Cochlear™ Nucleus® CI532 cochlear implant

Patient Information
Important: Warnings, Precautions and Electromagnetic Compatibility

United States of America

Contents

Glossary

- Best-aided listening condition – Best-aided is the best listening condition for a particular person in relation to their hearing loss. For example, if they have bilateral hearing loss, the best-aided condition might be having implants or hearing aids in both ears.
- Bilateral – Relating to both ears.
- Bimodal – Use of a hearing aid with a cochlear implant.
- Cochlea – Part of the inner ear that converts mechanical vibrations into electrical impulses.
- Cochlear™ Nucleus® CI532 cochlear implant system – The Cochlear Nucleus CI532 cochlear implant and sound processor including coil/cable, battery module, Smart App and Remote Assistant.
- Moderate hearing loss – Hearing loss in the range of approximately 40–55 dB HL.
- Moderately severe hearing loss – hearing loss in the range of 56–70 dB HL.
- Perilinguistic – During language acquisition.
- Postlinguistic – After language acquisition.
- Prelinguistic – Before language acquisition.
- Profound hearing loss – Hearing loss of approximately 90 dB HL or greater.
- Severe hearing loss – Hearing loss in the range of approximately 71–90 dB HL.
- Single Sided Deafness – Profound hearing loss in one ear and normal or near normal hearing loss in the other ear.
- Unilateral – Relating to one ear.

Why read this document?

Cochlear devices are designed to be safe and effective. However when using the devices it is essential you take care.

This document has important information for people with cochlear implants, their families and carers. The information is about safe use of Cochlear Nucleus cochlear implants, sound processors, remote assistants, and remote controls.

Very important safety information about device use and medical treatments is included. Before starting any medical treatment, tell your physician you have an implant and show them *Medical procedures that can cause harm* on page 13.

This document also covers what the Cochlear implant is, how it works, and how it is implanted.

User guides and other documents are supplied with your device. Please read these documents carefully—they could also contain important safety information.

Symbols used in this document

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.

What is the Cochlear Nucleus CI532 cochlear implant?

Cochlear Nucleus cochlear implant systems are designed to provide useful hearing. The system works by converting the sounds around you into electrical signals. These signals stimulate nerve endings in the cochlea, allowing the brain to perceive sound.

The Cochlear Nucleus cochlear implant system has external and implanted components.

External components

External components include a battery-operated sound processor with associated accessories and cables.

The sound processor is worn outside the ear and converts sounds into electrical signals. It is programmed to work with the implant using a Cochlear proprietary programming software.

Implanted component

The cochlear implant is surgically implanted under the skin behind the ear. The implant includes:

- a receiver/stimulator to decode electrical signals from the sound processor, and
- an electrode to deliver electrical signals to the cochlea.

Caution

Federal law restricts this device to sale by or on the order of a physician.

Why doctors use the Cochlear Nucleus CI532 cochlear implant – Indications

Doctors use the Cochlear Nucleus CI532 cochlear implant for people with sensorineural hearing loss. This type of hearing loss occurs when parts of the inner ear, the cochlea and hair cells, don't work properly.

With sensorineural hearing loss, sounds are softer and may be muffled or garbled, and harder to separate from each other. This type of hearing loss can make it difficult to understand the meaning of speech and sounds. Even the most powerful hearing aids may not assist.

Sensorineural hearing loss is typically total hearing loss in the mid to high pitches and partial to total hearing loss in the low pitches.

The cochlear implant is designed to restore hearing by bypassing the non-working parts of the inner ear and electrically stimulating the auditory nerve.

Nucleus Cochlear implants are approved to treat adults and children with bilateral sensorineural hearing loss. They are also approved to treat adults and children with deafness on one side. Deafness on one side with normal hearing in the other ear is known as single sided deafness, or SSD.

Bilateral sensorineural hearing loss

Adults

The Cochlear Nucleus 24 cochlear implant system is intended for use in individuals aged 18 years and older who have bilateral, prelinguistic, perilinguistic or postlinguistic sensorineural hearing loss and compromised functional benefit with appropriately fit amplification.

These individuals typically have moderate to profound hearing loss in the low frequencies and profound (≥ 90 dB HL) hearing loss in the mid to high speech frequencies. Limited benefit from amplification is defined by test scores of 50% correct or less in the ear to be implanted (60% or less in the best-aided listening condition) on recorded tests of open set sentence recognition.

Children

The Cochlear Nucleus 24 cochlear implant system is intended for children 9 months to 24 months of age who have bilateral profound sensorineural hearing loss and demonstrate limited benefit from appropriate bilateral hearing aids.

Children 2 years of age or older may demonstrate severe to profound hearing loss bilaterally.

In younger children, limited benefit is defined as lack of progress in the development of simple auditory skills with appropriate amplification and participation in intensive aural habilitation over a 3 month to 6 month period. It is recommended that limited benefit be quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test.

In older children, limited benefit is defined as ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

Unilateral Hearing Loss (UHL) / Single Sided Deafness (SSD)

Adults & Children

The Cochlear Nucleus 24 cochlear implant system is indicated for individuals with unilateral hearing loss who meet the following criteria:

- Individuals 5 years or older who have one ear with a severe to profound sensorineural hearing loss and obtain limited benefit from an appropriately fitted unilateral hearing device and one ear with normal or near normal hearing.
  - In the ear to be implanted, a severe to profound sensorineural hearing loss defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz of greater than 80 dB HL; and
  - In the contralateral ear, normal or near normal hearing is defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz less than or equal to 30 dB HL.
- Limited benefit from an appropriately fit unilateral hearing device is defined as a score of less than or equal to 5% on a Consonant Nucleus Consonant (CNC) word test. For individuals between 5 years and 18 years of age, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.
- It is recommended that prior to cochlear implantation, individuals with SSD have at least two (2) weeks to one (1) month experience wearing appropriately fit Contralateral Routing of Signal (CROS) hearing aid or another suitable hearing device.

Who cannot receive the Cochlear Nucleus CI532 cochlear implant – Contraindications

A Cochlear Nucleus cochlear implant is not suitable for individuals with the following conditions:

- Absence of cochlea development
- Absence of a cochlear nerve
- Active middle ear infections
- Tympanic membrane perforation in the presence of active middle ear disease.

For individuals with single sided deafness the following contraindications are also applicable:

- Duration of profound sensorineural hearing loss greater than ten years.

Note

- For patients who meet the indication and have an acoustic neuroma, cochlear implantation should be considered simultaneously or following removal of pathology.
- In certain cases, such as congenital single-side deafness, the presence of a cochlear nerve should be confirmed by an MRI examination prior to surgery.
- Outcomes are more variable for children with congenital single-sided deafness who are over the age of 5.

Deciding whether to get a Cochlear Nucleus CI532 cochlear implant

Before deciding on implantation, you should discuss the known benefits, risks and alternatives to Cochlear Nucleus CI532 hearing technology with your surgeon and audiologist.

Benefits

Potential benefits of receiving the Cochlear Nucleus CI532 cochlear implant relate to the following:

- Better understanding of speech in both quiet and noisy environments.
- Increased satisfaction based on hearing capabilities.

Risks

Certain risks are part of all surgery. You should discuss the known risks, benefits and alternatives to Cochlear Nucleus CI532 hearing technology with your surgeon and audiologist.

Known limitations associated with cochlear implantation, which may also apply to the Cochlear Nucleus CI532 cochlear implant, are:

- Speech and other sounds will not sound the same as they would for a normal-hearing person, though most recipients accommodate to the sound in a relatively short period of time.
- Some people may not have sufficient auditory nerve fibres to allow successful electrical stimulation.
- Some people may not experience useful understanding of speech.

Loss of residual hearing is a risk of receiving the Cochlear Nucleus CI532 cochlear implant.

What happens during the implantation procedure?

Before implantation

To decide if you can get a Cochlear Nucleus CI532 cochlear implant, your hearing healthcare professional will do a hearing test. They will also test your speech understanding while using your hearing aids.

During implantation

During implant surgery, the surgeon:

- makes an incision behind the ear,
- creates a pocket in the bone for the implant's receiver/stimulator, and
- threads the electrode into the cochlea.

You should discuss the length of your post-operative hospital stay with your surgeon as it can vary.

After implantation

To stimulate your implant you'll need an external sound processor.

After a healing period, you'll return to your audiologist to have your implant system activated and programmed. The audiologist will also explain how to use and care for your sound processor.

Please read:

- your Sound Processor and Remote Assistant User Guides for instructions on operation, care and maintenance of your external components.
- the rest of this guide for important safety information on how to avoid personal harm and damage to system components.

Avoiding serious harm – Warnings

This section has important warnings about personal safety. You should also refer to your external product user guides for additional warnings and cautions about those components.

Medical procedures that can cause harm

Before any medical or surgical treatment, tell your doctor you have a cochlear implant and show them this information. Some treatments that could injure you or damage your implant are listed below.

Medical treatments generating induced currents, heat and vibration

Below are some medical treatments that generate induced currents which could cause damage to tissue or the implant.

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

Electrosurgery	Electrosurgical instruments can induce radio frequency currents that could flow through the electrode. Do not use monopolar electrosurgical instruments on the head or neck of an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~½ in) from the electrodes.
Ionising radiation therapy	Do not use ionising radiation therapy directly over the implant. It may cause damage to the implant.
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.
Therapeutic ultrasound	Do not use therapeutic levels of ultrasound energy directly over the implant. It may inadvertently concentrate the ultrasound field and cause tissue damage or damage to the implant.

MRI safety information

The Cochlear Nucleus CI532 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 recipient 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 and 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.

Cochlear Nucleus implants and MRI compatibility

A Cochlear Nucleus implant is a medical treatment for moderate to profound hearing loss or single sided deafness. 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.

Head trauma

A blow to the head in the area of the implant may damage the implant and result in its failure. For recommendations on how to minimise the chance of experiencing head trauma see https://www.cdc.gov/traumaticbraininjury/prevention.html

Sound processor

Small parts

Caregivers should be counselled that the external sound processor contains small parts that may be hazardous if swallowed or may cause choking if ingested or inhaled.

Batteries and battery chargers

Battery use and ingestion

When using disposable batteries with the sound processor, only use battery types recommended by your clinician or Cochlear. Other types may not have enough 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 batteries are 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.

Caregivers should touch the recipient's processor to check for heat if the recipient is showing signs of discomfort.

Rechargeable batteries should NEVER be worn beneath clothing, including scarves and headwear covering the ears.

The rechargeable battery should not be used by patients who cannot remove the device by themselves, or cannot notify a caregiver that the device has become hot.

Overheating

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

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

Silver oxide batteries should **not** be used with your processor. In some circumstances, 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.

Also, use of silver oxide batteries may damage your processor.

Sleeping

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

Pressure

Do not apply continued pressure to the coil when in contact with the skin as this may result in pressure sores. For example, sleeping or lying on the coil, or wearing tight fitting headwear.

If the coil magnet is too strong or is in contact with the skin, pressure sores may develop at the coil site. If this happens or if you experience any discomfort in this area, contact your clinician.

Uncomfortable sound levels

If the sound becomes uncomfortable, remove your external equipment immediately (processor, coil, monitor earphones, acoustic component) and contact your clinician.

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, could cause extreme discomfort.

Adverse environments

Operation of your cochlear implant system could be adversely affected in environments of high magnetic field strength and high electric field strengths, e.g. close to high power commercial radio transmitters.

Seek medical advice before entering any environment that may adversely affect the operation of your cochlear implant, including areas with a warning notice preventing entry by patients fitted with a pacemaker.

Avoiding other harm – Cautions

This section includes information about safe and effective use of your cochlear implant system, and how to avoid damaging components.

General use

- Use your cochlear implant system only with approved devices and accessories listed in the user guide.
- If you experience a significant change in performance, turn off your processor and contact your implant centre.
- Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care.
- No modification of external equipment is allowed. If your processor is modified or opened by anyone other than Cochlear's qualified service personnel, the warranty is invalid.

Sound processor

- Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another person. Using the wrong processor could result in loud or distorted sounds that 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 approximately 1.6 km or 1 mile from 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 and certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

  To reduce or stop interference, move away from the source. If your processor stops working, turn the power switch off and then back on. 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 distorted sound sensation when passing through or near these devices. To avoid distortion, turn off your processor when near one of these devices.[1]

The materials used in the implant may activate metal detection systems. For this reason, always carry your Cochlear Implant Patient Identification Card with you.

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1 Cochlear performed Radio Frequency Identification (RFID) testing using the applicable Federal Communications Commission (FCC) Part 15 limit for electronic article surveillance in the USA and Canada. Frequency ranges typical of commercial theft detection systems were tested and demonstrated that implants operated normally when 20 cm (0.66 ft) away from the detection devices.

Mobile telephones

Some types of digital mobile telephones may interfere with the operation of external equipment, such as Global System for Mobile communications (GSM) as used in some countries. You may perceive a distorted sound sensation when within 1–4 m (~3–12 ft) of a digital mobile telephone in use.

Scuba diving

Implant type	Maximum depth
CI532 Implant	40 m (~131 ft)

Table 1: Maximum diving depths when wearing implants

The sound processor must be removed before diving. You should seek medical advice for conditions that might contraindicate diving, such as middle ear infection. When wearing a mask, avoid pressure over the implant site.

Air travel

Transmitting devices such as mobile/cell phones sometimes need to be switched off on aircraft. If you have a remote control (Remote Assistant) for your processor, check with the airline if you can use it. Your remote transmits high frequency radio waves so it might need to be switched off. You can wear your sound processor.

Retention aids

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

Do not attach the LiteWear beneath layers of clothing.

Electrostatic discharge (ESD)

Remove the processor before engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides. In rare cases, a discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the processor.

If static electricity is present (for example when removing or putting on clothes over your head, or getting out of a vehicle), before the cochlear implant system contacts any object or person you should touch something conductive, such as a metal door handle.

If you stop hearing and suspect your sound processor received a discharge of static electricity, turn it off and then on again.[2] If the problem continues, contact your clinician or a Cochlear representative.

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 could interfere with other medical devices, such as cardiac pacemakers and implantable defibrillators, when used nearby.

The Remote Assistant should be kept at least 6 in (~15.2 cm) away from devices that could receive electromagnetic interference. For added assurance, please also check the recommendations of the device manufacturer.

Magnetic fields

Magnetic fields that are very close to a cochlear implant can affect the operation of the implant. These magnetic fields can be created by magnets that are stronger than Cochlear sound processor coil magnets.

If you stop hearing and suspect that you have a strong magnetic field close to the location of the cochlear implant, move away from the source of the magnetic field. Hearing will then return. If the problem continues, contact your clinician or a Cochlear representative.

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2 During Cochlear electrostatic discharge testing, the sound processor stopped working when a discharge was applied directly to the upper or lower button. Loss of sound was temporary, with sound returning after the processor was turned off and on again.

Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration

Cochlear Nucleus Sound Processors, Remote Assistants and Remote Controls 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 2: Electromagnetic emissions

Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	See ***Electrostatic discharge (ESD)*** on page 23
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	30 A/m	1200 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 10 V/m 80 MHz to 2.7 GHz	Not applicable 20 V/m 80 MHz to 3.0 GHz	See ***Avoiding serious harm – Warnings*** on page 13, ***Avoiding other harm – Cautions*** on page 20, and ***Guidance*** on page 26.

Table 3: 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 3.0 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:

Note

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 3.0 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 4: 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.

Note

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.

Adverse effects

Prospective Cochlear Nucleus cochlear implant recipients should be advised of the following possible effects of receiving an implant:

- Normal risks associated with surgery and general anaesthesia.
- Increased surgical and anaesthetic risks for certain populations.
- Complications most frequently associated with this surgical procedure - stimulation of the facial nerve, taste disturbance, and tinnitus.
- Complications that may require additional medical treatment, surgery, and/or removal of the device, such as:
  - Acute Otitis Media (AOM)
  - facial nerve injury leading to temporary facial nerve weakness
  - perilymph fistula
  - Concurrent Cerebrospinal Fluid (CSF) leakage
  - vestibular dysfunction
  - subdural injury
  - subcutaneous haematoma
  - irritation, inflammation or breakdown of the skin flap; infection; and in some cases, extrusion of the device caused by the presence of a foreign body under the skin
  - decreased hearing ability caused by the electrode array migrating partially or completely out of the cochlea
  - perforation of external ear structures, such as the tympanic membrane or canal wall, by the electrode lead
  - perception of non-auditory sensations and poorer performance than expected from misplacement of the electrode array.

- Electrical stimulation may result in increased tinnitus, temporary facial nerve stimulation, temporary dizziness, or temporary pain.
- The long-term effects of electrode insertion trauma or chronic electrical stimulation are unknown. Such effects may include new bone growth in the cochlea or deterioration of the nerve cells. These effects may preclude replacement of the electrode array or may lead to eventual deterioration of cochlear response.
- Failure of component parts (both external and internal) could result in the perception of an uncomfortably loud sound sensation, intermittent sound, or no sound.
- Failure of various component parts of the implanted device could require removal or replacement of the implant, or a reduction in the number of electrodes used.

Meningitis

Before implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against micro-organisms that cause meningitis.

Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. 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
- CSF shunts or drains
- recurrent episodes of bacterial meningitis before implantation
- perilymph fistulas and skull fracture/defect with CSF communication.

For information on the use of vaccines to prevent meningitis in persons with cochlear implants refer to:
https://www.cdc.gov/vaccines/vpd/mening/hcp/dis-cochlear-gen.html

How we studied the Cochlear Nucleus cochlear implant system

Clinical studies were performed to test whether the Cochlear Nucleus cochlear implant system was safe and effective for use. Participants who were part of the studies had either bilateral sensorineural hearing loss or single sided deafness (SSD). Safety data and effectiveness data from the clinical studies are provided below.

Summary of safety data

The following information summarises adverse events for adults and children implanted with the Cochlear Nucleus 24 cochlear implant system. Safety data apply to all patients receiving a cochlear implant and are not specific to individuals with bilateral sensorineural hearing loss or single sided deafness/unilateral hearing loss.

Adults

Adult safety data are based on a total of 133 patients implanted with the Cochlear Nucleus 24 cochlear implant during the adult clinical investigation at 27 US sites. Twenty patients experienced either a medical/surgical or device-related complication.

Eleven of the 20 complications were medical/surgical in nature and the remaining nine were device-related. Eighteen of the 20 adverse events resolved without surgical or extensive medical intervention.

Medical/Surgical complications

One patient experienced device migration which required revision surgery to reposition the device. One patient experienced a wound haematoma which required minor surgery to resolve. One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery. Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming. Two patients experienced tinnitus related to cochlear implant use. One case resolved without intervention and the second case was resolved through reprogramming. One patient experienced short-term postoperative dizziness which resolved without medical treatment.

One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

Device-related complications

No device failures or other serious device malfunctions occurred during this study. Four patients experienced electrode insulation faults (short circuits) that were resolved through reprogramming. Two patients were inadvertently overstimulated during device programming and one patient reported a non-auditory sensation during device programming. Two patients experienced a mild skin reaction to the processor cable. These were resolved completely with topical medical treatment.

Children

Paediatric safety data are based on a total of 234 children implanted with the Cochlear Nucleus cochlear implants for two clinical investigations.

For the first clinical investigation, 150 children were implanted with Cochlear Nucleus 24 cochlear implants. Twenty four patients experienced 27 medical or surgical or device related complications. Nine of the 27 complications were medical or surgical in nature and the remaining 18 were device-related. Twenty four of the complications resolved without surgical or extensive medical intervention.

Medical/Surgical complications[3]

For the first study, one postmeningitically deafened child with bilaterally ossified cochleae failed to experience auditory stimulation through the fully functional cochlear implant. One patient developed streptococcal meningitis less than 24 hours following cochlear implant surgery. The infection was successfully managed with medical treatment. One patient experienced a wound infection that was resolved through surgical explantation of the device. One patient experienced extracochlear electrode placement related to a congenital malformation of the inner ear. This complication was resolved through surgical explantation of the device.

Two patients experienced slight compression of the electrode array which resulted in two short-circuited electrodes in one case and no electrode anomalies in the other. The case with electrode short circuits was resolved through reprogramming. One patient experienced facial nerve stimulation related to a severe congenital malformation of the inner ear. This complication was resolved through reprogramming, however, the patient continues to experience occasional slight facial nerve stimulation. Two patients experienced mild short-term postoperative dizziness. Both cases resolved without medical intervention.

3 Medical/surgical complications would be classified today as a procedure related adverse event.

Device-related complications

No device failures or other serious device malfunctions were observed during the first study. Thirteen patients experienced electrode faults (short-circuit or open-circuit electrodes) on one or more electrodes. All of these cases were resolved through reprogramming. One patient experienced non-auditory sensations during psychophysical testing. This case was resolved through reprogramming. One patient experienced an unanticipated overstimulation. This complication was resolved through replacement of external equipment.

Three patients experienced mild skin reactions to the processor cable. One case was resolved through covering the cable, one case was resolved through an alternative polyurethane coating of the cable, and one case resolved spontaneously without intervention.

Additional summary of safety for children

Cochlear performed a prospectively-designed, retrospective analysis from its own registry data to establish a reasonable assurance of safety of implantation with the Cochlear Nucleus 24 cochlear implant system for paediatric patients aged 9 months to 12 months. The retrospective review of 84 children that were between 9 months and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for this analysis. Twenty four patients experienced 28 medical or surgical complications and 26 of the complications were resolved without major surgical or medical intervention. Device-related complications (i.e. electrode faults) were not captured in this study. Six patients experienced minor post-operative complications, 4 of which were resolved without medical intervention. Two patients experienced cerebral spinal fluid leakage perioperatively. These were repaired during the CI surgery, and one patient required a revision surgery with reimplantation. Two patients experienced postoperative infections including mastoiditis, post-auricular abscess, and surgical site infection. All the infections were medically managed. Two patients developed seromas and one of these patients was reimplanted. Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of postoperative meningitis. Overall, the above adverse events are typical surgical, procedure or device events observed in children implanted in relatively young age.

As of February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess safety of implantation with a Cochlear Nucleus cochlear implant in infants aged between 9 months and 12 months. A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Safety studies that included children implanted at less than 12 months old covered a broad range of topics from surgical complications including anaesthesia and blood loss, to postoperative pain and dizziness, wound healing problems, and infections. The research literature reviewed on surgical and postoperative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

Summary of effectiveness data

Adults

Unilateral Hearing Loss (UHL) / Single Sided Deafness (SSD)

Cochlear analysed existing data to demonstrate the effectiveness of cochlear implantation in adult participants with single sided deafness, or SSD. In the analysis, data from a Cochlear sponsored multicentre study was combined with data gathered from two cochlear implant centres. Data was analysed from 42 participants.

Effectiveness testing included speech recognition testing using:

- The Hearing in Noise Test (HINT) and
- Bamford Kowall Bench Sentences in Noise test (BKB-SIN).

Localisation testing was also completed.

Effectiveness testing also included outcomes reported by the participant. These patient reported outcomes included the:

- Speech, Spatial, and Qualities (SSQ) Questionnaire
- Iowa Tinnitus Handicap Questionnaire.

Description of Tests

Hearing in Noise Test (HINT)

The Hearing in Noise Test or HINT (Nilsson et al., 1994) is a test made up of 25 10-sentence lists used to test how well an individual understands in noise. The sentences are presented in noise which is filtered to match the long-term average spectrum of the sentences. The HINT is an adaptive test whereby the signal-to-noise ratio (SNR) is increased or decreased by a fixed amount based on the listener's ability to repeat the sentences correctly or not.

Bamford Kowall Bench Sentences in Noise test (BKB-SIN)

The BKB-SIN Test (Etymotic Research, 2005) includes 18 lists of sentences. The sentences are spoken by a single male talker, are 5-6 words in length and are at a 1st grade reading level. The sentences are presented in noise using 4-talker babble. The test starts out easy where the sentences are presented much louder than the noise and depending on a listener's ability to correctly repeat the words in the sentence, the sentences are either made softer or louder until a level is reached where 50% of the words in a sentence are repeated correctly.

Localisation Testing

Localisation is the ability to tell where a sound is coming from. Localisation testing was assessed by delivering a noise from one of 12 locations. The locations are numbered 1 through 12 on a response sheet, from right to left. The sound comes from a speaker positioned to represent an arc from 97.5° (on the right) to 262.5° (on the left) of the participant. There is a 15° separation between each speaker. The participant selects one number to indicate the perceived location of the sound.

Speech, Spatial, and Qualities (SSQ) Questionnaire

The SSQ is a validated self-assessment metric commonly used in hearing aid and cochlear implant research. It is designed to measure self-reported auditory disability across a wide variety of domains, reflecting the reality of hearing in the everyday world. There are 49 questions (SSQ-49) scored by the participant using a scale of 0 through 10, where 0 corresponded to minimal ability and 10 corresponded to complete ability. There are three specific hearing domains assessed:

- Speech hearing scale – This includes hearing speech in quiet and in noise, in one-on-one conversation and in groups or meetings.
- Spatial hearing scale – This includes hearing where sounds are coming from, distance, movement, and ability to segregate sounds.
- Qualities of sound scale – This includes ease of listening, naturalness, clarity, identification of different speakers, musical pieces and instruments, as well as everyday sounds.

Iowa Tinnitus Handicap Questionnaire

The Iowa Tinnitus Handicap Questionnaire was used to assess tinnitus. Tinnitus was assessed before and after the cochlear implant was turned on. There are 27 questions that fall into 3 factors:

- Factor 1 examines social, physical and emotional wellbeing.
- Factor 2 examines hearing abilities.
- Factor 3 examines an individual's view of tinnitus.

Understanding Speech in Noise – Speech Recognition Results

Comparison 1: Performance using a cochlear implant and normal hearing ear compared to performance before surgery

Cochlear compared performance before surgery to performance after 6 months of cochlear implant use. Before surgery, the participant used a hearing aid in the ear to be implanted and their normal hearing ear for testing. Six months later, the participant used their cochlear implant and their normal hearing ear for testing. During testing, speech was presented from a speaker in front of the participant. At the same time, noise was presented from a speaker that was on the side of the better hearing ear. Twenty three participants are included in this analysis.

Results showed that after 6 months of cochlear implant use there was an improvement. Participants had an average improvement of 2.8 dB.

Comparison 2: Performance using a cochlear implant and normal hearing ear compared to the normal hearing ear alone

Cochlear compared performance for participants using a cochlear implant and the normal hearing ear to performance in the normal hearing alone. Both tests were completed after the participant had used a cochlear implant for at least 3 months. When normal hearing alone was measured, the cochlear implant was off. Thirty eight participants are included in this analysis.

Results showed that there was improvement when a cochlear implant was used for speech understanding in noise. Participants had an average 1.5 dB improvement.

To help determine the proportion of participants with 6 months of cochlear implant use who are performing to the same as or better than before receiving a cochlear implant, the following comparisons are provided.

When performance before cochlear implant surgery is compared to performance after cochlear implant surgery, it is found that:

- 18/23 (78%) participants demonstrated a clinically meaningful preoperative to postactivation improvement of 1.0 dB (10% improvement), with a range of -1.2 dB to -9.5 dB, (note that a negative score connotes improvement),
- 3/23 (13%) scored equal to their preoperative performance, with a range in difference scores from 0.0 dB to +0.8 dB, which suggests no change, and
- 2/23 (9%) participants had a difference score ≥ +1.0 dB, consistent with a decline in performance.

When performance with the cochlear implant on was compared to performance with the cochlear implant off, it was found that:

- 25/38 (66%) demonstrated a clinically meaningful improvement with cochlear implant on of 1.0 dB (10% improvement) with a range of -1.0 dB to -6.2 dB, (note that a negative score connotes improvement),
- 11/38 (30%) scored equal to their normal hearing when the cochlear implant was on, with a range of difference scores from -0.7 dB to +0.8 dB, which suggests no change, and
- 2/38 (5%) participants had a difference score > +1.0 dB, consistent with a decline in performance.

In the clinical study, 8/38 (21%) experienced a decrease in speech understanding when speech was presented in front and noise was directed to the cochlear implant side. This suggests potential interference with the hearing from the normal ear and the hearing from the cochlear implant. Additionally, a few published studies (Speck et al., 2020, Deep et al., 2021, and Zeitler et al.,2019) reported that very few people with SSD stop using their cochlear implant. Given these results, it is reasonable to conclude that a small number of recipients experience interference.

Cochlear performed subgroup analyses to see if subgroups were different for the co-primary effectiveness endpoints. The following subgroups were examined:

- Gender
- Median age at implant
- Median duration of hearing loss at baseline
- Cause of hearing loss
- Evaluation interval
- Median baseline/preoperative speech in noise score
- Median baseline CI off speech in noise score
- Preoperative pure tone average (PTA)

Results indicated that the only characteristics that affected the primary endpoint 1 outcomes were:

1. Duration of hearing loss.

   The mean score for participants below or equal to the median duration of hearing loss of 2 years was significantly poorer than that for duration of hearing loss above 2 years.

2. Cause of hearing loss.

   It was found that those participants with a sudden sensorineural hearing loss performed significantly better than those with any other cause for hearing loss in the participants.

3. Pre-operative speech in noise score.

   It was found that those participants who had poorer preoperative speech in noise scores demonstrated significantly greater improvement.

For coprimary effectiveness endpoint 2 outcomes, the only baseline characteristic that affected the endpoint was when speech was presented from the front and noise was directed to the normal ear while the cochlear implant was off. Participants with poorer speech understanding in noise in this condition demonstrated significantly more improvement when measuring listening with both the cochlear implant and normal ear.

There were no differences in the consistency of primary endpoints across investigational sites.

Localisation

Twenty four participants had localisation data available for analysis. Data showed an improvement when a participant had a cochlear implant turned on, compared to when the cochlear implant was turned off. Participants were more able to accurately identify the sound source. There was an average improvement of 18.8 degrees.

Patient reported outcomes

Speech, Spatial, and Qualities of Hearing Scale (SSQ)

There were 14 participants who completed the SSQ before surgery. There were 10 participants who completed it after 6 months of cochlear implant use.

The Speech Hearing Scale addressed how well participants could hear and understand speech in various quiet and noisy situations. These included one-on-one conversations and speech in small and large groups of people.

- After 6 months of cochlear implant use, scores on the speech and hearing rating scale increased by an average of 2.09 points.

Spatial Hearing Scale

The Spatial Hearing Scale addressed how well participants could judge directionality of sound. This included where a sound was coming from, how far away the sound was, and movement of sound (e.g., whether a sound was coming toward them or away from them).

- After 6 months of cochlear implant use, scores on the spatial hearing rating scale increased by an average of 2.38 points.

Sound Qualities Scale

The Sound Qualities Scale addressed how well participants could separate and sort out sounds and how well they could recognise different sounds. It also addressed how clear or natural sounds were, and how much effort listening required.

- After 6 months of cochlear implant use, scores on the sound qualities scale increased by an average of 1.04 points.

A total score for the SSQ, which reflected the average scores over the 3 subscales, was also reported at each test interval.

- After 6 months of cochlear implant use, total scores on the SSQ increased by an average of 1.84 points.

There was a significant average improvement on each subscale. The largest difference was found on the Spatial Hearing subscale.

Iowa Tinnitus Handicap Questionnaire

Data were available for 10 participants. After 6 months of cochlear implant use, 6 of the 9 (67%) participants with scores reported an improvement in their tinnitus. After 12 months of cochlear implant use, 7/10 (70%) participants reported an improvement in their tinnitus.

Children

As of February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess effectiveness of implantation with a Cochlear Nucleus cochlear implant in infants aged between 9 months and 12 months. A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Effectiveness outcomes from the literature data support that implantation before 12 months of age supports paediatric cochlear implant recipients' improved speech and language development.

Where you can find more information

For additional information concerning Cochlear Americas and the Cochlear Nucleus CI532 cochlear implant, visit Cochlear's website at www.cochlear.com or call 1 800 523 5798.

Notes

Hear now. And always

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