

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

Canada

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 Important Information Booklet, 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..... 6
 - Identifying the Cochlear Nucleus implant..... 6
 - X-ray information for identification of Cochlear Nucleus implants. 7
 - X-ray guidelines 7
- Implant model identification and related MRI safety information..... 8
 - MRI safety information for CI612 cochlear implants..... 12
 - CI612 cochlear implants and 1.5 T scans 12
 - CI612 cochlear implants and 3 T scans 14
 - MRI safety information for CI622 cochlear implants..... 16
 - CI622 cochlear implants and 1.5 T scans..... 16
 - CI622 cochlear implants and 3 T scans 18
 - MRI safety information for CI624 cochlear implants20
 - CI624 cochlear implants and 1.5 T scans.....20
 - CI624 cochlear implants and 3 T scans22
 - MRI safety information for CI632 cochlear implants..... 24
 - CI632 cochlear implants and 1.5 T scans.....24
 - CI632 cochlear implants and 3 T scans26
 - MRI safety information for CI512 and CI512P cochlear implants ...28
 - CI512/CI512P cochlear implants and 1.5 T scans.....28
 - CI512/CI512P cochlear implants and 3 T scans 30
 - MRI safety information for CI522 cochlear implants 32
 - CI522 cochlear implants and 1.5 T scans.....32
 - CI522 cochlear implants and 3 T scans.....34
 - MRI safety information for CI532 and CI532P cochlear implants ..35
 - CI532/CI532P cochlear implants and 1.5 T scans35
 - CI532/CI532P cochlear implants and 3 T scans 37

- MRI safety information for ABI541 auditory brainstem implants.. 38
 - ABI541 auditory brainstem implants and 1.5 T scans 38
 - ABI541 auditory brainstem implants and 3 T scans 40
- MRI safety information for CI422 cochlear implants42
 - CI422 cochlear implants and 1.5 T scans.....42
 - CI422 cochlear implants and 3 T scans 44
- MRI safety information for CI24REH cochlear implants 46
 - CI24REH cochlear implants and 1.5 T scans..... 46
 - CI24REH cochlear implants and 3 T scans 48
- MRI safety information for CI24RE (CA) cochlear implants.....49
 - CI24RE (CA) cochlear implants and 1.5 T scans49
 - CI24RE (CA) cochlear implants and 3 T scans 51
- MRI safety information for CI24RE (ST) cochlear implants.....52
 - CI24RE (ST) cochlear implants and 1.5 T scans52
 - CI24RE (ST) cochlear implants and 3 T scans.....54
- MRI safety information for CI24R (CA) cochlear implants.....55
 - CI24R (CA) cochlear implants and 1.5 T scans.....55
 - CI24R (CA) cochlear implants and 3 T scans56
- MRI safety information for CI24R (CS) cochlear implants57
 - CI24R (CS) cochlear implants and 1.5 T scans57
 - CI24R (CS) cochlear implants and 3 T scans.....58
- MRI safety information for CI24R (ST) cochlear implants.....59
 - CI24R (ST) cochlear implants and 1.5 T scans59
 - CI24R (ST) cochlear implants and 3 T scans 60
- MRI safety information for CI24M cochlear implants..... 61
 - CI24M cochlear implants and 1.5 T scans..... 61
 - CI24M cochlear implants and 3 T scans62
- MRI safety information for CI 11+11+2M cochlear implants63
 - CI 11+11+2M cochlear implants and 1.5 T scans63
 - CI 11+11+2M cochlear implants and 3 T scans.....63

MRI safety information for ABI24M auditory brainstem implants	64
ABI24M auditory brainstem implants and 1.5 T scans.....	64
ABI24M auditory brainstem implants and 3 T scans	65
MRI safety information for CI22M cochlear implants.....	66
CI22M cochlear implants with removable magnet and 1.5 T scans	66
Preparation prior to an MRI examination	67
Cooperation between specialists	67
Considerations for implant magnet removal.....	68
Considerations for conducting an MRI examination	69
Prerequisites.....	69
Bilateral recipients.....	69
Patient positioning	70
Patient comfort.....	70
Perform the MR scan	71
Performing an MR Scan on other body locations.....	71
Cochlear Nucleus Implant Bandage and Splint Kit for MRI (MRI Kit) ..	72
Intended use	72
MRI Kit contraindications.....	72
Obtaining an MRI Kit	73
MRI Kit contents	73
Using the MRI Kit.....	74
Considerations after an MRI examination	78
With the implant magnet in place.....	78
With the implant magnet removed.....	78
Considerations for referring physicians	79
Risks associated with MRI and Cochlear Nucleus implants.....	81
Labelling symbols.....	82

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 8 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 7 and *Implant model identification and related MRI safety information* on page 8.

X-ray information for identification of Cochlear Nucleus implants

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

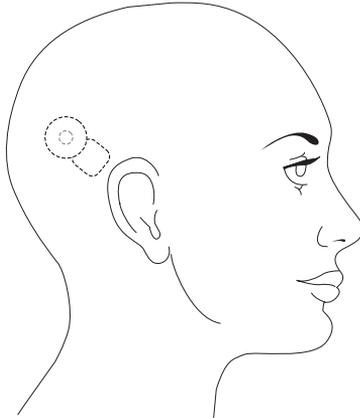


Figure 1: Location behind the ear for Cochlear Nucleus implants

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)
- CI24R Series – CI24R (CA), CI24R (CS), CI24R (ST)
- CI24M Series – CI24M, CI11+11+2M and ABI24M
- CI22 Series – CI22M

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

The second (middle) radiopaque character set identifies the implant model.

Cochlear Nucleus CI600 Series implants - CI612, CI622, CI624 and CI632 and CI500 Series implants – CI512/CI512P, CI522 and CI532/CI532P – 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.

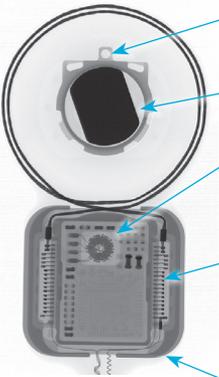
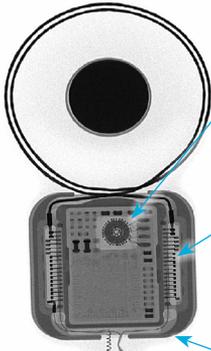
Cochlear Nucleus implant model	Electronic assembly	Unique identifier	MRI safety information
CI612	 <p data-bbox="336 799 547 858">Figure 2: CI600 Series implant X-ray</p>	Three holes adjacent to magnet	Page 12
CI622		Magnet shape	Page 16
CI624		Round shape at coil exit end of electronic assembly layout	Page 20
CI632		Series of wire connectors that are visible on both sides of the electronic assembly	Page 24
CI512/ CI512P	 <p data-bbox="336 1286 547 1345">Figure 3: CI500 Series implant X-ray</p>	Round shape at coil exit end of electronic assembly layout	Page 28
CI522		Series of wire connectors that are visible on both sides of the electronic assembly	Page 32
CI532/ CI532P		Square implant body shape	Page 35
ABI541			Page 38

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	 <p data-bbox="336 708 552 767">Figure 4: CI24RE Series implant X-ray</p>	13	Page 42
CI24REH		6	Page 46
CI24RE (CA)		5	Page 49
CI24RE (CS)		7	Page 49
CI24RE (ST)		4	Page 52
CI24R (CA)	 <p data-bbox="341 1262 549 1321">Figure 5: CI24R Series implant X-ray</p>	2	Page 55
CI24R (CS)		C	Page 57
CI24R (ST)		H	Page 59

Cochlear Nucleus implant model	Location of second (middle) radiopaque character set	Radiopaque characters	MRI safety information
CI24M		T	Page 61
CI 11+11+2M		P	Page 63
ABI24M		 <p>CI24M Series implant X-ray</p>	G
CI22M with removable magnet		L or J	Page 66
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.

Warning

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

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 cylindrical 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 4.9 °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.

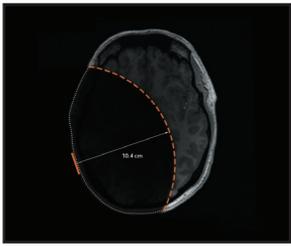
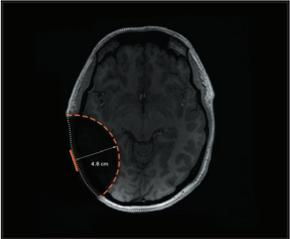
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends 10.4 cm (4.1 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends 4.8 cm (1.9 in.) from the centre of the CI612 cochlear implant 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 cylindrical 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 5.0 °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 10.7 cm (4.2 in.) from the centre of the CI612 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends 5.6 cm (2.2 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

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

WARNING

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

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 cylindrical 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 5.1 °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.

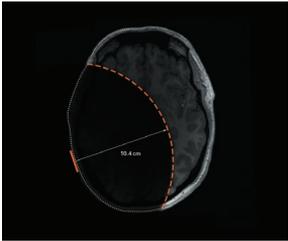
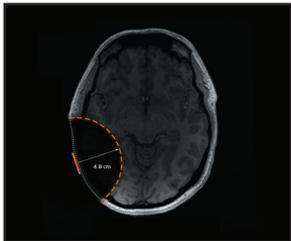
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends 10.4 cm (4.1 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends 4.8 cm (1.9 in.) from the centre of the CI622 cochlear implant 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

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 cylindrical 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 5.3 °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.

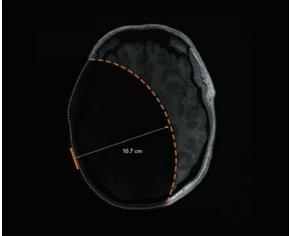
3 T with magnet cassette	3 T with non-magnetic cassette
	
<p>The image artefact extends 10.7 cm (4.2 in.) from the centre of the CI622 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends 5.6 cm (2.2 in.) from the centre of the CI622 cochlear implant when 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

MRI safety information for CI624 cochlear implants

Non-clinical testing has demonstrated that CI624 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.

Warning

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

CI624 cochlear implants and 1.5 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 cylindrical 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 CI624 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 CI624 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.

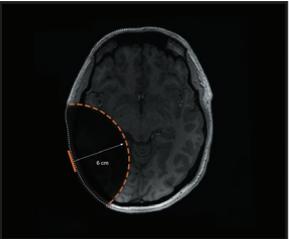
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI624 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI624 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 CI624 cochlear implants at 1.5 T scans

CI624 cochlear implants and 3 T scans

- Remove the sound processor before entering the MRI scan room. The sound processor is MR Unsafe.
- 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 cylindrical 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 CI624 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 CI624 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.

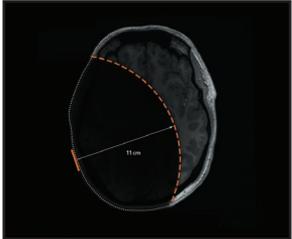
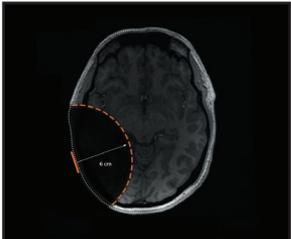
3 T with magnet cassette	3 T with non-magnetic cassette
	
<p>The image artefact extends approximately 11 cm (4.3 in.) from the centre of the CI624 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends approximately 6 cm (2.4 in.) from the centre of the CI624 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 CI624 cochlear implants at 3 T scans

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.

Warning

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

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 cylindrical 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 5.5 °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.

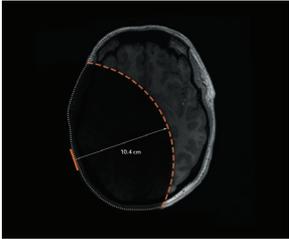
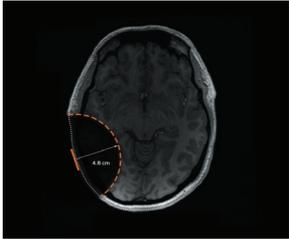
1.5 T with magnet cassette	1.5 T with non-magnetic cassette
	
<p>The image artefact extends 10.4 cm (4.1 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends 4.8 cm (1.9 in.) from the centre of the CI632 cochlear implant 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 9: Largest image artefact for CI632 cochlear implants at 1.5 T scans

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 cylindrical 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 5.7 °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.

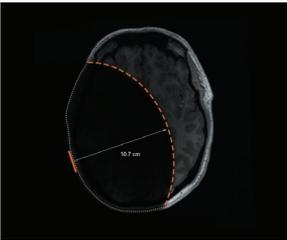
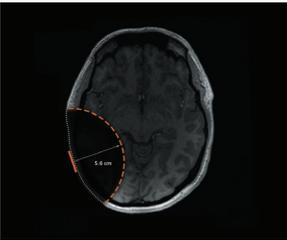
3 T with magnet cassette	3 T with non-magnetic cassette
	
<p>The image artefact extends 10.7 cm (4.2 in.) from the centre of the CI632 cochlear implant when using a gradient echo pulse sequence scan.</p>	<p>The image artefact extends 5.6 cm (2.2 in.) from the centre of the CI632 cochlear implant when 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 10: Largest image artefact for CI632 cochlear implants at 3 T scans

MRI safety information for CI512 and CI512P cochlear implants

Non-clinical testing has demonstrated that CI512 and CI512P cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.



WARNING

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

CI512/CI512P 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 72.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 and CI512P cochlear implants 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.

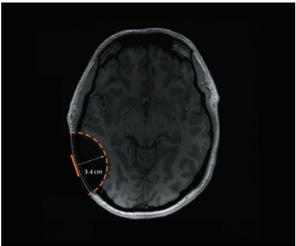
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 11: Largest image artefact for CI512 and CI512P cochlear implants at 1.5 T scans

CI512/CI512P 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI512 and CI512P cochlear implants 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.

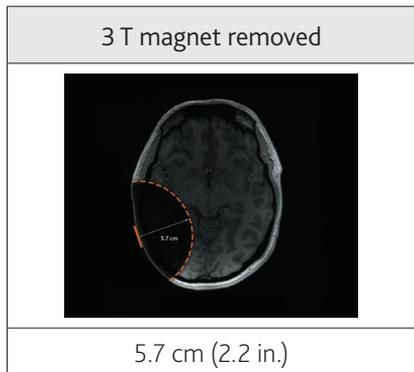


Table 12: Largest image artefact for CI512 and CI512P cochlear implants at 3 T scans

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.



Warning

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

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 72.
- 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.
- Maximum MRI scan time is 60 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.

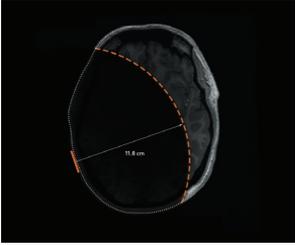
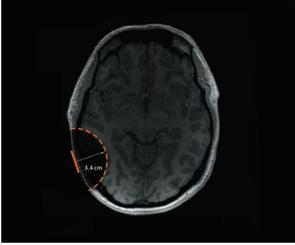
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 13: 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.
- Maximum MRI scan time is 60 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.

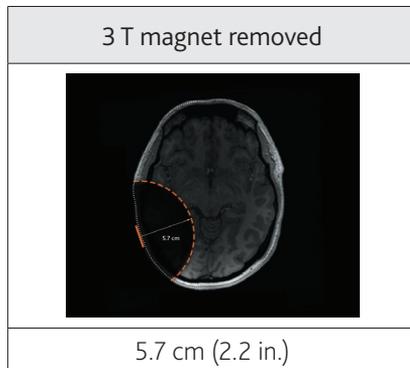


Table 14: Largest image artefact for CI522 cochlear implants at 3 T scans

MRI safety information for CI532 and CI532P cochlear implants

Non-clinical testing has demonstrated that CI532 and CI532P cochlear implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.



Warning

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

CI532/CI532P 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 72.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the CI532 and CI532P 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.

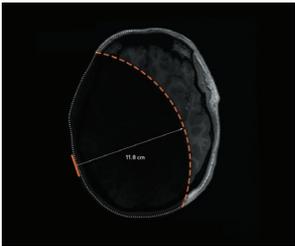
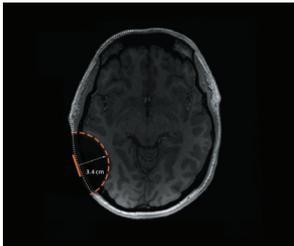
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 15: Largest image artefact for CI532 cochlear implants at 1.5 T scans

CI532/CI532P 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

In non-clinical testing¹, the image artefact caused by the CI532 and CI532P 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.

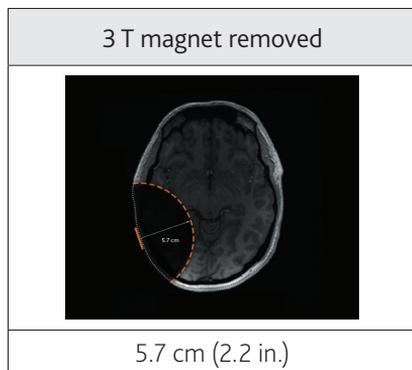


Table 16: Largest image artefact for CI532 cochlear implants at 3 T scans

MRI safety information for ABI541 auditory brainstem implants

Non-clinical testing has demonstrated that ABI541 auditory brainstem implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions.



Warning

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

ABI541 auditory brainstem 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 72.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the ABI541 auditory brainstem 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.

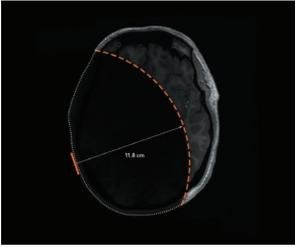
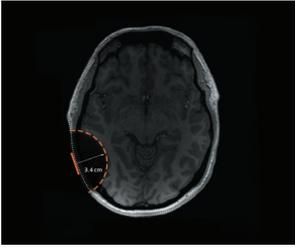
1.5 T magnet in place	1.5 T magnet removed
	
11.8 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 17: Largest image artefact for ABI541 auditory brainstem implants at 1.5 T scans

ABI541 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.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

In non-clinical testing, the image artefact caused by the ABI541 auditory brainstem 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.

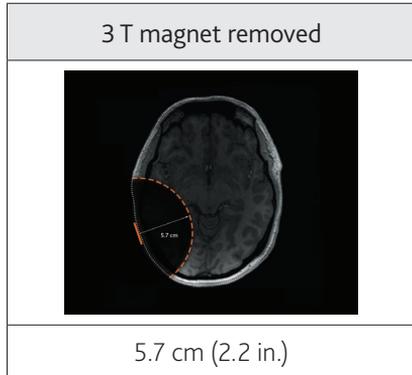


Table 18: Largest image artefact for ABI541 auditory brainstem implants at 3 T scans

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.



WARNING

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

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 72.
- 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.
- Maximum MRI scan time is 60 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.

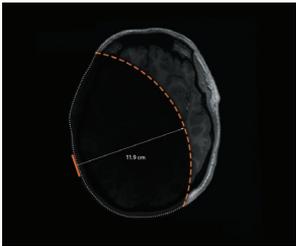
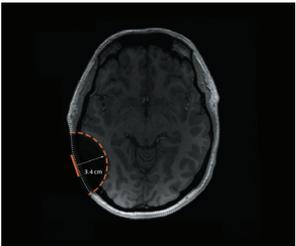
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 19: 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.
- Maximum MRI scan time is 60 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.

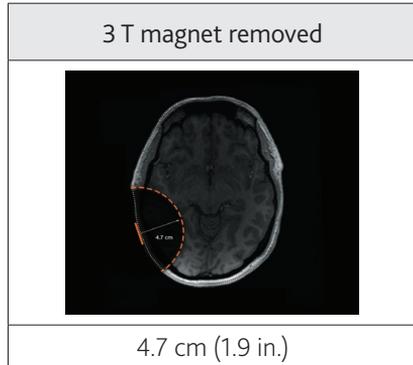


Table 20: Largest image artefact for CI422 cochlear implants at 3 T scans

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.



Warning

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

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 72.
- 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.
- Maximum MRI scan time is 60 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:

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.

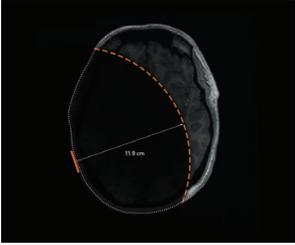
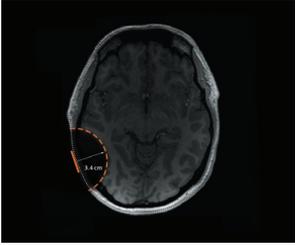
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 21: Largest image artefact for 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 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.
- Maximum MRI scan time is 60 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:

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.

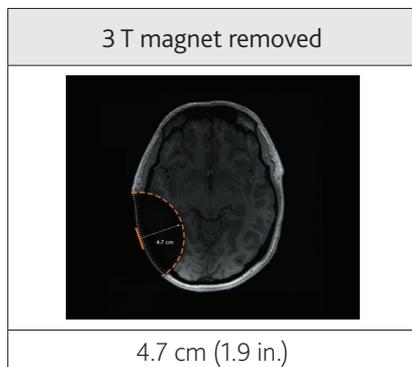


Table 22: Largest image artefact for CI24REH cochlear implants at 3 T scans

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.

WARNING

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

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 72.
- 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.
- Maximum MRI scan time is 60 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.

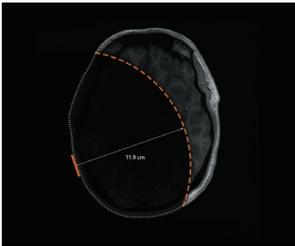
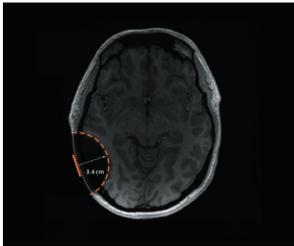
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 23: 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.
- Maximum MRI scan time is 60 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.

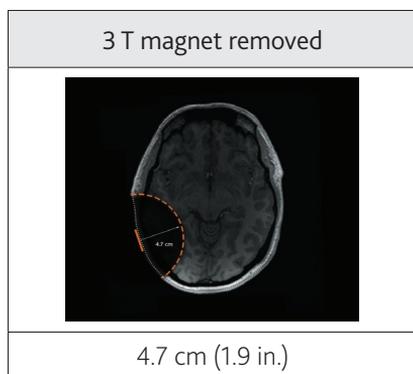


Table 24: Largest image artefact for CI24RE (CA) cochlear implants at 3 T scans

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.



Warning

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

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 72.
- 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.
- Maximum MRI scan time is 60 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.

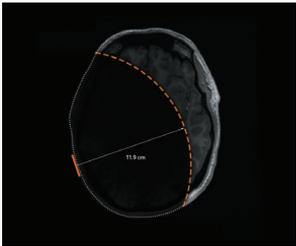
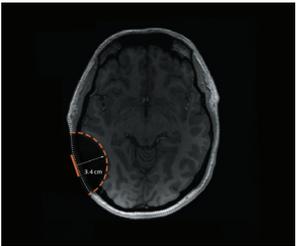
1.5 T magnet in place	1.5 T magnet removed
	
11.9 cm (4.6 in.)	3.4 cm (1.3 in.)

Table 25: 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.
- Maximum MRI scan time is 60 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.

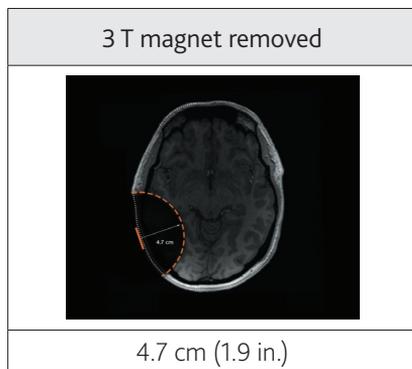


Table 26: Largest image artefact for CI24RE (ST) cochlear implants at 3 T scans

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.



Warning

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

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 72.
- 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 a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.



WARNING

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

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 72.
- 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 a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.



Warning

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

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 72.
- 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 a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.
- 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. .
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.



Warning

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

CI24M 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 72.
- 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 a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.
- 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. .
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.
- 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 72.
- 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 a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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

- MRI is contraindicated for CI 11+11+2M cochlear implants at 3 T.

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.
- 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 72.
- 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 a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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.
- 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.
- Maximum MRI scan time is 60 minutes of continuous scanning

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.
- Maximum spatial field gradient of 2000 gauss/cm (20 T/m).
- When using a transmit/receive head coil a maximum MR system reported, whole head averaged specific absorption rate (SAR) of <2 W/kg is required.
- When using a transmit body coil, a maximum MR system reported, whole body averaged specific absorption rate (SAR) of <1 W/kg is required.
- Maximum MRI scan time is 60 minutes of continuous scanning.

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 74 for instructions on how to apply the MRI Kit prior to the MR scan.

Bilateral recipients

Caution

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

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

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

When scanning with the implant magnet in place, ensure that the patient does not move more than 15 degrees (15°) from the centreline (Z-axis) of the bore during the MR scan.

Failure to position the patient correctly prior to the MR scan may result in increased torque on the implant and cause pain. 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 6 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 8 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, CI512P, CI522, CI532, CI532P and ABI541
- CI24RE Series – CI422, CI24REH, CI24RE (CA), CI24RE (CS) and CI24RE (ST)
- CI24R Series – CI24R (CA), CI24R (CS) and CI24R (ST)
- CI24M Series – CI24M, CI 11 +11+2M and ABI24M
- CI22 Series – CI22M (with removable magnet)



Warning

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

MRI Kit contraindications

The MRI Kit is contraindicated for use with:

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

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

Obtaining an MRI Kit

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

MRI Kit contents

Item	Description
Flat plastic splints	To be placed against the skin over the implant magnet site.
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.

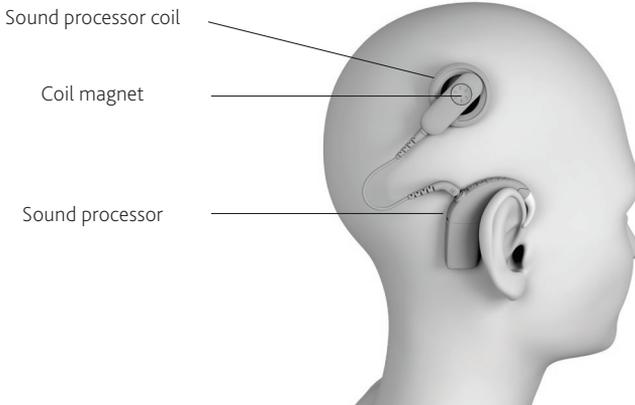


Figure 6: Location of the sound processor, sound processor coil and coil magnet

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

2. Bandaging

1. Use a splint from the MRI Kit and centre it over the implant magnet site (as marked) against the skin. Ensure the splint is held in place over the implant magnet. See *Figure 7* 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.

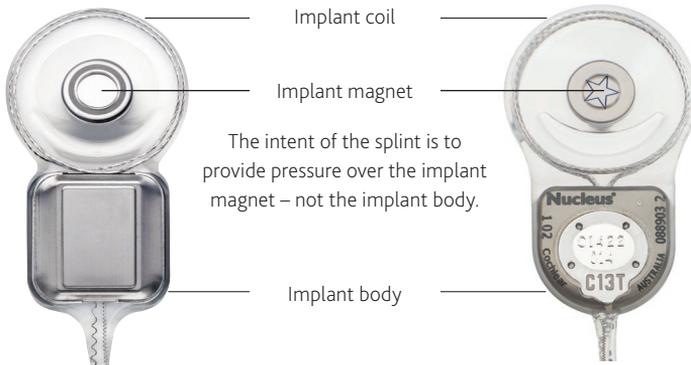


Figure 7: Location of the implant magnet on CI500 Series (left side) and CI24RE Series (right side) implants

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 8** below.

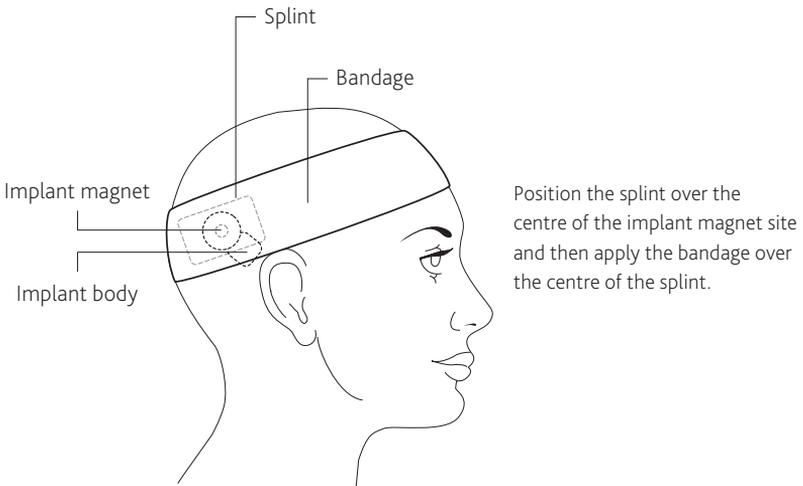


Figure 8: Fitting the MRI Kit splint and compression bandage

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 9* below.

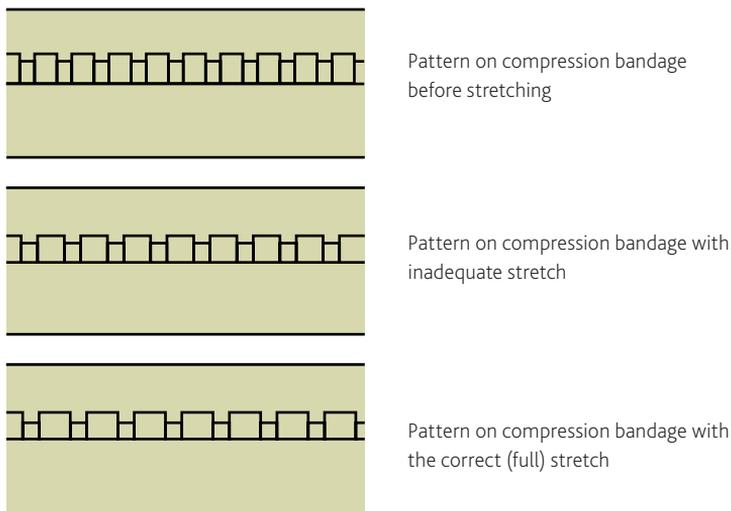


Figure 9: Comparison of compression bandage tightness

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 78.

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 68.

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 81.

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 8 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 and there are no identified safety risks.
- 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 71.

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



Figure 10: 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 73.

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

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