



Cochlear™

Nucleus® Hybrid™ L24 cochlear implant CI24REH

Professional Package Insert



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 indications and contraindications that apply to the following cochlear implant systems:

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



Caution

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





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Notes

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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 6 Sound Processor including coil/cable, battery module, and Remote Assistant, 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 ($<90\text{dB}$).
- Nonfunctional Acoustic Hearing – Acoustic (rather than electric) hearing of a profound degree ($\geq 90\text{dB}$).





Device description

The Cochlear Nucleus Hybrid L24 cochlear implant system is an electric-acoustic (E+A) stimulation system intended to address the needs of individuals who demonstrate normal to moderate low-frequency hearing loss and severe to profound mid- and high-frequency sensorineural hearing loss.

The Cochlear Nucleus Hybrid L24 system includes both implanted and external components. The implanted components of the system are:

- The Cochlear Nucleus Hybrid L24 cochlear implant consisting of the Cochlear Nucleus CI24RE receiver/stimulator assembly with the Hybrid L24 electrode array. The implant is provided sterile.

The external components are non-sterile and include:

- The Cochlear Nucleus 6 (N6) sound processor with coil/cable, battery module, acoustic component and accessories
- Two user options for Remote Assistants.

Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the oval window and round window. It is important that physicians be trained in the implantation procedure for the Cochlear Nucleus Hybrid L24 cochlear implant. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device.

Cochlear Americas conducts periodic training courses. For product-specific information, refer to the Surgeon's Guide supplied with each implant.



Indications for use

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 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- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL) in the ear to be implanted, 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 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.



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 cochlear development
4. A duration of severe to profound hearing loss of 30 years or greater.

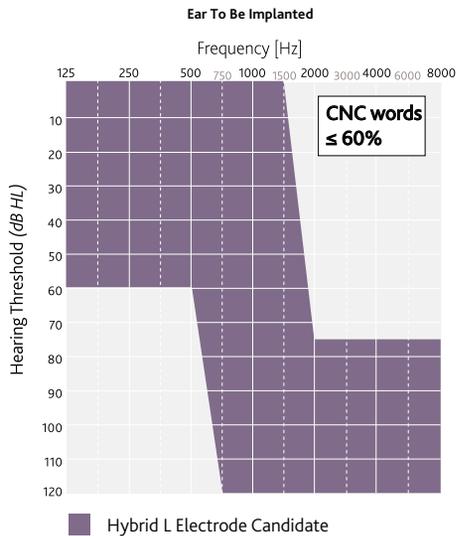


Figure 1: Shaded audiogram depicting the indicated thresholds for Cochlear Nucleus Hybrid L24 candidacy in the ear to be implanted





Warnings

Medical treatments generating induced currents

Below are some 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

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.



Neurostimulation

Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

Electroconvulsive therapy

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

Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the implant because it may cause damage to the implant.

Magnetic Resonance Imaging (MRI)



MRI is contraindicated for patients with the Cochlear Nucleus Hybrid cochlear implant.

Meningitis

Prior to implantation, candidates should be instructed to 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 should be appropriately counselled of this risk.



Warnings

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.

Hearing sensitivity

At six months postactivation most individuals (90%) retain a level of acoustic hearing and many (66%) utilize that hearing with or without amplification at the implant ear. For some individuals, a total loss of functional acoustic hearing in the implanted ear may occur. See the Safety Analysis section for additional information. Changes in low frequency hearing sensitivity at the six month study endpoint are summarized below:

- 33 subjects (66%) maintained hearing of a severe degree or better, referred to as functional acoustic hearing
- 17 (34%) experienced a decrease in low frequency hearing resulting in profound loss of hearing, referred to as nonfunctional acoustic hearing.

There is limited long-term data available on the effects of Cochlear Hybrid implantation on hearing sensitivity. Following the six month study endpoint, five additional subjects experienced a decrease in low frequency hearing resulting in profound loss of hearing, with the loss occurring up to 48 months post-surgery.





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.

Small parts hazard

Patients and caregivers should be counseled that the external implant system contains small parts that may be hazardous if swallowed or may cause choking if inhaled.

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 minimize the chance of experiencing head trauma, patients should refer to http://www.cdc.gov/ncipc/pub-res/tbi_toolkit/patients/preventing.htm

Use of batteries and battery ingestion

When using disposable batteries, patients should be instructed to only use battery types recommended by Cochlear. Other types may not have sufficient energy to allow the 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 and pets. If swallowed, patients should seek prompt medical attention at the nearest emergency center.



Warnings

Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT and could cause injury. The processor should be removed immediately if it becomes unusually warm or hot, and a clinician consulted for advice. Caregivers should be instructed to touch their 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, or notify a caregiver that the device has become hot.

Overheating of external devices

Patients should be cautioned to remove the processor immediately if it becomes unusually warm or hot, and seek advice from a clinician. Caregivers should be instructed to 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 the processor.



Precautions

If the recipient experiences a significant change in performance or the sound becomes uncomfortable, they should be instructed to turn off the processor and contact the implant center.

The cochlear implant system should be used only with the approved devices and accessories listed in the user guide.

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

Each processor is programmed specifically for each implant. Recipients should never wear another person's processor or lend theirs to another user. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

The processor should not be operated at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).

The processor should not be stored at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).



Precautions

The processor's sound quality may be intermittently distorted when it is 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)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

To reduce or eliminate the interference, the recipient should move the processor away from the source. If the processor stops working, the recipient should turn the power switch off and then back on. This effect is temporary and will not damage the processor.

Storage, handling and sterilization

Implants should be stored at normal room temperature. Implants may be stored at temperatures between -4 °F and +120 °F (-20 °C and +50 °C). The 'use by' date is stamped on the outside package. If it has expired, return the device to Cochlear. Handle the implant packages with care. Severe impact may rupture the inner sterile package. Cochlear implants are supplied sterile in gas-permeable packaging. The titanium plugs and replacement magnets are supplied separately in sterile gas-permeable packaging. These are single use items. The sterile package contains information indicating ethylene oxide processing. Before opening the sterile package, inspect it carefully. If the package is ruptured, or exposure to ethylene oxide processing is not indicated, please return the package to Cochlear.



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, the recipient should turn off the processor when in the vicinity of one of these devices. The materials used in the cochlear implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

Electrostatic discharge

A discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the processor. If static electricity is present (e.g. when putting on or removing clothes over the head or getting out of a vehicle), cochlear implant recipients should touch something conductive (e.g. a metal door handle) before the cochlear implant system contacts any object or person. Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

Mobile telephones

Some types of digital mobile telephones (e.g. 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.



Precautions

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

Recipients should not wear the processor while sleeping, as they may not become aware of the 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, recipients should also consult the recommendations provided by the device manufacturer.





Precautions

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. Recipients should take care to use the 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 <i>Electrostatic discharge</i> on page page 17
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 <i>Warnings</i> and <i>Precautions</i> sections, and <i>Guidance</i> below

Table 3: Electromagnetic immunity





Precautions

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):

$$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$$

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.



Precautions

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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



Clinical trial description

The objective of this multicenter, pivotal study was to evaluate the safety and effectiveness of the Cochlear Nucleus Hybrid L24 cochlear implant system. Participants in the study had sensorineural hearing loss, characterized by a normal through moderate range in the low frequencies and a severe to profound loss in the high frequencies. Subjects were assessed with and without use of an additional hearing aid in the contralateral (unimplanted) ear. When testing the implant ear alone, subjects made use of electric hearing and whatever low frequency hearing they had available to them in the same ear. Since participants made use of the device in conjunction with a hearing aid in the contralateral ear, speech perception was also measured in this, Everyday, listening condition.

Individual audiometric data were examined across test intervals to measure any changes in hearing sensitivity and to understand the impact of the procedure on hearing sensitivity in the low frequencies.

The co-primary endpoints of the study were based on a comparison of the change in average speech perception scores (both in quiet and in noise) between the preoperative and 6-month time points in the implanted ear alone with the patients utilizing electric hearing and whatever low frequency hearing was available in the implanted ear.

Secondary endpoints assessed the proportion of subjects who experienced statistically significant improvements on speech performance measures in the implanted ear.

Subject demographics and accountability

Key demographics are shown in Table 5 below.

Demographic Characteristics	Mean \pm SD N (min, max)
Age at CI in Years	64.1 \pm 14.7 50 (23.0 – 86.2)
Duration of Overall Hearing Loss in Years	28.1 \pm 14.9 50 (3.4 – 73.9)
Duration of High Frequency Hearing Loss in Years	13.1 \pm 7.2 50 (1.6 – 30.1*)
Male	25/50 (50.0%)
Female	25/50 (50.0%)
Pre-operative Degree of LF 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%)

* 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.

Table 5: Demographics for the 50 study subjects



Fifty subjects were enrolled and implanted among the investigative sites. Forty-nine of these subjects completed the six month evaluation. One subject was reimplanted with a full length array due to poor performance and loss of hearing sensitivity, and did not complete the six month evaluation. Of these forty-nine subjects, two completed only speech performance and SSQ measures, and one completed only speech perception measures, due to time constraints and clinician preference.

Study inclusion and exclusion criteria

Individuals who presented with the previously described hearing loss and met the specific inclusion/exclusion criteria were included in the study.

Criteria for Inclusion:

1. Eighteen years of age or older at the time of implantation.
2. Severe to profound (a threshold average of 2000, 3000, & 4000 Hz \geq 75dB HL) sensorineural hearing loss for frequencies $>$ 1500 Hz. Low frequency thresholds up to and including 500 Hz should be no poorer than 60 dB HL.
3. CNC word recognition score (mean of two lists) between 10% and 60%, inclusive (i.e., $10\% \leq \text{score} \leq 60\%$), in the ear to be implanted.
4. CNC word recognition score in the contralateral ear equal to, or better than, the ear to be implanted but not more than 80%.
5. English spoken as a primary language.



Clinical trial description

Criteria for exclusion:

1. Duration of severe to profound hearing loss > 30 years.
2. Congenital hearing loss (for the purpose of this study, onset prior to 2 years of age).
3. Medical or psychological conditions that contraindicate undergoing surgery.
4. Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array.
5. Conductive overlay of 15 dB or greater at two or more frequencies, in the range 250 to 1000 Hz.
6. Hearing loss of neural or central origin.
7. Diagnosis of Auditory Neuropathy.
8. Active middle ear infection.
9. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure(s) and prosthetic devices.
10. Unwillingness or inability of the candidate to comply with all investigational requirements.
11. Additional handicaps that would prevent or restrict participation in the audiological evaluations.





Description of tests

CNC Monosyllabic Word Recognition Test (Primary endpoint)

The CNC Monosyllabic Word Recognition Test is a measure of open-set word recognition consisting of 10 recorded lists of 50 monosyllabic words (consonant-nucleus-consonant) such as 'laud' and 'duck'. Two lists were administered in quiet at 60 dBA in the sound field and reported as percent correct for words and phonemes.

AzBio Sentence Test (Primary endpoint)

The AzBio Sentence Test is a measure that consists of 33 lists of 20 sentences (such as 'He cried when the pet goat was sent to market.') that contain low contextual information. Each list includes 5 sentences from each of four different speakers (two male, two female). Two lists of the AzBio sentences were presented at 60 dBA with competing noise (babble) presented at a level to achieve a +5 dB signal-to-noise ratio from the same loudspeaker.

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

The UW-CAMP test consists of three subtests each designed to provide an assessment of fundamental auditory skills important for music perception. The three subtests were presented at 65 dBA and provided an assessment of pitch perception, melody recognition and timbre.



Clinical trial description

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

The SSQ is a validated self-assessment metric commonly used in hearing aid and cochlear implant research. It is designed to measure self-reported auditory disability across a wide variety of domains, reflecting the reality of hearing in the everyday world. There are 49 questions 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 – hearing speech in quiet and in noise, one-on-one conversation and in groups/meetings
- Spatial hearing scale – hearing where sounds are coming from, distance, movement, and ability to segregate sounds
- Qualities of sound scale – ease of listening, naturalness, clarity, identification of different speakers, musical pieces and instruments as well as everyday sounds.

Device Use Questionnaire (DUQ)

This questionnaire (~90 questions) was developed by Cochlear and is used to collect information regarding device usability, subjective preferences and satisfaction with regards to device use in various listening conditions. The questions summarized in this document are those related to patient satisfaction; excluded questions centered around descriptions of device use by the study subjects.



Clinical trial results

Speech perception

Implant Ear Alone Condition (Co-Primary Endpoints)

Understanding Speech in Quiet – CNC Monosyllabic Word Test

Forty-nine of fifty subjects had CNC word recognition scores available pre- and post-operatively after six months of experience using the Nucleus Hybrid L24 cochlear implant in the Implant Ear Alone condition.

- Average performance after six months experience with the Implant Ear Alone condition was significantly higher than average performance for the subjects using a 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 for the 49 subjects.

Note

Data presented in this section does not include interpolation for the one subject who did not complete the primary study endpoint.



Clinical trial results

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

Forty-nine of fifty subjects had AzBio sentence recognition in noise (+5 dB SNR) scores available pre- and post-operatively after six months of experience using the Cochlear Nucleus Hybrid L24 cochlear implant in the Implant Ear Alone condition.

- Average performance after six months experience with the Implant Ear Alone condition 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 for the 49 subjects.





Additional test measures – Everyday Listening condition

Understanding Speech in Quiet – CNC Monosyllabic Word Test

Forty-nine of fifty subjects had CNC word recognition scores available pre- and post-operatively after six months of experience using the Nucleus Hybrid L24 cochlear implant in the Everyday Listening condition.

- Average performance after six months experience with the Everyday Listening condition was significantly higher than average performance for the subjects 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 in the Everyday Listening condition for the 49 subjects.
- After six months of experience using the Everyday Listening condition:
 - 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.
- Approximately half of the recipients recognized 84.0% or more of the words (CNC) and approximately three quarters recognized 67.0% or more words after six months experience in the Everyday Listening condition.



Clinical trial results

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

Forty-nine of fifty subjects had AzBio sentence recognition in noise (+5 dB SNR) scores available pre- and post-operatively after six months of experience using the Cochlear Nucleus Hybrid L24 cochlear implant in the Everyday Listening condition.

- Average performance after six months experience with the Everyday Listening condition 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 for the 49 subjects.
- After six months of experience using the Everyday Listening condition:
 - 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.
- Approximately half of the recipients recognized 71.6% or more of the words in a sentence when in background noise and approximately three quarters recognized 43.4% or more of the words in a sentence in background noise after six months experience in the Everyday Listening condition.



Proportion of subjects demonstrating similar performance or improved performance

As shown in Table 6, the secondary endpoints were met and exceeded for both metrics, as most (> 75%) of the subjects scored equal to or better than they did in the preoperative Unilateral Acoustic-Only condition. Though it was not a primary or secondary endpoint, when the Everyday Mode at six months is considered in the analysis, an even higher proportion of subjects showed significant improvement. Additionally, Table 7 shows the proportion of subjects with post-operative scores better than those obtained pre-operatively by the six month study interval.

Listening Mode	CNC Words	CNC Phonemes	AzBio in Noise
Implant Ear Alone (Study Endpoint)	96.0%	91.8%	89.8%
Everyday Condition	100%	100%	100%

Table 6: Proportion of subjects with post-operative score equal to or better than pre-operative at the six month study interval

Listening Mode	CNC Words	CNC Phonemes	AzBio in Noise
Implant Ear Alone (Study Endpoint)	81.6%	85.7%	73.5%
Everyday Condition	87.8%	89.9%	83.7%

Table 7: Proportion of subjects with post-operative score better than pre-operative at the six month study interval





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

Everyday Listening condition

Forty-six of fifty subjects had Pitch Discrimination scores available pre- and post-operatively after six months of experience using the Cochlear Nucleus Hybrid L24 cochlear implant in the Everyday Listening condition.

Pitch Discrimination

- Average pitch discrimination ability was similar to that observed for normally hearing individuals.¹
- Performance remained unchanged pre-operatively with two hearing aids to post-operatively at six months in the Everyday Listening condition.
 - 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 for the 46 subjects.
- After six months of experience using the Everyday Listening condition:
- Most recipients (42/46; 91.3%) demonstrated similar (within 1 semitone) or better pitch discrimination compared with their pre-operative performance using two hearing aids.
- Pitch discrimination ranged from 0.5 to 3.7 semitones after six months experience in the Everyday Listening condition.
- Approximately half of the recipients had pitch discrimination of 0.7 semitones or better and approximately three-quarters had pitch discrimination of 1.5 semitones or better after six months experience in the Everyday Listening condition.

1 Kang, S.Y., Nimmons, G.L., Drennan, W., Longnion, J., Ruffin, C., Nie, K., Won, J.H., Worman, T., Yueh, B., Rubinstein, J. (2009). Development and validation of the University of Washington clinical assessment of music perception test. *Ear Hear*, 30(4), 411-418.





Implant Ear Alone condition

Forty-six of fifty subjects had Pitch Discrimination scores available pre- and post-operatively after six months of experience using the Cochlear Nucleus Hybrid L24 cochlear implant in the Implant Ear Alone condition.

Pitch Discrimination

- Average performance remained relatively unchanged pre-operatively with one hearing aid to post-operatively at six months in the Everyday Listening condition
 - 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 for the 46 subjects.
- After six months of experience using the Implant Ear Alone listening condition:
- Most recipients (42/46; 91.3%) demonstrated similar (within 1 semitone) or better pitch discrimination compared with their pre-operative performance using one hearing aid.
- Pitch discrimination ranged from 0.5 to 8.9 semitones after six months experience in the Implant Ear Alone condition.
- Approximately half of the recipients had pitch discrimination of 0.9 semitones or better and approximately three-quarters had pitch discrimination of 1.8 semitones or better after six months experience in the Everyday Listening condition.



Clinical trial results

Device Use Questionnaire – Music

- When compared to pre-operative levels, satisfaction improved across all six music/sound quality related areas at the six month 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 – Everyday Listening condition

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

Forty-eight of fifty subjects had SSQ ratings available pre- and post-operatively after six months of experience using the Cochlear Nucleus Hybrid L24 cochlear implant in the Everyday Listening condition.



Speech Hearing Rating Scale

For this scale subjects answered questions concerning how well they heard and understood speech in various quiet and noisy situations involving one-on-one conversations and communication in small and large groups of people. The subject rated their ability to hear on a scale from 1 to 10, where 1 represented the poorest rating possible and 10 represented the best rating possible. A difference in a rating of 1 to 2 was indicative of a change in self-perceived benefit. Changes of more than 2 and less than 4 were indicative of high self-perceived benefit with changes of 4 or more indicative of very high self-perceived benefit.

- Average performance after six months experience with the Everyday listening condition was significantly higher than average performance for the subjects using two hearing aids prior to implantation.
 - Average SSQ ratings for the Speech Hearing Scale were 3.2 (0.8 – 6.2) out of 10 pre-operatively with two hearing aids and 5.4 (0.7 – 8.8) out of 10 at six months in the Everyday listening condition for the 48 subjects.
- After six months of experience using the Everyday Listening condition:
 - Most recipients (45/48; 93.8%) demonstrated similar or better ratings for the Speech Hearing Scale compared with their pre-operative performance using two hearing aids
 - Most (37/48; 77.1%) reported benefit to very high benefit on the Speech Hearing Scale compared with their pre-operative performance using two hearing aids.
 - 3/48 (6.3%) reported a negative benefit rating
 - 8/48 (16.7%) reported no change on the Speech Hearing Scale



Clinical trial results

- 11/48 (22.9%) reported benefit (1 to 2) on the Speech Hearing Scale
- 20/48 (41.7%) reported high benefit (2 to 4) on the Speech Hearing Scale
- 6/48 (12.5%) reported very high benefit (4 or more) on the Speech Hearing Scale.

Spatial Hearing Rating Scale

For this scale subjects answered questions concerning how well they could judge 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). The subject rated their ability to hear on a scale from 1 to 10, where 1 represented the poorest rating possible and 10 represented the best rating possible. A difference in a rating of 1 to 2 was indicative of a change in self-perceived benefit. Changes of more than 2 and less than 4 were indicative of high self-perceived benefit with changes of 4 or more indicative of very high self-perceived benefit.

- Average performance after six months experience with the Everyday Listening condition was significantly higher than average performance for the subjects using two hearing aids prior to implantation.
 - Average SSQ ratings for the Spatial Hearing Scale were 4.6 (1.4 – 9.2) out of 10 pre-operatively with two hearing aids and 5.5 (1.1 – 8.3) out of 10 at six months in the Everyday Listening condition for the 48 subjects.





- After six months of experience using the Everyday Listening condition:
 - Most recipients (39/48; 81.3%) demonstrated similar or better ratings for the Spatial Hearing Scale compared with their pre-operative performance using two hearing aids
 - Many (26/48; 54.2%) reported benefit to very high benefit on the Speech Hearing Scale compared with their pre-operative performance using two hearing aids.
 - 9/48 (18.8%) reported a negative benefit rating
 - 13/48 (27.1%) reported no change on the Spatial Hearing Scale
 - 12/48 (25.0%) reported benefit (1 to 2) on the Spatial Hearing Scale
 - 13/48 (27.1%) reported high benefit (2 to 4) on the Spatial Hearing Scale
 - 1/48 (2.1%) reported very high benefit (4 or more) on the Spatial Hearing Scale.

Sound Qualities Rating Scale

For this scale subjects answered questions concerning how well they could separate and sort out sounds, how well they could recognize different sounds, how clear or natural sounds were, and how much effort listening required. The subject rated their ability to hear on a scale from 1 to 10, where 1 represented the poorest rating possible and 10 represented the best rating possible. A difference in a rating of 1 to 2 was indicative of a change in self-perceived benefit. Changes of more than 2 and less than 4 were indicative of high self-perceived benefit with changes of 4 or more indicative of very high self-perceived benefit



Clinical trial results

- Average performance after six months experience with the Everyday Listening condition was significantly higher than average performance for the subjects using two hearing aids prior to implantation.
 - Average SSQ ratings for the Sound Qualities Scale were 5.0 (1.6 – 8.1) out of 10 pre-operatively with two hearing aids and 6.3 (2.7 – 9.1) out of 10 at six months in the Everyday Listening condition for the 48 subjects.
- 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 using two hearing aids
 - Many (28/48; 58.3%) reported benefit to very high benefit on the Sound Qualities Scale compared with their pre-operative performance using two hearing aids.
 - 5/48 (10.4%) reported a negative benefit rating
 - 15/48 (31.3%) reported no change on the Sound Qualities Scale
 - 8/48 (16.7%) reported benefit (1 to 2) on the Sound Qualities Scale
 - 16/48 (33.3%) reported high benefit (2 to 4) on the Sound Qualities Scale
 - 4/48 (8.3%) reported very high benefit (4 or more) on the Sound Qualities Scale.



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%.



Safety analysis

Hearing sensitivity

This study involved implanting subjects with functional low frequency hearing. Changes in hearing sensitivity were assessed and those that resulted in profound (> 90 dB HL) loss of low frequency hearing were also reported as anticipated adverse events.

Changes in low frequency hearing sensitivity at the six month study endpoint are summarized below:

- 33 subjects maintained hearing of a severe degree or better, referred to as functional acoustic hearing
- 17 experienced a decrease in low frequency hearing resulting in profound loss of hearing, referred to as nonfunctional acoustic hearing.

It is difficult to predict on an individual basis what post-operative hearing will be since the causes are likely multi-factorial. Pre- and post-operative hearing sensitivity changes at the six month endpoint are summarized below:

- Of the 14 subjects who began with a low frequency PTA of 40dB or better, 13 subjects had a post-operative low frequency PTA of 90dB or better (92.3%)
- Of the 26 subjects who began with a low frequency PTA of between 41dB and 55dB, 17 subjects had a post-operative low frequency PTA of 90dB or better (65.4%)
- Of the 10 subjects who began with a low frequency PTA of between 56dB and 70dB, 3 subjects had a post-operative low frequency PTA of 90dB or better (30.0%).





For the CNC word test in the implant ear alone condition, 96.0% of subjects performed equal to or better at the six month interval, as compared to pre-operative performance. For the AzBio sentence in noise test in the implant ear alone condition, 89.8% of subject performed equal to or better. No subject, regardless of changes in low frequency hearing, showed a significant decrement in speech perception pre- to post-operatively in the Everyday condition, regardless of the level of post-operative hearing. Averaged across frequencies, the largest drop 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.

As documented in the clinical study results, a percentage of individuals will lose their pre-operative low frequency acoustic hearing as a result of Cochlear Nucleus Hybrid L24 cochlear implant surgery. This known risk is disclosed in the Cochlear Nucleus Hybrid L24 cochlear implant system labeling and is strongly recommended as an integral component of pre-operative surgical and device counseling. Irrespective of the post-operative hearing status, most individuals can still be expected to receive substantial functional and speech recognition benefit in the Everyday condition when compared to pre-operative Bilateral Acoustic Mode.



Performance Based on Post-operative Hearing Sensitivity

Figure 2 plots pre-operative and six month postactivation mean scores for subjects with and without functional post-operative acoustic hearing for the CNC Word Recognition Test. Significant pre- to post-operative improvement was evident in both subpopulations, in both implant ear alone (left graph) and everyday conditions (right graph). In the Everyday condition, performance of subjects with functional acoustic hearing (Severe or Better) was 7 percentage points better when compared to the Implant Ear Alone, with a range of -13 to 46 percentage points. The Everyday condition performance of subjects who had nonfunctional acoustic hearing (Profound) was 28 percentage points better than the Implant Ear Alone condition, with a range of -4 to 64 percentage points. It is important to consider that when making use of the Hybrid cochlear implant in concert with all available acoustic hearing, significant improvement was noted for subjects with and without functional acoustic hearing in the implant ear.

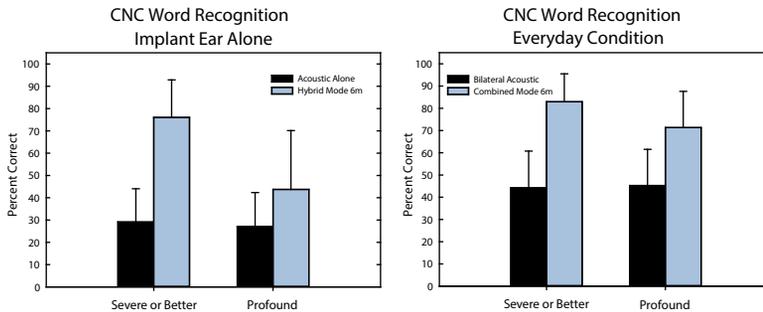


Figure 2: Pre- and 6 month postactivation mean scores for the CNC test for subjects who retained functional acoustic hearing (Severe or Better) and subjects who had nonfunctional acoustic hearing (Profound). The vertical line on each bar represents a +1 Standard Deviation.



Figure 3 plots pre-operative and six month postactivation mean scores for subjects with and without functional post-operative acoustic hearing for the AzBio Sentences in Noise Test. Significant improvement was observed in mean performance for both groups, with the exception of the Implant Ear Alone condition for subjects with nonfunctional acoustic hearing (Profound). In the Everyday condition, performance of subjects with functional acoustic hearing was 7 percentage points better over the Implant Ear Alone, with a range of -11.1 to 42.0 percentage points. The Everyday condition performance of subjects with nonfunctional acoustic hearing was 25 percentage points better than the Implant Ear Alone condition, with a range of -0.4 to 81.5 percentage points. It is important to consider that when making use of the Hybrid cochlear implant in concert with all available acoustic hearing, significant improvement was noted for subjects with and without functional acoustic hearing in the implant ear.

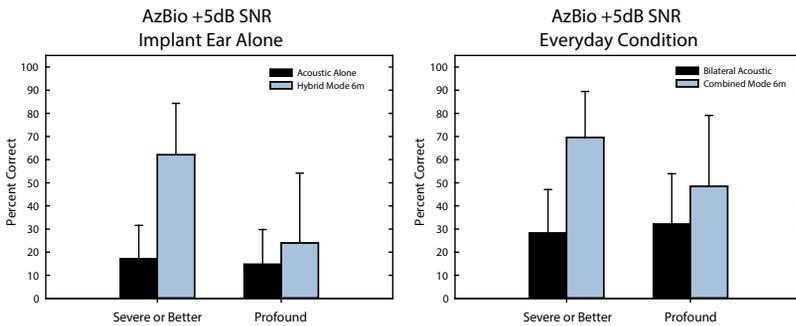


Figure 3: Pre- and 6 month postactivation mean scores for the AzBio test for subjects who retained functional acoustic hearing (Severe or Better) and subjects who had nonfunctional acoustic hearing (Profound). The vertical line on each bar represents a +1 Standard Deviation.





Explantation

Six subjects have been explanted and reimplanted with a conventional cochlear implant. All of these subjects had nonfunctional acoustic hearing and dissatisfaction with post-operative performance, coupled with either no change or a decrease in performance when compared to pre-operative hearing aid performance in the implanted ear. Explantation occurred at 175 days post implantation at the earliest, and 959 days post-implantation at the latest, with an average of 561 days post-implantation.

Each of these subjects underwent a revision surgery with no complications and were implanted with a conventional electrode array. Post-revision reports for four of the subjects indicate improvement in performance as compared to their pre-operative hearing aid condition, as well as prerevision Hybrid outcomes. Their performance is consistent with that seen in standard length CI recipients. Only limited data regarding two subjects' pre- and post-explant performance was available.





Adverse events

The primary safety endpoint was defined as any surgical and/or device-related event, reported as the number and proportion of individuals experiencing the adverse event across the duration of the study. See Table 8 below for a list of Adverse events:

Event	Number of Events	Percentage of Events	Number of Subjects with Event	Percentage of Subjects	Percentage Resolved
Profound Loss	22	31.0%	22	44.0%	0.0%
Open/short circuited electrodes	11	15.5%	11	22.0%	100.0%
Increased tinnitus	6	8.5%	6	12.0%	100.0%
Tinnitus not present pre-operatively	6	8.5%	6	6.0%	100.0%
Explantation/ Reimplantation	6	8.5%	6	12.0%	100.0%
Dizziness	3	4.2%	3	4.0%	100.0%
Dizziness with change in hearing	2	2.8%	2	4.0%	100.0%
Increased tinnitus with change in hearing	2	2.8%	2	4.0%	100.0%
Skin irritation due to externals	2	2.8%	2	4.0%	100.0%
Sound quality issue	2	2.8%	2	4.0%	50.0%
Decrease in performance	1	1.4%	1	2.0%	0.0%
Imbalance	1	1.4%	1	2.0%	100.0%
Imbalance with change in hearing	1	1.4%	1	2.0%	100.0%
Increased impedances with change in hearing	1	1.4%	1	2.0%	100.0%
Local stitch infection	1	1.4%	1	2.0%	100.0%
Overstimulation	1	1.4%	1	2.0%	100.0%
Pain in implant ear	1	1.4%	1	2.0%	100.0%
Vertiginous symptoms with change in hearing	1	1.4%	1	2.0%	100.0%
Vertigo	1	1.4%	1	2.0%	100.0%





Safety analysis

Table 8: Number and percentage of adverse events observed for Hybrid L24 subjects

As this study involved implanting subjects with low frequency hearing, unlike prior cochlear implant clinical trials, changes in hearing sensitivity were assessed and those that resulted in profound (> 90 dB HL) loss of low frequency hearing were also reported as anticipated adverse events.





Pre-operative counseling

Prospective cochlear implant candidates should be counseled regarding potential benefits, warnings, precautions and adverse effects of Cochlear Nucleus Hybrid L24 implantation, using the information in this document.





Notes

A series of 20 horizontal dotted lines for taking notes.





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Cochlear implant systems are protected by one or more international patents.

The statements made in this guide are believed to be true and correct as of the date of publication. However, specifications are subject to change without notice.

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Hear now. And always

415755 ISS3 MAR14



Cochlear™

Nucleus® Hybrid™ L24 cochlear implant CI24REH

Patient Information

Important: Warnings, Precautions and
Electromagnetic Compatibility



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.





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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 6 Sound Processor including coil/cable, battery module, and Remote Assistant, 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 ($<90\text{dB}$).
- Nonfunctional Acoustic Hearing – Acoustic (rather than electric) hearing of a profound degree ($\geq 90\text{dB}$).





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 CP900 series with associated 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 \geq 75 dB HL), and moderately severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 Hz \geq 60 dB HL) in the contralateral ear.
- The 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)

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.

Ionizing radiation therapy

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

Magnetic Resonance Imaging (MRI)



MRI is contraindicated for patients with the Cochlear Nucleus Hybrid cochlear implant.



Things you must do to avoid serious harm (Warnings)

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 minimize the chance of experiencing head trauma see http://www.cdc.gov/ncipc/pub-res/tbi_toolkit/patients/preventing.htm





Things you must do to avoid serious harm (Warnings)

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 by themselves, or 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)

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 +50 °C (+122 °F) or less than -20 °C (-4 °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.



Things you must do to avoid other harm (Precautions)

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.



Things you must do to avoid other harm (Precautions)

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.



Things you must do to avoid other harm (Precautions)

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.





Things you must do to avoid other harm (Precautions)

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





Things you must do to avoid other harm (Precautions)

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 <i>Electrostatic discharge</i> on page 16
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	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 <i>Warnings</i> and <i>Precautions</i> sections, and <i>Guidance</i> below

Table 3: Electromagnetic immunity





Things you must do to avoid other harm (Precautions)

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):

$$d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$$

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.





Things you must do to avoid other harm (Precautions)

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.



Things you must do to avoid other harm (Precautions)

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.



Things you must do to avoid other harm (Precautions)

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 fibers 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%) utilize 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 summarized below:

- 33 subjects maintained hearing of a severe degree or better, called functional acoustic hearing
- 17 experienced a decrease in low frequency hearing resulting in profound loss of hearing, called nonfunctional acoustic hearing.



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

Five more 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 nonfunctional 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 nonfunctional 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 nonfunctional acoustic hearing, scores increased from 45.3% to 71.3%.



Risks of receiving the Cochlear Nucleus Hybrid cochlear implant

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 nonfunctional 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 both functional and nonfunctional 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 nonfunctional 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 nonfunctional acoustic hearing, scores increased from 32.1% to 48.4%.



Risks of receiving the Cochlear Nucleus Hybrid cochlear implant

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 nonfunctional 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 nonfunctional 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 nonfunctional 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 (4 weeks after surgery). Average thresholds at the 3, 6, and 12 month intervals are consistent across time intervals.





Risks of receiving the Cochlear Nucleus Hybrid cochlear implant

Below is a table that summarizes 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





Risks of receiving the Cochlear Nucleus Hybrid cochlear implant

Event: Implantation with Cochlear Nucleus Hybrid cochlear implant			
Hazard	How often patient had the hazard	Harm	How often this hazard harmed them
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 patients
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





Risks of receiving the Cochlear Nucleus Hybrid cochlear implant

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 explantation 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 understand speech in both quiet and noisy environments
- 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 LF 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%)

* 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.

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.

Description of Tests

CNC Monosyllabic Word Recognition Test (Primary endpoint)

The CNC Monosyllabic Word Recognition Test 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 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 5dB louder than the competing noise, from the same loudspeaker.



How we studied the Cochlear Nucleus Hybrid cochlear implant

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

The UW-CAMP test 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 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:

The SSQ is a validated self-assessment widely used in hearing research. It is made to test the extent of hearing disability in a variety of situations. This way, it can capture the reality of hearing in the everyday world. There are 49 questions scored by the subject on a scale of 0 to 10. 0 corresponds to minimal ability, and 10 corresponds to complete ability. There are three different areas that are tested:

- 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.





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.





How we studied the Cochlear Nucleus Hybrid cochlear implant

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.



How we studied the Cochlear Nucleus Hybrid cochlear implant

- 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.



How we studied the Cochlear Nucleus Hybrid cochlear implant

80% (40/50) of recipients scored significantly better on word understanding in the implant ear than with a hearing aid alone.

100% (50/50) of subjects score same or better in quiet and noise when using the Cochlear Nucleus Hybrid cochlear implant in one ear and a hearing aid in the other ear than with hearing aids alone.

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 individuals¹
- 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 1 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.





How we studied the Cochlear Nucleus Hybrid cochlear implant

Sound Qualities Rating Scale

The Sound Qualities Scale addressed how well subjects could separate and sort out sounds and how well they could recognize 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%.



Where you can find more information

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.







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Hear now. And always

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