



Hear now. And always

Notice of update to MRI Guidelines and Patient Information

Cochlear is providing notice that updates to the the following documents are in process but were not available at the time of this shipment:

- Document Number D774756: Cochlear™ Nucleus® Implants Magnetic Resonance Imaging (MRI) Guidelines
- Document Number 563636: Nucleus CI532 cochlear implant Patient Information
- Document Number 551440: Nucleus CI522 cochlear implant Patient Information
- Document Number 491848: Nucleus CI512 cochlear implant Patient Information
- Document Number 216687: Nucleus CI24RE (CA) cochlear implant Patient Information
- Document Number 216687: Nucleus CI24RE (ST) cochlear implant Patient Information
- Document Number 264715: Nucleus CI422 cochlear implant Patient Information
- Document Number 415754: Nucleus CI24REH cochlear implant Patient Information

Effective January 6, 2020, the Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) is no longer offered by Cochlear in the United States.

The MRI Kit was offered for use with certain implant types shown below to provide access to MR scan at 1.5 Tesla. Based on these changes, recipients with these implants can obtain MR scans with the following considerations:

- The implant magnet must be removed for 1.5 T and 3 T scans.
- Follow all other conditions for safe scanning given in the MRI Safety Information in the MRI Guidelines documentation.

Consideration and steps for magnet removal are found in the implant Physician Guides and MRI Guidelines.

What implant models are affected by this change?

Profile Series: CI512, CI522, CI532

Freedom Series: CI422, CI24REH, CI24RE (CA), CI24RE (ST)

For any further questions about the changes within the MRI Guidelines, please call MRI Information Line at 1-866-210-9217 or contact your local Cochlear representative.

Cochlear Americas

13059 East Peakview Ave., Centennial CO, 80111 USA
Tel: 303 790 9010 Toll Free: 800 523 5798 Fax: 303 792 9025
www.Cochlear.com/US

FUN3814 ISS1

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

United States of America

Hear now. And always



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 +1 877 279 5411.

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

- About this guide..... 1
 - Symbols used in this guide 2
- MRI safety information..... 5
 - Identifying the Cochlear Nucleus implant..... 5
 - X-ray information for identification of Cochlear Nucleus implants. 6
 - X-ray guidelines 6
- Implant model identification and related MRI safety information..... 7
 - MRI safety information for CI612 cochlear implants..... 11
 - CI612 cochlear implants and 1.5 T scans 11
 - CI612 cochlear implants and 3 T scans 13
 - MRI safety information for CI622 cochlear implants 15
 - CI622 cochlear implants and 1.5 T scans..... 15
 - CI622 cochlear implants and 3 T scans 17
 - MRI safety information for CI632 cochlear implants 19
 - CI632 cochlear implants and 1.5 T scans..... 19
 - CI632 cochlear implants and 3 T scans 21
 - MRI safety information for CI512 cochlear implants..... 23
 - CI512 cochlear implants and 1.5 T scans 23
 - CI512 cochlear implants and 3 T scans 25
 - MRI safety information for CI522 cochlear implants 27
 - CI522 cochlear implants and 1.5 T scans 27
 - CI522 cochlear implants and 3 T scans..... 29
 - MRI safety information for CI532 cochlear implants 30
 - CI532 cochlear implants and 1.5 T scans..... 30
 - CI532 cochlear implants and 3 T scans..... 32
 - MRI safety information for CI422 cochlear implants 34
 - CI422 cochlear implants and 1.5 T scans..... 34
 - CI422 cochlear implants and 3 T scans 36

MRI safety information for CI24REH (Hybrid L24)	
cochlear implants	37
CI24REH (Hybrid L24) cochlear implants and 1.5 T scans.....	37
CI24REH (Hybrid L24) cochlear implants and 3 T scans.....	39
MRI safety information for CI24RE (CA) cochlear implants.....	41
CI24RE (CA) cochlear implants and 1.5 T scans	41
CI24RE (CA) cochlear implants and 3 T scans	43
MRI safety information for CI24RE (ST) cochlear implants.....	44
CI24RE (ST) cochlear implants and 1.5 T scans	44
CI24RE (ST) cochlear implants and 3 T scans.....	46
MRI safety information for CI24R (CA) cochlear implants.....	47
MRI safety information for CI24R (CS) cochlear implants	48
MRI safety information for CI24R (ST) cochlear implants.....	49
MRI safety information for CI24M cochlear implants.....	50
MRI safety information for CI 11+11+2M cochlear implants	51
MRI safety information for ABI24M auditory brainstem implants	52
MRI safety information for CI22M cochlear implants.....	53
Preparation prior to an MRI examination.....	54
Cooperation between specialists	54
Considerations for implant magnet removal.....	55
Considerations for conducting an MRI examination.....	56
Prerequisites.....	56
Patient positioning	56
Patient comfort.....	57
Perform the MR scan.....	57
Performing an MR Scan on other body locations.....	57

Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) ..58

- Intended use58
- MRI Kit contraindications.....58
- Obtaining an MRI Kit58
- MRI Kit contents58
- Using the MRI Kit.....59

Considerations after an MRI examination 64

- With the implant magnet in place..... 64
- Remove the MRI Kit bandage and splint..... 64
- With the implant magnet removed..... 64

Considerations for referring physicians65

Risks associated with MRI and Cochlear Nucleus implants67

Labelling symbols..... 68

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 9 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. See *X-ray information for identification of Cochlear Nucleus implants* on page 8 and *Implant model identification and related MRI safety information* on page 9.

X-ray information for identification of Cochlear Nucleus implants

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

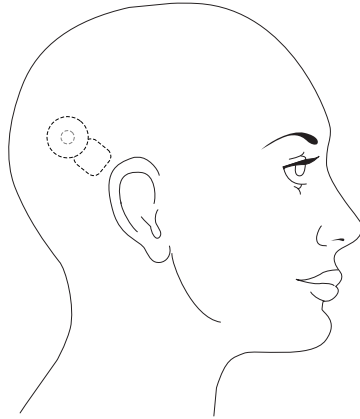


Figure 1: Location behind the ear for Cochlear Nucleus implants

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.

Implant model identification and related MRI safety information

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)
- Nucleus 24 – CI24R (CA), CI24R (CS), CI24R (ST), CI24M, CI11+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 CI600 Series implants - CI612, CI622 and CI632 and CI500 Series implants – CI512, CI522 and CI532 – 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 three holes next to the magnet, as illustrated below.

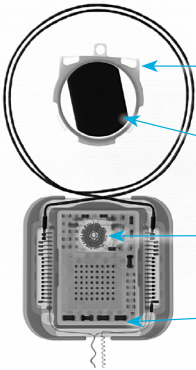
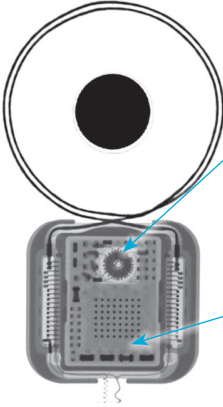
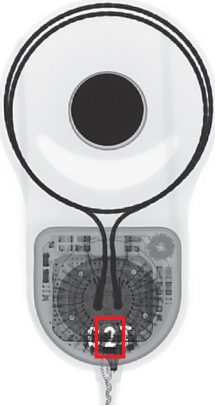

Cochlear Nucleus implant model	Electronic assembly	Unique identifier	MRI safety information
CI612	 <p data-bbox="342 791 551 852">Figure 2: CI600 Series implant X-ray</p>	Three holes adjacent to magnet	Page 13
CI622		Magnet shape	Page 16
CI632		Round shape at coil exit end of electronic assembly layout. Four rectangular shapes at electrode exit end.	Page 21
CI512	 <p data-bbox="342 1302 551 1362">Figure 3: CI500 Series implant X-ray</p>	Round shape at coil exit end of electronic assembly layout.	Page 25
CI522		Round shape at coil exit end of electronic assembly layout.	Page 29
CI532		Four rectangular shapes at electrode exit end.	Page 32

Table 1: Cochlear Nucleus implant models identified by their shape and electronic assembly.

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI422		13	Page 36
CI24REH (Hybrid L24)		6	Page 39
CI24RE (CA)		5	Page 43
CI24RE (CS)		7	Page 43
CI24RE (ST)		4	Page 46
CI24R (CA)		2	Page 49
CI24R (CS)		C	Page 50
CI24R (ST)		H	Page 51
CI24M		T	Page 52
CI 11+11+2M		P	Page 53
ABI24M		G	Page 54


Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI22M with removable magnet		L or J	Page 55
CI22M without removable magnet		Z	

Table 2: Cochlear Nucleus implant models identified by second (middle) radiopaque character set and related MRI safety information

MRI safety information for CI612 cochlear implants

Non-clinical testing has demonstrated that CI612 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

Note

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

CI612 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
 - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
 - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- 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.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI612 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI612 cochlear implant is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

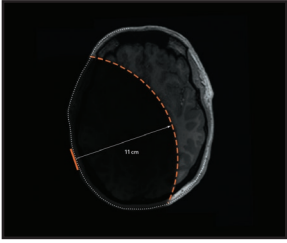
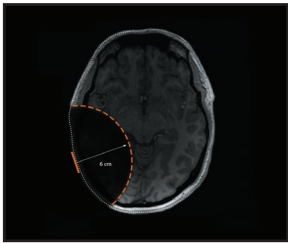
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI612 cochlear implant when using a spin echo pulse sequence scan.</p>
<p>For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.</p>	

Table 3: Largest image artefact for CI612 cochlear implants at 1.5 T scans

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

CI612 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 3 T with the implant magnet in place.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required.
 - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
 - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- 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.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI612 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI612 cochlear implant is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

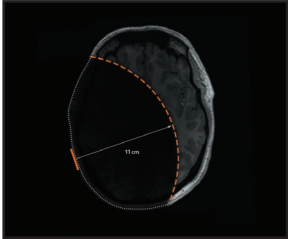
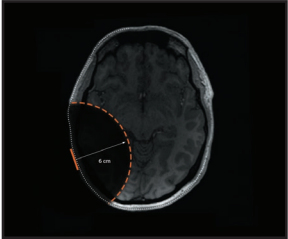
3 T with magnet cassette	3 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI612 cochlear implant when using a spin echo pulse sequence scan.</p>
<p>For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.</p>	

Table 4: Largest image artefact for CI612 cochlear implants at 3 T scans

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

MRI safety information for CI622 cochlear implants

Non-clinical testing has demonstrated that CI622 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

Note

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

CI622 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
 - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
 - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- 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.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI622 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI622 cochlear implant is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

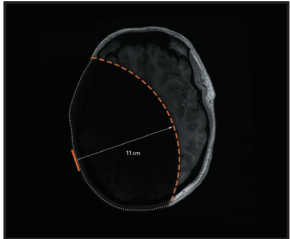
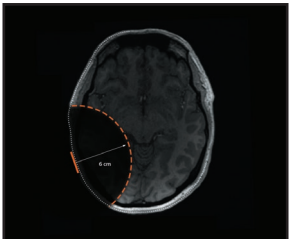
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI622 cochlear implant when using a spin echo pulse sequence scan.</p>
<p>For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.</p>	

Table 5: Largest image artefact for CI622 cochlear implants at 1.5 T scans

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

CI622 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 3 T with the implant magnet in place.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
 - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
 - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- 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.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI622 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI622 cochlear implant is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

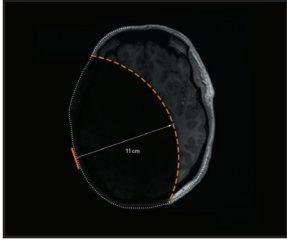
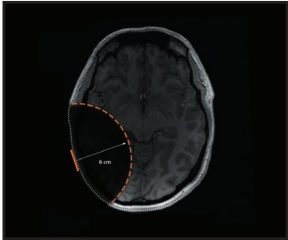
3 T with magnet cassette	3 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI622 cochlear implant when using a spin echo pulse sequence scan.</p>
<p>For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.</p>	

Table 6: Largest image artefact for CI622 cochlear implants at 3 T scans

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

MRI safety information for CI632 cochlear implants

Non-clinical testing has demonstrated that CI632 implants are MR Conditional. A patient with one or two of these devices can be safely scanned in an MR system meeting the following conditions.

Note

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

CI632 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 1.5 T with the implant magnet in place.
- Static magnetic field of 1.5 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
 - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
 - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <2 W/kg is required.
- 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.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI632 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI632 cochlear implant is as follows.

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

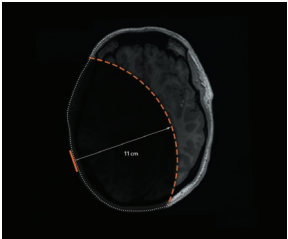
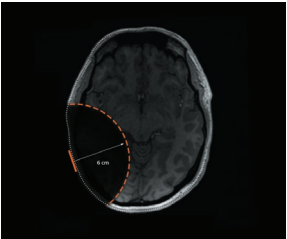
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI632 cochlear implant when using a spin echo pulse sequence scan.</p>
<p>For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.</p>	

Table 7: Largest image artefact for CI632 cochlear implants at 1.5 T scans

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

CI632 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- The MRI Kit is not required for MR scans at 3 T with the implant magnet in place.
- Static magnetic field of 3 T.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.4 W/kg is required.
 - It is safe to use local RF receive only coils with cochlear implants during MRI scanning.
 - Local planar (flat linearly polarized) receive only RF coils should be kept more than 10 cm (3.9 in) away from the cochlear implant
- When using a transmit/receive head coil, a maximum MR system reported, head averaged specific absorption rate (SAR) of <1 W/kg is required.
- 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.
- CI600 implants can be safely scanned at least ten times without any adverse effect on magnet strength.

Under the scan conditions defined above, the CI632 cochlear implant is expected to produce a maximum temperature rise of less than 6 °C after 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI632 cochlear implant is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

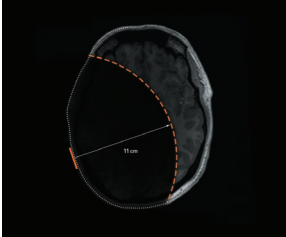
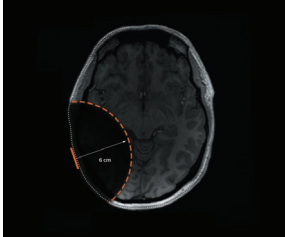
3 T with magnet cassette	3 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI632 cochlear implant when using a spin echo pulse sequence scan.</p>
<p>For CI600 series bilateral implant recipients, the image artefacts as shown above are mirrored on the opposite side of the head for each implant. There may be some extension of the artefact between the implants.</p>	

Table 8: Largest image artefact for CI632 cochlear implants at 3 T scans

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

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 *Using the MRI Kit* on page 61.
- 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 is required.

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:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

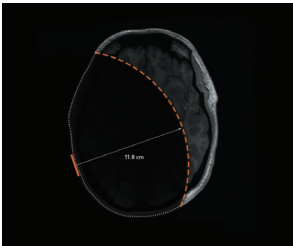
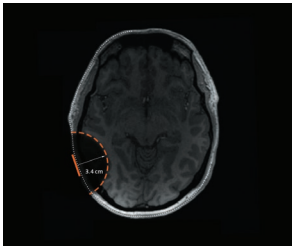
1.5 T magnet in place	1.5 T magnet removed
	
<p>11.8 cm (4.6 in.)</p>	<p>3.4 cm (1.3 in.)</p>


Table 9: 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. 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:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

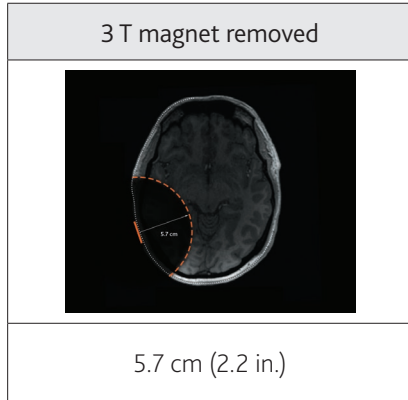


Table 10: Largest image artefact for CI512 cochlear implants at 3 T scans

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 *Using the MRI Kit* on page 61.
- 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 is required.

Under the scan conditions defined above, the CI522 cochlear implant is expected to produce a maximum temperature rise of less than 3.8 °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 2 minutes and 16 seconds is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

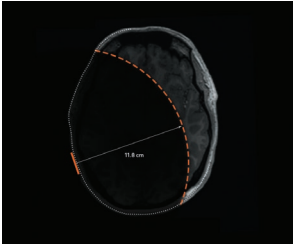
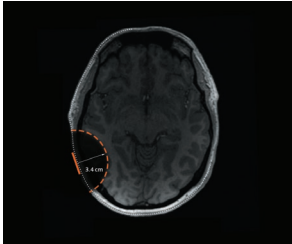
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 11: 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. 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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

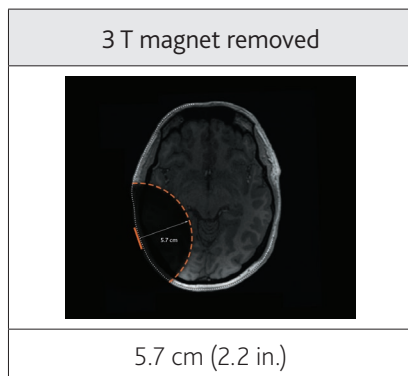


Table 12: Largest image artefact for CI522 cochlear implants at 3 T scans

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 *Using the MRI Kit* on page 61.
- 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 is required.

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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

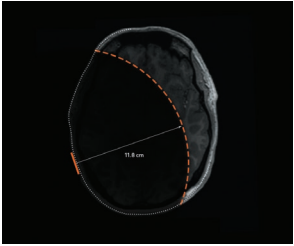
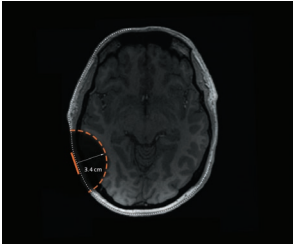
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 13: 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. 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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

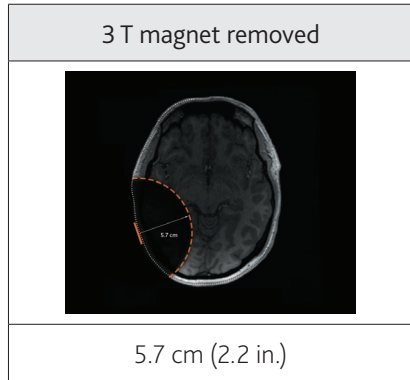


Table 14: Largest image artefact for CI532 cochlear implants at 3 T scans

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 *Using the MRI Kit* on page 61.
- 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 is required.

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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

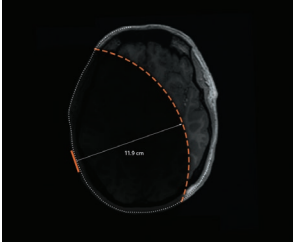
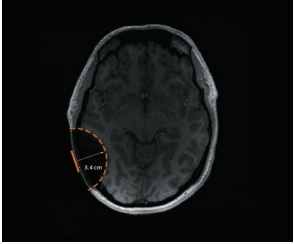
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 15: 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. 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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

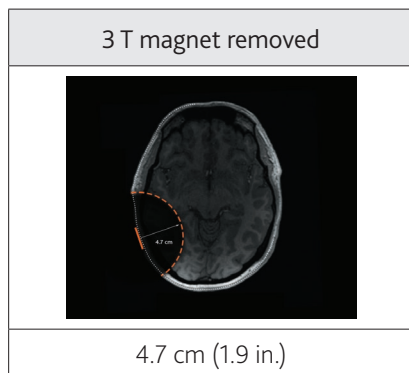


Table 16: Largest image artefact for CI422 cochlear implants at 3 T scans

MRI safety information for CI24REH (Hybrid L24) cochlear implants


Non-clinical testing has demonstrated that CI24REH (Hybrid L24) cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.

CI24REH (Hybrid L24) 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 *Using the MRI Kit* on page 61.
- 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 is required.

Under the scan conditions defined above, the CI24REH (Hybrid L24) 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 (Hybrid L24) cochlear implant when imaged with a gradient echo pulse sequence scan for 2 minutes and 16 seconds is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

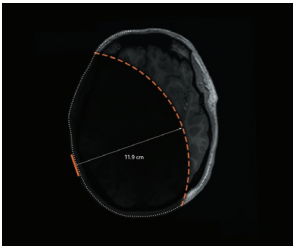
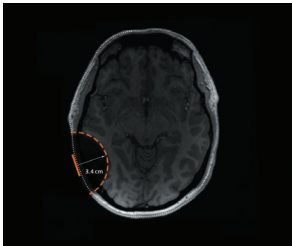
1.5 T magnet in place	1.5 T magnet removed
	
<p>11.9 cm (4.6 in.)</p>	<p>3.4 cm (1.3 in.)</p>


Table 17: Largest image artefact for CI24REH (Hybrid L24) cochlear implants at 1.5 T scans

CI24REH (Hybrid L24) 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. Scans must be performed in CP Mode.

Under the scan conditions defined above, the CI24REH (Hybrid L24) 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 (Hybrid L24) cochlear implant when imaged with a gradient echo pulse sequence scan for 3 minutes and 20 seconds is as follows:

 **Note**

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

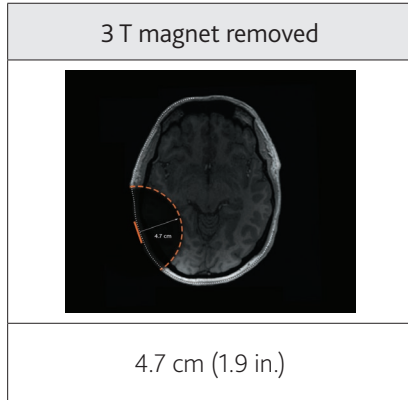


Table 18: Largest image artefact for CI24REH (Hybrid L24) cochlear implants at 3 T scans

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 *Using the MRI Kit* on page 61.
- 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 is required.

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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

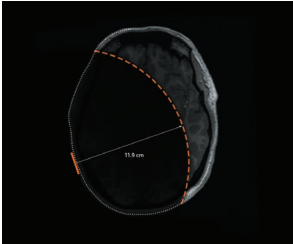
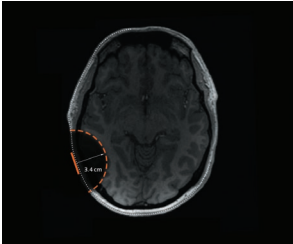
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 19: 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. 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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

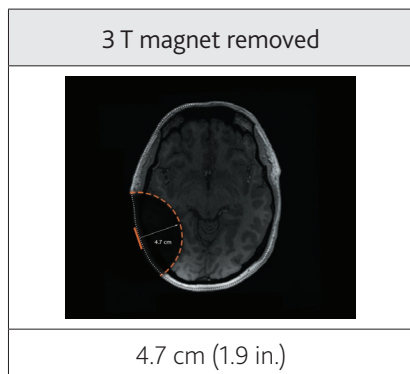


Table 20: Largest image artefact for CI24RE (CA) cochlear implants at 3 T scans

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 *Using the MRI Kit* on page 61.
- 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 is required.

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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

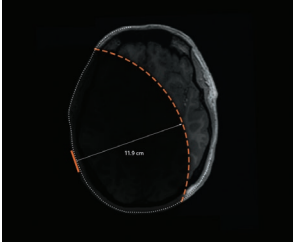
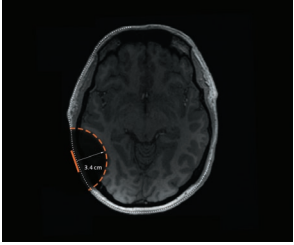
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 21: 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 is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <0.5 W/kg is required. 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:

Note

The following image artefact results are based on worst-case scenarios showing maximum artefact extension. The optimisation of scan parameters can be used to minimise the extent of the artefact.

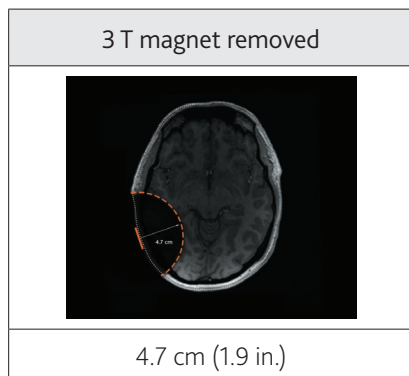


Table 22: Largest image artefact for CI24RE (ST) cochlear implants at 3 T scans

MRI safety information for CI24R (CA) cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (CA) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI24R (CS) cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (CS) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI24R (ST) cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24R (ST) cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI24M cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI24M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

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

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI 11+11+2M cochlear implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for ABI24M auditory brainstem implants



Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow patients with an ABI24M auditory brainstem implant to be in the room where an MRI scanner is located except under the following special circumstances.

The ABI24M auditory brainstem implant has a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher. If the ABI24M auditory brainstem implant magnet is in place, it must be removed surgically before the patient undergoes an MRI procedure.

The patient must take off the speech processor and headset before entering a room where an MRI scanner is located.

If the implant magnet is still in place, tissue damage may occur if the recipient is exposed to MRI. Once the magnet is surgically removed, the metal in the ABI24M auditory brainstem implant will affect the quality of the MRI. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, resulting in loss of diagnostic information in the vicinity of the implant.

ABI24M auditory brainstem implants have removable magnets. Once the magnet has been removed, MRI can be performed. The headset can be held in place on the recipient's head by a stick-on retainer disk.

If you require additional information about removal of the magnet, please contact Cochlear.

MRI safety information for CI22M cochlear implants

Caution

The instructions below are provided as a convenience, and restate the information that was included in the Physician's Package Insert for this product when it was initially approved. This information is not consistent with current standards for MR labelling as this information was created before the development of these standards. Specific information about spatial field gradient and maximum temperature rise were not part of the initially approved labelling.

Magnetic Resonance Imaging (MRI) is contraindicated except under the circumstances described below. Do not allow a patient with a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

The CI22M cochlear implant with removable magnet has specific design characteristics to enable it to withstand MRI up to 1.5 T, but not higher.

For patients with a CI22M cochlear implant without a removable magnet, MRI is contraindicated.

The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm (2.5 in.) from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

If you require additional information about removal of the magnet, please contact Cochlear.

Preparation prior to an MRI examination

Cooperation between specialists

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

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

Considerations for implant magnet removal

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

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



Warning

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

For all other 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.

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



Note

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

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

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

Considerations for conducting an MRI examination

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

Prerequisites

The following additional conditions must be met:

- The implant model has been identified.
- The implant magnet has been surgically removed if the referring physician has prescribed that the MR scan be performed with the implant magnet removed.
- For Cochlear implants other than CI600 Series implants, 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 *Using the MRI Kit* on page 61 for instructions on how to apply the MRI Kit prior to the MR scan.

Patient positioning

The patient should be positioned prior to entering the MRI machine. Prior to performing the MR scan, the patient should be placed in the supine position (lying flat on back, face upward), with their head aligned with the bore axis of the MRI machine.

The patient should be advised to lie as still as possible and to not move their head during the MR scan.



Caution

Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain. It may also result in implant demagnetisation. If the patient moves their head during the MR scan, this may also result in increased torque on the implant or possible magnet demagnetisation.

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 *Identifying the Cochlear Nucleus implant* on page 7 to find the location of the MRI safety information for the patient's implant model.

Performing an MR Scan on other body locations

When an implant recipient requires an MRI on a location of their body away from the implant site, you must still follow the MRI safety information for the recipient's implant model. See *Implant model identification and related MRI safety information* on page 9 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)

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 intended for use with the following Cochlear Nucleus implants:

- CI500 Series – CI512, CI522 and CI532
- CI24RE Series – CI422, CI24REH (Hybrid L24), CI24RE (CA), CI24RE (CS) and CI24RE (ST)

MRI Kit contraindications

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

Obtaining an MRI Kit

Contact Cochlear on +1 877 883 3101 to order an MRI Kit.

MRI Kit contents

Item	Description
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.

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. Preparation

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. 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.

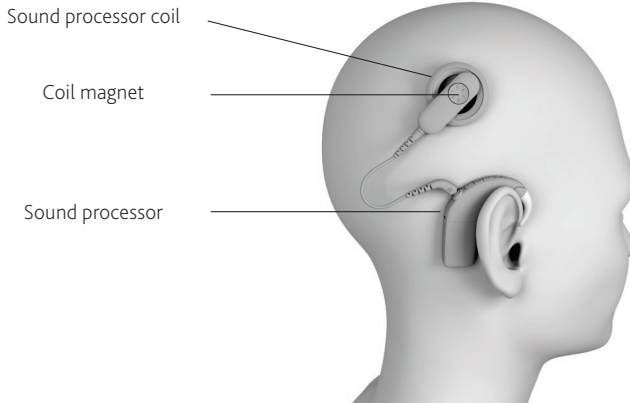


Figure 4: Location of the sound processor, sound processor coil and coil magnet

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 5* on page 63. 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. 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.

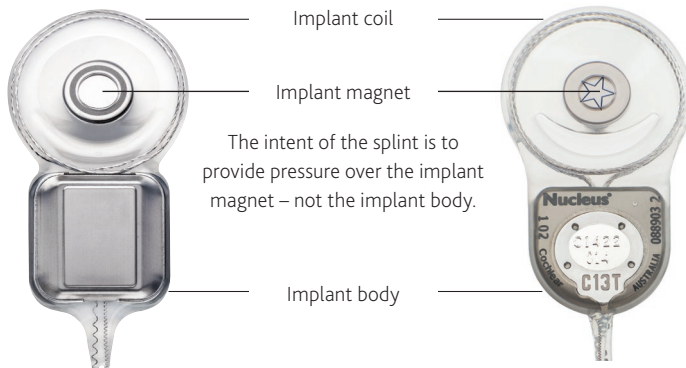


Figure 5: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants

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

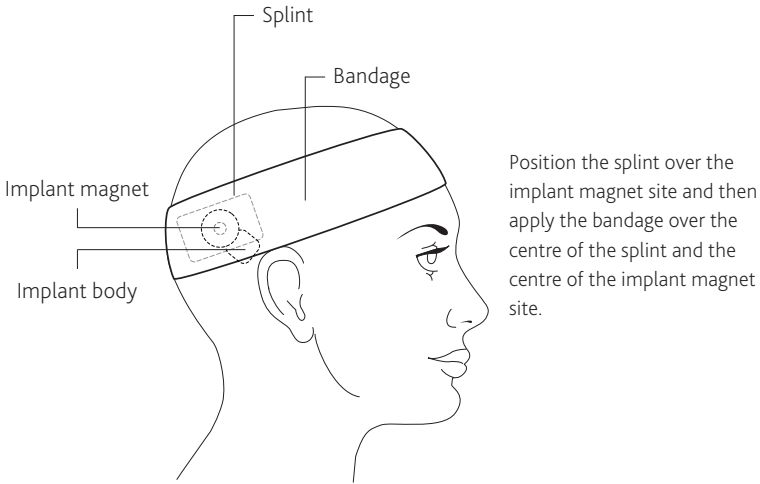


Figure 6: Fitting the MRI Kit splint and compression bandage

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.

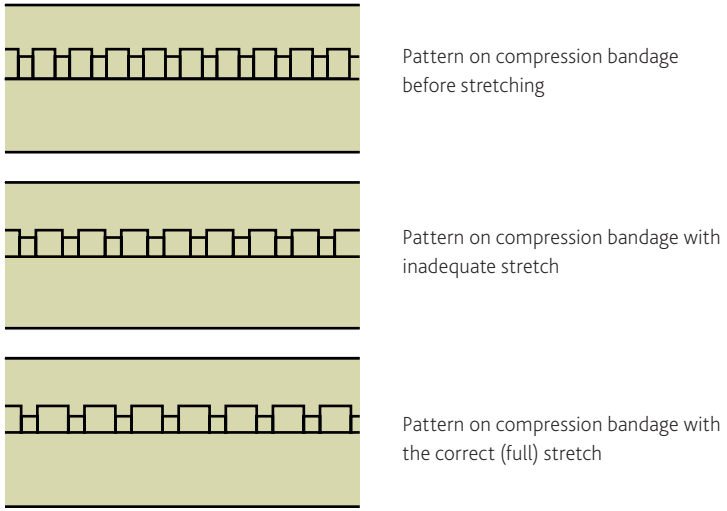


Figure 7: Comparison of compression bandage tightness

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 66.

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 clinician as soon as possible.

With the implant magnet removed

See *Considerations for implant magnet removal* on page 57.

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 69.

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 9 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 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 include movement or damage to the device, weakening of the implant magnet and uncomfortable sensation or skin/tissue trauma for the patient. Cochlear has evaluated the interaction of implants described in this guide with other nearby implanted devices during MRI scanning.
- 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 MRI Safety information for your implant.
- 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 59.

- For MR Scans at 1.5 T or 3 T, identify if the implant magnet needs to be removed.

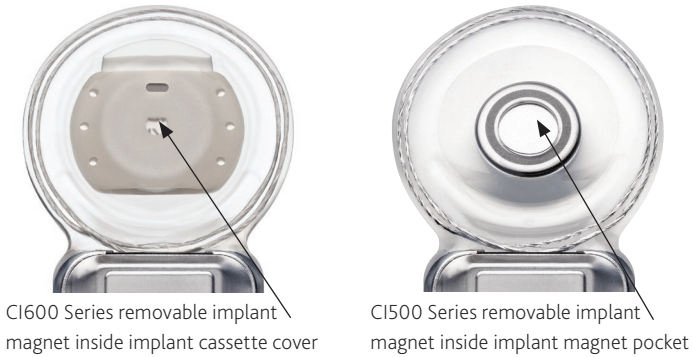


Figure 8: CI600 and CI500 Series implant with removable magnet

Consider the following:

- If the required diagnostic information is in the area of the implant, the implant magnet may need to be removed.
- Timing of the implant surgery and MRI exposure.
- Age and general health of the implant recipient and time to recover from the implant magnet surgery or potential trauma.
- Existing or potential for tissue scarring in the location of the implant magnet.
- If the implant magnet needs to be removed, refer the patient to an appropriate physician to arrange for the magnet to be removed before the MR scan.
- If the implant magnet is retained for an MR scan at 1.5 T, a Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) must be obtained beforehand for use during the MR scan, except for CI600 implants. See *Obtaining an MRI Kit* on page 60.

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.
 - Incorrect patient positioning prior to the MR scan or head movement during the scan may result in implant demagnetisation.
- **Uncomfortable sensation**

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

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

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

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

Labelling symbols

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



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

Hear now. And always

Cochlear Ltd (ABN 96 002 618 073) 1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352

Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove, NSW 2066, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352

CEIREP Cochlear Deutschland GmbH & Co. KG Karl-Wiechert-Allee 76A, 30625 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770

Cochlear Americas 13059 E Peakview Avenue, Centennial, CO 80111, USA
Tel: +1 303 790 9010 Fax: +1 303 792 9025

Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 416 972 5082 Fax: +1 416 972 5083

Cochlear AG EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205

Cochlear Europe Ltd 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400 Fax: +44 1932 26 3426

Cochlear Benelux NV Schaliënhoedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70

Cochlear France S.A.S. 135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National) Fax: +33 5 34 63 85 80

Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62

Cochlear Nordic AB Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel: +46 31 335 14 61 Fax: +46 31 335 14 60

Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Çubuklu Mah. Boğaziçi Cad., Boğaziçi Plaza No: 6/1, Kavacak, TR-34805 Beykoz-Istanbul, Turkey
Tel: +90 216 538 5900 Fax: +90 216 538 5919

Cochlear (HK) Limited Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road, Causeway Bay, Hong Kong
Tel: +852 2530 5773 Fax: +852 2530 5183

Cochlear Korea Ltd 1st floor, Cheongwon Building 33, Teheran-ro 8 gil, Gangnam-gu, Seoul, Korea
Tel: +82 2 533 4450 Fax: +82 2 533 8408

Cochlear Medical Device (Beijing) Co., Ltd
Unit 2608-2617, 26th Floor, No.9 Jianguo Road, Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800 Fax: +86 10 5909 7900

Cochlear Medical Device Company India Pvt. Ltd.
Ground Floor, Platina Building, Plot No C-59, G-Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111 Fax: +91 22 6112 1100

株式会社日本コクレア (Nihon Cochlear Co Ltd) 〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241 Fax: +81 3 3817 0245

Cochlear Middle East FZ-LLC
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor, Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400 Fax: +971 4 361 8925

Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403, Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218

Cochlear NZ Limited
Level 4, Takapuna Towers, 19-21 Como St, Takapuna, Auckland 0622, New Zealand
Tel: + 64 9 914 1983 Fax: 0800 886 036

www.cochlear.com

Cochlear implant systems are protected by one or more international patents.

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.

ACE, Advance Off-Stylet, AOS, AutoNRT, Autosensitivity, Beam, Button, CareYourWay, Carina, Cochlear, 科利耳, コクレア, Cochlear SoftWear, Codacs, ConnectYourWay, Contour, Contour Advance, Custom Sound, ESprit, Freedom, Hear now. And always, HearYourWay, Hugfit, Hybrid, Invisible Hearing, Kanso, MET, MicroDrive, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Off-Stylet, Slimline, SmartSound, Softsp, Sprint, True Wireless, the elliptical logo, WearYourWay and Whisper are either trademarks or registered trademarks of Cochlear Limited. Ardium, Baha, Baha SoftWear, BCDrive, DermaLock, EveryWear, Vistafix, and WindShield are either trademarks or registered trademarks of Cochlear Bone Anchored Solutions AB.
© Cochlear Limited 2019

