Cochlear™

Important Information

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Cochlear™

This document contains important information such as warnings and precautions that applies to cochlear implant systems.

Contents

Warnings

Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the cochlear 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 a cochlear 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 (~0.5 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 cochlear 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 a cochlear implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the cochlear implant.

Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the cochlear 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 a cochlear implant to be in a room where an MRI scanner is located except under the following special circumstances.

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

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. 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.

The magnet may need to be removed prior to undertaking MRI at certain levels as tissue damage may occur with the magnet in place.

All Nucleus® implants (except for some Nucleus 22) have a removable magnet.

To verify that the patient has a Nucleus cochlear implant with a removable magnet, the physician should use an X-ray to check the radiopaque lettering on the implant. There are three platinum characters printed on each implant. If the middle character is a 'Z' the implant does not have a removable magnet.

The Nucleus CI500 Series implant has a removable magnet but does not have radiopaque lettering unlike earlier cochlear implants.

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

Indications for MRI safety differ depending on the country in which the scan is performed. Contact Cochlear for more information.

Cochlear™ Nucleus® CI500 Series cochlear implants

Non-clinical testing has demonstrated that CI500 Series implants 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 CI500 Series implant produced a temperature rise of less than 2 °C (35.6 °F) at a maximum local SAR of 2 W/kg under specific test conditions stated above.

MRI in Australia and all other countries in the Asia Pacific region

CI500 Series cochlear implants (no radiopaque characters), CI24RE (Freedom), Hybrid and Nucleus 24 Series	
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. Before the MRI, bandage around the head as follows, to ensure the magnet does not move: • Use an elasticised compression bandage with a maximum width of 10 cm or 4 in. • Ensure the centreline of the bandage is over the implant site. • Use a minimum of two layers at or near full stretch to apply firm pressure to the implant site. The compression bandage will prevent the implant magnet from twisting; however, the patient may still sense the resistance to twisting 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. If the patient is not comfortable, or the sensation is considered excessive, remove them from the MRI scanner and consider an MRI at 0.2 T (where no bandaging is required). Alternatively, consult the patient's physician to determine whether the magnet should be removed or whether a local anaesthetic may be applied to reduce discomfort.
0.2 T or less	Leave the magnet in place for MRI. No bandaging required.

Nucleus 22 with removable magnet (middle radiopaque character: L or J)	
Up to and including 1.5 T	Surgically remove the magnet for MRI. Tissue damage may occur if the magnet is in place during MRI.
Nucleus 22 without removable magnet (middle radiopaque character: Z)	
All levels of tesla	MRI is contraindicated

Table 1: MRI in Australia and all other countries in the Asia Pacific region

Overheating

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.

Small parts hazard

The external implant system contains small parts that may be hazardous if swallowed or may cause choking if ingested or inhaled.

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.

Head trauma

A blow to the head in the area of the cochlear 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.

Batteries and battery chargers

Dispose of used batteries promptly and carefully, in accordance with local regulations. Keep away from children.

Wash hands after handling disposable batteries.

Do not recharge disposable batteries.

Do not disassemble, deform, immerse in water or dispose of batteries in fire.

Do not mix old and new batteries or batteries of different types or brands.

Replace batteries with those recommended in the user instructions supplied with your processor.

Do not allow children to replace batteries without adult supervision.

Do not short circuit batteries, e.g. do not let terminals of batteries contact each other or do not carry batteries loosely in pockets.

Store unused batteries in original packing in a cool dry place. When processor is not in use, disconnect batteries and store separately in a cool dry place.

Do not expose batteries to heat, e.g. Never leave batteries in sunlight, behind a window or in a car.

Do not use damaged or deformed batteries. If skin or eyes come into contact with battery fluid or liquid, wash out with water and seek medical attention immediately.

Never put batteries in mouth. If swallowed contact your physician or local poison information centre.

Only use rechargeable batteries and battery chargers supplied or recommended by Cochlear. Use of another battery or battery charger type and brand may present risk of harm or injury. Do not touch battery charger contacts or allow children to use the battery charger without adult supervision.

In certain circumstances, rechargeable batteries can become very hot and could cause injury.

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.

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 cochlear 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 or store your processor at temperatures other than those recommended in the user instructions supplied with your processor.

Your processor sound quality may 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 when in the vicinity of or passing through any theft and metal detection system devices. Recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. The materials used in the cochlear implant may activate metal detection systems.

Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices.

Electrostatic discharge

Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed.

A discharge of static electricity can in rare cases damage the electrical components of the cochlear 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, cochlear implant recipients should touch something conductive, e.g. a metal door handle, before the cochlear implant system contacts any object or person.

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, cochlear 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

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, so you should notify airline personnel that you are using a cochlear implant system. They can then alert you to safety measures which may include the need to switch the 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, it should also be switched off because it is transmitting high frequency radio waves when switched on.

Scuba diving

Implant type	Maximum depth
Nucleus CI24RE (Freedom) and CI500 Series	40 m (~131 ft)
Nucleus 24 and Nucleus 22 Series	25 m (~81 ft)

Table 2: 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.

Electromagnetic interference with medical devices

Cochlear Nucleus Remote Assistants meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the remote assistant radiates electromagnetic energy, it is possible that it could interfere with other medical devices such as cardiac pacemakers and implantable defibrillators when used nearby. It is recommended that the remote assistant is kept at least 6 in. (~15.2 cm) away from devices which could be subject to electromagnetic interference. For added assurance, please also consult the recommendations provided by the device manufacturer.

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, care giver 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 or request a copy from Cochlear at the address nearest you.

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