Warnings and Precautions

This document describes the warnings and precautions that apply to your cochlear implant system. Read this document carefully to ensure that you understand the care of your system.

Discuss these warnings and precautions with your physician before undergoing any major medical procedure.

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 or 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.

Cochlear

- **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 this therapy directly over the cochlear implant because it may cause damage to the implant.
- **Magnetic Resonance Imaging (MRI):** Magnetic Resonance Imaging (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 Nucleus® 24 cochlear implant and **some** Nucleus® 22 cochlear implants have a removable magnet and specific design characteristics to enable it to withstand MRI up to 1.5 tesla, but not higher.

  For patients with a Nucleus 22 cochlear implant without a removable magnet, MRI is contraindicated.

  If uncertain, 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 'C', 'H', 'J', 'L', 'P', 'T', '2', '5' or '7' the implant has a removable magnet.

  The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

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

  The quality of MRI will be affected by the metal in the cochlear implant. Image shadowing may extend as far as 6 cm or ~ 2 ½ in. from the implant, thereby resulting in loss of diagnostic information in the vicinity of the implant.

  If you require additional information about removal of the magnet, please contact Cochlear.

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 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 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.

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).

Precautions

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

Use the cochlear implant system only with the approved devices and accessories listed in the manual.

The speech processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The speech processor must not be opened by anyone other than Cochlear's qualified service personnel or the warranty will be invalidated.

Each speech processor is programmed specifically for each individual. Never wear another person's speech processor or lend yours to another user. Using another person's speech processor may result in uncomfortably loud or distorted sounds.

Do not operate the speech processor at temperatures above +40° C or +104° F or less than +5° C or +41° F.

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

The speech processor sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of a radio or television transmission tower. The effect is temporary and will not damage the speech processor.

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 speech 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 speech 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.

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

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, 1-4m 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 sign is illuminated. Your speech processor is a computer and therefore it 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 safety measures.

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Printed in Australia
N95408F IS52