Cochlear™

Nucleus® Hybrid™ L24 cochlear implant

CI24REH

Patient Information
Important: Warnings, Precautions and Electromagnetic Compatibility

United States of America

Hear now. And always

Cochlear®

Symbols

Note

Important information or advice. Can avoid inconvenience.

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.

This document contains important information such as warnings, cautions and privacy that apply to the following cochlear implant systems:

- Cochlear™ Nucleus® Hybrid™ L24 cochlear implant (CI24REH)

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.

Caution

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

Contents

Glossary

- Everyday Listening condition
  The use of the Cochlear Nucleus Hybrid L24 cochlear implant system in conjunction with a hearing aid in the other ear.
- Cochlear Nucleus Hybrid L24 cochlear implant system
  The Cochlear Nucleus Hybrid L24 cochlear implant and Nucleus 7 Sound Processor including coil/cable, battery module, and accessories, used with or without the acoustic component.
- Implant Ear Alone condition
  The use of the Cochlear Nucleus Hybrid L24 cochlear implant system with no sound input from the other ear or the use of electric hearing with the available low-frequency hearing in the same ear.
- Functional Acoustic Hearing
  Acoustic (rather than electric) hearing of a severe degree or better (≤ 90 dB HL).
- Non-functional Acoustic Hearing
  Acoustic (rather than electric) hearing of a profound degree (> 90 dB HL).
- CNC Monosyllabic Word Recognition Test
  CNC stands for Consonant-Nucleus-Consonant and monosyllabic refers to a word with one syllable.
- PTA
  Refers to pure-tone average, which is the average of hearing threshold levels over a set of specified frequencies.
- LMF
  When used with PTA, refers to low-frequency hearing thresholds averaged over the range 125 Hz through 1000 Hz.
- Measurable
  When referring to hearing measured during a hearing test (an audiogram), it means the listener responds to the tone as a sound as opposed to feeling it as a vibration only or not being able to hear it at all.

Description of the Cochlear Nucleus Hybrid L24 cochlear implant

A Cochlear Nucleus Hybrid L24 cochlear implant system is designed to bypass damaged parts of the cochlea and allow the auditory nerve to be stimulated. The system consists of a small battery-operated sound processor and microphone, both worn outside the ear, that convert sounds into electrical signals. The signals are transmitted to implant electrodes in the cochlea. The electrodes stimulate the nerve endings in the cochlea so sound can be perceived by the brain.

Cochlear Nucleus Hybrid hearing technology involves the use of an acoustic component in combination with the Hybrid L24 cochlear implant in the same ear to improve sound perception for patients with challenging hearing losses. The system consists of an in-the-ear (ITE) acoustic module and a cochlear implant, sound processor and microphone.

The cochlear implant is surgically implanted under the skin behind the ear. It includes a receiver/stimulator to receive and decode the electrical signals and an electrode array to deliver these signals to the cochlea.

The external components include the following sound processors:

- Cochlear Nucleus CP1000 Series (Nucleus 7) with associated coil, battery module, acoustic component, accessories and cables.

Why doctors use the Cochlear Nucleus Hybrid L24 cochlear implant (Indications)

Doctors use the Cochlear Nucleus Hybrid L24 cochlear implant for adults with severe hearing loss in the high pitches (such as birds chirping, children's and women's voices, consonant sounds like 's' and 'sh') but functional hearing in the low pitches. Often people with this hearing loss experience difficulty understanding speech, especially in noisy environments.

The Hybrid L24 cochlear implant system is intended to provide electric stimulation to the mid-frequency to high-frequency region of the cochlea and acoustic amplification to the low-frequency regions for patients with residual low-frequency hearing sensitivity. The system is indicated for unilateral use in patients aged 18 years and older who have residual low-frequency hearing sensitivity and severe to profound high-frequency sensorineural hearing loss, and who obtain limited benefit from appropriately fitted bilateral hearing aids.

- Typical preoperative hearing of candidates ranges from normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL up to and including 500 Hz), with severe to profound mid-frequency to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL), and moderately severe to profound mid-frequency to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 60 dB HL) in the contralateral ear.
- The Consonant-Nucleus-Consonant (CNC) word recognition score will be between 10% and 60%, inclusively, in the ear to be implanted in the preoperative aided condition and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.

Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fitted with hearing aids.

Who cannot receive the Cochlear Nucleus Hybrid L24 cochlear implant (Contraindications)?

A Cochlear Nucleus Hybrid L24 cochlear implant is not indicated for individuals who have the following conditions:

1. Deafness due to lesions of the acoustic nerve or central auditory pathway.
2. Active middle ear disease, with or without tympanic membrane perforation.
3. Absence of cochlea development.
4. A duration of severe to profound hearing loss of 30 years or greater.

⚠ Things you must do to avoid serious harm (Warnings)

Tell your doctor that you have a cochlear implant before undergoing any medical or surgical treatment. Certain types of treatments could injure you or cause damage to your cochlear implant. Some of these treatments are listed below

Medical treatments generating induced currents

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

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 cochlear implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the cochlear implant and should be kept more than 1 cm (~0.5 in) from the extracochlear electrodes.

Diathermy

Therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave) should not be used. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the cochlear implant.

Medical diathermy using ultrasound may be used below the head and neck.

Neurostimulation

Neurostimulation should not be used directly over the cochlear implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the cochlear implant.

Electroconvulsive therapy

Electroconvulsive therapy should not be used on a cochlear implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the cochlear implant.

Ionising radiation therapy

Ionising radiation therapy should not be used directly over the cochlear implant because it may cause damage to the cochlear implant.

MRI safety information

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

Full MRI safety information is available:

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

Refer to the *Cochlear Nucleus Implants MRI Guidelines* for a complete list of Warnings and Cautions.

All external components of the Cochlear implant system (for example, 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). MRI 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 MRI 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. 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 MRI scans, a non-magnetic plug is available to prevent fibrous tissue growing in the implant magnet recess.

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

Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding their vaccination status against organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates for the Hybrid L24 cochlear implant should be appropriately counseled 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.

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. There is no long-term data available on the effects of electrical stimulation on hearing sensitivity.

Head trauma

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

External sound processor warnings

Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your sound processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch the recipient's sound 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 themselves
- notify a caregiver that the device has become hot.

Overheating of external devices

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

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

The sound processor 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 sound processor.

⚠ Things you must do to avoid other harm (Precautions)

Use the Cochlear Nucleus Hybrid L24 cochlear implant system only with the approved devices and accessories listed in the user guide.

Your sound 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 sound processor by anyone other than Cochlear's qualified service personnel invalidates the warranty.

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

Each sound processor is programmed specifically for each cochlear implant. Never wear another person's sound processor or lend yours to another user.

Using the wrong sound processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

Do not operate your sound processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).

Do not store your sound processor at temperatures above +55 °C (+131 °F) or less than -10 °C (+14 °F).

Your sound processor's sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of 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 eliminate the interference, move away from the source. If your sound processor stops working, turn the power switch off and then back on. This effect is temporary and will not damage your sound processor.

Small parts hazard

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

Use of batteries and battery ingestion

When using disposable batteries with the sound processor, only use battery types recommended by your clinician or Cochlear. Other types may not have sufficient energy to allow your sound 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 swallowed, seek prompt medical attention at the nearest emergency center.

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 your 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 your sound processor.

If static electricity is present (for example, when putting on or removing clothes over the head, or getting out of a vehicle), cochlear implant recipients should touch something conductive (for example, 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 should be removed.

Mobile telephones

Some types of digital mobile telephones (for example, 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.

Scuba diving

Implant type	Maximum depth
CI24REH Implant	40 m (~131 ft)

Table 1: Maximum diving depths when wearing cochlear implants

The sound processor must be removed before diving. Recipients should seek medical advice before participating in a dive for conditions that might make diving contraindicated, for example middle ear infection, etc. When wearing a mask, avoid pressure over the cochlear implant site.

Sleeping

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

Retention aids

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

Do not attach the LiteWear beneath layers of clothing.

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.

Electromagnetic compatibility (EMC)

Guidance and manufacturer's declaration

The Cochlear Nucleus Series Sound Processor and Remote Assistant 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 sound 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	See *Electrostatic discharge* on page 14.
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	3 A/m	3 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 3 V/m 80 MHz to 2.5 GHz	3 V/m	See the *Warnings* and *Precautions* sections, and *Guidance* on page 19.

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 2.5 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 sound processor is used exceeds the applicable RF compliance level above, the sound processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the sound processor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances

Your sound 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 2.5 GHz $d = 2.3\sqrt{P}$
0.01	Not applicable	0.12	0.23
0.1		0.38	0.73
1		1.2	2.3
10		3.8	7.3
100		12	23

Table 4: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.

Risks of receiving the Cochlear Nucleus Hybrid L24 cochlear implant

Certain risks are a part of all surgery. Candidates should discuss the known risks, benefits and alternatives to Cochlear Nucleus Hybrid L24 hearing technology with their surgeon and audiologist. The following are known limitations associated with cochlear implantation, which may also apply to the Hybrid L24 cochlear implant.

- Speech and other sounds will not sound the same as they would for a normal-hearing person, though most patients accommodate to the sound in a relatively short period of time.
- Some participants may not have sufficient auditory nerve fibres to allow successful electrical stimulation.
- For some participants, the Hybrid L24 cochlear implant may not provide useful speech understanding.

The loss of residual hearing is a risk of receiving the Hybrid L24 cochlear implant. In a clinical study, at six months post-implant most individuals (90%) retain a level of acoustic hearing and many (66%) utilise that hearing with or without amplification at the implant ear. For some individuals (34% in this study), a profound loss of functional acoustic hearing in the implanted ear may occur.

Changes in low-frequency hearing sensitivity six months after surgery are summarised below:

- Thirty-three subjects maintained hearing of a severe degree or better, called functional acoustic hearing,
- Seventeen experienced a decrease in low-frequency hearing resulting in profound loss of hearing, called non-functional acoustic hearing.

Six months after implantation, the average change in low-frequency hearing was 33 dB.

Following completion and incorporation of low-frequency hearing data from a post-approval study that followed subjects for up to five years post-activation, six more clinical study subjects experienced a decrease in low-frequency hearing resulting in profound loss of hearing after six months, this happened between one and four years after surgery.

Speech performance data is listed below. This data includes subjects who had both functional and non-functional acoustic hearing.

Word Recognition Test

- Average performance after six months of experience using the device, in the Implant Ear Alone condition:
  - for subjects with functional acoustic hearing, scores increased from 29.1% to 76.0%
  - for subjects with non-functional acoustic hearing, scores increased from 26.7% to 43.7%.
- Average performance after six months of experience using the device, in the Everyday condition:
  - for subjects with functional acoustic hearing, scores increased from 44.2% to 82.9%
  - for subjects with non-functional acoustic hearing, scores increased from 45.3% to 71.3%.

As shown above, both subject groups showed significant improvement with and without functional acoustic hearing. This was true in both Implant Ear Alone and Everyday conditions. The addition of the opposite (not implanted) ear showed further benefit. Moving from the Implant Ear Alone to the Everyday condition further increased performance. For subjects with functional acoustic hearing, this increase was 7 percentage points. The range of this change was -13 to 46 percentage points. For subjects with non-functional acoustic hearing, this increase was 28 percentage points. The range of this change was -4 to 64 percentage points. When using the Hybrid L24 cochlear implant along with all acoustic hearing, significant improvement was noted. This was true for subjects with both functional and non-functional acoustic hearing.

Sentence Recognition in Noise Test

- Average performance after six months of experience using the device, in the Implant Ear Alone condition:
  - For subjects with functional acoustic hearing, scores increased from 17.2% to 62.1%.
  - For subjects with non-functional acoustic hearing, scores increased from 15.4% to 23.9%.
- Average performance after six months of experience using the device, in the Everyday condition:
  - For subjects with functional acoustic hearing, scores increased from 28.3% to 69.5%.
  - For subjects with non-functional acoustic hearing, scores increased from 32.1% 48.4%.

As shown above, both subject groups showed significant improvement with and without functional acoustic hearing. This was true in both Implant Ear Alone and Everyday conditions, with one exception. There was no significant difference for subjects with non-functional acoustic hearing in the Implant Ear Alone condition. The addition of the opposite (not implanted) ear showed further benefit. Moving from the Implant Ear Alone to the Everyday condition further increased performance. For subjects with functional acoustic hearing, this increase was 7 percentage points. The range of this change was -11.1 to 42.0 percentage points. For subjects with non-functional acoustic hearing, this increase was 25 percentage points. The range of this change was -0.4 to 81.5 percentage points. When using the Cochlear Nucleus Hybrid L24 cochlear implant along with all acoustic hearing, significant improvement was noted. This was true for subjects both functional and non-functional acoustic hearing.

For the CNC and AzBio tests in the implant ear alone, 96.0% and 89.8% of subjects performed equal to or better at six months as compared to preoperative scores. It is important to note that no subject, regardless of postoperative acoustic hearing, showed a decrease in the Everyday condition. Averaged across frequencies, the largest improvement in thresholds was seen at Initial Activation (four weeks after surgery). Average thresholds at the 3, 6, and 12 month intervals are consistent across time intervals.

Table 5 on page 26 summarises the most frequent hazards associated with implant surgery in the Cochlear Nucleus Hybrid L24 Clinical Trial. The events that occurred were anticipated and are reflective of those found in otologic procedures.

- Items in the *Hazard* column are the things that happened because of the use of the Hybrid L24 cochlear implant.
- Items in the *How often patient had the hazard* column are the frequencies that were observed for the 'Hazard'.
- Items in the *Harm* column are the results of the *Hazard* that were observed.
- Items in the *How often this hazard harmed them* column are the frequencies at which the *Harm* happened for this *Hazard*.

Event: Implantation with Cochlear Nucleus Hybrid L24 cochlear implant			
Hazard	How often patient had the hazard	Harm	How often this hazard harmed them
Tinnitus	14 out of 50 patients	Tinnitus that did not resolve or change in hearing	0 of these 14 patients had tinnitus that did not resolve, 2 out of these 14 patients had a change in hearing
Dizziness (Imbalance/ Vertigo)	9 out of 50 patients	Dizziness, imbalance, or vertigo that did not resolve or a change in hearing	0 of these 9 patients had dizziness (imbalance/ vertigo) that did not resolve, 4 of these 9 patients had a change in hearing
Profound loss of hearing	22 out of 50 patients	No recovery	22 out of these 22 patients
Electrode malfunction	11 out of 50 patients	Possible performance decrement	0 of these 11 patients
Explantation/ Reimplantation	6 out of 50 patients	Additional surgery due to hearing loss	6 of the 6 patients
Skin irritation	2 out of 50 patients	Discomfort	0 of these 2 patients
Sound quality issue	2 out of 50 patients	Long term sound quality issue	1 of these 2 patients
Decrease in performance	1 out of 50 patients	Long term decreased performance	1 of the 1 patient
Increased impedances with change in hearing	1 out of 50 patients	Change in hearing	0 of the 1 patient
Local stitch infection	1 out of 50 patients	Discomfort, use of antibiotics	1 of the 1 patient
Overstimulation	1 out of 50 patients	Discomfort that did not resolve	0 of the 1 patient
Pain in implant ear	1 out of 50 patients	Discomfort that did not resolve	0 of the 1 patient

Table 5: Most frequent hazards from Cochlear Nucleus Hybrid L24 Clinical Trial

Explantation

As part of the study, six subjects had surgery to remove their Hybrid L24 cochlear implant and replace it with a typical cochlear implant. All of these subjects had no functional acoustic hearing in the implanted ear, and were dissatisfied with their performance. This was coupled with either a decrease or no change in the performance of the implanted ear. The earliest explantation occurred after 175 days, and the latest after 959 days. The average time before explanation for these subjects was 561 days.

No subjects had complications with revision surgery. Data gathered after the reimplantation for four of the subjects shows performance improvement. This is true when compared to performance both before the initial surgery and before the revision. After being reimplanted, the subjects' performance was similar to performance of conventional cochlear implant recipients. Limited data was available for two of the subjects.

Benefits of receiving the Cochlear Nucleus Hybrid L24 cochlear implant

The potential benefits of the Cochlear Nucleus Hybrid L24 cochlear implant for recipients relate to improvements in:

- better understanding of speech in quiet
- better understanding of speech in noise
- increased satisfaction based on hearing capabilities.

The Cochlear Nucleus Hybrid L24 Clinical Trial showed that recipients on average improved their hearing performance by doubling their hearing performance in quiet and in noise:

- 80% (40/50) of recipients scored significantly better on word understanding in the implant ear than they could hear with a hearing aid alone in that ear.
- 100% (50/50) of subjects score same or better in quiet and noise when using the cochlear implant in one ear and a hearing aid in the other ear than with hearing aids alone.

For further detail on the benefits of the Hybrid L24 cochlear implant, see *How we studied the Cochlear Nucleus Hybrid L24 cochlear implant* on page 33.

How to decide whether to get the Cochlear Nucleus Hybrid L24 cochlear implant

Candidates for the Cochlear Nucleus Hybrid L24 cochlear implant should discuss the known risks, benefits and alternatives to Hybrid L24 hearing technology with their surgeon and audiologist prior to deciding whether to proceed with implantation.

Before implantation of the Cochlear Nucleus Hybrid L24 cochlear implant

To decide if you are a candidate for the Cochlear Nucleus Hybrid L24 cochlear implant, your hearing healthcare professional will perform a hearing test. They will also test your speech understanding while using your hearing aids to determine if you meet the criteria for a Hybrid L24 cochlear implant.

During implantation of the Cochlear Nucleus Hybrid L24 cochlear implant

During cochlear implant surgery, the surgeon makes an incision behind the ear, creates a pocket in the bone to house the implant's receiver/stimulator, and threads the electrode array into the cochlea. The postoperative hospital stay is variable and will be determined by the surgeon.

Using the Cochlear Nucleus Hybrid L24 cochlear implant after surgery

An external sound processor is required in order for stimulation of the Cochlear Nucleus Hybrid L24 cochlear implant to occur. Following a healing period of approximately four weeks, the participant will return to the audiologist for initial programming. During this appointment, the audiologist will activate and program the Hybrid L24 cochlear implant system. The recipient will also be instructed on the use and care of the sound processor.

Please refer to the Sound Processor and Remote Assistant User Manuals for instructions on the operation, care and maintenance of the external components.

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 sound processor, it might also need to be switched off because it is transmitting high frequency radio waves when switched on. You should check with your airline for more information about whether or not you can use your remote. You can wear your sound processor.

How we studied the Cochlear Nucleus Hybrid L24 cochlear implant

A clinical trial was performed to test whether the Cochlear Nucleus Hybrid L24 cochlear implant system was safe and effective for use. Subjects who were part of the study had sensorineural hearing loss. This is usually caused by damage to the hair cells of the cochlea. Subjects also had a specific profile of hearing ability. Subjects had normal hearing to moderate hearing loss in the low frequencies, with severe to profound hearing loss in the high frequencies. Subjects were also tested both with and without a hearing aid in the opposite (not implanted) ear.

When testing the implant ear alone, subjects used the signals from the cochlear implant as well as whatever acoustic hearing they kept in the same ear. In everyday life, most patients used a hearing aid in the opposite (not implanted) ear. Because of this, speech understanding abilities were also tested with both ears. This was called the Everyday Listening condition.

The study also measured how well subjects could hear at different frequencies. This was tested over time, to measure any changes in hearing. This data was then used to understand what effect being implanted had on the remaining hearing in low frequencies.

Subject characteristics

Key characteristics of the subjects in the study are shown in *Table 6* below.

Demographic characteristics	Mean (min, max)
Age at CI in Years	64.1 (23.0 – 86.2)
Duration of Overall Hearing Loss in Years	28.1 (3.4 – 73.9)
Duration of High Frequency Hearing Loss in Years	13.1 (1.6 – 30.1[1])
Male	25/50 (50.0%)
Female	25/50 (50.0%)
Preoperative Degree of LMF PTA (Implanted Ear):	
Normal (0 – 25 dB HL)	1/50 (2.0%)
Mild (26 - 40 dB HL)	13/50 (26.0%)
Moderate (41 – 55 dB HL)	26/50 (52.0%)
Moderate-Severe (56 – 70 dB HL)	10/50 (20.0%)

Table 6: Demographics for the 50 study subjects

Fifty subjects were enrolled in the study and implanted. Forty-nine of these completed the six month testing. One subject was explanted before the six month testing. This occurred after poor performance and loss of hearing sensitivity. Of these forty-nine subjects, two only completed speech testing and the SSQ. One subject only completed speech testing. This was due to limits on time and the choice of the clinicians.

1 One subject met the requirement of < 30 years duration of severe to profound high frequency loss at candidacy assessment but was slightly over 30 years duration by the time surgery was approved for reimbursement and completed.

Description of tests

CNC Monosyllabic Word Recognition Test (Primary endpoint)

The CNC Monosyllabic Word Recognition Test[1] was a primary endpoint. This means it was one of the main tests used to judge whether the cochlear implant was a success or a failure. The test is made up of 10 recorded lists of 50 words, each with one syllable. Each of these words is made up of a consonant, a nucleus, and a second consonant, such as 'laud' or 'duck'. Two lists are given in quiet conditions, at a volume of 60 dBA. The scores are reported as percent of words correct, and percent of phonemes correct.

AzBio Sentence Test (Primary endpoint)

The AzBio Sentence Test[2] was the second primary endpoint. This test is made up of 33 possible lists of 20 sentences. Sentences are meant to have low contextual information, such as 'He cried when the pet goat was sent to market'. Each list includes 5 sentences, from 4 possible different speakers (2 male, 2 female). Two lists of the AzBio sentences are presented at a volume of 60 dBA. These sentences are presented with competing noise in the form of multiple people talking, or 'babble'. The sentences are presented 5 dB louder than the competing noise, from the same loudspeaker.

1 Peterson, G.E. & Lehiste I. (1962) Revised CNC lists for auditory tests. J Speech Hearing Disorders, 27:62-70.

2 Spahr, A.J., Dorman, M.F., Litvak L.L., Van Wie, S., Gifford, R.H., Loizou, P.C., Loiselle, L.M., Oakes, T., & Cook, S. (2012) Development and Validation of the AzBio Sentence Lists. Ear and Hearing, 33:112-7.

University of Washington Clinical Assessment of Music Perception (UW-CAMP)

The UW-CAMP test[1] is made up of three subtests. Each are made to test different auditory skills which are important for hearing music. The three subtests were presented at 65 dBA, and tested pitch perception, melody recognition, and timbre.

The Speech, Spatial, and Qualities of Sound Questionnaire (SSQ)

The SSQ[2] 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 scored by the subject 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/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.

1 Kang, R., Nimmons, G.L., Drennan, W., et al. (2009) Development and validation of the University of Washington Clinical Assessment of Music Perception test. Ear and Hearing, 30:411–8.

2 Gatehouse, S. & Noble, W. (2004) The Speech, Spatial and Qualities of Hearing Scale (SSQ). Int J of Audiol, 43(2), 85-99.

Device Use Questionnaire (DUQ)

The DUQ was created by Cochlear to collect information from patients directly. Specifically, the questionnaire asks about ease and satisfaction with the device in different environments and situations. The questionnaire is about 90 items long. The questions that appear in this bulletin are related to satisfaction. Other questions related to the ways the subjects used the device—these are left out for brevity.

Speech perception

Forty-nine of fifty subjects had speech perception data at the six month interval.

Understanding Speech in Quiet – CNC Monosyllabic Word Test

Everyday Listening condition

- Average performance after six months was significantly higher than average performance using two hearing aids prior to implantation.
  - Average CNC scores were 44.9% (2%–81%) preoperatively with two hearing aids and 79.4% (35%–98%) at six months postoperative in the Everyday Listening condition.
- After six months of postoperative experience:
  - All subjects (49/49; 100%) demonstrated similar or better word recognition (CNC) compared with their preoperative performance using two hearing aids
  - Most (43/49; 87.8%) demonstrated significantly better word recognition compared with their preoperative performance using two hearing aids.

Implant Ear Alone condition

- Average performance after six months was significantly higher than average performance for the subjects using one hearing aid prior to implantation.
  - Average CNC scores were 28.4% (9%–64%) preoperatively with one hearing aid and 65.4% (8%–98%) at six months in the Implant Ear Alone condition.
- After six months of postoperative experience:
  - Most subjects (47/49; 96%) demonstrated similar or better word recognition (CNC) compared with their preoperative performance using one hearing aid
  - Most (40/49; 81.6%) demonstrated significantly better word recognition compared with their preoperative performance using one hearing aid.

Understanding Speech in Noise – AzBio Sentence Test in Noise (+5 dB SNR)

Everyday Listening condition

- Average performance after six months was significantly higher than average performance for the subjects using two hearing aids prior to implantation.
  - Average AzBio sentences in noise scores were 29.6% (0.0%–76.5%) preoperatively with two hearing aids and 62.6% (3.6%–92.7%) at six months in the Everyday Listening condition.
- After six months of postoperative experience:
  - Most recipients (49/49; 100%) demonstrated similar or better sentence recognition in noise (AzBio) compared with their preoperative performance using two hearing aids
  - Most (41/49; 84%) demonstrated significantly better sentence recognition in noise (AzBio) compared with their preoperative performance using two hearing aids.

Implant Ear Alone condition

- Average performance after six months was significantly higher than average performance for the subjects using one hearing aid prior to implantation.
  - Average AzBio sentences in noise scores were 16.3% (0.0%–64.1%) preoperatively with one hearing aid and 49.2% (0.0%–91.5%) at six months in the Implant Ear Alone condition.
- After six months of postoperative experience:
  - Most subjects (44/49; 89.8%) demonstrated similar or better sentence recognition in noise (AzBio) compared with their preoperative performance using one hearing aid
  - Many (36/49; 73.5%) demonstrated significantly better sentence recognition in noise (AzBio) compared with their preoperative performance using one hearing aid.

Music Performance – University of Washington Clinical Assessment of Music Perception (UW-CAMP)

Forty-six of fifty subjects had music performance scores available at the six month interval.

Everyday Listening condition

Pitch Discrimination

- Postoperative average pitch discrimination ability was similar to that observed for normally hearing individuals.
- Performance was unchanged preoperatively with two hearing aids to postoperatively at six months:
  - Average pitch discrimination was 1.1 (0.5–6.3) semitones preoperatively compared to 1.1 (0.5–3.7) semitones at six months.
- After six months of postoperative experience:
  - Most recipients (41/47; 87.2%) demonstrated similar (within 1 semitone) or better pitch discrimination compared with their preoperative performance using two hearing aids.

Implant Ear Alone condition

Pitch Discrimination

- Average performance remained relatively unchanged preoperatively with one hearing aid to postoperatively at six months.
  - Average pitch discrimination was 1.1 (0.5–4.8) semitones preoperatively compared to 1.5 (0.5–8.9) semitones at six months.
- After six months of experience:
  - Most recipients (42/46; 91.3%) demonstrated similar (within one semitone) or better pitch discrimination compared with their preoperative performance using one hearing aid.

Device Use Questionnaire – Music

- When compared to preoperative levels, satisfaction improved across all six music/sound quality related areas at the six month postoperative interval:
  - When listening to live music with singing, satisfaction increased from 8.5% to 53.3%.
  - When listening to live music without singing, satisfaction increased from 42.6% to 62.2%.
  - When listening to recorded music with singing, satisfaction increased from 6.0% to 57.4%.
  - When listening to recorded music without singing, satisfaction increased from 28.6% to 66.0%.
  - When listening to music in general, satisfaction increased from 26.0% to 58.3%.

Self-assessment

Speech, Spatial, and Qualities of Hearing (SSQ) Scale – based on the Everyday Listening condition

Forty-eight of fifty subjects had SSQ ratings available at the six month interval. This data was divided into three sub-scales: Speech Hearing, Spatial Hearing and Sound Qualities. For all three scales, the subject rated their ability to hear. Ratings were on a scale from 1 to 10, where 1 was the poorest rating possible and 10 was the best rating possible. All subscales applied were applied to two hearing aids preoperatively. After implantation, the subscales were applied to the Everyday condition.

Speech Hearing Rating Scale

The Speech Hearing Scale addressed how well subjects 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.

- Average performance after six months was significantly higher than performance prior to implantation:
  - Preoperatively, average ratings were 3.2 (0.8–6.2) out of 10 compared to 5.4 (0.7–8.8) out of 10 at six months.
- After six months of experience:
  - Most recipients (45/48; 93.8%) demonstrated similar or better ratings for the Speech Hearing Scale compared with their preoperative performance
  - Most (37/48; 77.1%) reported benefit to very high benefit on the Speech Hearing Scale compared with their preoperative performance.

Spatial Hearing Rating Scale

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

- Average performance after six months was significantly higher than average performance prior to implantation for the Spatial Hearing Scale:
  - Preoperatively, average ratings were 4.6 (1.4–9.2) out of 10 compared to 5.5 (1.1–8.3) out of 10 at six months.
- After six months of experience:
  - Most recipients (39/48; 81.3%) demonstrated similar or better ratings for the Spatial Hearing Scale compared with their preoperative performance
  - Many (26/48; 54.2%) reported benefit to very high benefit on the Spatial Hearing Scale compared with their preoperative performance.

Sound Qualities Rating Scale

The Sound Qualities Scale addressed how well subjects 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.

- Average performance after six months was significantly higher than average performance prior to implantation for the Spatial Hearing Scale
  - Preoperatively, average ratings were 5.0 (1.6–8.1) out of 10 with two hearing aids and 6.3 (2.7–9.1) out of 10 at six months.
- After six months of experience using the Everyday Listening condition:
  - Most recipients (43/48; 89.6%) demonstrated similar or better ratings for the Sound Qualities Scale compared with their preoperative performance
  - Many (28/48; 58.3%) reported benefit to very high benefit on the Sound Qualities Scale compared with their preoperative performance.

Device Use Questionnaire

- When compared to preoperative levels, overall satisfaction increased at the six month interval:
  - The number of subjects satisfied with their performance increased from 8.0% to 79.2%.
- When compared to preoperative levels, satisfaction improved across all seven listening situations at the six month interval:
  - When listening using a telephone, satisfaction increased from 10.0% to 29.2%.
  - When listening in a noisy environment, satisfaction increased from 0.0% to 33.3%
  - When listening in a quiet environment, satisfaction increased from 34.0% to 85.4%.
  - When listening in a one-on-one situation, satisfaction increased from 44.0% to 93.8%.
  - When listening in a small group situation, satisfaction increased from 16.0% to 75.0%.
  - When listening in a large group situation, satisfaction increased from 2.0% to 45.8%.
  - When listening to a source at a distance (in church, at a music hall), satisfaction increased from 6.0% to 50.0%.
  - When listening to the outdoors (birds, nature sounds, etc.), satisfaction increased from 32.7% to 83.0%.

Cochlear Nucleus Hybrid L24 cochlear implant system post-approval studies summary

There were two post-approval studies conducted with the Cochlear Nucleus Hybrid L24 cochlear implant system:

1. Hybrid Extended Duration (HED) study
2. Hybrid New Enrollment (HNE) study.

Additional findings were collected from the clinical records from University of Iowa. The data collected from clinical records is also referred to as real-world data (RWD). Speech perception and hearing information were obtained out to 5 years after cochlear implant surgery.

Results were collected for 150 participants in total. There were 53 participants in the pivotal + Hybrid Extended Duration study (53 participants up to 1 year and 35 participants up to 5 years), 52 participants in the Hybrid New Enrollment study, and 45 participants from real-world data. Key characteristics identified for each of the study groups above are summarised in ***Table 7*** on page 45.

Demographic characteristics	HED study group	HNE study group	RWD study group
	Mean ± SD N (min, max)	Mean ± SD N (min, max)	Mean ± SD N (min, max)
Age at time of surgery in years	63.3 ± 14.9 (23.0 – 86.2)	59.9 ± 15.6 (18.9 – 80.2)	61.4 ± 17.3 (18.0 – 84.0)
Duration of overall hearing loss in years	28.9 ± 15.1 (10.7 – 74.0)	24.4 ± 13.5 (3.9 – 61.5)	30.8 ± 16.3 (3.0 – 61.0)
Duration of high-frequency hearing loss in years	13.6 ± 7.8 (1.6 – 34.4)	11.8 ± 9.6 (0.5 – 54.0)	13.3 ± 13.9 (1.0 – 49.0)
Male	26 (49.1%)	25 (48%)	27 (60.0%)
Female	27 (50.9%)	27 (52%)	18 (40.0%)
Preoperative degree of LMF PTA (125, 250, 500, 750, 1000 Hz)			
Normal (0 – 25 dB HL)	1/53 (1.9%)	3/52 (5.8%)	0/45 (0.0%)
Mild (26 - 40 dB HL)	13/53 (24.5%)	18/52 (34.6%)	8/45 (17.8%)
Moderate (41 – 55 dB HL)	29/53 (24.5%)	27/52 (51.9%)	24/45 (53.3%)
Moderate-severe (56 – 70 dB HL)	10/53 (18.9%)	4/52 (7.7%)	13/45 (28.9%)

Table 7: Demographic characteristics and preoperative degree of LMF PTA

Changes in residual low-frequency hearing

For the Hybrid Extended Duration and Hybrid New Enrollment and real-world data study groups combined, functional low-frequency acoustic hearing (<90 dB HL) was retained for the majority of patients through 3 years. The data was analysed to account for patients without functional hearing dropping out of the study. Nonetheless, actual results may vary due to patients dropping out of the studies.

- 6 months:
  - 77% (107 out of 139 patients).
- 1 year:
  - 70% (96 out of 137 patients).
- 3 years:
  - 59% (65 out of 111 patients).
- 5 years:
  - 49% (49 out of 100 patients).

After studying if the differences between the study groups affected the hearing results above, it was found that males had significantly poorer hearing outcomes than females. Also, older individuals had significantly poorer hearing outcomes than younger individuals. The length of time of hearing loss before receiving the cochlear implant was not significantly associated with hearing outcomes.

Safety outcomes

Table 8 on page 47 summarises the most frequent hazards associated with cochlear implant surgery or device use for the combined Hybrid Extended Duration and Hybrid New Enrollment and real-world data study groups. There are not significant differences between groups. The events that occurred were anticipated and are reflective of those found in otologic procedures.

- Items in the *Hazard* column are the things that happened because of the use of the Hybrid L24 cochlear implant.
- Items in the *How often patient had the hazard* column are the frequencies that were observed for the *Hazard*.
- Items in the *Harm* column are the results of the *Hazard* that were observed.
- Items in the *How often this hazard harmed them* column are the frequencies at which the *Harm* happened for this *Hazard*.

Event: Implantation with Cochlear Nucleus Hybrid L24 cochlear implant			
Hazard	How often patient had the hazard	Harm	How often this hazard harmed them
Profound loss	58 out of 150 patients	No recovery	100%
Tinnitus	25 out of 150 patients	Tinnitus that did not resolve	64%
Vertigo/dizziness	27 out of 150 patients	Vertigo or dizziness that did not resolve	48%
Open or wrong connection in the electrode wire	13 out of 150 patients	Decreased sound quality	0%
Skin irritation related to use of the external coil or sound processor	13 out of 150 patients	Discomfort that did not resolve	69%
Explantation/ reimplantation	11 out of 150 patients	Additional surgery due to hearing loss	100%

Table 8: Most frequent hazards associated with cochlear implant surgery or device use for combined HED , HNE and RWD study groups

Explantations

Eleven subjects opted to have the Hybrid L24 cochlear implant surgically removed (that is, explanted). Ten subjects did so due to loss of functional hearing and dissatisfaction with performance. During the explant surgery they were reimplanted with a full-length electrode replacement to improve hearing performance. One subject had functional hearing but chose to have their device surgically removed due to sound quality issues. They were reimplanted with a full-length electrode at a later surgery. Explantation occurred on average approximately 2.5 years after the initial surgery. All explantation surgeries were performed without complications, and patients benefitted from a full-length cochlear implant.

Speech perception outcomes

Speech outcomes using the CNC Monosyllabic Word Test in quiet and AzBio Sentence Test in Noise (+5 dB signal-to-noise ratio) were collected in the Hybrid Extended Duration and Hybrid New Enrollment studies. CNC and AzBio performances were significantly higher at all timepoints after surgery compared to performance before surgery for both implant ear alone and both ears. Speech perception outcomes remained stable through 5 years post-surgery (that is, the end of the studies). There was no statistically significant effect of sex (that is, male versus female), age at implantation (that is, older versus younger), or duration of hearing loss (that is, longer duration vs. shorter duration) on speech perception outcomes. The average test results for speech perception outcomes are provided on the next pages.

Understanding Speech in Quiet – CNC Monosyllabic Word Test

Everyday Listening condition (both ears)

- For the Hybrid Extended Duration study, average CNC scores were 44.4% (2%–81%) preoperatively with bilateral hearing aids.

  Postoperatively, scores were 83.4% (49%–97%) at 1 year and 81.0% (50%–97%) at 5 years using the Hybrid L24 cochlear implant in one ear and a hearing aid in the opposite ear.
- For the Hybrid New Enrollment study, average CNC scores were 45.5% (12%–84%) preoperatively with bilateral hearing aids.

  Postoperatively, scores were 76.6% (40%–97%) at 1 year and 77.6% (34%–97%) at 3 years using the Hybrid L24 cochlear implant in one ear and a hearing aid in the opposite ear.

  Results were stable and not significantly different from 1 year to 3 years ($p>.05$).

Implant Ear Alone condition (one ear)

- For the Hybrid Extended Duration study, average CNC scores were 27.0% (9%–64%) preoperatively with one hearing aid.

  Postoperatively scores were 73.6% (10%–97%) at 1 year and 71.2% (21%-96%) at 5 years using the Hybrid L24 cochlear implant.
- For the Hybrid New Enrollment study, average CNC scores were 29.4% (7%–62%) preoperatively with one hearing aid.

  Postoperatively scores were 65.8% (3%–96%) at 1 year and 66.6% (3%–92%) at 3 years using the Hybrid L24 cochlear implant.

Understanding Speech in Noise – AzBio Sentence Test in Noise (+5 dB SNR)

Everyday Listening condition (both ears)

- For the Hybrid Extended Duration study, average AzBio sentences in noise scores were 28.8% (0.0%–76.5%) preoperatively with bilateral hearing aids.

  Postoperatively scores were 67.8% (7.0%–97.5%) at 1 year and 61.4% (14.6%–99.3%) at 5 or more years using the Hybrid L24 cochlear implant in one ear and a hearing aid in the opposite ear.
- For the Hybrid New Enrollment study, average AzBio sentences in noise scores were 34.7% (0%–80.7%) preoperatively with bilateral hearing aids.

  Postoperatively scores were 63.0% (2.7%–90.6%) at 1 year and 62.5% (24.7%–95.6%) at 3 years using the Hybrid L24 cochlear implant in one ear and a hearing aid in the opposite ear.

Implant Ear Alone condition (one ear)

- For the Hybrid Extended Duration study, average AzBio sentences in noise scores were 15.7% (0.0%–64.1%) preoperatively with one hearing aid.

  Postoperatively scores were 53.2% (0.0%–90.2%) at 1 year and 49.6% (0.7%–94.0%) at 5 years using the Hybrid L24 cochlear implant.
- For the Hybrid New Enrollment study, average AzBio sentences in noise scores were 22.2% (0%–61.3%) preoperatively with one hearing aid.

  Postoperatively scores were 44.4% (0.0%–88.4%) at 1 year and 40.4% (0.7%–95.2%) at 3 years using the Hybrid L24 cochlear implant.

Conclusions

These studies provided outcomes using well recognised and validated measures of hearing sensitivity and speech perception outcomes. They provide long-term data for recipients of the Cochlear Nucleus Hybrid L24 cochlear implant system with 3 to 5 years of device experience. Not all patients completed long-term follow-up. For those that did, a majority maintained a level of functional low-frequency acoustic hearing. They also demonstrated improved speech perception capabilities through 3 to 5 years of device experience, relative to preoperative performance when using two hearing aids.

Where you can find more information

For additional information concerning Cochlear Americas and the Cochlear Nucleus Hybrid L24 cochlear implant, visit Cochlear's website at: www.cochlear.com or call 1 800 523 5798.

Hear now. And always

AU **Cochlear Ltd** (ABN 96 002 618 073)
1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555

EC REP DE **Cochlear Deutschland GmbH & Co. KG**
Mailänder Straße 4 a, 30539 Hannover, Germany
Tel: +49 511 542 770

CH REP CH **Cochlear AG**
Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204

US **Cochlear Americas**
10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 (800) 523 5798

CA **Cochlear Canada Inc**
2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 (800) 523 5798

GB **Cochlear Europe Ltd**
6 Dashwood Lang Road, Bourne Business Park, Addlestone,
Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400

BE **Cochlear Benelux NV**
Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11

FR **Cochlear France S.A.S.**
135 Route de Saint-Simon, 31035 Toulouse, France
Tel: +33 5 34 63 85 85 (International) or 0805 200 016 (National)

IT **Cochlear Italia S.r.l.**
Via Trattati Comunitari Europei 1957-2007 n.17,
40127 Bologna (BO), Italy
Tel: +39 051 601 53 11

SE **Cochlear Nordic AB**
Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61

www.cochlear.com

TR **Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.**
Küçükbakkalköy Mah, Defne Sok, Büyükhanlı Plaza No:3 Kat:3
Daire: 9-10-11-12, 34750, Ataşehir, İstanbul, Türkiye
Tel: +90 216 538 5900

HK **Cochlear (HK) Limited**
Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road,
Causeway Bay, Hong Kong
Tel: +852 2530 5773

KR **Cochlear Korea Ltd**
2nd Floor, Yongsan Centreville Asterium, 25,
Hangang-daero 30 gil, Yongsan-gu, Seoul, Korea (04386)
Tel: +82 2 533 4450

CN **Cochlear Medical Device (Beijing) Co., Ltd**
Unit 2608-2617, 26th Floor, No.9 Building, No.91 Jianguo Road,
Chaoyang District, Beijing 100022, P.R. China
Tel: +86 10 5909 7800

IN **Cochlear Medical Device Company India Pvt. Ltd.**
Ground Floor, Platina Building, Plot No C-59, G-Block,
Bandra Kurla Complex, Bandra (E), Mumbai – 400 051, India
Tel: +91 22 6112 1111

JP **株式会社日本コクレア(Nihon Cochlear Co Ltd)**
〒113-0033 東京都文京区本郷2-3-7 お茶の水元町ビル
Tel: +81 3 3817 0241

AE **Cochlear Middle East FZ-LLC**
Dubai Healthcare City, Al Razi Building 64, Block A, Ground Floor,
Offices IR1 and IR2, Dubai, United Arab Emirates
Tel: +971 4 818 4400

PA **Cochlear Latinoamérica S.A.**
International Business Park, Building 3835, Office 403,
Panama Pacifico, Panama
Tel: +507 830 6220

NZ **Cochlear NZ Limited**
Level 4, Takapuna Towers, 19-21 Como St, Takapuna,
Auckland 0622, New Zealand
Tel: + 64 9 914 1983

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