

# Cochlear™

## Nucleus® ABI541 auditory brainstem implant

Important information for  
implant recipients

*Hear now. And always*



Cochlear®



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# About this document

This document applies to Cochlear™ Nucleus® ABI541 auditory brainstem implants, sound processors, remote assistants, and remote controls. It is intended for brainstem implant recipients and their carers.

## Read this document carefully

The information in this document contains important safety warnings and cautions relating to the device and its use. These warnings and cautions relate to:

- implant recipient safety
- device function
- environmental conditions, and
- medical treatments.

Before starting medical treatment, discuss the medical treatment warnings in this document with the recipient's physician.

Additional details on device use and care are included in the user guides and product information supplied with the device. Please read these documents carefully—they may contain additional warnings and cautions.

## Symbols used in this document

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### **Note**

Important information or advice.

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### **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.

---

# For implant recipients

Cochlear devices are designed to be safe and effective. However, it is also essential that you take care when using them.

This section contains warnings and precautions for safe and effective use of your device. You should also refer to your user guide for specific warnings and cautions related to the use of external components.



## Warnings

This section includes general warnings to ensure your personal safety.

### Feeling unwell when using your sound processor

If you feel unwell when using your sound processor, remove your external equipment immediately (processor, coil, any attached accessories) and contact your clinician. This includes dizziness, palpitations, light-headedness, chest pains, difficulties swallowing, or other uncomfortable side effects.

### Sound processors not programmed for the implant

Only use the sound processor programmed for your ABI541 auditory brainstem implant. Using a sound processor programmed for another recipient, or a sound processor programmed for any implant type used on a different ear, could cause undesirable effects, such as disturbing your heart rhythm.

## Small parts hazard

Small parts and accessories could be hazardous if swallowed or cause choking if ingested or inhaled.

## Overheating

Remove your processor or coil immediately if they become unusually warm or hot, and seek advice from your clinician.

Do not use your remote assistant or remote control if it becomes unusually warm. Notify your clinician immediately.

## Uncomfortable sound levels

If the sound becomes uncomfortable, remove your external equipment immediately (processor, coil, monitor earphones, acoustic component) and contact your clinician.

If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, could cause extreme discomfort.

## Head trauma

A blow to your head in the area of the implant could damage the implant and result in its failure.

Impact to external components (e.g. sound processor, acoustic component) while being worn could result in damage to the device or injury.



## Pressure

Do not apply continued pressure to the coil when in contact with the skin as this may result in pressure sores, e.g. sleeping/lying on coil or using tight fitting headwear.

If the coil magnet is too strong or is in contact with the skin, pressure sores may develop at the coil site. If this happens or if you experience any discomfort in this area, contact your clinician.

## Batteries and battery chargers

Batteries can be hazardous if used incorrectly. For information on safe battery use refer to your external component user guides.

## Long-term effects of electrical stimulation by the implant

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. The long-term effects of such stimulation in humans are unknown. These effects may lead to the eventual deterioration of nerve cells in the central auditory nervous system.

## Adverse environments

Operation of your implant system could be adversely affected in environments of high magnetic field strength and high electric field strengths, e.g. close to high power commercial radio transmitters.

Seek medical advice before entering any environment that may adversely affect the operation of your implant, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.



## Cautions

This section includes general cautions to ensure safe and effective use of your implant system, and to avoid causing damage to system components.

### General use

- Use your implant system only with approved devices and accessories listed in the user guide.
- If you experience a significant change in performance, turn off your processor and contact your clinician.
- Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- No modification of external equipment is allowed. If your processor is modified or opened by anyone other than Cochlear's qualified service personnel, the warranty is invalid.

### Sound processor

- Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another person.
- Your processor's sound quality could be intermittently distorted when you are within approximately 1.6 km (~1 mile) of a radio or television transmission tower. The effect is temporary and will not damage your processor.

## Theft and metal detection systems

Turn off your processor if near or passing through a theft and metal detection system.

You could experience a distorted sound sensation when passing through or near one of these devices. Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields.

The materials used in your implant may activate metal detection systems. Carry the Cochlear Patient Identification Card with you at all times.

## Mobile telephones

Some types of digital mobile telephones, e.g. Global System for Mobile communications (GSM) as used in some countries, may interfere with the operation of your external equipment. You could perceive a distorted sound sensation when close, 1-4 m (~3-12 ft), to a digital mobile telephone in use.

## Air travel

Some airlines request that passengers turn off portable electrical devices, such as laptop computers and electronic games, during take-off and landing or whenever the seat belt sign is illuminated. Your processor is considered to be a medical portable electronic device.

Notify airline personnel that you are using an implant system. They can then alert you to safety measures, which may include the need to switch your processor off.

Transmitting devices such as mobile/cell phones are required to be switched off on aircraft. If you have a remote control (remote assistant) for your processor, switch it off before take-off. The remote control (remote assistant) transmits high frequency radio waves when switched on.

## Scuba diving

For Cochlear Nucleus ABI541 auditory brainstem implants, the maximum diving depth when wearing an implant is 40 m (~131 ft).

Seek medical advice before participating in a dive to ensure you do not have any conditions that might make diving contraindicated, e.g. middle ear infection.

When wearing a mask, avoid pressure over the implant site.

## Electromagnetic interference with medical devices

Cochlear Nucleus Remote Assistants and Cochlear Nucleus Sound Processors meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the remote assistant and sound processor radiate electromagnetic energy, it is possible that they could interfere with other medical devices such as cardiac pacemakers and implantable defibrillators when used nearby.

It is recommended that you keep your remote assistant and sound processor at least 15 cm (~6 in.) away from devices which could be subject to electromagnetic interference. For added assurance, also consult the recommendations provided by the device manufacturer.

## Electrostatic discharge (ESD)

Before engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, remove your processor. In rare cases, a discharge of static electricity can damage the electrical components of the implant system or corrupt the program in the processor.

If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), before the implant system contacts any object or person you should touch something conductive such as a metal door handle.

# For parents and carers of implant recipients

This section includes general warnings for parents and carers of implant recipients to ensure recipient safety. Please also read the user guide, which contains specific warnings on external component use, and the information earlier in this document.



## Warnings

### Feeling unwell when using the sound processor

If the recipient feels unwell when using their sound processor, remove the external equipment immediately (processor, coil, any attached accessories) and contact your clinician. This includes dizziness, palpitations, light-headedness, chest pains, difficulties swallowing, or other uncomfortable side effects.

### Sound processors not programmed for the implant

Only use the sound processor programmed for the ABI541 auditory brainstem implant. Using a sound processor programmed for another recipient, or a sound processor programmed for any implant type used on a different ear, could cause undesirable effects, such as disturbing heart rhythm.

## Small parts hazard

Keep small parts and accessories out of reach of children.

Small parts and accessories could be hazardous if swallowed or cause choking if ingested or inhaled.

## Strangulation

Parents and carers are advised that unsupervised use of long cables (such as coil or accessory cables) may present a risk of strangulation.

## Overheating

Parents and carers should touch the processor to check for heat if the recipient is showing signs of discomfort.

Remove the processor or coil immediately if they become unusually warm or hot, and seek advice from your clinician.

## Uncomfortable sound levels

Carers should routinely check that the acoustic component is working at a comfortable volume level. If the sound becomes uncomfortable, remove the external equipment immediately (processor, coil, monitor earphones, acoustic component) and contact your clinician.

If the recipient has two processors (one for each ear), ensure they always wear the processor programmed for their left ear on the left and the processor programmed for their right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, could cause extreme discomfort.

## Head trauma

Young children who are developing motor skills are at greater risk of receiving an impact to the head from a hard object, e.g. table or chair.

A blow to the head in the area of the implant could damage the implant and result in its failure.

Impact to external components (e.g. sound processor, acoustic component) while being worn could result in damage to the device or injury.



# For discussion with physicians of implant recipients

Having an implant means extra care must be taken when receiving some medical treatments. Before starting medical treatment, the information in this section should be discussed with the recipient's physician.



## Warnings

### Preoperative imaging

All potential Cochlear Nucleus ABI541 auditory brainstem implant recipients should undergo appropriate imaging around the area of the cochlear nucleus preoperatively, to determine the integrity of the cochlear nucleus and surrounding structures.

### Gamma knife radiation

Due to possible injury to the cochlear nucleus resulting from radiotherapy treatment, prospective auditory brainstem implant recipients who have undergone gamma knife radiation should undergo MRI of the cochlear nucleus preoperatively to determine the integrity of the cochlear nucleus and brainstem anatomy.

## Medical treatments generating induced currents, heat and vibration

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Before initiating any of the following treatments deactivate the device.

The sound processor must be removed before starting any of the medical treatments listed in this section.

Warnings for specific treatments are provided below.

<b>Diathermy</b>	Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the brainstem or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.
<b>Electroconvulsive therapy</b>	Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy can cause tissue damage or damage to the implant.
<b>Electrosurgery</b>	<p>Electrosurgical instruments can induce radio frequency currents that could flow through the electrode.</p> <p>Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause tissue damage or permanent damage to the implant.</p> <p>When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in.) from the electrodes.</p>

Ionizing radiation therapy	Do not use ionizing radiation therapy directly over the implant. It may cause damage to the implant.
Neurostimulation	Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage or permanent damage to the implant.
Therapeutic ultrasound	Do not use therapeutic levels of ultrasound energy directly over the implant. It may inadvertently concentrate the ultrasound field and cause tissue damage or damage to the implant.

## Magnetic resonance imaging (MRI)



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

If the patient is implanted with other implants, consult the manufacturer's instructions before performing MRI.



### Warning

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

The implant will create shadowing on the MRI in the vicinity of the implant, resulting in loss of diagnostic information. The physician should evaluate shadowing near the brainstem created by the electrode array and apply alternative imaging techniques if necessary.

The quality of MRI will be affected by the implant. With the magnet removed, image shadowing may extend as far as 6 cm (~2.5 in.) from the implant, when scanned for 3 minutes at 3 tesla (T).

With the magnet in place, image shadowing may extend as far as 12 cm (~4.7 in.) from the implant when scanned for 2 minutes at 0.2 T or 1.5 T.

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

## Indications for using MRI safety

Indications for MRI safety depend on the model of the implant. Cochlear Nucleus ABI541 auditory brainstem implants have removable magnets. At some field strengths, the magnet must be removed surgically before the patient undergoes an MRI procedure.



### Note

In the United States of America, MRI with the magnet in place is not approved at any field strength.

## Implant identification

To verify the model of the implant look for the characteristics listed below.



### Note

Unlike earlier Cochlear implants, the Cochlear Nucleus ABI541 auditory brainstem implants do not have radiopaque lettering.

## Cochlear Nucleus ABI541 auditory brainstem implant

If required, the implant type and model can be identified without the need of surgical intervention, using X-ray or Cochlear programming software.

When interpreting a sagittal X-ray image of a Cochlear implant, the device series can be identified by the electronic assembly layout.

Cochlear ABI541 auditory brainstem implants have:

- a round shape at the coil exit end
- four large components at the electrode exit end.

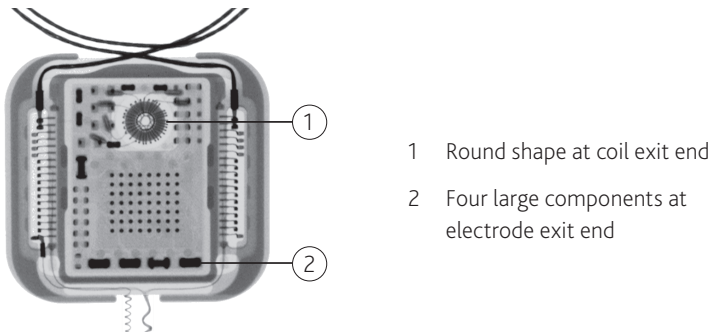


Figure 1: Plain X-ray of ABI541 auditory brainstem implant

### Results of MRI testing (non-clinical)

Cochlear Nucleus ABI541 auditory brainstem implants are designed to withstand Magnetic Resonance Imaging (MRI) at field strengths described as follows.

The results of non-clinical testing according to ASTM F2182 are shown in the following table.

Implant type	MRI field strength (T)	Maximum spatial gradient field (T/m)	Maximum head SAR (W/kg)	Whole body average SAR (W/kg)	
				Landmark location	
				<40 cm from top of head	≥40 cm from top of head
ABI541	0.2	8	0.525	0.525	1.5
	1.5	8	0.525	0.525	1.5
	3.0	20	0.35	0.35	0.85

Table 1: Recommended SAR levels for maximum 15 minutes MRI scan time

## Cochlear Nucleus ABI541 auditory brainstem implant

Non-clinical testing according to ASTM F2182 has demonstrated that the above implant can be scanned safely in 0.2 T, 1.5 T and 3.0 T static magnetic fields for a maximum of 15 minutes scanning.

### Note

MRI machine manufacturers may claim that the scanning of patients with implanted devices is generally contra-indicated. This is a general precautionary claim, as MRI machine manufacturers are unable to ensure safety for all types of implantable devices.

Cochlear has performed specific testing for the above implant and established the necessary SAR safety limits as outlined. MRI machines are able to monitor SAR levels. The MRI machine manufacturer should be able to provide advice on how to maintain SAR levels with their machine.



### Using MRI safely

To use MRI safely on a cochlear implant recipient who has a Cochlear Nucleus ABI541 auditory brainstem implant, follow the guidance below.

MRI strength	Guidance
More than 1.5 T, up to and including 3.0 T	Surgically remove the magnet for MRI. Tissue damage may occur if the magnet is in place during MRI.
More than 0.2 T, up to and including 1.5 T	Leave the magnet in place for MRI. Bandaging and splint are required.
0.2 T or less	Leave the magnet in place for MRI. Bandaging is optional.

Table 2: MRI in Canada, Europe, Australia, and other countries in the European and Asia Pacific regions<sup>3</sup>

For more information about magnet removal, refer to the *Physician's Guide* or contact Cochlear.

## Performing an MRI scan with the magnet in place

Read the complete *Magnetic resonance imaging (MRI)* section before following the instructions below.

The magnet can only be left in place for some implants at certain field strengths. To determine if the magnet can be left in place see *Table 2: MRI in Canada, Europe, Australia, and other countries in the European and Asia Pacific regions*<sup>3</sup> on page 25.



### Warning

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

1. Inform the patient that they may feel a slight pulling sensation during the scan. For details see *Patient comfort* on page 28.
2. Remove the patient's external equipment (processor and coil) before they enter the MRI room.

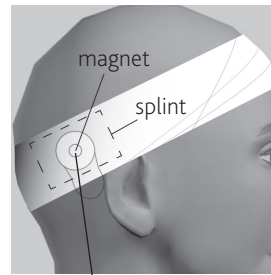


### Note

The patient cannot hear without the external equipment.

If the scan is at 0.2 T or less, bandaging is not required but acceptable to do so. Proceed to step 3.

If the scan is at more than 0.2 T, up to and including 1.5 T (the magnet must be removed at over 1.5 T), bandage around the head to reduce the likelihood of the magnet moving. Although unlikely with the recommended bandaging, it is possible for the magnet to move during MRI and dislodge from the implant magnet pocket.



Implant magnet site

Bandage around the head as follows:

- Use an elasticised compression bandage with a maximum width of 10 cm or 4 in. Generic bandages are suitable. No special bandage is required.
- Ensure the centreline of the bandage is over the implant magnet site.
- Use a minimum of two layers at or near full stretch to apply firm pressure to the implant site. 'Full stretch' = no elasticity remaining in bandage.
- Use a splint (see table below) placed against the skin over the site of the magnet to maximise magnet stability.

Splint material	Instruction
A4, 80 gsm sheet of printer/copy paper	Fold five times along the longer edge and place between the implant magnet site and the bandage.
Plastic card (similar to a credit or ID card) without magnetic strip or SIM chip	Place between the implant magnet site and the bandage.
Re-usable adhesive e.g. Bostik Blu-Tack	Flatten a 1.5 cm to 2 cm diameter ball of Blu-Tack into a disc approximately 0.5 cm thick and place between the implant magnet site and the bandage.

Table 3: Options for stabilising the implant magnet during MRI

3. Conduct the MRI scan. There is no need to position the patient in a particular way because of the implant.

## Patient comfort

Explain to the patient that the compression bandage (for MRI above 0.2 T) will reduce the likelihood of the implant magnet moving. However, the patient may still sense the 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 with the bandage in place, check that it is not too tight, and if necessary, consider performing an MRI scan at 0.2 T (no bandaging required). Alternatively, consult the patient's physician to determine if the magnet should be removed or if a local anaesthetic may be applied to reduce discomfort.



### Caution

If administering local anaesthetic, take care not to perforate the implant silicone.

# Electromagnetic compatibility (EMC)

## Guidance and manufacturer's declaration

The Nucleus range of sound processors, remote assistants and remote controls are intended for use in the electromagnetic environments specified in this document.

They have been tested and found to be in compliance as shown. You should take care to use your equipment as described.

## Electromagnetic emissions

Emission test	Compliance	Guidance
RF emissions CISPR 11	Group 1	RF energy is only used for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3		

Table 4: Electromagnetic emissions

## Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	See <i>Electrostatic discharge (ESD)</i> on page 13
Electrical fast transient/burst IEC 61000-4-4	Not applicable		
Surge IEC 61000-4-5			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6  Radiated RF IEC 61000-4-3	Not applicable  3 V/m 80 MHz to 2.5 GHz	  3 V/m	See <i>Warnings</i> and <i>Cautions</i> sections, and <i>Guidance</i> below

Table 5: Electromagnetic immunity

## Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

$$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range<sup>b</sup>.

Interference may occur in the vicinity of equipment marked with the following symbol:



### Note

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations.  
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

### Explanatory notes:

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the processor is used exceeds the applicable RF compliance level above, the processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the processor.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Recommended separation distances

Your processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled.

To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.



Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

Table 6: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

### Note

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

# Privacy and the collection of personal information

During the process of receiving a Cochlear device, personal information about the user/recipient or their parent, guardian, carer and hearing health professional will be collected for use by Cochlear and others involved in care with regard to the device.

For more information please read Cochlear's Privacy Policy on [www.cochlear.com](http://www.cochlear.com) or request a copy from Cochlear at the address nearest you.



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

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

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