Cochlear™

Nucleus® CI422 cochlear implant with straight electrode

Important Information: Warnings, Precautions and Electromagnetic Compatibility

Hear now. And always

Cochlear™

This document contains important information such as warnings, precautions and privacy that applies to the following cochlear implant systems:

- Cochlear™ Nucleus® CI422 cochlear implant with straight electrode

Read this document carefully to ensure that you understand the care of your system.

Discuss this information with your physician before undergoing any major medical procedure.

Contents

Warnings

Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Warnings for specific treatments are given below.

Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~½ in.) from the extracochlear electrodes.

Diathermy

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 cochlea or permanent damage to the implant.

Medical diathermy using ultrasound may be used below the head and neck.

Neurostimulation

Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

Electroconvulsive therapy

Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the implant.

Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the implant because it may cause 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.

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

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. With the magnet in place, image shadowing may extend as far as 11 cm (~4.3 in.) from the implant. Shadowing results in loss of diagnostic information in the vicinity of the implant.

Indications for MRI safety depend on the model of the implant. If uncertain, to verify the model, the physician should use an X-ray to check the radiopaque lettering on the implant. There are platinum characters printed on each implant. The middle character indicates the model.

CI422 (middle radiopaque character: 13)	
More than 1.5 tesla (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 required.
0.2 T or less	Leave the magnet in place for MRI. No bandaging required.

Table 1: MRI in Canada

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

Cochlear™ Nucleus® CI422 implant SAR levels

Implant type	MRI field strength	Maximum Head SAR	Average Whole Body SAR		
			Landmark location above shoulder	Landmark location chest	Landmark location below chest
CI422	1.5 T and 3.0T	2.0 W/kg	0.5 W/kg	1.0 W/kg	2.0 W/kg

Table 2: SAR levels during MRI (non-clinical testing)

Non-clinical testing according to the international standard ASTM F2182 has demonstrated that the CI422 implant can be scanned safely in 1.5 tesla and 3.0 tesla static magnetic fields at a maximum head averaged Specific Absorption Rate (SAR) of 2 W/kg for 15 minutes of scanning. In non-clinical testing, the above implants produced a temperature rise of less than 2 °C (3.6 °F) at a maximum local SAR of 2 W/kg under specific test conditions stated above.

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 CI422 implant and established the necessary SAR safety limits as outlined. Recently available 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.

Performing an MRI scan with the magnet in place

The CI422 magnet can only be left in place for at certain field strengths. See Table 1 to determine if the magnet can be left in place.

1. Inform the patient that they may feel a slight pulling sensation during the scan. See Patient comfort below.
2. Remove the patient's external equipment (processor and coil) before they enter the MRI room.

   The patient cannot hear without the external equipment.

3. If the scan is at 0.2 T or less, bandaging is not required but acceptable to do so. Proceed to step 4. 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 as follows:


Implant magnet site

- 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.
- 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. See Patient comfort below.

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

4. 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 prevent the implant magnet from 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 and will not damage the implant or hurt the patient.

Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. In addition, certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

Loss of residual hearing

Insertion of the electrode into the cochlea will result in complete loss of residual hearing in the implanted ear.

Long-term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

Small parts hazard

Parents and caregivers should be counselled that the external implant system contains small parts that may be hazardous if swallowed or may cause choking if ingested or inhaled.

Head trauma

A blow to the head in the area of the implant may damage the implant and result in its failure. Young children who are developing their motor skills are at greater risk to receive an impact to the head from a hard object (e.g. a table or chair). For recommendations on how to minimize the chance of children experiencing head trauma see http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000130.htm.

Use of batteries and battery ingestion

When using disposable batteries, only use battery types recommended by your clinician or Cochlear. Other types may not have sufficient energy to allow your processor to operate for a long time. Cochlear does not recommend the use of silver oxide or alkaline batteries.

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If swallowed, seek prompt medical attention at the nearest emergency centre.

Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). Use of the rechargeable battery is contraindicated in patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

Overheating of external devices

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Parents and caregivers should touch their child's or recipient's processor to check for heat if the child or recipient is showing signs of discomfort.

The manufacturer only recommends the use of Cochlear rechargeable battery modules and zinc air disposable batteries.

The CP810 is not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your processor.

Precautions

If you experience a significant change in performance or the sound becomes uncomfortable, turn off your processor and contact your implant centre.

Use the implant system only with the approved devices and accessories listed in the user guide.

Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The opening of your processor by anyone other than Cochlear's qualified service personnel invalidates the warranty.

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. 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, may cause extreme discomfort.

Do not operate your processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).

Do not store your processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).

Your processor's sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

To reduce or eliminate the interference, move away from the source. If your processor stops working, turn the power switch off and then back on. This effect is temporary and will not damage your processor.

Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off your processor when in the vicinity of one of these devices.

The materials used in the implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

Electrostatic discharge

A discharge of static electricity can damage the electrical components of the implant system or corrupt the program in your processor.

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

Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming an implant recipient.

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 the external equipment. As a result, implant recipients may perceive a distorted sound sensation when in close proximity, 1–4 m (~3–12 ft), to a digital mobile telephone in use.

Air travel

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, it should also be switched off because it is transmitting high frequency radio waves when switched on.

Scuba diving

Implant type	Maximum depth
CI422 implant	40 m (~131 ft)

Table 3: Maximum diving depths when wearing implants

Recipients should seek medical advice before participating in a dive for conditions that might make diving contraindicated, e.g. middle ear infection, etc. When wearing a mask, avoid pressure over the implant site.

Sleeping

Do not wear your processor while sleeping, as you may not become aware of your processor becoming unusually warm or hot.

Do not allow children or recipients with disabilities to wear their processor while sleeping.

Retention aids

When using retention aids such as the Snugfit™ or LiteWear, be aware that it may take longer to remove the processor if the processor becomes unusually warm or hot.

Do not attach the LiteWear beneath layers of clothing.

Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration

The Nucleus CP800 Series Sound Processor, Nucleus Freedom, Nucleus Hybrid, Nucleus ESPrit 3G, Nucleus SPrint processors and the CR100 Series Remote Assistant 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 processor 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 (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Refer to *Electrostatic Discharge* section
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	Refer to the • Warnings and Precautions, and • guidance 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):

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

$d = 2.3\sqrt{P}$ 800 MHz to 2.5 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,[a] should be less than the compliance level in each frequency range.[b]

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

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 G Hz** $d = 2.3\sqrt{P}$
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.

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.

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Printed in Australia
389415 ISS1 MAY12