Cochlear™

Nucleus® Hybrid™ L24 cochlear implant

CI24REH

Important Information for Cochlear implant recipients

Canada

Hear now. And always

Cochlear®

Symbols

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

Introduction

This document contains important information that applies to the Cochlear™ Nucleus® CI24REH cochlear implant system.

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

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

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⚠ 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 provided 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 (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 cochlear implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

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Electroconvulsive therapy

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

Ionising radiation therapy

Do not use this therapy directly over the implant. It may cause damage to the implant.

Theft and metal detection systems

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

The materials used in the cochlear 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 cochlear implant system or corrupt the program in the sound processor.

If static electricity is present (e.g. when putting on or removing clothes over your 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

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

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Mobile telephones

Some types of digital mobile telephones (e.g. 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 or 3-12 ft, to a digital mobile telephone in use.

Air travel

Some airlines request that passengers turn off electrical equipment, such as laptop computers, during take-off and landing or whenever the seat-belt light is illuminated. Your sound processor is a computer and should be turned off when such a request is made. You should notify airline personnel of your hearing impairment so they can alert you to any safety measures.

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MRI safety information

The Cochlear Nucleus Hybrid L24 (CI24REH) implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe injury or device malfunction.

Full MRI safety information is available:

- in the Cochlear Nucleus Implants MRI Guidelines
- by visiting www.cochlear.com/warnings
- by calling your regional Cochlear office – contact numbers are available on the back cover of this guide.

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.

What is an MRI?

Radiologists / MR technologists are medical specialists experienced in diagnosing disease and injuries using a range of imaging techniques. One of these imaging techniques is magnetic resonance imaging (MRI).

MRI is a diagnostic tool to obtain images of organs and tissues using a very powerful magnetic field measured in tesla (T). MR scans can range in strength from 0.2 T to 7 T, with 1.5 T being the most common.

Safety concerns for medical device implants and MRI

Due to the powerful magnetic and radio-frequency fields, medical device implants with metallic or ferromagnetic components such as pacemakers, defibrillators, catheters, pumps and cochlear implants can create problems for MR scans. The risks include the potential for device repositioning, localised heating, unusual sounds or sensations, pain or injury and distortion of the MR image.

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Cochlear Nucleus implants and MRI compatibility

A Cochlear Nucleus implant is a medical treatment for moderate to profound hearing loss. Inside each Cochlear Nucleus implant is a magnet.

To ensure MRI compatibility, Cochlear Nucleus implants feature a removable magnet. The magnet is easy to remove and replace if needed. In the rare case that a recipient needs serial MR scans, a non-magnetic plug is available to prevent fibrous tissue growing in the implant magnet recess.

Cochlear Nucleus implants are also approved for MR scans under specific conditions at 1.5 T with the magnet in place and at 3 T with the magnet removed.

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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 CSF shunts or drains, recurrent episodes if bacterial meningitis prior to implantation, perilymph fistulas and skull fracture/ defect with CSF communication.

Loss of residual hearing

The Nucleus Hybrid™ implant with its shorter electrode, is designed to minimise trauma during insertion into the cochlea. Retention of a high degree of residual hearing is therfore likely when using the Hybrid implant in combination with good surgical techniques. There is, however, a possibility that the residual hearing could be lost.

Long-term effects of electrical stimulation by the cochlear 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.

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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 inhaled.

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.

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).

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⚠ 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 manual
- The sound processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The sound processor must not be opened by anyone other than Cochlear's qualified service personnel or the warranty will be invalidated.
- Each sound processor is programmed specifically for each implant. Never wear another person's sound 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 the sound processor at temperatures above 40°C or 104°F or less than 5°C or 41°F.
- Do not store the sound processor at above 55°C (131°F) or less than -10°C (14°F).
- The sound processor sound quality may be intermittently distorted when you are within approximately 1.6km or 1 mile of a radio or television transmission tower. The effect is temporary and will not damage the sound processor.

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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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