CI622

Cochlear™ Nucleus® CI622 cochlear implant with Slim Straight electrode

Physician's Guide

United States of America

For Professionals

Hear now. And always

Cochlear®

About this guide

This guide applies to the Cochlear™ Nucleus® CI622 cochlear implant, which is a CI600 Series implant.

This guide is intended for surgical staff involved in implanting the device.

Surgeons implanting the device should be experienced in cochlear implant surgery.

Before surgery, ensure you are thoroughly familiar with the information in this guide and the product labelling. The guide includes important information on MRI, indications, contraindications, adverse effects, warnings and precautions. A surgical procedure for implanting the device is also explained.

This guide does not take account of any particular circumstances or factors relevant to an individual patient or case. Other surgical approaches and variations are practised and may be more appropriate in certain circumstances. After considering all relevant circumstances, factors and information in each case, the appropriate surgical procedure is determined by the relevant physician exercising independent medical judgment.

Symbols used in this guide

Note

Important information or advice.

Caution (no harm)

Special care to be taken to ensure safety and effectiveness.

Could cause damage to equipment.

Warning (harmful)

Potential safety hazards and serious adverse reactions.

Could cause harm to person.

Contents

Warnings and Cautions for device use

This section does not contain all the important information required to use and implant the device, only critical information to implant the device safely and effectively. Read the full ***Physician's Guide*** before implanting the device.

⚠ Warnings

Pre-operative

- **Meningitis** is a known risk of inner ear surgery. You should counsel candidates of this risk and determine their immunisation status for micro-organisms that cause meningitis.
- **Wound infection** after cochlear implant surgery or explantation may be prevented by administering broad-spectrum antibiotic before and during surgery.
- The implant is sterilised using **ethylene oxide (EtO)**. After the sterilisation process, residual EtO is less than 0.4 mg per device. This residual level is suitable for a recipient with a body weight of 7 kg or greater.*
- Cochlear Nucleus implants contain magnets, which should be kept away from neurostimulation devices (for example, deep brain stimulators) and magnetic ventricular shunts, as the magnets may affect the function of these devices. The maximum magnetic field strength at 2.5 cm (1 in) from the edge of the implant, with or without external sound processor magnet coupled to it, in any direction is less than 300 gauss.
- To reduce the risk of anaesthetic-related adverse events, a paediatric anaesthesiologist should be present during surgery for infants implanted under 12 months of age.

* Calculated with guidance from EN ISO 10993-7.

Medical treatments generating induced currents, heat and vibration

- **Electrosurgical instruments** can induce radio frequency currents that could flow through the electrode.

  When using bipolar electrosurgical instruments on the head and neck of a patient, the cautery electrodes must not contact the implant and should be kept more than 1 cm (½ in) from the electrodes.

- **High currents** induced into the electrode lead can cause damage to cochlea and neural tissues, and the implant.

  Do not use:

  – **monopolar electrosurgical instruments** on the head or neck of an implant patient.

  – **therapeutic or medical diathermy** (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave).

  – **neurostimulation** directly over the implant.

- **Ultrasound fields** can be inadvertently concentrated at the implant and cause tissue damage or damage to the implant.

  Do not use:

  – **therapeutic levels of ultrasound energy** directly over the implant

  – **medical diathermy using ultrasound** on the head and neck of an implant patient.

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

Magnetic Resonance Imaging (MRI)

The Cochlear Nucleus CI622 implant is **MR Conditional**. MRI is contraindicated except under specific circumstances. Refer to *MRI safety information* on page 84.

Cautions

- When using **sharp instruments** near the implant, take care to avoid nicking or damaging the case, insulation, electrode lead, exposed magnet cassette cover or non-magnetic cassette cover.
- **Ionising radiation therapy** can cause damage to the implant. Do not use ionising radiation therapy directly over the implant.

Note

- **Facial nerve monitor** use is advised, particularly for cases where the facial nerve may be at greater risk such as congenital temporal bone anomalies and revision surgeries.

Intended use and indications

Intended use

Cochlear Nucleus CI600 Series implants are prescription only, single use devices intended for long term implantation under the skin in the mastoid region of either side of the head.

Indications

The cochlear implant is intended to restore a level of auditory sensation via electrical stimulation to the auditory nerve. Both adults and paediatrics are candidates for cochlear implantation. There is an indication for adult and paediatric candidates with bilateral sensorineural hearing loss and an indication for adult and paediatric candidates with unilateral hearing loss or single sided deafness.

Bilateral Sensorineural Hearing Loss

Adults

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

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

Children

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

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

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

In older children, limited benefit is defined as ≤ 30% correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A 3 month to 6 month hearing aid trial is recommended for children without previous aided experience.

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

Adults and children

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

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

Contraindications

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

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

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

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

Note

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

Adverse effects

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

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

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

Meningitis

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

Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk. Certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- CSF shunts or drains
- recurrent episodes of bacterial meningitis before implantation
- perilymph fistulas and skull fracture/defect with CSF communication.

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

Loss of residual hearing

Inserting the electrode into the cochlea may result in complete loss of residual hearing in the implanted ear.

Results of clinical studies

The following information summarises adverse events (AEs) for adults and children implanted with the Cochlear Nucleus 24 cochlear implant system. The studies referenced below included individuals with bilateral sensorineural hearing loss and single sided deafness (SSD); however, safety information may apply to any person who receives a cochlear implant.

1. Summary of safety data - adults

Adult safety data are based on a total of 133 patients implanted with the Cochlear Nucleus 24 cochlear implant during the adult clinical investigation at 27 US sites.

- 20 patients experienced either a medical or surgical complication, or a device-related complication.
- 11 of the 20 complications were medical or surgical in nature and the remaining nine were device-related.
- 18 of the 20 AEs resolved without surgical or extensive medical intervention.

Medical or surgical complications[1]

- One patient experienced device migration which required revision surgery to reposition the device.
- One patient experienced a wound haematoma which required minor surgery to resolve.
- One patient experienced a slightly compressed electrode array and the surgeon elected to remove the device and replace it with a second one during the initial surgery.
- Four patients experienced facial nerve stimulation. All cases of facial nerve stimulation were resolved through reprogramming.

1 Medical or surgical complications would be classified today as a procedure related adverse event.

- Two patients experienced tinnitus related to cochlear implant use.
- One case resolved without intervention and the second case was resolved through reprogramming.
- One patient experienced short-term postoperative dizziness which resolved without medical treatment.
- One patient experienced fluctuating psychophysical levels related to a relatively thick (10+ mm) skin flap. This case was resolved through replacement of external equipment.

Device-related complications

No device failures or other serious device malfunctions occurred during this study.

- Four patients experienced electrode insulation faults (short circuits) that were resolved through reprogramming.
- Two patients were inadvertently overstimulated during device programming.
- One patient reported a nonauditory sensation during device programming.
- Two patients experienced a mild skin reaction to the sound processor cable. These were resolved completely with topical medical treatment.

2. Summary of safety data - children 12 months and older

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

For the first clinical investigation, 150 children were implanted with Cochlear Nucleus 24 cochlear implants:

- 24 patients experienced 27 medical or surgical complications, or device related complications.
  - 9 of the 27 complications were medical or surgical in nature.
  - The remaining 18 were device-related complications.
  - 24 of the complications resolved without surgical or extensive medical intervention.

Medical or surgical complications[1]

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

1 Medical or surgical complications would be classified today as a procedure related adverse event.

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

Device-related complications

No device failures or other serious device malfunctions were observed.

- 13 patients experienced electrode faults (short-circuit or open-circuit electrodes) on one or more electrodes. All of these cases were resolved through reprogramming.
- One patient experienced non-auditory sensations during psychophysical testing. This case was resolved through reprogramming.
- One patient experienced an unanticipated overstimulation. This complication was resolved through replacement of external equipment.
- Three patients experienced mild skin reactions to the sound processor cable:
  - One case was resolved through covering the cable.
  - One case was resolved through an alternative polyurethane coating of the cable.
  - One case resolved spontaneously without intervention.

3. Summary of safety data - children 9 months to 12 months old

3.1 Premarket study

Cochlear performed a premarket, prospectively-designed, retrospective analysis from its own registry data to establish a reasonable assurance of safety of implantation with the Cochlear Nucleus 24 cochlear implant system for paediatric patients between the ages of 9 months and 12 months.

The retrospective review of 83 children that were between 9 months and 12 months of age and implanted with Cochlear Nucleus cochlear implants was completed for this analysis.

Device-related complications, such as electrode faults, were not captured in this study.

Twenty-four patients experienced 28 medical or surgical complications and 26 of the complications were resolved without major surgical or medical intervention:

- Six patients experienced minor postoperative complications, four of which were resolved without medical intervention.
- Two patients experienced cerebral spinal fluid leakage perioperatively. These were repaired during the cochlear implant surgery.
- One patient required a revision surgery with reimplantation.
- Two patients experienced postoperative infections including mastoiditis, postauricular abscess, and surgical site infection. All the infections were medically managed.
- Two patients developed seromas and one of these patients was reimplanted.
- Two patients experienced temporary facial weakness which resolved with steroid administration. There were no reports of postoperative meningitis.

Overall, the above AEs are typical surgical, procedure or device events observed in children implanted at a relatively young age.

Additionally, in February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess safety of implantation with a Cochlear Nucleus cochlear implant in children between the ages of 9 months and 12 months.

A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old. Safety studies that included children implanted at less than 12 months old covered a broad range of topics from surgical complications including:

- anaesthesia
- blood loss
- postoperative pain and dizziness
- wound healing problems
- infections.

The research literature reviewed on surgical and postoperative outcomes reported specific to the population under the age of 12 months at implantation did not identify an elevated incidence of complications.

3.2 Post-approval study

Summary of the post-approval study methods

Cochlear performed a post-approval, prospectively-designed, retrospective analysis among 83 patients who were enrolled in the premarket study and 50 additional patients – data collected out to two years postoperatively – to assess long-term safety of cochlear implantation in children between 9 months and 12 months of age.

The purpose of this study was to supplement the premarket study with:

- additional patient profiles of children implanted more recently
- longer-term outcomes data.

Data was collected from medical records and chart notes.

Summary of the post-approval study results

Adverse events (AEs) included any device, procedure, and otologic-related unexpected medical occurrences occurring from time of surgery through two years postoperatively.

The AEs were classified as major or minor AEs using well-established criteria (Cohen & Hoffman, 1991).

- Major AEs were defined as those requiring hospitalisation and/or additional surgical intervention.
- Minor AEs were defined as those using the expected route of treatment and/or medication.

Seventeen new AEs were reported in this post-approval dataset of 133 total patients.

- 6 AEs were reported for the extended study group of 83 patients for either:
  - AEs spanning between 6 months to 24 months postoperatively
  - or AEs that had not been previously reported in the original dataset.
- 11 AEs were reported for the 50 new patients.

Of the 17 new AEs, five were considered major AEs and 12 were considered minor AEs:

- Four patients experienced postoperative complications.
- Eight patients experienced ear-related infections, four of which were considered major AEs:
  - one patient developed seroma and was reimplanted.
  - one patient with bilateral acute otitis media was re-hospitalised for myringotomy and tubes.
  - one patient was noted to have recurrent ear infections.
  - one patient reported chronic middle ear dysfunction.
- One patient was readmitted to the hospital postoperatively with a fever and received fluids and antibiotics, categorised as a major AE.
- One patient experienced cerebral spinal fluid leakage during surgery.
- Three patients experienced minor AEs that did not fall into the categories above.

There were no unanticipated AEs reported in this new dataset of 133 patients. All 17 AEs were reported as resolved.

Primary safety endpoint

The combined dataset of 133 patients demonstrates the overall safety of cochlear implantation in children between 9 months and 12 months of age. The rate of AEs gathered in the post-approval study is qualitatively similar to the AEs reported in the original pre-market study from 6 months to 24 months. There were differences seen between the groups 0 months to 6 months, with a higher rate of AEs for the premarket study group. Refer to ***Table 1***.

Group	0-6 months postoperative	6-24 months postoperative	0-24 months postoperative
83 premarket study patients (N=143 ears)	42 AEs (29.4%)	5 AEs (3.5%)	47 AEs (32.9%)
50 new patients (N=82 ears)	9 AEs (11.0%)	2 AEs (2.4%) AEs	11 AEs (13.4%)
133 combined patients (N=223 ears)	51 AEs (22.7%)	7 AEs (3.1%)	58 AEs (25.8%)

Table 1: Primary safety endpoint

Group: premarket study patients

A total of 42 AEs for patients initially enrolled during the premarket study were collected and resolved between 0 months and 6 months postoperatively, yielding a complication rate of 29.4%.

An additional five AEs were collected and reported as resolved during the expanded 6 month to 24 month postoperative time window for this patient group.

Of the five AEs reported during this time window:

- two were new AEs
- three were previous AEs that began during the 0 month to 6 month postoperative window, but were not resolved until 6 months to 24 months postoperatively.

These five AEs yield a complication rate of 3.5%.

There was a total complication rate of 32.9% for the 47 AEs collected 0 months to 24 months for this group.

Group: new patients

A total of nine AEs were reported for the new patients during the 0 months to 6 months postoperative time period, yielding a complication rate of 11%.

- Two AEs began during the 0 months to 6 months reporting window but were not resolved until the 6 month to 24 month period, yielding a complication rate of 2.4%.
- No AEs beginning beyond the 6 month time period were reported for this new patient group.

There was a total complication rate of 13.4% for AEs collected 0 months to 24 months for this group.

Complication rates for the premarket study were collectively higher than the new patients, especially in the 0 months to 6 months range. However, there is evidence of surgical protocol improvement for the postmarket study, leading to improved surgical outcomes and decreased reported complication rates.

Group: combined

Of the 58 AEs reported across the combined group of 133 patients, with data collected 0 months to 24 months postoperatively:

- 13 AEs met criteria as a major AE equating to an incidence rate of 5.8%.
- 45 AEs met criteria as a minor AE, equating to an incidence rate of 20.0%.

Findings of this post-approval study align with published cochlear implant literature specific to the paediatric population for major AEs related to cochlear implants, which ranges between 1.5% and 6.6% of all cases across variable postoperative time periods.

Minor AEs in this combined dataset were reported at a higher incidence rate than published literature due to variation in categorisation criteria and reporting timelines.

In summary, data collected as part of the premarket study and this subsequent post-approval study provide a dataset of over 100 patients who received a Cochlear Nucleus cochlear implant between 9 months and 12 months of age. Data was collected postoperatively out to two years or date of final protocol approval (May 15, 2020).

The data provided continues to support the safety of cochlear implantation with the Cochlear Nucleus device in infants as young as 9 months of age. Findings of this post-approval study demonstrate agreement with previously published literature (Cohen & Hoffman, 1991; Farinetti et al., 2014; Ikeya et al., 2013; Loundon et al., 2010; Petersen et al., 2018) for the primary safety endpoint.

The following information summarises effectiveness data for adults and children implanted with the Cochlear Nucleus 24 cochlear implant system.

4. Summary of effectiveness data - adults

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

Cochlear analysed retrospective data to demonstrate the effectiveness of cochlear implantation in adults with SSD. For the data analysed:

- the ear to be implanted had a profound sensorineural hearing loss (PTA of 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) ≥ 70 dB HL, and an aided CNC word score of ≤ 10%
- the contralateral ear had normal or near normal hearing (PTA 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) ≤ 30 dB HL.

This study was a prospective analysis of previously collected data from a Cochlear sponsored multicentre prospective feasibility study and real world data.

- The feasibility study had ten participants (N=10).
- The real world data was collected from two cochlear implant centres who had data available for 32 participants (N=32).
- Data was analysed for a total of 42 participants.

Effectiveness testing included speech recognition testing using:

- Hearing in Noise Test (HINT)
- Bamford Kowal Bench Sentences in Noise Test (BKB-SIN)
- Localisation testing.

Patient reported outcomes were evaluated using:

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

Audiometric thresholds were also obtained for each ear.

4.1 Description of Tests

Hearing in Noise Test (HINT)

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

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

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

Localisation testing

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

4.2 Evaluation methods

Speech, Spatial, and Qualities (SSQ) Questionnaire

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

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

Iowa Tinnitus Handicap Questionnaire

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

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

4.3 Effectiveness testing: speech recognition results

The primary and secondary effectiveness objectives and endpoints of the study are shown in *Table 2*.

Primary effectiveness objective	Primary effectiveness endpoints
To evaluate if the restoration of hearing sensation in both ears results in improved spatial hearing for speech in noise, when the target and competing signals are spatially separated.	1. The improvement in sentences in noise scores obtained postactivation in the bimodal listening condition, cochlear implant + normal hearing (CI + NH), compared to scores obtained preoperatively in the best listening condition, normal hearing (NH) alone, or hearing aid + normal hearing (HA + NH) when the speech is presented from the front and noise to the normal hearing ear ($S0N_{NH}$). 2. The improvement in group and individual bimodal (CI + NH) sentence in noise scores compared to scores obtained postoperatively with the NH ear alone, cochlear implant off (CI off) when speech is presented from the front and noise is presented to the NH configuration ($S0N_{NH}$).
Secondary effectiveness objectives	**Secondary effectiveness endpoint**
To evaluate if the restoration of hearing sensation in both ears results in improved spatial hearing for locating sound sources in the horizontal plane.	Group and individual bimodal (CI + NH) localisation scores (Root Mean Square or RMS error) will be compared with NH ear alone (CI off) scores at the most recent postactivation evaluation.

Table 2: Summary of study effectiveness objectives and endpoints

4.4 Primary effectiveness endpoint

Co-primary effectiveness endpoint 1: Bimodal (CI + NH) performance relative to preoperative performance

Twenty three (23/42) participants had preoperative and postactivation data and were included in the analysis.

As shown in ***Table 3***, when speech was presented from the front speaker and noise to the NH ear ($S0N_{NH}$), there was a postactivation improvement in the bimodal listening condition (CI + NH) compared to the best preoperative listening condition. On average, participants experienced an improvement of 2.8 dB, (95% confidence interval, -4.1 to -1.4). A negative value connotes benefit with a cochlear implant for this test.

	Preoperative (HA + NH alone)	Postactivation (CI + NH)	Difference		
	Mean ± SD[1] Median (IQR)[2]	Mean ± SD Median (IQR)	Mean ± SD Median (IQR)	95% confidence interval	1-sided p-value (mean difference <-1.5)
Sentence recognition in noise HINT/BKB SIN $S0N_{NH}$	0.9 ± 3.3 0.6 (-1.0, 2.7)	-1.9 ± 2.6 -1.6 (-3.1, -1.0)	-2.8 ± 3.1 -2.5 (-4.3, -1.2)	(-4.1, -1.4)	0.032

Table 3: Co-primary endpoint 1:
Speech understanding in noise preoperative to postactivation ($S0N_{NH}$) (N=23)

1 SD = standard deviation
2 IQR = interquartile range

Co-primary effectiveness endpoint 2: Bimodal (CI + NH) performance relative to NH ear alone (CI off) performance postoperatively

Table 4 summarises the results for 38 participants, who had data available postactivation comparing performance in the bimodal listening condition (CI + NH) compared to performance in NH ear alone condition (CI off).

The postactivation interval ranged from 3 months to 86 months with a mean of 20 months. Improvement was found in the bimodal condition (CI + NH) compared to NH alone (CI off) for speech understanding in noise ($S0N_{NH}$).

Participants on average experience a 1.5 dB improvement (95% confidence interval, -2.1 to -0.9) in the bimodal condition compared to listening with the NH ear alone. A negative value connotes benefit with a cochlear implant for this test.

	Postactivation (CI off) NH alone	Postactivation (CI on + NH)	Difference		
	Mean ± SD Median (IQR)	Mean ± SD Median (IQR)	Mean ± SD Median (IQR)	95% confidence interval	1-sided p-value
Sentence recognition in noise HINT/BKB SIN $S0N_{NH}$	-0.7 ± 2.3 -1.2 (-1.6, 1.0)	-2.2 ± 2.5 -1.9 (-4.1, -1.0)	-1.5 ± 1.8 -1.6 (-2.8, 0.0)	(-2.1, -0.9)	< 0.001

Table 4: Statistical summary for co-primary effectiveness endpoint 2: Bimodal (CI + NH) performance relative to NH ear alone (CI off) performance postoperatively (N=38)

These analyses support that both co-primary endpoints were met for this study, namely:

- For speech understanding in noise, when the speech is presented from the front speaker and noise is presented to the NH ear, there was a significant improvement of 2.8 dB, (95% confidence interval, -4.1 to -1.4) postactivation at the most recent evaluation in the bimodal (CI + NH) listening condition compared to preoperative hearing performance.
- For speech understanding in noise, when the speech is presented from the front speaker and noise is presented to the NH ear, there was a significant difference at the most recent evaluation interval in the bimodal (CI + NH) listening condition compared to NH alone (CI off). Mean improvement was 1.5 dB (95% confidence interval, -2.1 to -0.9).

In examining individual subject performance, it was found in the preoperative best bilateral listening (HA + NH / NH alone) to postactivation (CI + HA) comparison that:

- 18/23 (78%) participants demonstrated a clinically meaningful preoperative to postactivation improvement of 1.0 dB (10% improvement), with a range of -1.2 dB to -9.5 dB, (note that a negative score connotes improvement)
- 3/23 (13%) participants scored equal to their preoperative performance, with a range in difference scores from 0.0 dB to +0.8 dB
- 2/23 (9%) participants had a difference score ≥ +1.0 dB, consistent with a decline in performance.

When comparing performance postactivation in the bimodal condition (CI + NH) (CI on) compared to NH ear alone (CI off), it was found that:

- 25/38 (66%) participants demonstrated a clinically meaningful improvement with CI on of 1.0 dB (10% improvement) with a range of -1.0 dB to -6.2 dB, (note that a negative score connotes improvement)
- 11/38 (30%) participants scored equal to their NH alone score, with a range of difference scores from -0.7 dB to +0.8 dB
- 2/38 (5%) participants had a difference score > +1.0 dB, consistent with a decline in performance.

In the clinical study, it was found that 8/38 (21%) experienced a decrease in speech understanding in noise when speech was presented from the front speaker and noise was directed to the cochlear implant side, suggesting potential interference of the overlapping electric and acoustic signal in bilateral hearing.

Additionally, a few published studies (Speck et al., 2020, Deep et al., 2021, and Zeitler et al.,2019) reported that there was a low incidence of cochlear implant nonuse presumably because of lack of perceived benefit of the cochlear implant. Given these results, it is reasonable to conclude that a small number of recipients experience perceptual interference of overlapping acoustic and electric bilateral hearing.

Cochlear performed subgroup analyses to examine the consistency of co-primary effectiveness endpoints. The subgroups examined were:

- gender
- median age at implant
- median duration of hearing loss at baseline
- etiology of hearing loss
- evaluation interval
- median baseline/preoperative speech in noise score
- median baseline CI off speech in noise score
- preoperative pure tone average (PTA).

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

- Duration of hearing loss

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

- Etiology of hearing loss

  It was found that those participants with an etiology of sudden sensorineural hearing loss performed significantly better than those with Meniere's disease or the other group.

- Preoperative speech in noise score.

  This result should be interpreted with caution as the majority of etiologies were classified as other. It was found that those participants who had poorer preoperative speech in noise scores demonstrated significantly greater improvement.

For coprimary effectiveness endpoint 2, the only baseline characteristic that affected the endpoint was baseline speech in noise for the spatial configuration $S0N_{NH}$ obtained in the CI off condition (NH alone).

Participants with poorer speech understanding in noise (>1.2 dB) in the CI off condition demonstrated significantly more improvement in the bimodal listening condition (CI + NH).

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

4.5 Secondary effectiveness endpoint

Twenty-four participants had localisation data available for analysis. ***Table 5*** summarises the results on the localisation test showing the root mean square (RMS) error. The RMS error was significantly improved by 18.8 degrees in the bimodal condition (CI + NH) compared to the CI off condition (NH alone).

	CI off	CI on	Difference		
	Mean ± SD Median (IQR)	Mean ± SD Median (IQR)	Mean ± SD Median (IQR)	95% confidence interval	1-sided p-value
Localisation (RMS error)	54.3 ± 16.8 52.2 (41.8, 63.0)	35.5 ± 16.7 33.0 (26.4, 44.5)	-18.8 ± 16.1 -18.9 (-26.7, -11.8)	(-25.6, -12.0)	< 0.001

Table 5: Localisation outcomes (N=24)

Patient reported outcomes

There were 14 participants who completed the SSQ preoperatively and 10 participants who completed it at 6 months postactivation. As shown in ***Table 6***, there was a significant mean improvement on each subscale, with the biggest difference found on the Spatial Hearing subscale. Preoperative to postactivation mean differences were significant based on paired t-tests.

	Preoperative			6 months postoperative
	N	Mean ± SD Median (IQR)	N	Mean ± SD Median (IQR)
Speech & Hearing	14	4.26 ± 1.15 4.09 (3.40, 5.07)	10	6.18 ± 1.37 6.45 (5.50, 7.10)
Spatial Hearing	14	3.19 ± 1.67 3.60 (1.70, 4.70)	10	5.66 ± 2.04 5.65 (5.20, 7.50)
Sound Qualities	14	6.24 ± 1.44 6.00 (5.10, 7.39)	10	6.89 ± 1.51 6.50 (5.70, 7.20)
Total	14	4.56 ± 1.09 4.65 (3.90, 5.20)	10	6.25 ± 1.44 6.15 (5.40, 7.30)
	Difference			
	N	Mean ± SD Median (IQR)	95% confidence interval	1-sided p-value (mean difference >0)
Speech & Hearing	10	2.09 ± 1.59 2.15 (1.00, 2.60)	(0.95, 3.23)	0.001
Spatial Hearing	10	2.38 ± 1.34 2.70 (0.70, 3.30)	(1.42, 3.34)	< 0.001
Sound Qualities	10	1.04 ± 1.24 1.05 (0.50, 1.70)	(0.15, 1.93)	0.013
Total	10	1.84 ± 1.17 1.80 (1.20, 2.50)	(1.00, 2.68)	< 0.001

Table 6: Preoperative to 6 month postactivation statistical outcomes for the SSQ-49

Iowa Tinnitus Handicap Questionnaire

Preoperative and postactivation data were available for 10 participants. At 6 months postoperative, 6 of the 9 (67%) participants with preoperative to postactivation scores reported an improvement in their tinnitus. At 12 months, 7/10 (70%) participants reported an improvement in their tinnitus.

5. Summary of effectiveness data - children 9 months to 12 months old

5.1 Premarket study

In February 2020, Cochlear performed a systematic literature search in PubMed and EMBASE databases to assess effectiveness of implantation with a Cochlear Nucleus cochlear implant in children between 9 months and 12 months of age.

A multi-step literature search process resulted in a final set of studies (49 peer-reviewed articles) representing additional relevant research on cochlear implantation for patients less than 12 months old.

Effectiveness outcomes from the literature data support that implantation before 12 months of age supports paediatric cochlear implant recipients' improved speech and language development.

5.2 Post-approval study

5.2.1 Summary of the post-approval study methods

Cochlear performed a post-approval, prospectively-designed, retrospective analysis among 83 patients who were enrolled in the premarket study and 50 additional patients – data collected out to two years postoperatively – to gather effectiveness information on cochlear implantation in a population between 9 months and 12 months of age.

5.2.2 Summary of the post-approval study results

Primary effectiveness endpoint

The primary effectiveness endpoint of this post-approval study was to evaluate the performance of the cochlear implant on commonly validated and used parental questionnaires (Uhler & Gifford, 2014).

Available IT-MAIS and LittlEARS questionnaires data were collected preoperatively and posoperatively out to two years, or date of final protocol approval, for both sets of patients.

Infant Toddler Meaningful Auditory Integration Scale (IT-MAIS)

The IT-MAIS is a parental questionnaire designed to assess the auditory skill development in infants and toddlers. The questionnaire is administered by a clinician to parents/caregivers in an interview style. It consists of 10 probes designed to assess various auditory behaviours. Each probe has a possible score ranging from 0 (never) to 4 (always). Examples of additional follow up questions that can be asked by the clinician are provided for each probe in order to help determine an appropriate ranking for each probe. The questionnaire is scored out of a total of 40 possible points. The questionnaire can be administered before and after cochlear implantation.

LittlEARS

The LittlEARS is parental questionnaire designed to assess auditory skill development in infants and toddlers. It consists of 35 yes/no questions that ask parents/caregivers to identify whether their child exhibits a certain auditory response or behaviour. Examples are provided for each question. 1 point is provided for each auditory response that is answered as a "yes". The questionnaire is scored out of a total 35 possible points. The questionnaire can be administered before and after cochlear implantation.

Analysis was completed for two population groups:

1. Intent to Treat – consists of all participants who had an available baseline assessment.
2. Per Protocol – consists of only those participants with available assessments at both the preoperative and postoperative time points.

As shown in *Table 7* on page 39 and *Table 8* on page 40 , children in this post-approval study who underwent cochlear implantation between the ages of 9 months and 12 months demonstrated a significant improvement in auditory skill development compared to their preoperative baseline.

The tables provide LittlEARS and IT-MAIS scores reported as a percent correct. Children included in this post-approval study demonstrated significantly improved auditory skill development compared with their baseline performance, with children exhibiting an average improvement of 61.4% at ~9-month post-implantation compared with their preoperative scores.

Questionnaire	Preoperative N Mean ± SD[1], median (min, max)	Postoperative N Mean ± SD, median (min, max)	Change N Mean ± SD, median (min, max)	Change Mean (95% confidence interval)[2]	p-value[2]
LittlEARS	28 15.8 ± 19.1 5.7 (0, 54)	62 81.6 ± 20.3 88.6 (17, 100)	20 61.4 ± 27.4 67.1 (3, 100)	60.7 (38.4, 82.9)	<.0001
IT-MAIS	33 16.8 ± 16.3 12.5 (0, 78)	35 76.9 ± 21.7 85.0 (3, 100)	25 58.5 ± 23.9 62.5 (-3, 100)	55.4 (9.1, 101.8)	0.0308

Table 7: Primary effectiveness endpoint - Intent to Treat

1 SD = standard deviation

2 The mean and confidence interval for change, and p-value, are based on multiple imputation.

Questionnaire	Preoperative N Mean ± SD[1], median (min, max)	Postoperative N Mean ± SD, median (min, max)	Change N Mean ± SD, median (min, max)	Change Mean (95% confidence interval)	p-value[2]
LittlEARS	20 15.7 ± 20.7 5.7 (0, 54)	20 77.1 ± 20.9 82.9 (31, 100)	20 61.4 ± 27.4 67.1 (3, 100)	61.4 (48.6, 74.3)	<.0001
IT-MAIS	25 15.7 ± 16.7 10.0 (0, 78)	25 74.2 ± 24.0 77.5 (3, 100)	25 58.5 ± 23.9 62.5 (-3, 100)	58.5 (48.6, 68.4)	<.0001

Table 8: Primary effectiveness endpoint - Per Protocol

When comparing outcomes of this post-approval study to published literature, please note the literature refers to hearing age – when the cochlear implant was activated – whereas Cochlear's dataset for IT-MAIS and LittlEARS questionnaires refers to time from cochlear implant surgery.

To appropriately compare Cochlear's dataset to published literature, postoperative performance by hearing age has been provided at various intervals, up to 24 months, as shown in *Table 9* on page 41 and *Table 10* on page 42 .

1 SD = standard deviation

2 The p-values are based on two-sided paired t-test.

Study	Preoperative score Mean (% correct)	Postoperative score Mean (% correct)	Change pre- to postoperative score Mean (% correct)
PAS Intent to Treat 9.0 mo-11.99 mo	5.5 (15.8%)	9.9 mo postop: 28.5 (81.6%)	9.9 mo: 21.5 (61.4%)
PAS Per Protocol 9.0 mo-11.99 mo	5.5 (15.7%)	9.0 mo postop: 27 (77.1%)	9.0 mo: 21.5 (61.4%)
May-Mederake et al. (2010) under 12 mo at implant	7 (20%)	6 mo hearing age: 17 (48.6%)	6 mo: 10 (28.6%)
		9 mo hearing age: 23 (65.7%%)	8 mo: 14 (45.7%)
		12 mo hearing age: 28 (80%)	12 mo: 21 (60%)
		18 mo hearing age: 35 (100%)	18 mo: 28 (80%)
		24 mo hearing age: 35 (100%)	24 mo: 28 (80%)
May-Mederake et al. (2010) over 12 mo at implant	15 (42.8%)	6 mo hearing age: 21 (60%)	6 mo: 6 (17.2%)
		9 mo hearing age: 24 (68.6%)	8 mo: 9 (25.8%)
		12 mo hearing age: 27 (77.1%)	12 mo: 12 (34.3%)
		18 mo hearing age: 34 (97.1%)	18 mo: 19 (54.3%)
		24 mo hearing age: 35 (100%)	24 mo: 20 (57.2%)
Connix et al. (2009) Normative values	NA	8 mo hearing age: 10-18 (28.6-51.4%)	NA
		9 mo hearing age: 12-20 (34.3-57.1%)	
		12 mo hearing age: 16-24 (45.7-68.6%)	
		6 mo hearing age: 8-9 (22.9%-25.7%)	
		18 mo hearing age: 23-30 (65.7%-85.7%)	
		24 mo hearing age: 26-34 (74.2%-97.1%)	

Table 9: LittlEARS questionnaire pre- to postoperative change scores reported as a standard score and percent correct

Study	Preoperative score Mean (% correct)	Postoperative score Mean (% correct)	Change pre- to postoperative score Mean (% correct)
PAS Intent to Treat 9.0 mo-11.99 mo	6.7 (16.8%)	7.7 mo postop: 30.7 (76.9%)	7.7 mo: 23.4 (58.5%)
PAS Per Protocol 9.0 mo-11.99 mo	6.3 (15.8%)	6.8 mo postop: 29.7 (74.3%)	6.8 mo: 23.4 (58.5%)
Waltzman & Roland (2005) CI under 12 mo	0.7 (1.8%)	6 mo hearing age: 30.4 (76%) (~25% above the mean for NH children at 6 mo)	6 mo: 29.7 (74.2%)
		12 mo hearing age: 34.8 (87%) (~7% above mean for NH children at 12 mo)	12 mo: 34.1 (85.3%)
Robbins et al (2004) CI Group 1: (12 mo-18 mo at implant)	~10%	3 mo hearing age: ~65% (outside normative range)	3 mo: 55%
		6 mo hearing age: ~80% (within normative range)	6 mo: 70%
		12 mo hearing age: ~85% (within normative range)	12 mo: 75%
Robbins et al (2004) CI Group 2: (19 mo-23 mo at implant)	~10%	3 mo hearing age: ~55% (outside normative range)	3 mo: 45%
		6 mo hearing age: ~65% (outside normative range)	6 mo: 55%
		12 mo hearing age: ~75% (within normative range)	12 mo: 65%
Zimmerman-Phillips, Robbins, & Osberger (2000) CI at 18 mo-20 mo	Average 1.4%	3 mo hearing age: 49.2%	3 mo: 47.8%
Robbins et al (2004) Normative Values	NA	6 mo hearing age: ~20-50%	NA
		8 mo hearing age: ~40-65%	
		9 mo hearing age: ~45-70%	
		12 mo hearing age: ~50-75%	
		18 mo hearing age: ~70-85%	
		24 mo hearing age: ~75-95%	

Table 10: IT-MAIS questionnaire pre- to postoperative change scores reported as a standard score and percent correct

A review of the post-approval study data collected reveals that IT-MAIS questionnaire data was obtained between 3 months and 17 months postoperatively, and LittlEARS questionnaire data was obtained between 3 months and 21 months postoperatively.

Neither questionnaire had data out to the 24 month postoperative time point. However, the available data still shows that children who receive a cochlear implant between 9 months and 12 months of age demonstrated improved auditory skill development, which is likely due to improved access to sound through their cochlear implant.

The numbers provided in *Table 9* on page 41 and *Table 10* on page 42 reflect the mean postoperative time point for each test and condition (Intent to Treat and Per Protocol) for ease of reporting purposes due to the number of available data points and the need to compare results of this study to the published literature.

Results of this study reveal IT-MAIS scores of:

- 76.9% at a mean of 7.7 months postoperatively for Intent to Treat
- 74.3% at a mean of 6.8 months postoperatively for Per Protocol.

These outcomes are aligned with reported scores:

- at 6 months hearing age for children implanted under age 12 months (76%) Waltzman & Roland (2005)
- at 6 months hearing age for children implanted at 12 months to 18 months (approximately 80%) Robbins et al. (2004).

Data for slightly older children implanted beyond 12 months of age are poorer compared to this dataset. Specifically, reported scores:

- at 6 months hearing age for children implanted between 19 months and 23 months (approximately 65%) Robbins et al. (2004)
- at 3 months hearing age for children implanted between 18 months and 20 months (approximately 49%) Zimmerman-Phillips, Robbins, & Osberger (2000).

When reviewing LittlEARS data, children in this study demonstrated a mean score of:

- 81.6% at a mean of 9.9 months postoperatively for Intent to Treat
- 77.1% at a mean of 9.0 months postoperatively for Per Protocol.

This data is slightly higher than scores reported by May-Mederake et al. (2010) who reported scores of approximately 65.7% and approximately 68% for children implanted under 12 months and over 12 months respectively, at a hearing age of 9 months.

Scores in this post-approval dataset better align with 12 month hearing age outcomes reported by May-Mederake et al. (2010), which demonstrated scores of approximately 80% for children implanted under 12 months of age, and approximately 77.1% for children implanted over 12 months of age.

Results of May-Mederake (2010) also showed that children who were implanted before 12 months of age had lower baseline scores, but demonstrated steeper trajectories, such as faster improvement and/or development, compared to children who were older at time of implantation (that is, over 12 months of age).

Data from this study showed that children who receive a cochlear implant between 9 and 12 months of age demonstrated improved auditory skill development as evidenced through these clinically relevant parental questionnaires.

Secondary Effectiveness Endpoint

The secondary effectiveness endpoint of this study was to evaluate the performance of the cochlear implant on aided audiometric thresholds.

Data collected demonstrated a significant improvement in audiometric thresholds following cochlear implantation. This demonstrates that use of the device provides improved access to auditory information.

In summary, this post-approval study provides a dataset of over 100 patients who received a Cochlear Nucleus cochlear implant between 9 months and 12 months of age. Data was collected preoperatively and postoperatively out to two years or date of final protocol approval.

The data provided continues to support the effectiveness of cochlear implantation with the Cochlear Nucleus device in infants as young as 9 months of age. Findings of this post-approval study demonstrate agreement with previously published literature (Connix et al., 2019; May-Mederake et al., 2010; Robbins et al., 2004; Waltzman & Roland, 2005; Zimmerman-Phillips, Robbins, & Osberger, 2000) for both effectiveness endpoints.

Study strengths and weaknesses

Strengths of the post-approval study include the use of data from multiple implanting centres over an 8-year period, which resulted in a large cohort of eligible participants and ears receiving treatment with a cochlear implant.

Weaknesses of this study include the retrospective nature of the study, which can limit the amount of data that is available for review in comparison to a prospective study. An additional limitation to consider is the selection of sites who participated in this study. Sites were specifically chosen to participate in the post-approval study due to their known use of cochlear implantation in children under 12 months of age.

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Device description

Cochlear Nucleus cochlear implant systems are designed to provide useful hearing. The system works by converting sound in the environment into electric pulses that stimulate the auditory nerve, allowing the brain to perceive sound.

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

Implanted component

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

External components

The external components include a sound processor, and associated accessories and cables.

The system is programmed by a Cochlear proprietary programming software.

For information on compatibility between implants and sound processors, refer to the *Custom Sound® User Guide*.

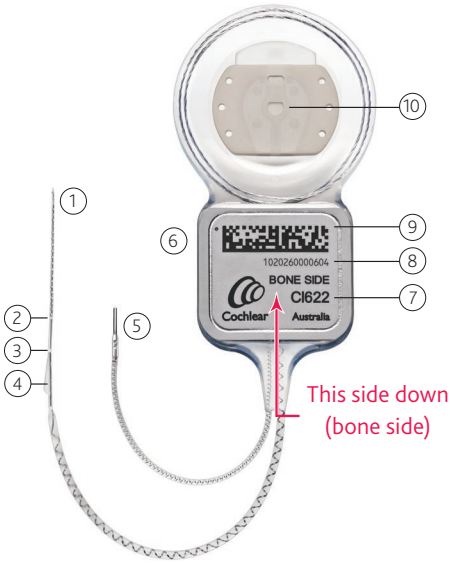
New features

CI600 Series implants have implant coil plates either side of a magnet pocket which contains a removable magnet cassette. This design allows for magnet removal and replacement from the distal end of the implant coil, if required.

Figure 1: CI622 cochlear implant with magnet cassette partially removed from pocket

The Cochlear™ Nucleus® CI622 cochlear implant with Slim Straight electrode

The CI622 implant is a CI600 Series implant.

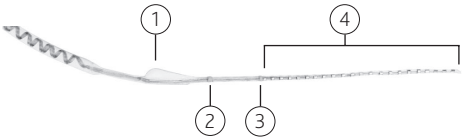


1 Intracochlear electrode
2 White marker indicating 20 mm insertion depth
3 White marker indicating 25 mm (max) insertion depth
4 Handle
5 Extracochlear electrode
6 Receiver/stimulator (printed information on bone side)
7 Model number
8 Serial number
9 Barcode
10 Implant coil plate with magnet cassette in pocket

Figure 2: CI622 cochlear implant with Slim Straight electrode (bone side)

1 Implant coil plate with magnet cassette in pocket
2 Extracochlear electrode (plate) to face upwards/skin
3 Intracochlear electrode

Figure 3: CI622 cochlear implant with Slim Straight electrode (skin side)



1 Handle
2 White marker indicating 25 mm (max) insertion depth
3 White marker indicating 20 mm active array
4 Intracochlear electrode with 22 half-band contacts

Figure 4: Slim Straight electrode

1 SKIN SIDE engraving denoting correct orientation of magnet cassette in magnet pocket
2 Magnet cassette cover

Figure 5: Cochlear Magnet Cassette (skin side)

Surgical instruments and accessories

Instruments and accessories in this section are appropriate for use with Cochlear Nucleus CI600 Series implants.

All items except the Sterile Silicone Implant Template are available to be ordered individually. As indicated below, some items are included in the CI500 Series Surgical Instrument Kit. An upgrade kit is also available.

Instruments	Product code	CI500 Series Instrument Kit	CI500 Series Instrument Upgrade Kit
AOS™ Forceps for the Contour Advance® Electrode	Z60770	✓	✓
BTE Template	Z33011	✓	–
CI500 Series Recess Gauge	Z139274	✓	✓
CI500 Series Implant Template	Z139273	✓	✓
Contour® Electrode Claw	Z33021	✓	–
Electrode Claw (Straight)	Z30090	–	–
Contour Advance® Depth Gauge	Z179994	–	–
Depth Gauge (Straight)	Z60006	–	–
Sterile Silicone Implant Template*	Y119819	–	–
CI500 Series Non-Sterile Silicone Implant Template	Z179609	–	–
Accessories			
Non-Magnetic Cassette	P782484	–	–
Replacement Magnet Cassette	P782485	–	–

* Supplied with implant; not available separately

Items used with the Cochlear Nucleus CI622 cochlear implant are referenced in the *Surgical procedure* and *MRI safety information* sections of this guide.

Dispose of used items according to your institution's policy on the disposal of used instruments and accessories.

Warning

Do not use surgical instruments or accessories supplied or intended to be sterile if they become non-sterile, for example if dropped or mishandled in theatre.

Reusable after reprocessing

These instruments are stainless steel, and can be cleaned and resterilised as instructed in the *Surgical Instrument Sterilisation Reprocessing Guide*.

AOS™ Forceps for the Contour Advance® Electrode Z60770

Used to grasp or hold the Contour Advance electrode during its insertion into the cochlea. Curved tip ends gently cup the array to improve stability and minimise rotation.

Caution

To avoid damaging the electrode, before each use hold forceps tips closed and ensure they are parallel and aligned. If not, do not use, as it may be difficult to release the electrode after insertion.

BTE Template Z33011

Used to ensure the implant position provides space for a behind-the-ear sound processor.

CI500 Series Recess Gauge Z139274

Used to mark the bone recess on the skull, measure the depth of the bone recess and check the location of the electrode exit excavation after drilling.

CI500 Series Implant Template Z139273

Used to determine, or check, the shape of the implant bone recess excavation and the position of the implant.

Contour Electrode Claw Z33021

Aids insertion of the Contour Advance electrode into the cochlea. Gold-plated handle.

Electrode Claw (Straight) Z30090

Aids insertion of the Straight electrode into the cochlea.

Single-use sterile

These items are supplied sterile for single-use only.

Warning

Do not resterilise. Do not use more than once. Re-use could cause infection.

Non-Magnetic Cassette	P782484

If the recipient requires single or multiple MRI examinations on the head, a non-magnetic cassette is used to replace the magnet cassette.

For more information refer to *MRI safety information* on page 84.

Replacement Magnet Cassette	P782485

Used to replace a non-magnetic cassette after MRI examinations are complete.

For more information refer to *MRI safety information* on page 84.

Note

- Non-magnetic cassettes and replacement magnet cassettes are supplied in a silicone carrier, as illustrated below. Remove the cassette from the silicone carrier before use.

- When marking the incision site, the silicone carrier can be used as a template. For details refer to *Removing and replacing the magnet cassette or non-magnetic cassette after implantation* on page 92.

Depth Gauges	
Contour Advance Depth Gauge Z179994	Depth Gauge (Straight) Z60006
	

Depth gauges are typically used in the sterile field when:

- pre-operative imaging to assess cochlea patency is inconclusive or unavailable, and
- it is suspected that cochlear obstruction such as ossification may prevent successful electrode insertion.

Use of depth gauges is not intended for normal cochleae where there is no suspicion of obstruction or malformation.

For more information refer to the appropriate *Depth Gauge User Guide*.

Sterile Silicone Implant Template Y119819

Used in the sterile field to check periosteal pocket size, implant bone recess shape and depth, and tie-down hole positions.

Provided with the implant; not available separately. For more information refer to warnings below and *2. Opening the Sterile Silicone Implant Template* on page 62.

Warning

- For temporary use only. Not for implantation.
- Supplied sterile. Sterilised in ethylene oxide. Do not resterilise.
- Single-use item. Do not use more than once. Re-use could cause infection.
- Do not use if packaging is damaged.
- Do not use if item becomes non-sterile, for example if dropped or mishandled in theatre after removal from packaging.

Non-sterile

These items are supplied non-sterile and are single use. They should not be sterilised.

Warning

Do not use more than once. Re-use could cause infection.

CI500 Series Non-Sterile Silicone Implant Template	Z179609

Used to determine/check the optimum implant position and mark it on the skin before incision.

Warning

Do not use in the sterile field. Use in the sterile field could cause infection.

Surgical procedure

The surgical procedure described in this guide is only one approach to implanting the Cochlear Nucleus CI622 cochlear implant.

The surgical procedure includes the following:

1. Pre-incision: non-sterile field – page 61
2. Opening the Sterile Silicone Implant Template – page 62
3. Incision – page 63
4. Mastoidectomy and preparing the bone recess – page 64
5. Drilling tie-down holes – page 67
6. Opening the facial recess – page 68
7. Preparing the cochleostomy or round window – page 69
8. Inspecting the cochlear implant and electrodes – page 72
9. Positioning and securing the implant – page 73
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11. Inserting the intracochlear electrode – page 75
12. Securing and sealing the intracochlear electrode – page 77
13. Performing intraoperative measurements – page 79
14. Closure – page 80

Where a surgical instrument is mentioned in the procedure, refer to *Surgical instruments and accessories* on page 52.

1. Pre-incision: non-sterile field

1. Place the BTE Template in position on the ear. Ensure there will be sufficient clearance between the receiver/stimulator and an ear level sound processor so that the sound processor will not rest on the receiver/stimulator.
2. Place the Non-Sterile Silicone Implant Template on the skin so that the antero-inferior edge is at least 10 mm behind the edge of the BTE Template and above the canthomeatal line. Angle the Non-Sterile Silicone Implant Template 30 to 45 degrees postero-superiorly, to lie on a flat portion of the skull. Mark its position on the scalp.

   Note

   - For bilateral patients, position the second receiver/stimulator so that it is symmetrical with the first.
   - If the recipient has an Osia implant on the contralateral side, make sure to have a distance of at least 10 cm between the coils of the implants to avoid interference between the systems.
3. Mark the incision with a marking pen. Allow at least 15 mm between the implant and the incision.

   The incision must be large enough to accommodate the cochlear implant. The flap may be inferiorly- or anteriorly-based but must allow the surgeon to secure the implant to the bone.
4. The Implant Template can be used to mark the position of the electrode lead exit for the proposed bone excavation for the receiver/stimulator. Mark with a drop of methylene blue on the bone using a 21 gauge needle through the skin.
5. Before incision, the incision line may be infiltrated with local anaesthetic and 1:100 000 or 1:200 000 adrenaline, or epinephrine, unless contraindicated.

2. Opening the Sterile Silicone Implant Template

One Sterile Silicone Implant Template is packaged with each implant. For more information on use of the template refer to *Sterile Silicone Implant Template* on page 58.

Non-sterile field

1. Remove the cardboard box (outer packaging).
2. Break the seal on the outer tray, and confirm that:
   - exposure to ethylene oxide processing is indicated by a green dot on the outer tray
   - the two inner trays are not damaged.
3. Notice that the tray containing the Sterile Silicone Implant Template has a blue stripe. The tray containing the cochlear implant displays the Cochlear logo.

Warning

To avoid infection, if the sterile package is damaged do not use the template.

Sterile field

4. Remove the Template tray (blue stripe) and break the seal.

Note

Keep the cochlear implant tray (white seal) to one side, within the sterile field, with the seal intact until later in the surgery.

5. Lift the Sterile Silicone Implant Template from the tray.

3. Incision

Warning

If the patient has an implant in the other ear, do not use monopolar electrosurgical instruments. Bipolar electrosurgical instruments may be used.

1. Make the incision down to the avascular plane of the periosteum and temporalis fascia, long enough to provide sufficient access. Stabilise the area using retraction as necessary.
2. Use the Implant Template or the Sterile Silicone Implant Template to check the position of the implant.
3. Incise the underlying periosteum and lower portion of the temporalis fascia creating a fibromuscular/periosteal flap based either anteriorly or posteriorly.
4. Elevate a periosteal pocket to accommodate the implant coil.
5. Elevate a narrow periosteal pocket against the bone under the temporalis muscle. This is to make a place for the extracochlear electrode between the skull and the periosteum, that is, under the temporalis muscle.

4. Mastoidectomy and preparing the bone recess

The cortical mastoidectomy is described next. Some surgeons prefer to drill the implant recess first.

The cortical mastoidectomy

Create an adequate cortical mastoidectomy cavity, allowing an overhang both superiorly and posteriorly to accommodate any redundant proximal electrode lead.

Note

For children, it is recommended that a mastoidectomy be performed.

The bone recess

The blue dye dot on the bone indicates the position of the channel for the electrode lead exit.

Use the Recess Gauge, Bone Recess Template, Implant Template or the Sterile Silicone Implant Template to determine the angular orientation of the implant. This is usually placed at 30 to 45 degrees above the temporal line.

Warning

When drilling the bone recess, take care to avoid injury to the underlying dura.

To drill the bone recess:

1. Mark the recess using a surgical marker with the aid of the Recess Gauge, Implant Template, or the Sterile Silicone Implant Template.
2. Drill the bone recess. Aim to achieve a flat surface 'ramp', starting deeper on the anterior end of the implant and tapering off posteriorly. The ramp should be approximately 2.2 mm deep at the antero-inferior end of the implant, depending on the thickness of the skull. Providing that the skull is sufficiently thick, drilling deeper will result in a lower profile beneath the skin flap.

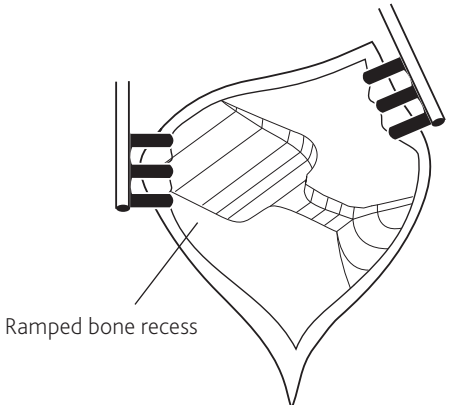
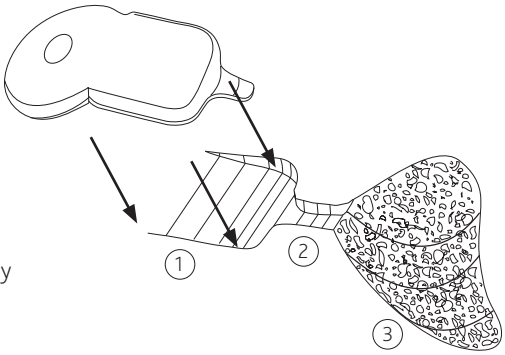


Figure 6: Ramped bone recess

3. Check the final dimensions of the bone recess using the Recess Gauge or Implant Template.



1 Ramped bone recess
2 Channel
3 Mastoidectomy cavity

Figure 7: Ramped bone recess, electrode channel and mastoidectomy

4. Place the Implant Template or Recess Gauge in the bone recess and use it to mark the exit of the electrode.
5. Drill a channel to connect the bone recess and mastoid cavity – refer to ***Figure 7*** above. The channel will help protect the electrode against trauma.
6. Use the Recess Gauge to check the position and depth of the electrode exit.

5. Drilling tie-down holes

1. Using the implant seat for orientation (refer to *The bone recess* on page 64), mark tie-down holes above and below the anterior portion of the receiver/stimulator to ensure the implant can be secured.
2. Drill these holes with a 2 mm diamond burr.

Note

For children, an elevator may be used to protect the dura.

For additional support, posterior tie-down holes may be drilled or the implant coil can be placed under a pericranium pocket.

Figure 8: Tie-down holes for CI600 Series implants

Warning

When drilling the tie-down holes, take care to avoid injury to the underlying dura.

6. Opening the facial recess

1. Open the facial recess ensuring it gives as much visibility and access as possible. The horizontal canal and short process of the incus should be clearly visualised.
2. Identify the facial nerve and chorda tympani nerve, but do not expose them.

   The posterior portion of the middle ear, including the stapedius tendon, promontory and round window niche (RWN), should be clearly visualised.

   In some instances of poor round window visualisation, the chorda tympani nerve is unavoidably cut to perform an extended facial recess approach.

7. Preparing the cochleostomy or round window

The CI622 cochlear implant with Slim Straight electrode is compatible with both round window and cochleostomy approaches.

This section describes site preparation for both approaches. For details on inserting the electrode refer to *11. Inserting the intracochlear electrode* on page 75.

Cochleostomy

1. Visualise the stapes to confirm the site of the round window, and visualise the round window membrane. It is approximately 2 mm inferior and slightly posterior to the oval window.

   The round window membrane may be obscured by the overhang of the lateral margin of the niche and a mucosal false membrane. It may be necessary to gently drill away the overhang to see the round window membrane.

2. Perform a cochleostomy into the scala tympani using a 1.4 mm or 1.0 mm diamond burr at low speed.

   Position the cochleostomy inferior and slightly anterior to the round window membrane. It should be close to, or incorporating, the round window niche (RWN). A slight blue line of endosteum should become visible as the bone is being thinned for the cochleostomy. This indicates the location of the scala tympani.

   Warning

   Damage to the cochlea or vestibular system may be caused by drilling too far anteriorly or superiorly. This will result in the endosteum appearing white and the scala media or vestibuli may be entered.

   Caution

   Incorrect electrode placement may result from drilling too far inferiorly. This will miss the cochlea entirely and a hypotympanic air cell may be entered. Take care to remove bone dust, blood and other fluids from the cochleostomy.

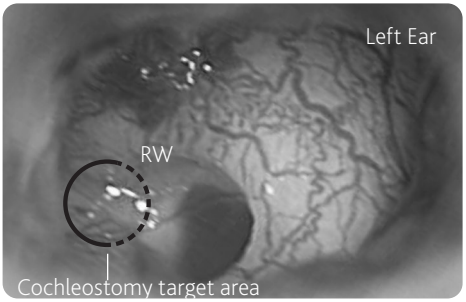


Figure 9: Cochleostomy target area

3. Drill sufficient bone with the 1.4 mm or 1.0 mm diamond burr to expose at least 1.5 mm of endosteum.

Warning

To avoid risk of contamination do not open the endosteum until immediately before insertion of the electrode as described in *11. Inserting the intracochlear electrode* on page 75.

Round window

1. Visualise the stapes to confirm the site of the round window, and visualise the round window membrane. It is approximately 2 mm inferior and slightly posterior to the oval window.

   The round window membrane may be obscured by the overhang of the lateral margin of the niche. It may be necessary to drill away the overhang to see the round window membrane.

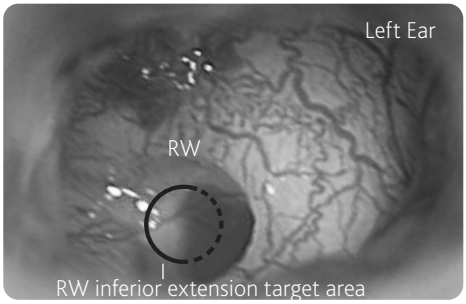


Figure 10: Round window target area

2. Remove the false membrane.

Warning

Do not open the round window membrane until immediately before insertion of the electrode as described in *11. Inserting the intracochlear electrode* on page 75.

8. Inspecting the cochlear implant and electrodes

If the Sterile Silicone Implant Template is not unpacked refer to *2. Opening the Sterile Silicone Implant Template* on page 62.

Sterile field

1. Remove the cochlear implant from the sterile packaging tray.
2. Confirm the cochlear implant is not damaged.

Warning

- To avoid infection or revision surgery, do not use the implant if the sterile package or the implant are damaged.
- To avoid damage to tissue or the implant, from this point do not use monopolar electrosurgical instruments on the neck and head of the patient.

  Bipolar electrosurgical instruments may be used; however the cautery electrode tips must not contact the cochlear implant and should be kept more than 1 cm (½ in) from the electrodes.

Caution

To avoid damaging the cochlear implant:

- do not bend the electrode as the stiffening element inside is malleable and will deform.
- leave the protective tube on the electrode until just before insertion.

9. Positioning and securing the implant

1. Place the receiver/stimulator skin side up in the bone recess, with the implant coil in the subperiosteal or pericranial pocket between the tie-down holes.

   For information on correct implant orientation refer to *Device description* on page 48.

   Caution

   To avoid damage, do not bend the implant coil.

2. Place the electrode lead in the centre of the channel.
3. Secure the receiver/stimulator with a single suture, using a non-absorbable synthetic material.

   Move the knot to the edge of the cochlear implant.

   Note

   Do not suture directly over the magnet as this may obstruct potential magnet removal. Refer to *Figure 15* on page 87.

10. Securing the extracochlear electrode

Carefully place the extracochlear electrode against the bone under the temporalis muscle.

Caution

To avoid mechanical stress on the electrode lead, do not place the extracochlear electrode in the temporalis muscle.

11. Inserting the intracochlear electrode

Warning

- In the event of suboptimal placement, it is recommended to remove the electrode and use the backup implant instead.

Caution

- Use minimal force. Do not rush the insertion
- During insertion, ensure the array does not kink and the half-band electrode contacts remain oriented towards the modiolus.

Before insertion

The following should be performed immediately before insertion of the electrode:

Inserting via a cochleostomy

1. Open the endosteum with an otologic hook and ensure that the cochleostomy is wide enough to accommodate the electrode.
2. Remove any sharp edge of bone which might snag the electrode.

Warning

To avoid residual hearing loss or vestibular issues, do not suction the perilymph.

Inserting via the round window

Make a straight incision the width of the round window.

Insertion

1. Grasp the protective tube (in the end section) and carefully remove the tube from the electrode. Do not squeeze or stretch the electrode.

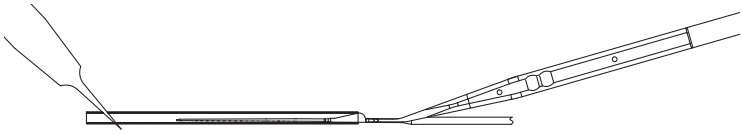


Figure 11: Removing the tube

2. Guide the tip of the array toward the cochleostomy or round window using AOS forceps to hold the electrode by the handle. The Electrode Claw can also be used to help guide the electrode.
3. Begin slowly inserting the electrode, ensuring that the half-band electrode contacts remain oriented toward the modiolus. The handle can be used to identify electrode orientation, as it is located on the opposite side of the electrode contacts.
4. Continue inserting the electrode to a suitable depth using the white markers located at 20 mm and 25 mm on the electrode as a guide.

   The maximum recommended insertion depth is 25 mm. It is not necessary to insert the electrode to the maximum depth of 25 mm. Partial insertion is better than forcing the electrode beyond the point of first resistance.
5. Stabilise the lead to prevent movement of the electrode in the cochlea.

12. Securing and sealing the intracochlear electrode

Warning

Movement of the excess electrode lead could result in the electrode twisting and potentially damaging cochlear structures. Immediately after inserting the electrode and before arranging the excess proximal electrode lead in the mastoid cavity, the electrode must be immobilised. Ensure the electrode is held continuously by the handle.

To limit the risk of migration or breaking the seal, the electrode may be secured. The method of fixation, and choice of fixation points, will depend on surgical access and the surgeon's discretion.

1. Pack completely around the electrode in the cochleostomy or round window with an autograft consisting of strips of fascia or pericranium to ensure there are no gaps in the seal.

   Warning

   Seal the cochleostomy or round window to avoid an open pathway to the inner ear.

   Note

   If there is a perilymph leak, extra tissue may be needed to ensure that the seal is tight.

2. Coil the excess redundant proximal electrode lead inside the mastoid cavity under the bony overhangs.
3. Place any excess loop of the extracochlear electrode in the mastoid cavity.

   Note

   If the electrodes are able to migrate into subcutaneous tissue they may be subject to excessive movement and fatigue. To avoid this, ensure the leads are secure within the cavity, but do not suture over the electrode leads with fine gauge sutures.

Confirmation of electrode placement

Before closure, an X-ray may be obtained (preferably a lateral or modified Stenver's view) to confirm proper electrode placement.

For information on Stenver's view, contact Cochlear or refer to *Xu J, Xu SA, Cohen LT, Clark GM. Cochlear View: Post-operative Radiography for Cochlear Implantation. Am J Otol, 21(1):49-56, 2000*.

13. Performing intraoperative measurements

Intraoperative measurements via telemetry may now be performed.

1. Replace the flap.
2. Put the processor coil and cable in a sterile sleeve.
3. Place the external coil over the implant magnet.

Note

- The transmitting range of the cochlear implant is 1 mm to 10 mm. However, maximum skin flap thicknesses of 6 mm for off-the-ear (OTE) sound processors and 10 mm for behind-the-ear (BTE) sound processors are required for good magnet retention.
- The cochlear implant may not function properly if the processor coil is placed directly on top of the receiver/stimulator.
- Methods to determine that the cochlear implant is functioning properly include impedance measurement using a Cochlear proprietary programming system.

14. Closure

1. Pack the facial recess with soft tissue.
2. Suture the palva flap over the proximal portion of the intracochlear electrode lead.
3. Close the wound in layers. Drainage is not recommended.
4. Apply a large mastoid pressure dressing.

Post-operative management

Monitor the patient as for all procedures involving general anaesthesia. Keep the pressure dressing on for one day, then inspect the wound and apply another dressing for five days.

Fitting the sound processor

The initial fitting procedure for the sound processor should be scheduled after a healing period. Fitting should be checked at three months, six months and one year postoperatively, then at yearly intervals (or more frequently if required by the condition of the patient).

Registering the implant

Registration form

Complete the registration form. Send the completed form to Cochlear within 30 days of receiving the product.

Patient Implant Card and Important Information document

Fill out the implant model number and ear details on the Patient Implant Card. Give the card and the Important Information document to the patient or their carer.

The patient or their carer should carry the Patient Implant Card with them at all times.

Identifying the implant

For information on identifying Cochlear implants without surgical intervention, refer to the *Cochlear Nucleus Implants MRI Guidelines*.

Explanting the implant

In rare circumstances, it may be necessary to explant a cochlear implant. Please follow the steps below.

1. Contact Cochlear to order a Retrieved Device Kit. The kit must be used to transport the explanted device to Cochlear.
2. Read the instructions provided with the kit.
3. Before explanting the device, examine it for any defects. Note these on the form provided with the kit.
4. Try to keep the explanted device intact and undamaged. To assist in removing the device undamaged you can cut the intracochlear electrode lead. Refer to *Cutting the intracochlear electrode lead* on page 83.
5. If the intracochlear electrode lead is removed from the cochlea, place it in the kit, even if it is damaged.
6. Return the kit containing the explanted device to the Cochlear address nearest you.

Cutting the intracochlear electrode lead

Cut the intracochlear electrode lead if it will assist you to remove the device without damaging it. The cut should be in the region of the electrode lead shown below.

If required to remove the electrode lead without damage, cut the electrode lead before the handle:

Figure 12: Slim Straight electrode lead cut location for explantation

If the extracochlear electrode is difficult to remove, cut the extracochlear lead and leave the electrode in place.

Reporting incidents

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. All serious incidents should be reported to:

- your local Cochlear office
  www.cochlear.com/intl/contact/global-offices
- your National Regulator.

MRI safety information

The Cochlear Nucleus CI622 cochlear implant is MR Conditional. MRI examinations can be performed safely on a person with this implanted device only under very specific conditions. MRI examinations performed under different conditions may result in severe patient injury or device malfunction.

Full MRI safety information is available:

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

All external components of the Cochlear implant system (for example, sound processors, remote controls and related accessories) are MR Unsafe. The patient must remove all external components of their Cochlear implant system before entering a room where an MRI scanner is located.

Removing the magnet cassette

Cochlear Nucleus CI600 Series implants are designed to withstand MRI at static magnetic field strengths described in the *Cochlear Nucleus Implants MRI Guidelines*.

Before an MRI examination, in some instances the magnet cassette must be removed in a sterile surgical environment. If single or multiple MRI examinations on the head are needed with the magnet cassette removed, replace the magnet cassette with a non-magnetic cassette.

Warning

To prevent infection, do not leave the magnet pocket empty. When removing the magnet cassette, replace the magnet cassette with a non-magnetic cassette.

Caution

When removing or inserting a magnet cassette or non-magnetic cassette:

- Take care to not damage the implant silicone or coil wires.
- Minimise force applied to the implant and electrodes.
- Minimise pressure applied to the implant coil.

Note

While the magnet cassette is removed, the recipient must wear a Cochlear Disk Retainer to hold their sound processor coil in place. Disk retainers are available from Cochlear.

Replacement magnet cassettes and non-magnetic cassettes

Warning

To avoid implant damage during an MRI examination and potential revision surgery, ensure CI600 Series magnet cassettes and non-magnetic cassettes are used.

Do not use magnets and non-magnetic plugs for other implants, such as CI500 and CI24RE Series.

Replacement magnet cassettes and non-magnetic cassettes are available from Cochlear.

Figure 13: Replacement Magnet Cassette P782485

Figure 14: Non-Magnetic Cassette P782484

Removing the magnet cassette before implantation

If an MRI examination is scheduled in the near future, it may be appropriate to replace the magnet cassette with a non-magnetic cassette before the device is implanted.

The replacement procedure should take place under sterile conditions.

Replacing magnet cassette with non-magnetic cassette before implantation

1. In sterile conditions, remove the implant from its sterile packaging and place it on a flat and stable surface with the bone side (engraved side) facing down.

1 Implant coil plate (skin side)
2 Implant coil silicone
3 Magnet cassette cover

Figure 15: CI622 implant with magnet cassette

Warning

To avoid infection, if the sterile package or implant are damaged do not use the implant.

2. At the distal end of the implant coil, carefully position forceps or similar instrument under the silicone lip to hold the centre of the magnet cassette cover.

1 Silicone lip
2 Forceps tip under silicone lip
3 Magnet cassette cover

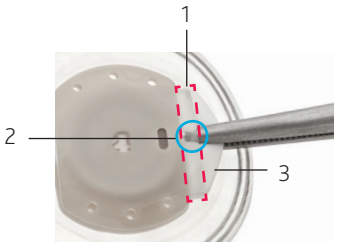


Figure 16: Forceps position on CI622 magnet cassette cover

Caution

When holding the magnet cassette cover, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

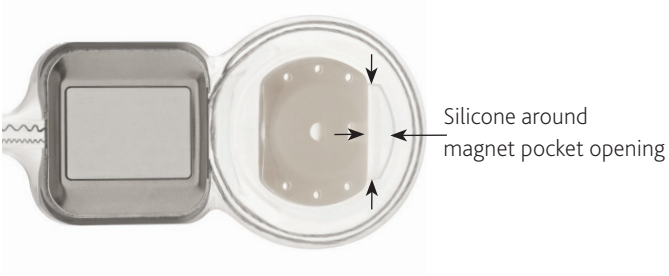


Figure 17: CI622 implant with magnet cassette removed

3. Using constant traction, remove the magnet cassette from the magnet pocket. The magnet cassette cover is designed to stretch under the constant traction applied during removal.

   The removal direction is in the same plane as the implant coil, towards the distal end of the implant – refer to arrow in *Figure 18* below.

Caution

To avoid damaging the magnet pocket, do not apply vertical pulling force to the implant coil.

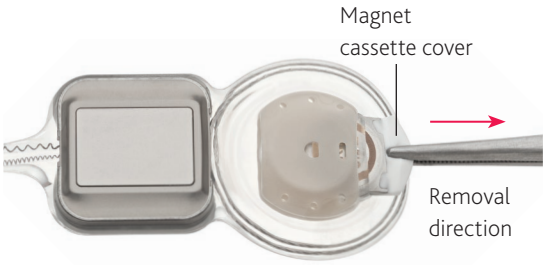


Figure 18: CI622 implant with magnet cassette partially removed

Note

If the magnet cassette cover pulls away, use forceps to hold the metal tab and continue removal.

Figure 19: Metal tab on magnet cassette

Figure 20: CI622 implant, magnet cassette removal using metal tab

4. Dispose of the removed magnet cassette. It is not re-usable.
5. To insert the sterile non-magnetic cassette into the magnet pocket, remove it from the packaging and silicone carrier. Ensure the MRI engraving is facing up (skin side).

Warning

To avoid infection, if the sterile package is damaged do not use the non-magnetic cassette.

Insert the non-magnetic cassette into the magnet pocket between the implant coil plates, being careful not to exert undue force or pressure on the implant or implant coil.

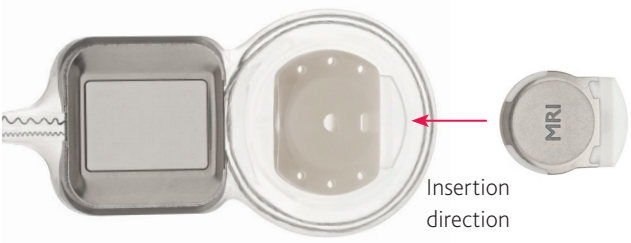


Figure 21: Non-magnetic cassette insertion direction

6. Ensure the non-magnetic cassette is fully inserted into the magnet pocket and the non-magnetic cassette cover is flush with the surrounding implant silicone.

The implant is now ready for implantation.

When there is no further need for MRI examinations, replace the non-magnetic cassette as instructed in ***Removing and replacing the magnet cassette or non-magnetic cassette after implantation*** on page 92.

Removing and replacing the magnet cassette or non-magnetic cassette after implantation

Warning

Do not use vertical force. Take care not to displace the implant.

Use of excessive or vertical force could lead to implant or electrode migration, causing the implant to malfunction and require removal, replacement or revision surgery.

Caution

- Take care not to damage the implant silicone or coil wires.
- When holding the magnet cassette cover or non-magnetic cassette cover, take care not to damage the silicone lip or the silicone around the magnet pocket opening.

Note

The magnet cassette or non-magnetic cassette can be safely removed and replaced with a new sterile magnet cassette or non-magnetic cassette up to eight times without any adverse effect to the implant.

Remove the magnet cassette or non-magnetic cassette in sterile conditions, using either general or local anaesthetic.

1. Make an incision beyond the distal end of the implant coil.

Note

You may use the cassette's silicone carrier to mark the incision:

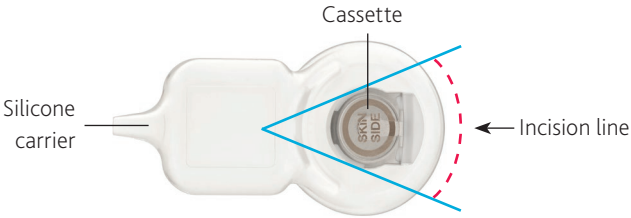


Figure 22: Marking the incision using the silicone carrier

2. Cut through any fibrous growth around the implant, exposing the distal end of the implant coil and the cassette cover. Ensure there is good visibility and access to the cassette cover.
3. Stabilise the implant, taking care to minimise force applied to the implant coil.
4. At the distal end of the implant coil, carefully position forceps or similar instrument under the silicone lip to hold the centre of the cassette cover.

1 Silicone lip
2 Forceps tip under silicone lip
3 Cassette cover

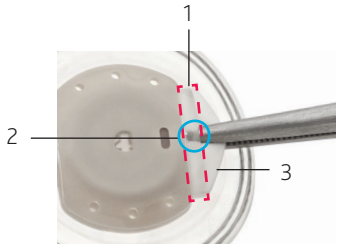


Figure 23: Forceps position on CI622 implant, cassette cover

5. Using constant traction, remove the magnet cassette or non-magnetic cassette from the magnet pocket. The removal direction is in the same plane as the implant coil, towards the distal end of the implant – refer to arrow in *Figure 24* below.

Note

The magnet cassette and non-magnetic cassette have been designed to remain in place and not move during an MRI examination. Therefore additional force may be required to remove the magnet cassette or non-magnetic cassette. In such cases, ensure the implant is sufficiently stabilised during removal.

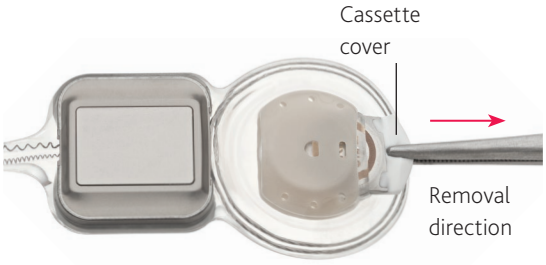


Figure 24: CI622 implant with cassette partially removed

Note

If the cassette cover pulls away, use forceps to hold the metal tab and continue removal.

Figure 25: Metal tab on cassette

Figure 26: CI622 implant, cassette removal using metal tab

6. Dispose of the removed magnet cassette or non-magnetic cassette. They are not re-usable.

7. To insert a sterile replacement magnet cassette or non-magnetic cassette, remove it from the packaging and silicone carrier.

   Ensure that:

   - the engraving SKIN SIDE (or MRI) is facing up – refer to *Figure 27* below
   - there is good visibility and access to the magnet pocket.

   Warning

   To avoid infection, if the sterile package is damaged do not use the replacement magnet cassette or non-magnetic cassette.

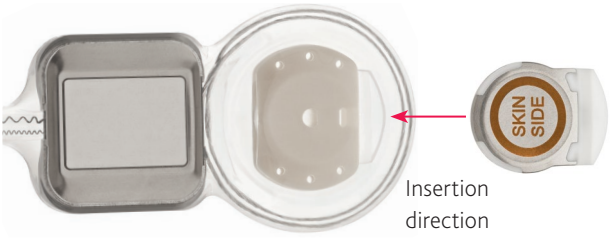


Figure 27: Replacement magnet cassette insertion direction

8. Stabilise the implant, taking care to minimise force applied to the implant coil.
9. Insert the replacement magnet cassette or non-magnetic cassette into the magnet pocket between the implant coil plates, being careful not to exert undue force or pressure on the implant or implant coil.

   Ensure the replacement magnet cassette, or non-magnetic cassette, is fully inserted into the magnet pocket and the cassette cover is flush with the surrounding implant silicone.
10. Closure – close the wound in layers (drainage is not recommended) and apply a large pressure bandage.

How the implant is supplied

The implant, non-magnetic cassette and replacement magnet cassette are single-use items, not to be used more than once. Non-magnetic cassettes and replacement magnet cassettes are supplied separately.

All of the above components are supplied in sterile gas-permeable packaging. Ethylene oxide processing is indicated on the label of each sterile package.

Before opening the sterile package, inspect it carefully. Return the device and packaging to Cochlear if:

- the 'use by' date stamped on the outside package has expired
- the sterile package containing the implant is ruptured
- exposure to ethylene oxide processing is not indicated by a green dot on the sterile pack.

Transport and handling

Cochlear Nucleus cochlear implants inside their sterile packaging within the implant box have been validated for transport and handling temperatures from -10 °C (+14 °F) to +55 °C (+131 °F).

Handle with care. Severe impact may rupture the sterile package inside.

Storage

Store Cochlear Nucleus cochlear implants inside their sterile packaging within the implant box at room temperature. Keep dry.

The product and its packaging have been designed to withstand storage temperatures from +1 °C (+34 °F) to +30 °C (+86 °F) and transient and seasonal excursions beyond this range.

CI622 implant specifications

Intracochlear electrodes	
Number of electrodes	22 electrodes
Distance between centre of electrode contacts	0.85 mm to 0.95 mm when straight
Diameter of electrodes (cross-sectional dimension)	0.6 mm x 0.5 mm at proximal end, tapering to 0.35 mm x 0.25 mm at distal end
Contact surface area	0.14 mm^2 to 0.20 mm^2
Active array length when straightened	19.1 mm
Nominal electrode length when straightened	• 20 mm from tip to distal marker • 25 mm from tip to proximal marker
Lead length from receiver/ stimulator to array tip	105 mm

Extracochlear electrodes
• Plate on receiver/stimulator • Cylindrical electrode 0.6 mm (typical) diameter with hemispherical • tip, on a lead 60 mm in length

Receiver/Stimulator	
Dimensions	Case: 24 mm x 23 mm x 3.9 mm Coil: 31 mm diameter x 3.9 mm thick
Volume	4.2 cm^3 without lead
Mass	9.2 g including electrode array

Operating characteristics	
Power and data	Received by 5 MHz inductive link from sound processor headset coil
Current	Biphasic pulses
Stimulation mode	Monopolar, bipolar or common ground
Stimulus amplitudes	Programmable from 0 µA to 1750 µA nominal at 37 °C
Maximum stimulus amplitude	Median: 1750 µA Range: 1575 µA to 1925 µA as measured according to EN 45502-2-3 / ISO 14708-7
Stimulus duration	Programmable from 9.6 µs to 400 µs per phase
Maximum stimulus pulse width	Median: 400 µs Range: 398 µs to 410 µs as measured according to EN 45502-2-3 / ISO 14708-7
Transmitting range	1 mm to 10 mm Maximum skin flap thickness required for good magnet retention: • 6 mm for OTE sound processors • 10 mm for BTE sound processors

Measurement functions	
Compliance	Displays compliance limits using Cochlear proprietary programming software
Neural response telemetry	Measure of electrically evoked compound action potential (ECAP)
Impedance	Measure of electrode impedances in monopolar and common ground modes
Impedance measurement accuracy	80% measured according to EN 45502-2-3 / ISO 14708-7
Implant ID and type check	Enables the sound processor to confirm whether it is coupled to the nominated implant

Materials in contact with body tissues	
Silicone elastomer	Lead and receiver/stimulator protective coating and insulation Magnet cassette cover, non-magnetic cassette cover
Titanium	Receiver/stimulator case
Platinum	Electrode contacts

General information

Warranty

To the purchaser: the law in some countries requires that the written warranty for this cochlear implant must be made available for the patient's review before it is sold to them. The Cochlear terms and conditions of warranty should therefore be given to the patient before implantation of the cochlear implant. The warranty is included in the document pack.

Reliability reports

Reliability reports are available on www.cochlear.com.

Symbols

The following symbols may appear on your implant or implant packaging:

	Fragile, handle with care
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use
	Specific warnings or precautions associated with the device, which are not otherwise found on the label
	Do not re-use
	Do not resterilise
	Date of manufacture
	Manufacturer
	Use-by date
	Keep dry
	Sterilised using ethylene oxide
	Unique Device Identifier

Rx Only	Caution: US law restricts this device to sale by, or on the order of, a physician
REF	Catalogue number
	Single sterile barrier system with protective packaging inside
SN	Serial number
LOT	Batch code
EC REP	Authorised representative in the European Community/European Union
CH REP	Authorised representative in Switzerland
CE 0123	CE registration mark with notified body number
	MR Conditional
MD	Medical Device
BONE SIDE	Bone side of implant, to be implanted with this side facing down
SKIN SIDE	Skin side of magnet cassette and replacement magnet cassette

Notes

Hear now. And always

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

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

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

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

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

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

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

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

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

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

www.cochlear.com

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

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

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

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

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

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

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

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

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

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