Cochlear™

Nucleus® CI422 cochlear implant with straight electrode

Important Information

Hear now. And always

Cochlear™

This document contains important information such as warnings, precautions, privacy, Electrostatic Discharge (ESD) and Electromagnetic Compatibility (EMC) that applies to the following 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 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 the speech 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.

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

MRI in Japan, Thailand and Indonesia

The CI422 implant has a removable magnet and specific design characteristics that enables it to withstand MRI up to 1.5 tesla, but not higher.

MRI instructions for CI422 implants	
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. An instruction for radiographers is available from Cochlear.
0.2 T or less	Leave the magnet in place for MRI. No bandaging required.

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

Non-clinical testing 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 CI422 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.

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 a cochlear 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 may result in complete loss of residual hearing in the implanted ear.

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. 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).

Battery ingestion

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.

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 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

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 their 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

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 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, 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 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.

Privacy and the collection of personal information

Cochlear Limited and its subsidiaries and affiliates (together referred to as “we”, ”us”, “Cochlear” and “Cochlear Group”) is committed to protecting the privacy of personal information in accordance with applicable privacy and data protection laws.

For the hearing health professional

The following explains why we collect the information and how we use and store it.

Cochlear collects personal information including your name and contact details to:

- Support and improve the use, maintenance, performance and reliability monitoring and development of Cochlear's products, services and events
- Share within Cochlear Group to get a groupwide picture of your dealings and relationship
- Maintain product distribution records
- Keep you informed by post, telephone, or, when you have given us permission to do so, by email, text messaging or other reasonable electronic methods, about new products, services and events from Cochlear Group and others where relevant to your relationship with Cochlear. You can inform us at any time if you no longer wish to receive any of this information by contacting us at privacy@cochlear.com.

The information may be accessible within Cochlear Group and to those we engage in performing activities, who will sometimes be located in other countries. In the course of managing our products, services, and events, we may disclose certain information to:

- The clinic or hospital at which the recipient receives treatment, and their health insurer

- Business partners, suppliers and distributors engaged by Cochlear to perform services or functions on our behalf
- Government regulators if required or where appropriate
- Health insurers
- Any new owners of Cochlear if the business is sold, restructured or integrated with another group, for use by them in the same way.

With some exceptions, you can gain access to the personal information Cochlear holds about you by contacting the Cochlear company you deal with.

For more information or a list of Cochlear Group companies, please read Cochlear's Privacy Policy on www.cochlear.com, or request a copy from the Cochlear address nearest you.

For the recipient or their parent, guardian or care giver

During the process of receiving a Cochlear device, personal information about the user/recipient will be collected for use by Cochlear and others involved in your care with regard to the device. The information is usually collected by completing and returning various forms to Cochlear. These include an implant registration form which is completed on your behalf by the surgical team. It includes information such as your contact details, date of birth, surgery and implant details. Also, a device registration form will be completed by you or your audiologist at the time of your device fitting.

The following explains why we collect the information and how we use and store it. Cochlear collects and uses personal information, including health information to:

- Support and improve the use of the device (e.g. enable fitting, activation, maintenance, performance and reliability monitoring, management and medical liaison regarding the device) and any other of Cochlear's products and services, including warranty rights
- Share with others within Cochlear Group to create a profile from the dealings we have with you, to help understand what information you might be interested in receiving from us

- Inform and manage the maintenance and development of Cochlear products, services and events
- Maintain product distribution records
- Keep you informed by post, telephone, or, when you have given us permission to do so, by email, text messaging or other reasonable electronic methods about new products, services and events from Cochlear Group, or others where relevant to your relationship with Cochlear. You can inform us at any time if you no longer wish to receive any of this information by contacting us at privacy@cochlear.com.

The information may be accessible to your clinic, to Cochlear Group companies, and to those engaged by us in performing activities who will sometimes be located in other countries. In the course of managing our products, services, and events, we may disclose certain information to:

- The surgeon or audiologist, the clinic or hospital at which treatment is received and if applicable, to the parent, guardian or care giver
- Business partners, suppliers and distributors engaged by Cochlear to perform services or functions on our behalf
- Government regulators if required or where appropriate
- Health insurers
- Others within Cochlear Group
- Any new owners of Cochlear if the business is sold, re-structured or integrated with another group, for use by them in the same way.

Without this information, Cochlear may not be able to effectively support and manage its products and services. With some exceptions, you can gain access to the personal information Cochlear holds about you by contacting the Cochlear company you deal with. For more information or a list of Cochlear Group companies, 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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