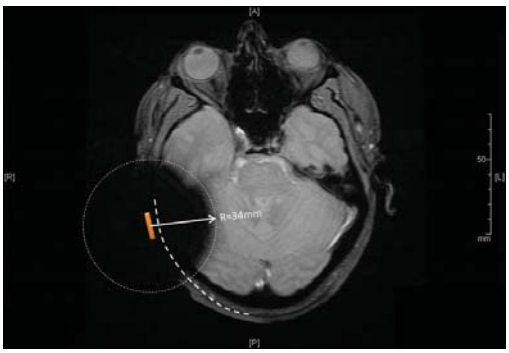
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 6: Largest image artefact for CI532 cochlear implants at 1.5 T scans

CI532 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI532 cochlear implant is expected to produce a maximum temperature rise of less than 5.4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

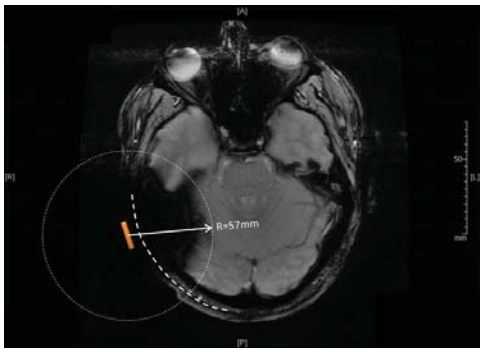
3 T magnet removed

5.7 cm (2.2 in.)

Table 7: Largest image artefact for CI532 cochlear implants at 3 T scans

MRI safety information for CI422 cochlear implants

Non-clinical testing has demonstrated that CI422 cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI422 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI422 cochlear implant is expected to produce a maximum temperature rise of less than 4.1 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI422 cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

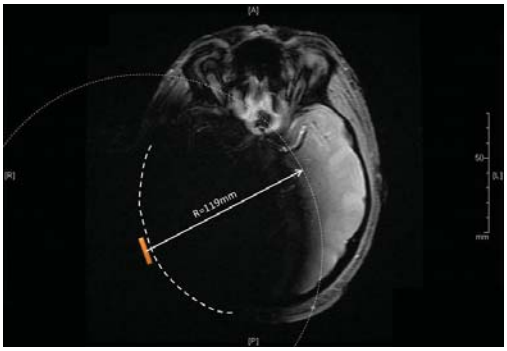
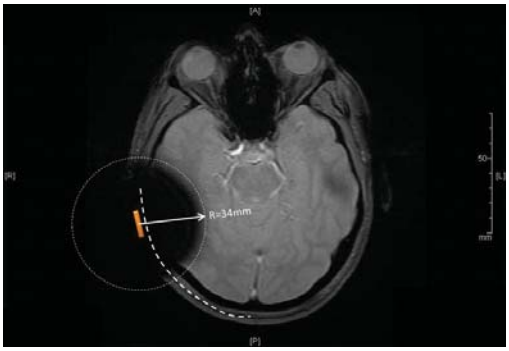
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 8: Largest image artefact for CI422 cochlear implants at 1.5 T scans

CI422 cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI422 cochlear implant is expected to produce a maximum temperature rise of less than 2.2 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI422 cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

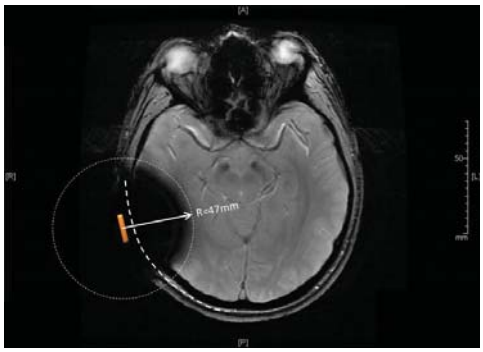
3 T magnet removed

4.7 cm (1.9 in.)

Table 9: Largest image artefact for CI422 cochlear implants at 3 T scans

MRI safety information for CI24REH cochlear implants

Non-clinical testing has demonstrated that CI24REH cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24REH cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI24REH cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24REH cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

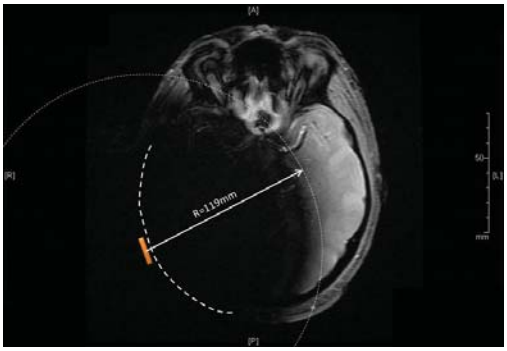
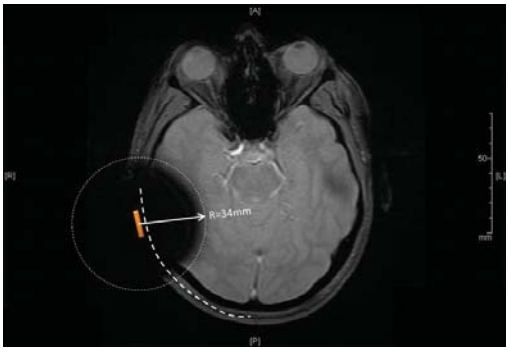
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 10: Largest image artefact for CI24REH cochlear implants at 1.5 T scans

CI24REH cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24REH cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24REH cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

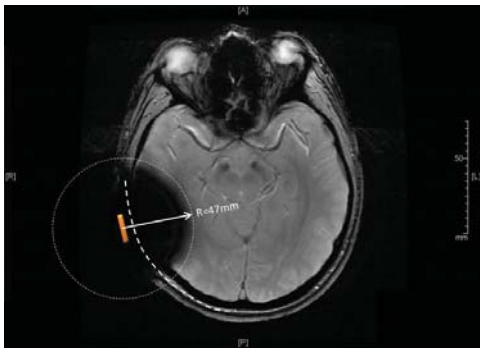
3 T magnet removed

4.7 cm (1.9 in.)

Table 11: Largest image artefact for CI24REH cochlear implants at 3 T scans

MRI safety information for CI24RE (CA) cochlear implants

Note

This MRI safety information also applies to CI24RE (CS) cochlear implants.

Non-clinical testing has demonstrated that CI24RE (CA) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24RE (CA) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI24RE (CA) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

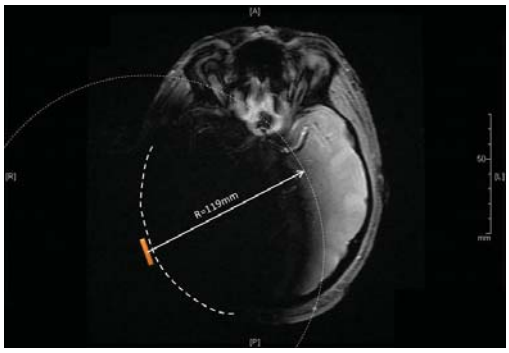
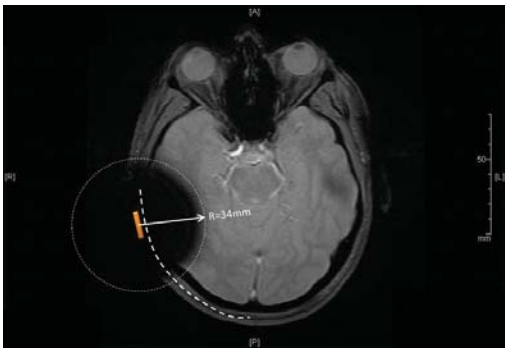
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 12: Largest image artefact for CI24RE (CA) cochlear implants at 1.5 T scans

CI24RE (CA) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24RE (CA) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (CA) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

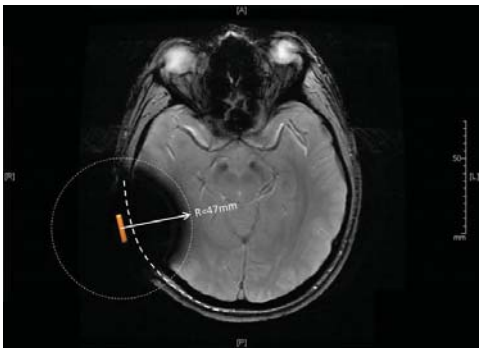
3 T magnet removed

4.7 cm (1.9 in.)

Table 13: Largest image artefact for CI24RE (CA) cochlear implants at 3 T scans

MRI safety information for CI24RE (ST) cochlear implants

Non-clinical testing has demonstrated that CI24RE (ST) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24RE (ST) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil or a transmit body coil, a maximum MR system reported, whole body or whole head averaged specific absorption rate (SAR) of <1 W/kg.

Under the scan conditions defined above, the CI24RE (ST) cochlear implant is expected to produce a maximum temperature rise of less than 3.6 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

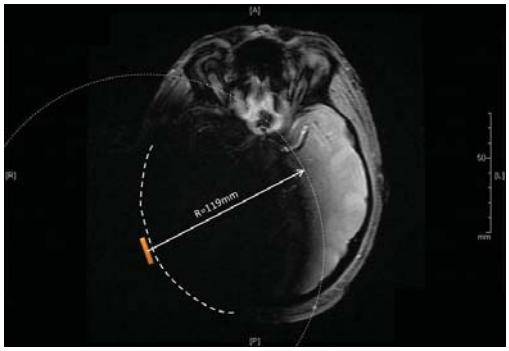
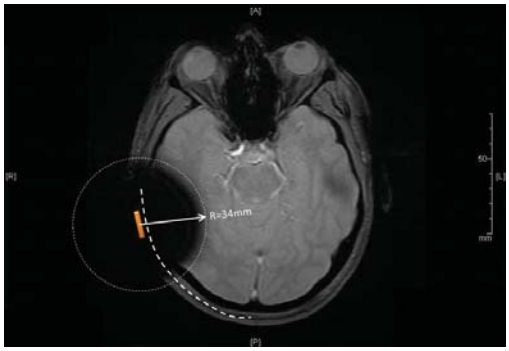
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 14: Largest image artefact for CI24RE (ST) cochlear implants at 1.5 T scans

CI24RE (ST) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24RE (ST) cochlear implant is expected to produce a maximum temperature rise of less than 3.3 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI24RE (ST) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

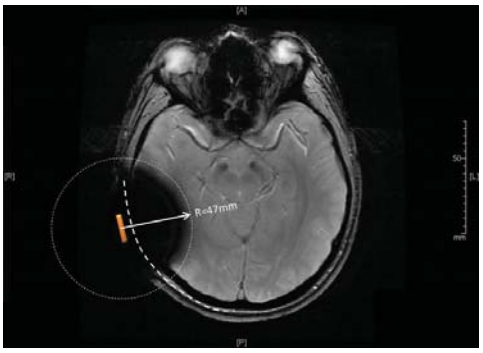
3 T magnet removed

4.7 cm (1.9 in.)

Table 15: Largest image artefact for CI24RE (ST) cochlear implants at 3 T scans

MRI safety information for CI24R (CA) cochlear implants

The quality of MRI will be affected by the metal in the cochlear implant. With the implant magnet in place, image shadowing may extend as far as 11.9 cm (4.6 in.) from the implant. With the implant magnet removed, image shadowing may extend as far as 3.4 cm (1.3 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24R (CA) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.

CI24R (CA) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.

MRI safety information for CI24R (CS) cochlear implants

The quality of MRI will be affected by the metal in the cochlear implant. With the implant magnet in place, image shadowing may extend as far as 11.9 cm (4.6 in.) from the implant. With the implant magnet removed, image shadowing may extend as far as 3.4 cm (1.3 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24R (CS) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.

CI24R (CS) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.

MRI safety information for CI24R (ST) cochlear implants

The quality of MRI will be affected by the metal in the cochlear implant. With the implant magnet in place, image shadowing may extend as far as 11.9 cm (4.6 in.) from the implant. With the implant magnet removed, image shadowing may extend as far as 3.4 cm (1.3 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24R (ST) cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Use the MRI Kit for MR scans at 1.5 T with the implant magnet in place. For instructions, see *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
- Static magnetic field of 1.5 T.

CI24R (ST) cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.

MRI safety information for CI24M cochlear implants

The quality of MRI will be affected by the metal in the cochlear implant. With the implant magnet in place, image shadowing may extend as far as 11 cm (4.3 in.) from the implant. With the magnet removed, image shadowing may extend as far as 6 cm (2.5 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24M cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- For MR scans at 1.5 T with the implant magnet in place, bandage around the head as follows, to ensure the implant magnet does not move:
  - Use an elasticised compression bandage with a maximum width of 10 cm (4 in.). You can use the elasticised compression bandage included in the *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
  - Ensure the centre line of the bandage is over the implant magnet site.
  - Use a minimum of two layers at or near full stretch to apply firm pressure to the implant magnet site.
- Static magnetic field of 1.5 T.

CI24M cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.

MRI safety information for CI 11+11+2M cochlear implants

The quality of MRI will be affected by the metal in the cochlear implant. With the implant magnet in place, image shadowing may extend as far as 11 cm (4.3 in.) from the implant. With the magnet removed, image shadowing may extend as far as 6 cm (2.5 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI 11+11+2M cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- For MR scans at 1.5 T with the implant magnet in place, bandage around the head as follows, to ensure the implant magnet does not move:
  - Use an elasticised compression bandage with a maximum width of 10 cm (4 in.). You can use the elasticised compression bandage included in the *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
  - Ensure the centre line of the bandage is over the implant magnet site.
  - Use a minimum of two layers at or near full stretch to apply firm pressure to the implant magnet site.
- Static magnetic field of 1.5 T.

CI 11+11+2M cochlear implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.

MRI safety information for ABI24M auditory brainstem implants

The quality of MRI will be affected by the metal in the cochlear implant. With the implant magnet in place, image shadowing may extend as far as 11 cm (4.3 in.) from the implant. With the magnet removed, image shadowing may extend as far as 6 cm (2.5 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

ABI24M auditory brainstem implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- For MR scans at 1.5 T with the implant magnet in place, bandage around the head as follows, to ensure the implant magnet does not move:
  - Use an elasticised compression bandage with a maximum width of 10 cm (4 in.). You can use the elasticised compression bandage included in the *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.
  - Ensure the centre line of the bandage is over the implant magnet site.
  - Use a minimum of two layers at or near full stretch to apply firm pressure to the implant magnet site.
- Static magnetic field of 1.5 T.

ABI24M auditory brainstem implants and 3 T scans

- Surgically remove the implant magnet before MR scans at 3 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 3 T with the implant magnet surgically removed.

MRI safety information for CI22M cochlear implants

Some Nucleus 22 (CI22M) cochlear implants have a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

CI22M implants without a removable magnet are MR Unsafe. For patients with a CI22M implant without a removable magnet, MRI is contraindicated.

CI22M implants with removable magnets were introduced from 1995. If a patient received their CI22M implant prior to this date, they will have an implant without a removable magnet.

The quality of MRI will be affected by the metal in the cochlear implant. With the magnet removed, image shadowing may extend as far as 6 cm (2.5 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI22M cochlear implants with removable magnet and 1.5 T scans

- Surgically remove the implant magnet before MR scans at 1.5 T.
- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- Static magnetic field of 1.5 T with the implant magnet surgically removed.

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 – Surgically removes the implant magnet and replaces it with a new sterile replacement implant magnet, if the referring physician has requested the implant magnet be removed.
- 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 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.

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

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

The non-magnetic plug and replacement 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.
- The implant magnet has been surgically removed if the referring physician has prescribed that the MR scan be performed with the implant magnet removed.
- The Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) is required for MR scans at 1.5 T with the implant magnet in place. See *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38 for instructions on how to apply the MRI Kit prior to the MR scan.

Patient comfort

Explain to the patient that 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 *Implant model identification and related MRI safety information* on page 10 to find the location of the MRI safety information for the patient's implant model.

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

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 contains:

Flat-plastic splints – to be placed against the skin over the implant magnet site.

Elasticised compression bandage – for securing the splint against the implant magnet site.

Surgical tape – for securing the bandage and splint in place.

The MRI Kit is intended for use with the following Cochlear Nucleus implants:

- CI500 Series – CI512, CI522 and CI532
- CI24RE Series – CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- CI24R (CA), CI24R (CS) and CI24R (ST)

MRI Kit contraindications

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

Obtaining an MRI Kit

Contact the nearest Cochlear office or official distributor to order an MRI Kit.

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 magnet movement when in or near the MRI scanner.

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 2*** 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. 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.

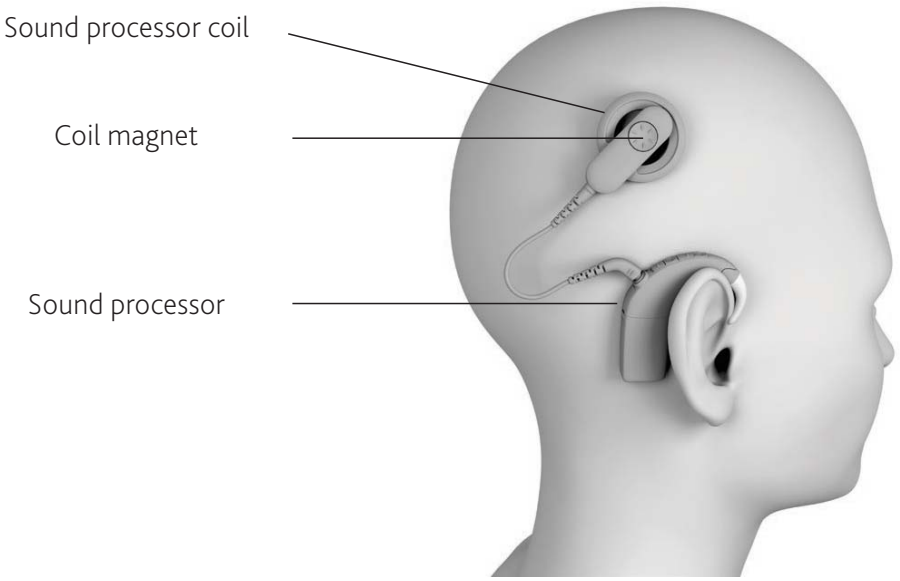


Figure 2: Location of the sound processor, sound processor coil and coil magnet

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 3*** below. The implant magnet will be at the centre of the implant coil.

3. Use a splint from the MRI Kit 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 3*** 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.

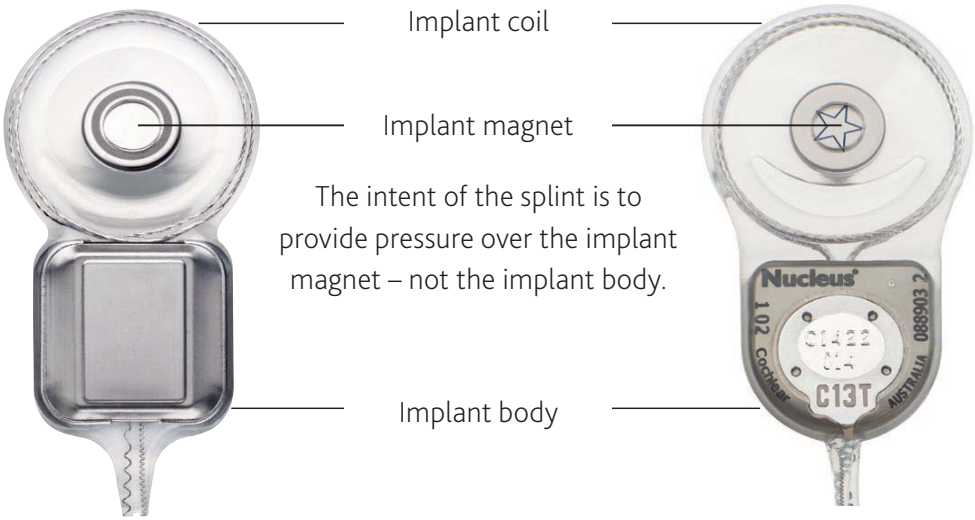


Figure 3: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants

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

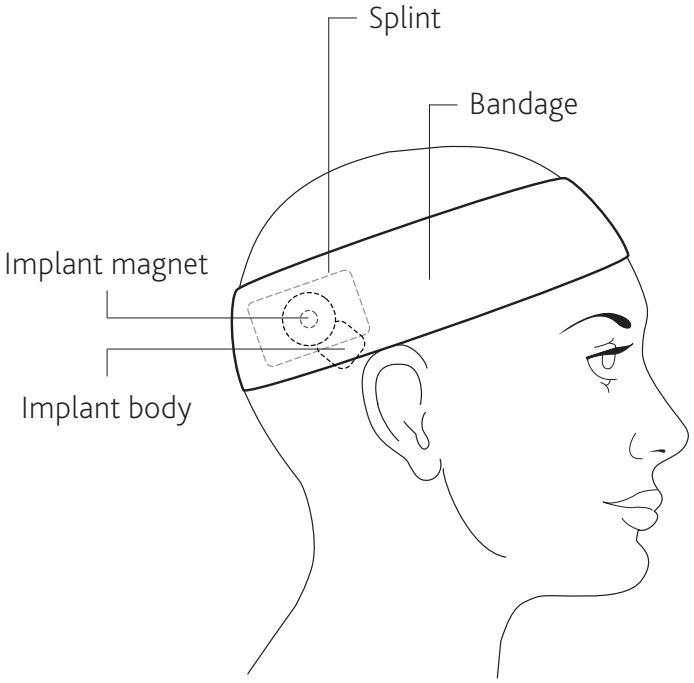


Figure 4: Fitting the MRI Kit splint and compression bandage

5. 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 5* below.

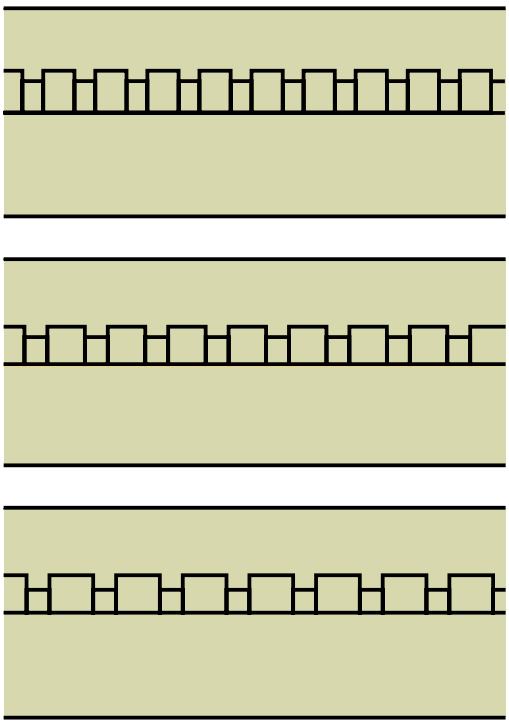


Figure 5: Comparison of compression bandage tightness

6. 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.
7. Conduct the MR scan.
8. Once the MR scan is complete, follow the instructions in *Considerations after an MRI examination* on page 44.

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 35.

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 47.

  Understand the conditions for an MR scan and ensure that there is a clear indication for the MRI examination. See *Implant model identification and related MRI safety information* on page 10 to find the location of the MRI safety information for the patient's implant model.
- Identify if the patient has any other medical device implants, active or abandoned. If the patient has multiple medical device implants, the most restrictive MRI exposure requirements must be used.
- The Cochlear Nucleus implant will create shadowing on the MR image in the vicinity of the implant, resulting in a loss of diagnostic information. See *Image interference and artefacts* on page 48.

- For MR Scans at 1.5 T, identify if the implant magnet needs to be removed.

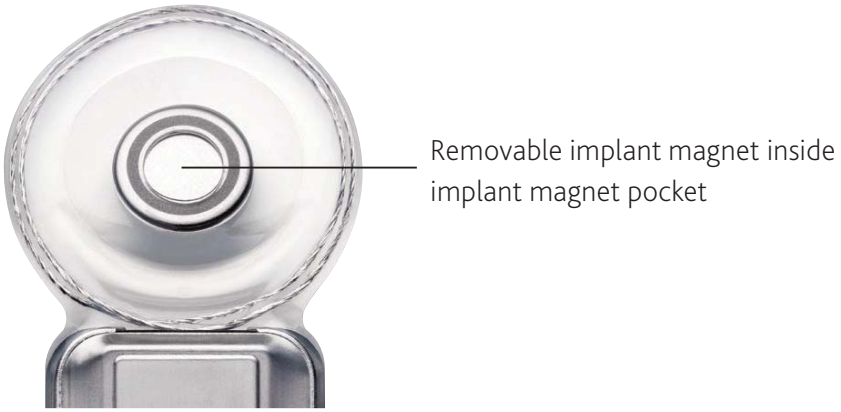


Figure 6: CI500 Series implant with removable magnet

Consider the following:

  - If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.
  - 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 Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) must be obtained beforehand for use during the MR scan. See *Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit)* on page 38.

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 artefact

  See *Image interference and artefacts* on page 48.

Image interference and artefacts

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.

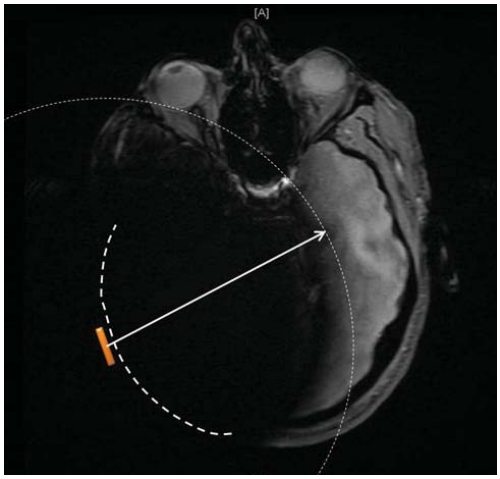


Figure 7: Sample MR image with the implant magnet in place. Significant amount of shadowing and artefact present

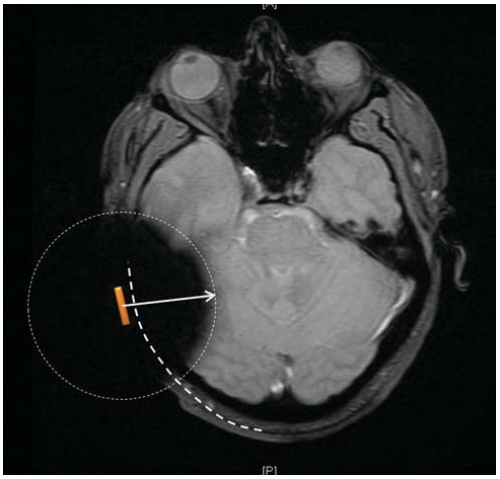


Figure 8: Sample MR image with the implant magnet removed. Shadowing and artefact significantly less than *Figure 7*

Labelling symbols

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

	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
Rx Only	By prescription
	MR Conditional

Notes

Notes

Notes

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