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

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 cochlear implant system in conjunction with a hearing aid in the other ear.
- Cochlear Nucleus Hybrid 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 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 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 cochlear implant

A Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid 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 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 cochlear implant (Indications)

Doctors use the Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid L24 cochlear implant system is intended to provide electric stimulation to the mid- 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 pre-operative 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- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL), and moderately severe to profound mid- 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 pre-operative 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 cochlear implant (Contraindications)?

A Cochlear Nucleus Hybrid 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 cochlear 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 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 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 an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~0.5 in.) from the extracochlear electrodes.

Diathermy

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 implant.

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

Neurostimulation

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

Electroconvulsive therapy

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

Ionising radiation therapy

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

MRI safety information

The Cochlear Nucleus Hybrid L24 (CI24REH) 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.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 / 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. 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.

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 Cochlear Nucleus Hybrid cochlear implant should be appropriately counseled of this risk.

In addition, certain pre-operative conditions may increase the risk of meningitis with or without an 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 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

External sound processor warnings

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 themselves
- notify a caregiver that the device has become hot.

Overheating of external devices

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch their recipient's 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 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 processor.

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

Use the implant system only with the approved devices and accessories listed in the user guide.

Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The opening of your processor by anyone other than Cochlear's qualified service personnel invalidates the warranty.

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

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

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

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

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

Your 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 processor stops working, turn the power switch off and then back on. This effect is temporary and will not damage your 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 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 implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off your processor when in the vicinity of one of these devices.

The materials used in the implant may activate metal detection systems. For this reason, recipients should carry 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 implant system or corrupt the program in your processor.

If static electricity is present (e.g. when putting on or removing clothes over the head, or getting out of a vehicle), implant recipients should touch something conductive (e.g. a metal door handle) before the implant system contacts any object or person.

Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed.

Mobile telephones

Some types of digital mobile telephones (e.g. Global System for Mobile communications (GSM) as used in some countries) may interfere with the operation of the external equipment. As a result, implant recipients may perceive a distorted sound sensation when in close proximity, 1–4 m (~3–12 ft), to a digital mobile telephone in use.

Scuba diving

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

Table 1: Maximum diving depths when wearing 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 implant site.

Sleeping

Do not wear your processor while sleeping, as you may not become aware of your 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 processor if the 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 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 15.
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 20.

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 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 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 cochlear implant

Certain risks are a part of all surgery. Candidates should discuss the known risks, benefits and alternatives to Cochlear Nucleus Hybrid hearing technology with their surgeon and audiologist. The following are known limitations associated with cochlear implantation, which may also apply to the Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid cochlear implant may not provide useful speech understanding.

The loss of residual hearing is a risk of receiving the Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid 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 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 pre-operative scores. It is important to note that no subject, regardless of post-operative 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 27 summarises the most frequent hazards associated with implant surgery in the Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid 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 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 Clinical Trial

Explantation

As part of the study, six subjects had surgery to remove their Cochlear Nucleus Hybrid 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 cochlear implant

The potential benefits of the Cochlear Nucleus Hybrid 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 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 implant in one ear and a hearing aid in the other ear than with hearing aids alone.

Further detail on the benefits of the Cochlear Nucleus Hybrid cochlear implant is provided in the ***How we studied the Cochlear Nucleus Hybrid cochlear implant*** section of this booklet.

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

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

Before implantation of the Cochlear Nucleus Hybrid cochlear implant

To decide if you are a candidate for the Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid cochlear implant.

During implantation of the Cochlear Nucleus Hybrid cochlear implant

During 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 post-operative hospital stay is variable and will be determined by the surgeon.

Using the Cochlear Nucleus Hybrid cochlear implant after surgery

An external sound processor is required in order for stimulation of the Cochlear Nucleus Hybrid 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 Cochlear Nucleus Hybrid 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 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 cochlear implant

A clinical trial was performed to test whether the Cochlear Nucleus Hybrid 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 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*)
Male	25/50 (50.0%)
Female	25/50 (50.0%)
Pre-operative 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

* 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.

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.

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 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 60dBA. 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[3] 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[4] 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.

3 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.

4 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%) pre-operatively with two hearing aids and 79.4% (35% - 98%) at six months post-operative in the Everyday Listening condition.
- After six months of post-operative experience:
  - All subjects (49/49; 100%) demonstrated similar or better word recognition (CNC) compared with their pre-operative performance using two hearing aids
  - Most (43/49; 87.8%) demonstrated significantly better word recognition compared with their pre-operative 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%) pre-operatively with one hearing aid and 65.4% (8% - 98%) at six months in the Implant Ear Alone condition.
- After six months of post-operative experience:
  - Most subjects (47/49; 96%) demonstrated similar or better word recognition (CNC) compared with their pre-operative performance using one hearing aid
  - Most (40/49; 81.6%) demonstrated significantly better word recognition compared with their pre-operative 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%) pre-operatively with two hearing aids and 62.6% (3.6% - 92.7%) at six months in the Everyday Listening condition.

- After six months of post-operative experience:
  - Most recipients (49/49; 100%) demonstrated similar or better sentence recognition in noise (AzBio) compared with their pre-operative performance using two hearing aids
  - Most (41/49; 84%) demonstrated significantly better sentence recognition in noise (AzBio) compared with their pre-operative 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%) pre-operatively with one hearing aid and 49.2% (0.0% - 91.5%) at six months in the Implant Ear Alone condition.
- After six months of post-operative experience:
  - Most subjects (44/49; 89.8%) demonstrated similar or better sentence recognition in noise (AzBio) compared with their pre-operative performance using one hearing aid
  - Many (36/49; 73.5%) demonstrated significantly better sentence recognition in noise (AzBio) compared with their pre-operative 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

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

Implant Ear Alone condition

Pitch Discrimination

- Average performance remained relatively unchanged pre-operatively with one hearing aid to post-operatively at six months.
  - Average pitch discrimination was 1.1 (0.5 – 4.8) semitones pre-operatively 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 pre-operative performance using one hearing aid.

Device Use Questionnaire – Music

- When compared to pre-operative levels, satisfaction improved across all six music/sound quality related areas at the six month post-operative 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 pre-operatively. 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:
  - Pre-operatively, 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 pre-operative performance
  - Most (37/48; 77.1%) reported benefit to very high benefit on the Speech Hearing Scale compared with their pre-operative 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 (e.g., 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:
  - Pre-operatively, 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 pre-operative performance
  - Many (26/48; 54.2%) reported benefit to very high benefit on the Spatial Hearing Scale compared with their pre-operative 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
  - Pre-operatively, 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 pre-operative performance
  - Many (28/48; 58.3%) reported benefit to very high benefit on the Sound Qualities Scale compared with their pre-operative performance.

Device Use Questionnaire

- When compared to pre-operative 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 pre-operative 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%.

Nucleus Hybrid L24 Implant System Extended Duration Post-Approval Study Summary

The objective of the post-approval study was to provide long-term safety and effectiveness data on subjects implanted as part of the clinical study, described above, that resulted in approval of the Cochlear Nucleus Hybrid L24 Cochlear Implant System. In this post-approval study, speech perception and hearing information were obtained from 35 clinical study subjects who were followed for five years after receiving their Hybrid cochlear implant.

Fifty subjects were implanted in the pivotal clinical study and three subjects under a continued access supplement. Of these 53 subjects:

- Six subjects were explanted and reimplanted with traditional cochlear implants prior to the post-approval study
- Four subjects discontinued participation prior to the post-approval study
- Four subjects were not available to enrol because their study site declined participation
- Four additional subjects chose not to participate in the post-approval study
- The remaining 35 subjects met the inclusion/exclusion criteria required for participation in the study.

Demographics for the 35 post-approval study subjects and the 18 subjects who did not participate are shown in ***Table 7***, below. Both groups display similar characteristics to those of the pivotal clinical trial study group, which is to be expected given the majority participated in both studies. The only difference to note is that the non-study group was six years older on average, although the age range is similar across both groups.

The non-study group presents a potential bias because the group had more subjects who experienced significant changes in low-frequency acoustic hearing during the pivotal study. Thirteen of the 18 subjects experienced a profound loss of hearing, at various time intervals after surgery. Only 9 of the 35 subjects who proceeded into the post-approval study had a profound loss.

Demographic Characteristics	Post-approval Subjects	Non-study Subjects
	Mean ± SD N (min, max)	Mean ± SD N (min, max)
Age at CI in Years	61.3 ± 16.1 (23.0 – 86.2)	67.2 ± 11.6 (18.0 - 85.7)
Duration of Overall Hearing Loss in Years	27.9 ± 12.9 (3.4 – 52.4)	25.7 ± 18.9 (10.7- 74.0)
Duration of High-Frequency Hearing Loss in Years	14.2 ± 7.3 (1.6 – 30.1)	12.1 ± 7.4 (3.7 - 27.5)
Male	16 (45.7%)	10 (55.6%)
Female	19 (54.3%)	8 (44.4%)
Pre-operative Degree of LMF PTA (Implanted Ear):		
Normal (0 – 25 dB HL)	0/35 (0.0%)	1/18 (5.6%)
Mild (26 - 40 dB HL)	9/35 (25.7%)	4/18 (22.2%)
Moderate (41 – 55 dB HL)	19/35 (54.3%)	10/18 (55.6%)
Moderate-Severe (56 – 70 dB HL)	7/35 (20.0%)	3/18 (16.7%)

Table 7: Demographics for the 35 post-approval study subjects and the 18 non-study subjects

Changes in residual low-frequency hearing during the Post-Approval Study

In the post-approval study, five years after surgery, most individuals (94.3%) retained a level of acoustic hearing beyond the conclusion of the 1 year clinical study. One year after surgery, 29 out of 35 subjects (82.9%) had functional low-frequency hearing. At five years, 25 out of 35 subjects (71.4%) had functional low-frequency acoustic hearing. Four of the 35 subjects (11.4%), who had moderately severe or severe hearing loss one year after surgery, had profound loss of hearing loss after five years. There were no additional cases of total hearing loss during the post-approval study.

Changes in low-frequency hearing sensitivity five years after surgery are summarised below:

- Thirty-one out of the 35 subjects maintained the same level of low-frequency hearing they had after completing the clinical trial,
    - Twenty-five maintained hearing of a severe degree or better, called functional acoustic hearing,
    - Six individuals, who already experienced profound or total loss of hearing before the post-approval study, still had profound or total hearing loss at 5 years.
- Four of the 35 subjects, who already had moderately severe or severe low-frequency hearing loss before the post-approval study, progressed to a profound loss of hearing by five years.

To try and understand if the 18 non-study subjects not being available for the longer-term follow up affected the results above, all available data from the clinical trial and the post-approval studies were used to compare the most recent, latest hearing results with results after one year of Hybrid use.

Most subjects who had severe or better levels of low-frequency hearing still had functional acoustic hearing after five years (27 of 30 subjects). Three subjects with severe or better hearing loss had reached 2.5, 3.5 and 4.5 years before withdrawing from the post-approval study. In effect, longer-term audiometric data were available for the majority of the 53 subjects across both the clinical and the post-approval studies.

When looked at this way, changes in hearing sensitivity could be assessed over five years for just about everybody:

- Thirty out of the 53 subjects kept hearing of a severe degree or better by 2.5 to 5 years (most at 5 years), and
- Twenty-three individuals had profound or total hearing loss by five years.

Table 8 below summarises the most frequent hazards associated with implant surgery in the long-term post-approval study. 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 Cochlear Nucleus Hybrid 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 cochlear implant			
Hazard	How often patient had the hazard	Harm	How often this hazard harmed them
Profound loss of hearing	1 out of 35 patients	No recovery	1 out of 1 of these patients
Explantation/ Reimplantation	1 out of 35 patients	Additional surgery due to hearing loss	1 out of 1 of these patients
Tinnitus	1 out of 35 patients	Tinnitus that did not resolve	0 out of 1 of this 1 patient (tinnitus resolved)
Pain related to use of the external coil or sound processor	2 out of 35 patients	Discomfort that did not resolve	0 of these 2 patients (both cases resolved)

Table 8: Most frequent hazards from the post-approval study.

Speech perception

Thirty-five subjects had speech perception data at the 5-year interval in the post-approval study.

Understanding Speech in Quiet – CNC Monosyllabic Word Test

Everyday Listening condition

- After five years of experience, average performance remained significantly higher than average performance for the subjects using two hearing aids (i.e., in both ears) prior to implantation, as was the case during the clinical trial.
  - Average CNC scores were 44.4% (2% - 81%) pre-operatively with bilateral hearing aids, 81.8% (49% - 98%) at 6 months, 83.4% (49%-97%) at 1 year and 81% (50%-97%) after five or more years in the implanted ear alone for the 35 subjects.
- After five years of experience:
  - Most recipients (34/35; 97.1%) demonstrated similar or better word recognition (CNC) compared with their pre-operative performance using two hearing aids
  - Most (30/35; 85.7%) demonstrated significantly better word recognition compared with their pre-operative performance using two hearing aids.
- Approximately half of the recipients recognised 86.0% or more of the words (CNC) and approximately three quarters recognised 71.5% or more of the words after five years of experience.

Implant Ear Alone condition

- After five years of experience, average performance remained significantly higher than average performance for the subjects using a hearing aid prior to implantation, as was the case during the pivotal clinical trial.
  - Average CNC scores were 27% (9% - 64%) pre-operatively with one hearing aid, 71.3% (29% - 98%) at 6 months, 73.6% (10%-97%) at 1 year and 71.2% (21%-96%) after 5 or more years in the implanted ear alone for the 35 subjects.
- After five years of experience:
  - Most recipients (33/35; 94.3%) demonstrated similar or better word recognition (CNC) compared with their pre-operative performance using two hearing aids
  - Most (31/35; 88.6%) demonstrated significantly better word recognition compared with their pre-operative performance using two hearing aids.
- Approximately half of the recipients recognised 75.0% or more of the words (CNC) and approximately three quarters recognised 61.0% or more of the words after 5 years of experience.

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

Everyday Listening condition

- After five years of experience, average performance remained significantly higher than average performance for the subjects using bilateral hearing aids (i.e., in both ears) prior to implantation, as was the case during the pivotal clinical trial.
  - Average AzBio sentences-in-noise scores were 28.8% (0% - 76.5%) pre-operatively with one hearing aid, 64.5% (14.9% - 92.7%) at 6 months, 67.8% (7%-97.5%) at 1 year and 61.4% (14.6%-99.3%) after 5, or more, years in the implanted ear alone for the 35 subjects.
- After five years of experience:
  - Most recipients (32/35; 91.4%) demonstrated similar or better word recognition (AzBio) compared with their pre-operative performance using two hearing aids
  - Most (26/35; 74.3%) demonstrated significantly better word recognition compared with their pre-operative performance using two hearing aids.
- Approximately half of the recipients recognised 65.9% or more of the words (AzBio) and approximately three quarters recognised 43.8% or more of the words after 5 years of experience in the Everyday Listening condition.

Implant Ear Alone condition

- After five years of experience, average performance for the implanted ear alone remained significantly higher than average performance for the subjects using a hearing aid prior to implantation, as was the case during the pivotal clinical trial.
    - Average AzBio sentences-in-noise scores were 15.7% (0% - 64.1%) pre-operatively with one hearing aid, 52.1% (1.1% - 91.5%) at 6 months, 53.2% (0%-90.2%) at 1 year and 49.6% (0.7%-94%) after 5, or more, years in the implanted ear alone for the 35 subjects.
- After five years of experience:
    - Most recipients (32/35; 91.4%) demonstrated similar or better word recognition (AzBio) compared with their pre-operative performance using two hearing aids
    - Most (29/35; 82.9%) demonstrated significantly better word recognition compared with their pre-operative performance using two hearing aids.
- Approximately half of the recipients recognised 50.4% or more of the words (AzBio) and approximately three quarters recognised 27.2% or more of the words after 5 years of experience in the Everyday Listening condition.

As discussed above, there were 18 clinical trial subjects who did not enrol in the post-approval study. As a result, longer-term speech perception data are not available for these subjects after the clinical trial, which ended at the 1 year evaluation. It is possible that the overall speech scores at five years may have been different (the speech perception results may have been worse or better) if the 18 subjects, who experienced more hearing loss, had enrolled in the 5 year post-approval study. However, since the 35 post-approval subjects were also tested at 1 year post-activation the average speech scores can be compared at that time point to see if they were any differences between the two groups.

Table 9 below summarises the average CNC word recognition and AzBio sentences in noise for the implanted ear alone and for the Everyday Listening condition (i.e., using both ears) for the 18 non-study subjects and the 35 post-approval studies. While there is a trend for the post-approval subjects to perform better the differences are not significant due the large variability in the individual scores. The largest difference is observed for the CNC word test, but the other scores are quite close, interestingly for the sentences in noise test, which is usually more difficult to complete. And, importantly, in the Everyday condition when the subjects use both ears the average scores are very close.

Listening Condition	Study Group	CNC Words Average (SD)		Sentences in Noise Average (SD)	
		Preoperative	1 Year	Preoperative	1 Year
Implant Ear	Non-Study (N=18)	29.7% (15.2%)	54.3% (33.8%)	17.0% (15.9%)	49.0% (34.6%)
	Post-Approval (N=35)	27.0% (14.6%)	73.6% (20.9%)	15.7% (13.7%)	53.2% (27.0%)
Everyday Condition (Both Ears)	Non-Study (N=18)	43.2% (14.5%)	77.3% (16.3%)	29.6% (17.2%)	62.9% (32.2%)
	Post-Approval (N=35)	44.4% (17.3%)	83.4% (11.9%)	28.8% (20.6%)	67.8% (19.8%)

Table 9: Average speech perception scores for the non-study and post-approval subjects by 1 year post -activation

Study conclusions

This study provided outcomes using well recognised and validated measures of hearing sensitivity and speech perception outcomes. It is exceptional in that it provides long-term data for recipients of the Cochlear Nucleus Hybrid L24 Cochlear Implant System with five or more years of device experience. Outcomes for 35 subjects showed improved speech perception capabilities through five years of device experience, relative to pre-operative performance when using acoustic amplification via hearing aids. However, a weakness of the study is that not all 53 subjects who completed an earlier clinical trial were available for long-term follow up in the post-approval study. The comparatively small sample size of 35 subjects presents limited power to detect relatively rare adverse events related to device use.

Accounting for all 53 subjects followed during the clinical and the post-approval studies, functional (severe loss or better) low-frequency acoustic hearing was maintained in 37 or 69.8% of the 53 subjects by 1 year post-activation, with 16 subjects (30.2%) having profound or total loss of hearing in the implanted ear. By five years, 30 or 56.6% of the 53 subjects maintained functional low-frequency acoustic hearing, with 23 of the 53 subjects (43.4%) having profound or total loss that did not appear to recover.

The smaller sample size also presents a potential bias in that speech perception outcomes for the 18 clinical trial subjects, who had more significant loss of hearing in the implanted ear as a group, are not available beyond 1 year post-activation. It is possible that the overall longer-term speech perception outcomes may have been better (e.g., with more experience) or worse (e.g., if further hearing loss were to occur) if they had been included through 5 years post-activation. However, comparisons made between these 18 subjects and the 35 post-approval subjects showed similar outcomes through 1 year post-activation. These comparisons taken together with the relatively stable speech perception shown by the 35 post-approval subjects suggest outcomes for the 18 non-study subjects would also have remained improved over preoperative hearing aids. However, without the additional data through five years it is acknowledged that definitive conclusions cannot be made with regards to the longer-term speech perception outcomes for the 18 non-study subjects.

Considering the above, results demonstrate that the Nucleus L24 Hybrid System remains an effective treatment for people with severe high-frequency hearing impairment after five years of device use. Measurable hearing was achieved and maintained in 94.3% of subjects after five years of implant use. Speech perception in quiet and in noise improved significantly over pre-operative performance and remained stable through five years of device use. in the post-approval subjects. It is important to understand that while the best outcomes are observed in those who retain functional acoustic hearing in both ears, improved speech perception remains likely over that available via bilateral hearing aids alone. In the absence of the Hybrid implant, high-frequency speech information is not available to either ear even with bilateral hearing aids. Individuals who do not retain low-frequency acoustic hearing in the implanted ear are still able to make use of important high-frequency speech information via the Hybrid implant in conjunction with acoustic hearing in the opposite ear to derive benefit for speech perception.

Outcomes from the pivotal clinical trial can be found in Roland et al. (2016). Longer-term results for 32 of the recipientspost-approval subjects described hereabove can also be found in (Roland, Gantz, Waltzman, & Parkinson, et al. (2018).

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Where you can find more information

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

Notes

Cochlear™

Cochlear Ltd (ABN 96 002 618 073) 1 University Avenue, Macquarie University, NSW 2109, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
Cochlear Ltd (ABN 96 002 618 073) 14 Mars Road, Lane Cove, NSW 2066, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352
EC REP **Cochlear Deutschland GmbH & Co. KG** Karl-Wiechert-Allee 76A, 30625 Hannover, Germany
Tel: +49 511 542 770 Fax: +49 511 542 7770
Cochlear Americas 10350 Park Meadows Drive, Lone Tree, CO 80124, USA
Tel: +1 303 790 9010 Fax: +1 303 792 9025
Cochlear Canada Inc 2500-120 Adelaide Street West, Toronto, ON M5H 1T1, Canada
Tel: +1 416 972 5082 Fax: +1 416 972 5083
Cochlear AG EMEA Headquarters, Peter Merian-Weg 4, 4052 Basel, Switzerland
Tel: +41 61 205 8204 Fax: +41 61 205 8205
Cochlear Europe Ltd 6 Dashwood Lang Road, Bourne Business Park, Addlestone, Surrey KT15 2HJ, United Kingdom
Tel: +44 1932 26 3400 Fax: +44 1932 26 3426
Cochlear Benelux NV Schaliënhoevedreef 20 i, B-2800 Mechelen, Belgium
Tel: +32 15 79 55 11 Fax: +32 15 79 55 70
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) Fax: +33 5 34 63 85 80
Cochlear Italia S.r.l. Via Larga 33, 40138 Bologna, Italy
Tel: +39 051 601 53 11 Fax: +39 051 39 20 62
Cochlear Nordic AB Konstruktionsvägen 14, 435 33 Mölnlycke, Sweden
Tel +46 31 335 14 61 Fax +46 31 335 14 60
Cochlear Tıbbi Cihazlar ve Sağlık Hizmetleri Ltd. Şti.
Çubuklu Mah. Boğaziçi Cad., Boğaziçi Plaza No: 6/1, Kavacık, TR-34805 Beykoz-Istanbul, Turkey
Tel: +90 216 538 5900 Fax: +90 216 538 5919
Cochlear (HK) Limited Room 1404-1406, 14/F, Leighton Centre, 77 Leighton Road, Causeway Bay, Hong Kong
Tel: +852 2530 5773 Fax: +852 2530 5183
Cochlear Korea Ltd 1st floor, Cheongwon Building 33, Teheran-ro 8 gil, Gangnam-gu, Seoul, Korea
Tel: +82 2 533 4450 Fax: +82 2 533 8408
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 Fax: +86 10 5909 7900
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 Fax: +91 22 6112 1100
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 Fax: +81 3 3817 0245
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 Fax: +971 4 361 8925
Cochlear Latinoamérica S.A.
International Business Park, Building 3835, Office 403, Panama Pacifico, Panama
Tel: +507 830 6220 Fax: +507 830 6218
Cochlear NZ Limited
Level 4, Takapuna Towers, 19-21 Como St, Takapuna, Auckland 0622, New Zealand
Tel: + 64 9 914 1983 Fax: 0800 886 036

www.cochlear.com

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415754 V7 2020-09